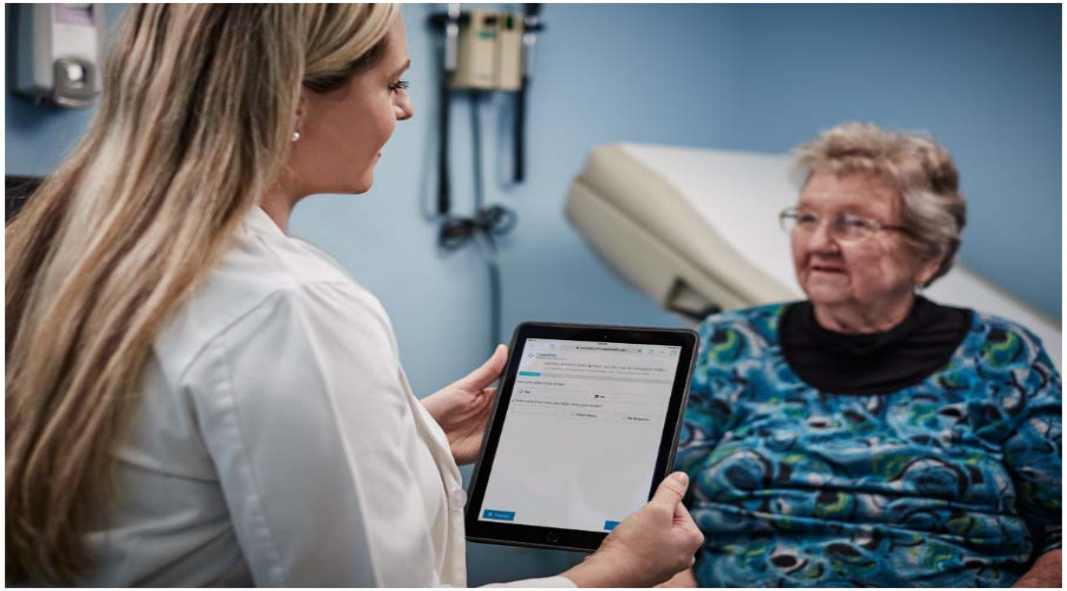
Capturing Outcomes After Stroke



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 0utcome 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, hemicraniectomy 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

Motor - UE - LE

Depressed - Not Depressed

Cognition - Language

Severity

Male - Female

Severity Defines Trajectory of Recovery and Degree of Recovery

Impairment

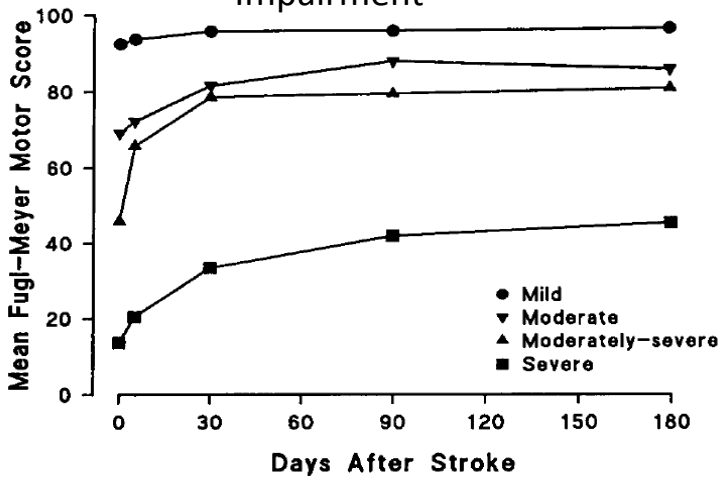


FIGURE 1. *Graph showing recovery of motor function after stroke based on Fugl-Meyer motor scores. Patients are stratified into groups based on the initial severity of motor deficit measured with Fugl-Meyer Assessment (see text). Regardless of initial severity of stroke, the most dramatic recovery occurs 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.*

***Stroke*. 1992;23:1084-1089.**

Function - ADL

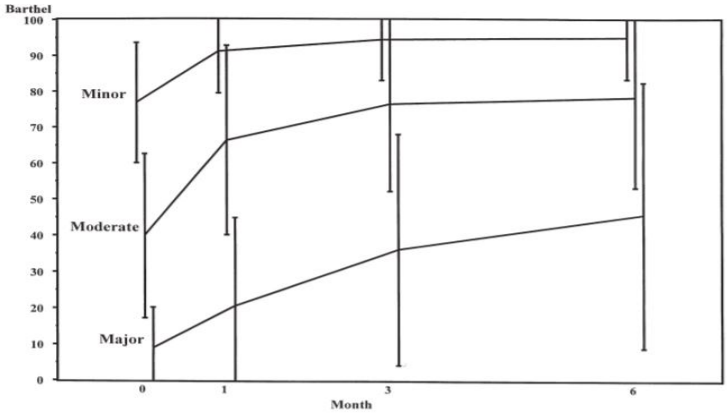


Fig. 4. Plot of means and 1 SD of Barthel ADL after stroke.

