Patient Financial Burden: Considerations for Oncology Care and Access

One organization's approach to addressing financial toxicity

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EXECUTIVE SUMMARY

A growing body of evidence suggests that financial toxicity has an impact on access to care. Provider organizations can take a leading role in addressing financial barriers to care. However, few roadmaps exist for organizations that want to create a patient-centric approach to facilitating timely and comprehensive treatment.

Over more than two decades, the Cleveland Clinic Cancer Institute has responded to incremental changes in care delivery and financing that impede access. More recently, the Cancer Institute has embarked on a cohesive series of internal operational enhancements intended to improve access to care — redesigning care processes, developing a sophisticated approach to securing financial aid for patients, investing in resources to sustain these efforts, developing policies and tools to support them, and creating metrics to gauge their success. In mitigating financial barriers to care, the Cancer Institute helps patients to focus on their health.

The program and its components represent a dynamic, multifaceted approach to addressing some common effects of financial toxicity on patients. It may be instructive for provider organizations that wish to prioritize the patient experience and improve access to care.

Introduction

The term *financial toxicity* refers to a patient's out-of-pocket treatment expense and the concerns a patient may experience as a result of those expenses (Zafar 2013). Although the term has been adopted by oncologists, the concept of financial toxicity is applicable across many high-cost chronic diseases (PAN Foundation 2018).

Evidence is mounting to show that financial toxicity has numerous effects. A patient's inability to afford treatment can be a barrier to timely and comprehensive care, such as potential delays in treatment initiation (Carrera 2018).

The effects of financial toxicity underscore the need to address "whole-patient" well-being and not just treat the diagnosis. Recognizing many of these effects in its own patient population, the Cleveland Clinic Cancer Institute has engaged in a series of continual process improvements and developed and refined a template for financial navigation. These efforts have been intended to improve internal efficiencies and to provide patients with access to resources that may enable more timely care.

Taking intentional steps to remove barriers to care is consistent with the Cleveland Clinic Cancer Institute's patient-centric culture. The Cleveland Clinic Foundation's Strategic Agenda includes a "Patient First" principle that refers to continuous internal improvements in quality, safety, and the patient experience. Improving access to care is a top enterprise priority (Cleveland Clinic Foundation 2017) and, in keeping with its mission, the Cleveland Clinic Cancer Institute turns no patient away because of financial need.

This publication describes the Cleveland Clinic Cancer Institute's experience in designing and implementing a patient-focused model for addressing access issues related to financial toxicity.

Responses to changing needs over more than 20 years

Financial barriers to care are multifaceted and extend beyond the cost of treatment itself. As examples, some barriers may be administrative (e.g., the need to seek payer approval for a scan or treatment), related to internal resources (e.g., the lack of "navigators" to help patients understand their options), or practical (e.g., lack of access to transportation or inability to afford food or housing during treatment). Each of these barriers may contribute to delays in treatment.

Access challenges are not fixed and continue to emerge over time. For instance, as financial responsibility has shifted to patients in the form of high-deductible benefit plans, the need for new strategies to help patients with access to care has become evident. The ever-changing nature of financial barriers means that improving access is not a one-and-done process; rather, it requires continuous evaluation of what works, what has become inefficient,

and how new barriers may be addressed.

The Cleveland Clinic's approach to financial barriers to care has evolved over more than two decades (Figure 1), well before financial toxicity was recognized and defined. As managed care took root in the early 1990s, the Cleveland Clinic Foundation hired its first two financial counselors (CCCI 2018), recognizing that payer criteria and coverage can be challenging for patients to navigate. These individuals conducted benefit investigations, precertifications, and authorizations, and helped patients to understand their out-of-pocket costs. Financial counselors also assisted patients in completing applications for financial assistance from the Cleveland Clinic and from the Ohio Hospital Care Assurance Program (HCAP), which offers help with unpaid hospital bills to Ohioans at or below the federal poverty level and who are ineligible for Medicaid coverage.

