Financial Toxicity of Hematologic Malignancy Therapies, Including Cellular Therapy and its Impact on Access to Care

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Submitted to: JMIR Cancer
on: October 28, 2024

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Lemchukwu Amaeshi[1]; Lauren Laufer[2]; Kateryna Fedorov[1]; Alex Sisto[1]; David Levitz[1]; Rosmi Mathew[1]; Dennis Cooper[1]; Karen Wright[1]; Mendel Goldfinger[1]; Ridhi Gupta[1]; Ioannis Mantzaris[1]; R. Alejandro Sica[1]; Kira Gritsman[3]; Marina Konopleva[3]; Noah Kornblum[1]; Chenxin Zhang[3]; Mimi Kim[3]; Amit Verma[3]; Bruce Rapkin[3]; Aditi Shastri[1]; Nishi Shah[1] MBBS

[1]Montefiore Medical Center Bronx US
[2]Montefiore Medical center Bronx US
[3]Albert Einstein college of Medicine Bronx US

Corresponding Author:
Nishi Shah MBBS
Montefiore Medical Center
111 East 210th St
Bronx
US

Abstract

Background: Cancer continues to be a significant public health concern. According to the American Cancer Society, in 2022, there were nearly 2 million new cancer cases and over 600,000 cancer-related deaths in the U.S. (1) . Receiving a new cancer diagnosis brings untold physical, emotional, and psychological distress to the patient and their caregivers. While the survival rates of cancer patients have improved over the years due to increasing treatment options and advances in cancer diagnosis and therapy, the cost of cancer care has become a significant challenge in oncology. Financial toxicity (FT) has emerged in oncologic care to describe the psychological, material, and behavioral hardships arising from the financial burden of cancer (2) . Indeed, several studies have reported a close association between FT and reduced quality of life, delays in seeking medical care, non-adherence with treatment, emotional and psychological distress, and reduced overall survival in cancer patients.

The impact of FT is particularly pronounced in patients with hematologic malignancies (HM) as they must deal with the high cost of therapy, especially with the shift from conventional chemotherapy to immunotherapy, multiple infusion visits, prolonged hospitalizations due to life-threatening presentations, long-duration of intensive therapy, and treatment-related complications (3,4) . In 2014, the average cumulative costs for hematologic cancers ranged from $200,000 (USD) for chronic leukemias to >= $800,000 (USD) for acute leukemias in the first 3 years of treatment compared with $250,000 for lung and $150,000 for colorectal cancers (5) . The severity of FT is also determined by the patient's sociodemographic and socioeconomic factors. Extremes of age, black race, lower income level, limited ability to provide basic household needs, unemployment, and insurance status are associated with worse FT (2,6–8) .

The factors associated with worse FT are predominant in households living below the federal poverty line (FPL). This population primarily comprises Native Americans, Blacks, and Hispanics (8). Despite several studies and systematic reviews on FT, most were predominantly conducted on the white racial population. To the best of our knowledge, no similar studies in the U.S. have specifically targeted minority ethnic patients with HM in underserved areas.

Objective: This study aims to determine the burden of FT and sociodemographic factors affecting FT and explore the subjective experience among patients with HM receiving care at different treatment timelines in a large academic hospital in the Bronx, where >=25% of the population live below the FPL (9) .

Methods: Selection and Description of Participants
We conducted an observational-based longitudinal study over 12 months at Montefiore Medical Center, Bronx, New York. Patients were recruited from the outpatient and inpatient oncology units after they had met the eligibility criteria and consented to participate in the study. We included adults with newly diagnosed HM and those with HM being evaluated for cellular therapy (CT), either autologous/allogeneic stem cell therapy (auto/allo SCT) or Chimeric Antigen Receptor T-cell therapy (CAR-T cell). Eligible participants were categorized into two cohorts: those with a new diagnosis of HM and those undergoing CT (either receiving SCT or CART).

Data Collection and Measurements

We used an investigator-designed questionnaire (in English and Spanish) to obtain participants' socio-demographic information, the type of HM, and their subjective experience of care. The severity of FT was measured using The Comprehensive Score for Financial Toxicity – Functional Assessment of Chronic Illness Therapy (COST-FACIT), a validated instrument measuring financial distress/toxicity among people living with cancer (10) . It is categorized into grades 0 to 4, based on the level of FT severity, with scores ranging from 0 to 44. A score of 0 represents grade 0 or "severe toxicity," 1-13 - grade 2 or "moderate toxicity," 14-25 - grade 3 or "mild toxicity," and greater than 25 - grade 4 or "no toxicity." Hence, higher scores indicated less severe FT. The patients were assessed at three different time points: day 0, the initial visit time, day 30, and day 90.

Statistics

Analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 29. Descriptive statistics were used to summarize the participants' sociodemographic characteristics, subjective care experience, and FT grade. Frequency and percentages were computed for categorical data, while medians (Interquartile range [IQR]) were computed for continuous data. Comparison of the severity of FT across the timelines was determined using Friedman's test. The Kruskal-Wallis and Wilcoxon rank analyses were conducted to examine the association between socio-demographic factors and the degree of FT among the participants. A two-sided p-value of <0.05 was deemed statistically significant.

Results: Socio-demographic characteristics

Over 12 months, we recruited 90 patients who met eligibility criteria and consented to the study. The sociodemographic characteristics of these patients are shown in Table 1. Fifty-seven percent of these patients were newly diagnosed (ND), while the remaining 43% were either on, or about to receive CT. The median age of all patients was 59 (IQR 44-66 years). Most participants were male (n=56, 62%), 27% were African American, more than 50% were Hispanics, more than a third were employed, and more than one-third of our patients were on Medicaid (n=33, 37.1%). On the type of HM, there were slightly more patients with plasma cell dyscrasias (PCD) than other HM (n=33, 37%).

Severity of Financial Toxicity across time

Table 2.1 and Figure 1 show the median FT scores across different time points. More than 75% of the patients experienced some degree of financial toxicity, with a median COST score of 19.4 on day 0. While the median COST score indicates mild FT, many patients experienced moderate FT at the individual level. The CT showed significant changes in FT score over time (Day 0 – 19.9, Day 30 – 19.0, Day 90 – 15.5; p=0.017). When comparing the severity of FT between the ND and CT groups, shown in Table 2.2, there was no statistically significant difference between the treatment groups at any of the time points (Day 0, p=0.88; Day 30, p=0.54; Day 90, p=0.75).

