Poster # **CML-068**

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Quantifying the Financial Impact of Treatment Intolerance in Chronic Myeloid Leukemia on Oncology Clinical Practices: A Mixed-Methods Study

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KEY FINDINGS & CONCLUSIONS

- Navigating **payer-imposed restrictions** and **peri-hospitalization coordination**, which are largely **not reimbursable**, were key drivers of increased practice costs in addressing CML treatment intolerance
- **Payer utilization management protocols delay care and increase administrative workload**, particularly when switching medications due to intolerance, with non-reimbursable tasks such as peer-to-peer review requiring staff overtime.
- CML treatment intolerance **episodes involving hospitalization were twice as costly** to the practice versus those not requiring hospitalization. Disjointed healthcare systems compel oncology practices to oversee inpatient care to ensure safety and appropriateness.
- The unpaid resource burdens on oncology practices can have **far-reaching impacts on healthcare delivery**, including the growing shortage of oncology practices caused by provider burn-out from excessive administrative tasks.[5]
- CML treatment intolerance imposes additional economic burden on oncology practices, and most of these activities are not reimbursed by public or private payers. Stakeholders should consider how de-escalation of intolerance-related administrative burdens may be achieved to improve the operational stability of oncology practices.

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INTRODUCTION

- While tyrosine kinase inhibitors (TKIs) have greatly improved the prognosis of patients with chronic myeloid leukemia (CML), many patients still experience **treatment intolerance**.[1]
- Forms of TKI treatment intolerance include hematologic (neutropenia, thrombocytopenia, anemia) and non-hematologic (e.g., gastrointestinal toxicity, hepatic toxicity, edema, muscle cramps, rash, joint pain) toxicities.[2,3]
- The **time and cost impact** of treatment intolerance for oncology practices, including addressing patient symptoms, coordinating with hospital staff (if needed), and determining if the patient needs to switch medications, has not been previously measured.

METHODS

- This **mixed methods** study combined interviews of 10 US oncology practice decision-makers (conducted October 2023-January 2024) with economic modeling to identify and quantify real-world cost factors of CML treatment intolerance to the practice.
- Oncology **practice decision-makers** recruited via convenience sampling included nurses/nurse administrators, physician assistants, and oncologists/hematologists from academic oncology practices across the US, all actively treating CML patients.
- Open-ended interview responses on the range of activities associated with typical treatment intolerance episodes were compiled into a dataset for analysis.
- An episode of treatment intolerance was defined as occurrence of an adverse effect of CML treatment that could not be managed through dose reduction or treatment of symptoms, potentially requiring interruption or discontinuation of therapy.
- Participants were asked to describe their general experience addressing intolerance episodes rather than specific intolerance events, conditions, or patients.
- Time impacts of intolerance-related activities were converted into monetary terms using benefits-adjusted hourly wage rates for specific staff (e.g., nurse practitioner, insurance coordinator) needed to complete the task.[4]
- The practice cost per treatment intolerance episode was calculated as the sum of staff time and material costs per episode across all cost factors.

RESULTS

Participant Characteristics

- Ten practice decision-makers participated from academic oncology practices (**Table 1**).
- These 10 individuals came from practices in the US Northeast (n=7), South (n=2), and West (n=1), most of which treated >100 patients in the past year (n=6), with CML accounting for ≤25% of patients (n=9).

