

# Patient and Caregiver Burden of Oncology Clinic Visits for Granulocyte-Colony Stimulating Factor Therapy in the United States

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## INTRODUCTION

- Cancer patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drug therapy often have suppressed white blood cell counts and are at risk for febrile neutropenia (FN). Treatment with granulocyte-colony stimulating factors (G-CSFs) at least 24 hours after administration of myelosuppressive chemotherapy is indicated for patients with a clinically significant risk of FN. In the United States (US) most doses of G-CSFs are administered in the clinic during separate visits after the chemotherapy session, to ensure on label administration.
- Patients must return to the clinic, usually the next day, for G-CSF administration, often accompanied by a family member or other informal caregiver. The time and economic burden on patients and informal caregivers of clinic visits for G-CSF injections may be significant, and has not previously been estimated from a societal perspective in the US.

## OBJECTIVE

- To estimate the annual economic burden on patients and caregivers of clinic visits for G-CSF injections in the US.

## METHODS

- Total 2015 visits for G-CSF injections following myelosuppressive chemotherapy for non-myeloid malignancies were estimated from models using data collected from oncology literature, cancer patient databases (SEER<sup>1</sup>, Oncology Services Comprehensive Electronic Records (OSCEER)<sup>2</sup>), and publically-available G-CSF pricing data<sup>3</sup>.
- Patient and caregiver travel times per visit, plus time in the clinic, were estimated from responses to a questionnaire administered to patients in an ongoing prospective observational study (Prospective Study of the Relationship between Chemotherapy Dose Intensity and Mortality in Early-Stage (I-III) Breast Cancer Patients (CABS))<sup>4</sup>. Responses were analyzed by census region. Statistical tests of differences by region were determined by chi-square.
- Models of travel distance in miles, travel costs and patient office copays were developed from various sources (Table 1). The economic value of travel time, plus time spent in G-CSF visits, was monetized for patients and caregivers as an opportunity cost using a combination of foregone wage and replacement cost approaches. Patient office copays were estimated based on insurance benefit designs and insurer costs for G-CSF visits, and from data in the literature. Sensitivity analyses were conducted to test the robustness of model estimates, using a reasonable range of estimates from the literature for each key variable in the model.

Table 1: Data Sources and Assumptions Used to Estimate Annual Patient/Caregiver Costs

