Women’s Health Initiative Annual Meeting

Chicago, Illinois
May 3-4, 2018
Where did you travel from?

Germany
Overview of the Agenda

• Scientific sessions
  • Today
    • Cancer Keynote—Scarlett Gomez
    • Themed sessions on sleep, physical activity, resilience
    • Science spectrum
  • Tomorrow
    • Genomics Keynote—Jerome Rotter
    • Themed session on CVD

• Ignite and Core/Ancillary Study sessions
  • Brief presentations to catalyze discussions of new research directions
  • Break-out groups will over lunch and tomorrow

• Poster session/happy hour (10th floor)
Active WHI Participants as of March 31, 2018

<table>
<thead>
<tr>
<th>Age on 3/31/2018</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;75</td>
<td>6181</td>
<td>8.7</td>
</tr>
<tr>
<td>75-79</td>
<td>18631</td>
<td>26.3</td>
</tr>
<tr>
<td>80-84</td>
<td>20321</td>
<td>28.7</td>
</tr>
<tr>
<td>85-89</td>
<td>15527</td>
<td>21.9</td>
</tr>
<tr>
<td>90-94</td>
<td>8201</td>
<td>11.6</td>
</tr>
<tr>
<td>95+</td>
<td>1981</td>
<td>2.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian/Alaska Native</td>
<td>237</td>
<td>0.3</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>1512</td>
<td>2.1</td>
</tr>
<tr>
<td>Black/African American</td>
<td>4590</td>
<td>6.5</td>
</tr>
<tr>
<td>Hispanic/Latina</td>
<td>1999</td>
<td>2.8</td>
</tr>
<tr>
<td>White</td>
<td>61686</td>
<td>87.1</td>
</tr>
<tr>
<td>Unknown</td>
<td>818</td>
<td>1.2</td>
</tr>
</tbody>
</table>

Total (N=70,842)
www.whi.org

• Progress reports

• Data documentation
  • Frequency of data collection for each study phase
  • Data dictionary
  • Questionnaires
  • Data Preparation and Use Document Archive

• Query builder

• helpdesk@whi.org
Form 158: Supplemental Questionnaire 2017

As of March 31, 2018, N=57,751 forms returned
(95% of expected)

Data will be released at the end of September, 2018
Pregnancy complications among ever-pregnant women

- Baby 3 weeks early
- Baby weight <5 lb 8 oz
- Baby weight >9 lb 14 oz
- Preeclampsia
- Hypertension
- Gestational diabetes

Percent of Total (N=48,343)
Condition of Mouth and Teeth (Currently and 5 Years Ago)
(Form 155)

Excellent  Very good  Good  Fair  Poor

Current (N=56,458)  5 years ago (N=54,869)
Dental Visits in Past Three Years

- Twice or more per year
- Once or less per year
- As needed
- Never

Percent of Total (N=56,390)
Dental Health

- Ever told had gum disease (Total N=54,655)
- Lost all teeth (Total N=56,322)
Self-report of Memory Becoming Worse by Age (N=55,600)

- No
- Yes but not worried
- Yes and worried

Age at Form 158 Completion

Percent (%)
Cognitive Change Index

Cognitive Change Index (CCI)--a tool used to assess the perception of cognitive decline in memory, executive function, and language domains from both self and informant perspectives.

The 12 memory items from the self-report of the CCI are also used in the Alzheimer’s Disease Neuroimaging Initiative (ADNI) cohort study as a criterion to identify subjects with significant memory concern.

The 12 questions address memory concerns that the subject rates on a scale from 1 to 5 as to whether there has been no change (score of 12) or some degree of change over the past 5 years.

A score ≥ 16 indicates significant memory concern.
Significant Cognitive Change by Age (N=50,655)

Age at Form 158 Completion

Percent (%)

- <75
- 75-79
- 80-84
- 85-89
- 90-94
- 95+

The graph shows the percentage of significant cognitive change by age, with the highest percentage occurring in the 90-94 age group and the lowest in the <75 age group.
Significant Cognitive Change by Race/Ethnicity (N=50,655)

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>70</td>
</tr>
<tr>
<td>Black</td>
<td>70</td>
</tr>
<tr>
<td>Hispanic</td>
<td>70</td>
</tr>
<tr>
<td>American Indian</td>
<td>70</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>80</td>
</tr>
<tr>
<td>Unknown</td>
<td>60</td>
</tr>
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</table>
Individual Components of CCI

Remembering, compared with 5 years ago

- Recall information
- New names and faces
- Recent events
- Conversations a few days later
- Where things are kept
- New information

Percent (%)

Individual Components of CCI

No change | Minimal change | Some change | Clearly noticeable change | Much worse
Individual Components of CCI
Remembering, compared with 5 years ago, cont.

