Capturing Outcomes After Stroke

Pamela W Duncan, PhD, FAPTA, FAHA
Professor of Neurology
Senior Policy Advisor for Innovations and Transitional Outcomes
Wake Forest Baptist Medical Center
Winston Salem, North Carolina
Pduncan@wakehealth.edu
Goals : Outcomes Presentation

• Discuss Timing and Selection of Outcome Measures for Clinical Trials

• Introduce an application (COMPASS-CP) of Patient Reported Outcomes to Develop Actionable Care Plans- Experience from the COMPASS Study

Conflict of Interests:

– Recipient of royalties from University of Kansas if Stroke Impact Scale for pharma trials.

– WF Innovations is considering plans to commercialize COMPASS-CP
Move from what is Easy and Global to what is More Meaningful, Precise and Patient-Centered

Over 130+ acute stroke trials:
• TPA, endovascular interventions, hemicranieotomy for malignant infarction
• Primary outcome - global rating of disability (RANKIN)

Rehabilitation Trials-(Targeted Interventions):
• Constraint Induced Movements, Locomotor Training, Fluoxetine
• Primary outcome - performance measures (Gait Speed, Action Arm Test, Fugl-Meyer) and quality of life measures
Stroke Patients are a Heterogeneous Group

Young - Old

Depressed - Not Depressed

Severity

Motor - UE - LE

Cognition - Language

Male - Female
Severity Defines Trajectory of Recovery and Degree of Recovery

**Figure 1.** Graph showing recovery of motor function after stroke based on Fugl-Meyer motor scores. Patients are stratified into groups based on the initial severity of motor deficit measured with Fugl-Meyer Assessment (see text). Regardless of initial severity of stroke, the most dramatic recovery occurs within the first 30 days. Moderate and most severe stroke patients continue to experience some recovery for 90 days. Graph represents mean Fugl-Meyer scores.


**Figure 4.** Plot of means and 1 SD of Barthel ADL after stroke.

**Figure 5.** Plot of means and 1 SD of physical functioning after stroke.

Maximize Ability To Detect a Difference

1. Consider the severity of the stroke and expected outcome(s)

2. Select measures which do not have significant floor and ceiling effects
Optimal End Points for Acute Therapy Trials Saver Stroke 2011;42:2356-2362

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Trial(s)</th>
<th>Time to enrollment</th>
<th>Age</th>
<th>NIHSS</th>
<th>Dichotomized 0-1 (p value)</th>
<th>Dichotomized 0-2 (p value)</th>
<th>Dichotomized 0-4 (p value)</th>
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</thead>
<tbody>
<tr>
<td>IV TPA &lt;3h</td>
<td>NINDS 1+2</td>
<td>1h 30m</td>
<td>67</td>
<td>14</td>
<td>0.02</td>
<td>0.10</td>
<td>0.31</td>
</tr>
<tr>
<td>IA Pro-UK &lt; 6h</td>
<td>PROACT 2</td>
<td>4h 54m</td>
<td>64</td>
<td>17</td>
<td>0.16</td>
<td>0.04</td>
<td>0.99</td>
</tr>
<tr>
<td>Hemicraniectomy</td>
<td>D/D/H</td>
<td>23h 30m</td>
<td>46</td>
<td>22</td>
<td>0.99</td>
<td>0.12</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Floor and Ceiling Effects of Measures Vary By Stroke Severity

Barthel Index:
- Major ceiling effect in mild and moderate strokes
- Majority of stroke survivors achieve basic activities of daily living

SF - Physical Function:
- Floor effects in severe and moderately severe strokes
  - Vigorous activities (running, lifting heavy objects, etc.)
  - Moderate activities (moving a table, pushing a vacuum cleaner, etc.)
  - Climbing stairs
  - Bending, kneeling or stooping
  - Walking a mile, one block, several block, etc.
  - Bathing or dressing
NIHSS, Barthel, Rankin in 2 NINDS Trials

*Figure 1.* Final 90-day outcome scores in the 2 NINDS tissue-type plasminogen activator trials. The NIHSS and Barthel Index both show a markedly skewed U-shape distribution unfavorable for analytic power and clinical interpretation. The Barthel Index also shows strong ceiling effect. In contrast, the modified Rankin Scale distributes substantial groups of patients among all hierarchical ranks, permitting more robust analysis and interpretation.