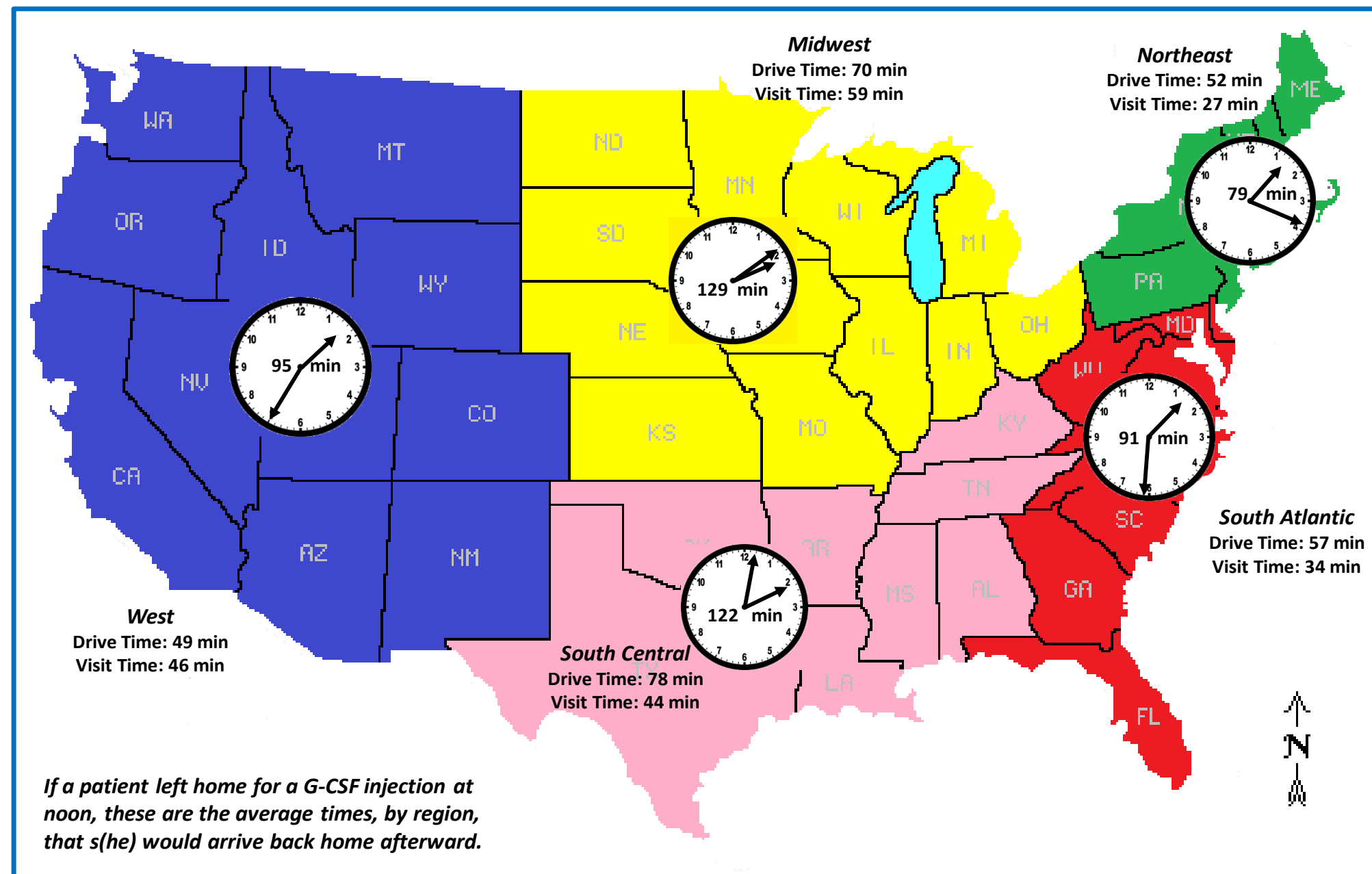
Category	Source(s)	Assumptions/Estimates Used
<b>National Annual Clinic Visits for G-CSF Injection following MC</b>		
Cancer Prevalence, by type	SEER Cancer Statistics Review 1975-2012 <sup>1</sup>	2012 5-year prevalence estimates, 1 <sup>st</sup> invasive tumor ever
Percent of cancer patients receiving chemotherapy	American Cancer Society report <i>Cancer Treatment &amp; Survivorship Facts &amp; Figures 2014-2015</i> <sup>5</sup>	Estimates made in 7 categories. Overall average in non-myeloid cancers was 28%
Chemo cycles per patient	Chemocare: <i>How Long is Chemotherapy Given?</i> <sup>6</sup>	4 cycles per patient
G-CSF Cycle penetration rates, by cancer type	OSCEER database <sup>2</sup>	Estimates made in 7 categories. Overall average in non-myeloid cancers was 31.5%
Percent of G-CSF cycles by daily vs long-acting	OSCEER database <sup>2</sup>	68% long-acting, 32% daily
Average Days Treated per Cycle (Daily G-CSFs)	OSCEER database <sup>2</sup>	2.4 days per cycle
Percent delivered in office (vs at home)	Daily G-CSFs: IMS G-CSF Report from June 2013 <sup>7</sup> . Long-Acting G-CSFs: from Phillips et al, 2012 <sup>8</sup>	60% for daily G-CSFs 91% for long-acting G-CSFs
<b>Patient and Caregiver Time Devoted to G-CSF Visits (per visit)</b>		
Mean Travel Time (Round-trip)	CABS Survey <sup>4</sup>	62 minutes
Mean Clinic Time	CABS Survey <sup>4</sup>	41 minutes
Percent of Trips Accompanied	CABS Survey <sup>4</sup>	66.3%
Value of Patient Time	BLS National Average Wage all Occupations <sup>9</sup>	\$22.71 per hour