The next decade saw greater use of payer authorizations for treatment and medications. There was also a gradual shift in patient out-of-pocket responsibility through higher copayments and coinsurance. In the early 2000s, the Cleveland Clinic Cancer Institute hired financial specialists to complete drug preauthorizations and to locate copayment-assistance and free-drug opportunities for commercial patients who received their medications through retail pharmacies (CCCI 2018).

As benefit designs evolved over time, it became more challenging to initiate treatment in a timely way. In response, the Cancer Institute leadership team designed a more systematic approach to resolving access and financial challenges. In 2014, the team established the patient huddle for patients facing delays in access (CCCI 2018). In the huddle, schedulers, clinicians, financial counselors, and administrators review the status of time to a physician appointment, out-of-network authorizations, and financial clearance for patients who are out of network or have high deductibles.

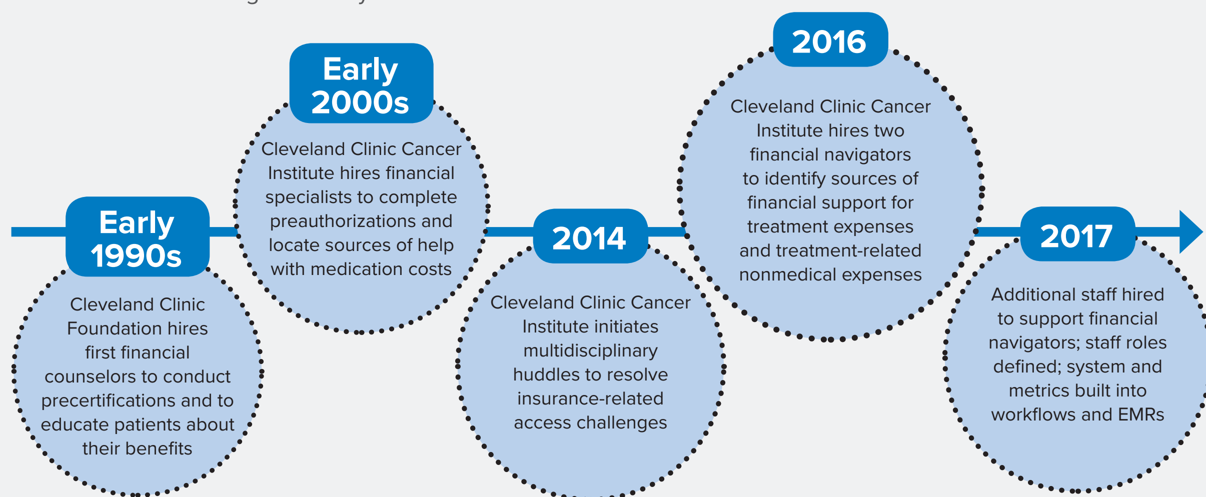
Concurrently, several changes in the environmental landscape were emerging. The aging of America has been linked to a significant rise in the number of people diagnosed with cancer (Sharpless 2018). In the years after the Affordable Care Act (ACA) was adopted, the uninsured rate fell (Garfield 2019), also contributing to the higher volume of patients. Even with the broader availability of coverage through the ACA, many patients faced high deductibles (KFF 2014, Rae 2015), making access to care a continued challenge. The need to serve more patients — including many who struggled with financial responsibility for their care — were among the factors that led the Cancer Institute in 2016 to expand its efforts to improve access (CCCI 2018).

Two new financial navigators, versed in financial counseling and coverage benefits, were hired to locate copayment-assistance dollars and free medication available through manufacturer-sponsored patient-assistance programs (PAPs) for uninsured, underinsured, or com-

FIGURE 1

Evolution of the Cleveland Clinic Cancer Institute's financial navigation program

The Cleveland Clinic Cancer Institute's Financial Navigation Program has evolved over more than two decades from early efforts to precertify patients and educate them about their benefits to a sophisticated program dedicated to removing financially related access barriers.