Financial Toxicity and sociodemographic factors

In Table 3, we examined the association between financial toxicity with sociodemographic factors such as race, ethnicity, type of HM, and employment status. Differences in FT across racial groups were marginally significant, with white patients experiencing relatively milder FT at Day 0 (median FT: 27.0 for Whites, 16.5 for African Americans, 14.0 for other racial groups, p=0.76) and at Day 90 (median FT: 37.0 for Whites, 13.5 for African Americans, 15.0 for other racial groups, p=0.06). In the ND group, white patients had significantly less severe FT compared to other racial groups at Day 0 (median FT: 33.5 for White, 15.4 for African Americans, 14.0 for other racial groups, p=0.04). A similar trend was observed in the CT group at day 90 (median FT: 39.5 for Whites, 33.0 for African Americans, 13.0 for other racial groups; p=<0.001). Overall, non-Hispanic patients experienced relatively milder FT compared to their Hispanic counterparts, although this difference was not statistically significant. Similarly, most patients with PCD had relatively milder FT compared to other HM groups, but this difference was also not statistically significant.

Social factors, subjective experience of Financial Toxicity

More than 75 % of our patients in our survey were evaluated by our social workers at the time of diagnosis (78% in the ND group and 100% in the CT group). A little over a third of our patients were employed, while more than sixty percent were either retired, on disability, or unemployed. Table 4 shows the results of our investigator-based questionnaire. Most of the patients reported having financial difficulties in carrying out their daily activities, such as paying for food, heating/air-conditioning, or warm clothes over the past six months (ND group: 53.8 % at day 0, 67.5% at day 30, 75.0% at day 90; CT group: 60.5% at day 0, 64.6% at day 30 and 56.3% at day 90). Additionally, over half of the patients experienced some degree of emotional distress in their daily lives (ND group: 56.8% at day 0, 61% at day 30, and 50% at day 90; CT group: 47.3% at day 0, 49.9 at day 30 and 50.1% at day 90). About 15% and 26.3% in the ND and CT groups, respectively, delayed seeking medical care due to financial constraints, and less than 10% of them missed their appointment due to caregiver issues. Regarding transportation, the median distance from patients' homes to the treatment center was 3.6 miles in both groups. Although less than 15% missed their appointments due to lack of transportation, many of them expressed concerns about the cost and accessibility to transportation for their medical appointments (ND group: 52% on day 0; CT group: 47.4% on day 0). Interestingly, many patients showed interest in telemedicine visits alongside in-person visits. (ND group: 52.9% and CT group: 40% at day 0). We looked at differences in social factors and subjective experience of financial toxicity by ethnicity and no statistical difference was found at day 0 in either cohorts.

Conclusions: In our study, we aimed to determine the burden of FT and sociodemographic factors affecting it and to explore the subjective experiences of patients with HM receiving care in the Bronx, an underserved area in the US. We found that most of our patients experienced some degree of FT. The severity of FT remained largely the same across the study period, with no significant variance between the two cohorts; however, those in the CT group experienced worse FT on day 90 than on the baseline. Non-Hispanic whites (NHW) experienced relatively less severe FT than other racial groups. Although most of the patients could meet their oncology appointments and receive their treatment, they were worried about access to and the cost of transportation to their appointments. Additionally, most of them felt financially constrained in meeting essential expenses such as food and clothing and had to cope with emotional problems such as depression and anxiety in their daily lives. Like several studies on FT, our study underscores FT as a perennial issue in cancer care. From a clinician's perspective, we see how the burden of FT in patients plays out in the high cost of chemotherapy, especially with the novel agents, multiple hospitalizations, and outpatient oncology visits (11) . Our patients in the CT group experienced worse FT on day 90 than on day 0, as published in a previous study for CAR-T therapy (12) . A study by Richard Maziarz et al. on healthcare costs in patients receiving allogeneic transplants reported that the median cost of healthcare for a patient receiving a transplant was over $300,000 (13) . Besides the high cost of SCT and CAR-T, prolonged hospital stays and multiple hospitalizations from treatment-related toxicities add to the burden of FT in these patients (16,17). Indirect costs such as transportation, loss of employment from poor productivity due to illness, or switching to low-income jobs because they are less physically demanding also add to the burden of FT (18,19). In our study, although most patients made their oncology appointments, over a third were worried about access and the cost of transportation to attend them. Patients undergoing scheduled chemotherapy infusions need to make multiple visits to the clinic, which can be burdensome, especially for those in the cellular therapy group who must travel long distances to a FACT-accredited center. In addition to fatigue while driving for chemotherapy, those undergoing CAR-T therapy are advised not to drive for at least 30 days after their infusion. This adds to their gas and public transportation costs, ultimately increasing the overall treatment cost burden (20,21). Health insurance may alleviate the FT burden; however, with the rising cost of cancer care, these companies have gradually shifted the burden to patients through higher deductibles, rising co-payments, and coinsurance. Ultimately, these patients still face substantial out-of-pocket expenses for their cancer care. Our study does not look at the out of pocket expenses that a patient undergoes or formally study medical debt for patients.

Several studies have examined the impact of sociodemographic characteristics on the burden of FT. In our study, NHWs had a lower FT burden than other races. In those receiving SCT or CAR-T cell therapy, there was a significantly lower FT among NHWs. Our results do not differ from studies on race and cancer-related FT in the literature (20–22) . Most of our patients are essentially racial/ethnic minorities and immigrants, and some are undocumented. They are likely to have lower incomes compared to their white counterparts, to be in the lowest socio-economic tier, and have only access to public health insurance with limited coverage or even be uninsured (24–26). Additionally, these patients are likely to have a lower health literacy than their white counterparts, leading to late and advanced disease presentation, requiring multiple lines of therapy, which may be unaffordable. As a result, these patients are likely to face unprecedented financial burdens, a leading cause of healthcare disparities in cancer care.