Table 1. Participant characteristics

Characteristic	N = 10
Participant Current Role in Practice (%)	
Oncologist/Hematologist	1 (10%)
Nurse Practitioner	2 (20%)
Nurse Administrator	3 (30%)
Registered Nurse	2 (20%)
Physician Assistant	2 (20%)
Participant in Current Practice >5 Years (%)	3 (30%)
Participant General Experience in Oncology Practices >10 Years (%)	6 (60%)
Practice Census Region (%)	
Northeast	7 (70%)
South	2 (20%)
Midwest	0 (0%)
West	1 (10%)
Annual Number of Cancer Patients Treated at Practice (%)	
<100	0 (0%)
100-500	2 (20%)
>500	4 (40%)
Unknown	4 (40%)
Annual Share of Cancer Patients with CML at Practice (%)	
<10%	3 (30%)
10-25%	6 (60%)
>25%	1 (10%)
Number of Oncologists/Hematologists in Practice >5 (%)	7 (70%)
Number of Nurse Practitioners in Practice ≤5 (%)	9 (90%)

Abbreviations: CML – Chronic Myeloid Leukemia

Table 2. Costs of addressing CML treatment intolerance to oncology practices

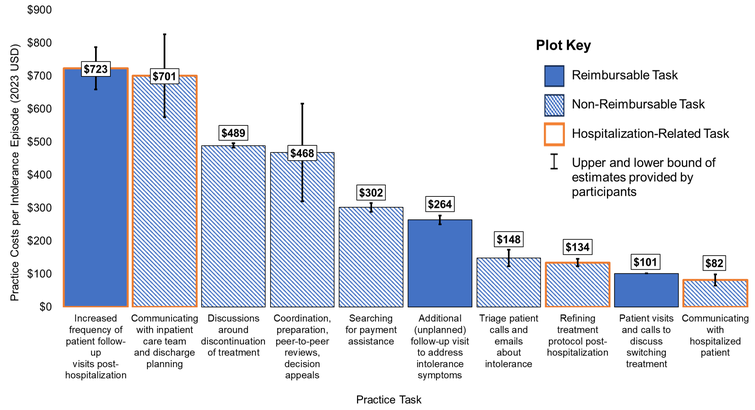
Cost Factor	Task	Coded for Reimbursement	Participant 1	2	3	4	5	6	7	8	9	10	Practice Hours	Practice Cost	Practice Hourly Cost
													Mean (Range) per Intolerance Episode[†]		
1 Navigating payer prior authorization for medication switch	Coordination, preparation, peer-to-peer reviews, decision appeals[1]	No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10 (8-12)	$871 ($710-$1033)	$87 ($84-$93)
	Searching for payment assistance[2]	No	✓	✓	✓	✓			✓	✓	✓	✓			
	Patient visits and calls to discuss switching treatment[3]	Yes	✓	✓	✓	✓	✓	✓	✓	✓		✓			
2 Increased patient monitoring and treatment adjustments post-hospitalization*	Increased frequency of patient follow-up visits[4]	Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	8 (8-8)	$858 ($782-$933)	$107 ($102-$112)
	Refining treatment protocol post-hospitalization[5]	No	✓	✓	✓	✓	✓		✓	✓	✓	✓			
3 Coordinating care during patient hospitalization*	Communicating with inpatient care team and discharge planning[6]	No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	9 (8-11)	$782 ($640-$925)	$82 ($81-$85)
	Communicating with hospitalized patient[4]	No	✓	✓	✓	✓	✓	✓		✓	✓	✓			
4 Discussions around discontinuation of treatment[7]		No	✓		✓	✓	✓	✓	✓	✓	✓	✓	3 (3-3)	$489 ($483-$496)	$169 ($166-$173)
5 Responding to patient calls, emails, and visits regarding symptoms	Additional (unplanned) follow-up visit to address intolerance symptoms[6]	Yes	✓	✓	✓		✓	✓	✓	✓	✓	✓	4 (3-4)	$412 ($374-$451)	$113 ($112-$114)
	Triage patient calls and emails about intolerance[6]	No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
6 Risk of patients switching practices		N/A					✓		✓			✓	N/A	N/A	N/A
7 Patient dissatisfaction	Coverage denials	N/A		✓	✓								N/A	N/A	N/A
	High copays		✓	✓	✓	✓			✓	✓					
	Treatment delays due to prior authorization		✓		✓	✓	✓	✓							
	Quality of life						✓		✓	✓	✓	✓			
8 Oncology practice staff dissatisfaction	Prior authorization process	N/A		✓	✓	✓							N/A	N/A	N/A
Total practice cost per intolerance episode not requiring hospitalization		**20.6%**											**17 (14-19)**	**$1,772 ($1,566-$1,980)**	**$107 ($103-$114)**
Total practice cost per intolerance episode requiring hospitalization		**31.9%**											**34 (29-39)**	**$3,413 ($2,988-$3,838)**	**$100 ($98-$103)**

