

**SUPPLEMENTAL MATERIAL**

**Comparison of Medicare Claims vs. Physician Adjudication for Identifying Stroke Outcomes in the Women's Health Initiative**

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## **Supplemental Methods**

### **Ascertainment of stroke events in the WHI – Requesting Medical Records**

The WHI process uses self-report via annual questionnaires completed by participants (or their proxies) who are asked if they were hospitalized overnight since their last report. If a hospitalization was reported, further details including hospital name, hospitalization dates and reasons for hospitalization were asked. Stroke or TIA diagnosis and other cardiovascular outcomes were specifically queried for in the list of hospitalization reasons. Women reporting hospitalization for serious events such as stroke, myocardial infarction (MI) or venous thromboembolism were then asked to provide signed releases to obtain medical records. In addition, medical records were obtained for less specific reasons for hospitalizations to confirm that outcomes monitored in WHI were not missed. One exception was that no records were requested if the reported reason for hospitalization suggested low likelihood of WHI outcome, e.g. bunionectomy. All records were reviewed by disease specific panels of expert adjudicators who used agreed upon criteria and panels cross-referred to a second committee if they noticed signs of another outcome (e.g. the MI panel would refer MI cases to the stroke committee if the medical records supported a stroke diagnosis). Failure to report a hospitalization (e.g. lack of recall by participant or proxy, significant disability, death) resulted in medical records not being requested. The WHI did however incorporate additional processes to ascertain fatal strokes (e.g. matching to the National Death Index records) and when found hospital records were requested and adjudicated.

## ONLINE TABLES

**Table I.** Person-based comparison of the performance of the different Medicare stroke definition algorithms vs. physician adjudicated WHI stroke events in the training data set. This analysis uses a 30 day match window. \*

|   | Total | WHI Yes<br>CMS Yes | WHI No<br>CMS Yes | WHI Yes<br>CMS No | WHI No<br>CMS No | SN   | SP    | PPV  | NPV  | Kappa |
|---|-------|--------------------|-------------------|-------------------|------------------|------|-------|------|------|-------|
| <b>Stroke (any diagnosis code; definition 1)</b>  |       |                    |                   |                   |                  |      |       |      |      |       |
| All   | 24428 | 505                | 240               | 77                | 23606            | 86.8 | 99.0  | 67.8 | 99.7 | 0.75  |
| WHI Hospitalization reported <sup>1</sup>         | 24309 | 505                | 125               | 73                | 23606            | 87.4 | 99.5  | 80.2 | 99.7 | 0.83  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 24249 | 505                | 65                | 73                | 23606            | 87.4 | 99.7  | 88.6 | 99.7 | 0.88  |
| <b>Stroke (principal diagnosis; definition 2)</b> |       |                    |                   |                   |                  |      |       |      |      |       |
| All   | 24428 | 458                | 182               | 124               | 23664            | 78.7 | 99.2  | 71.6 | 99.5 | 0.74  |
| WHI Hospitalization reported <sup>1</sup>         | 24337 | 458                | 95                | 120               | 23664            | 79.2 | 99.6  | 82.8 | 99.5 | 0.81  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 24299 | 458                | 57                | 120               | 23664            | 79.2 | 99.8  | 88.9 | 99.5 | 0.83  |
| <b>Hemorrhagic Stroke (definition 3)</b>          |       |                    |                   |                   |                  |      |       |      |      |       |
| All   | 24428 | 85                 | 42                | 24                | 24277            | 78.0 | 99.8  | 66.9 | 99.9 | 0.72  |
| WHI Hospitalization reported <sup>1</sup>         | 24409 | 85                 | 23                | 24                | 24277            | 78.0 | 99.9  | 78.7 | 99.9 | 0.78  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 24394 | 85                 | 8                 | 24                | 24277            | 78.0 | >99.9 | 91.4 | 99.9 | 0.84  |
| <b>Ischemic Stroke (definition 4)</b>             |       |                    |                   |                   |                  |      |       |      |      |       |
| All   | 24428 | 388                | 233               | 65                | 23742            | 85.7 | 99.0  | 62.5 | 99.7 | 0.72  |
| WHI Hospitalization reported <sup>1</sup>         | 24323 | 388                | 132               | 61                | 23742            | 86.4 | 99.4  | 74.6 | 99.7 | 0.80  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 24276 | 388                | 85                | 61                | 23742            | 86.4 | 99.6  | 82.0 | 99.7 | 0.84  |

Abbreviations: CMS, Centers for Medicare & Medicaid Services data, i.e., Medicare data; NPV, negative predictive value; PPV, positive predictive value; SN, Sensitivity; SP, Specificity; WHI, Women’s Health Initiative data.