EMR=electronic medical record.
Source: Cleveland Clinic Cancer Institute.

mercially insured patients who qualify (CCCI 2018). The team also established relationships with independent not-for-profit organizations (INOs), private foundations, and philanthropic organizations (collectively referred to hereafter as foundations) that may be able to help patients who are ineligible for PAP awards, financial assistance from the Cleveland Clinic, or from HCAP. Foundations provide financial support for treatment expenses, as well as nonmedical costs related to treatment, such as transportation, parking, utilities, and other living expenses.

In 2017, the Cancer Institute built on these efforts, hiring additional staff to support financial navigators (CCCI 2018), establishing staff roles and procedures, and creating metrics for its financial navigation program. These metrics and a workflow of interactions among the financial assistance team, treatment team, and patients were embedded into the electronic medical record (EMR) to ensure a sustained focus on patients' needs.

Components of the financial navigation program

The Cleveland Clinic Cancer Institute's financial navigation program incorporates processes for identifying all possible avenues for patient financial help. These processes are supported by staffing and technology considerations, quality metrics, and standard operating procedures (Table 1).

The financial navigation program relies on a collaborative approach among three defined staff positions. Collectively, their goal is to help make medical treatment financially sustainable to the patient, but individually, each member of the team has a distinct role:

A *patient financial advocate* (PFA) is the first person on the financial navigation team to contact the patient. The PFA confirms the patient's insurance eligibility and benefit design and initiates the financial clearance process, in which the patient's payment arrangements for the initial consultation are established. The PFA is also involved in weekly huddles (CCCI 2018).

A *financial navigator* works in partnership with the PFA to assist patients in resolving financial barriers to access (CCCI 2018). The financial navigator researches and monitors the availability of PAP resources (drug-copayment or free-drug assistance), sources of assistance for non-drug treatment, and foundation dollars, and enrolls patients in financial assistance programs for which they qualify. Importantly, the financial navigator stays with

TABLE 1

Elements of the Cleveland Clinic Cancer Institute's infrastructure for addressing financial toxicity

Operational plan	• Patient and workflow pathway (refer to Figure 2)
Processes	• Benefits investigation/prior authorizations/precertifications • Patient out-of-pocket cost determination • Huddle for resolving access challenges • Investigate options for third-party assistance
Personnel considerations	• Advanced practice nurses for intake and triage • Financial navigation team (patient financial advocate, financial navigator, social worker) • Staffing ratios to support productivity metrics
Information technology	• Navigation database for management of entire process and patients • Tool for identifying third-party sources of assistance • Tool for estimating patient financial responsibility • Revenue-cycle management system to reconcile applications with awards and to track award balances • EHR programming and required documentation
Metrics and reporting	• Treatment report to trigger services of financial navigator • Percentage of all treatment patients reached by financial navigator • Documentation of financial navigator contact with patient • Dollars applied/dollars received • Impact of receipt of assistance on patient financial burden • Access-to-care metric
Sustainability	• Standard operating procedures • Procedural manual

Source: Cleveland Clinic Cancer Institute.

the patient throughout the treatment process, exploring options for financial help at each stage of treatment. Currently, seven financial navigators staff the program.

A *social worker* considers all of the patient's psychosocial needs, as well as other conditions that may contribute to financial toxicity and adversely affect treatment outcomes. The social worker connects patients with community resources and public organizations that offer assistance with nonmedical needs that may arise during treatment, such as access to food, housing, transportation, or support groups (CCCI 2018).

