Biomarker-calibrated estimates for dietary intake for Women's Health Initiative (WHI) analyses – When and How to Apply

When to apply

Calibrate dietary intakes of energy (kcal/day), protein (g/day), protein density (% energy from protein), sodium, or potassium assessed by the WHI Food Frequency Questionnaire (FFQ) in WHI analyses when one or more of these nutrients (or nutrient densities) is a primary exposure. This applies to Clinical Trial (CT) or Observational Study (OS) participants.

How to Apply

Considerations for the WHI Trial or OS components

- Dietary Modification Trial Year 1 or follow-up years. Follow the foundational guidelines from the Nutritional Biomarkers Study (NBS) biomarker analyses [1] or the Nutrition and Physical Activity Assessment Study (NPAAS) [2] depending on dietary assessment instrument of interest (FFQ, 4-day food record [4DFR] or 24hour dietary recall [24HR]) and nutrient of interest (energy, protein, protein density [1,2], or sodium, potassium. [3] Use DM Trial Year 1 as the starting point for analyses. Do not use baseline data due to the truncated mean and resultant upwardly biased mean due to the WHI DM Trial exclusion criterion of FFQ-reporting <32% energy from fat. [4] Exclude outcomes of interest prior to year 1. Covariates from year 1 are preferable to baseline if available.
- Observational Study Baseline or year 3. Follow the foundational guidelines from the Nutrition and Physical Activity Assessment Study (NPAAS) biomarker analyses for the Food Frequency Questionnaire (FFQ) for energy, protein, protein density[2], or sodium, potassium. [3]
- Baseline Hormone Trial. Follow the foundational guidelines that best align with the study sample of interest. Either the NBS or NPAAS foundational references may be used. The Hormone Trial participants completed an FFQ at baseline.

NBS and NPAAS Data Access

- The NBS and/or NPAAS data are needed to compute calibrated the calibrated estimates of dietary intakes assessed by FFQ. It is incorrect to use published estimates. See methods for guidelines.
- The NBS and NPAAS data are available from the WHI website study pages (W8 for NBS, AS 218 for NPAAS) **after investigators have met the following criteria**: (1) lead author of an approved paper proposal using biomarker-calibrated data, (2) signed current Data Use Agreement (DUA), (3) having requested WHI investigator data set access and receiving a login, and (4) for WHI ancillary studies, having returned study data to the WHI.
- The NBS and NPAAS data dictionaries are available from the WHI website study pages without needing a login. (W8 for NBS, AS 218 for NPAAS)

Methods

1. Develop the calibration equations. For the FFQ, refer to the details presented in the appendix from Neuhouser et al. [1] The paper describes the basic participant characteristics to include in the regression calibration

estimator. Each analysis needs to consider participant characteristics as well as parameters specific to the outcome of interest. The following list is suggested:

a. Subject characteristics as described in Neuhouser et al. [1] for the DM Trial, Prentice et al. [2] for the OS, Huang et al. for sodium and potassium. [3]
b. Covariates and confounders pertinent to the outcome of interest

Biomarker calibration equations are unique to the analyses of interest, which in combination with the necessary bootstrapping to compute estimated standard errors, precludes computation and posting of a "standard" set of calibrated intake or activity estimates.

After developing the calibration equations, regress the covariates or confounders on the intake biomarkers as described in the relevant papers listed above. Determine which covariates and confounders to retain based on *a priori* selection or statistical significance (per investigator decision).

2. Consider how to address possible outliers, e.g., values from the dietary assessment instruments falling outside the interquartile range by more than 3 times its width may be excluded as outliers. [2] The exact handling may vary depending on analysis of interest per investigator discretion.

3. Estimate biomarker-calibrated intakes for the analytic cohort by applying the regression calibration equations to the WHI sample pertinent to the analytic aim. If NBS or NPAAS participants are among the sample, then either the direct biomarkers may be used or the calibration equations may be applied.

4. Conduct the outcome analysis, e.g., Cox proportional hazards model.
   a. Estimate the standard errors and significance levels (i.e. p-values) for all estimated parameters using bootstrap procedures. Sample bootstrapping r code is posted to the study pages (W8 for NBS, AS 218 for NPAAS).

5. For nutrient biomarker analyses, use models of an increased percentage of nutrient of interest, e.g., 20% increased energy. Several examples have been published. [5-17] A list of publications from 2008-2015 is presented in the Appendix. Search the WHI Bibliography (https://www.whi.org/papers) as papers are added upon publication.

6. Evolving methodology: The methodology of the biomarker calibration equations is dynamic and evolving. These guidelines reflect current thinking. The foundational references provide details relative to their time of publication, and thus analyses conducted today may not exactly replicate earlier work.

