Attitudes and Comprehension of the Informed Consent Form by the Oncology Patients

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Research article

Keywords: Informed consent form, autonomy, oncology patients, chemotherapy

Posted Date: December 5th, 2019

DOI: https://doi.org/10.21203/rs.2.18275/v1

Abstract

The main purpose of this study was to investigate knowledge and perceptions of the informed consent form by cancer patients receiving chemotherapy. The participants were selected through a random sampling methodology. Out of 30 cancer patients, 28 volunteered to be involved in the study. They completed a sociodemographic form. The findings revealed that the informed consent form does not greatly affect patients about chemotherapy and their decisions. They mostly were not aware of the content and purpose. The factors behind that included incomprehensible language, less time, crowded clinics, and belief on the doctor. It is suggested that chemotherapy patients should obtain more accurate and memorable information about the treatment process and its side effects with informed consent

Background

The informed consent form is defined as “accepting the medical procedure voluntarily and without any pressure by the patients following adequate explanation by the physician about the form, possible issues, benefits, alternative treatments” [1]. It is ethically and legally critical for the oncology patients to be informed regarding the medical treatments and related issues preceding them. Such an objective could be accomplished with an informed consent form. Thus, it should be appropriately generated and clarified by the physician or the specialist.

An informed consent form provides important functions for the doctor-patient relation [2,3,4]. Initially, it should be designed with the principles of biomedical ethics such as respect for patient autonomy, beneficence, non-maleficence, and justice. Additionally, it should include the trust-based relationship between the doctor and the patient as well as individuals' legal rights for decision making. Lastly, it needs to protect the patient’s privacy and protect health workers from pressure and fraudulent actions.

Previous studies [5, 6, 7, 8] proposed that the informed consent form should consist of four fundamental components to provide preferred information and gather rich feedback from the patients. The following sections were suggested for an informed consent form;

- Disclosure of the associated information.
- Understanding of information.
- Voluntary consent.
- Competency to provide consent.

Various studies [9, 10, 11, 12, 13, 14, 15, 16] have been conducted on the understanding and perceptions of the informed consent form in the clinical studies involving oncology patients. For example, Davis et al. (9) proposed a hypothesis that it should be less intimidating and more easily comprehensible by oncology patients. They also tested their hypothesis with 53 patients diagnosed with various medical conditions including cancer and 130 healthy people. They were examined for reading ability and asked to evaluate a typical consent form. Then, they were interviewed concerning their attitudes toward and

understanding of the informed consent form. An alternative informed consent form was also given and a comparison between the typical and alternative forms was done. Their findings revealed that the alternative form developed by the researchers was found easier to read than the typical form. On the other hand, the degree of comprehension for both consent forms was alike.

Another related study [17] suggested some practical improvements for the quality of the informed consent form to protects patients' personal information and promote ethical issues of the research. They described a new informed consent form particularly emphasizing comprehension of the purpose, process, risks, benefits, and alternatives of the standard consent form. Also, the consent form in terms of principles, structure, language, explanation, readability, and comprehension was analyzed. In conclusion, certain revisions regarding such issues were recommended. For example, the form writers should consider using analogous texts and ideas in the statements, short and plain sentences, and bullet points to break-up long explanations, but implementing the professional language. They, additionally, recommended the use of readability checkers to estimate reading levels and the prevention of misleading narratives. Finally, checking for understanding of the statements in the informed consent form should be highlighted for better outcomes.

Joffe and friends [18] focused on measuring the quality of comprehension among the oncology patients to explore correlations between understanding of the form and providers' beliefs about clinical research. They applied a cross-sectional survey with 207 adult patients. 90% of them indicated that they were satisfied with the information and explanations in the informed consent form as well as its implementation. However, many patients were particularly worried about non-standard treatment (74%), the unproven nature of treatment (70%), the uncertainty of the benefits (29%) and potential risks from the participants (63%) regarding the informed consent form. Besides, misconceptions about the statements and information included in the consent form were explored.

With the findings of the related previous studies, this study was aimed to investigate oncology patients' attitudes and comprehension of the informed consent form. Also, it was designed to increase the knowledge level of patients concerning the consent form, ensuring that it plays a critical role in their decision-making. This study is also important since it will prepare the chemotherapy patients for the treatment process by obtaining more accurate and helpful information about the treatment process including side effects. The findings of this study will also contribute to physicians' awareness of potential insufficiencies in the informed consent form. It is additionally expected that it serves as an asset to improve the contents of the informed consent form for readability and understandability.