<sup>1</sup> Excludes strokes in the outpatient setting only. Also, excludes events for which no WHI hospitalization was reported by the participant or a proxy with admission date within +/-30 days of the Medicare hospitalization.

<sup>2</sup> Excludes events for which no medical records were received due to administrative reasons (e.g., no record release or no documents) or when reasons reported for hospitalization did not trigger adjudication (e.g. bunionectomy). \*Analysis based on a nationwide dataset.

**TABLE II.** Event Level Analysis of Test Data Set. Comparison of the Performance of Different Medicare Stroke Definition Algorithms vs. Physician Adjudicated WHI Stroke Events Using a 7-day Match Window.\*

|   | Total N | WHI Yes CMS Yes | WHI No CMS Yes | WHI Yes CMS No | WHI No CMS No | SN   | SP    | PPV  | NPV  | Kappa |
|---|---------|-----------------|----------------|----------------|---------------|------|-------|------|------|-------|
| <b>Stroke (any diagnosis code; definition 1)</b>  |         |                 |                |                |               |      |       |      |      |       |
| All   | 32263   | 478             | 352            | 114            | 30319         | 80.7 | 98.9  | 57.6 | 99.6 | 0.67  |
| WHI Hospitalization reported <sup>1</sup>         | 31050   | 478             | 148            | 105            | 30319         | 82.0 | 99.5  | 76.4 | 99.7 | 0.79  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 30989   | 478             | 87             | 105            | 30319         | 82.0 | 99.7  | 84.6 | 99.7 | 0.83  |
| <b>Stroke (principal diagnosis; definition 2)</b> |         |                 |                |                |               |      |       |      |      |       |
| All   | 31302   | 439             | 255            | 153            | 30455         | 74.2 | 99.2  | 63.3 | 99.5 | 0.68  |
| WHI Hospitalization reported <sup>1</sup>         | 31139   | 439             | 101            | 144            | 30455         | 75.3 | 99.7  | 81.3 | 99.5 | 0.78  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 31102   | 439             | 63             | 144            | 30455         | 75.3 | 99.8  | 87.5 | 99.5 | 0.81  |
| <b>Hemorrhagic Stroke (definition 3)</b>          |         |                 |                |                |               |      |       |      |      |       |
| All   | 31173   | 70              | 57             | 23             | 31023         | 75.3 | 99.8  | 55.1 | 99.9 | 0.64  |
| WHI Hospitalization reported <sup>1</sup>         | 31143   | 70              | 27             | 23             | 31023         | 75.3 | 99.9  | 72.2 | 99.9 | 0.74  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 31129   | 70              | 13             | 23             | 31023         | 75.3 | >99.9 | 84.3 | 99.9 | 0.79  |
| <b>Ischemic Stroke (definition 4)</b>             |         |                 |                |                |               |      |       |      |      |       |
| All   | 31241   | 383             | 320            | 92             | 30446         | 80.6 | 99.0  | 54.5 | 99.7 | 0.64  |
| WHI Hospitalization reported <sup>1</sup>         | 31058   | 383             | 146            | 83             | 30446         | 82.2 | 99.5  | 72.4 | 99.7 | 0.77  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 31011   | 383             | 99             | 83             | 30446         | 82.2 | 99.7  | 79.5 | 99.7 | 0.81  |

Abbreviations: CMS, Centers for Medicare & Medicaid Services data, i.e., Medicare data; NPV, negative predictive value; PPV, positive predictive value; SN, Sensitivity; SP, Specificity; WHI, Women’s Health Initiative data.

<sup>1</sup> Excludes strokes in the outpatient setting. Also, excludes events for which no WHI hospitalization was reported by the participant or a proxy with admission date within +/-7 days of the Medicare hospitalization.

<sup>2</sup> Excludes events for which no medical records were received due to administrative reasons (e.g., no record release or no documents) or when reasons reported for hospitalization did not trigger adjudication (e.g. bunionectomy).

\*Analysis based on a nationwide dataset.