Where I placed objects
What I intended to do
Family and friend names
Without notes and reminders
People who know me would say
Compared to my age group

Percent (%)

No change
Minimal change
Some change
Clearly noticeable change
Much worse
Question 8 was designed to collect the participants birth name for eventual linkage with the US Census

8. Are you willing to provide your full birth name for this purpose?

Yes: N=34,086 (59.0%)
No: N=3,334 (5.8%)
No response: N=20,331 (35.2%)
Willing to Provide Birth Name, Estimated Percent With Name (Total N=57,751)

- Missing and no name: 29%
- Yes and name provided: 49%
- Missing and name provided: 6%
- Yes but no name: [CATEGORY NAME] [PERCENTAGE]
Steering Committee/CCC report

• Coordinating efforts of the large ancillary studies
• Potential protocol modifications to enhance retention
• Outcomes data
  • Considering changes for outcomes collection beginning October 2018
  • Improving outcomes definitions based combining self-report and Medicare data
  • Using Medicare data to initiate outcomes documentation
• Committee structure
  • Review of Scientific Interest Group activities
  • Rotating leadership
  • Refreshing membership
  • Created a Nominations Committee
Thanks to . . .

Karen Margolis, Outcomes Advisory Comm

Robert Brunner, Ancillary Study Comm

Barbara Howard, Publications and Presentations
WHI P&P Committee
Proposals Approved by Year
2010-2018 as of 4/18/18

<table>
<thead>
<tr>
<th>Year</th>
<th>Proposals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>143</td>
</tr>
<tr>
<td>2011</td>
<td>233</td>
</tr>
<tr>
<td>2012</td>
<td>219</td>
</tr>
<tr>
<td>2013</td>
<td>182</td>
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<td>2014</td>
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<td>2015</td>
<td>206</td>
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<tr>
<td>2016</td>
<td>179</td>
</tr>
<tr>
<td>2017</td>
<td>179</td>
</tr>
<tr>
<td>2018</td>
<td>56</td>
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*Approved Proposals (1613)*
Status of Ancillary Study
Funding Submissions with a CCC Workscope,
by Year of Funding Submission*

<table>
<thead>
<tr>
<th>Year</th>
<th>Awarded</th>
<th>Denied</th>
<th>Pending</th>
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<tbody>
<tr>
<td>2010</td>
<td>18</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>9</td>
<td>27</td>
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<tr>
<td>2012</td>
<td>20</td>
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<td>2013</td>
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<td>30</td>
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<tr>
<td>2014</td>
<td>6</td>
<td>33</td>
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<td>2015</td>
<td>20</td>
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<td>2016</td>
<td>7</td>
<td>16</td>
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<td>2017</td>
<td>2</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

% Funded
- 2010: 49%
- 2011: 25%
- 2012: 45%
- 2013: 30%
- 2014: 15%
- 2015: 43%
- 2016: 30%
- 2017: 6%
- 2018: 6%

*Includes resubmissions of the same study.

Feasibility Studies
Awarded WHI Ancillary Studies and BAAs by Institute, for Funding Submissions 2010-2018

*OTHER Includes Foundation, Investigator, and Institutional funds
Awarded WHI Ancillary Studies by Institute, for Funding Submissions 2010-2018 (excluding BAAs and RC and CCC Funded Feasibility Studies)

*OTHER Includes Foundation, Investigator, and Institutional funds
Current Status of Ancillary Study Proposals
By Investigators New to WHI

<table>
<thead>
<tr>
<th>Year</th>
<th># Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>13</td>
</tr>
<tr>
<td>2013</td>
<td>6</td>
</tr>
<tr>
<td>2015</td>
<td>8</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td><strong>27</strong></td>
</tr>
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**# of Awarded Feasibility Studies, by Year Approved by ASC**
## Data release schedule

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Current</th>
<th>Next Release</th>
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<tbody>
<tr>
<td>Investigator Data (whi.org)</td>
<td>February 2017</td>
<td>September 2018</td>
</tr>
<tr>
<td>Medicare in VDE</td>
<td>2014</td>
<td>Summer 2018 (2016 data prep under way)</td>
</tr>
<tr>
<td>dbGAP</td>
<td>December 2017</td>
<td>May 2018</td>
</tr>
<tr>
<td>BioLINCC</td>
<td>July 2017</td>
<td>July 2018</td>
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Virtual Data Enclave usage

- Limits on number of users/institutions imposed by SAS
WHI 2020-2027 renewal planning

• Strong scientific agenda based on
  • Embedded clinical trials
  • Genomic studies
  • Aging/resilience
  • Vascular Dementia
  • Other?

• Strength of the overall resource
• Track record of productivity
• Engagement of new investigators
We miss you . . .