Apart from the direct effects of FT, objectively measured using tools such as the COST-FACIT scoring system, the impact of FT on the patient's overall quality of life, referred to as subjective financial distress, is also an integral part of FT (2,27). This refers to the depletion of household wealth and non-medical budget and worry about the effectiveness of coping strategies available and used by the patient (27) . In our study, over 50% of our patients experienced some degree of financial difficulty in paying for basic needs such as food. More than 50 % of our patients reported some level of emotional distress in their day-to-day lives similar to a study by Huihui Yu et al (28) . Although our study reports a considerable degree of emotional distress among the patients, further research is needed to delineate if they were distressed because of the trauma of being diagnosed with cancer, due to the financial burdens from cancer care, or a combination of both. In our study, where over 50 percent of patients are either retired, on disability, or unemployed, most of them will likely have to adjust their monthly budget and spend less on basic needs to pay for their cancer treatment. As their cancer treatment lingers, which is often the case in most HM, they may face increasing financial burdens, hence resorting to coping strategies such as relying on retirement savings, selling valuable possessions, and obtaining loans from friends, family, or the bank (29) . In some cases, patients may resort to extreme and potentially maladaptive strategies such as missing hospital appointments, medication non-adherence, or even stopping treatment entirely (30) . In our study, though a few patients missed or delayed treatments due to financial constraints, we see a decrease in the number of patients when followed up on day 30 and day 90. Although our study does not explain the reason for the loss of follow-ups, the possibility of patients being unable to pay for their treatment cannot be ruled out. These strategies may temporarily mitigate the financial impact of cancer care but ultimately lead to reduced quality of life, emotional distress, and devastating clinical outcomes.

Mitigating the burden of FT will involve developing and implementing intervention strategies at multiple levels, from the state/national level down to the health insurance/payor, hospital, and provider levels (31) . In our study, many patients were worried about the transportation cost to their oncology appointments but were open to telemedicine visits. Therefore, incorporating telemedicine visits as an option in the care of our patient population could offer more flexibility for patients, reducing the travel burden and lost income from missed work (32) . Most of our patients were assessed by a social worker. While they play a role in identifying patients at high risk of financial distress, their assistance may not be sufficient, and they may not have the expertise to help mitigate the severity of FT. A dedicated financial navigator, especially in a quaternary

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academic medical center, is required to help patients understand the economic aspects of their cancer care, budget appropriately, and maximize their employment and disability benefits in the context of ongoing financial commitment (33) .

Our study certainly has limitations. We had a low sample size, especially at the 90-day time point. Furthermore, a sizeable number of our patients were lost to follow-up, deceased, or chose not to continue with the study. Although our study was observational, the follow-up period may not have been long enough to detect a significant change in FT across time. Also, we did not collect data on the participants' monthly income and the number of cycles of chemotherapy received at each survey time. This may have provided additional insights into assessing the severity of FT in our patient population. With our pilot study, we aimed to capture some of the barriers to cancer care in a unique patient population. Potential solutions include adopting a co-management model with our community cancer physicians to make cancer care more patient centered (33) and avoid transportation for long distances when possible. The cancer center is also looking into a dedicated financial navigator for hematologic malignancy patients and to improve financial literacy for cancer patients. A larger cancer center wide study to evaluate social determinants of health is underway to better understand its implications on patient outcomes.

This study highlights the significant and far-reaching impact of financial toxicity experienced by cancer patients, particularly those from socioeconomically disadvantaged and ethnic/racial minority backgrounds. There is an urgent need for coordinated, long-term, and short-term solutions involving all stakeholders - including government, pharmaceutical companies, health insurance providers, hospitals, healthcare professionals, and the patients themselves - to combat the widespread financial burden our patients living with cancer face. Clinical Trial: Not applicable

(JMIR Preprints 28/10/2024:68101)
DOI: https://doi.org/10.2196/preprints.68101

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Lemchukwu C. Amaeshi, MD1,2; Lauren R. Laufer, MD, BA1,5; Kateryna Fedorov, MD3,4; Alex N. Sisto, MD1,6; David B. Levitz, MD3; Rosmi Mathew1; Karen G. Wright, RN, MS, OCN1; Dennis L. Cooper, MD3; Mendel Goldfinger, MD3; Ioannis Mantzaris, MD3; R. Alejandro A. Sica, MD3; Kira Gritsman, MD, PhD3; Marina Konopleva, MD, PhD3,7; Ridhi Gupta, MD3; Noah S. Kornblum, MD3; Chenxin Zhang, M.S2; Mimi Kim, Sc.D2; Amit K. Verma, MD3; Bruce D. Rapkin, Ph.D1,2; Aditi Shastri, MD3; Nishi N. Shah, MD, MPH3.

Affiliated institution(s):

Montefiore Medical Center, Bronx, NY

Albert Einstein College of Medicine/Montefiore Medical Center, Bronx, NY

Department of Oncology, Montefiore Medical Center and Albert Einstein College of Medicine, Bronx, NY

Oncology, Vanderbilt University Medical Center, Nashville NY

University of California, Los Angeles, Department of Medicine

Department of Internal Medicine, Rutgers Robert Wood Johnson Medical School, New Brunswick, NJ

Department of Leukemia, The University of Texas MD Anderson Cancer Center, Houston, TX

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Acknowledgments:

*** This manuscript is dedicated to the exceptional life and work of Karen Wright, an oncology nurse and a dedicated patient advocate for patients at Montefiore Medical Center.

Corresponding author:

Name: Nishi N. Shah, MD, MPH

Affiliation: Department of Oncology, Montefiore Medical Center and Albert Einstein College of Medicine, Bronx, NY

Email address: nisshah@montefiore.org

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Part of this study was presented at the American Society of Hematology Annual Meeting in San Diego, California, 2023 (abstract presentation and online publication) and the American Society of Clinical Oncology Annual Meeting in Chicago, 2023 (online publication)

Disclaimers: none

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Abstract

Purpose

Financial toxicity (FT) is involved in all aspects of cancer care and associated with a lower quality of life. Our research assessed the severity and impact of FT in patients receiving care for hematologic malignancies (HM) in a socioeconomically disadvantaged population where most individuals live below the federal poverty line.

