

WHI-MS Publications and Ancillary Studies Committee

Progress Report

September, 2004

WHIMS Paper #2a
WHI Paper #173

Association of Blood Pressure, Hypertension
and Antihypertensive Therapy with Cognition in
Older Women

Writing Group Members:

Chair: Karen Johnson (Memphis)
CCC facilitator: Mark Espeland (CCC)
Primary data analyst: Mark Espeland (CCC)
Other members: Karen Margolis (Minneapolis)
Kamal Masaki (Honolulu)
Charles Mouton (San Antonio)
Ron Prineas (WHI-CFC)
Sylvia Smoller (NYC)

Status:

Manuscript proposal approved by WHI P&P, WHI PO and WHIMS PASC. Group met via conference call in May, June, August and October 2002. Data analyses are complete and the chair has a complete draft in hand. The group plans to review the completed manuscript in early December. Journal submission is planned for the near future. PASC sent a memo to Chair on 7/23/03 requesting an update on publication plans. The chair responded by sending a draft manuscript. The WHIMS PASC approved the draft manuscript after requested revisions were incorporated. The manuscript was reviewed by the WHI P&P/PO on their 2/26/04 call and approved. The Chair submitted the approved manuscript to Hypertension. The manuscript was reviewed and rejected by the journal. **As of 8/04 the Chair plans to submit the manuscript to the Journal of the American Geriatric Society.**

WHIMS Paper #8
WHI Paper #157

Type 2 Diabetes and Change in Cognitive Functioning in WHIMS: The Effects of Diabetic Risk Factors and Treatment for Diabetes and Hypertension

Writing Group Members:

Chair: Mary Haan (Michigan)
CCC facilitator: Patricia Hogan (CCC)
Primary data analyst: Patricia Hogan (CCC)
Other members: Laura Coker (CCC)
Kathleen Hall (Minneapolis)
Judith Ockene (Worcester)
Robert Wallace (Iowa)

Status:

Manuscript proposal and title changed to reflect inclusion of longitudinal data. Proposal approved by WHI P&P, WHI PO and WHIMS PASC. The paper is at the data analyses stage. PASC sent a memo on 7/23/03 to Chair requesting an update on the progress of the paper. The chair contacted the WHIMS CCC facilitator/data analyst to begin the initial analyses. The first round of analyses has been completed and returned to the Chair. The CCC facilitator contacted the Chair via e-mail and is awaiting a reply. **In May, 2004 the PASC discussed changing the focus of this paper to include both arms of the HT study, as well as Dr. Laura Coker assuming the chair's position. Dr. Coker was informed of this discussion.**

WHIMS Paper #9
WHI Paper #138

Baseline Experience with Modified Mini Mental State Exams: The WHI-MS

Writing Group Members:

Chair: Steve Rapp (CCC)
CCC facilitator: Steve Rapp (CCC)
Primary data analyst: Patricia Hogan (CCC)
Other members: Beth Dugan (Neri)
Mark Espeland (CCC)
Bev Jones (CCC)

Status:

Manuscript approved by WHI P&P, WHI PO and WHIMS PASC. Submitted to Aging and Mental Health in June 2002. Revised, resubmitted and accepted in November 2002. **Published 2003.**

WHIMS Paper #11	Training Maintenance in a Low Event Long-Term Clinical Trial (WHIMS)
Writing Group Members:	Chair: Maggie Dailey (CCC) CCC facilitator: Debbie Felton (CCC) Primary data analyst: Patricia Hogan (CCC) Other members:
Status:	Chair currently developing proposal. Proposal submission to WHI P&P, WHI PO and WHIMS PASC after completion. Following proposal approval, paper will be opened to studywide writing group nominations. The proposal has been put on-hold.

WHIMS Paper #31 WHI Paper #161	Reproductive History and Cognitive Function in WHIMS
Writing Group Members:	Chair: Mary Haan (Michigan) CCC facilitator: Kristin Kidd (CCC) Primary data analyst: Patricia Hogan (CCC) Other members: Ruth Freeman (NYC) Susan Hendrix (Detroit) Marcia Stefanick (Stanford)
Status:	Proposal approved by WHI P&P, WHI PO and WHIMS PASC. Data obtained with analyses currently being done at the WHIMS CCC. PASC sent a memo to Chair on 7/23/03 requesting an update on the progress of the paper. The Chair has begun work on preliminary data analyses with the WHIMS CCC data analyst. The Chair was sent an e-mail in early February asking for an update, but no response was received. The Chair was sent a follow-up e-mail in mid-May requesting an update, but no response has been received.

