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Purpose: A 2006 National Cancer Institute clinical announcement recommended the use of combined intravenous (IV) and intraperitoneal (IP) chemotherapy over IV chemotherapy alone for women with International Federation of Gynecology and Obstetrics (FIGO) stage 3 optimally debulked ovarian cancer due to significant survival benefit demonstrated in multiple randomized clinical trials. We examined uptake of IP chemotherapy in community practice before and after this recommendation.

Methods: We identified 288 women with FIGO stage 2 or greater incident ovarian cancer diagnosed from 2003 to 2008 at three integrated delivery systems in the US. Administrative health plan data were used to determine patient characteristics and receipt of IV and IP chemotherapy within 12 months of diagnosis. We compared characteristics of women receiving IV chemotherapy alone vs. IP chemotherapy (with or without IV chemotherapy) and assessed temporal trends in IP chemotherapy use.

Results: Overall 12.5% (n = 36) of women received IP chemotherapy during the study period. IP chemotherapy use was non-existent between 2003 and 2005. Use of IP chemotherapy occurred among 26.9% of women diagnosed in 2006 and plateaued at 20.4% of women diagnosed in 2008. IP recipients were younger (mean age 55.9 vs. 63.5 years, p < 0.001) and more likely to have stage 3 ovarian cancer (77.8 vs. 50.4% p = 0.039) compared to their IV-only chemotherapy counterparts.

Conclusion: Use of IP chemotherapy for newly diagnosed advanced stage ovarian cancer patients was uncommon in this community setting. Future research should identify potential patient, physician, and system barriers and facilitators to using IP chemotherapy in this setting.

Keywords: ovarian cancer, chemotherapy, intraperitoneal, diffusion, age, stage

INTRODUCTION
Approximately 22,280 new ovarian cancers were diagnosed in 2012, and an estimated 15,500 women died from the disease (1). While ovarian cancer is uncommon, long-term cure is poor with an overall 5-year survival rate of 43.7% (1). Prior to 2006, women with late-stage ovarian cancer were treated primarily with intravenous (IV) chemotherapy, which generally included a combination of platinum and taxane given every 3 weeks for six courses (2). However, this treatment has resulted in only a 26.9% 5-year survival rate when prognosis is grim (1). The development and testing of new, more effective treatments is currently our best hope of improving ovarian cancer survival.

On January 4, 2006, the National Cancer Institute (NCI) released a clinical announcement that recommended combined IV and intraperitoneal (IP) chemotherapy for women with FIGO stage 3 optimally debulked ovarian cancer (3). The announcement was based on national randomized trial data with 415 women with stage 3 ovarian cancer and <1 cm residual disease (GOG 172). GOG 172 showed a 16-month increase in overall survival for women receiving IP chemotherapy over IV chemotherapy alone (both groups received paclitaxel plus cisplatin) in women with <1 cm residual disease (4). The survival rate represented a marked improvement over previous trials (GOG 104 and 114), which were limited to cisplatin-only IP therapy and showed improvements in overall survival of 8 and
11 months, respectively (5, 6). IP chemotherapy delivers treat-
mant directly into the abdominal cavity and targets the tumor
site much more directly than IV chemotherapy, which is deliv-

ered through the bloodstream. While IP chemotherapy promises
a significant advancement in survival, the side effects are gen-
erally more significant than for IV chemotherapy. Clinical stud-
ies have shown that side effects for IP chemotherapy include
infection, abdominal pain, and bowel damage, all of which may
limit patient tolerability (4, 7). This has limited uptake of IP
chemotherapy, even in academic settings, and created contro-
versy about the generalizability of trial results, particularly in
community settings (i.e., outside of cancer centers) where familiar-
tarity with ovarian cancer and intra-abdominal catheters is more
limited.

The purpose of our study was to examine patterns of IP and
IV chemotherapy treatment in three sites of the Cancer Research
Network (CRN), a consortium of research groups associated with
integrated delivery systems in the United States with over 11 mil-

don enrollees (8). We examined treatment patterns by patient
characteristics and over time to better understand the use of IP
chemotherapy in community practice for women with advanced
ovarian cancer.