Patients and Methods

This longitudinal study was conducted at The Montefiore Medical Center. Adult patients with newly diagnosed (ND) HM receiving standard care and those undergoing cellular therapy (CT) were recruited. A COST-FACIT questionnaire was used to measure the severity of FT, while an investigator-designed questionnaire was used to assess the impact of FT on the subjective experience of these patients from their cancer care. Data was collected at the initial presentation, 30 days, and 90 days after recruitment.

Results

Ninety patients participated in the study (ND=51, CT=38). The median age was 59, with 27% African Americans and 47% Hispanics. Most patients experienced varying degrees of FT (n=67/88, 76.3%). Although there was no significant difference in the severity of FT between the ND and CT groups, those in the CT group experienced worse FT at day 90 than Day 0 (median FT: Day0=19.9; Day90=15.5, p=0.017). African Americans and Hispanics experienced worse FT compared to other racial and ethnic groups. A significant number of patients reported financial constraints in paying for basic needs (ND: n=28/53, 53.8%, CT: n=23/39, 60.6%), and many were worried about access to, and the cost of transportation for their medical appointments (ND: n=26/50, 52%; CT: n=18/38, 47.4%).

Conclusion

A significantly high number of patients experienced financial toxicity, and its impact was predominantly seen in the Hispanic and African American populations. A detailed evaluation of subjective experience of hematologic malignancy patients is also provided.

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Introduction

Cancer continues to be a significant public health concern. According to the American Cancer Society, in 2022, there were nearly 2 million new cancer cases and over 600,000 cancer-related deaths in the U.S. (1) . Receiving a new cancer diagnosis brings untold physical, emotional, and psychological distress to the patient and their caregivers. While the survival rates of cancer patients have improved over the years due to increasing treatment options and advances in cancer diagnosis and therapy, the cost of cancer care has become a significant challenge in oncology. Financial toxicity (FT) has emerged in oncologic care to describe the psychological, material, and behavioral hardships arising from the financial burden of cancer (2) . Indeed, several studies have reported a close association between FT and reduced quality of life, delays in seeking medical care, non-adherence with treatment, emotional and psychological distress, and reduced overall survival in cancer patients.

The impact of FT is particularly pronounced in patients with hematologic malignancies (HM) as they must deal with the high cost of therapy, especially with the shift from conventional chemotherapy to immunotherapy, multiple infusion visits, prolonged hospitalizations due to life-threatening presentations, long-duration of intensive therapy, and treatment-related complications (3,4) . In 2014, the average cumulative costs for hematologic cancers ranged from $200,000 (USD) for chronic leukemias to >= $800,000 (USD) for acute leukemias in the first 3 years of treatment compared with $250,000 for lung and $150,000 for colorectal cancers (5) . The severity of FT is also determined by the patient's sociodemographic and socioeconomic factors. Extremes of age, black race, lower income level, limited ability to provide basic household needs, unemployment, and

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insurance status are associated with worse FT (2,6–8) .

The factors associated with worse FT are predominant in households living below the federal poverty line (FPL). This population primarily comprises Native Americans, Blacks, and Hispanics (8). Despite several studies and systematic reviews on FT, most were predominantly conducted on the white racial population. To the best of our knowledge, no similar studies in the U.S. have specifically targeted minority ethnic patients with HM in underserved areas. This study aims to determine the burden of FT and sociodemographic factors affecting FT and explore the subjective experience among patients with HM receiving care at different treatment timelines in a large academic hospital in the Bronx, where >=25% of the population live below the FPL (9) .

Methods:

Selection and Description of Participants

We conducted an observational-based longitudinal study over 12 months at Montefiore Medical Center, Bronx, New York. Patients were recruited from the outpatient and inpatient oncology units after they had met the eligibility criteria and consented to participate in the study. We included adults with newly diagnosed HM and those with HM being evaluated for cellular therapy (CT), either autologous/allogeneic stem cell therapy (auto/allo SCT) or Chimeric Antigen Receptor T-cell therapy (CAR-T cell). Eligible participants were categorized into two cohorts: those with a new diagnosis of HM and those undergoing CT (either receiving SCT or CART).

Data Collection and Measurements

We used an investigator-designed questionnaire (in English and Spanish) to obtain participants' socio-demographic information, the type of HM, and their subjective experience of care. The severity of FT was measured using The Comprehensive Score for Financial Toxicity – Functional Assessment of Chronic Illness Therapy (COST-FACIT), a validated instrument measuring financial distress/toxicity among people living with cancer (10) . It is categorized into grades 0 to 4, based on the level of FT severity, with scores ranging from 0 to 44. A score of 0 represents grade 0 or "severe

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toxicity," 1-13 - grade 2 or "moderate toxicity," 14-25 - grade 3 or "mild toxicity," and greater than 25 - grade 4 or "no toxicity." Hence, higher scores indicated less severe FT. The patients were assessed at three different time points: day 0, the initial visit time, day 30, and day 90.

Statistics

Analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 29. Descriptive statistics were used to summarize the participants' sociodemographic characteristics, subjective care experience, and FT grade. Frequency and percentages were computed for categorical data, while medians (Interquartile range [IQR]) were computed for continuous data. Comparison of the severity of FT across the timelines was determined using Friedman's test. The Kruskal-Wallis and Wilcoxon rank analyses were conducted to examine the association between socio-demographic factors and the degree of FT among the participants. A two-sided p-value of <0.05 was deemed statistically significant.

Results

Socio-demographic characteristics

Over 12 months, we recruited 90 patients who met eligibility criteria and consented to the study. The sociodemographic characteristics of these patients are shown in Table 1. Fifty-seven percent of these patients were newly diagnosed (ND), while the remaining 43% were either on, or about to receive CT. The median age of all patients was 59 (IQR 44-66 years). Most participants were male (n=56, 62%), 27% were African American, more than 50% were Hispanics, more than a third were employed, and more than one-third of our patients were on Medicaid (n=33, 37.1%). On the type of HM, there were slightly more patients with plasma cell dyscrasias (PCD) than other HM (n=33, 37%).

