Informed consent practice in cancer clinical trials in Taiwan

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~5,000-10,000 compounds

IND SUBMITTED

DOSAGE

SafetY

EFFECTIVENESS

NUMBER OF VOLUNTEERS

TENS

HUNDREDS

THOUSANDS

3 - 6 YEARS

6 - 7 YEARS

0.5 YEARS

INDEFINITE

(US FDA infographic, 2015)
Informed consent

• Information
• Comprehension
• Voluntariness (The Belmont Report, 1979)
Informed consent

• Provide adequate information to enable patients to make an informed decision

• Ensure that patients participate voluntarily in research and only when the research is consistent with their values, interests, preferences and without coercion

(Emanuel, Wendler, & Grady, 2000)
Clinical problem

- People with a life-threatening illness may be influenced to participate in a trial because they see it as their only hope, not based on the true nature of the clinical trial (Brown, Bylund, Siminoff, & Slovin, 2011).
Informed consent
Understanding
Decision making
Purpose

• Exploring the current informed consent process in cancer clinical trials in Taiwan
Methods

• Using semi-structure interview guides to interview 10 clinical research nurses (CRNs)
• Content analysis
Current informed consent process

- PI call CRN for screening
- Informed consent preparation (30mins-hours)
- Conducting informed consent (20mins-hours)
- Decision making (immediately-a week)
- Record in source document
Informed consent preparation

• Find a space to conduct informed consent
• Understand patients’ medical history, family support system
• Understand patients’ current disease, emotional state
• “When I get a call from PI to screen, I need to prepare myself to understand this patient. I normally use a limited time to browse this patient’s history, see whether he has any critical medical experience, and see the reason he is offered this trial. Usually, if he is new diagnosis or his disease is progression, he is very sad or upset at that time.” (CRN1)
• “You cannot just meet this person, and say listen carefully, I am going to conduct the informed consent to you. If he is very sad or shocked, you need to spend the time with him, talking about his feeling, letting him calm down. If you think he is not ready to receive the trial information today, we could do this next time. The point is that you need to make sure he is ready for informed consent. Otherwise, it just wastes your time and he is not going to understand what you say.” (CRN1)
Conducting informed consent

• Informed consent situation
  ➢ Unequal power relationship
  ➢ Facing the pressure of disease progression
Conducting informed consent

• Informed consent communication
  ➢ Too much trial information and pressure from disease progression make patients turn to trust their physician’s recommendation.
“Sometimes you say too much is not helpful, even though you have organized a timetable for them to understand the trial procedures. But it is still too much for them. They normally say: I trust you, you tell me what I need to do and I just follow it. Most of these patients are the elderly, not accompanied by a family member.” (CRN2)
• “You can feel the patient is overwhelmed by the trial information. They are just listening, and then let the information go without understanding. They just know they need to receive the treatment, and they must trust their physician.” (CRN3)
• “Part of patients trust their physician, and they just want to sign the consent form and start the treatment as soon as possible. They don’t want to listen me.” (CRN4)
Conducting informed consent

- Informed consent communication
  - Family members play an important role in the informed consent process when the patient is not ready to informed consent.
• “If the patient is still upset, he has not recovered from the negative emotional state, but need to make an decision regarding next treatment plan, I will explain the trial information to their family first. Then let their family members discuss with the patient after they go home.” (CRN2)
• “Sometimes if the elderly still do not understand what I said, I will ask them invite their young family members to come with them next time or ask them bring the consent form to discuss with their family and come together next time.” (CRN4)
Decision making

• Trust of their physician
• An opportunity
• Hope
• Better care from the research team
• Financial consideration
• Support from the family
• “It does happen when the patient 100% trust their physician, they signed the consent form without thinking. Even though we showed our concerns regarding his decision and asked him to discuss with their family, he just responded firmly: no need, I can decide by myself”. (CRN4)
• “For some patients, the trial participation is their last chance or hope to receive treatment. They think they could have better care and being close monitoring by the research team. They go to hospital regularly, and research team members always take care for them, listen to them. They feel more safe in a trial, not being abandoned.” (CRN1)
• “If the patient has financial difficulties, he may think he has 50% of chance to receive the new drug without extra costs. If he fails to receive the new drug, he can still receive the standard treatment. This is a good deal for him.” (CRN1)
Decision making

• Being afraid of offending their physician
• Uncertainty (side effects, risks, benefit)
• Frequent travel from home to hospital
• Trial requirements (frequent travelling for blood tests, scans)
• “The patient may feel clinical trial is too much for her. It has unknown benefits, and she needs to go to hospital more frequently than the standard treatment for blood tests, clinical visits and so on…” (CRN3)
• “Patients with some physical symptoms may think they have become so weak, why they need to choose a risky treatment, especially this treatment is unable to guarantee to improve their weakness.” (CRN3)
Dilemmas of informed consent

- Misunderstanding
- Conflicts with the physicians
• “Some people may think they are so lucky to enroll a trial because they met the screening criteria and someone failed....they can receive the latest treatment...even though I tried to clarify their misunderstanding, but they still have a positive belief in the trial.” (CRN2)
• “The PI may think why you spend so much time in informed consent. You can save more time to do other things.” (CRN1)
• “The patient had signed the DRN, but the PI thought he still had a chance to be treated...so the patient signed the consent form on his bed in front of the physician.... You can see he was afraid of offending their physician....He died after receiving the trial treatment a week later...Until now, it is still my pain. I do want I can do something for this patient, but I cannot fight the PI.” (CRN2)
Conclusions

• Rather than informed consent, cancer patients participate in a trial is based on the pressure of disease progression and trust of their physicians.
Conclusions

• How to improve patient understanding and assist with making an “informed” decision regarding a clinical trial are critical issues.