Geographic Accessibility to Clinical Trials for Advanced Cancer in the United States

Clinical trials yield critical evidence to guide the care of patients with cancer. According to commonly used practice guidelines, “...the best management of any cancer patient is in a clinical trial.” Nonetheless, only about 2% to 7% of US adult patients with cancer participate in clinical trials. Poor accrual to clinical trials has far-reaching implications in the way it affects the pace of progress, cost of drug development, and generalizability of study findings.

Prior studies exploring trial enrollment have identified several barriers. However, geographic barriers to participation in clinical trials remain underexplored. A survey of patients with cancer revealed that most were not willing to travel for trial participation. We sought to estimate the geographic accessibility of clinical trials for advanced cancer in the United States.

Methods | Data regarding clinical trials and associated sites were derived from ClinicalTrials.gov. We identified all actively accruing trials that evaluated first-line treatments for metastatic breast, prostate, colorectal, and non–small cell lung cancers. Inclusion was limited to these malignant neoplasms because they are the most commonly diagnosed and most frequent causes of cancer death in the United States. Institutional review board approval was waived by Icahn School of Medicine at Mount Sinai.

ClinicalTrials.gov was queried on September 16, 2012, and 227 trials associated with 5011 sites met the criteria for inclusion. The 1-way driving time from each US zip code to the nearest breast, prostate, colorectal, or non–small cell lung cancer trial site was calculated using MapPoint 2013 (Microsoft Corporation). Calculations for each cancer type were performed with each zip code in the contiguous United States as the point of origin and the zip code of the nearest trial site as the destination.

The proportion of patients with metastatic breast, prostate, colorectal, or non–small cell lung cancer residing within x minutes of the nearest trial site was calculated by weighting each origin zip code by the estimated proportion of the total number of people in the United States with metastatic cancer represented within that zip code. Because data regarding the geographic distribution of patients with metastatic disease in the United States are not available, we used cancer-specific mortality data (wonder.cdc.gov) to approximate the number and distribution of patients with metastatic disease because most of these patients die of their illness; cancer-related deaths are uncommon at earlier stages of disease.

Results | We found that 45.6%, 50.2%, 52.2%, and 38.4% of patients with metastatic breast, prostate, colorectal, and non–small cell lung cancer, respectively, would need to drive more than 60 minutes 1 way to access a clinical trial site (Table). The Mountain, West North Central, and West South Central regions were generally associated with the longest travel times (Figure).

Discussion | We found that clinical trials for advanced cancer have poor geographic accessibility for many people in the United States. According to a 2010 Institute of Medicine report, “Sites for clinical trials are frequently selected on the basis of where the investigators are located, as opposed to where the patients are, creating difficulties in patient recruitment.”

There are limitations to our analysis. The minimum travel time that affects the decisions that patients with cancer make about their care is not known. Patients living in metropolitan and rural areas may value travel time differently. We likely underestimated travel time, and many patients will not meet eligibility criteria for the trial that is nearest to them. We also examined the most common cancer types; for rare cancers, trial accessibility is likely worse. We limited our analysis to metastatic cancers. Although

Table. Proportion of US Patients With Metastatic Disease Across Categories of Driving Time to the Nearest Clinical Trial Site

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Patients, No.</th>
<th>Population, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;30 min</td>
<td>30 min to &lt;1 h</td>
</tr>
<tr>
<td>Breast</td>
<td>40 981</td>
<td>24.9</td>
</tr>
<tr>
<td>Prostate</td>
<td>28 699</td>
<td>23.4</td>
</tr>
<tr>
<td>Colorectal</td>
<td>50 641</td>
<td>21.1</td>
</tr>
<tr>
<td>Non–small cell lung</td>
<td>157 183</td>
<td>28.1</td>
</tr>
</tbody>
</table>

*Number and geographic distribution of patients with metastatic disease approximated by using cancer-specific mortality data from wonder.cdc.gov.
travel time is only one aspect of the accessibility of trials, it may be the most important factor for many patients.

Our findings suggest that innovative approaches are needed to improve the geographic accessibility of trials for patients with advanced cancer in the United States.

