Empowering Cancer Patients Groups for Informed Participation in Clinical Trials

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EXECUTIVE SUMMARY

INTRODUCTION

There is a common public perception that human volunteers in biomedical research are not totally aware about the objectives, procedures and nature of their participation in clinical trials. Often, such volunteers are not able to distinguish between the therapeutic objective of medical practice as different from hypothesis testing in research protocols. In developed countries like the United States and Europe, research participants are fully aware of their rights and responsibilities. But in developing countries like the Philippines, patients are often recruited into clinical trials to gain access to experimental drugs and medical care to treat their illness.

While there has been training in good clinical practice and research ethics among the researchers, there is no similar training being conducted to enhance awareness of the human participants about their rights and responsibilities in clinical trials.

During the past few years, there has been an increase in the number of clinical trials being done in developing countries like the Philippines. Hence, there is a need to do empirical research to measure the levels of awareness (knowledge, attitude, practices) of patients related to their entitlements when they are recruited in clinical research related to adherence to vulnerability protection, confidentiality, full disclosure, risk-benefit assessment, voluntary participation and right to withdraw, etc.

The study was undertaken, not only to measure the awareness of human participants about ethical conduct of research, but to develop an educational intervention to educate patient groups about their rights and responsibilities when they are involved in clinical trials. An iterative process will be used to first determine their initial awareness to develop an educational intervention that will again be tested for its effectiveness in terms of better knowledge, attitudes and practice related to participation in clinical trials.

REVIEW OF LITERATURE

According to Gray et al (1991), empowerment is any process wherein people increase their capability to influence the people and organizations which affects the way they live. Viewing it as a construct,
empowerment encompasses the personal and psychological dimension. It is similar to self-efficacy and personal control, but is more comprehensive because it takes into consideration the inherent social and political dimensions of individual power (Gray et al., 1991). Palviainen et al (as cited in Hewitt-Taylor, 2004, p. 33) depicted power as a matter of "authority and control."

In medicine, it was assumed that doctors have the power to decide the best kind of care and treatment to their patients (Hewitt-Taylor, 2004). According to Roscam Abbing (2010), patients’ rights must be positioned in the broader context of the shifting balances of power. When a realignment in the balance of power in favor of patients occurs, they will be able to act without undue control from the healthcare staff, thereby making them capable of making decisions about their healthcare, instead of having it made for them (Hewitt-Taylor, 2004). The same principle applies to health research, where patient empowerment has the potential to make research participants proactive stakeholders in clinical researches that are intended to develop better drugs and interventions to cure diseases and improve health.

Over the past decade, empowerment has gained prominence in health as an ideal way to strengthen doctor/patient and researcher/subject relationships. The advocates of empowerment deemed it preferable to authoritarian practices due to its underlying humanistic values and its potential to improve efficiency in health care delivery and conduct of clinical by making protocol compliance, adherence to health care advice more effective. (Traynor, 2003)

Patients’ rights and empowerment issues are relevant to people diagnosed with cancer due to the fact that their disease warrants them to lose control over their own body. Those that want to extend their life expectancy become potential participants to clinical trials that test new drugs and modes of treatments. The study of Gray et al (1991) pointed out the different strategies for patient empowerment and discussed the possible barriers to its implementation. Healthcare professionals in charge of taking care of cancer patients are now tasked to empower patients in order to help them increase their self-care behavior and also to decrease the anxiety level about the severity of their symptoms (Szczepanik, 2007). It includes coping with the uncertainty of the possible progression or recurrence of the disease, treatment side effects and complications, and unbalanced power relations with healthcare professionals (Gray et al., 1991).

According to Szczepanik (2007), today's healthcare facilities must provide a formal education program that addresses patient education. Such education should not only include health care matters but also the domain of health research. Healthcare workers can support and give appropriate care to cancer patients by creating a climate wherein informed choice and consent are genuine (Mizrahi, 1992). Through the practice of assertiveness and self-advocacy, the needs and wants of patients can help them gain independence and personal control (Gray et al., 1991).

During clinical trials of therapeutic medicinal procedures, the codes of ethical research practice clearly state that it is mandatory for human subjects to provide a written informed consent (Sengupta et al., 2001). According to the US Department of Health and Human Services (as cited in Sengupta et al., 2001, p. 1382), the federal regulations requires eight basic elements for a valid informed consent document in a research to be disclosed to human participants: (1) explanation of the research and subjects’ expected participation; (2) description of foreseeable risks to subjects; (3) description of benefits to subjects; (4)
disclosure of alternative courses of treatment; (5) description of how subjects’ confidentiality will be protected; (6) for research involving more than minimal risk, an explanation of any compensation with respect to injury; (7) explanation of whom to contact about the research and research subjects’ rights; and (8) a statement that participation is voluntary.

The US Institutional Review Boards (IRBs) are also required to follow the federal mandate and ensure that the eight basic elements disclosed in a given informed consent form are followed by the researchers (Jefford & Moore, 2008). However, there are still issues about the quality and effectiveness of the informed consent process in clinical research and the overall success of the informed consent process in reaching its mandated goals is still being questioned (Bristol, 2014).

According to a study by Flory & Emanuel (2004), the extent to which human subjects actually understand the informed consent elements even after signing the consent forms are still being questioned. Many research participants, upon signing the consent forms, still continue to show gaps in their knowledge and understanding of pertinent research information (Bristol, 2014). It was suggested by Flory & Emanuel (2004) that extended discussion interactions as part of the consent process were more effective in improving informed consent understanding of the research participants.

A research participant's understanding of an informed consent form is equally important as obtaining consent from participants in clinical trial research. However, the development of procedures to target gaps in the participants’ informed consent understanding still remains a challenge (Sengupta et al., 2011). A study by Bristol (2014) proposes the use of innovative monitoring methodologies to improve outcomes while safeguarding consent relationships and activities. Consequently, rigorous research that will help direct policy efforts in standardizing quality improvement processes can pave the way for a better-informed consent understanding of research participants.

Patient groups are increasingly getting involved in patient education and advocacy initiatives with favorable results. Cancer patient advocates who represented those affected by cancer in the United States have developed perspectives different from cancer experts from academia and industry and were found to be able to contribute to educational dialogue between investigators and patient communities and made positive suggestions to improve clinical trials (Collyar, 2005). Advocacy organizations for genetic diseases who are involved in biomedical research have made inputs towards improvement of translational research (Terry S. et al, 2007). Patient groups in Europe are formally organized to “provide scientifically reliable, objective, comprehensive information to patients on medicines research and development” and to “increase the capacities and capabilities of well-informed patients. They sit as members of scientific committees of the European Medicines Agency (EMA) and provide feedback based on their own experiences. One such group is the European Cancer Patient Coalition founded in 2003 and listed as partner of EMA has stated as part of its mission the promotion of cancer research ‘including all applicable information on well-designed clinical trials.’

If patient volunteers/participants are to become a core stakeholder of ethical research in the Philippines, there is need to determine their knowledge, attitudes and practices related to research, develop an educational program for them and organize them to be able to become informed participants in clinical trials.
OBJECTIVES AND EXPECTED OUTPUT

OBJECTIVES
The overall objective of the project is to contribute to capacity building for empowerment of patient groups for informed participation in clinical trials with the following specific objectives:

1. To determine the perception of clinical trials by cancer patients about clinical trials
   a. Nature of clinical trial protocols
   b. Scientific and ethical issues
   c. Patient rights and responsibilities
   d. Role of pharmaceutical sponsors and physician investigators
   e. Factors that influence decision-making
   f. To assess the effect of an educational intervention on the patient knowledge, attitudes and practices about clinical trials
2. To assess the effect of an educational intervention on the patient knowledge, attitudes and practices about clinical trials

EXPECTED OUTPUTS
1. Baseline and post intervention data of the knowledge, attitudes and practices of cancer patients about clinical trials
2. Interactive training module for cancer patients to improve their knowledge, attitudes and practices about clinical trials
3. Policy recommendations to enhance measures to empower patients to participate in ethics training of research stakeholders and provide valuable inputs in the drug development process

STUDY POPULATION
The study was done among cancer patients for several reasons:

1. Cancer studies consistently rank among the top 3 diseases being subjected to clinical trials due to its high incidence not only in the Philippines but globally;
2. Most pharmaceutical companies conduct their own cancer studies;
3. Cancer patients, survivors and support groups are better organized and it is easier to do a study among them. Methodology

MIXED METHOD

QUALITATIVE METHODS
Initially, focus group discussions with patient groups and key informant interviews with leaders or patient support groups were used to gather information to formulate the survey instruments.

