| | | Danis | Foley | Grant | Kubo | Ondra | Pauker | Sloan | Weiner | Fried | Alvir | Richner | Gerber | Roth | Voting Member Average | Overall Average |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | There is the tendency to generalize stroke research to large, heterogeneous populations. How confident are you that the strategies below represent meaningful comparators in observational studies? | | | | | | | | | | | | | | | |
| | *1 Not Confident    -2-     3 Moderately Confident    -4-    5 Highly Confident* | | | | | | | | | | | | | | | |
| | a. Protocol driven usual treatment versus protocol driven usual treatment using the same parameters *plus* the specified intervention | 4 | 4 | 4 | 5 | 4 | 4 | 4 | 4 | 5 | 4 | 5 | 5 | 5 | **4.22** | **4.38** |
| | b. patient him/herself, before and after intervention | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 2 | 3 | 2 | 4 | 3 | 3 | **2.67** | **2.77** |
| | c. patient him/herself, before and after treatment then with treatment withdrawn and reinstituted (as appropriate) | 3 | 3 | 2 | 4 | 4 | 4 | 3 | 3 | 2 | 3 | 3 | 3 | 4 | **3.11** | **3.15** |
| | d. non-protocol driven usual care versus intervention | 2 | 3 | 3 | 1 | 3 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 2 | **1.78** | **1.69** |
| 3 | What is the minimum period of time that interventions be followed in order to identify a durable treatment effect? | | | | | | | | | | | | | | | |
| | *Numbers indicate voting of the combined panel.* | | | | | | | | | | | | | | | |
| | a. 0-6 months - 1 | | | | | | | | | | | | | | | #DIV/0! |
| | b. 6-12 months - 9 | | | | | | | | | | | | | | | #DIV/0! |
| | c. 12-18 months - 3 | | | | | | | | | | | | | | | #DIV/0! |
| | d. > 18 months - 0 | | | | | | | | | | | | | | | #DIV/0! |
| 4 | How confident are you that outcome measures like the ones that follow or those that are comparable are reliable, valid, and responsive indicators of change in clinical trials that aim to improve an individual's functional capacity in the performance of ADLs/IADLs and locomotion/transfer abilities? | | | | | | | | | | | | | | | |
| | *1 Not Confident    -2-     3 Moderate  -4-  5 Highly Confident    * Do Not Know* | | | | | | | | | | | | | | | |
| | a. Barthel Index and/or Six Minute Walk and/or Functional Independence Measure (FIM) and/or Fugl-Meyer Assessment | 4 | 3 | 4 | * | * | * | * | 3 | * | 4 | * | 4 | 4 | **3.50** | **3.71** |
| 5 | *How confident are you that each of the outcome measures like thos below or those that are comparable, are reliable, valid and responsive indicators  of change in clinical trials that aim to improve individual's funtional capacity in the performance of language and communication skills?* | | | | | | | | | | | | | | | |
| | a. Aphasia Quotient of the Western Aphasia Battery (WAB) and/or Porch Index of Communicative Ability | 2 | 4 | 3 | * | * | * | * | 2 | 1 | 3 | 1 | * | 4 | **2.40** | **2.50** |
| 6 | How confident are you that outcome measures like the ones that follow or those that are comparable are reliable, valid, and responsive indicators of change in clinical trials that aim to improve an individual's performance of swallowing? | | | | | | | | | | | | | | | |
| | *1 Not Confident    -2-     3 Moderate  -4-  5 Highly Confident  * Do Not Know* | | | | | | | | | | | | | | | |
| | a. coughing/choking frequency during a meal and/or the use of videofluoroscopy | * | 4 | * | * | * | 3 | * | * | * | 3 | * | 5 | 4 | **3.50** | **3.80** |