P.W. Duncan et al. / Neuropharmacology 39 (2000) 835–841

Quality of Life - PROs

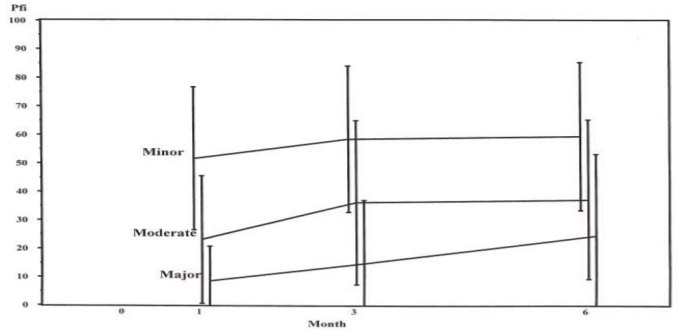


Fig. 5. Plot of means and 1 SD of physical functioning after stroke.

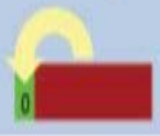
***Neuropharmacology*. 2000;39:835-841.**

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

Treatment	Trial(s)	Time to enrollment	Age	NIHSS	Dichotomized 0-1 (p value) 	Dichotomized 0-2 (p value) 	Dichotomized 0-4 (p value) 
IV TPA <3h	NINDS 1+2	1h 30m	67	14	0.02	0.10	0.31
IA Pro-UK < 6h	PROACT 2	4h 54m	64	17	0.16	0.04	0.99
Hemicraniectomy	D/D/H	23h 30m	46	22	0.99	0.12	<0.001

n,

Floor and Ceiling Effects of Measures Vary By Stroke Severity

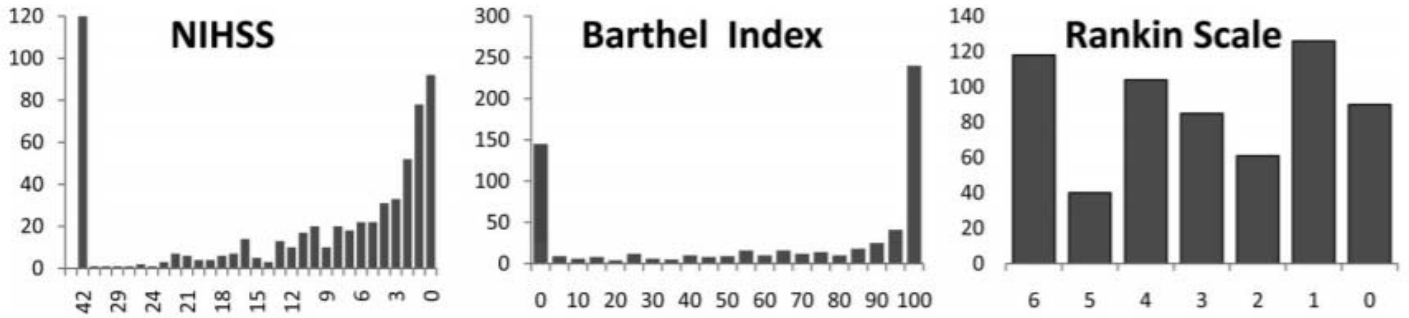
Barthel Index:

- 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



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

Saver Stroke 2011;42:2356-2362

KCSS Percentage Who Recovered At 3 Months

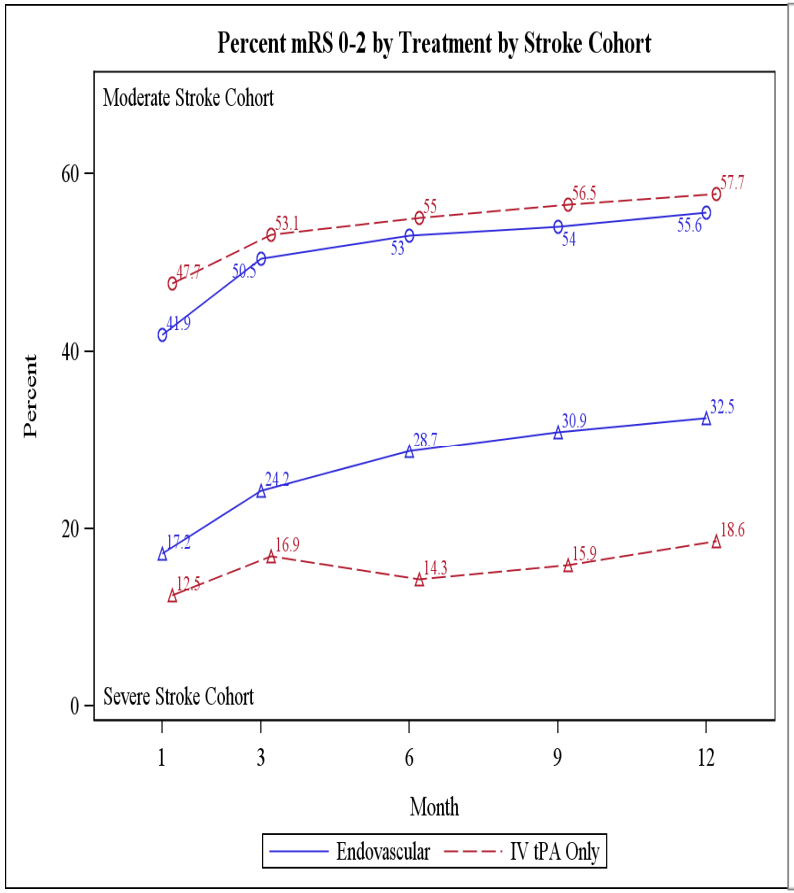
- NIH <= 1 45%
- Fugl-Meyer > 90 37%
- Barthel > 90 57%
- Rankin <=1 24%
- Rankin <=2 64%
- Women SF-36 >66 24%
- Men Sf-36 > 75 28%