Matthew D. Galsky, MD
Kristian D. Stensland, MD
Russell B. McBride, PhD
Asma Latif, MD
Erin Moshier, MS
William K. Oh, MD
Juan Wisnivesky, MD, DrPH

Author Affiliations: Division of Hematology/Oncology, Department of Medicine, Tisch Cancer Institute, New York, New York (Galsky, Stensland, Latif, Moshier, Oh); Institute for Translational Epidemiology, Icahn School of Medicine at Mount Sinai, New York, New York (McBride); Divisions of General Internal Medicine and Pulmonary and Critical Care, Department of Medicine, Icahn School of Medicine at Mount Sinai, New York, New York (Wisnivesky).

Corresponding Author: Matthew D. Galsky, MD, Icahn School of Medicine at Mount Sinai, One Gustave Levy Place, New York, NY 10029 (matthew.galsky@mssm.edu).

Published Online: December 1, 2014. doi:10.1001/jamainternmed.2014.6300.

Author Contributions: Dr Galsky had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Galsky, Stensland, McBride, Latif. Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Galsky, Stensland, McBride, Latif, Moshier. Critical revision of the manuscript for important intellectual content: All authors.


Conflict of Interest Disclosures: None reported.

Funding/Support: This study was supported by a Prostate Cancer Foundation Young Investigator Award (Dr Galsky) and a Clinical and Translational Science Award KL2 Faculty Scholars Award (Dr McBride).

Role of the Funder/Sponsor: The funding institutions had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Additional Contributions: We thank Ryan Hendricks, BS, Tisch Cancer Institute, for his assistance in compiling data for the current analysis. Mr Hendricks was not financially compensated.


Rise of Post–Acute Care Facilities as a Discharge Destination of US Hospitalizations

Medicare’s payment reforms in the 1990s significantly affected hospital length of stay and post-acute care (PAC) (eg, skilled nursing or rehabilitation) facility use.1,2 However, few studies describe contemporary length of stay and postdischarge care trends in a nationally representative sample of Medicare and non-Medicare patients. We sought to understand these trends using the National Hospital Discharge Survey (NHDS) from 1996 to 2010.

Methods | The NHDS is a nationally representative annual probability sample of discharges from hospitals in all 50 states.2 We included all hospital discharges of patients 18 years or older, excluding patients transferred to other hospitals, discharges against medical advice, discharges without a destination coded, or hospital lengths of stay more than 31 days (together, <7% of all discharges). We used NHDS definitions for discharge to home or a care facility.

We evaluated trends in discharges to PAC facilities as well as length of stay over the 15-year period, then calculated relative percentage changes for each year, using 1996 rates as a baseline. To account for the aging of the population, all trends were age-adjusted by the US Census population in 2003 (www.census.gov). The derived age-specific estimates for each individual year were weighted to reflect the age distribution in 2003, the midpoint of our analysis. Analyses were conducted using SAS statistical software (version 9.3; SAS Institute Inc) and graphics created in R (R Foundation for Statistical Computing). The study received approval by the Colorado Multiple Institutional Review Board (COMIRB).

Results | The study population included 2.99 million sampled patient discharges, representing approximately 386 million discharges nationally during the 15-year study period. The proportion of hospitalizations resulting in discharges to PAC facilities increased from 9.2% in 1996 to 13.7% in 2010 (a 49.0% relative increase), while the proportion of discharges home decreased from 90.8% to 86.3% (a 5.0% relative decrease) (Figure 1). This corresponds to an absolute increase of 1.67 million discharges to PAC facilities in 2010, or 1.2 million more discharges to PAC facilities in 2010 than if the rate from 1996 had remained the same through 2010, adjusted for changes in the census. The mean length of stay decreased over this time period for patients being discharged to PAC facilities from 8.8 to 7.8 days; the trend for patients discharged home was 4.6 to 4.1 days (Figure 2).

Discussion | Discharges to PAC facilities rose nearly 50% over the 15 years, resulting in 1.2 million more discharges to PAC facilities in 2010 compared with 1996 rates. Concurrently, hospital lengths of stay progressively decreased, particularly for discharges to PAC facilities.

There are several potential explanations for these findings. Medicare’s prospective payment system may have influenced other payers leading to “quicker and sicker” discharges,4 and penalties for 30-day readmissions (currently assessed for readmissions from the community but not from PAC facilities) may have had the unintended consequence of increased...