WHIMS Paper #32 WHI Paper #225	Estrogen Plus Progestin and the Incidence of Dementia and Mild Cognitive Impairment in Postmenopausal Women: the WHIMS
Writing Group Members:	Chair: Sally Shumaker (CCC) CCC facilitator: Steve Rapp (CCC) Primary data analyst: Claudine Legault (CCC) Other members: Annlouise Assaf (Pawtucket) Susan Hendrix (Detroit) Rebecca Jackson (Columbus) Bev Jones (CCC) Jane Kotchen (Milwaukee) Judy Ockene (Worcester)

Sylvia Smoller (NYC)
 Leon Thal (EAB)
 Jean W-Wende (Buffalo)
 Bob Wallace (Iowa)

Status: Writing group members met in early December at the WHI Steering Committee meeting in Baltimore, MD to discuss the manuscript proposal. A draft proposal was reviewed by WHI P&P, WHI PO and WHIMS PASC and approved by all. The group met via conference call on 1/9 & 1/16, with another call scheduled for 2/4/03. 2/26/03 draft manuscript submitted to WHI P&P, WHI PO, NIH & Wyeth. 3/10/03 paper resubmitted to WHI & NIH. Paper approved by WHI & NIH. **Submitted to JAMA, publication date 5/28/03.**

WHIMS Paper #33
WHI Paper # 226

The Effect of Estrogen Plus Progestin on Global Cognitive Function in Postmenopausal Women: Results From the WHIMS

Writing Group Members:

Chair: Steve Rapp (CCC)
 CCC facilitator: Maggie Dailey (CCC)
 Primary data analyst: Mark Espeland (CCC)
 Other members: Deb Bowen (WHI-CCC)
 Bob Brunner (Nevada)
 Laura Coker (CCC)
 Margery Gass (Cincinnati)
 Jennifer Hays (Houston)
 Victor Henderson (EAB)
 Karen Johnson (Memphis)
 Dorothy Lane (Stonybrook)
 JoAnn Manson (Boston)
 Sally Shumaker (CCC)
 Marcia Stefanick (Stanford)

Status: Writing group members met in early December at the WHI Steering Committee meeting in Baltimore, MD to discuss the manuscript proposal. A draft proposal was reviewed by WHI P&P, WHI PO and WHIMS PASC and approved by all. The group met via conference call on 1/16 & 1/24/03, with plans to meet on an as-needed basis. 2/26/03 draft manuscript submitted to WHI P&P, WHI PO, NIH & Wyeth. 3/10/03 paper resubmitted to WHI & NIH. Paper approved by WHI & NIH. **Submitted to JAMA, publication date 5/28/03.**

WHIMS Paper #34
WHISCA paper #1
WHI Paper #216

**Effects of Combination Estrogen-Progestin
Hormone Replacement Therapy on Cognition
and Affect: The WHI Study of Cognitive Aging
(WHISCA)**

Writing Group Members:

Chair: Susan Resnick (NIA)
CCC facilitator: Patricia Hogan (CCC)
Primary data analyst: Susan Resnick (NIA)
Other members: Sally Shumaker (CCC)
Stephen Rapp (CCC)
Laura Coker (CCC)
Mark Espeland (CCC)
Pauline Maki (NIA)
Robert Brunner (Nevada)
Iris Granek (Stony Brook)
Judith Ockene (Worcester)

Status:

Manuscript proposal approved by WHISCA P&P, WHIMS PASC, and WHI P&P Committees. Writing committee met via conference call on 4/15/03, 6/6/03 and 6/13/03. Data analyses and draft manuscript completed. The draft manuscript underwent a simultaneous review by the WHISCA P&P/WHIMS PASC/WHI P&P/PO. Based on feedback from these committees, the manuscript was revised and approved. Submitted to the Journal of the American Medical Association (JAMA) for review. The manuscript was rejected by the journal. The writing group plans to meet via conference call to re-examine the manuscript based on the journal's feedback. As of 3/16/04 the group plans to meet via conference call to address JAMA revisions. **As of 8/04 the group will revise the manuscript, but plans to submit to The Journal of Neurology.**

WHIMS Paper #35
WHISCA Paper #3
WHI Paper #237

**The Women's Health Initiative Study of
Cognitive Aging (WHISCA): Rationale,
Objectives, and Description of a Randomized
Clinical Trial of the Effects of Hormone Therapy
on Age-Associated Cognitive Decline**