Special Considerations

1. Body mass index (BMI). When examining the associations of biomarker-calibrated estimates of energy intake on disease risk, including BMI in the outcomes model may over-adjust for BMI. The reason, and assumption, being that BMI is the result of an energy over-balance, and thus the biomarker-calibrated energy intake estimate is the sufficient parameter to include in the analytic model. Further including BMI may over-adjust the model. However, additional or alternate effects of BMI on the disease of interest– in addition to long-term energy intake surplus– may exist and thus not including BMI may under-adjust the model. Investigators are encouraged to analyze the models both with and without BMI. Further discussion of this important concept may be found in the work of Prentice and Huang [18] and Zheng and colleagues. [19]

2. Combining OS and DM Trial data for FFQ analyses. The NBS and NPAAS data may be combined when computing dietary intake biomarker calibration equations.

3. Cubic spline analyses. Calibrated intake estimates themselves incorporate quite a lot of 'noise', precluding them to be used directly to study dose response shape using complex models, like cubic splines. This is why we have confined our analyses to linear HR models for log-transformed intake under which ordinary regression estimates based on calibrated intake is appropriate (under normality of log transformed intakes). Statistical methods are not available for handling a (large) noise component of the calibrated intakes under more complex HR models.

4. Calibrating covariate exposures. In general, calibrating covariates is not recommended. An exception is if the covariate is a major risk factor for the disease outcome, e.g., sodium as a covariate with hypertension or CVD as the outcome. In this example, calibrating sodium is recommended.

5. Dietary Quality Indices. Nutrients within dietary quality indices, such as the Healthy Eating Index (HEI), Alternative Healthy Eating Index (AHEI), Dietary Approaches to Stop Hypertension (DASH), Alternative Mediterranean Index (aMed), etc., should not be calibrated. Analyses and papers are underway to investigate the possibility of calibrating dietary quality indices.

References

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Appendix
PUBLICATIONS LIST 2008-2015
R01 CA119171, Nutrition and Physical Activity Assessment Study (NPAAS)
Search the WHI publications list for newer publications

2008

Neuhouser ML, Tinker L, Shaw PA, Schoeller DA, Bingham SA, Van Horn L, Beresford SAA, Caan B, Thomson C, Satterfield S, Kuller L, Heiss G, Smit E, Sarto GE, Ockene J, Stefanick ML, Assaf A, Runswick S, Prentice RL. Use of recovery biomarkers to calibrate nutrient consumption self-reports in the Women's Health Initiative. Am J Epidemiol 2008;167:1247-1259. [Exempt from PMC requirements; manuscript accepted before 4/7/08]

2009

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Prentice RL, Shaw PA, Bingham SA, Beresford SA, Caan B, Neuhouser ML, Patterson RE, Stefanick ML, Satterfield S, Thomson CA, Snetselaar L, Thomas A, Tinker LF. Biomarker-calibrated energy and protein consumption and increased cancer risk among postmenopausal women. Am J Epidemiol 2009;169(8):977-989. [PMCID: PMC2732977]

2010

Beasley JM, LaCroix AZ, Neuhouser ML, Huang Y, Tinker L, Woods N, Michael Y, Curb JD, Prentice RL. Protein intake and incident frailty in the Women's Health Initiative Observational Study. J Am Geriatr Soc 2010;58(6):1063-1071. [PMCID: PMC2924946]

Prentice RL. Dietary assessment and the reliability of nutritional epidemiology research reports. J Natl Cancer Inst 2010;102(9):583-585. [PMCID: PMC2864292]

Prentice RL. Chronic disease prevention research methods and their reliability, with illustrations from the Women's Health Initiative. JASA 2010;105:1431-1443. [Exempt from PMC requirement; not peer-reviewed]

2011

Beasley JM, Aragaki AK, LaCroix AZ, Neuhouser ML, Tinker LF, Cauley JA, Ensrud KE, Jackson RP, Prentice RL. Higher biomarker-calibrated protein intake is not associated with impaired renal function in postmenopausal women. J Nutr 2011;141(8):1502-1507. [PMCID: PMC3138641]

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2012

Shaw PA, Prentice RL. Hazard ratio estimation for biomarker-calibrated dietary exposures. Biometrics 2012;68(2):397-407. [PMCID: PMC3648661]

2013

Beasley JM, Wertheim BC, LaCroix AZ, Prentice RL, Neuhouser ML, Tinker LF, Kritchevsky S, Shikany JM, Eaton C, Chen Z, Thomson CA. Biomarker-calibrated protein intake and physical function in the Women's Health Initiative. J Am Gerontol Soc 2013;61(11):1863-1867. [PMCID: PMC3928025]

Mossavar-Rahmani Y, Tinker LF, Huang Y, Neuhouser ML, McCann SE, Seguin RA, Vitolins MZ, Curb JD, Prentice RL. Factors relating eating style, social desirability, body image and eating meals at home increase the precision of calibration equations correcting self-report measures of the diet using recovery biomarkers: findings from the Women's Health Initiative. Nutr 2013;12:63. [PMCID: PMC3658913]

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2014

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