Themes explored/ discussed during KII/ FGDs with research participants were
1. Clinical trial experience of participants
2. Reasons for participation
3. Treatment options
4. Perception of risks in clinical trials as different from risks involved in clinical care
5. Perception of benefits in clinical trials as different from benefits from clinical care
6. Personal relationship with clinicians and researchers
7. Perception related to conflict of interest
8. Perception of vulnerability
9. Informed consent issues
10. Understanding of scientific issues/ nature of research
11. Compensation related to injury
12. Post-trial access

Quantitative Methods
Cancer patients who had registered with the Philippine Cancer Society for information or for assistance for drugs they needed were invited to attend an educational session to know more about clinical trials. Informed consent was taken before participation. Then, they filled up a survey questionnaire to determine their knowledge, attitudes and practices related to cancer treatment and experimental drugs. Based on the items in the pre-intervention questionnaire, the study team made use of an interactive discussion to implement two training modules: 1. Learning about the nature of cancer clinical trials, 2. Improving informed consent for participants in clinical trials.

The project utilized a pre- and post-intervention survey that measured participant knowledge, attitudes, and practices about clinical trials and the necessary elements of the informed consent process. The pre- and post-survey scores were compared and outcomes were measured in terms of better post intervention scores.

These set of respondents underwent a training intervention which was intended to empower the patients, in terms of better understanding of the nature, procedures and ethical issues in clinical trials.

Study Setting
The study was conducted in Metro Manila with cancer patients being recruited from hospitals, cancer institutions, and cancer support/patient groups.

Study Population
The inclusion criteria were as follows:

- Cancer patient who is currently included in a clinical trial study
- Cancer patient/survivor who have participated in a clinical trial in the last ten years
- Cancer patients/survivor who have not joined any clinical trial
**Sampling Scheme/Design**

The study is about cancer patient perception of clinical trials that made use of 80 patients without clinical trial participants recruited from the Philippine Cancer Society and 15 patients with clinical trial experience recruited with the help of clinicians from various hospitals and patient groups. A purposive sampling method was used to recruit a total of 95 participants. All of them answered the questionnaire about their knowledge, attitudes and practices of clinical trials with 85 patients participating in the educational intervention where pre- and post intervention surveys were done.

<table>
<thead>
<tr>
<th>Type of Respondents</th>
<th>Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Cancer patients who have participated or currently involved in a clinical trial</td>
<td>N = 15</td>
</tr>
<tr>
<td>B. Cancer patients/survivors who have not joined any clinical trial</td>
<td>N = 80</td>
</tr>
<tr>
<td>C. Total</td>
<td>N = 95</td>
</tr>
</tbody>
</table>

**Instrumentation and Training Module**

A survey questionnaire was developed, pre-tested and validated prior to actual implementation. The results of the FGD and KII formed the basis for the contents of the survey questionnaire.

For the educational intervention, the FERCAP Human Participant Protection module was consulted, cited and modified based on the results of the FGDs and KII. It will be translated, pre-tested and validated for Filipino patient groups. The FERCAP module has been developed for members of ethics committees and investigators and it is desirable that the same module is adopted to the level of the patients to ensure a common understanding of issues among important research stakeholders.

**Data Collection**

**Preparatory Activities**

*Scientific and Ethics Review*

Funding was provided by the Philippine Council for Health Research and Development that conducted both scientific and ethical review. It was approved by the National Ethics Committee for implementation.

*Development and Validation of Instruments and Modules*

Before the actual data collection, the FGDs and KII guide were developed. The instruments were pre-tested to a set of target respondents then reviewed and amended as appropriate. The instrument was done in English and Filipino, after which training modules were developed and translated into Filipino.

*Social Preparation and Social Mitigation Measures*

The investigators and researchers coordinated and ask permission from the leadership of the cancer support groups for the various data collection activities explaining as thoroughly as possible, and administered simple consent forms before data collection from patients,
For patients currently involved in clinical trials, mitigation measures were adopted by the investigators in case some issues or problems developed related to their participation. Privacy and confidentiality protection were adhered to as mitigation measures.

Recruitment and Training of Interviewers
Members of the Study Group were trained before project implementation, that included training about the interview guide, conduct of FGDs, KIIIs and the educational interventions and data analysis.

Recruitment of Respondents
Members of patient groups/societies and clinicians recruited participants for the study.

DATA COLLECTION PROPER
Informed consent was obtained before the respondents were interviewed, participated in FGDs and/or educational intervention and answered the survey questionnaires.

Study group members conducted the FGDs and the KIIIs among the first set of target respondents from referral of clinicians and patient groups. Results were used to formulate the survey questionnaire. After pre-testing of the survey tool, the second list of possible respondents were obtained from the target cancer centers, hospitals and patients groups. The schedule and venue of the pre- and post-intervention surveys were made to coincide with the training intervention.

Patient Empowerment Training
Respondents participated in the research ethics training largely based on the FERCAP Human Protection Course and clinical trial information used by the United Kingdom National Health Service (www.nhs.uk) translated into Filipino.

An educational intervention made up of two modules was done with patients from the Philippine Cancer Society.

Module 1: What is a clinical trial?
Topics covered:
  • Patient sharing about onset of cancer
  • Health seeking behavior
  • Awareness about clinical trials in cancer
    o Meaning and nature of clinical trials
    o Role of clinical trial in drug development
    o Elements
    o Regulations
    o Role of stakeholders in clinical trials (sponsor, investigator, ethics committee, FDA, participant)
  • Participation in clinical trials
    o Elements of good participation
Module 2: Informed Consent

Topics covered:

- Protocol details (sample size, inclusion/exclusion criteria, clinical procedures)
- Informed consent process
  - Patient information sheet
  - Informed consent document
  - Elements of informed consent
    - Voluntariness
    - Full disclosure of information
      - Role of sponsor, investigator, ethics committee, regulator
      - Nature of the investigational drug
      - Clinical procedures
      - Risks and benefits
      - Cost of participation
      - Responsibilities of subjects
    - Comprehension by study subjects
- Case study

The modules were translated into Filipino and were used to provide inputs to respondents regarding their rights as participants in clinical trials. The pre-and post-intervention questionnaires were administered before and after the training to determine if there was improvement of knowledge, attitudes and perception about clinical trials, particularly among patients without clinical trial experience.

Documentation

Documentation of FGD and KII responses were done manually and through the use of a digital recorder. The audio recording of information was done with the consent of the respondent(s), with an explanation of the rationale of audio recording such as to avoid or minimize errors in the documentation of responses. Manual documentation was done during FGDs as the facilitator was preoccupied with facilitating the discussion. Each facilitator has a documenter. In the survey, completion of the forms was conducted by the enumerator/interviewer.

Post Data Collection

All the data forms were field edited by the Interviewers before submission to the encoder and analyst. Data were then encoded, consolidated, and placed in the Data Analysis matrix.

Data Analysis

Survey results were inputted in Excel 2010 using the specific design file for the study. Simple correlation studies were done to determine factors that affect the knowledge, attitudes and practices of patients related to their participation in clinical trials. The results of the survey were triangulated with the documented results of the FGDs and Key Informant Interviews. Generalizations and conclusions from the data were formulated.
RESULTS

A. PROFILE OF THE STUDY POPULATION

- Cancer patients: N = 95
  - Those who have not participated in clinical trials: N = 80
  - Those who have participated in clinical trials: N = 15
- Patient profile (majority were recruited from PCS)
  - Sex: F=85%; M=15%
  - Median age: 41-60
  - Unemployed: 55%
  - Married: 60%
  - High school graduates: 46%
  - Type of cancer: mostly stage 2/3 breast cancer

B. HEALTH SEEKING BEHAVIOR AMONG CANCER PATIENT RESPONDENTS

Majority of the respondents were recruited from the Philippine Cancer Society (PCS). These patients sought assistance from PCS to access expensive cancer drugs during or after chemotherapy. These were shown by the pre-intervention results below.

- Majority have undergone chemotherapy and surgery: 90%
- Known standard treatments:
  - Surgery w/ chemotherapy
  - Radiation
- Optimistic about treatment: 91%
- Have visited a hospital: 99%
- Majority want doctors to tell their families about their cancer: 82%

Cancer ranks high as a leading cause of mortality and morbidity in the Philippines and most Filipinos have fears about getting this disease. The respondents were asked to describe the sources of their worries once they found out that they had cancer. Those without clinical trial experience worried more about the cost of treatment (85%) as compared to those with clinical trial experience who had assurance of some access to expensive treatments available in the clinical trial. Generally, those with clinical trial experience were more optimistic and less anxious about their disease.

