**Unfunded innovative cancer therapies recommendations: ethical vs. clinical perspectives among oncologists in a public healthcare system - a mixed method study**

**Abstract**

Background: Some recently developed cancer treatment technologies are not funded under the Israeli public healthcare system. There is a need for careful and balanced use of innovative treatments and technologies, while putting patients at the center of discourse on this complex and controversial issue. The present study examined ethical aspects of recommending innovative but unfunded cancer treatments.

Patients and methods: The combination of methods included a survey of 127 oncologists regarding their attitudes toward use of unfunded innovative cancer treatment technologies, and in-depth interviews with 16 oncologists.

Results: 86% of respondents indicated that patients should be offered all treatment alternatives, regardless of their financial situation. However, 59% indicated that they often face dilemmas regarding recommending new unfunded treatments to patients with financial difficulties and without private health insurance. Over a third (38%) stated that they felt embarrassed and uncomfortable discussing the cost of treatment with patients. The in-depth interviews revealed four key themes: economic considerations in choosing treatment, therapist-patient discourse, the public healthcare fund, and discussion of treatment costs. A predictive model found that physicians facing patients whose medical condition worsened due to an inability to access unfunded new treatments, and who expressed the opinion that physicians could assist in locating funding for treatments for patients who cannot afford them, were more likely to recommend unfunded innovative treatments to patients (F = 5.22, R2 = 0.15, p < 0.001).

Conclusions: Physicians feel a professional commitment to offer patients the best medical care, and a moral commitment to discuss costs and minimize patients’ financial difficulty. It is important to develop a psychosocial support program for physicians and patients dealing with ethical and psychosocial dilemmas during the course of the illness, and to set guidelines for oncologists to conduct a comprehensive and collaborative physician-patient discourse regarding all aspects of cancer treatment.

Background

Objective considerations of innovative cancer treatments have become essential, due to the rapid development of new and expensive medications and innovative treatment methods.1,2 The value of a new treatment is usually determined by examining the clinical benefit it provides versus its cost.3 Potential clinical benefit is usually defined by its ability to prolong or improve patients’ lives. This is measured by examining the effect of treatment on overall survival, maintaining quality of life, and controlling disease-related symptoms.4 A study examining 23 indicators of immunotherapy found that only three of them met the measure of improved patient survival over time, and there is not yet data on patient survival for 13 of the indicators due to their approval in an accelerated procedure in the US Drug Administration.5 Nevertheless, many of these expensive treatments are offered by oncologists and some are funded by public healthcare systems or private health insurance companies.

Oncologists agree that there is a need for careful and balanced use of innovative technologies while putting the patient at the center of the discourse.6 This balance requires meaningful interaction between a physician who has clinical knowledge, and patients who have knowledge regarding their personal preferences, socioeconomic status, experiences, expectations, and degree of support from family and immediate environment.7 Regarding patients in advanced stages of the disease, the challenge of meeting cost-benefit standards becomes impossible, as the value of life-years is not linear.8 In these cases, which involve the majority of the newest and most expensive cancer treatments, the personal and social value of the treatment is higher than its quantitatively measured and assessed utilitarian value. In addition, cost-benefit considerations may contradict ethical and social considerations, such as concern for equality in receiving medical care. Therefore, in decisions regarding expensive treatments, failure to achieve utilitarian value may sometimes be justified by ethical considerations.9

Despite guidelines for a cooperative physician-patient discussion regarding the costs and benefits of innovative cancer treatments, the goals of such a discussion, as well as how and when to conduct it, are not adequately clear.10 Some argue that oncologists have a social commitment to make careful and optimal use of limited resources.11 Others argue that oncologists should be solely committed to the patient, based on the cost-benefit considerations of each individual treatment.12 Another approach argues that it is not the role of oncologists to discuss financial issues, and that the decision to offer appropriate treatment to the patient should be based solely on considerations of clinical efficacy.10 As a result, although many physicians recognize the importance of having discussions with patients about clinical efficacy (which is often unclear) and about the cost of treatment, few physicians actually conduct these discussions, presumably due to a lack of consensus on how and when to do so.

The State of Israel has a public healthcare system, according to its National Health Insurance Law, within which a designated set medical of treatments is funded by the state for every citizen. The funded treatments are updated every year and new treatments and technologies are added. The current study addresses the perceptions of oncologists regarding use of treatments and technologies that are not covered by the public healthcare fund and therefore must be paid for privately by cancer patients in the final stages of the disease, when treatments are likely to prolong life or improve quality of life only for a limited time.