Severity of Financial Toxicity across time

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While the median COST score indicates mild FT, many patients experienced moderate FT at the individual level. The CT showed significant changes in FT score over time (Day 0 – 19.9, Day 30 – 19.0, Day 90 – 15.5; p=0.017). When comparing the severity of FT between the ND and CT groups, shown in Table 2.2, there was no statistically significant difference between the treatment groups at any of the time points (Day 0, p=0.88; Day 30, p=0.54; Day 90, p=0.75).

Financial Toxicity and sociodemographic factors

In Table 3, we examined the association between financial toxicity with sociodemographic factors such as race, ethnicity, type of HM, and employment status. Differences in FT across racial groups were marginally significant, with white patients experiencing relatively milder FT at Day 0 (median FT: 27.0 for Whites, 16.5 for African Americans, 14.0 for other racial groups, p=0.76) and at Day 90 (median FT: 37.0 for Whites, 13.5 for African Americans, 15.0 for other racial groups, p=0.06). In the ND group, white patients had significantly less severe FT compared to other racial groups at Day 0 (median FT: 33.5 for White, 15.4 for African Americans, 14.0 for other racial groups, p=0.04). A similar trend was observed in the CT group at day 90 (median FT: 39.5 for Whites, 33.0 for African Americans, 13.0 for other racial groups; p=<0.001). Overall, non-Hispanic patients experienced relatively milder FT compared to their Hispanic counterparts, although this difference was not statistically significant. Similarly, most patients with PCD had relatively milder FT compared to other HM groups, but this difference was also not statistically significant.

Social factors, subjective experience of Financial Toxicity

More than 75 % of our patients in our survey were evaluated by our social workers at the time of diagnosis (78% in the ND group and 100% in the CT group). A little over a third of our patients were employed, while more than sixty percent were either retired, on disability, or unemployed. Table 4 shows the results of our investigator-based questionnaire. Most of the patients reported having financial difficulties in carrying out their daily activities, such as paying for food, heating/air-conditioning, or warm clothes over the past six months (ND group: 53.8 % at day 0, 67.5% at day 30,

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75.0% at day 90; CT group: 60.5% at day 0, 64.6% at day 30 and 56.3% at day 90). Additionally, over half of the patients experienced some degree of emotional distress in their daily lives (ND group: 56.8% at day 0, 61% at day 30, and 50% at day 90; CT group: 47.3% at day 0, 49.9 at day 30 and 50.1% at day 90). About 15% and 26.3% in the ND and CT groups, respectively, delayed seeking medical care due to financial constraints, and less than 10% of them missed their appointment due to caregiver issues. Regarding transportation, the median distance from patients' homes to the treatment center was 3.6 miles in both groups. Although less than 15% missed their appointments due to lack of transportation, many of them expressed concerns about the cost and accessibility to transportation for their medical appointments (ND group: 52% on day 0; CT group: 47.4% on day 0). Interestingly, many patients showed interest in telemedicine visits alongside in-person visits. (ND group: 52.9% and CT group: 40% at day 0). We looked at differences in social factors and subjective experience of financial toxicity by ethnicity and no statistical difference was found at day 0 in either cohorts.

Discussion:

In our study, we aimed to determine the burden of FT and sociodemographic factors affecting it and to explore the subjective experiences of patients with HM receiving care in the Bronx, an underserved area in the US. We found that most of our patients experienced some degree of FT. The severity of FT remained largely the same across the study period, with no significant variance between the two cohorts; however, those in the CT group experienced worse FT on day 90 than on the baseline. Non-Hispanic whites (NHW) experienced relatively less severe FT than other racial groups. Although most of the patients could meet their oncology appointments and receive their treatment, they were worried about access to and the cost of transportation to their appointments. Additionally, most of them felt financially constrained in meeting essential expenses such as food and clothing and had to cope with emotional problems such as depression and anxiety in their daily lives. Like several studies on FT, our study underscores FT as a perennial issue in cancer care. From

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a clinician’s perspective, we see how the burden of FT in patients plays out in the high cost of chemotherapy, especially with the novel agents, multiple hospitalizations, and outpatient oncology visits (11) . Our patients in the CT group experienced worse FT on day 90 than on day 0, as published in a previous study for CAR-T therapy (12) . A study by Richard Maziarz et al. on healthcare costs in patients receiving allogeneic transplants reported that the median cost of healthcare for a patient receiving a transplant was over $300,000 (13) . Besides the high cost of SCT and CAR-T, prolonged hospital stays and multiple hospitalizations from treatment-related toxicities add to the burden of FT in these patients (16,17). Indirect costs such as transportation, loss of employment from poor productivity due to illness, or switching to low-income jobs because they are less physically demanding also add to the burden of FT (18,19). In our study, although most patients made their oncology appointments, over a third were worried about access and the cost of transportation to attend them. Patients undergoing scheduled chemotherapy infusions need to make multiple visits to the clinic, which can be burdensome, especially for those in the cellular therapy group who must travel long distances to a FACT-accredited center. In addition to fatigue while driving for chemotherapy, those undergoing CAR-T therapy are advised not to drive for at least 30 days after their infusion. This adds to their gas and public transportation costs, ultimately increasing the overall treatment cost burden (20,21). Health insurance may alleviate the FT burden; however, with the rising cost of cancer care, these companies have gradually shifted the burden to patients through higher deductibles, rising co-payments, and coinsurance. Ultimately, these patients still face substantial out-of-pocket expenses for their cancer care. Our study does not look at the out of pocket expenses that a patient undergoes or formally study medical debt for patients.

Several studies have examined the impact of sociodemographic characteristics on the burden of FT. In our study, NHWs had a lower FT burden than other races. In those receiving SCT or CAR-T cell therapy, there was a significantly lower FT among NHWs. Our results do not differ from studies on race and cancer-related FT in the literature (20–22) . Most of our patients are essentially racial/ethnic minorities and immigrants, and some are undocumented. They are likely to have lower incomes compared to their white counterparts, to be in the lowest socio-economic tier, and have only access to public health insurance with limited coverage or even be uninsured (24–26). Additionally, these patients are likely to have a lower health literacy than their white counterparts, leading to late and advanced disease presentation, requiring multiple lines of therapy, which may be unaffordable. As a result, these patients are likely to face unprecedented financial burdens, a leading cause of healthcare disparities in cancer care.