MATERIALS AND METHODS
The HMO CRN consists of the research programs, enrollee pop-
ulations, and databases of 14 members of the HMO Research
Network (8). An overall goal of the CRN is to conduct collabora-
tive research to determine the effectiveness of preventive, curative,
and supportive interventions for major cancers that span the nat-
ural history of those cancers among diverse populations and health
systems. The 14 health plans, with nearly 11 million enrollees are
distinguished by their longstanding commitment to prevention
and research, and collaboration among themselves and with affili-
ated academic institutions. This study was conducted in three
sites from the CRN: Group Health (Washington State), Kaiser
Permanente Colorado, and Kaiser Permanente Northwest (Ore-
gon/Southwest Washington). Institutional Review Board oversight
and approval was ceded to Group Health for all sites involved in
this study.

STUDY POPULATION
We identified all women with incident ovarian cancer diagnosed
between January 1, 2003 and December 31, 2008 from each site’s
local Surveillance Epidemiology and End Results (SEER) or tumor
registry (N = 921). We included women with epithelial and other
morphologies of ovarian cancer who had records of IV chemother-
apy and/or IP chemotherapy following diagnosis (N = 381). We
excluded morphologies for myomatous neoplasms (ICD-O-3 code
8890), malignant lymphoma (ICD-O-3 9590 and 9680), sex cord
stromal (ICD-O-3 8590, 8600, 8620, 8621, 8630, 8631, 8640, 8670,
8810), germ cell (ICD-O-3 8240, 8246, 9060, 9064, 9070, 9071,
9072, 9080, 9081, 9084, 9085, 9090, 9100), and follicular and mar-
ginal lymphoma (ICD-O-3 9690) (N = 4). We further excluded
women with FIGO stage I disease (N = 52) and women who
started chemotherapy treatment more than 12 months after their
cancer diagnosis (N = 37). Even though IP chemotherapy is only
recommended for stage 3 ovarian cancers, we included stages 2
and 4 to evaluate whether treatment was administered outside
of guidelines. Most women were treated by oncologists employed
by their health plan (most of whom are medical oncologists, not
gynecologic oncologists). However, women may have received
oncology care outside of the health plan (such as at a cancer
center) based on their insurance coverage and preferences; treat-
mant received outside of the health plans was collected for this
analysis via claims. Our final sample size for analysis was 288
women.

DATA COLLECTION
We obtained data from each site’s virtual data warehouse (VDW),
which has been described in detail elsewhere (9). Briefly, the VDW
includes standardized variables derived from administrative data-
bases at each CRN site. A programmer at Group Health wrote
standardized code to execute at the other sites; programmers then
transferred limited datasets to Group Health for analysis. Using
VDW data, we linked tumor registry data to health plan data on
demographics and enrollment to identify patient characteristics,
including age at diagnosis, race, and ethnicity. We used tumor
registry data to identify ovarian cancer stage at diagnosis and
receipt of surgery. We linked to health plan utilization data to
identify women’s encounters with the health plan within 1 year fol-
lowing diagnosis including ambulatory visits, emergency depart-
ment visits, hospital stays, e-mails with providers, and telephone
visits.

We collected data on chemotherapy administration (including
claims) using validated VDW procedure codes (10–12). Chemotherapy procedure data included healthcare common pro-
cedure coding system (HCPCS) and current procedural termin-
ology (CPT-4) codes. We used CPT-4 code 96445 to identify
the receipt of IP chemotherapy. We explored whether CPT-4
codes 49419 and 49422 (insertion and removal of an IP
catheter) indicated use of IP chemotherapy and decided not
to include these codes because they were not used consis-
tently among women who received IP chemotherapy (based
on CPT-4 code 96445). We used CPT-4 codes 96408-96417 and
HCPCS codes C8953–C8955, G0359–G0361, Q0084, Q0085,
S9330, and S9331 to identify receipt of IV chemotherapy.
For both IP and IV chemotherapy, we collected informa-
tion on the date of first administration and total number of
administrations.