Patients and methods

The study was approved by the Ethics Committee of the Ashkelon Academic College (Approval # 4-2019). Methods included a survey and in-depth interviews among oncologists.

Population sample

Out of approximately 250 physicians who specialize in oncology and are members of the Israeli Association of Clinical Oncology and Radiotherapy, 127 physicians responded to a telephone survey (50.8% response rate). The survey examined attitudes towards the use of innovative unfunded treatments. At the end of the survey, respondents were asked if they would be willing to be interviewed on the subject. Subsequently, 16 oncologists were interviewed during the months of December 2019 to April 2020. Of the interviewees, eight were male and eight were female. Eight worked in two hospitals in southern Israel, seven worked in two hospitals in the center of the country, and one worked in a hospital in the north. Six were interns towards the end of their internship and ten were specialist physicians. Six of the respondents were current or former members of the Health Fund Committee, which discusses the introduction of treatments for public funding.

The interviewees worked in various specialties, including urinary tract, genital system, breast, digestive system, skin, and lung cancers. The interviews lasted between forty minutes and an hour. They were conducted face-to-face in the hospitals, with the exception of two interviews that were conducted over the telephone due to Covid-19 restrictions. All were conducted by a research assistant who is a graduate student in clinical psychology.

Research tools

Survey among oncologists: The questionnaire was written by the researchers and validated using the content validation method by two physicians specializing in oncology and one specialist in public health and health policy. Following their comments, three ambiguous questions were clarified. The questionnaire included 15 statements describing perceptions and dilemmas regarding cancer treatment using innovative technologies that are not publicly funded. Respondents were asked to rate their degree of agreement on a Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Reliability of the questionnaire was α = 0.73. The questionnaire also included background questions regarding: gender, age, level of religiosity, country of birth, country where the respondent studied medicine, number of years of experience in oncology, whether the respondent works among the social periphery of Israel, and whether the respondent is a participant in processes of assessing treatments for the National Healthcare Fund Committee (Appendix 1). The statements in the questionnaire were grouped into several categories, as shown in Table 1.

**Table 1: Research variables with averages and standard deviations**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Positions regarding issues** | **Number** **of statements** | **Mean ± SD** |
| Dependent variables | Recommending innovative unfunded treatments to patients  | 1 | 4.41±0.89 |
|  | Actual use of innovative unfunded treatments  | 1 | 4.07±0.83 |
|  | Use of innovative tests that are not funded | 1 | 2.74±1.18 |
|  |  |  |  |
| Independent variables | Perception of the physician's role in achieving compassionate care | 1 | 3.88±1.08 |
|  | Need for physician-patient discussion about costs and benefits of innovative cancer treatments | 3 | 3.76±0.90 |
|  | Responsibility for choosing the treatment | 2 | 3.45±1.11 |
|  | Social and ethical dilemmas associated with recommending innovative cancer treatments | 3 | 3.14±0.92 |
|  | Preference for clinical efficacy of treatment for the patient | 1 | 3.00±1.07 |
|  | Physician's responsibility for considering costs of innovative cancer treatments | 2 | 2.81±1.03 |
|  | Inequality in healthcare that harms the patient | 1 | 2.79±1.39 |

In-depth interviews: The interviews were semi-structured. The wording and order of the questions changed according to the dynamics of the interview, in order to maintain continuity and flow and encourage openness among the interviewees. (Interview guides appear in Appendix 2).

Statistical analysis

Data collected in the survey were analyzed using SPSS V. 26. Relationships between the variables were examined via Pearson correlations. Differences between groups were examined using t-tests for independent samples and single-factor variance analysis, which included post-hook analysis using the Tueky method. Finally, a model of linear regression was constructed to predict attitudes towards recommending unfunded treatments. Based on Thiese et al.13 and in light of the limited sample size, a significance level of p < 0.10 was determined. The interviews were analyzed using a thematic analysis method in the ATLAS.ti software. The analysis included both deductive themes arising from the research topic and literature review, and inductive themes that emerged from the data.14

Results

Table 2 presents the characteristics of the sample of survey respondents. The mean age of the respondents was 57.06 ± 10.3. The mean years of work experience was 25.39 ± 9.9.