Apart from the direct effects of FT, objectively measured using tools such as the COST-FACIT scoring system, the impact of FT on the patient's overall quality of life, referred to as subjective financial distress, is also an integral part of FT (2,27). This refers to the depletion of household wealth and non-medical budget and worry about the effectiveness of coping strategies available and used by the patient (27) . In our study, over 50% of our patients experienced some degree of financial difficulty in paying for basic needs such as food. More than 50 % of our patients reported some level of emotional distress in their day-to-day lives similar to a study by Huihui Yu et al (28) . Although our study reports a considerable degree of emotional distress among the patients, further research is needed to delineate if they were distressed because of the trauma of being diagnosed with cancer, due to the financial burdens from cancer care, or a combination of both. In our study, where over 50 percent of patients are either retired, on disability, or unemployed, most of them will likely have to adjust their monthly budget and spend less on basic needs to pay for their cancer treatment. As their cancer treatment lingers, which is often the case in most HM, they may face increasing financial burdens, hence resorting to coping strategies such as relying on retirement savings, selling valuable possessions, and obtaining loans from friends, family, or the bank (29) . In some cases, patients may resort to extreme and potentially maladaptive strategies such as missing hospital appointments, medication non-adherence, or even stopping treatment entirely (30) . In our study, though a few patients missed or delayed treatments due to financial constraints, we see a decrease in

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the number of patients when followed up on day 30 and day 90. Although our study does not explain the reason for the loss of follow-ups, the possibility of patients being unable to pay for their treatment cannot be ruled out. These strategies may temporarily mitigate the financial impact of cancer care but ultimately lead to reduced quality of life, emotional distress, and devastating clinical outcomes.

Mitigating the burden of FT will involve developing and implementing intervention strategies at multiple levels, from the state/national level down to the health insurance/payor, hospital, and provider levels (31) . In our study, many patients were worried about the transportation cost to their oncology appointments but were open to telemedicine visits. Therefore, incorporating telemedicine visits as an option in the care of our patient population could offer more flexibility for patients, reducing the travel burden and lost income from missed work (32) . Most of our patients were assessed by a social worker. While they play a role in identifying patients at high risk of financial distress, their assistance may not be sufficient, and they may not have the expertise to help mitigate the severity of FT. A dedicated financial navigator, especially in a quaternary academic medical center, is required to help patients understand the economic aspects of their cancer care, budget appropriately, and maximize their employment and disability benefits in the context of ongoing financial commitment (33) .

Our study certainly has limitations. We had a low sample size, especially at the 90-day time point. Furthermore, a sizeable number of our patients were lost to follow-up, deceased, or chose not to continue with the study. Although our study was observational, the follow-up period may not have been long enough to detect a significant change in FT across time. Also, we did not collect data on the participants' monthly income and the number of cycles of chemotherapy received at each survey time. This may have provided additional insights into assessing the severity of FT in our patient population. With our pilot study, we aimed to capture some of the barriers to cancer care in a unique patient population. Potential solutions include adopting a co-management model with our community cancer physicians to make cancer care more patient centered (33) and avoid transportation for long distances when possible. The cancer center is also looking into a dedicated financial navigator for hematologic malignancy patients and to improve financial literacy for cancer patients. A larger cancer center wide study to evaluate social determinants of health is underway to better understand its implications on patient outcomes.

Conclusion

This study highlights the significant and far-reaching impact of financial toxicity experienced by cancer patients, particularly those from socioeconomically disadvantaged and ethnic/racial minority backgrounds. There is an urgent need for coordinated, long-term, and short-term solutions involving all stakeholders - including government, pharmaceutical companies, health insurance providers, hospitals, healthcare professionals, and the patients themselves - to combat the widespread financial burden our patients living with cancer face.

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Tables:

Table 1: Sociodemographic characteristics

Sociodemographic characteristics	Newly diagnosed group (ND) N = 51	Cellular therapy group (CT) N = 38	Total N = 90
Age, median (IQR)	59 (42.5 – 66.0)	58 (50.0 – 67.0)	59 (43.5 – 66.0)
Sex, n (%)			
Male	31 (61)	24 (65)	56(62)
Female	20 (39)	13 (35)	34(38)
Race, n (%)			
African American	15 (29)	8 (22)	24(27)
Non-Hispanic white	6 (12)	8 (22)	14(16)
Others	30 (59)	21 (57)	51(57)

Ethnicity, n (%)			
Hispanic	26 (52)	20 (57)	47(54)
Non-Hispanic	24 (48)	15 (43)	40(46)
Employment Status, n (%)			
Employed	21 (41.2)	11 (30.5)	32 (36.7)
Retired	13 (25.5)	9 (25)	22 (25.2)
On Disability	9 (17.6)	8 (22.2)	17 (19.5)
Unemployed	8 (15.7)	8 (22.2)	16 (18.3)
Health Insurance, n (%)			
Private	22 (43.1)	16 (42.1)	38 (42.6)
Medicare	10 (18.8)	8 (21.0)	18 (20.2)
Medicaid	19 (35.8)	14 (36.8)	33 (37.1)
Type of Hematologic malignancy, n (%)			
Leukemias	21 (41)	10 (27)	31 (34)
Lymphomas	16 (31)	9 (24)	26 (29)
Plasma cell dyscrasias	14 (27)	18 (49)	33 (37)

ND – newly diagnosed, CT – cellular therapy, IQR – interquartile range.