| # | Question | | | | | | | | | | | | | | Mean | Mean |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 7 | How confident are you that the following outcome measures are reliable, valid, and responsive indicators of change in clinical trials to assess patient, proxy, or caregiver perceptions of the patient's health and satisfaction with life and community re-integration? *1 Not Confident -2- 3 Moderate -4- 5 Highly Confident * Do Not Know* | | | | | | | | | | | | | | | |
| | | 4 | 2 | 4 | * | 2 | * | * | * | 1 | 3 | 1 | 1 | 2 | 2.60 | 2.22 |
| | b. Modified Ashworth Scale | 1 | 2 | 2 | * | 1 | 2 | 2 | * | 1 | 1 | 1 | 1 | 1 | 1.57 | 1.36 |
| | c. EuroQoL: Quality of life for patient and carer [caregiver] | 4 | 4 | 4 | * | 2 | 4 | * | 4 | 4 | 4 | 4 | 4 | 4 | 3.71 | 3.82 |
| 8 | How important are caregiver reports as indices of successful rehabilitation? 1 Not Confident -2- 3 Moderate -4- 5 Highly Confident | | | | | | | | | | | | | | | |
| | a. Narrative Report | 3 | 4 | 3 | 2 | 3 | 4 | 2 | 2 | 3 | 2 | 2 | 3 | 4 | 2.89 | 2.85 |
| | b. Validated Scale | 4 | 3 | 5 | 5 | 4 | 5 | 4 | 4 | 5 | 5 | 4 | 4 | 4 | 4.33 | 4.31 |
| 9 | How confident are you that these conclusions can be generalized to community practice settings outside the context of specialized treatment centers? 1 Not Confident -2- 3 Moderate -4- 5 Highly Confident | 3 | 4 | 3 | 3 | 4 | 3 | 4 | 3 | 4 | 2 | 4 | 5 | 5 | 3.44 | 3.62 |
| 10 | How confident are you that these conclusions can be generalized to the population of Medicare beneficiaries? 1 Not Confident -2- 3 Moderate -4- 5 Highly Confident | 3 | 5 | 4 | 4 | 5 | 4 | 4 | 5 | 5 | 2 | 5 | 4 | 5 | 4.33 | 4.23 |

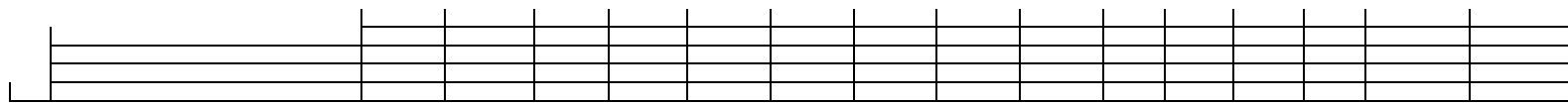| | | McNeil | Krist |
|---|---|---|---|
| **1** | For the treatment of parties with ARAS, how confident are you that the evidence is adequate to draw conclusions about safety and clinical effectiveness of the following renal artery interventions: | | |
| | *5 Highly Confident -4- 3 Uncertain -2- 1 Not Confident RAR* | | |
| | Surgical renal artery reconstruction (RAR)? | | 2 |
| | PTRA without stent placement? | | 2 |
| | PTRAS with bare metal stents? | | 2 |
| | PTRAS with drug-eluting stents? | | 1 |
| | | | |
| 2 | Based on the evidence presented, how confident are you that the published results apply to: | | |
| | *5 Highly Confident -4- 3 Uncertain -2-* | | |
| | Medicare patients with typical comorbidities? | | 3 |
| | Providers (facilities/physicians) in community practice? | | 2 |

| | | | |
|---|---|---|---|
| | Patient subgroups not represented in the study populations? | | 2 |
| | | | |
| 3 | Based on the evidence presented for patients with ARAS, how confident are you that compared to aggressive medical treatment alone there are improved key health outcomes attributable to the following co-interventions: *5 Highly Confident  -4-   3 Uncertain      -2- 1 Not Confident* | | |
| | Surgical RAR? | | 1 |
| | PTRA without stent placement? | | 2 |
| | PTRAS with bare metal stents? | | 2 |
| | PTRAS with drug-eluting stents? **Evidence not adequate** | | |
| | | | |
| 4 | Based on the evidence presented, should Medicare national coverage of any non-medical treatments for astherosclerotic RAS be limited only to patients enrolled in qualified clinical research studies? *5 Strongly disagree  -4-   3 Uncertain  -2-* | | 1 |