Economic Value of Caregiver Time	Average of State Minimum Wages <sup>10</sup> , BLS Mean Home Health Aide Wage <sup>9</sup> and Median Private Pay cost of hiring a home health aide <sup>11</sup>	\$12.80 per hour
<b>Travel Costs</b>		
Average travel distance to treatment (round-trip)	Converted travel time to miles, based on mean travel speed of 34 MPH (from Houts et al 2006 <sup>12</sup> )	35.13 miles
Mode of transport	CABS Survey <sup>4</sup>	33.5% self-drive, 64.5% other driver, 1% taxi, 1% public transit
Per mile costs for self-driven, other driver miles	Based on 2015 IRS mileage rates <sup>13</sup> . Medical rate applied to self-transported miles. Full business rate applied to other driver miles.	Self-drive: 23 cents per mile Other drivers: 57.5 cents per mile
Costs of other modes of transport	American Public Transit Association (APTA) 2014 Fact Book <sup>14</sup> . Summary of US Taxi Fares from taxifarefinder.com <sup>15</sup>	Cost per mile for Taxis: \$2.91 Cost per Trip: Taxis: \$2.85+mileage, Public Transit: \$2.13 per trip
<b>Insurance Cost-Sharing/Copays</b>		
G-CSF Market Share by Insurance Segment	Amgen, Inc. data on file. Payer Mix for 2014 for the Neulasta and Neupogen franchises <sup>7</sup>	Assumed payer mix in office/OPD setting would mirror mix across all settings
Cost-Share per Visit	Commercial Plans: from Tomic et al 2013 <sup>16</sup> . Medicare FFS: Based on 20% coinsurance for Part B services, times Medicare Allowed amounts <sup>3</sup> . Medicaid: Based on average of state-level office copays <sup>18</sup>	Assumed 83% of Medicare FFS had supplemental insurance <sup>17</sup> . Medicare Advantage: same as commercial. VA, Military, Uninsured: assumed no cost sharing