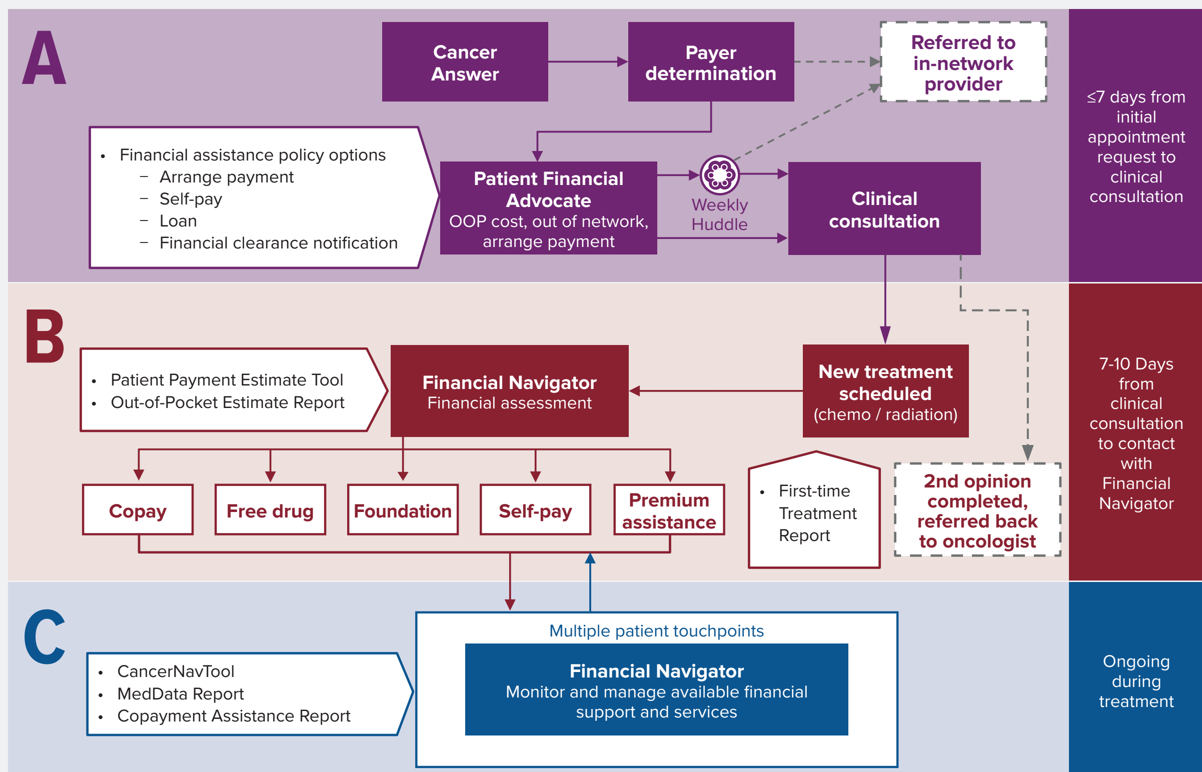
A number of information technology (IT) tools assist the financial navigation team in identifying sources of financial assistance, tracking receipt of awards, estimating patients' out-of-pocket costs, and feeding quality metrics. Among them:

- CancerNAV is an internally developed database used by lay navigators to track patients' financial barriers to care and time-to-treat metrics (CCCI 2018). CancerNAV is undergoing programming enhancements and in the future may be used to document unique circumstances, such as when a change in a medication regimen may trigger eligibility for a new source of funding.
- A separate database, licensed from MedData, tracks applications for dollars and medication replacement (CCCI 2018). It also is used to track distribution of these resources to patients, remaining funds in approved PAP awards, and external or internal foundation grants for each patient. MedData updates pharmacy forms to initiate applications and reconciles assistance amounts applied for with amounts received. This information is reviewed monthly.
- A manual of standard operating procedures and workflows helps to facilitate staff education and to assure adherence to the program (CCCI 2018).

FIGURE 2

Financial navigation program patient and work flow

As oncology patients flow through the program, several interactions among the financial assistance and treatment teams and patients take place, and a series of tools is used to facilitate these activities. Panel A represents activities from the first contact with a patient ("Cancer Answer") through clinical consultation. Concurrent with treatment initiation, the financial navigator investigates the sources of patient assistance shown in Panel B. The financial navigator stays with the patient throughout the course of treatment and, as shown in Panel C, monitors new sources of financial assistance as they become available.



Source: Cleveland Clinic Cancer Institute.

Patient and process flow

Figure 2 (page 5) illustrates the flow of oncology patients through the financial navigation program and interactions between the financial navigation and treatment teams. The program also has defined "touchpoints" with patients (CCCI 2018).