*Saver Stroke 2011;42:2356-2362*
KCSS Percentage Who Recovered At 3 Months

- NIH $\leq 1$ 45%
- Fugl-Meyer $> 90$ 37%
- Barthel $> 90$ 57%
- Rankin $\leq 1$ 24%
- Rankin $\leq 2$ 64%
- Women SF-36 $> 66$ 24%
- Men SF-36 $> 75$ 28%
Maximize Ability To Detect a Difference

1. Consider the severity of the stroke and *time to recover*

* More severe strokes have a longer trajectory of recovery. Observed differences in outcome between treatment groups may not be maximal at 3 months.
IMS III: Percent achieved mRS 0-2 by Severity Cohort Stroke. 2015 May; 46(5): 1321-1327
Meaningful Outcomes Should Be Sustainable: Evaluate Beyond 90 days

1. Evaluate Sustainability

“Demonstrating a persistent benefit for more than 3 months is important to judge the impact of a therapy over time in the population and is key for accurate cost-effectiveness analyses and policy implications.”

- Broderick: Early vs Late Assessment Stroke May 2016
Walking speed trajectory by intervention group and severity at screening, 2-(baseline), 6-, and 12-months post-stroke*

* Screening at 26.0±11.6 days post-stroke. 2-month baseline = point of randomization. The bars indicate 95% confidence interval.
• Data at later time points (6 months to < 12 months)
  ➢ Assess the full extent of recovery
  ➢ Durability of Recovery
  ➢ Full Effect of the Intervention
Stroke Effects Multiple Domains

- Motor - UE and LE difference
- Cognition
- Language
- Visual

*Cannot assume interventions have same effect across all domains*
To Maximize Ability To Detect a Difference: Evaluate Domains of Impairment

1. Consider using domain specific measures rather than global assessment

2. Consensus panel on motor function
   • Studies recommended that the Fugl-Meyer Upper and Lower Extremity scales be used as primary outcomes in intervention trials targeting motor function in populations with chronic stroke. ([Circ Cardiovasc Qual Outcomes. 2015;8:S163-S169](https://doi.org/10.1161/CIRCQUAL.Outcomes.2015.000406))

3. Domain-specific performance measures
   • Fugl-Meyer for motor impairment
   • MOCA for cognition

4. Quality of Life Measures
   • Stroke Impact Scale - 8 Domains
Effect of Constraint Induced Movement for Upper Extremity

CIMT improved:

• Motor control (The Wolf Motor Function Test)
• Use of the upper extremity (Motor Activity Log)
• Patient’s self report of difficulty (Stroke Impact Scale- Hand Function)

“The paretic upper extremity was used at least half as much as before the stroke on twice as many activities following the interventions and that this behavior persisted through the 12 month follow up”
Quality of Life Measures Must Be Included As Outcome Measures


- Survival
- Patient Reported Outcomes (PROMIS 10)- pain, fatigue, mood, mobility, return to usual activities, social participation, global cognitive functioning, ability to communicate, feeding, self-care and grooming

* If required for outcomes of clinical care, why not outcomes for interventional trials?

- PROMIS - HealthMeasures
- www.healthmeasures.net/explore-measurement-systems/promis

• **PROMIS physical function (PF) scale: A promising scale for use in patients with ischemic stroke (AMBULATORY Outpatients)**
  - PROMIS PF is an option for measurement of physical function in ischemic stroke patients. It had similar test characteristics as the SIS-16 but with lower patient burden and minimal ceiling effect.