**TABLE III.** Person Level Analysis of Test Data Set. Comparison of the Performance of Different Medicare Stroke Definition Algorithms vs. Physician Adjudicated WHI Stroke Events Using a 7-day Match Window. \*

|   | Total N | WHI Yes CMS Yes | WHI No CMS Yes | WHI Yes CMS No | WHI No CMS No | SN   | SP    | PPV  | NPV  | Kappa |
|---|---------|-----------------|----------------|----------------|---------------|------|-------|------|------|-------|
| <b>Stroke (any diagnosis code; definition 1)</b>  |         |                 |                |                |               |      |       |      |      |       |
| All   | 24422   | 513             | 277            | 79             | 23553         | 86.7 | 98.8  | 64.9 | 99.7 | 0.74  |
| WHI Hospitalization reported <sup>1</sup>         | 24261   | 513             | 125            | 70             | 23553         | 88.0 | 99.5  | 80.4 | 99.7 | 0.84  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 24209   | 513             | 73             | 70             | 23553         | 88.0 | 99.7  | 87.5 | 99.7 | 0.87  |
| <b>Stroke (principal diagnosis; definition 2)</b> |         |                 |                |                |               |      |       |      |      |       |
| All   | 24422   | 472             | 205            | 120            | 23625         | 79.7 | 99.1  | 69.7 | 99.5 | 0.74  |
| WHI Hospitalization reported <sup>1</sup>         | 24295   | 472             | 87             | 111            | 23625         | 81.0 | 99.6  | 84.4 | 99.5 | 0.82  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 24263   | 472             | 55             | 111            | 23625         | 81.0 | 99.8  | 89.6 | 99.5 | 0.85  |
| <b>Hemorrhagic Stroke (definition 3)</b>          |         |                 |                |                |               |      |       |      |      |       |
| All   | 24422   | 75              | 48             | 18             | 24281         | 80.6 | 99.8  | 61.0 | 99.9 | 0.69  |
| WHI Hospitalization reported <sup>1</sup>         | 24397   | 75              | 23             | 18             | 24281         | 80.6 | 99.9  | 76.5 | 99.9 | 0.78  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 24385   | 75              | 11             | 18             | 24281         | 80.6 | >99.9 | 87.2 | 99.9 | 0.84  |
| <b>Ischemic Stroke (definition 4)</b>             |         |                 |                |                |               |      |       |      |      |       |
| All   | 24422   | 412             | 256            | 63             | 23691         | 86.7 | 98.9  | 61.7 | 99.7 | 0.71  |
| WHI Hospitalization reported <sup>1</sup>         | 24284   | 412             | 127            | 54             | 23691         | 88.4 | 99.5  | 76.4 | 99.8 | 0.82  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 24243   | 412             | 86             | 54             | 23691         | 88.4 | 99.6  | 82.7 | 99.8 | 0.85  |

Abbreviations: CMS, Centers for Medicare & Medicaid Services data, i.e., Medicare data; NPV, negative predictive value; PPV, positive predictive value; SN, Sensitivity; SP, Specificity; WHI, Women’s Health Initiative data.

<sup>1</sup> Excludes strokes in the outpatient setting. Also, excludes events for which no WHI hospitalization was reported by the participant or a proxy with admission date within +/-7 days of the Medicare hospitalization.

<sup>2</sup> Excludes events for which no medical records were received due to administrative reasons (e.g., no record release or no documents) or when reasons reported for hospitalization did not trigger adjudication (e.g. bunionectomy). \*Analysis based on a nationwide dataset.

. **TABLE IV.** Person-based comparison of the performance of the different Medicare stroke definition algorithms vs. physician adjudicated WHI stroke events in the test data set. This analysis uses a 30 day match window. \*