Methods

Data of this study was collected through interview sessions with 28 cancer patients who were receiving chemotherapy treatment at a private university in Istanbul. Only five were residing outside Istanbul and visit only for treatment purposes.

Once agreed to get involved in the research, they answered interview protocol questions regarding knowledge and perceptions of the written consent form. Two data collection tools were utilized; sociodemographic data form and interview questions. The interview protocol included eleven items. A verbal consent form was obtained from the participants before the data collection process. The participants were randomly selected and interviewed.

Each interview session took place about 20–30 minutes. Firstly, the participants responded to the sociodemographic questions about their age, gender, income, education levels, etc. Next, the patients were asked questions about how they were informed before chemotherapy, what informed consent means, what they knew about the risk and efficacy of the procedure, and how effective they were in accepting or refusing the treatment. Also, the general behaviors of the participants were observed during the interview process.

This study was designed as a mixed research methodology. Following the interviews, the patients' responses were transcribed and analyzed. The datasheet was carefully inspected by the researchers. Sociodemographic factors were analyzed via comparative analysis. Themes and code lists were determined with the use of framework analysis (grounded theory) according to the qualitative data analysis approach.

Results

The current study was structured to collect data regarding attitudes towards and understanding of the written consent form from a group of oncology patients. The results are expected that it plays an effective role in chemotherapy patients' decision making and prepares them for the treatment process with more accurate and notable information.

Sociodemographic Factors

Firstly, sociodemographic characteristics were collected via the sociodemographic data form. According to the findings in Table 1, most of the patients (53.58%) were 60 years or older with an average of 61.79.

Table 1*. Sociodemographic Factors of the Participant*

Sociodemographic Factor	Frequency (N)	Percentage (%)
Gender		
Male	14	50.00
Female	14	50.00
Ages		
Average	61.79	
< 60	13	46.42
60-69	11	39.29
> 70	4	14.29
Education Levels		
Elementary	5	17.86
Middle School	12	42.86
High School	7	25.00
university	4	14.28
Occupation		
Retired	11	39.29
Housewife	8	28.57
Businessman	4	14.29
Other	5	17.85
Types of Cancer		
Breast	9	32.14
Colorectal	7	25.00
Lung	5	17.86
Other	7	25.00

Table 1 also shows that the participants were mainly (60.72%) elementary and middle school graduates. The number of male participants was equal to the number of females. Also, most of them (67.76%) were either retired or housewives. Some of them were employed as a teacher, attorney, or police officer. The most common kinds of cancer were found in breast cancer (32.14%) or colorectal cancer (25.00%). Also, nine females were suffering from breast cancer and five males from lung cancer. Other types of cancers were reported as stomach, prostate, and liver cancer. Only three participants were recently diagnosed with cancer and just started chemotherapy treatment.

Knowledge and Perceptions of The Written Informed Consent Form

The first question in the interview protocols was related to how well they knew about the informed consent form. Three indicated that they knew and heard it in the past. Some of them (N= 10) stated that it was handed during the doctor meeting, but others (N= 10) stated no form of any kind before the treatment. Only six patients remembered that they were given a “form or paper” during the meeting. For example, a 37 years old housewife diagnosed with breast cancer said, "I had signed a paper before my surgery. The doctor gave me information before chemotherapy”. In conclusion, the majority of the patients indicated that they did not hear any type of informed consent form. Many patients perceived the informed consent form as just the physicians’ regular reports about the patients’ health conditions during personal interviews. They also did not think the form that includes any specific information for themselves and their medical conditions.

Most of the patients (N=15) said that they were verbally informed about the content of the written consent form. Half of them (50%) stated that they were given sufficient information about the statements in the written consent form. However, some (N=8) believed that inadequate information was provided. One implied that “it wasn’t enough, I was scared because I didn’t have any information about the disease. They should have given some specifics about the drugs and treatment. I think it is somewhat commercial” (42 y.o, housewife, breast cancer). Some believed that the language of the form should be written more clearly for the patients.

Most of the patients believed that the informed consent form was not necessary, but a simple procedure and it should be completed because it gives them more information about the process and better prepares for the treatment. 23 (82%) were satisfied with the delivered information.

Regarding the issues of chemotherapy, the patients were experiencing certain side effects. They also suffer from nausea, loss of appetite, and skin rash. On the other hand, the participants with no side effect credited it to their healthy and strong body structures. An 80 years old housewife suffering from breast cancer explained that “I had dizziness, weakness, loss of appetite, inability to walk, and hair loss. I was feeling better when I stopped the treatment”.