• Innovations in Stroke The Use of PROMIS and NeuroQoL Scales in Clinical Stroke Trials Stroke. 2016;47:e27-e30
  
  **Conclusion:**
  
  “PROMs provide additional valuable information compared to the mRS alone in stroke patients seen in the ambulatory setting. SIS-16 may have better ability to identify change than mRS in health status of relevance to the patient. PROMs may be a useful addition to mRS in the assessment of health status in ambulatory clinical practice”.

*PROMs in clinical practice: SIS-16 is better able to detect change in functional status than the modified Rankin ISC 2016*
Must Select Patients or Adjust for Factors that are Predicative of Outcomes

1. Will reduce the variability in the outcome

2. Improve the estimate of the treatment effect

## Age, Sex, Depression, Prior Function

| Outcome: Completion of eight of nine IADL<sup>a</sup> without assistance |  |
|---|---|---|
| Female sex | 0.51 (0.32-0.79) | .002 |
| Age (years) | 0.97 (0.95-0.99) | .001 |
| Prestroke physical function | 1.03 (1.02-1.04) | <.001 |
| Stroke severity (NIHSS) | 0.76 (0.70-0.83) | <.001 |
| Depressive status | 0.58 (0.34-0.99) | .04 |

*Neuropharmacology. 2000;39:835-841*
Barthel > 90 at 3 Months

Orpington Scale Ranges

%

1.6 - 2.4
2.8 - 3.6
> 3.6

Normal  Depressive

Journal of Rehabilitation Research and Development. 2002;39:589-596
Gender and Age Dependency at 3 and 12 months

Changes in Functional Outcome Over the First Year After Stroke An Observational Study From the Swedish Stroke Register: (Stroke. 2015;46:389-394)
Cultural and Linguistic Validation

It is extremely important before launching an international trial that PROs are culturally and language validated

- MAPI LYON France (http://mapigroup.com/)
  - SIS translations and validation – over 40 languages

- PROMIS
  - Select domains are translated
    - Chinese-Traditional
    - Dutch
    - German
    - Spanish
    - Portuguese-Br
    - French
    - Italian
Summary

• Focus of Trial (e.g. Phase I – safety vs. Phase III long-term functional outcome)
• Natural history of outcome in population of patients under study (mild vs severe)
• What are you most likely to effect: motor, cognitive, mood, visual, language
• The endpoint itself and definition of recovery: dichotomous, ordinal, shifts, or differences in continuous
• Maximizing detection of differences requires consideration of predictors of outcome for selection of subjects or co-variate risk adjustment
• Sustainability of differences and cost-effectiveness in outcomes
• Quality of life is IMPORTANT to patients and should be IMPORTANT for Trialists
Using PROMs for Dynamic Generation of Patient Specific eCare Plans in a Pragmatic Trial

Pamela W Duncan PhD. FAPTA, FAHA
Professor on Neurology
Wake Forest Baptist Health
PI COMPASS Trial
pduncan@wakehealth.edu
What is a PRO?

...is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.

— FDA 2009
What is a PRO?

- **Less Complex:** Symptomatic (i.e. response to headache)
- **More Complex:** Ability to carry out activities of daily living
- **Extremely Complex:** Quality of Life (multi-domain concept w/ physical, psychological and social components)
Why are PROs Important?

• Provide information not available from other sources. (i.e. insights of patient health status using past performance)

• Incorporates the patients personal standards, values, and expectations.

• identify manageable drivers of poor self-management or “adherence”.
CMS Mandates

- New Directions for Care for Complex Chronic Conditions

- MACRA
- Conditions of HH Participation

- Chronic Care Plus
- TCM & CCM

Common to all CMS mandates for new care models is an individualized electronically available care plan.
- Plans should include PROMS, patient goals and preferences for care
- The care plan must be electronically available to all providers and the patient.
• Patient Reported Outcomes Should INFORM and Be Source of ACTIONS for Individualized Care

Patient Engagement

Patient Self Management
COMPASS Overview
Methods Paper:
https://bmcneurol.biomedcentral.com/articles/10.1186/s12883-017-0907-1

- Multi-site, pragmatic, clinical trial
- Stroke patients who go home directly from the hospital
- COMPASS (combines transitional care and early supported discharge for) Vs. usual care