Table 2.1 Financial toxicity at Day 0, 30, and 90

Newly diagnosed group				
	Day 0, N=50	Day 30, N=39	Day 90, N = 32	P-value
Median FT (IQR)	16.5 (8.9,27.5)	17.0(9.5,21.0)	17.5(9.0,27.0)	0.848
Grade Category n (%)				
No toxicity	11 (22)	7 (18)	9 (28.1)	
Mild toxicity	17 (34)	18 (46)	10 (31.3)	
Moderate toxicity	21 (42)	14 (36)	13 (40.6)	
Severe toxicity	1 (2.0)	0 (0)	0	
Cellular therapy group				
	Day 0, N=36	Day 30, N=29	Day 90, N = 16	P-value
Median FT (IQR)	19.9(9.0,27.0)	19.0(13.8,28.0)	15.5(12.3,32.3)	0.017
Grade Category n (%)				
No toxicity	10 (28)	8 (28)	5 (29.4)	
Mild toxicity	11 (31)	14 (48)	4 (23.6)	
Moderate toxicity	15 (42)	7 (24)	5 (29.4)	

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Severe toxicity	0 (0)	0 (0)	0	
Total population				
	Day 0, N=88	Day 30, N=69	Day 90, N = 48	P-value
Median FT (IQR)	19.4 (8.95,27.0)	18(10,25)	17(10,17.5)	0.309
Grade Category n (%)				
No toxicity	21 (24)	15 (22)	14 (30)	
Mild toxicity	29 (33)	33 (48)	14 (30)	
Moderate toxicity	36 (41)	21 (30)	18 (39)	
Severe toxicity	2 (2.3)	0 (0)	0	

Table 2.2 Comparison of financial toxicity between newly diagnosed and cellular therapy groups on days 0, 30, and 90

Day 0	**ND, N=50**	**CT, N=37**	**p-value**
Median FT (IQR)	16.5(8.9,27.5)	19.9(9.0,27.0)	0.879
Day 30	**ND, N = 36**	**CT, N=32**	
Median FT (IQR)	17.0(9.5,21.0)	19.0(13.8,28.0)	0.539
Day 90	**ND, N=31**	**CT, N=15**	
Median FT (IQR)	17.5(9.0,27.0)	15.5(12.3,32.3)	0.752

Table 3: Association of Financial toxicity and sociodemographic characteristics

Socio-Demographics	Median FT (IQR) Day 0	Median FT (IQR) Day 30	Median FT (IQR) Day 90
Total Cohort			
Race			
African American	16.5 (8.8,25.2)	18.0 (10.0,25.8)	13.5 (6.0,26.0)
White	27.0 (22.0,36.0)	20.6 (17.0,30.8)	37.0 (19.0,41.0)
Other	14.0 (8.9,24.1)	16.8 (10.5,21.2)	15.0 (10.0,27.5)
P value	0.076	0.38	0.06
Ethnicity			
Hispanic	13.5 (8.9, 24.8)	15.5 (8.9, 21.2)	14.5(9.8,28.0)
Non-Hispanic	20.0(8.5, 27.5)	18.0(14.0, 26.5)	19.0 (7.8,31.5)
P value	0.45	0.17	0.49
Diagnosis			
Leukemia	19.4(10.3,24.5)	18.0(17.0,22.0)	17.0(8.8,25.8)
Lymphoma	10.0(8.0,28.0)	14.4 (8.4, 17.6)	15.0(4.5,27.8)
Plasma cell	20.0(8.8,28.0)	19.5(9.8,28.2)	18.0(10.0,30.0)

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dyscrasias P value	0.75	0.11	0.77
Employment status Employed Retired Disabled Unemployed P value	12.0(8.0,24.0) 26.0(10.0,36.0) 12.0(7.25,23.5) 24.0(19.0,31) 0.11	19.0(17.0,22.0) 20.0(19.0,35.0) 15.5(8.75,23.5) 31.0(5.0,34.0) 0.38	17.0(8.0,23.0) 26.0(12.0,37.0) 13.0(5.5,22.0) 10.0(0.0,30.0) 0.56
Newly diagnosed cohort			
Race African American White Other P value	15.4(8.2,20.4) 33.5(26.7,36.0) 14.0(8.8,24.2) 0.04	18.0(9.0,22.5) 19.8(18.4,31.9) 16.5(9.0,20.0) 0.46	13.5(6.0,22.0) 22.0(16.0, 40.0) 19.0(10.0,28.0) 0.159
Ethnicity Hispanic Non-Hispanic P value	14.0(9.0,28.0) 16.5(7.9,25.5) >0.99	15.0(9.0,20.0) 18.0(15.5,23.8) 0.29	21.5(10.0,28.0) 18.0(9.0,24.0) 0.38
Diagnosis Leukemia Lymphoma Plasma cell dyscrasias P value	17.0(8.0,23.0) 9.8(9.0,27.5) 22.0(9.1,28.0) 0.92	18.0(15.8,20.0) 12.0(8.9,17.3) 19.4(8.0,28.8) 0.29	19.5(8.5,27.3) 11.0(4.0,27.0) 19.0(10.0,28.0) 0.48
Employment status Employed Retired Disabled Unemployed P value	11.0(7.25,26.0) 26.0(10.0, 29.0) 15.5(1.75,29.0) 20.5(10.0,31.0) 0.69	18.0(13.3, 20.5) 20.0(9.0,35.0) 13.5(4.25,28.0) 18.0(5.0,31.0) 0.57	11.0(7.25,26.0) 20.0(9.0,35.0) 8.0(3.75, 29.3) 20.0(10.0,30.0) 0.82
Cellular therapy cohort			
Race African American White Other P value	19.5(8.8,28.3) 22.0(13.8,29.5) 19.9(10.0,24.0) 0.77	24.0(14.5,29.2) 22.8(10.9,29.4) 18.0(13.9,21.5) 0.55	33.0(7.0,44.0) 39.5(37.0,42) 13.0(8.75,16.25) <0.001
Ethnicity Hispanic Non-Hispanic P value	16.0(8.9,22.5) 24.5(9.5,31.0) 0.29	16.0(11.3,21.5) 22.5(14.5,30.9) 0.24	13.0(8.75,16.3) 37.0(20.0,43.0) 0.05