The patients were also asked about the issues related to chemotherapy. 21 participants said that they were previously informed about the side effects. Two didn't have any experience of side effect so didn't know anything about it. They mostly heard about the side effects on the Internet or doctor meetings. Some of them were taking various precautions for protection from the side effects.

Some patients made suggestions to improve the informed consent form such as patients' expectations, more comprehensive explanations of the after-treatment procedure. They also emphasized that it should give more in-depth information regarding employment and social life issues during chemotherapy in addition to providing rich and diverse text content. For example, a 58 years old male patient diagnosed with abdominal mass stated that “I read the informed consent form and it had everything the doctor said. Other than that, what else could be in it? However, the expectations for the patient were missing. For instance, it stated that herbaceous plants were forbidden, but I didn’t know if it included dill and parsley. I later found out that it meant nettle. If it included how we would feel after the treatment, it would be better. I wanted to work but they didn’t inform me about it. Chemotherapy informed consent form is very general. They shouldn’t be a single common form”.

Some of the patients indicated particular factors for not willing to read the informed consent form. They listed the reasons for why not reading it as follows:

- It wasn't written with a plain language,
- Less time and too many patients,
- The patients were shocked when discussing it,
- Felling forced to sign it no matter what,
- Being a novice person in the process,
- Full reliance on the doctor.

Among the aforementioned reasons, the most popular explanations (N=12) were that; because they trusted their doctors and absolute belief in their treatments. Also, seven patients stated that they weren’t given any choices, but they signed it anyway.

Considering whom the written informed consent form should be obtained for, the patients provided different explanations such as only for the patients (N=9) or doctors (N=6) and both of them (N=6). The reason for answering ‘only for doctors' lies in putting the responsibility of the treatment on the patient,

protecting their rights in case of any bad scenarios, and proving that the patients were informed. On the other hand, some participants expressed that it was written for the patients only because being better informed about the process, learning any side effects, accepting the treatment consciously. Only two of them didn't know its purpose. They also listed some reasons behind their responses, "Doctors needs to avoid responsibilities; we learn about negative sides of treatment; practitioner learns them with us".

Those that adversely affect a doctor's verbal explanation about the process included the patients being shocked, having a bad mood or physical state, relatives conducting the meeting, relatives taking care of the patient, and relatives trying to hide the disease from the patient.

Some of the patients were considering the informed consent form as 'procedure' and 'just a formality' because they had to accept the situation and felt completely helpless. Having a misconception about the informed consent form intended to protect the doctor, or the idea that the patients need the form when not trusting in the doctor makes it unnecessary for them.

Discussion

This study was designed to investigate the knowledge and perceptions of cancer patients regarding written informed consent form at the beginning of the chemotherapy treatment process. The participants were mostly pleased with the information given about the informed consent form. However, findings revealed that the informed consent form does not play an active role in informing the patients about chemotherapy and the decision-making process. It was a vague and unaware practice for patients who will receive chemotherapy treatment.

The patients were mostly not satisfied with the existing consent form. Specifically, they stated various concerns and issues about its content, language, and explanations by doctors or nurses. Besides, most of the patients did not hear about the form earlier, which indicated that informed consent form did not have any impact on their previous doctor visits regarding any health issues that requires any such forms.

Although they complained they weren't well informed about the consent form, they said they signed it because they trusted their doctors. This decision-making behavior was observed in some of the previous research findings [19, 20, 21]. Besides, they signed it because of the fear of worsening of the disease.

The doctors should give patients more time to read and understand the information in the written consent form. Also, patients should be aware of the process thoroughly. The doctors should identify that it is both doctor and patients to understand the process [22]. Though not having enough time to discuss it with every patient, the doctors should be present in the room, when other associates (residents or nurses) explain it. However, among high numbers of cancer patients, it is difficult for physicians to attend all the

meetings. Also, patients occasionally take medicine during such meetings or interruptions by the nurses. The chemotherapy unit in the common area makes it difficult for better explaining the written consent form [23].

Patients need to increase knowledge and understanding of the informed consent form. It is expected to ensure that chemotherapy patients should take an active role in the decision-making process regarding treatment. They should also obtain more accurate, rich, and memorable information about the process and side effects [24]. A consent form should provide more information about social life [25].