A very strong belief in God was noted among the cancer patients and this was a prevalent theme when discussing health seeking behavior. They believed in miracles and faith and prayers could unleash divine intervention that they fervently sought. Faith in God together with good doctors and effective medicines were sure fire formula to treat cancer. They needed to have faith that they will be healed.

The use of herbal supplements and vitamins was explored during the discussion with the participants. They believed that aside from the standard treatment like operation, chemotherapy and radiation, it is important for them to take herbal supplements and vitamins in order to strengthen their immune system. The participants readily shared personal and family experiences about herbal supplements and vitamins. During the educational intervention, it was explained that these supplements were not meant
to replace the drugs to cure them, unless there was systematic evidence of therapeutic effects. They were made to understand that these supplements might help but were not yet meant to cure their cancer until scientific evidence became available.

It is important to note that all the patients were aware that they had to go to hospitals, clinics, etc. to avail of drugs or scientific treatment as against going to a faith healer alone. The necessity of seeking evidence based medicine was emphasized during the educational intervention in terms of having access to good diagnosis and treatment regimens for cancer. Patients seeking assistance from the Philippine Cancer Society needed referral and prescriptions from physicians before being given free or subsidized drugs.

### Table 1. Leading Causes of Anxiety about Cancer Treatments

<table>
<thead>
<tr>
<th></th>
<th>w/o CT</th>
<th>w/ CT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment related expense</td>
<td>85%</td>
<td>47%</td>
</tr>
<tr>
<td>Side effects of cancer</td>
<td>44%</td>
<td>33%</td>
</tr>
<tr>
<td>Side effects of cancer</td>
<td>44%</td>
<td>33%</td>
</tr>
<tr>
<td>General body weakness</td>
<td>36%</td>
<td>33%</td>
</tr>
<tr>
<td>Death</td>
<td>31%</td>
<td>20%</td>
</tr>
</tbody>
</table>

The major concern of patients with cancer was their financial capacity to access treatment for their disease. This constituted 85% of the patients without clinical trial experience, when asked to identify their main concern when they found out they had cancer.

The issue of patient vulnerability (economic/financial, social, emotional, etc.) was highlighted during the lectures to make the patients aware of their emotional condition and the necessity of rational and informed decision making if ever they would be invited to join a cancer study. Such vulnerabilities might constitute barriers to informed participation.

Since most of the participants had undergone some previous cancer treatments, the side effects of follow up treatments constituted a major source of anxiety. Many of them had seen or had experienced hair loss, vomiting, nausea, general body weakening after chemotherapy or radiation and they had realistic expectation that experimental treatments would not free them of adverse drug reactions.

### C. Perception about Clinical Trials

The data in Table 2 shows that prior to participation in clinical trials, there was very low awareness about the presence of clinical trials in the country. Generally, people know but medical treatments but not about research and drug experiments. Participation in clinical trials has improved knowledge but probably, the low number of research and clinical trials in the country will explain the high scores of insufficient awareness. The physician ranks highest as the source of information about treatments and participation in clinical trials. It is worthwhile to note that among clinical trial participants, the internet ranks high (47%) as source of information for those with clinical trial experience.
### Table 2. Knowledge about Treatments/Clinical Trials

<table>
<thead>
<tr>
<th>Source of Information about Cancer Treatment</th>
<th>w/o CT</th>
<th>w/ CT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>86%</td>
<td>93%</td>
</tr>
<tr>
<td>Fellow Patients</td>
<td>41%</td>
<td>40%</td>
</tr>
<tr>
<td>Hospital/Clinics</td>
<td>39%</td>
<td>33%</td>
</tr>
<tr>
<td>Internet</td>
<td>36%</td>
<td>47%</td>
</tr>
<tr>
<td>TV/Radio</td>
<td>36%</td>
<td>33%</td>
</tr>
</tbody>
</table>

The results of the pre-intervention survey showed that non-CT participants scored significantly higher (more agreement) regarding misconception about clinical trials than CT participants:

- There is no danger in joining CTs
- I believe that my doctor can cure my cancer
- CTs are only for poor patients who cannot afford to pay for medications
- CTs are done only by medical students

The study respondents were made to check the information that they would like to know before joining a clinical trial. Similarities and differences were noted between the answers of non-CT participants as compared to CT participants.

### Table 3. What do you like to know before joining a clinical trial?

<table>
<thead>
<tr>
<th>Information</th>
<th>Non-CT (n=80)</th>
<th>w CT (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsibilities of the physician</td>
<td>78%</td>
<td>80%</td>
</tr>
<tr>
<td>Side effects of treatment</td>
<td>74%</td>
<td>87%</td>
</tr>
<tr>
<td>FDA approved</td>
<td>73%</td>
<td>80%</td>
</tr>
<tr>
<td>Free drugs</td>
<td>68%</td>
<td>93%</td>
</tr>
<tr>
<td>Responsibilities of the participant</td>
<td>68%</td>
<td>80%</td>
</tr>
<tr>
<td>Treatment procedures</td>
<td>66%</td>
<td>73%</td>
</tr>
<tr>
<td>Knowledge and experience with study drug.</td>
<td>64%</td>
<td>81%</td>
</tr>
<tr>
<td>Party responsible for any study injury</td>
<td>61%</td>
<td>80%</td>
</tr>
<tr>
<td>Pharmaceutical sponsor</td>
<td>55%</td>
<td>73%</td>
</tr>
<tr>
<td>Procedures that participants will pay for</td>
<td>54%</td>
<td>60%</td>
</tr>
<tr>
<td>Approval by an ethics committee</td>
<td>50%</td>
<td>67%</td>
</tr>
<tr>
<td>Countries conducting the drug study</td>
<td>48%</td>
<td>73%</td>
</tr>
</tbody>
</table>

Non-CT and CT participants had common concerns about how they would be affected by the study drug:

- Is it free?
- Side effects
- Responsibilities of the study doctor
- FDA approved
- Responsibilities of participant
- Who is liable for untoward events?

However, CT participants who had previous experience to be given information before they joined a study generally gave higher scores to items found in patient information sheet. The non-CT respondents were less sure about their answers as shown by their lower scores.

**TABLE 4. ABILITY TO MAKE DECISIONS TO PARTICIPATE IN A CANCER TREATMENT STUDY**

<table>
<thead>
<tr>
<th></th>
<th>CT (n=15)</th>
<th>Non-CT (n=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>100%</td>
<td>61%</td>
</tr>
<tr>
<td>No</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>Not sure</td>
<td>16%</td>
<td></td>
</tr>
<tr>
<td>No Answer</td>
<td>3%</td>
<td></td>
</tr>
</tbody>
</table>

All CT participants felt that they had the capacity to decide on whether to join a study about cancer treatments or not. Although majority of non-CT patients felt the same way, a substantial proportion expressed the opinion that they did not have the capacity to decide, were not sure or would not give an answer.

**TABLE 5. WHOM TO CONSULT BEFORE PARTICIPATING IN A CANCER TREATMENT STUDY**

<table>
<thead>
<tr>
<th></th>
<th>Non-CT (n=80)</th>
<th>CT (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spouse/ children</td>
<td>63%</td>
<td>80%</td>
</tr>
<tr>
<td>Doctor</td>
<td>48%</td>
<td>47%</td>
</tr>
<tr>
<td>Parents</td>
<td>23%</td>
<td>33%</td>
</tr>
<tr>
<td>Other relatives</td>
<td>16%</td>
<td>7%</td>
</tr>
<tr>
<td>Me alone</td>
<td>15%</td>
<td>13%</td>
</tr>
<tr>
<td>Friend</td>
<td>10%</td>
<td>20%</td>
</tr>
</tbody>
</table>

 Majority of the patients would like to consult their spouse/ children prior to joining a study about cancer. They would like to consult their doctors first before making a decision. They would also prefer to consult parents, relatives and friends prior to joining a cancer study.

The next question (Table 6) was about giving consent as different from consultation. The same trend was noted with a high percentage seeking the consent of their spouse or a family member before joining a cancer treatment study. Only 27%-28% of the respondents would exercise their autonomy and give consent using their own judgment. Non-CT patients would seek consent from their physicians, considering that they did not have any encounter with a study doctor yet.
The incidence of cancer made the patients realize their own mental, emotional and financial vulnerabilities. The manner of addressing their vulnerability was to consult and arrive at decisions together with members of their family who would have their welfare in mind when giving advice or making treatment decisions for their sick relative.

