Re: Has Demand for Clinical Trial Participants Outpaced Supply?

Tam-McDevitt et al. (1) recently queried the National Institutes of Health Web site for all open US trials of breast, lung, or prostate cancers. They excluded trials that involved more than one type of cancer and counted 50% of the accrual goal for trials that also recruited participants from other countries. They found that the number of participants needed to complete these trials represented 58.7%, 15.4%, and 22.7% of the estimated new cases of breast, lung, and prostate cancers, respectively, in the United States for the year 2005. They concluded that for some types of cancers, the demand for trial participants might be outpacing the current supply (1). This suggestion is inaccurate.

Tam-McDevitt et al. may not have accounted for several factors in their study that could potentially inflate the results of their calculations. First, they should have excluded trials that allow concomitant participation in another treatment trial (i.e., supportive care trials, nontherapeutic trials, and surgical trials for primary cancers that do not include a systemic or radiation therapy component). Second, it would be more appropriate to count 50% of the accrual goal only for trials that included both previously treated and untreated patients because patients diagnosed from previous years would also be eligible. Examples of such trials include those for stage IV cancers that allowed newly diagnosed patients as well as patients who were previously diagnosed with earlier stage disease and had relapsed. Third, most trials are designed with a timetable of several years to complete accrual because the time it takes for a trial to be approved varies considerably among institutions (i.e., from several months to more than a year). Even assuming that there is an overwhelmingly great demand for a specific trial, it is generally not possible for a trial (especially a phase III trial) to be completed within 1 year of activation. Consequently, the trial sponsor is unlikely to open another trial that would accrue a similar patient population until the earlier trial is completed. Moreover, two prospective studies that examined clinical trial accruals at both academic and community-based cancer centers reported a lack of trials appropriate for the types and stages of cancer diagnosed in more than 50% of the new patients (2,3).

Hence, we performed a reanalysis using clinical trial information obtained from the National Cancer Institute Web site (4) to ask whether the demand for clinical trial participants has outpaced the supply. We used the same search criteria as Tam-McDevitt et al. but also took into account the additional factors noted above. Estimates of the 2007 incidence rates for specific cancers were obtained from the American Cancer Society (5). Even though we used appropriate Web filters to specifically look for trials that were accruing new patients, a large proportion of the trials were subsequently excluded because they were in fact studies for previously treated patients. We found that the numbers of participants needed for trial completion represent only 32.8%, 5.5%, and 7.0% of the estimates of the numbers of new cases of breast, lung, and prostate cancers, respectively (Table 1).

We therefore conclude that there is a lack of clinical trials for new cancer patients in the United States. The demand for clinical trial participants has clearly not outpaced the supply and is unlikely to do so in the near future.

RONALD S. GO
KATHLEEN A. MEYER

References

Notes
R.S. Go is supported by the Gundersen Lutheran Center for Cancer and Blood Disorders and the Gundersen Lutheran Medical Foundation.

Affiliations of authors: Center for Cancer and Blood Disorders, Gundersen Lutheran Health System, La Crosse, WI.

Correspondence to: Ronald S. Go, MD, Center for Cancer and Blood Disorders, Gundersen Lutheran Health System, Mail Stop: EB02-001, 1900 South Ave, La Crosse, WI 54601 (e-mail: rsgo@gundluth.org).

DOI: 10.1093/jnci/djm001
© The Author 2007. Published by Oxford University Press. All rights reserved. For Permissions, please e-mail: journals.permissions@oxfordjournals.org.

Response
We thank Go et al. for their comments about our study, which has generated active discussions with various organizations since its presentation at the 2006 American Society for Clinical Oncology meeting.

Our finding that the demand for trial participants may be outpacing the supply was based on current estimates that only 5%–10% of all cancer patients participate in clinical trials. We recognize that there are limitations to this study and have discussed

Table 1. Number of patients needed to complete clinical trials relative to American Cancer Society (ACS) 2007 incidence estimates

<table>
<thead>
<tr>
<th>Cancer type</th>
<th>No. of trials in database</th>
<th>No. of trials included</th>
<th>ACS cancer incidence estimate for 2007</th>
<th>Total No. of patients needed for trial accrual (% of ACS 2007 incidence rates)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>200</td>
<td>120</td>
<td>180510</td>
<td>59178 (32.8)</td>
</tr>
<tr>
<td>Lung</td>
<td>247</td>
<td>103</td>
<td>213380</td>
<td>11794 (5.5)</td>
</tr>
<tr>
<td>Prostate</td>
<td>168</td>
<td>52</td>
<td>218890</td>
<td>15264 (7.0)</td>
</tr>
</tbody>
</table>
them in our American Society for Clinical Oncology presentation. Space limitations in the Correspondence section precluded a full discussion of the limitations; we welcome the opportunity to do so here.

First, the use of incidence numbers as a point of comparison is likely to overestimate the percentage of patients needed for the completion of the evaluated trials. Indeed, it was not our intent to include only new patients. We felt it was important to look at all active trials to give a more complete picture of the current clinical trial landscape. Second, even though many of the trials included in our study had an enrollment period that spanned several years, we believe that the number of trial participants needed is still quite daunting based on the current participation rate.

Go et al. suggested that a trial sponsor is unlikely to open another trial that would accrue a similar patient population until the earlier trial is completed. However, given that clinical trials can be sponsored by independent sponsors (i.e., academic centers, government agencies, and pharmaceutical companies), it is possible that concurrent trials will enroll similar population of patients. Hence, our suggestion on the importance of an open dialog among these organizations to discuss potential prioritization of studies as well as other factors such as effective patient enrollment strategies. Indeed, our study results may underestimate the number of patients needed to complete the existing trials because not all currently recruiting trials may have been included in the clinical trials registry we searched and not all trials in the registry specified the recruitment goal (i.e., 12.8% of lung cancer trials, 8.5% of breast cancer trials, and 7.1% prostate cancer trials did not specified number of patients needed).

Go et al. mentioned two studies (1,2) that examined clinical trial accruals at both academic and community-based cancer centers and reported a lack of trials appropriate for the types and stages of cancer diagnosed in more than 50% of new patients. Because not all patients are eligible for the existing trials, this finding actually supports our conclusion that the demand may be outpacing the supply given that only 5%–10% of all cancer patients participate in clinical trials. Go et al. found that 32.8% of new breast cancer patients would be needed to complete the breast cancer trials, which further supports our conclusion that, given the current trial participation rate, the completion of existing trials for some tumor types may be problematic.

As more anti-cancer agents are being developed and tested in clinical trials, it is important to increase the awareness and understanding of clinical trials and to address organization infrastructure issues to ensure adequate patient accrual and the timely completion of clinical trials. Studies designed to address the underrepresented trial participants (such as older cancer patients) will also be needed to help answer pertinent questions.

JENNIFER TAM-McDEVITT
LODOVICO BALDUCCI
ROBERT HAUSER
STUART LICHTMAN

References


Notes

Affiliations of authors: Geriatric Oncology Consortium, Baltimore, MD (JTM, RH); Senior Adult Oncology Program, H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL (LB); Department of Medicine, Memorial Sloan-Kettering Cancer Center, Commack, NY (SL).

Correspondence to: Jennifer Tam-McDevitt, PharmD, PhD, Geriatric Oncology Consortium, 3600 Clipper Mill Rd, Ste 110, Baltimore, MD 21211 (e-mail: jtam@thegoc.org).

DOI: 10.1093/jnci/djm003

© The Author 2007. Published by Oxford University Press. All rights reserved. For Permissions, please e-mail: journals.permissions@oxfordjournals.org.