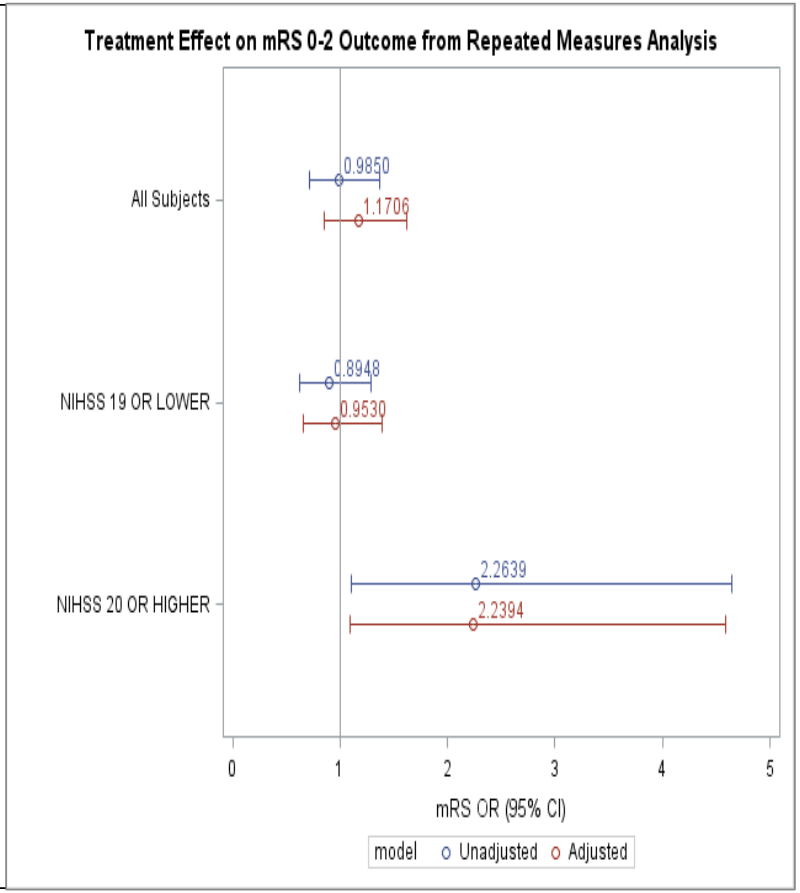
Maximize Ability To Detect a Difference

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





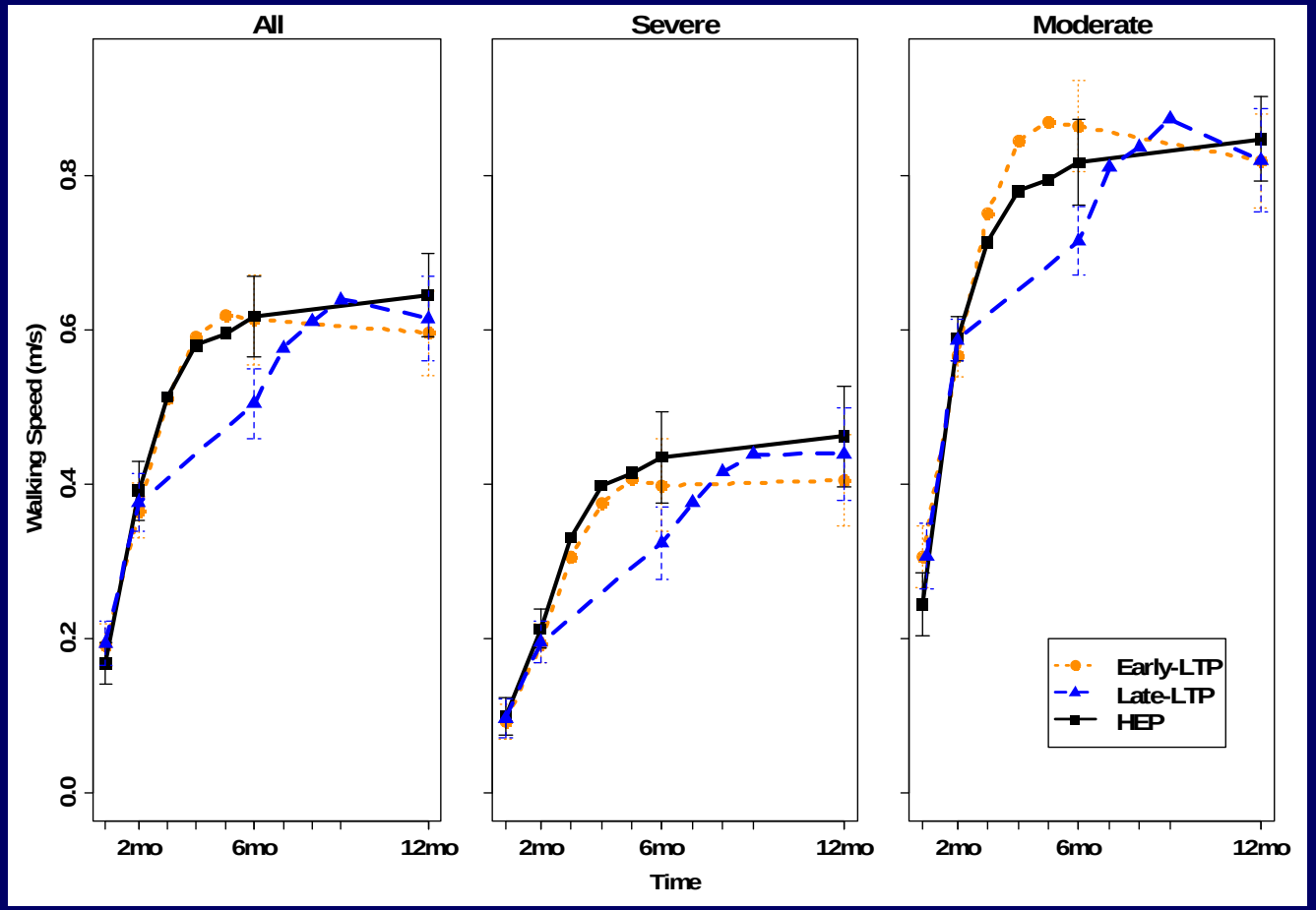
Meaningful Outcomes Should Be Sustainable: Evaluate Beyond 90 days

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.