**Table 6. Who should give consent before you join a cancer treatment study?**

<table>
<thead>
<tr>
<th></th>
<th>Non-CT (n=80)</th>
<th>CT (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spouse</td>
<td>46%</td>
<td>60%</td>
</tr>
<tr>
<td>Doctor</td>
<td>44%</td>
<td>27%</td>
</tr>
<tr>
<td>Children</td>
<td>35%</td>
<td>47%</td>
</tr>
<tr>
<td>Me alone</td>
<td>28%</td>
<td>27%</td>
</tr>
<tr>
<td>Other relatives</td>
<td>19%</td>
<td>13%</td>
</tr>
<tr>
<td>Parents</td>
<td>16%</td>
<td>20%</td>
</tr>
<tr>
<td>Friends</td>
<td>8%</td>
<td>7%</td>
</tr>
<tr>
<td>Others</td>
<td>1%</td>
<td>7%</td>
</tr>
<tr>
<td>No answer</td>
<td>1%</td>
<td></td>
</tr>
</tbody>
</table>

**Table 7. Who should be responsible for study related injury?**

<table>
<thead>
<tr>
<th></th>
<th>Non-CT (n=80)</th>
<th>CT (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>48%</td>
<td>47%</td>
</tr>
<tr>
<td>Researcher</td>
<td>45%</td>
<td>33%</td>
</tr>
<tr>
<td>Pharmaceutical sponsor</td>
<td>38%</td>
<td>80%</td>
</tr>
<tr>
<td>Hospital</td>
<td>30%</td>
<td>20%</td>
</tr>
<tr>
<td>DOH</td>
<td>29%</td>
<td>13%</td>
</tr>
<tr>
<td>Research Ethics Committee</td>
<td>23%</td>
<td>27%</td>
</tr>
<tr>
<td>Insurance</td>
<td>20%</td>
<td>7%</td>
</tr>
<tr>
<td>No answer</td>
<td>11%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Non-CT participants thought that doctors and researchers should be accountable if untoward incidents happen during a clinical trial. In contrast, majority of CT participants knew that the sponsor, more than the doctors or researchers should be held liable. Some felt that the hospital and ethics committees were also accountable.

**What support do you need to participate in a clinical trial?**

- Both CT and non-CT participants need the following support:
  - Information on efficacy of study drug
  - Continued consultation with study doctor
  - Continuous information on new cancer treatments
  - Membership in cancer survivor support groups
- More Non-CT participants needed information and doctor consultations than CT participants
DISCUSSION

Part 1 Non-Clinical Trial Group

A pre-intervention survey was done to explore knowledge, attitudes and practices related to clinical trials. After the educational intervention, a post-intervention questionnaire was administered to the participants. Most of the patients who participated in the educational intervention had no CT experience (n= 80) and only a few of them had CT experience (n=5). The effect of the intervention was shown to be significant among the non-CT group.

Table

Chart 30. Pre vs Post Intervention Ratings among Non-CT Patients (Means)

A cursory inspection of the graph indicates that patients tended to give higher ratings to statements after the intervention. Differences in pre-vs post-intervention rating scores were statistically significant in 28 out of 50 ratings.

Agreement to the following statements about the nature of a clinical trial and its benefits to patients were significantly higher after the lectures as shown below:

- Contribution to scientific knowledge
- A clinical trial should use scientific research methods.
- A clinical trial is an experiment that makes use of human subjects.
- Free consultation
- More attention from doctor
- Post-trial access to drugs
- Free x-ray and laboratory procedures

COMPARISON OF PRE VS. POST INTERVENTION SURVEY RESULTS

A. Safety Concerns
In the course of the lectures, the patients became aware of the importance of inquiring about the risks and benefits of their participation in research. They were made to realize that they were entitled to know the risks and benefits of participation in a clinical trial as well as the possible adverse events that might happen in the course of the experimental study, including their possible entitlements like free hospitalization, access to drug, etc. as stated in the ICF. It was possible that the experimental drug would cure them of their illness. But there was no guarantee of successful treatment. That was part of the risks of participation.

It was also explained that a placebo might be used by a drug company in the process of experimentation where a pill or substance that might look the same as the experimental drug but would not have an actual effect might be given to a subject. This should be taken as one of the risks that patients are willing to accept, should they be included in the placebo group.

Randomization was explained in terms of the possibility of patients being assigned to different treatment groups. The subjects were asked if it would be alright if some of would get cured while others would not benefit from the drug. They answered in the affirmative provided that they would have an assurance they would have access to standards of care.

Concerns were raised about the debilitating effects of cancer and adverse events that might result with the use of the study drug. One issue raised by the participants during discussion was assurance of measures to address the side effects of treatment to improve their quality of life.

The role of the Research Ethics Committee that reviews research before it was implemented was explained from the perspective of preventing harm to human subjects. Its function was to protect human participants in research by reviewing the protocol before implementation to ensure that it followed both scientific and ethical standards. It was also the ethics committee that was tasked to monitor the conduct of research. The nature of serious adverse event that could happen in the course of a study was explained. Investigators should report SAE to the research ethics committee.

One participant enrolled in a clinical trial privately shared with the lecturer her experience of a serious adverse event related to drug infusion that was hurriedly done. She had to be confined overnight in the hospital but was not aware of the meaning of SAE. She was not sure if the event was reported by the study doctor at the same time that she did not want her study doctor to know that she told another person about her SAE experience for fear that she would be removed from the clinical trial.

Statements dealing with safety showed significant improvement at post intervention, particularly on:

- Concern about side effects
- May pose a danger to patients
- Medication may not be effective
- I can be harmed if I join
- There is no danger to me if I join (Decreased agreement indicates improvement)

The results showed that the intervention taught the patients to have a realistic and truthful expectations about participation in clinical trials. They understood the experimental nature of the study drug and there was no guarantee that they would get well.

**B. Qualifications of the Study Doctor**
Although Filipino patients had a very high regard for their doctors, they also agreed that the study doctors should take measures to make themselves qualified before conducting the study. The intervention emphasized the required qualifications of a study physician to include scientific experience, integrity and GCP training. Their financial and professional conflicts of interest should be declared and managed. All these desirable qualifications should also be met by the members of the study team who would assist the study doctor in the conduct of research.

Statements dealing with study doctor showed significant improvement at post intervention, particularly on:

- Doctor should specialize before doing a CT
- Only a trained doctor can do a CT
- The doctor will benefit professionally after doing a CT
- The doctor will earn more money by doing a CT

The results showed that the intervention addressed the misconception that clinical trials were being done only by medical students who use patients as guinea pigs to develop their clinical skills. They understood that clinical trials should be done by trained and qualified physicians who might benefit professionally and financially by doing clinical trials.

C. ROLE OF SPONSOR

During the lectures, patients were made aware that they should also inquire about the track record of the company who manufactured/developed the drug, whether they were reputable and generally adhered to good manufacturing practice (GMP). It was the responsibility of the pharmaceutical sponsor to take care of study related injury and to provide insurance in case something went wrong.

Statements dealing with a pharmaceutical sponsor showed significant improvement.

- A drug company sponsors a CT to discover new drugs.
- A drug company sponsors a CT to test the efficacy of drugs on cancer patients.
- A pharmaceutical company funds CTs so that more people will buy their drug.
- A drug company sponsors a CT to increase sales of their drugs.

Non-CT participants understood the role of pharmaceutical sponsors in drug development that involved testing and providing evidence of efficacy data derived from clinical trials. Generally, pharmaceutical sponsors needed to invest money in research to increase their profitability.

D. OTHER STATEMENTS

Other statements showed improvement in understanding the elements of the informed consent process, as shown by the following statements:

Consent should be freely given without undue pressure and coercion from the study doctor:

- Doctors should ask permission of patients before enrolling them in a CT.
- After being given appropriate information on a CT, I am open to joining it.
- A doctor can use patient data from CT without the patient’s consent (Decreased agreement indicated improvement.)
Patients join CT because they cannot refuse their doctor’s invitation (Decreased agreement indicated improvement.)
Before I join a CT, I should determine if I will be paid if I am harmed.

The lectures emphasized that the patient had the right to ask and consult anybody they wanted before signing the informed consent form (ICF). Ultimately, they themselves or their representative would make the decision and sign the ICF.

It was explained that the consent the patient signed to undergo chemotherapy was totally different from the informed consent form that he/she was made to sign as evidence of their voluntary participation in a study. Aside from the voluntary nature of their participation, they should be in the right state of mind together with the ability to comprehend and sign the ICF.

One of the educational strategies was to present an example of a 22-page informed consent form used by a drug company for its clinical trial. They were told to examine, scrutinize and criticize the ICF. A common agreement among these patients was the difficulty of understanding the highly technical language used in the ICF. Some of the comments from the participants were as follows:

- According to them, the ‘flowery language’ used was not appropriate and could not be easily understood. Instead, everyday language should be used.
- It would take 2 hours to read it.
- The language used were direct or literal translations.