STATISTICAL ANALYSIS
We compared the distribution of patient characteristics, tumor
characteristics, and healthcare utilization between women who
received any IP chemotherapy (with or without IV chemother-
apy) and women who received IV chemotherapy alone. We
used the two-sample Wilcoxon rank-sum test to evaluate dif-
fences in continuous variables (e.g., age) and Fisher’s exact
test to evaluate differences in categorical variables (e.g., stage).
We calculated the cumulative count of first IP and IV proce-
dures separately over time. If a woman had more than one IP
or IV procedure, only the first one of each was counted. All
analyses were descriptive and unadjusted. All statistical analyses
were conducted in SAS software version 9.3 (SAS Institute, Cary,
NC, USA).
Table 1 | Patient characteristics by IP chemotherapy status.

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>IV chemotherapy without IP</th>
<th>IP with or without IV chemotherapy</th>
<th>p-Value comparing IV alone to IP</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>N = 288</td>
<td>N = 252</td>
<td>N = 36</td>
<td></td>
</tr>
<tr>
<td>Age at diagnosis, mean (SD)</td>
<td>62.7 (11.6)</td>
<td>63.7 (11.7)</td>
<td>55.9 (8.2)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Age group at diagnosis, n (%)</td>
<td>N (Column %)</td>
<td>N (Column %)</td>
<td>N (Column %)</td>
<td></td>
</tr>
<tr>
<td>under 40</td>
<td>3 (1.0)</td>
<td>3 (1.2)</td>
<td>0</td>
<td>0.001</td>
</tr>
<tr>
<td>40–9</td>
<td>35 (12.2)</td>
<td>26 (10.3)</td>
<td>9 (26)</td>
<td></td>
</tr>
<tr>
<td>50–59</td>
<td>81 (28.1)</td>
<td>67 (26.6)</td>
<td>14 (38.9)</td>
<td></td>
</tr>
<tr>
<td>60–69</td>
<td>85 (29.5)</td>
<td>73 (29.0)</td>
<td>12 (33.3)</td>
<td></td>
</tr>
<tr>
<td>70–79</td>
<td>61 (21.2)</td>
<td>60 (23.8)</td>
<td>1 (2.8)</td>
<td></td>
</tr>
<tr>
<td>80 And higher</td>
<td>23 (8.0)</td>
<td>23 (9.1)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>White, n (%)</td>
<td>240 (83.3)</td>
<td>207 (82.1)</td>
<td>33 (91.7)</td>
<td>0.48</td>
</tr>
<tr>
<td>FIGO/AJCC stage at diagnosis, n (%)</td>
<td>N (Column %)</td>
<td>N (Column %)</td>
<td>N (Column %)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>24 (8.3)</td>
<td>21 (8.3)</td>
<td>3 (8.3)</td>
<td>0.039</td>
</tr>
<tr>
<td>3</td>
<td>155 (53.8)</td>
<td>127 (50.4)</td>
<td>28 (77.8)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>69 (24.0)</td>
<td>65 (25.8)</td>
<td>4 (11.1)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>40 (13.9)</td>
<td>39 (15.5)</td>
<td>1 (2.8)</td>
<td></td>
</tr>
<tr>
<td>Surgery receipt, n (%)</td>
<td>250 (86.8)</td>
<td>214 (84.9)</td>
<td>36 (100.0)</td>
<td>0.007</td>
</tr>
<tr>
<td>Days from diagnosis to first chemotherapy, mean (SD)</td>
<td>59.0 (56.3)</td>
<td>59.3 (57.2)</td>
<td>56.2 (47.9)</td>
<td>0.75</td>
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<tr>
<td>Days from diagnosis to first chemotherapy, n (%)</td>
<td>N (Column %)</td>
<td>N (Column %)</td>
<td>N (Column %)</td>
<td></td>
</tr>
<tr>
<td>0–30 days</td>
<td>62 (21.5)</td>
<td>57 (22.6)</td>
<td>5 (13.9)</td>
<td>0.42</td>
</tr>
<tr>
<td>31–60 days</td>