The process typically begins when a new person calls the Cancer Institute's "Cancer Answer" call center to arrange a consultation (Figure 2, Panel A). The Cancer Answer program is staffed by scheduling coordinators who are responsible for patient registration and appointments with the appropriate disease teams and physicians. Two advanced nurse practitioners assist coordinators with questions related to triaging and/or urgency of care.

The PFA conducts a benefit investigation. If the patient requires preauthorization or is out of network, the PFA begins the preauthorization process. For patients who have a high copayment or deductible, the PFA educates patients and their families about the cost of care related to their treatment and provides patients with an estimate of their out-of-pocket expenses.

A small share of cases (4% in 2018) goes to huddle, which is reserved for instances in which patients do not receive a consultation within seven days or have not yet received payer preauthorization (CCCI 2018). The purpose of the huddle is to determine the cause of the delay. To prevent out-of-network patients from experiencing delays, the discussion in huddle may focus on whether it is clinically necessary for the patient to be treated at the Cleveland Clinic. These patients may be referred to a high-quality tertiary care center within their own networks — depending on whether the center can offer a comparable evidence-based regimen at a lower out-of-pocket cost and if the patient believes a referral is in his or her best interest.

Time to treatment is a quality metric at the Cleveland Clinic Cancer Institute (Khorana 2019). Half of all patients are scheduled for a consultation within seven days, and another 25% are scheduled beyond seven days because of patient requests (CCCI 2018). For all others, if a consultation was scheduled beyond seven days, a discussion is held with physician leadership to determine if there is an opportunity to improve the timing of appointments.

For patients who stay with the Cleveland Clinic Cancer Institute for care after a consultation, scheduling of treatment initiation generates a First-Time Treatment Report (CCCI 2018). This report, which is updated daily, triggers the services of the financial navigator (Figure 2, Panel B). On their first day of treatment, out-of-network patients are introduced to the financial navigator and, if necessary, a social worker.

The financial navigator uses the Patient Payment Estimate Tool, an Experian Health software program, to determine the patient's benefit coverage and out-of-pocket costs for the upcoming course of treatment. The financial navigator provides this information to every patient within 7 to 10 days after the consultation (CCCI 2018). Documentation of this contact is captured on an Out-of-Pocket Estimate Report and in the EMR (CCCI 2018).

Once a patient's out-of-pocket cost is determined, the financial navigator works with the patient and social worker to manage any barriers to treatment stemming from psychosocial needs or financial toxicity.

To help patients bridge gaps in coverage, the financial navigator investigates options for third-party assistance, then contacts the patient about programs for which the patient may qualify. With consent of the patient, the financial navigator works to secure copayment assistance or free medication through pharmaceutical company PAPs. Some of these sources of assistance, however, often come with eligibility limitations; in cases where alternative sources of support may be needed, the financial navigator may have access to philanthropic funds for nonmedical expenses, such as utility bills, car payments, or housing needs, while the patient receives care.[1]

The financial navigator's work on behalf of the patient is ongoing, as other sources of financial help may become available during the patient's course of treatment (Figure 2, Panel C). The navigator reviews the EMR frequently to identify treatment changes that may trigger a patient's eligibility for other financial resources. Similarly, nurses and social workers will refer a patient back to the financial navigator when appropriate. Patients are also encouraged to contact the financial navigator if they become aware of resources for which they may qualify.

Quantification of access-related activities

From January through December of 2018, 10,939 people who called the Cancer Answer hotline were scheduled for consultation. The median time to consultation was six to seven days. Among patients who received a consultation during this period, 7,960 proceeded with treatment (CCCI 2018).[2]

Following the consultation, a financial navigator reached 99% of these patients prior to treatment initiation (CCCI 2018). Financial navigators determined that 2,754

1. This is in addition to any financial assistance available under the Cleveland Clinic's Financial Assistance Policy. It applies to uninsured patients and to insured patients with catastrophic medical costs. See: https://my.clevelandclinic.org/patients/billing-insurance/financial-assistance.
2. 25% of consultations at the Cleveland Clinic Cancer Institute involve patients seeking second opinions, most of whom will return to their referring oncologist (CCCI 2018).