Does COMPASS...
- Improve patients’ daily function?
- Reduces caregiver strain?
- Reduce hospital readmission rates?
- Reduce use of health care?
- Reduce mortality
COMPASS Principal Investigators

• PI: Pamela Duncan, PhD, PT, FAPTA, FAHA
  Professor of Neurology, Wake Forest Baptist Health

• Co-PI: Cheryl Bushnell, MD, MHS, FAHA
  Professor of Neurology and Director, WFB Comprehensive Stroke Center

• Co-PI: Wayne Rosamond, PhD, MS, FAHA
  Professor of Epidemiology, UNC Gillings School of Global Public Health and Director, North Carolina Stroke Care Collaborative
• **Model:** Early supported discharge

• **Care Team:** stroke trained APP and post-acute coordinator (RN) for care coordination

• **eCOMPASS:**
  – **Chronic disease management:** Connects hospitals, community providers, and community agencies
  – **Billable** with Transitional Care Management or Complex Clinical Management, consistent with MACRA requirements
  – **Individualized care plan** addresses the needs of stroke survivors and their caregivers
PRO example

Post Stroke Functional Assessment for Personalized Care

Have you fallen in the last 3 months?

- Yes
- No

a. In the last 3 months, did you get injured and need to go to the doctor or emergency room due to a fall?

- Yes
- No
- No Response

b. Have you fallen more than once in the last 3 months?

- Yes
- No
- No Response
eCare WebApp

**COMPASS**
COMPREHENSIVE POST-ACUTE STROKE SERVICES

- **EHR**
  - Key EHR data delivered via FHIR (future version)
  - Local community resource lists

- **CR**

Mobile friendly eCare App

eCare download reports

- Patient eCare Plan
- Provider report
- Clinician handoff report
- Performance reports
- Risk Calc - 90day Outcomes

**eCare Assessments**
- Two Day Post-Discharge Follow up
- Post Stroke Functional Assessment
- Stroke Caregiver Assessment
- Post Stroke Advanced Practice Assessment

**eCare Data Repository at WFBH**
Patient Specific Care Plans

• Generated using proprietary algorithms
  – SAS code is dynamically run each time care plan is generated
  – Gathers most current data we have from that patient or their care team
  – Runs through a series of algorithms to determine what specific health concerns exist for this patient
  – Prompt provider for customizations
  – Generate PDF, available electronically
eCare App Patient Demo
**COMPASS: Finding my Way for Recovery, Independence, and Health**

**Name:** Christina Condor  
**ID:** 7  
**January 19, 2016**  
**Page 3**

<table>
<thead>
<tr>
<th>Engage: Be engaged in my overall health and well-being</th>
<th>What are my concerns?</th>
<th>Why is this important to me?</th>
<th>How do I find my way forward?</th>
</tr>
</thead>
</table>
| It is difficult to use my hand affected by my stroke. | Therapy, exercise, and physical activity will improve the use of my hand and arm. | I can improve the use of my hand and arm by:  
- Working with a physical and/or occupational therapist in my home or an outpatient clinic.  
- Exercising regularly on my own or in an exercise class.  
- Being physically active in my daily life and trying to use my arm and hand as much as possible. |
| My muscles feel stiff and I am having trouble moving, walking, or using my hand and arm. | Medicines, therapy, exercise, and physical activity can decrease the stiffness (also called spasticity) in my muscles. This will help me be more independent and safe in my daily activities. | I can decrease the stiffness in my muscles by:  
- Working with a physical and/or occupational therapist in my home or an outpatient clinic.  
- Doing stretching and strengthening exercises.  
- Taking medicines to relax my muscles.  
- Seeing a specialist in spasticity treatment. |
| I have fallen or I am at risk for falling. | I am more likely to fall since I had a stroke. Improving my balance and strength will help decrease my chances of falling and improve my overall independence. | I can decrease my chances of falling by:  
- Working with a physical therapist in my home or an outpatient clinic.  
- Attending a falls prevention class.  
- Using appropriate walking aids for support.  
- Having a home safety assessment. |
| I am not independent in some of my routine activities like dressing or bathing myself, or being able to control my bladder/bowels. | Being as independent as possible will increase my confidence in my recovery. This will make it easier for my loved ones to care for me. | I can become more independent in my routine activities by:  
- Working with a physical and/or occupational therapist in my home or an outpatient clinic.  
- Working with a home health aide on bathing and dressing.  
- Getting adaptive equipment (e.g., tub chair) that can help with my activities. |
# Community Resources