In conclusion, this study will be a great asset for similar investigations in the future because it provides information from different perspectives. However, for future studies, it would be more beneficial if more quantitative data and analysis is also included. In that way, the researchers could explore the situation from both research methodologies that could lead to construct superior, more understandable (with plain language) [17] and trustworthy informed consent form for not only cancer patients but also all patients [26, 27, 28].

Conclusion

This research study was conducted to investigate the perspectives of oncology patients towards the informed consent form. This form is extremely important for the patients to acknowledge regarding their illness such as treatment, specifics, and other issues they have the right to learn from their specialists. The participants were mainly found to be unaware of the items and statements in the informed consent form. One of the leading reasons for this findings was based on their initial emotional reactions to the illness. Such immediate and uncontrolled reactions of the patients prevent them from gathering the necessary information regarding the process.

One of the major complaints by the participants were regarding their doctors not informing them about the process. This might be due to the doctors being unaware or uninformed about the important issues regarding their illness and treatment. Also, some doctors underestimate the form since it was just a piece of paper that should be read to the patients for just formality nothing serious.

Another issue in relation with the first one above raised by the patients was that the doctors didn’t give enough time to read it through or understand the data and the contents of the form. This is also based on their avoidance behaviors toward the information in the written consent form. In conclusion, it is important for the patients to be well informed regarding the process of their illnesses such as treatments, side effects, and other important features.

Appendix 1

Interview Protocol Items

1. Any earlier knowledge about the written consent form?

2. Who is the written consent form for?
3. What is the main reason for signing the written consent form?
4. Who, when and how informed about the written consent form?
5. Competence of the written consent form?
6. Any need for the written consent form?
7. Any missing information in the written consent form?
8. Any side effects related to chemotherapy?
9. Any knowledge of the side effects related to chemotherapy?
10. Acceptance and perspective of the disease and any comments?
11. Any feedback about the written consent form?

Declarations

Acknowledgements

We are grateful to all participants in this study. We also thank Dr. Seda Aksoy, Dr. Aysenur Avarasli, Dr. Muhammed E. Kizilay, Dr, Kevser N. Yalciner for their help in collecting data from patients. Also, we thank Prof. Dr. Mustafa Tasdemir for his advice.

Funding

This study was supported by the Bezlialem Vakif University scientific research unit.

Authors' contributions

Ibrahim Topçu conducted the design, implementation, and data analysis of the study. He also wrote down all of the sections in the manuscript.

Availability of data and materials

Data used and analyzed by the researcher (Ibrahim Topcu) are available from the corresponding author on reasonable request.

Ethics Approval and consent to participate

The research was conducted in respect to informed consent, respect for personal information, the right for privacy. All procedures were in accordance with ethical standards of responsible institutional committee on Human Experimentation and the Declaration of Helsinki.

Informed consent was collected from all participants included in this study allowing them to withdraw at any time in the study.

This study was approved by the Bezmialem University clinical research ethics board (71306642-050.01.04-) in 2015.

Consent for publication

The author of the study gave full written informed consent form for participation and publication.

Competing interests

The authors declare no conflict of interest or no competing interest.

Acknowledgments

We gratefully thank Dr. Seda Aksoy, Dr. Aysenur Avaraslı, Dr. Muhammed E. Kızılay, Dr, Kevser N. Yalçıner for their help in collecting data from patients. Also, we thank Prof. Dr. Mustafa Taşdemir for his advice.

References

1. Barnett JE., Wise EH, Johnson-Greene D, Bucky, SF. Informed consent: Too much of a good thing or not enough?. Professional Psychology: Research and Practice. 2007; 38(2): 179a.
2. Breitfeld PP, Weisburd M, Overhage JM, Sledge Jr G, Tierney WM. A pilot study of a point-of-use decision support tool for cancer clinical trials eligibility. Journal of the American Medical Informatics Association. 1999; 6(6): 466-477.
3. Sand K., Eik-Nes NL, Loge JH. Readability of informed consent documents (1987–2007) for clinical trials: A linguistic analysis. Journal of Empirical Research on Human Research Ethics. 2012; 7(4): 67-78.
4. Dunn LB, Jeste DV. Enhancing informed consent for research and treatment. Neuropsychopharmacology. 2001; 24(6), 595-607.
5. White Douglas R. Informed consent: patient information forms in chemotherapy trials. American journal of clinical oncology. 1984; 7(2): 183-190.
6. Grossman S, Piantadosi S, Covahey C. Are informed consent forms that describe clinical oncology research protocols readable by most patients and their families? *Journal of Clinical Oncology.* 1994; 12(10): 2211-2215.
7. Daugherty CK. Impact of therapeutic research on informed consent and the ethics of clinical trials: a medical oncology perspective. Journal of Clinical Oncology. 1999; 17(5): 1601-1601.
8. Jones JW., Lawrence BM, Richman BW. Informed consent: it's not just signing a form. Thoracic surgery clinics. 2005; 15(4): 451-460.
9. Davis TC., Berkel HJ, Holcombe RF, Pramanik S, Divers SG. Informed consent for clinical trials: a comparative study of standard versus simplified forms. JNCI: Journal of the National Cancer