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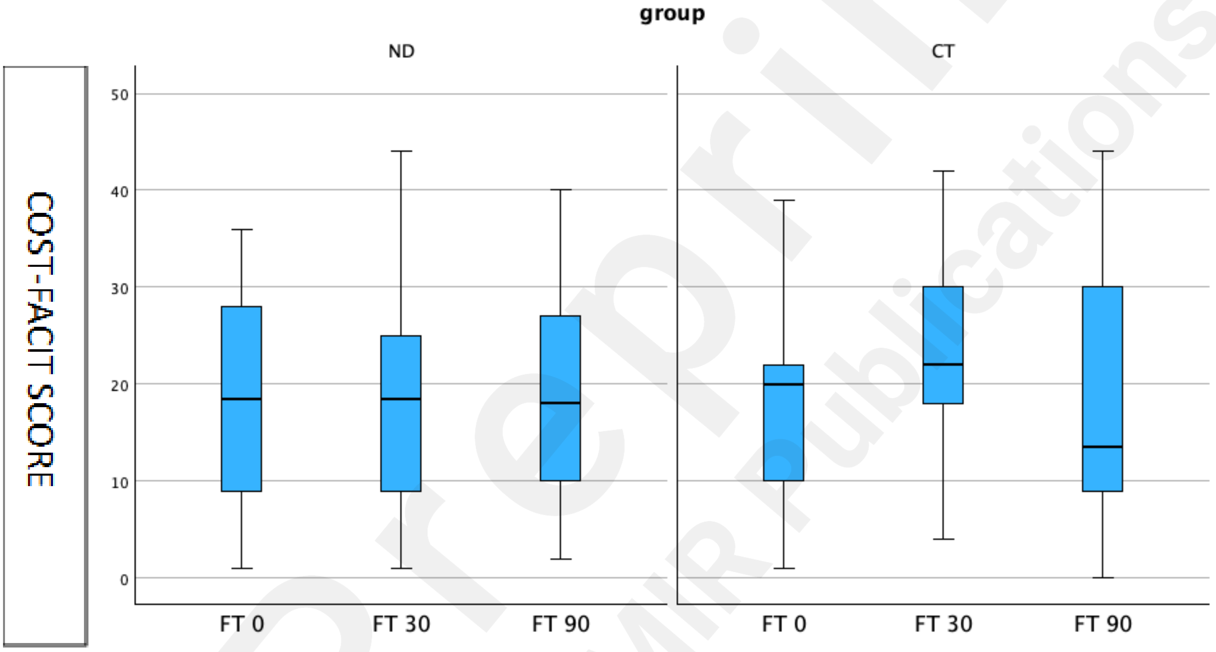
Diagnosis			
Leukemia	20.0(13.0,25.0)	22.0(19.5,29.5)	13.5(8.75,25.5)
Lymphoma	13.0(8.0,28.0)	15.0(10.7,17.0)	n/a
Plasma cell dyscrasias	19.9(8.7,27.8)	20.0(13.5,26.8)	14.0(8.25,32.25)
P value	0.94	0.21	0.95
Employment status			
Employed	20.0(5.0,20.0)	22.0(12.0,29.5)	12.0(8.0,30.0)
Retired	30.0(12.3, 38.8)	27.0(20.0,39.3)	26.0(12.0,40.5)
Disabled	12.0(10.3, 18.3)	16.0(12.5,21.0)	13.5(13.0,17.0)
Unemployed	n/a	n/a	n/a
P value	0.09	0.23	0.32

Figure 1: Box-plot graph comparing COST-FACIT scores across the timelines for both groups.



FT 0 – Financial toxicity score day 0, FT 30 – Financial toxicity score day 30, FT 90 – Financial toxicity score day 90. ND – Newly diagnosed group, CT- cellular therapy group

Supplementary data

Table 4: Subjective experience of financial toxicity on patient’s well-being and access to care.

	Newly diagnosed	Cellular therapy group
	Day 0 (N=53)	Day 0 (N=39)

Social factors		
Have you felt financially constrained such as paying for food, heating/cooling in the last 6 months, n (%)		
Never	24 (46.2)	15 (39.5)
Sometimes	13 (25.0)	14 (36.8)
Often	5 (9.6)	4 (10.5)
Most of the time	10 (19.2)	5 (13.2)
During the past 4 weeks, have you had any problems with your work or daily life due to any emotional problems, such as feeling depressed, sad, or anxious? n (%)		
Never	22 (43.1)	20 (52.6)
Sometimes	22 (43.1)	11 (28.9)
Often	3 (5.9)	1 (2.6)
Most of the time	4 (7.8)	6 (15.8)
Over the last 6 months, have you felt particularly low for more than 2 weeks, n (%)		
Yes	14(26.9)	10 (26.3)
No	38(73.1)	28 (73.7)
Are you worried about access and cost of transportation for medical appointments, n (%)		
Yes	26 (52)	18 (47.4)
No	24 (48)	20 (52.6)
Have you missed an oncology appointment due to lack of transportation, n (%)		
Never	44(86.3)	32 (84.2)
Sometimes	6(11.8)	5(13.2)

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Often	1(2.0)	1 (2.6)
Have you delayed seeking medical care due to financial toxicities, n (%)		
Yes	7 (15.2)	10 (26.3)
No	39 (84.8)	28 (73.7)
Which mode of transportation do you use to come to medical appointments?		
Personal	25(53.2)	19(52.8)
Self-paid transportation	5(10.6)	5(13.9)
Insurance transportation	6(12.8)	6(16.7)
Public transportation	11(23.4)	6(16.7)
Distance from Treatment Clinic		
Median (range) miles	3.6 (0-81.4)	3.6 (0-134.9)
How do you feel about telephone or video visits in addition to in-person visits, n (%)		
I feel comfortable with phone/video visits	27 (52.9)	14 (40.0)

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I prefer phone visits to video visits due to technological challenges	3 (5.9)	2 (3.3)
I always prefer in-person visits	21 (41.2)	22 (56.7)
Have you missed doses or delayed treatments due to not being able to pay for medications, n (%)		
Yes	6(11.8)	5 (13.5)
No	45(88.2)	32 (86.5)
Have you missed an oncology appointment due to caregiver issues, n (%)		
never	47 (92.2)	34(89.5)
Sometimes	2 (3.9)	3 (7.9)
often	2(3.9)	1 (2.6)
Evaluated by a social worker?n (%)		
Yes	40 (78.4)	38 (100)
No	11(21.5)	0(0)

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