Table 2: Characteristics of Survey Sample

|  |  |  |  |
| --- | --- | --- | --- |
| **Variable** |  | **N** | **%** |
| Gender | Male | 63 | 50% |
|  | Female | 63 | 50% |
| Country of birth | Israel | 67 | 53% |
| Country of medical education | Israel | 64 | 52% |
| Works in social periphery | Yes | 61 | 49% |
| Participant in National Healthcare Fund Committee | Yes | 86 | 69% |
| Which public Health Maintenance Organization the respondent works with |  |  |  |
|  | Clalit | 31 | 25% |
|  | Maccabee  | 8 | 6% |
|  | Meuchedet | 7 | 6% |
|  | Leumit | 1 | 1% |
|  | None | 77 | 62% |
| Religion | Jewish | 116 | 92% |

Analysis of the distribution of the survey population’s responses shows that 86% of respondents agreed that patients should be offered all treatment alternatives, including those that are not funded, regardless of their financial situation. Similarly, 88% indicated that physicians tend to recommend innovative cancer treatments even if they are not funded. At the same time, 59% indicated that they often face a dilemma as whether to recommend innovative treatment to patients with financial difficulties and without private health insurance. Over a third of respondents (38%) stated that they felt embarrassed and uncomfortable discussing the cost of treatment with patients. (Distribution table in Appendix 3).

In order to examine differences according to age regarding various aspects of innovative unfunded cancer treatments, the respondents were divided into three age groups: under 50, 50-64, 65 and over; then a one-way ANOVA test and post-hook test using the Tueky method were performed. The findings are presented in Table 3.

Table 3: Analysis of variance for comparisons between age groups regarding the study variables

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Variable | Age group | Mean | SD | ? | DF | F |
| Physician's responsibility to consider costs of innovative cancer treatments |  |  |  | 2 | 94 | 7.272\*\*\* |
|  | Under 50 | 3.39 | 0.90 |  |  |  |
|  | 50-64 | 2.65 | 0.92 |  |  |  |
|  | 65 and over | 2.56 | 0.88 |  |  |  |
| Responsibility for choosing the treatment |  |  |  | 2 | 92 | 4.115\*\* |
|  | Under 50 | 2.96 | 1.13 |  |  |  |
|  | 50-64 | 3.49 | 1.12 |  |  |  |
|  | 65 and over | 3.80 | 0.91 |  |  |  |
| Inequalities in healthcare |  |  |  | 2 | 91 | 4.035\*\* |
|  | Under 50 | 2.26 | 1.23 |  |  |  |
|  | 50-64 | 3.15 | 1.37 |  |  |  |
|  | 65 and over | 2.46 | 1.45 |  |  |  |
| Social and ethical dilemmas associated with recommending innovative cancer treatments |  |  |  | 2 | 94 | 3.127\*\* |
|  | Under 50 | 3.51 | 0.80 |  |  |  |
|  | 50-64 | 3.15 | 0.93 |  |  |  |
|  | 65 and over | 2.91 | 0.88 |  |  |  |
| Preference for clinical efficacy of treatment for the patient |  |  |  | 2 | 92 | 2.783\* |
|  | Under 50 | 2.88 | 0.95 |  |  |  |
|  | 50-64 | 2.90 | 1.14 |  |  |  |
|  | 65 and over | 3.50 | 1.21 |  |  |  |
| Use of innovative unfunded treatments |  |  |  | 2 | 93 | 2.710\* |
|  | Under 50 | 4.15 | 0.60 |  |  |  |
|  | 50-64 | 4.12 | 0.84 |  |  |  |
|  | 65 and over | 3.96 | 0.97 |  |  |  |
| Need for physician-patient discussion about costs and benefits of innovative cancer treatments |  |  |  | 2 | 93 | 1.538 |
|  | Under 50 | 3.58 | 0.76 |  |  |  |
|  | 50-64 | 3.93 | 0.88 |  |  |  |
|  | 65 and over | 3.88 | 0.82 |  |  |  |
| Use of innovative unfunded tests |  |  |  | 2 | 90 | 1.334 |
|  | Under 50 | 2.41 | 1.25 |  |  |  |
|  | 50-64 | 2.87 | 1.32 |  |  |  |
|  | 65 and over | 2.52 | 0.96 |  |  |  |
| Recommendation for unfunded innovative treatments |  |  |  | 2 | 92 | 1.011 |
|  | Under 50 | 4.12 | 0.82 |  |  |  |
|  | 50-64 | 4.45 | 0.99 |  |  |  |
|  | 65 and over | 4.37 | 1.01 |  |  |  |
| Perception of the physician's role in achieving compassionate care |  |  |  | 2 | 92 | 0.187 |
|  | Under 50 | 3.65 | 1.13 |  |  |  |
|  | 50-64 | 3.83 | 1.09 |  |  |  |
|  | 65 and over | 3.77 | 1.24 |  |  |  |