✓ = Task reported by participant.
*Hospitalization-related cost factor.
†Hours and costs (2023 USD) reported are the average, low-end, and high-end of estimates provided by participants. Time costs are based on benefits-adjusted hourly wage data obtained from the US Bureau of Labor Statistics (BLS). The sums of hours and costs displayed may slightly differ from the totals displayed due to rounding of hours and costs to the nearest hour and dollar, respectively.
Aggregate of hourly wages for: [1]Hematologist/Oncologist, Nurse/Nurse Practitioner, APP Team Member, Insurance Coordinator; [2]Nurse/Nurse Practitioner, Insurance Coordinator; [3]Nurse/Nurse Practitioner, APP Team Member; [4]Hematologist/Oncologist, Nurse/Nurse Practitioner; [5]Nurse/Nurse Practitioner; [6]Hematologist/Oncologist, Nurse/Nurse Practitioner, APP Team Member; [7]Hematologist/Oncologist, Nurse/Nurse Practitioner; Social Worker; Palliative Care Specialist.

Time and Cost Burdens

- Estimated practice time and cost per treatment intolerance episode requiring hospitalization were **34 hours** and **$3,413**, respectively, which were largely attributable to navigating **payer prior authorization** for medication switch (10 hours, $871), **additional follow-up visits** (8 hours, $858), and **care coordination** with inpatient team (9 hours, $782) (**Figure 1**).
- Activities that could be coded for reimbursement represented only **31.9%** of incurred practice cost (**Table 2**).
- The time and cost per treatment intolerance episode requiring no hospitalization were **17 hours** and **$1,772**, respectively.

Figure 1. Oncology practice costs by task performed to address CML treatment intolerance



Bar plots display the mean and range of estimates provided by participants. Note: cost factors 6 (risk of patients switching practice), 7 (patient dissatisfaction), and 8 (oncology staff dissatisfaction) were not explicitly quantified.

Limitations

- The study had a modest sample size (n=10). Nevertheless, the sample size was sufficient to reach saturation.[6]
- All respondents were from academic practices; thus, generalizability to community practices is limited.
- The study focused on costs of treatment intolerance in CML, thus generalizability to other types of cancers is limited.

References

1. García-Gutiérrez V, Hernández-Boluda JCC. Current Treatment Options for Chronic Myeloid Leukemia Patients Failing Second-Generation Tyrosine Kinase Inhibitors. *Journal of Clinical Medicine. 2020;9(7):2251.* **2.** Deangelo DJ. Managing chronic myeloid leukemia patients intolerant to tyrosine kinase inhibitor therapy. *Blood Cancer J. 2012;2(10):e95.* **3.** Pinilla-Ibarz J, Cortes J, Mauro MJ. Intolerance to tyrosine kinase inhibitors in chronic myeloid leukemia. *Cancer. 2011;117(4):688-97.* **4.** U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics [Internet]. Division of Occupational Employment and Wage Statistics; 2023 April. Available from: https://data.bls.gov/oes. **5.** American Society of Clinical Oncology. Oncology Workforce Shortages. 2023. Available from: https://society.asco.org/sites/new-www.asco.org/files/content-files/news-initiatives/documents/2023-workforce-brief.pdf. **6.** Hennink M, Kaiser BN. Sample sizes for saturation in qualitative research: A systematic review of empirical tests. *Soc Sci Med. 2022;292:114523.*