Writing Group Members:

Chair: Susan Resnick (NIA)
CCC facilitator: Mark Espeland (CCC)
Primary data analyst: Mark Espeland (CCC)
Other members: Deborah Farmer (CCC)
Anita Hege (CCC)
Pauline Maki (NIA)
Stephen Rapp (CCC)
Laura Coker (CCC)

Sally Shumaker (CCC)

Status: Manuscript proposal approved by WHISCA P&P and WHIMS PASC. The WHI P&P has agreed to review the completed manuscript. The completed manuscript was submitted to the WHIMS PASC in April, 2003 and approved. The completed manuscript has been approved by the WHI PO & the WHI P&P. Submitted to the Journal of Clinical Trials on 8/7/03. The manuscript was reviewed and revisions were requested by the journal. As of 6/04 the group plans to revise the manuscript based on the journal's requested revisions. **As of 7/20/04 the manuscript has been accepted by the journal Clinical Trials.**

WHIMS Paper #36 WHISCA Paper #2 WHI Paper #236	Women's Health Initiative Study of Cognitive Aging (WHISCA): Study Design, Implementation, and Data Management
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Writing Group Members:	Chair: Laura Coker (CCC)
	CCC facilitator: Mark Espeland (CCC)
	Primary data analyst: Mark Espeland (CCC)
	Other members: Stephen Rapp (CCC)
	Susan Resnick (NIA)
	Pauline Maki (NIA)
	Anita Hege (CCC)
	Deborah Farmer (CCC)
	Sally Shumaker (CCC)

Status: Manuscript proposal approved by WHISCA P&P and WHIMS PASC. The WHI P&P has agreed to review the completed manuscript. The completed manuscript was submitted to the WHIMS PASC in April, 2003 and approved. The completed manuscript has been approved by the WHI PO & the WHI P&P. Submitted to the journal Clinical Trials on 8/7/03. The manuscript was reviewed and revisions were requested by the journal. As of 6/04 the group plans to revise the manuscript based on the journal's requested revisions. **As of July, 2004 this manuscript was combined with the previous manuscript and is no longer active.**

WHIMS Paper #37
WHI Paper #274

Association Between Self-Reported Alcohol Intake and Changes in Cognition: Results from the WHIMS

Writing Group Members:

Chair: Mark Espeland (CCC)
CCC facilitator: Lin Gu (CCC)
Primary data analyst: Lin Gu (CCC)
Other members: Laura Coker (CCC)
Bob Langer (LaJolla)
Kamal Masaki (Honolulu)
Judy Ockene (Worcester)
Steve Rapp (CCC)
Marcia Stefanick (Stanford)

Manuscript proposal approved by WHIMS PASC, WHI P&P, WHI PO. Opened to studywide writing group nominations, with membership finalized on 8/28/03. Draft manuscript approved by PASC. WHI P&P/PO reviewed the manuscript on their 1/8/04 call and approved it contingent upon requested revisions. The manuscript was submitted to the American Journal of Epidemiology but was returned with requested revisions. The manuscript has been resubmitted. **As of 8/17/04 the journal requested a 3rd round of revisions. These revisions have been completed and the manuscript has been returned to the American Journal of Epidemiology for publication.**

WHIMS Paper #38
WHI Paper #275

Association of Prior Hormone Therapy With Cognition During the WHIMS E+P Clinical Trial

Writing Group Members:

Chair: Mark Espeland (CCC)
CCC facilitator: Patricia Hogan (CCC)
Primary data analyst: Patricia Hogan (CCC)
Other members: David Curb (Honolulu)
Karen Johnson (Memphis)
Judy Ockene (Worcester)
Steve Rapp (CCC)
Sylvia Smoller (NYC)
Marcia Stefanick (Stanford)
Jean W-Wende (Buffalo)

Manuscript proposal approved by WHIMS PASC, WHI P&P, WHI PO. Opened to studywide writing group nominations, with membership finalized on 8/28/03. Analyses are underway. **Currently, the manuscript is on-hold, but plans are to continue.**