Institute. 1998; 90(9): 668-674.

10. Bergenmar M, Johansson H, Wilking N. Levels of knowledge and perceived understanding among participants in cancer clinical trials–factors related to the informed consent procedure. Clinical Trials. 2011; 8(1): 77-84.
11. Harth SC, Thong YH. Parental perceptions and attitudes about informed consent in clinical research involving children. Social science & medicine. 1995; 41(12): 1647-1651.
12. Hack TF, Whelan T, Olivotto IA, Weir L, Bultz BD, Magwood B, Brady J. Standardized audiotape versus recorded consultation to enhance informed consent to a clinical trial in breast oncology. Psycho-Oncology: Journal of the Psychological, Social and Behavioral Dimensions of Cancer. 2007; 16(4): 371-376.
13. Armstrong N, Dixon-Woods M, Thomas A, Rusk G, Tarrant C. Do informed consent documents for cancer trials do what they should? A study of manifest and latent functions. Sociology of health & illness. 2012; 34(8): 1230-1245.
14. Olver IN. The adequacy of consent forms for informing patients entering oncological clinical trials. Annals of Oncology. 1995; 6(9): 867-870.
15. Olver IN. Impact of an information and consent form on patients having chemotherapy. The Medical Journal of Australia, 1995; 162(2): 82-83.
16. Montgomery C, Lydon A, Lloyd K. Psychological distress among cancer patients and informed consent. Journal of Psychosomatic Research. 1999;46(3): 241-245.
17. Jefford M, Moore R. Improvement of informed consent and the quality of consent documents. The lancet oncology. 2008; 9(5): 485-493.
18. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC. Quality of informed consent in cancer clinical trials: a cross-sectional survey. The Lancet. 2001; 358(9295): 1772-1777.
19. Nisbett RE, Ross L. Human inference: Strategies and shortcomings of social judgment. Prentice-Hall. 1980.
20. McKneally MF, Ignagni E, Martin DK, D'Cruz J. The leap to trust: the perspective of cholecystectomy patients on informed decision making and consent. Journal of the American College of Surgeons. 2004; 199(1): 51-57.
21. Hall DE, Prochazka AV, Fink AS. Informed consent for clinical treatment. Cmaj. 2012; 184(5): 533-540.
22. Mulsow JJ, Feeley TM, Tierney S. Beyond consent—improving understanding in surgical patients. The American Journal of Surgery. 2012; 203(1): 112-120.
23. Stacey D, Samant R, Bennett C. Decision making in oncology: a review of patient decision aids to support patient participation. CA: a cancer journal for clinicians. 2008; 58(5): 293-304.
24. Falagas ME, Korbila IP, Giannopoulou KP, Kondilis BK, Peppas G. Informed consent: how much and what do patients understand?. The American Journal of Surgery. 2009; 198(3): 420-435.

25. Wagner CD, Bigatti SM, Storniolo AM. Quality of life of husbands of women with breast cancer. Psycho-Oncology: Journal of the Psychological, Social and Behavioral Dimensions of Cancer. 2006; 15(2): 109-120.
26. Worst BC, van Tilburg CM, Balasubramanian GP, Fiesel P, Witt R, Freitag A, Chotewutmontri S. Next-generation personalized medicine for high-risk pediatric cancer patients–The INFORM pilot study. European Journal of Cancer. 2016; 65: 91-101.
27. Clemens MW, Miranda RN, Butler CE. Breast implant informed consent should include the risk of anaplastic large cell lymphoma. Plastic and reconstructive surgery. 2016; 137(4): 1117-1122.
28. Spatz ES, Krumholz HM, Moulton BW. The new era of informed consent: getting to a reasonable-patient standard through shared decision making. Jama. 2016; 315(19): 2063-2064.