The voluntary nature of their participation had been repeatedly emphasized in all both modules. They also had the freedom to withdraw anytime they wanted. Moreover, they were made to understand that the usual standard of care that they were entitled to would continue even if they decided to withdraw from the study.

When the patients were asked if they would join a CT, if they were invited, one common answer was “It depends”. They did not give a categorical answer of ‘yes or no’. It was noted that not many of them were not familiar with a CT or had even heard of it. Given their little knowledge, they had to give their participation ample thought, a good indication of the value they associate with autonomy. It was emphasized that the patient should be able to make appropriate decision about their own health and well-being. The consent for treatment and clinical care like chemotherapy should be separate from the consent to join a clinical trial. A researcher should allow patients to ask questions and sufficient time to accept an invitation to join a study. They were warned that they should not sign documents that they did not fully understand. Refusal to join research was not sufficient reason to deprive them of the standard of care.

**PART 2: COMMON THEMES FROM PATIENTS WITH CLINICAL TRIAL EXPERIENCE**

There were four patients with clinical trial experience who were present during the educational intervention and they helped explain the meaning of clinical trial and the informed consent process. On
the other hand, there were 11 patients with CT experience who were interviewed by the research group. From these interviews, these were the common themes that emerged:

A. Financial Concerns

Financial capacity was the primary concern of patients with cancer. All of the 15 cancer patients with clinical trial experience said that their main worry upon learning that they had cancer was the expensive cost of treatment. Thus, when they heard of the clinical trial being conducted from fellow cancer patients and from their doctors, they became interested and inquired about the possibility of being included. Many of them had also sought assistance from the Philippine Cancer Society or the Philippine Charity Sweepstakes where the cancer patients sometimes had to queue for 8 hours to get help. Not all of them were indigents, some were professionals but all of them found the cost of treatment unaffordable. Cancer drugs were very expensive and the main reason for them to join a clinical trial was access to drugs.

B. Health Seeking Behavior

The patients with clinical trial experience had sought and had undergone some forms of cancer treatment, like radiation or chemotherapy where they experienced the side effects like vomiting, dizziness, weight loss, general body weakening, etc. All of them sought God’s help and prayed that they would be cured of their illness. Their reactions upon learning that they had cancer ranged from crying, asking for God’s mercy and resignation to God’s will. Most of them clung to their faith in God and were optimistic that they will be cured.

They believed that family played a major role as they went through their treatment process. The emotional support from immediate family members (husband, children, sister, etc.) and friends were very important in facing the challenges related to their illness. One patient preferred her husband to be by her side when told about her cancer as different from another patient who kept her illness from her husband so he would not worry. They also told their children about their disease. But all of them worried about the effect on family members when once they knew about their cancer.

Generally, those in CT did not take any herbal supplements when they were active in the study. They were aware of the possible contraindicated effects of herbal supplements to their cancer drugs and they opted to follow their treatment protocol very strictly. Some comments from patients in CT:

- Patient 1: I did not ‘entertain any herbal’ since ‘it will complicate my treatment.’
- Patient 2: I did not take any herbal product because I have more confidence in drugs.
- Patient 3: I have heard about ‘herbal medicine’ from people selling them who tried to convince me to buy them but I said ‘not now, maybe later.’
- Patient 4: Even if it is only a ‘food supplement,’ it might be contraindicated to my medicine.
- Patient 5: When another patient was asked if she believed that herbal products could cure her, she replied that she believed the claims for other indications but not for cancer. Herbals might be effective for prevention and during the early signs of disease but not during the onset of cancer when they might need more radical medical procedures that she decided to undergo after getting the results of her biopsy.
- Patient 6: I don’t believe in herbal medicines.
C. Learning about Clinical Trials

Initially, those patients who participated in CT had no idea about the nature of a clinical trial. They also had no idea about patient rights in research before they participated in the study. Since many of them had no idea at all, they did not inquire about the drug to be tested, the purpose of the study and whether or not they could have access the results of the study. But they appreciated the advantages of being included in a CT due to free treatment, financial allowance as well as the special treatment from the study doctors.

They heard about clinical trials for cancer patients being conducted by drug companies from fellow patients and from their doctors and they inquired about the possibility of being included. All of them had been referred and recommended by their doctors and they were given some laboratory tests to determine if they were qualified. A few had read about experimental drugs on the internet or from materials available in hospitals. They also researched and googled the drug.

D. Participation in Clinical Trials

• Invitation to join a clinical trial

Patients with clinical trial experience recalled that they welcomed the chance and were very willing to join a clinical trial. Their main concern was the financial burden for the cost of their medicines and the invitation was an answered prayer. They paid attention to the contents of the patient information sheet that made them aware of the risks and benefits considering that they were joining a scientific experiment. Generally, they have developed a positive attitude about future participation in clinical trials. Looking back at their experience, they shared their thoughts and motivations when they gave their consent.

  ▪ One patient explained her ‘theory about a trial.” There may “errors” during the trial but that was better than spending “3 million pesos” for her treatment. Another one said that she fully realized that the treatment procedures were experimental and it involves “health testing.”
  ▪ Another patient said she received guidance from her doctor who explained to her that the standard of care for cancer patients will be made available to her aside from the experimental drug.
  ▪ One shared her ambivalence when she received the invitation. However, she was previously prescribed the same drug after her cancer surgery in a private hospital. Later, she decided that it was better for her to join the study using the same drug but involves a different design. She would take that gamble to join the trial to extend her life.
  ▪ Looking back at her CT experience, one volunteer realized the special care and attention accorded to CT patients as different from the regular care given to ordinary patients.
  ▪ Another noted the strict criteria of the drug company before a patient is included in a CT and was impressed that the new intervention was developed abroad. Given such impressions, she decided to join the study.
  ▪ One other patient appreciated the recruitment of clinical trial participants from the marginalized group. She believed that the poor should be given priority in the recruitment of
participants since the rich could afford to buy their medication. It gave hope to resource poor cancer patients.

- Patients were aware that their participation was voluntary but considered their inclusion as a privilege.
- Most of the participants said they exercised their autonomy when they made the decision to consent to be part of the study, even if they sought the opinion of the members of their family.

### Awareness of Risks and Benefits

In general, patients who had participated in clinical trials were aware of the risks and benefits since these were disclosed in the patient information sheet. They decided to take the risks because the greatest possible benefit was being cured of their cancer since free drugs would be provided. The protocol that clearly described the procedures that the patients should follow were explained to them. For some, it gave them the assurance that following these procedures which were under their control somehow minimized the occurrence of ‘errors.’

From the four patients who joined the educational intervention, they had the same opinion about the positive benefits of joining a CT, that included the free treatment regimen. One obvious advantage was that they did not have to line up like regular patients who waited for their turn to see the doctor. They were also being constantly monitored through phone calls for check-ups and follow-up treatments. Besides, they were given an allowance given for every follow up visit.

Some of their perspectives about risks of participation:

- One patient shared that she read about the risks and accepted them due to her desire to get well. She would not blame anyone if something happened to her. The study team followed her up for 5 years and was provided free ultrasound and laboratory support.
- Another patient said that joining a CT was no different from getting sick since there was no assurance that you would get well.
- One shared that participation is like taking a gamble and betting on a chance to have a longer life. The assurance comes from the previous evidence and experience with the drug.
- A fourth patient wanted to know about the benefit of the study, if she would be cured and if the drug would be effective.
- A fifth patient was aware that there were no promises made by the clinical trial team. However, she wanted a clearer provision in the ‘contract’ that she signed as to who would be responsible if she was harmed, hospitalized or incapacitated.

### Doctor Factor

It was remarkable that CT patients held a very high regard for their respective doctors. All of them were very thankful with the way that they were given special treatment and care by these doctors. They were all praises for their doctors and had few complaints about them. There was a prevailing perception
among CT patients that they were given another chance to live longer because the doctor served as an instrument for this.

- One patient who asked her doctor if she would die soon, was given a very encouraging answer that she would live for another 20 years. She became more optimistic and hopeful about finding a cure for her disease. She appreciated her doctor for showing concern as different from other doctors who were only interested in money. Materialistic doctors would be answerable to God.
- Another patient said that the doctor was used as an instrument who extended her life whom she now considered as part of her family.
- A third patient said that she had no complaints since her doctor was kind and his assistant was very helpful to assist her whenever she called about any side effect and might even schedule her visit in the hospital.

The CT patients were aware that a clinical trial was research about an experimental drug. All respondents agreed that the doctor must be qualified before conducting research.