## RESULTS

### Patient Travel and Time in the Clinic

- From the CABS patient questionnaire, mean (SD) travel time (round-trip) per visit was 62 (50) minutes; with mean (SD) time in the clinic of 41 (68) minutes. Mode of transport was 98% by car (33.5% self-drive, 63.5% another drives) and 2% taxi or public transportation. Two-thirds of patients were accompanied to the visit. Results varied significantly by geographic region (Figure 1, Table 1). Differences in travel time by region were statistically significant (p <0.05) between South Central and all other regions except Midwest, and between Midwest and the Northeast and West.

Figure 1: Mean Time Required per Visit (Minutes) for G-CSF Clinic Visits, by Region



Source: CABS Patient Questionnaire.<sup>4</sup> Region is based on the address of the treatment site.

Table 2: Modes of Transport to G-CSF Clinic Visits, by Region

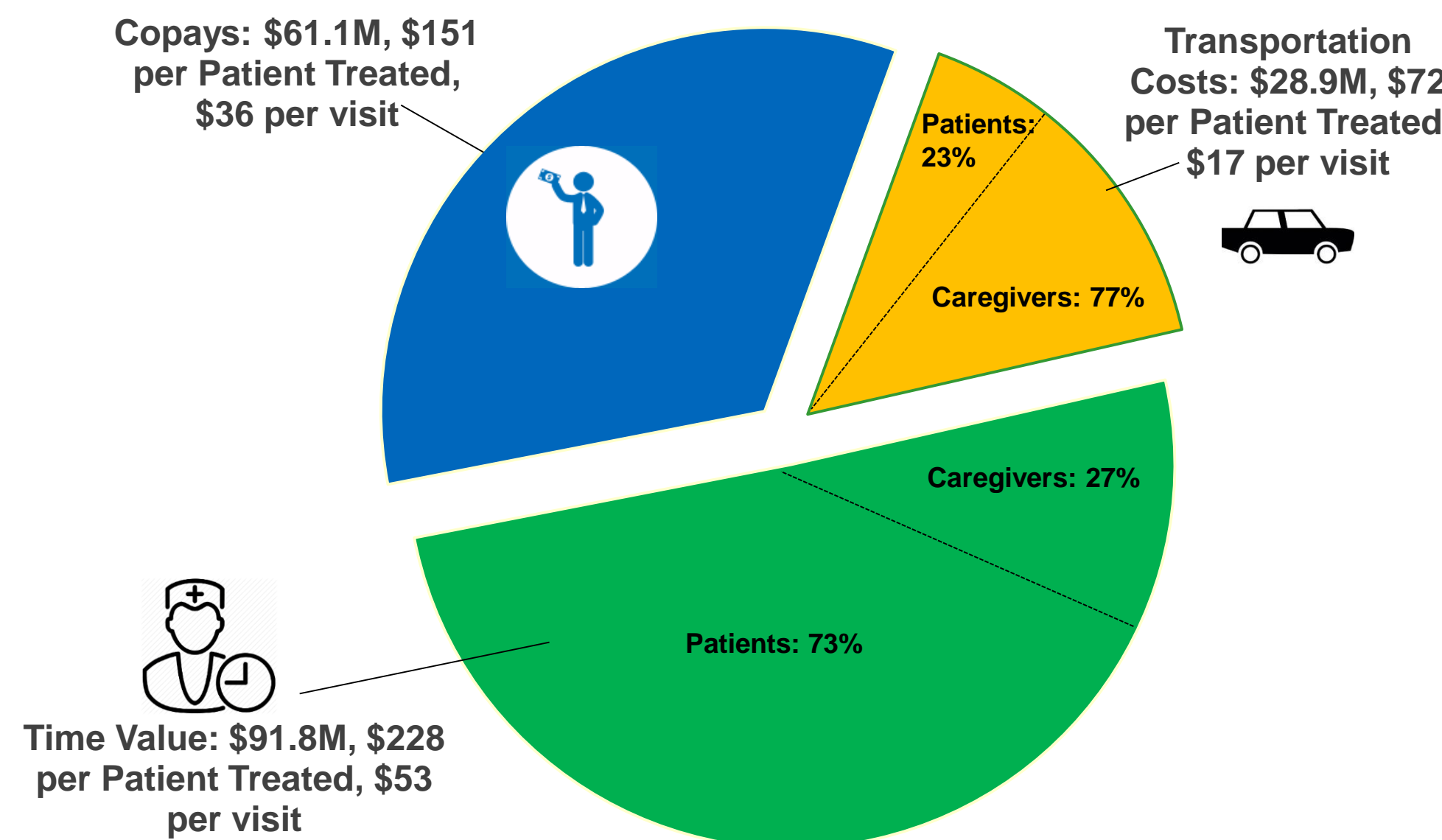
Q4 Usual transport to office	Midwest	Northeast	South Atlantic	West	South Central	Total
Someone else drove me	60%	61%	61%	62%	78%	64%
I drove myself	36%	38%	37%	36%	22%	34%
Public transportation	3%	0%	1%	0%	0%	1%
Taxi	1%	1%	2%	2%	0%	1%

Source: CABS Patient Questionnaire.<sup>4</sup> Region is based on the address of the treatment site.

### National Visit and Cost Projections

- The estimated total number of clinic visits for G-CSF injections in the United States following myelosuppressive chemotherapy for non-myeloid malignancies is 1.713 million visits for approximately 403,000 patients in 2015. The total economic impact to patients and caregivers is \$181.8 million (Figure 2).

Figure 2: Estimated Total National Economic Impact on Patients of G-CSF Clinic Visits for 2015