*Uncertain -2-*

*1- Strongly Agree*
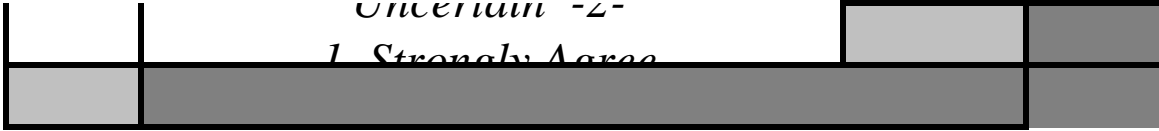
| Charytan | Flamm | Fendrick | Lewis | Maisel | Pressman |
|----------|-------|----------|-------|--------|----------|
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| 2        | 4     | 3        | 3     | 3      | 2        |
| 2        | 3     | 4        | 3     | 2      | 3        |
| 1        | 1     | 1        | 1     | 1      | 1        |
|          |       |          |       |        |          |
| 3        | 3     | 4        | 5     | 5      | 4        |
| 2        | 2     | 2        | 2     | 3      | 3        |

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| S.Schwartz | Slaughter | Lacey | Bergthold | Edwards | Textor |
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| 2 | 4 | 5 | 1 | 2 | 1 |

| Voting Member Average | Overall Average |
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| 2.89 | 2.92 |
| 2.92 | 2.92 |
| 2.85 | 2.85 |
| 1.00 | 1.00 |
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| 3.69 | 3.69 |
| 2.15 | 2.15 |

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| 1.67 | 1.69 |
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| #DIV/0! | #DIV/0! |
| 2.31 | 2.31 |
| 2.08 | 2.08 |
| 3.15 | 3.15 |
| #DIV/0! | #DIV/0! |
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| 2.36 | 2.23 |
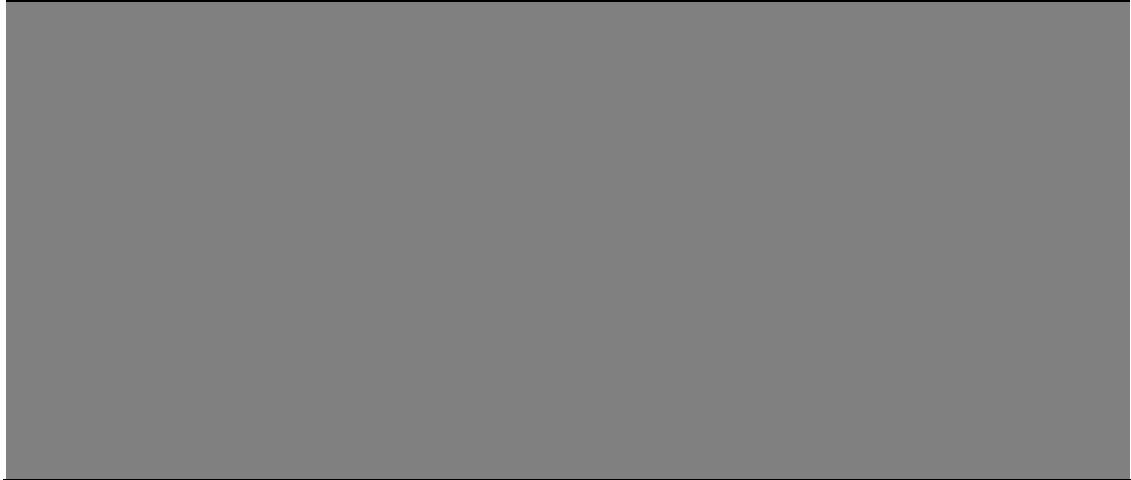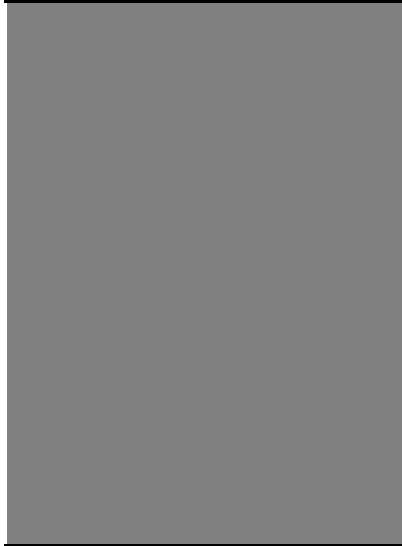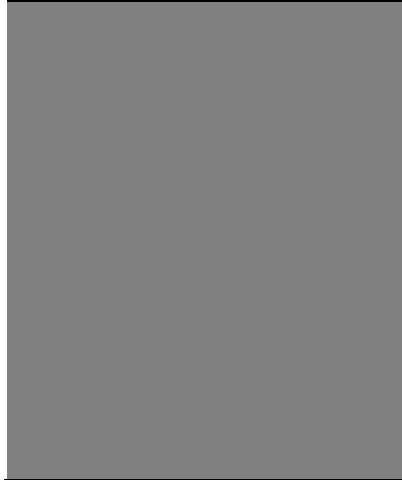
Question 1:

Please rate the following complications according to their
Medicare patients with type 2 diabetes. Rank each item in
and use each ranking only once. Maximal score: 8x8=64. I
8 most important.

| Krist | | Relative Prevalence |
|---|---|---|
| | a. All cause mortality | |
| | b. Fatal and non-fatal cardiovascular disease including CHF secondary to ischemic disease & non-hemorrhagic stroke | |
| | c. Retinopathy resulting in legal blindness | |
| | d. Other retinopathy | |
| | e. Nephropathy resulting in dialysis or transplantation | |
| | f. Other nephropathy including micro/macroalbuminemia | |
| | g. Amputation | |
| | h. Abnormal neuropathy testing | |

| Black | | |
|---|---|---|
| | a. All cause mortality | |
| | b. Fatal and non-fatal cardiovascular disease including CHF secondary to ischemic disease & non-hemorrhagic stroke | |
| | c. Retinopathy resulting in legal blindness | |
| | d. Other retinopathy | |
| | e. Nephropathy resulting in dialysis or transplantation | |
| | f. Other nephropathy including micro/macroalbuminemia | |
| | g. Amputation | |
| | h. Abnormal neuropathy testing | |
| Bradham | | |
| | a. All cause mortality | |
| | b. Fatal and non-fatal cardiovascular disease including CHF secondary to ischemic disease & non-hemorrhagic stroke | |
| | c. Retinopathy resulting in legal blindness | |

| | | |
|---|---|---|
| | d. Other retinopathy | |
| | e. Nephropathy resulting in dialysis or transplantation | |
| | f. Other nephropathy including micro/macroalbuminemia | |
| | g. Amputation | |
| | h. Abnormal neuropathy testing | |
| Piper | | |
| | a. All cause mortality | |
| | b. Fatal and non-fatal cardiovascular disease including CHF secondary to ischemic disease & non-hemorrhagic stroke | |
| | c. Retinopathy resulting in legal blindness | |
| | d. Other retinopathy | |
| | e. Nephropathy resulting in dialysis or transplantation | |
| | f. Other nephropathy including micro/macroalbuminemia | |
| | g. Amputation | |
| | h. Abnormal neuropathy testing | |