## Community Resources: Numbers

<table>
<thead>
<tr>
<th>Organization and Program Information:</th>
<th>(336) 904-0300</th>
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<tbody>
<tr>
<td></td>
<td>1398 Carrollton Crossing Drive, Kernersville, NC 27284</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.ptrc.org/index.aspx?page=204">http://www.ptrc.org/index.aspx?page=204</a></td>
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</tbody>
</table>

*This program has a special referral process, please see website.*

<table>
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<tr>
<th>Organization and Program Information:</th>
<th>(919) 855-3500</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>101 Blair Drive</td>
</tr>
<tr>
<td></td>
<td>Raleigh, NC 27603</td>
</tr>
<tr>
<td></td>
<td><a href="https://www.ncdhhs.gov/divisions/dvrs/vr-local-offices">https://www.ncdhhs.gov/divisions/dvrs/vr-local-offices</a></td>
</tr>
</tbody>
</table>

*This program has special eligibility requirements, please see website.*
COMPASS an eCare Application

Good Care is Good Business

"[We] implemented this today and what a difference it made. Our time was greatly reduced from check in to check out~ You can't imagine what a sense of accomplishment that was!!"

Young L MCA occlusion stroke w/cryptogenic etiology. PMH included anxiety, pelvic mass suspicious of cancer, heart fluttering (no atrial fib dx to date), PE w/last admission. I saw her during last hospitalization.

She presented today w/initial SBP 170. After visit SBP 140. Again, this was a classic engaged, yet "highly anxious" patient. She had multiple visits pre-op. Cryptogenic stroke w/high suspicion of hypercoag state for days. Prior to admission, she had stroke symptoms during her GYN w/hysterectomy. She did not make it to surgery and came in for a consult. She was reported w/rew in SICU. She was taken to OR w/OB/GYN regarding her bleeding and pelvic mass, where she was treated with IV tPA (clot cleared). She was then taken back to OR by the OB/GYN. Post tPA, her stroke score was 0-1. Her main concerns today centered around why she was feeling so weak. She told me she was doing well, but she was not as well as she used to be. She was tired of feeling poorly. She had high expectations for her care and the future of her health.
Results

Presented in Table 1 and Figure 2 are selected findings from the first 342 patients with complete eCOMPASS® care plans, enrolled July 2016 through April 2017.

Table 1. Selected eCOMPASS® Domains Identifying Concerns, N=342, Freq. [%]

<table>
<thead>
<tr>
<th>Medication Management</th>
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</tr>
</thead>
<tbody>
<tr>
<td>&gt; 5 medications/day</td>
<td>253 (74.0)</td>
</tr>
<tr>
<td>Low Adherence</td>
<td>74 (21.9)</td>
</tr>
<tr>
<td>Financial Challenges</td>
<td>75 (21.9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cognitive / Psychosocial Factors</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive Deficits</td>
<td>141 (41.2)</td>
</tr>
<tr>
<td>Depression</td>
<td>128 (37.4)</td>
</tr>
<tr>
<td>Social Isolation</td>
<td>29 (8.5)</td>
</tr>
<tr>
<td>Limited Social Support</td>
<td>86 (25.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lack of Risk Factor Knowledge</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>Blood Pressure</td>
<td>125 (36.5)</td>
</tr>
<tr>
<td>Smoking</td>
<td>247 (72.2)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>271 (79.2)</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>320 (95.6)</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>304 (89.9)</td>
</tr>
<tr>
<td>High Cholesterol</td>
<td>155 (47.0)</td>
</tr>
<tr>
<td>Physical Inactivity</td>
<td>288 (84.2)</td>
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</table>