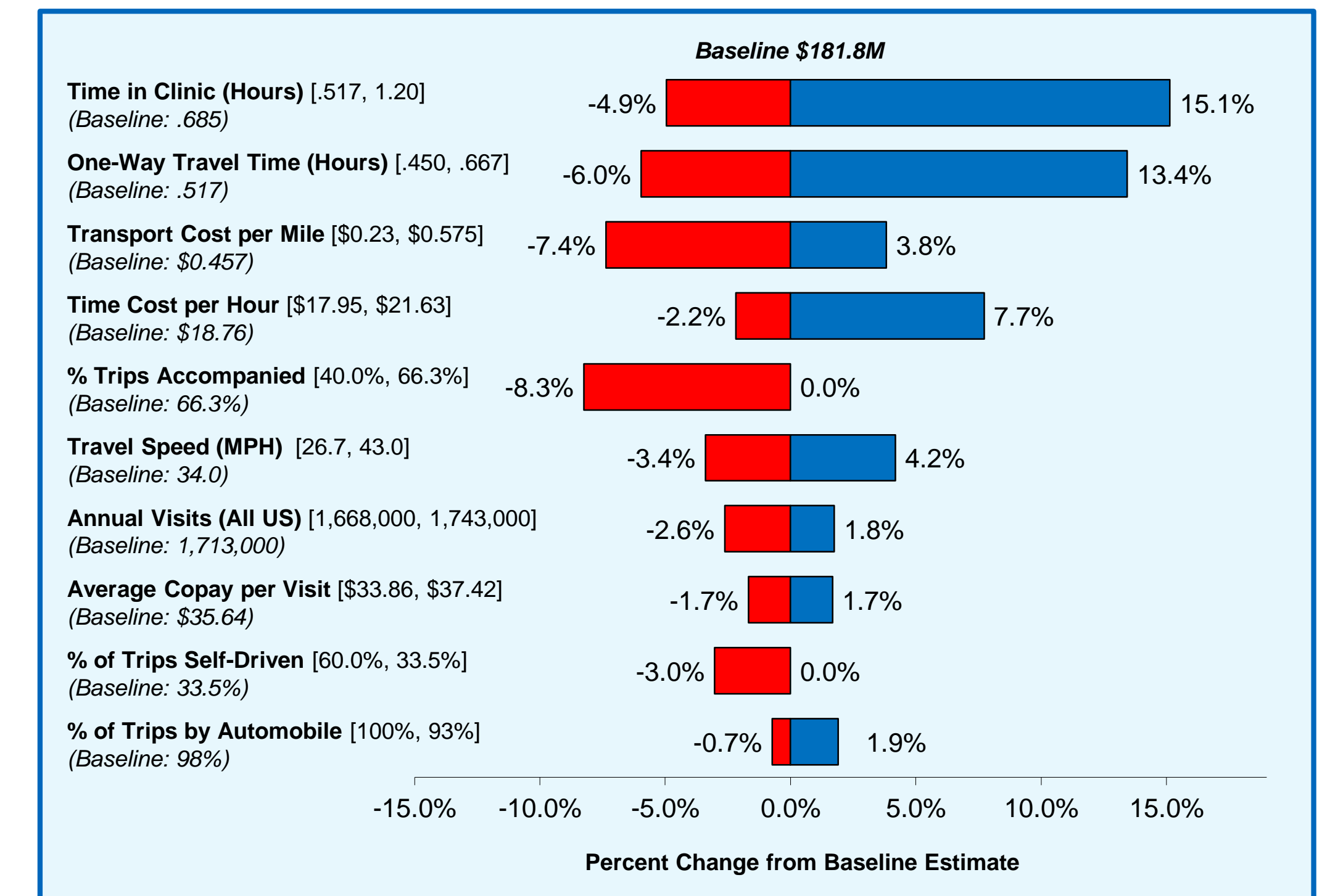


- The total national patient and informal caregiver time commitment for one year for travel to and from the clinic, plus time at the clinic, is estimated at 4.9 million hours (12.1 hours per patient), with their time valued at approximately \$91.8 million.
- Average round-trip travel distance per G-CSF visit was estimated at 35.1 miles. The cumulative annual travel distance for G-CSF clinic visits was estimated at 60.2 million miles, at a total transportation cost of \$28.9 million.

### Sensitivity Analysis

- The largest effects on overall costs result from the estimates of time spent in the oncology clinic and travel time to the clinic (Figure 3). Unit costs (travel cost per mile and time cost per hour) had the next largest effects.

Figure 3: Sensitivity Analysis: Effects of Changes to Estimates on Key Factors Driving Cost



Red bars represent outcomes based on minimum plausible values. Blue bars represent outcomes based on maximum plausible values. Numbers in square brackets to the right of the labels denote the ranges of values used.

## DISCUSSION

- This study was limited by the lack of available estimates on how many G-CSF clinic visits occur for FN prophylaxis in the US in a year, and the lack of any current data on the breakdown of the total US G-CSF market by setting of service and clinical indication.
- There are patient and caregiver costs that were not captured by this study; specifically, we did not estimate lost work time, which could be in addition to the time needed to travel to and from the clinic and time spent in the clinic.
- Balancing the clinical needs of patients with patient preferences and the cost and time burden of G-CSF treatments is an ongoing challenge. Opportunities to reduce the burden on patients while maintaining optimal therapies toward complete recovery from cancer should be thoroughly explored by treating oncologists and their patients.

## CONCLUSION

- The patient and informal caregiver burden of clinic visits for G-CSF therapy following myelosuppressive chemotherapy is a significant addition to the total disease burden borne by patients and their families. Efforts to reduce this burden for the patient and caregiver should be pursued.

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## DISCLOSURE

This study was sponsored by Amgen Inc. MS received consulting fees in association with this study. XL, MR, WS and ST are employees of Amgen, Inc. and own stock and/or stock options in Amgen, Inc.