WHIMS Paper #39 WHI Paper #276	Social Support and Cognitive Functioning in Post-Menopausal Women
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Writing Group Members:	Chair: Catherine Messina (S-Brook) CCC facilitator: Sally Shumaker (CCC) Primary data analyst: Lin Gu (CCC) Other members: Dorothy Lane (Stony Brook) Manuscript proposal approved by WHIMS PASC and WHI PO. WHI P&P approval pending revision. Will open to studywide writing group nominations once WHI P&P approval has been obtained. As of 8/04 the chair plans to continue with requested revisions.
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WHIMS Paper #40 WHI Paper #283	Baseline Memory Impairment and Hormone Replacement Therapy as Moderators of the Association Between Change in Cognition and Dementia in WHIMS
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Writing Group Members:	Chair: Donald Royall (San Antonio) CCC facilitator: Mark Espeland (CCC) Primary data analyst: Mark Espeland (CCC) Other members: Chris Colenda (Texas A&M) Jennifer Hays (Houston) Judith Ockene (Worcester) Manuscript proposal revised, resubmitted and approved by WHIMS PASC. The WHI P&P/PO approved the proposal on their 10/09/03 conference call. The proposal was opened to WHIMS investigators study-wide for writing group nominations on 11/06/03 and finalized on 12/11/03. The WHIMS CCC provided the Chair with requested data in mid-January, 2004. Currently, primary analyses are being conducted by Dr. Royall's group.
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WHIMS paper #41 WHI Paper #299	Association Between Hypertension and Change in Cognitive Function in Postmenopausal Women: Results from the WHIMS
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Writing Group Members:	Chair: Karen Margolis (Minneapolis) CCC facilitator: Mark Espeland (CCC) Primary data analyst: Mark Espeland (CCC) Other members: Karen Johnson (Memphis) Manuscript proposal reviewed by WHIMS PASC. Approval is contingent upon requested revisions. Once revised, submission to WHI P&P/PO will follow. Pending their approval, the proposal will be opened to WHIMS investigators study-wide for writing group nominations. As of 8/04 the Chair plans to continue with the proposal.
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WHIMS Paper #42 WHISCA Paper #4 WHI Paper #	Association of Alcohol Intake With Cognition During the Women’s Health Initiative Study of Cognitive Aging (WHISCA) Estrogen/Progestin Clinical Trial
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Writing Group Members:	Chair: Mark Espeland (CCC) CCC facilitator: Primary data analyst: Other members:
Status:	Manuscript proposal approved by WHIMS PASC on 2/23/04. Reviewed by WHI P&P on their 3/11/04 conference call with revisions requested. The manuscript proposal was revised and will be resubmitted to the WHI P&P.

WHIMS Paper #43 WHI Paper #336	Conjugated Equine Estrogen Alone, Pooled Hormone Therapy, and Incidence of Probable Dementia and Mild Cognitive Impairment in Postmenopausal Women: Results from the WHIMS
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Writing Group Members:	Chair: Sally Shumaker (CCC) CCC facilitator: Steve Rapp (CCC) Primary data analyst: Claudine Legault (CCC) Other members: Laura Coker (CCC) Howard Fillit (EAB) Susan Hendrix (Detroit) Lew Kuller (Pittsburgh) Dorothy Lane (S-brook) Beth Lewis (B-ham) Kamal Masaki (Honolulu) Marcia Stefanick (Stanford)
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Status:

Leon Thal (EAB)

Manuscript proposal reviewed by the WHIMS PASC on their 3/16/04 conference call and approved. The WHI P&P conducted an expedited review of the proposal on their 3/26/04 conference call and requested revisions. A draft manuscript was reviewed by the WHI P&P & PO on their 4/22/04 conference call and revisions were requested. The PASC review was completed on 4/26/04 and approval was given contingent upon revisions. As of 4/27/04 revisions are complete and the revised version has gone back to the WHI P&P/PO for a final review prior to journal submission. As of 5/4/04 the WHI P&P/PO approved the revised manuscript. The manuscript was submitted to JAMA and requested revisions were completed and returned with a final approval on 6/7/04. **The manuscript was published in JAMA on 6/23/04.**

**WHIMS Paper #44
WHI Paper #332**

**Effect of Conjugated Equine Estrogens on
Global Cognitive Function in Postmenopausal
Women: Results from the WHIMS**

Writing Group Members:

- Chair: Steve Rapp (CCC)
- CCC facilitator: Mark Espeland (CCC)
- Primary data analyst: Patricia Hogan (CCC)
- Other members: Sally Shumaker (CCC)
- Maggie Dailey (CCC)
- Bob Brunner (Nevada)
- Ruth Freeman (NYC)
- Jennifer Hays (Houston)
- Judy Hsia (GWU)
- JoAnn Manson (Boston)
- Karen Margolis (Minneapolis)
- Barbara Sherwin (EAB)
- Bob Wallace (Iowa)