- An expert should conduct the study, otherwise the patients might die.
- Before somebody practices on your life, he/she should have the training before doing a clinical trial.

- Role of Sponsor

All of the CT patients knew that there was a pharmaceutical sponsor for the clinical trial who would finance the study that included funding the total treatment regimen. They expected the sponsor to fund even the standard drug and treatment procedures that were involved in the study. They also wanted to know if the sponsor was a reputable company and were more likely to agree to participate if they were familiar with the name of the drug company. They wanted the assurance that the sponsor would also take care of study related accidents or injury.

**CONCLUSION/RECOMMENDATIONS**

Generally, Filipino patients have very limited knowledge about clinical trials. Among the cancer patient respondents without clinical trial experience, they were hardly aware about the difference between clinical practice and clinical research. This may probably be attributed to the low level of research being done in hospitals. Teaching hospitals in the Philippines are not required to do research and focus training opportunities to health care delivery as different from other countries like South Korea where teaching hospitals are required to develop research competency as evidenced by the number of publications attributed to them. The low research volume restricts opportunities for participation in clinical trials that accounts for low awareness about clinical trials. Various research stakeholders that include national research programs and institutes should initiate relevant researches that adhere to priority programs simultaneously with patient/volunteer education about priority research programs.

To increase patient awareness about clinical trials and research in general, the following measures are being proposed:
• The agencies within the Philippine National Health Research System should develop a comprehensive strategic plan to encourage or even mandate research in key sectors (universities, teaching hospitals, research institutes, etc.)

• Institutions should require competency training in research. The Department of Health has issued a department order that 2% of hospital budgets should be allocated for research.

• Pharmaceutical sponsors, health research institutes like the National Institutes of Health in UP Manila should initiate patient research education programs to develop a pool of knowledgeable participants who are ready to be recruited for various researches.

• Patient group should be encouraged to initiate health research literacy projects. As an example, they can be involved in pharmacovigilance research projects where they gather safety reports among their members, organize them to enable systematic reporting from patients afflicted with a specific disease.

In the end, it is worthwhile to remember that knowledgeable patient volunteers would contribute to better quality of clinical research.
• 95 patients participated in this study:
  o 15 have participated in clinical trials in the past
  o 80 have never participated in any clinical trial
• Most clinical trial patients are younger, between 41-50 years old (47%) while non-clinical trial patients fall within the broader range from 41-60 years old (59%).

• Many participants, regardless of clinical trial participation, are unemployed
• There are more employed patients in the clinical trial group than in the non-clinical trial group
Chart 3. Civil Status

- Majority of patients regardless of clinical trial participation are married
- Only about a fifth are single and another fifth are widowed/separated

Chart 4. Gender

- Ratio of females to males is about the same regardless of clinical trial experience
- Majority of study participants are females
Chart 5. Education

- CT patients appear to be better educated than non-CT patients
- There are more college level/graduate patients in the clinical trial group (74%) than in the non-clinical trial group (40%)
- Better education plus being employed may have pre-disposed the CT group to better learning outcomes after intervention

Chart 6. Area of Residence

- Most study participants come from Metro Manila
- A few patients hail from outside Metro Manila such as Cavite, Laguna and Rizal and even as far away as Oriental Mindoro, Olongapo and Iloilo
Chart 7. Religion

- Almost 3 out of 4 patients are Roman Catholic
- Born Again Christians are the second largest group
- Minimal membership in other religions

Chart 8. Type of Cancer

- Most patients in this study have breast cancer
- A substantial proportion of CT patients have leukemia
- Non-CT patients have colon, ovarian, cervical and other types of cancer
Chart 9. Stage of Cancer

Most study participants suffer from Stage 2 and 3 cancer

Chart 10. Kayo ba ay may sakit na kanser?

On questions regarding their medical condition, most patients recognize that they have cancer; a few say they are healed
Chart 11. Sa inyong kaalaman, may lunas ba ang iyong sakit?

Based on what they know, virtually all patients are convinced that there is a cure for cancer.

Chart 12. Ano na ang inyong ginawa upang kayo ay gumaling?

- Patients have undergone chemotherapy and surgery for their cancer
- Majority consult their doctors
- Less than half of non-CT patients take cancer medications
- Less than half of CT patients undergo radiation treatments
- Few take herbal medicines
Chart 13. Saang lugar kayo nagpapagamot?

- All go to the hospital for treatment
- A very small proportion go to health center or clinic for treatment

Chart 14. Sino sa iyong palagay ang dapat kausapin ng doktor tungkol sa iyong sakit?

- All study participants feel that doctors should talk to family members about cancer
- Among clinical trial participants, majority feel that doctors should talk to the patients themselves and their family members about their cancer
Chart 15. Alam ba ninyo ang kahulugan ng clinical trial?

<table>
<thead>
<tr>
<th></th>
<th>CT (n=15)</th>
<th>Non-CT (n=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oo</td>
<td>87%</td>
<td>39%</td>
</tr>
<tr>
<td>Hindi</td>
<td>13%</td>
<td>45%</td>
</tr>
<tr>
<td>Hindi Alam</td>
<td>14%</td>
<td>3%</td>
</tr>
<tr>
<td>No Answer</td>
<td>3%</td>
<td>2%</td>
</tr>
</tbody>
</table>

- Majority of those who have participated in clinical trials say they know what clinical trial means.
- Among those who have not participated in CT, some claim to know what it means but majority say they know nothing about it.

Chart 16. Kayo ba ay nakalahok na sa pag-aaral na gumagamit ng eksperimental na gamot?

<table>
<thead>
<tr>
<th></th>
<th>CT (n=15)</th>
<th>Non-CT (n=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oo</td>
<td>93%</td>
<td>5%</td>
</tr>
<tr>
<td>Hindi</td>
<td>7%</td>
<td>88%</td>
</tr>
<tr>
<td>Hindi Alam</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>No Answer</td>
<td>5%</td>
<td>5%</td>
</tr>
</tbody>
</table>

- Almost all who participated in clinical trials acknowledge that they have participated in a trial before.
- Majority of those in the non-clinical trial group say that they have not participated in CT.
- The rest are unsure about their participation.
Chart 17. Meron ba kayong kamag-anak na nakalahok sa ganitong uri ng pag-aaral?

- Most participants say that their relatives have not participated in a clinical trial
- Others say they do not know if their relatives have participated in CT in the past

Chart 18. Ano sa iyon kaalaman ang epektibong lunas sa iyong sakit?

- Chemotherapy is considered an effective cure for cancer, followed by surgery
- Radiation is likewise considered effective by about half of patients
- A few patients believe herbal medicines to be effective
- A third of clinical trial participants consider clinical trials as an effective cure
Chart 19. Mga bagay na bumbagabag sa akin dahil sa aking kanser

- In both CT and non-CT groups, cost of treatment is what worries patients the most
- More non-CT participants are worried about cost than CT participants
- Patients also worry about side effects, body weakness and dying
- More non-CT participants are worried about their impending death and not being able to earn a living
- CT participants are worried about the emotional effect on their families

Chart 20. Meron ba kayong alam na pag-aaral na tungkol sa paglunas sa kanser?

Awareness of studies on cancer treatment is higher among CT participants than non-CT participants
Chart 21. Sa tingin ninyo, kayo ba ay may kakayahang gumawa ng desisyon na makilahok sa pag-aaral tungkol sa gamot ng kanser?

- All CT participants feel that they have the capacity to decide on whether to join a study about cancer treatments or not
- Although majority of non-CT patients feel the same way, a substantial proportion feel they do not have the capacity to decide or are undecided

Chart 22. Sino ang nais ninyong konsultahin bago kayo sumali ng isang pag-aaral tungkol sa kanser?

- Majority of patients would like to consult their spouses prior to joining a study about cancer
- Patients would like to consult their doctors first before making a decision
- Patients would also prefer to consult parents, relatives and friends prior to joining a cancer study
Chart 23. Sino ang nais ninyong magbigay pahintulot sa pagsali ninyo sa isang pag-aaral ng gamot tungkol sa kanser?

- CT participants would also seek the consent of their spouse and children before joining a cancer medication study.
- Non-CT participants likewise would ask not only for the consent of their spouse, but also their doctor.
- Only less than a third would decide on the matter alone.