<td>127 (44.1)</td>
<td>111 (44.0)</td>
<td>16 (44.4)</td>
<td></td>
</tr>
<tr>
<td>61–90 days</td>
<td>32 (11.1)</td>
<td>31 (12.3)</td>
<td>1 (2.8)</td>
<td></td>
</tr>
<tr>
<td>91–180 days</td>
<td>21 (7.3)</td>
<td>20 (7.9)</td>
<td>1 (2.8)</td>
<td></td>
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<tr>
<td>181–365 days</td>
<td>13 (4.5)</td>
<td>11 (4.4)</td>
<td>2 (5.6)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>33 (11.5)</td>
<td>22 (8.7)</td>
<td>11 (30.6)</td>
<td></td>
</tr>
<tr>
<td>IV chemo administrations, n (%)</td>
<td>N (Column %)</td>
<td>N (Column %)</td>
<td>N (Column %)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>4 (1.4)</td>
<td>0</td>
<td>4 (11.1)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>1–5</td>
<td>47 (16.3)</td>
<td>42 (16.7)</td>
<td>5 (13.9)</td>
<td></td>
</tr>
<tr>
<td>6–10</td>
<td>40 (13.9)</td>
<td>30 (11.9)</td>
<td>10 (27.8)</td>
<td></td>
</tr>
<tr>
<td>11 Or more</td>
<td>197 (68.4)</td>
<td>180 (71.4)</td>
<td>17 (47.2)</td>
<td></td>
</tr>
<tr>
<td>IP Chemo administrations, n (%)</td>
<td>N (Column %)</td>
<td>N (Column %)</td>
<td>N (Column %)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>252 (87.5)</td>
<td>252 (100.0)</td>
<td>0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>1–5</td>
<td>20 (6.9)</td>
<td>0</td>
<td>20 (55.6)</td>
<td></td>
</tr>
<tr>
<td>6–10</td>
<td>11 (3.8)</td>
<td>0</td>
<td>11 (30.6)</td>
<td></td>
</tr>
<tr>
<td>11 Or more</td>
<td>5 (1.7)</td>
<td>0</td>
<td>5 (13.9)</td>
<td></td>
</tr>
<tr>
<td>Encounters within 1 year following diagnosis, mean [minimum, median, maximum]</td>
<td>N (row %)</td>
<td>N (row %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ambulatory visits</td>
<td>30.6 [4, 27, 111]</td>
<td>29.5 [4, 26, 90]</td>
<td>38.0 [12, 36, 111]</td>
<td>0.003</td>
</tr>
<tr>
<td>Emergency department</td>
<td>0.9 [0, 0.17]</td>
<td>0.9 [0, 0.17]</td>
<td>1.0 [0, 0.4]</td>
<td>0.60</td>
</tr>
<tr>
<td>Email encounters</td>
<td>0.5 [0, 0.36]</td>
<td>0.2 [0, 0.15]</td>
<td>2.4 [0, 0.36]</td>
<td>0.0003</td>
</tr>
<tr>
<td>Acute inpatient stay</td>
<td>1.7 [0, 1.8]</td>
<td>1.7 [0, 1.8]</td>
<td>2.1 [1, 2, 5]</td>
<td>0.018</td>
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<tr>
<td>Telephone encounters</td>
<td>12.0 [0, 6.97]</td>
<td>11.4 [0, 6.97]</td>
<td>16.1 [0, 9, 76]</td>
<td>0.38</td>
</tr>
<tr>
<td>Study site, n (%)</td>
<td>N</td>
<td>N (row %)</td>
<td>N (row %)</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>138</td>
<td>121 (87.7)</td>
<td>17 (12.3)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>B</td>
<td>92</td>
<td>88 (95.7)</td>
<td>4 (4.3)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>58</td>
<td>43 (74.1)</td>
<td>15 (25.9)</td>
<td></td>
</tr>
<tr>
<td>Year of diagnosis, n (%)</td>
<td>N</td>
<td>N (row %)</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>2003</td>
<td>39</td>
<td>39 (100.0)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>42</td>
<td>42 (100.0)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>49</td>
<td>48 (98.0)</td>
<td>1 (2.0)</td>
<td></td>
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</tbody>
</table>