patients (35%) needed some type of financial assistance (CCCI 2018), leading to discussions about the potential availability of PAP and foundation resources for help with medication and other expenses. The number of applications filed and approved for manufacturer-sponsored PAP awards during 2018, and the dollar values of these awards, are shown in Table 2 (CCCI 2018).[3]

The monthly dollar value of approved copayment assistance applications is documented on a Copayment Assistance Report (CCCI 2018). The growth in receipt of awards during 2017 and 2018 (Figure 3, page 8) (CCCI 2018) corresponds with the hiring of additional financial navigators to administer the Cleveland Clinic Cancer Institute's financial navigation program during these years.

Similarly, the addition of financial navigators and social workers since the expansion of the financial navigation program in 2016 has had a direct effect on the ability to secure philanthropic dollars for patients who do not qualify for PAP or foundation awards. The annual total of these awards is shown in Figure 4 (page 8) (CCCI 2018).

These activities should not be viewed in isolation, however, but as part of a progression of process improvements dating back to the establishment of the huddle. What is learned in huddles about barriers to care has led to procedural changes, staffing additions, and the development of a structured financial navigation program. The Cleveland Clinic Cancer Institute believes that the cumulative effect of these activities has been to enable access improvements. From 2014 to 2018, the median time from first positive biopsy to first treatment fell 33%, from 39 days to 26 days (Khorana 2019).

3. The difference between the number of patients determined to be in need and the volume of applications filed as shown in Table 2 reflect the eligibility requirements of each program. Publicly insured patients (who make up 62% of the Cleveland Clinic Cancer Institute's patient mix [55% Medicare, 7% Medicaid]) (CCCI 2018) are ineligible for manufacturer-sponsored PAPs. Free-drug programs each have differing eligibility requirements, but in general household income limits typically apply, and this type of assistance often is available only to uninsured individuals or those whose benefit design precludes coverage of the drug.

Insights and observations

Addressing financial toxicity has come to represent a new standard for treating the "whole patient." Ubel (2013) has argued for full disclosure of the financial consequences of treatment in the same manner as physicians would inform patients about treatment side effects. All too often, however, patients' desire to talk with their clinicians about the financial impact of care is ignored. In a recent study of 2,502 patients with breast cancer, 55% of those who expressed a desire to talk with health care providers reported no relevant discussion with their provider and 73% of patients who were worried about finances indicated physicians and their staff did not help (Jagsi 2018). The authors noted that as mortality rates in breast cancer have improved, affordability now matches survival as a prime patient concern.

As a best practice, the Cleveland Clinic Cancer Institute regards complete financial disclosure, along with financial assistance and supportive services, as of equal importance to medical care. Staff members make a point to talk with patients to understand and address their financial concerns. In 2018, Cleveland Clinic Cancer Institute determined that 35% of its oncology patients were in need of some sort of financial support (CCCI 2018).

There is, however, a right time and place for these conversations to take place. In a recent quality-directed survey, Cleveland Clinic Cancer Institute patients said

TABLE 2

Copayment assistance and free drug applications and receipts, January–December 2018

Activity	Copayment assistance[a]	Free drug
Applications filed	464	1,048
Applications approved (%)	415 (89%)	935 (88%)
Aggregate of approved copayment assistance applications collected	$1,121,840[b]	(n/a)
Total dollar amount of approved applications for free drug	(n/a)	$11,171,779[c]
Average total dollar amount per application	$2,703	$11,948

[a]Represents direct out-of-pocket cost assistance (copayment cards from patient-assistance programs or grants from foundations). Some patients qualified for more than one award.

[b]Represents dollar amounts collected, which are lower than amounts approved, typically because patients meet their out-of-pocket maximum or change treatment regimens, leaving approved assistance amounts unused.