Chart 24. Ano ang nais mong malaman bago ka sumali sa isang pag-aaral tungkol sa kanser?(CT)

CT participants are more concerned about how they will be affected the study drug:
- Is it free?
- Side effects
- Responsibilities of the study doctor
- FDA approved
- Responsibilities of participant
- Who is liable for untoward incidents
Chart 25. Ano ang nais mong malaman bago ka sumali sa isang pag-aaral tungkol sa kanser? (Non-CT)  

<table>
<thead>
<tr>
<th>Question</th>
<th>Non-CT (n=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sino/ano ang responsibilidad ng doktor na tingin sa...</td>
<td>78%</td>
</tr>
<tr>
<td>Ano ang mga pangalibot at side effects ng gamot?</td>
<td>74%</td>
</tr>
<tr>
<td>Ito ba ay aprobado ng FDA?</td>
<td>73%</td>
</tr>
<tr>
<td>Libre ba ang gamot?</td>
<td>68%</td>
</tr>
<tr>
<td>Ano ang mga responsibilidad mo bilang kalahok?</td>
<td>68%</td>
</tr>
<tr>
<td>Iba’t-ibang halaga ng gawak na nagpatamaan ninyo</td>
<td>68%</td>
</tr>
<tr>
<td>Ano ne ang kaalaman o keresensan tungkol sa pinag...</td>
<td>66%</td>
</tr>
<tr>
<td>Sino ang mananagot kung sakaling likaw ay mapinsala?</td>
<td>64%</td>
</tr>
<tr>
<td>Sino ang kompanya ng gamot (sponsor) ng pag-aaral</td>
<td>61%</td>
</tr>
<tr>
<td>Mga bakal ng pag-aaral na likaw ang magbabayad...</td>
<td>61%</td>
</tr>
<tr>
<td>Ito ba ay aprobado ng isang ethics committee?</td>
<td>50%</td>
</tr>
<tr>
<td>Saang mga bansa ginagawa ang pag-aaral?</td>
<td>48%</td>
</tr>
<tr>
<td>Magisang ang magpatong sa bawat bista na...</td>
<td>31%</td>
</tr>
<tr>
<td>Pagkaikeroon ng grupo ng pasyente na biniibigan ng...</td>
<td>28%</td>
</tr>
<tr>
<td>No answer</td>
<td>3%</td>
</tr>
</tbody>
</table>

Non-CT participants are dependent on the study doctor, are concerned about the study drug and the stages of treatment:  
- Responsibilities of the study doctor  
- Side effects  
- FDA approved  
- Is it free?  
- Responsibilities of participant  
- Different stages of treatment

Chart 26. Saan nakakakuha ang isang pasyente ng kaalaman ng mga bagong paraan ng panggagamot sa kanser?  

<table>
<thead>
<tr>
<th>Source</th>
<th>CT (n=15)</th>
<th>Non-CT (n=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doktor</td>
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<td>86%</td>
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<tr>
<td>Kapwa pasyente</td>
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<td>41%</td>
</tr>
<tr>
<td>Ospital/Klinika</td>
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<td>39%</td>
</tr>
<tr>
<td>Internet</td>
<td>36%</td>
<td>47%</td>
</tr>
<tr>
<td>Telebisyon/radyo</td>
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<td>36%</td>
</tr>
<tr>
<td>Libro/magasin</td>
<td>20%</td>
<td>33%</td>
</tr>
<tr>
<td>Kamag-anak/ kaibigan</td>
<td>15%</td>
<td>33%</td>
</tr>
<tr>
<td>Dyaryo</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>Iba pa</td>
<td>13%</td>
<td>20%</td>
</tr>
<tr>
<td>No answer</td>
<td>1%</td>
<td></td>
</tr>
</tbody>
</table>

- Doctors are the primary source of information about new methods in cancer treatment, as well as hospitals/clinics  
- Word-of-mouth particularly from other patients and relatives are also named as sources of information  
- Media such as TV, books/magazines, newspapers and the Internet are named as other sources
Chart 27. Sino ang dapat na may kaalaman tungkol sa siyentipikong pamamaraan ng pag-aaral?

- Doctors are expected to be the experts on methods of scientific research used in the study
- DOH officials and hospitals should likewise be knowledgeable
- Patients themselves should know about methods used in studies
- CT participants think drug companies and ethics committees should also be knowledgeable

Chart 28. Sino ang dapat managot kung ako ay mapinsala sa clinical trial?

- Non-CT participants think that doctors and researchers should be accountable if untoward incidents happen during a clinical trial
- Majority of CT participants feel that the sponsor, more than the doctors or researchers should be held liable
- Others feel that the hospital and ethics committees are also accountable
Chart 29. Bukod sa gamot, ano pa ang nais mong suporta sa pagsali sa clinical trial?

Both CT and non-CT participants need the following support:
- Information on efficacy of study drug
- Continued consultation with study doctor
- Continuous information on new cancer treatments
- Membership in cancer survivor support groups

More Non-CT participants need information and doctor consultations than CT participants

Chart 30. Pre vs Post Intervention Ratings among Non-CT Patients (Means)

5=Lubos na sumasang-ayon, 1=Lubos na hindi sumasang-ayon
Chart 31. Pre vs Post Intervention Ratings among Non-CT Patients – Sponsor

12. Ang clinical trial ay itinataguyod ng kompanya ng gamot upang makuwala ng bagong gamot.
   Pre (n=80) 4.4
   Post (n=80) 3.8

48. Ang kompanya ng gamot ay nagtataguyod ng clinical trial upang gamitin ang mga maysakit ng kanser sa paghahanap ng mabang gamot
   Pre (n=80) 4.2
   Post (n=80) 4.0

13. Ang clinical trial ay tinutustusan ng kompanya ng parasyutiko upang dumami ang bibili ng kanilang gamot
   Pre (n=80) 3.6
   Post (n=80) 3.1

47. Ang kompanya ng gamot ay nagtataguyod ng clinical trial upang tumubo sa pagbebenta ng gamot
   Pre (n=80) 3.1
   Post (n=80) 2.8

Chart 32. Pre vs Post Intervention Ratings among Non-CT Patients – Benefits to Patients

41. Mayroon benepisyo ang kaalaman pang taguyod kapag ako ay sumali sa clinical trial.
   Pre (n=80) 4.3
   Post (n=80) 4.0

35. Libre ang konsultayon ko sa doktor kapag ako ay sumali sa clinical trial.
   Pre (n=80) 4.2
   Post (n=80) 3.9

36. Makakapalo ako ng karagdagang atensyon sa isang doktor kapag ako ay sumali sa clinical trial.
   Pre (n=80) 4.2
   Post (n=80) 3.6

38. Dapat na patuloy akong bigyan ng libreng gamot pagkatapos ng clinical trial.
   Pre (n=80) 4.1
   Post (n=80) 3.9

40. Dapat bigyan ako ng suporting gamot kahit tapos na ang clinical trial.
   Pre (n=80) 4.1
   Post (n=80) 3.8

34. Maari ako makakuha ng libreng eksaminasyon sa laboratoryo at x-ray kapag ako ay sumali sa clinical trial.
   Pre (n=80) 4.1
   Post (n=80) 3.9

33. Maaring gumaling ang aking kanser kapag ako ay sumali sa clinical trial.
   Pre (n=80) 3.8
   Post (n=80) 3.6

39. Wala akong makukuhang benepisyo kapag ako ay sumali sa clinical trial.
   Pre (n=80) 2.6
   Post (n=80) 2.2
Chart 31. Pre vs Post Intervention Ratings among Non-CT Patients (Means)

- Cursory inspection of the graph (Chart 30) indicates that patients tend to give higher ratings to statements after intervention.
- Differences in pre vs post-intervention rating scores are statistically significant in 28 out of 50 ratings.
- Agreement to statements about benefits to patients was significantly higher after the lectures as follows:
  - Contribution to scientific knowledge *(Mayroong benepisyo ang kaalamang pangsiyensya kapag ako ay sumali sa clinical trial)*
  - Free consultation *(Libre ang konsultasyon ko sa doktor kapag ako ay sumali sa clinical trial)*

Chart 31. Pre vs Post Intervention Ratings among Non-CT Patients (Means) – cont’d

- More attention from doctor *(Makakakuha ako ng karagdagang atensyon sa isang doktor kapag ako ay sumali sa clinical trial)*
- Should receive continued free medication after CT *(Dapat na patuloy akong bigyan ng libreng gamot pagkatapos ng clinical trial)*
- Should receive supporting medications after CT *(Dapat bigyan ako ng suportang gamot kahit tapos na ang clinical trial)*
- Receive free laboratory and xray *(Maari akong makakuha ng libreng eksaminasyon sa laboratoryo at xray kapag ako ay sumali sa clinical trial)*
Chart 33. Pre vs Post Intervention Ratings among Non-CT Patients (Means) - Benefits