| Puklin | | |
|--------|---|---|
| | a. All cause mortality | |
| | b. Fatal and non-fatal cardiovascular disease including CHF secondary to ischemic disease & non-hemorrhagic stroke | |
| | c. Retinopathy resulting in legal blindness | |
| | d. Other retinopathy | |
| | e. Nephropathy resulting in dialysis or transplantation | |
| | f. Other nephropathy including micro/macroalbuminemia | |
| | g. Amputation | |
| | h. Abnormal neuropathy testing | |
| Weiner | | |
| | a. All cause mortality | |
| | b. Fatal and non-fatal cardiovascular disease including CHF secondary to ischemic disease & non-hemorrhagic stroke | |
| | c. Retinopathy resulting in legal blindness | |

| | | |
|---|---|---|
| | d. Other retinopathy | |
| | e. Nephropathy resulting in dialysis or transplantation | |
| | f. Other nephropathy including micro/macroalbuminemia | |
| | g. Amputation | |
| | h. Abnormal neuropathy testing | |
| Fendrick | | |
| | a. All cause mortality | |
| | b. Fatal and non-fatal cardiovascular disease including CHF secondary to ischemic disease & non-hemorrhagic stroke | |
| | c. Retinopathy resulting in legal blindness | |
| | d. Other retinopathy | |
| | e. Nephropathy resulting in dialysis or transplantation | |
| | f. Other nephropathy including micro/macroalbuminemia | |
| | g. Amputation | |

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| | h. Abnormal neuropathy testing | |
| Queenan | | |
| | a. All cause mortality | |
| | b. Fatal and non-fatal cardiovascular disease including CHF secondary to ischemic disease & non-hemorrhagic stroke | |
| | c. Retinopathy resulting in legal blindness | |
| | d. Other retinopathy | |
| | e. Nephropathy resulting in dialysis or transplantation | |
| | f. Other nephropathy including micro/macroalbuminemia | |
| | g. Amputation | |
| | h. Abnormal neuropathy testing | |
| Rucker | | |
| | a. All cause mortality | |

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|---|---|---|
| | b. Fatal and non-fatal cardiovascular disease including CHF secondary to ischemic disease & non-hemorrhagic stroke | |
| | c. Retinopathy resulting in legal blindness | |
| | d. Other retinopathy | |
| | e. Nephropathy resulting in dialysis or transplantation | |
| | f. Other nephropathy including micro/macroalbuminemia | |
| | g. Amputation | |
| | h. Abnormal neuropathy testing | |
| Hayward | | |
| | a. All cause mortality | |
| | b. Fatal and non-fatal cardiovascular disease including CHF secondary to ischemic disease & non-hemorrhagic stroke | |
| | c. Retinopathy resulting in legal blindness | |

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| | d. Other retinopathy | |
| | e. Nephropathy resulting in dialysis or transplantation | |
| | f. Other nephropathy including micro/macroalbuminemia | |
| | g. Amputation | |
| | h. Abnormal neuropathy testing | |
| Molich | | |
| | a. All cause mortality<br><br>b. Fatal and non-fatal cardiovascular disease including CHF secondary to ischemic disease & non-hemorrhagic stroke<br>c. Retinopathy resulting in legal blindness<br>d. Other retinopathy<br>e. Nephropathy resulting in dialysis or transplantation<br>f. Other nephropathy including micro/macroalbuminemia<br>g. Amputation | |

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| | h. Abnormal neuropathy testing | |
| Reiber | | |
| | a. All cause mortality<br>b. Fatal and non-fatal cardiovascular disease including CHF secondary to ischemic disease & non-hemorrhagic stroke<br>c. Retinopathy resulting in legal blindness<br>d. Other retinopathy<br>e. Nephropathy resulting in dialysis or transplantation<br>f. Other nephropathy including micro/macroalbuminemia<br>g. Amputation<br>h. Abnormal neuropathy testing | |

burden (prevalence x severity) in
the prevalence and severity columns 1-8
Minimal score: 1x1=1. 1 least important;

| Clinical Severity | Composite Score | Relative Rank based on Composite |
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