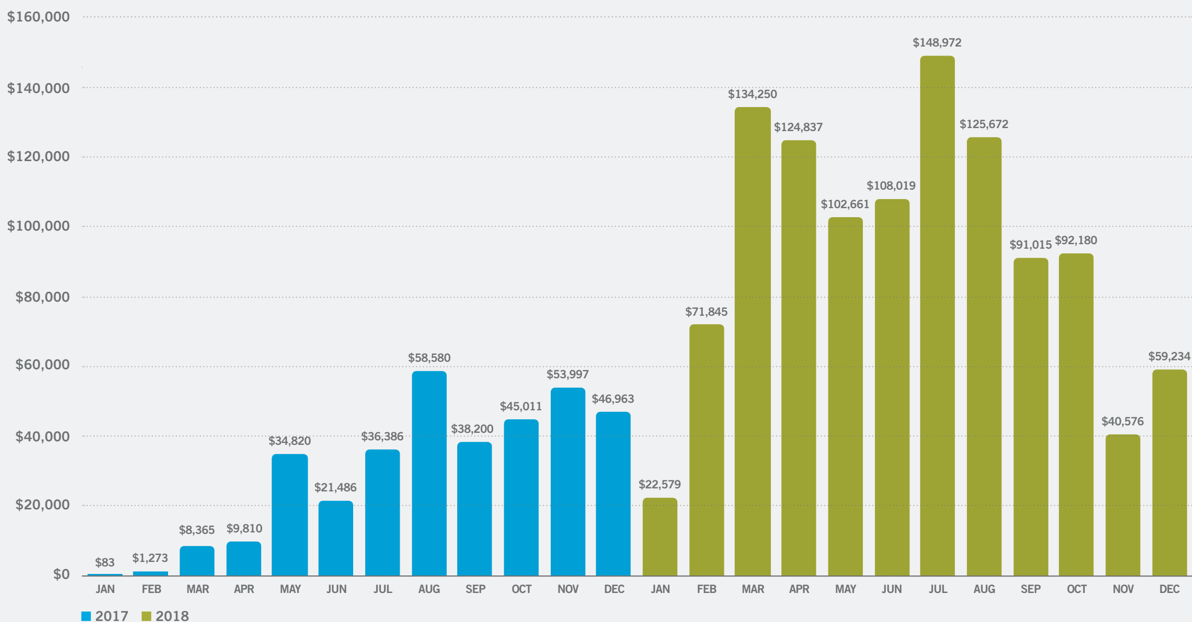
[c]Represents the value of pharmaceuticals provided by manufacturers for the uninsured and underinsured.

Source: Cleveland Clinic Cancer Institute.

FIGURE 3

Copayment Assistance Report, 2017–2018

The Copayment Assistance Report documents the aggregate dollar value of all patient-assistance awards received on a monthly basis. In the spring of 2017, the Cleveland Clinic Cancer Institute began to hire additional full-time equivalents to administer its financial navigation program. This had a direct effect on the volume of awards.

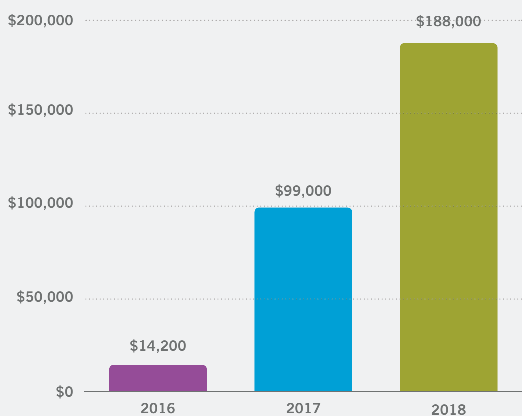


Source: Cleveland Clinic Cancer Institute.

FIGURE 4

Receipt of philanthropic dollars, 2016–2018

For patients who do not qualify for PAP or foundation awards, philanthropic funds for premium assistance or nonmedical expenses (e.g., transportation to appointments, gasoline, parking, or utilities) may help to offset the cost of living while undergoing care. The value of such funding obtained by the Cleveland Clinic Cancer Institute increased more than 12-fold after the expansion of the financial navigation program in 2016.