<table>
<thead>
<tr>
<th>Healthcare Utilization</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>No PCP</td>
<td>23 (6.7)</td>
</tr>
<tr>
<td>ED Visit in last 3 mos</td>
<td>68 (18.4)</td>
</tr>
<tr>
<td>Hospitalized in last 3 mos</td>
<td>37 (10.8)</td>
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Table 1. (continued)

<table>
<thead>
<tr>
<th>Functional Health</th>
<th></th>
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<tbody>
<tr>
<td>Upper extremity difficulty</td>
<td>74 (21.6)</td>
</tr>
<tr>
<td>Spasticity</td>
<td>59 (17.3)</td>
</tr>
<tr>
<td>Physical mobility/safety</td>
<td>129 (37.7)</td>
</tr>
<tr>
<td>Poor/fair self-rated health *</td>
<td>75 (22.1)</td>
</tr>
<tr>
<td>Fall in the last 5 mos</td>
<td>80 (23.4)</td>
</tr>
<tr>
<td>ADL Limitations</td>
<td>83 (24.3)</td>
</tr>
<tr>
<td>IADL Limitations</td>
<td>59 (17.3)</td>
</tr>
<tr>
<td>Communication Deficits *</td>
<td>31 (9.8)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Caregiver Health *</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No Able/Willing Caregiver</td>
<td>25 (8.0)</td>
</tr>
<tr>
<td>Caregiver Stress</td>
<td>50 (14.7)</td>
</tr>
<tr>
<td>Caregiver Requires Help</td>
<td>18 (5.3)</td>
</tr>
<tr>
<td>Caregiver Health Limitations</td>
<td>28 (8.2)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Lifestyle Factors*</th>
<th></th>
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<tbody>
<tr>
<td>Smoking</td>
<td>60 (17.0)</td>
</tr>
<tr>
<td>Alcohol Abuse</td>
<td>15 (4.7)</td>
</tr>
<tr>
<td>Recreational Drug Use</td>
<td>10 (3.0)</td>
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<tr>
<td>Physical Inactivity</td>
<td>147 (42.1)</td>
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<table>
<thead>
<tr>
<th>Risk Factors*</th>
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<tbody>
<tr>
<td>Systolic BP &gt; 140</td>
<td>99 (31.2)</td>
</tr>
<tr>
<td>Diastolic BP &gt; 90</td>
<td>25 (7.5)</td>
</tr>
<tr>
<td>LDL &gt; 100</td>
<td>109 (31.7)</td>
</tr>
<tr>
<td>HgbA1c &gt; 8.0</td>
<td>28 (8.2)</td>
</tr>
</tbody>
</table>

* Missing values excluded: Denominator <342

Results (continued)

Figure 2. Selected eCOMPASS® Referrals, N=342

<table>
<thead>
<tr>
<th>Assisted Living</th>
<th>Skilled Nursing Facility</th>
<th>Home Health PT/OT</th>
<th>Home Health Nursing</th>
<th>Home Health SLP</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0%</td>
<td>0.6%</td>
<td>19.3%</td>
<td>15.2%</td>
<td>9.4%</td>
</tr>
</tbody>
</table>

There were significant differences in patients who were identified as needing services by age, gender, insurance type, NIH Stroke Scale, and primary stroke center status, but not race/ethnicity, or geography.
High User Satisfaction: 67% Very Satisfied
eCompass Sustainability

- Sustainability of eCompass as a research platform is quite limited
  - Once Compass funding ends, support for the research platform ends, data transfer issues, etc.
  - Long term sustainability requires integration with EHR
    - Could build the functionality into the EHR but would be time consuming, $$$$, etc.
    - Could leverage the EHR system as a software platform…
      - Cloud-based application
      - Enter Smart on FHIR…
eCompass Smart on FHIR

