150PD - Breast cancer-specific survival in >4,600 patients with lymph node-positive (LN+) hormone receptor-positive (HR+) invasive breast cancer (BC) and 21-gene recurrence score® (RS) results in the SEER registries

D. P. Miller (Redwood City, United States of America) M. Roberts (Rockville, United States of America) V. I. Petkov (Rockville, United States of America) S. Shak (Redwood City, United States of America) N. Howlader (Rockville, United States of America) K. Cronin (Rockville, United States of America) L. Penberthy (Rockville, United States of America)

Background
The 21-gene RS assay has been shown to predict BC recurrence and adjuvant chemotherapy benefit in LN+, HR+, HER2-negative BC. We assessed 5-year BC-specific survival (BCSS) in LN+ patients with 21-gene RS results in the SEER registries, a cancer surveillance program that covers 30% of the US population.

Methods
All SEER BC cases diagnosed 2004-2012 were linked to 21-gene assays performed by the Genomic Health Clinical Laboratory. The analysis was restricted to single primary invasive BC, LN+, no distant metastases, HR+ (per SEER), HER2-negative (per RT-PCR). Using the actuarial method in SEER*Stat, BCSS was assessed for those who were diagnosed 2004-2011 with survival follow-up through 2012, by RS category and by number of positive nodes.

Results
The proportion of women with LN+, HR+ BC who had RS results (n = 7695) increased over time between 2004 (0.3%, n = 33) and 2012 (13.8%, n = 2010), and was lower with increasing nodal involvement, from micrometastases only (36.0%, n = 792) to 4+ nodes (2.6%, n = 81) in 2012. BCSS differed significantly by both RS category (log-rank p < 0.001) and number of positive nodes (p < 0.001). Five-year BCSS outcomes for those with RS <18 ranged from 99.4% (95% CI, 97.4%-99.9%) in those with micrometastases to 85.7% (95% CI, 33.4%-97.9%) in those with 4+ nodes. Similar patterns were found for those with RS 18-30 and RS ≥31 (Table).

<table>
<thead>
<tr>
<th># of positive LN N</th>
<th>5-y BCSS (95% CI) N</th>
<th>5-y BCSS (95% CI) N</th>
<th>5-y BCSS (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micromets only</td>
<td>1207 99.4 (97.4-99.9)</td>
<td>732 99.3 (98.2-99.7)</td>
<td>135 84.2 (69.2-92.2)</td>
</tr>
<tr>
<td>1</td>
<td>1084 99.2 (97.2-99.8)</td>
<td>675 96.3 (91.8-98.4)</td>
<td>135 91.3 (79.5-96.4)</td>
</tr>
<tr>
<td>2</td>
<td>300 97.9 (92.7-99.4)</td>
<td>192 96.0 (84.6-99.0)</td>
<td>36 73.2 (20.4-94.1)</td>
</tr>
<tr>
<td>3</td>
<td>103 94.7 (77.4-98.9)</td>
<td>70 94.0 (75.9-98.6)</td>
<td>22 85.4 (51.6-96.3)</td>
</tr>
<tr>
<td>4+</td>
<td>82 85.7 (33.4-97.9)</td>
<td>93 79.5 (58.0-90.8)</td>
<td>31 75.1 (39.2-91.6)</td>
</tr>
</tbody>
</table>
Conclusions
Overall, 5-year BCSS is excellent in patients with RS <18 and few positive nodes and worsens with increasing number of involved lymph nodes and with higher RS. Updated data with longer follow-up is will be presented.

Clinical trial identification
N/A

Legal entity responsible for the study
Dave P. Miller, Megan Roberts, Lynne Penberthy

Funding
National Cancer Institute

Disclosure
D.P. Miller, S. Shak: Employed by Genomic Health; stock ownership in Genomic Health
All other authors have declared no conflicts of interest.