Source: Cleveland Clinic Cancer Institute.

discussing outstanding balances at the time of a medical appointment would be stressful and anxiety-provoking, and some indicated it may cause them not to follow through with their appointments (CCCI 2018). The presence of a financial navigator and a program that can engage patients in a separate, private conversation is a quality-of-care matter that allows the patient to focus on health at the time of an appointment.

High out-of-pocket costs and inadequate insurance coverage are well-documented barriers that lead to delays in receiving appropriate care (HealthyPeople.gov 2019). Healthcare payers and providers are also beginning to recognize that everyday living expenses are up-front costs that may pose additional barriers to treatment (Japsen 2018). But however helpful a systematic approach to procuring financial aid for patients may be, it alone does not guarantee access improvements. The Cleveland Clinic's experience has been that a multidisciplinary approach to problem-solving and the willingness of senior leadership to commit to a level of resources adequate for the job are equally critical. Additional considerations for implementing a program can be found in Table 3 at the end of this publication.

The sum of these activities was a reduction in time

to treatment, which itself is a priority and is discussed regularly at meetings of the Cancer Institute Executive Committee (Khorana 2019). The Cleveland Clinic Cancer Institute views this outcome as a quality-of-care improvement.

In describing the evolution of a comprehensive program for addressing patients' financial burden, this analysis builds on the limited number of studies (Conner 2013, Burley 2016, Zullig 2017) of financial assistance programs. Learnings from this experience provide insights for other institutions and providers that wish to improve care and access for patients who struggle with OOP costs. As described in the *Genentech Oncology Trend Report,* the typical community oncology practice collects full OOP responsibility from only about 25% of patients (Genentech 2017). This directly affects quality of care, with 83% of oncology practices reporting delays or discontinuation of treatment because of a patient's inability to afford care (Genentech 2018).

The processes described in this article should not be viewed as an endpoint. A program for addressing patients' financial and access challenges must be dynamic and responsive to emerging environmental factors. Although the way in which these activities have unfolded is encouraging, there are still improvements to be made in the patient experience. Looking forward, the Cleveland Clinic Cancer Institute is investigating additional ways to help patients with everyday living expenses, such as ridesharing options and improving access to food.

Conclusion

The Cleveland Clinic Cancer Institute's financial navigation program illustrates a multifaceted approach to financial toxicity. The Cleveland Clinic Cancer Institute and Genentech present these observations in the hope that other provider organizations will consider enhancing practices and principles to reduce financial barriers for patients.

As the gap between the cost of care and what patients can afford widens (Emanuel 2017), the Cleveland Clinic Cancer Institute will continue to address challenges and conduct research to understand how financial toxicity may affect the clinical and emotional quality of care for the patient. At a broader level, however, a solution will require all stakeholders, including manufacturers, employers, payers, and policymakers, to focus greater attention on the access challenges created by patients' financial burden.

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TABLE 3

Considerations for organizations to address financial toxicity

Possible components of a comprehensive program for minimizing patients' cost burden

CREATE

- ☐ Build a patient-focused culture
- ☐ Establish clear goals for the program

ENGAGE

- ☐ Gain senior leadership and staff buy-in for the need
- ☐ Seek complementary expertise from external organizations

PLAN

- ☐ Develop an operational plan with multidisciplinary input
- ☐ Populate plan with processes to be followed for each patient (or for stratified groups of patients)
- ☐ Identify specific people responsible for carrying out processes
- ☐ Determine a level of staffing adequate for the challenge
- ☐ Develop a system (e.g., the huddle) to resolve access and financial challenges

ACTION

- ☐ Implement standard operating procedures
- ☐ Educate staff on processes and create a manual for referral
- ☐ Hardwire processes into the EHR
- ☐ Configure information technology to support program goals
- ☐ Document completion of processes

MEASURE

- ☐ Decide which values represent "quality metrics" for the organization

REPORT

Share data to:

- ☐ Show progress
- ☐ Celebrate wins
- ☐ Trigger improvements

Source: Cleveland Clinic Cancer Institute.