(Continued)
Table 1 | Continued

<table>
<thead>
<tr>
<th></th>
<th>All IV chemotherapy</th>
<th>IP with or without IV chemotherapy</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>N = 288</td>
<td>N = 252</td>
</tr>
<tr>
<td>2006</td>
<td>51</td>
<td>37 (72.6)</td>
</tr>
<tr>
<td>2007</td>
<td>53</td>
<td>43 (81.1)</td>
</tr>
<tr>
<td>2008</td>
<td>54</td>
<td>43 (79.6)</td>
</tr>
</tbody>
</table>

IP, intraperitoneal; IV, intravenous; SD, standard deviation; FIGO, International Federation of Gynecology and Obstetrics; AJCC, American Joint Committee on Cancer. P-values for categorical items are from Fisher’s exact test, and those for continuous items are from the Wilcoxon rank-sum test. Frequencies from “unknown” categories do not contribute to statistical tests.

RESULTS

A total of 288 women were identified with FIGO stage 2 or greater incident ovarian cancer between 2003 and 2008. Of these, 36 (12.5%) women received IP chemotherapy with or without IV chemotherapy and 254 (87.5%) received IV chemotherapy only (Table 1). Women who received IP chemotherapy were younger (mean age 55.9 years) than women who received IV chemotherapy alone (mean age 63.5 years, \( p < 0.001 \)). Women who received IP chemotherapy differed in disease stage compared with those who received IV chemotherapy alone \( (p = 0.039) \); a larger percentage of women receiving IP had stage 3 disease (77.8%) than women receiving IV chemotherapy alone (50.4%).

Treatment patterns differed somewhat by group (Table 1). All women who received IP chemotherapy received surgery as their primary therapy; 15.1% of women who received IV chemotherapy did not have surgery. The time to chemotherapy initiation was similar between groups (mean 56.2 days for IP chemotherapy and 59.1 days for IV chemotherapy).

No evidence of IP chemotherapy use was found from 2003 through 2005. Use was first identified in 2006 when IP chemotherapy was received by 27.4% of women in our sample. In 2007, 18.9% of women received IP chemotherapy while 20.4% of women diagnosed in 2008 received IP chemotherapy. Figure 1 illustrates that the use of IP chemotherapy was much less common than IV chemotherapy over time. Treatment differed by study site and year of diagnosis. Among women at each site, 12.3% received IP chemotherapy at site A, 4.3% at site B, and 25.9% at site C.

DISCUSSION

In this study, we examined the use of IP chemotherapy for advanced stage ovarian cancer in a community setting. Our results suggest that despite the 2006 NCI announcement recommending IP chemotherapy as the new standard of care treatment for women with stage 3 optimally debulked tumors, use of IP chemotherapy was uncommon in women insured at three CRN healthcare delivery systems immediately following the announcement. Of the estimated 22,000 new diagnoses in the U.S. in 2012, approximately 60% were likely diagnosed with distant disease and could have been eligible for IP chemotherapy treatment (1). In our community-based patient population, use of IP chemotherapy increased after the clinical guideline recommendation, but plateaued at about 20% of women, with notable differences in receipt of IP chemotherapy by age.