- SMART on FHIR is an open, standards-based platform for building reusable/interchangeable medical apps
  - SMART, which stands for Substitutable Medical Applications & Reusable Technologies
  - SMART’s mission was to create a platform specification allowing app developers to write medical apps once and have them run (“plug-and-play”) across diverse healthcare IT systems
A Tool for Clinical Trials: Assessment of Social and Functional Determinants of Health could support adherence for interventions (behavioral or medication)
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  - SMART’s mission was to create a platform specification allowing app developers to write medical apps once and have them run (“plug-and-play”) across diverse healthcare IT systems
More Information on eCOMPASS

• YouTube:  
  https://www.youtube.com/watch?v=K7dCCTvRxa4&

• pduncan@wakehealth.edu
Thanks & Some Required Disclosures

• **FUNDING ACKNOWLEDGEMENT:** Patient-Centered Outcomes Research Institute (PCORI) Award (PCS-1403-14532).
  
  – REDCap support of the Wake Forest Clinical and Translational Science Institute (WF CTSI), which is supported by the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, through Grant Award Number UL1TR001420.

• **DISCLAIMER:** All statements are solely those of the presenters and do not necessarily represent the views of PCORI or its Board of Governors or Methodology Committee.

• **NCT Number for ClinicalTrials.gov:** NCT02588664
• Reference Slides
Rankin

• 0 No symptoms at all

• 1 No significant disability despite symptoms; able to carry out all usual duties and activities

• 2 Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance

• 3 Moderate disability; requiring some help, but able to walk without assistance

• 4 Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance

• 5 Severe disability; bedridden, incontinent and requiring constant nursing care and attention

• 6 Dead
SIS-16 Components

- Dress top part of body
- Bathe yourself
- Get to toilet on time
- Control bladder
- Control bowels
- Stand without losing balance
- Go shopping
- Do heavy household chores

- Stay sitting without losing balance
- Walk without losing balance
- Move from bed to chair
- Walk fast
- Climb one flight of stairs
- Walk one block
- Get in and out of car
- Carry heavy objects

Domains of Stroke Impact Scale Version 3.0: Physical Domains

- Strength (Upper and Lower Extremity)
- Hand Function
- ADL/IADL
- Mobility
- Physical (Combined)
Stroke Impact Scale: Version 3
59 Items and Domains

• Communication

• Memory and Thinking

• Emotion

• Participation (Role Limitations)
**Global Health - PROMIS Global Health (10) SF**

Please respond to each item by marking one box per row.

<table>
<thead>
<tr>
<th>Item</th>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global 01: In general, would you say your health is:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Global 02: In general, would you say your quality of life is:</td>
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<tr>
<td>Global 03: In general, how would you rate your physical health?</td>
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<tr>
<td>Global 04: In general, how would you rate your mental health, including your mood and your ability to think?</td>
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<tr>
<td>Global 05: In general, how would you rate your satisfaction with your social activities and relationships?</td>
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</tr>
<tr>
<td>Global 06: In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Item</th>
<th>Completely</th>
<th>Mostly</th>
<th>Moderately</th>
<th>A Little</th>
<th>Not At All</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global 06: To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Item</th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global 10: In the past 7 days, how often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?</td>
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<tr>
<td>Global 08: How would you rate your fatigue on average?</td>
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<tr>
<td>Global 07: How would you rate your pain on average?</td>
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</tbody>
</table>

**Scoring:**

Re-code Global07. The recoded score ranges from 1 to 5.

(0 No pain = 5, 1, 2, or 3 = 4; 4, 5, or 6 = 3; 7, 8, or 9 = 2; 10 worst pain imaginable = 1)

After recoding, the
Global Physical Health score = SUM responses to G03 + G06 + G07 + G08.
Global Mental Health score = SUM G02 + G04 + G05 + Global10.

<table>
<thead>
<tr>
<th>TOTAL</th>
<th>Raw Score</th>
<th>T-Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Physical Health</td>
<td></td>
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<tr>
<td>Global Mental Health</td>
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</tbody>
</table>