Status:

Manuscript proposal approved by WHIMS PASC on 3/16/04. The WHI P&P conducted an expedited review on their 3/26/04 conference call and requested revisions. A draft manuscript was reviewed by the WHI P&P & PO on their 4/22/04 conference call and revisions were requested. The PASC review was completed on 4/26/04 and approval was given contingent upon revisions. As of 4/27/04 revisions are complete and the revised version has gone back to the WHI P&P/PO for a final review prior to journal submission. As of 5/4/04 the WHI P&P/PO approved the revised manuscript. The manuscript was submitted to JAMA and requested

revisions were completed and returned with a final approval on 6/7/04. **The manuscript was published in JAMA on 6/23/04.**

WHIMS Paper #45 WHI Paper #	Is There an Association Between Macronutrient Intake and Changes in Cognition? Results from the WHIMS		
Writing Group Members:	Chair:	Mara Vitolins	(W-S)
	CCC facilitator:	Mark Espeland	(CCC)
	Primary data analyst:	Mark Espeland	(CCC)
	Other members:	Cyndi Thompson	(Tucson)
Status:	Draft proposal reviewed by WHIMS PASC (3/15/04 review deadline). Revisions were requested. Contingent upon revisions, proposal will be sent to the WHI P&P/PO for review and approval. Once approved the manuscript will be opened to studywide writing group nominations.		

WHIMS Paper #46 WHI Paper #360	Obesity and Risk of Dementia in Postmenopausal Women		
Writing Group Members:	Chair:	Diana Kerwin	(Milwaukee)
	CCC facilitator:	Sarah Gaussoin	(CCC)
	Primary data analyst:	Sarah Gaussoin	(CCC)
	Other members:	Mark Espeland	(CCC)
		Raymond Hoffmann	(Milwaukee)
		Jane Kotchen	(Milwaukee)
Status:	Draft proposal reviewed by PASC and approved. The proposal was reviewed by the WHI P&P/PO on their 6/24/04 call and approved contingent upon requested revisions. Once requested revisions have been incorporated, the manuscript will be opened to studywide writing group nominations.		

WHIMS Paper #47 WHI Paper #	Predictors of Incident Dementia in a Cohort of Women Aged 65-80		
Writing Group Members:	Chair:	Laura Coker	(CCC)
	CCC facilitator:	Claudine Legault	(CCC)
	Primary data analyst:	Claudine Legault	(CCC)
	Other members:	Chris Colenda	(EAB)
		Nancy Greep	(Irvine)
		Marian Limacher	(G-ville)
		Anne Murray	(Minneap)
		Monique Rainford	(MedStar)
		Mara Vitolins	(W-S)
		Bob Wallace	(Iowa)

Status: **The Chair has been given the writing group members' contact information. The members (in bold) will be asked to assist the Chair in developing a proposal.**

WHIMS Paper #48 WHI Paper#	Performance of a Longitudinal Screening Program to Identify All-Cause Dementia: Results from WHIMS
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Writing Group Members:	Chair:	Mark Espeland	(CCC)
	CCC facilitator:	Mark Espeland	(CCC)
	Primary data analyst:	Mark Espeland	(CCC)
	Other members:	Marilyn Albert	(EAB)
		Tammie Bassford	(Tucson)
		Iris Granek	(S-Brook)
		Carol Murphy	(C-Hill)
		Steve Rapp	(CCC)

Status: **The writing group met via conference call to develop a proposal. The proposal was reviewed by the WHIMS PASC and approved. Currently, the proposal is under review by the WHI P&P/PO. Once approved, writing group membership will be opened to study-wide writing group nomination.**

WHIMS Paper #49 WHI Paper #	Using Artificial Neural Networks to Assess Risks and Benefits for the Individual Postmenopausal Woman
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Writing Group Members:	Chair:	Eva Hogervorst	(Oxford)
	CCC facilitator:	Mark Espeland	(CCC)
	Primary data analyst:	Mark Espeland	(CCC)
	Other members:	Stephan Bandelow	(Oxford)
		Susan Resnick	(NIA)
		Bob Wallace	(Iowa)

Status: **The manuscript topic was approved by PASC in June, 2004. Currently, the manuscript proposal is under review by PASC. Once approved and contingent upon revisions, the manuscript will be sent to the WHI P&P/PO for their review. Upon final approval, the manuscript will be opened to study-wide writing group nomination.**