• On the other hand, improvement is shown by the decrease in agreement to the following statements after lectures:
  o My cancer may be cured if I join CT (Maaring gumaling ang aking kanser kapag ako ay sumali sa clinical trial - Significantly fewer participants believed this after the lecture)
  o I will not get any benefit if I join CT (Wala akong makakuha ng benepisyo kapag ako ay sumali sa clinical trial - Significantly fewer participants believed this after the lecture)

Note: means were obtained by multiplying weights to the rating scales (5="Lubos na sumasang-ayon", 4="Sang-ayon", 3="Hindi alam", 2="Hindi sumasang-ayon", 1="Lubos na hindi sumasang-ayon")

Chart 34. Pre vs Post Intervention Ratings among Non-CT Patients (Means) - Safety

• Statements dealing with safety showed significant improvement, particularly on:
  o Side effects (Maaari akong makaranas ng side effects ng gamot kapag ako ay sumali sa clinical trial)
  o May pose a danger to patients (Ang clinical trial ay maraming panganib na maaring mangyari sa pasyente)
  o Medication may not be effective (Maaring mapatunayan na walang bisa ang gamot na ginamit sa clinical trial)
  o I can be harmed if I join (Maaari akong mapinsala kapag ako ay sumali sa clinical trial)
  o There is no danger of me if I join (Walang panganib ang pagsali sa clinical trial - Decreased agreement indicates improvement)
Chart 35. Pre vs Post Intervention Ratings among Non-CT Patients – Safety

28. Maaari akong makaranas ng side effects ng gamot kapag ako ay sumali sa clinical trial. 3.2 3.9
8. Ang clinical trial ay maraming panganib na maaring mangyari sa pasyente. 3.3 3.8
29. Maaring mapatunayan na walang bisa ang gamot na ginamit sa clinical trial. 3.3 3.7
27. Maaari akong mapinsala kapag ako ay sumali sa clinical trial. 2.9 3.6
31. Walang panganib ang pagsali sa clinical trial. 2.4 3.4

Chart 36. Pre vs Post Intervention Ratings among Non-CT Patients – Study Doctor

- Statements dealing with study doctor showed significant improvement, particularly on:
  - Doctor should specialize before doing a CT (Nangangailangan ng pagsasanay ang isang doktor bago gumawa ng clinical trial)
  - Only a trained doctor can do a CT (Ang clinical trial ay ginagawa lamang ng dalubhasang doctor)
  - The doctor will benefit professionally after doing a CT (Lalago ang propesyong ng doktor na mananaliksik kapag siya ay gumawa ng clinical trial)
  - The doctor will earn more money in a CT (Ang doktor na mananaliksik ay kikita ng karagdagang pera sa clinical trial)
Chart 36. Pre vs Post Intervention Ratings among Non-CT Patients – Sponsor

- Statements dealing with sponsor showed significant improvement, particularly on:
  - A drug company sponsors a CT to discover new drugs *(Ang clinical trial ay itinataguyod ng kompanya ng gamot upang makatuklas ng bagong gamot)*
  - A drug company sponsors a CT to test the efficacy of drugs on cancer patients *(Ang kompanya ng gamot ay nagtataguyod ng clinical trial upang gamitin ang mga maysakit ng kanser sa paghahanap ng mabalisang gamot)*
  - A pharmaceutical company funds CTs so that more people will buy their drug *(Ang clinical trial ay tinutustusan ng kompanya ng parmasuyutiko upang dumami ang bibili ng kanilang gamot)*
  - A drug company sponsors a CT to increase sales of their drugs *(Ang kompanya ng gamot ay nagtataguyod ng clinical trial upang tumubo sa pagbebenta ng gamot)*

Chart 36. Pre vs Post Intervention Ratings among Non-CT Patients – Other Statements

- Other statements showed improvement particularly on:
  - Doctors should ask permission of patients before enrolling them in a CT *(Dapat humingi ng pahintulot ang doktor sa isang pasyente bago siya isali sa clinical trial)*
  - Patients join CT because they cannot refuse their doctor’s invitation *(Sumasali ang pasyente sa clinical trial dahil hindi makatanggi sa doktor na nag-imbita - Decreased agreement indicates improvement)*
  - A clinical trial should use scientific research methods *(Katlangang siyentipiko ang pamamaraan ng pag-aaral sa isang clinical trial)*
Chart 36. Pre vs Post Intervention Ratings among Non-CT Patients – Other Statements – cont’d

- Before I join a CT, I should determine if I will be paid if I am harmed (Bago ako lumahok sa isang pag-aaral, dapat kong malaman kung ako ay babayaran sakaling ako ay mapinsala)
- A clinical trial is an experiment that uses human subjects (Ang clinical trial ay eksperimento na gumagamit ng taong maysakit)
- After being given appropriate information on a CT, I am open to joining it (Matapos akong mabigyan ng wastong impormasyon tungkol sa clinical trial, bukas ang aking isipan na sumali dito - Decreased agreement indicates improvement)
- A doctor can use patient data from CT without the patient’s consent (Maaring gamitin ng isang doktor ang datos ng kanyang pasyente sa clinical trial nang walang pahintulot - Decreased agreement indicates improvement)

Chart 37. Pre vs Post Intervention Ratings among Non-CT Patients – Study Doctor

| 14. Nangangaliangan ng pagsasanay ang isang doktor bago gumawa ng clinical trial. | 4.0 | 4.3 |
| 11. Ang clinical trial ay ginagawa lamang ng dalubhasang doktor | 3.7 | 4.0 |
| 43. Lalago ang propesyong ng doktor na mananaliksik kapag siya ay gumawa ng clinical trial. | 3.5 | 3.9 |
| 42. Ang doktor na mananaliksik ay kikita ng karagdagang pera sa clinical trial. | 2.8 | 3.0 |

Pre (n=80)  Post (n=80)
Chart 37. Pre-Intervention Ratings among Non-CT Patients vs CT Patients (Means)

5=Lubos na sumasang-ayon, 1=Lubos na hindi sumasang-ayon
Chart 38. Pre vs Post Intervention Ratings among Non-CT Patients – Other Statements

17. Kailangang siyentipiko ang pamamaraan ng pag-aaral sa isang clinical trial.
32. Bago ako lumahok sa isang pag-aaral, dapat kong malaman kung ako ay babayaran sakaling ako ay mapinsala.
6. Ang clinical trial ay eksperimento na gumagamit ng taong maysakit.
50. Matapos ako ng wastong impormasyon tungkol sa clinical trial, bukas ang aking isipan na sumali...
15. Maaring gamitin ng isang doktor ang datos ng kanyang pasyente sa clinical trial nang walang pahintulot

Chart 38. Pre-Intervention Ratings among Non-CT Patients vs CT Patients (Means)

- Pre-intervention ratings given by Non-CT participants were compared with those of CT participants. Despite the disparity in sample sizes, significant improvement in scores were noted on the following with CT participants scoring significantly higher agreement than non-CT participants:
  - Free consultation (Libre ang konsultasyon ko sa doktor kapag ako ay sumali sa clinical trial)
  - Free laboratory exam and xray (Maari akong makakuha ng libreng eksaminasyon sa laboratoryo at xray kapag ako ay sumali sa clinical trial)
  - More attention from doctor (Makakakuha ako ng karagdagang atensyon sa isang doktor kapag ako ay sumali sa clinical trial)
  - Side effects (Maari akong makararos ng side effects ng gamot kapag ako ay sumali sa clinical trial)
  - I can be harmed by joining (Maaari akong mapinsala kapag ako ay sumali sa clinical trial)
  - The study doctor will earn from the CT (Ang doktor na mananaliksik ay kikita ng karagdagang pera sa clinical trial)
Chart 38. Pre-Intervention Ratings among Non-CT Patients vs CT Patients (Means) – cont’d

- On the other hand, non-CT participants score significantly higher (more agreement) on the following statements than CT participants:
  - There is no danger in joining CTs *(Walang panganib ang pagsali sa clinical trial)*
  - I believe that my doctor can cure my cancer *(Naniniwala ako na kaya akong pagalingin ng aking doctor)*
  - CTs are only for poor patients who cannot afford to pay for medications *(Ang clinical trial ay para lamang sa mga mahihirap na walang perang pambayad sa gamot)*
  - CTs are done only by medical students *(Ang clinical trial ay ginagawa lamang ng mga mag-aaral ng medisina)*

Chart 39. Post-Intervention Ratings among Non-CT Patients vs CT Patients (Means)

5=Lubos na sumasang-ayon, 1=Lubos na hindi sumasang-ayon

Caution: Small sample (n=4) of CT patients
Chart 40. Post-Intervention Ratings among Non-CT Patients vs CT Patients (Means)

- No statistically significant differences in ratings were noted between clinical trial patients and non-clinical trial patients after intervention.