|   | Total N | WHI Yes CMS Yes | WHI No CMS Yes | WHI Yes CMS No | WHI No CMS No | SN   | SP    | PPV  | NPV  | Kappa |
|---|---------|-----------------|----------------|----------------|---------------|------|-------|------|------|-------|
| <b>Stroke (any diagnosis code; definition 1)</b>  |         |                 |                |                |               |      |       |      |      |       |
| All   | 24422   | 513             | 277            | 79             | 23553         | 86.7 | 98.8  | 64.9 | 99.7 | 0.74  |
| WHI Hospitalization reported <sup>1</sup>         | 24281   | 513             | 145            | 70             | 23553         | 88.0 | 99.4  | 78.0 | 99.7 | 0.82  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 24213   | 513             | 77             | 70             | 23553         | 88.0 | 99.7  | 86.9 | 99.7 | 0.87  |
| <b>Stroke (principal diagnosis; definition 2)</b> |         |                 |                |                |               |      |       |      |      |       |
| All   | 24422   | 472             | 205            | 120            | 23625         | 79.7 | 99.1  | 69.7 | 99.5 | 0.74  |
| WHI Hospitalization reported <sup>1</sup>         | 24307   | 472             | 99             | 111            | 23625         | 81.0 | 99.6  | 82.7 | 99.5 | 0.81  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 24266   | 472             | 58             | 111            | 23625         | 81.0 | 99.8  | 89.1 | 99.5 | 0.84  |
| <b>Hemorrhagic Stroke (definition 3)</b>          |         |                 |                |                |               |      |       |      |      |       |
| All   | 24422   | 75              | 48             | 18             | 24281         | 80.6 | 99.8  | 61.0 | 99.9 | 0.69  |
| WHI Hospitalization reported <sup>1</sup>         | 24404   | 75              | 30             | 18             | 24281         | 80.6 | 99.9  | 71.4 | 99.9 | 0.76  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 24385   | 75              | 11             | 18             | 24281         | 80.6 | >99.9 | 87.2 | 99.9 | 0.84  |
| <b>Ischemic Stroke (definition 4)</b>             |         |                 |                |                |               |      |       |      |      |       |
| All   | 24422   | 412             | 256            | 63             | 23691         | 86.7 | 98.9  | 61.7 | 99.7 | 0.71  |
| WHI Hospitalization reported <sup>1</sup>         | 24299   | 412             | 142            | 54             | 23691         | 88.4 | 99.4  | 74.4 | 99.8 | 0.80  |
| WHI Hospitalization adjudicated <sup>2</sup>      | 24247   | 412             | 90             | 54             | 23691         | 88.4 | 99.6  | 82.1 | 99.8 | 0.85  |

Abbreviations: CMS, Centers for Medicare & Medicaid Services data, i.e., Medicare data; NPV, negative predictive value; PPV, positive predictive value; SN, Sensitivity; SP, Specificity; WHI, Women’s Health Initiative data.

<sup>1</sup> Excludes strokes in the outpatient setting only. Also, excludes events for which no WHI hospitalization was reported by the participant or a proxy with admission date within +/-30 days of the Medicare hospitalization.

<sup>2</sup> Excludes events for which no medical records were received due to administrative reasons (e.g., no record release or no documents) or when reasons reported for hospitalization did not trigger adjudication (e.g. bunionectomy). \*Analysis based on a nationwide dataset.

## Iatrogenic Stroke

We explored the issue of iatrogenic or procedure related stroke. The WHI data has an additional variable which allows the abstraction of information indicating whether a stroke was procedure related or not. A WHI stroke is defined as procedure-related if it occurs within 24 hours after any procedure or within 30 days after a cardioversion or invasive cardiovascular procedure. We explored the concordance between WHI procedure related stroke and Medicare Claims use of codes for iatrogenic stroke: 997.02, "Iatrogenic Cerebrovascular Infarction of Hemorrhage", 998.11, "Hemorrhage Complicating a Procedure" and 998.9, Unspecified Complication of Procedure Nor Elsewhere Classified. In the person-based analysis, by definition 1 (Table 2, row 1, Definition 1) there were 30 procedure related strokes identified by the WHI. Of these,

- a) WHI Yes / CMS Yes = 22; Of these, we saw that 8 had one of the procedure related codes above in addition to the regular CMS definition 1 stroke codes within a week of WHI hospitalization; 14 did not have a CMS Procedure code within a week of stroke event despite being identified as a CMS stroke and a WHI procedure related stroke.
- b) WHI Yes / CMS No = 8; Of these, 5 had a CMS procedure related code within a week of WHI hospitalization.

The use of CMS procedure codes above would have increased our Sensitivity slightly by moving 5 cases from the WHI Yes/CMS No to the WHI Yes/CMS Yes cell; however, there is substantial under-reporting of the relationship of procedure to strokes. 22 of procedure related strokes in the WHI had a CMS stroke code but only 8 (36%) could have been identified as having had a procedure related stroke in CMS. So there is under-coding of this procedural relationship in the CMS.