The reasons for differences we observed in IP chemotherapy treatment by age may be related to aggressiveness of care. Younger women may be more willing to tolerate the additional toxicities of IP chemotherapy than older women and their providers may be more likely to recommend this aggressive treatment because of their younger age. Interestingly, while most women who received IP chemotherapy had stage 3 disease, about 20% of women who received IP chemotherapy were stages 2 or 4. This finding suggests that some treatment was received outside of guidelines (13) or that stage was incorrectly or incompletely documented when IP chemotherapy treatment was initiated.

The reasons for low IP chemotherapy use in these community settings are not clear. Providers may be reluctant to offer IP chemotherapy given the potential for toxicity and complexities in administration. Centers may not be adequately trained in IP chemotherapy administration performed in an inpatient setting. The low use is concerning as it suggests women with advanced ovarian cancer potentially eligible for this treatment may not have access to appropriate care or may not be offered IP chemotherapy, for a number of physician or system-related reasons. Alternatively, after additional counseling on and follow-up for side effects, women may refuse IP chemotherapy.
Our study does have limitations. Most notably, we did not collect data on patient, provider or systemic reasons for not using IP chemotherapy. We do not have comprehensive information on the eligibility of these women for IP chemotherapy (including information on residual disease following surgery) or whether they had local access to properly trained surgeons with experience in catheter placement and care or IP chemotherapy administration. We did not collect information on treating physicians and have no way of identifying the small number of patients treated outside of their health plan through the treatment codes we used. The small number of IP users limits our ability to conduct sub- and multi-variable analyses. Between 20 and 40% of women presenting with advanced ovarian cancer will have suboptimal surgical debulking, which would make them ineligible for IP treatment (13). Unfortunately, we were not able to determine this important surgical variable in this study. Finally, we do not have data beyond 2008; thus these results are only generalizable to the period of time immediately following the clinical announcement. Use of IP chemotherapy may have increased since then, and may continue to do so in the future; however, we are unable to examine this in our study.

Despite these limitations, our study has several strengths. To our knowledge, this was the first study to document the diffusion of IP chemotherapy in community-based clinical settings. We were able to conduct this analysis because of our data linkages between procedure data, tumor registry data, and other administrative health plan data using the CRN VDW, a validated source of information regarding community cancer patients. We also had complete and valid data on chemotherapy use from CPT and HCPCS codes, which have been validated in prior studies (10–12) and include any claims for treatment from external treatment centers (such as a cancer center). In addition, our study is a multi-site study, improving generalizability of our results. Finally while other diffusion studies may be influenced by provider reimbursement for treatment, our three study sites employed salaried physicians during the study period and should not have been influenced by reimbursement.

In conclusion, our study shows treatment with IP chemotherapy for women with advanced stage ovarian cancer is uncommon in our three community-based integrated delivery systems. This may be due to system, provider, and/or patient factors. However, the lack of uptake IP chemotherapy use is concerning as ovarian cancer patients may not be receiving therapy that would give them the best chance at survival. Additional research into the barriers and facilitators to IP chemotherapy treatment is needed.

AUTHOR CONTRIBUTIONS
The authors contributed to this manuscript as follows: conception and design of the work (Erin J. Aiello Bowles, Karen J. Wernli, Larissa Nekhlyudov, Elizabeth Trice Loggers); acquisition, analysis, or interpretation of data for the work (Erin J. Aiello Bowles, Karen J. Wernli, Heidi J. Gray, Andy Bogart, Thomas Delate, Maureen O’Keefe-Rosetti, Larissa Nekhlyudov, Elizabeth Trice Loggers); drafting the work or revising it critically for important intellectual content (Erin J. Aiello Bowles, Karen J. Wernli, Heidi J. Gray, Andy Bogart, Thomas Delate, Maureen O’Keefe-Rosetti, Larissa Nekhlyudov, Elizabeth Trice Loggers); final approval of the version to be published (Erin J. Aiello Bowles, Karen J. Wernli, Heidi J. Gray, Andy Bogart, Thomas Delate, Maureen O’Keefe-Rosetti, Larissa Nekhlyudov, Elizabeth Trice Loggers).

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REFERENCES


**Conflict of Interest Statement:** The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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