Controversies in Stroke

Section Editors: Carlos A. Molina, MD, PhD, and Magdy H. Selim, MD, PhD

Early Versus Late Assessment of Stroke Outcome

Kennedy R. Lees, MD; Magdy H. Selim, MD, PhD; Carlos A. Molina, MD, PhD; Joseph P. Broderick, MD

- 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 May 2016

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**)

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"

JAMA 2006, 296: 2095-2104

Quality of Life Measures Must Be Included As Outcome Measures

International Standard Set of Patient-Centered Outcomes Measures After Stroke: Stroke 2016: 47: 180-186

- 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**

Katzan- Evaluation of PROMIS

Neurology. 2016 May 10;86(19):1801-7

- **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 TrialsStroke. 2016;47:e27-e30Conclusion:

  "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

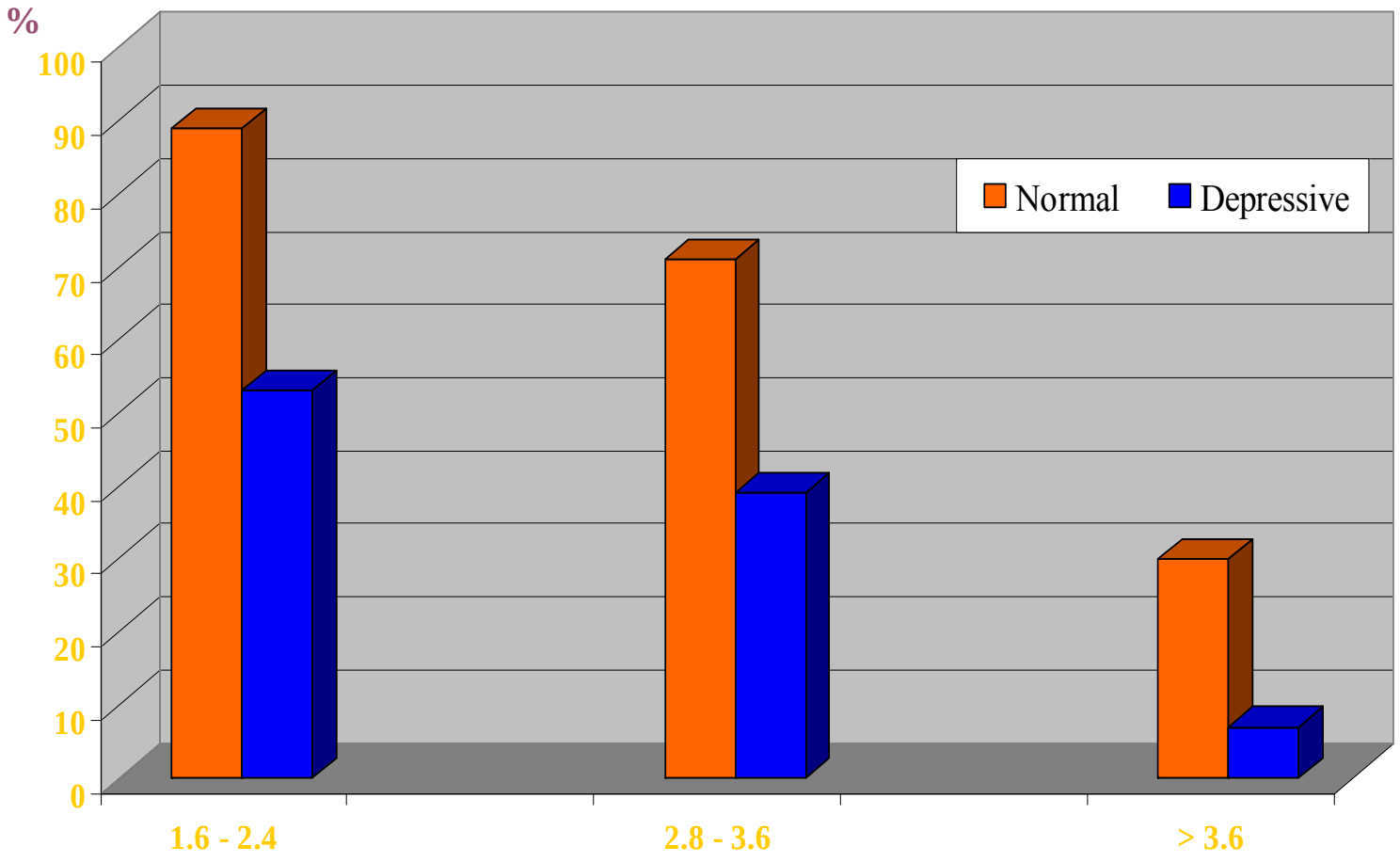
Stroke. 2012;43:1171-1178.

Age, Sex, Depression, Prior Function

Outcome: Completion of eight of nine IADL[b] 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



Journal of Rehabilitation Research and Development. 2002;39:589-596

Gender and Age Dependency at 3 and 12 months

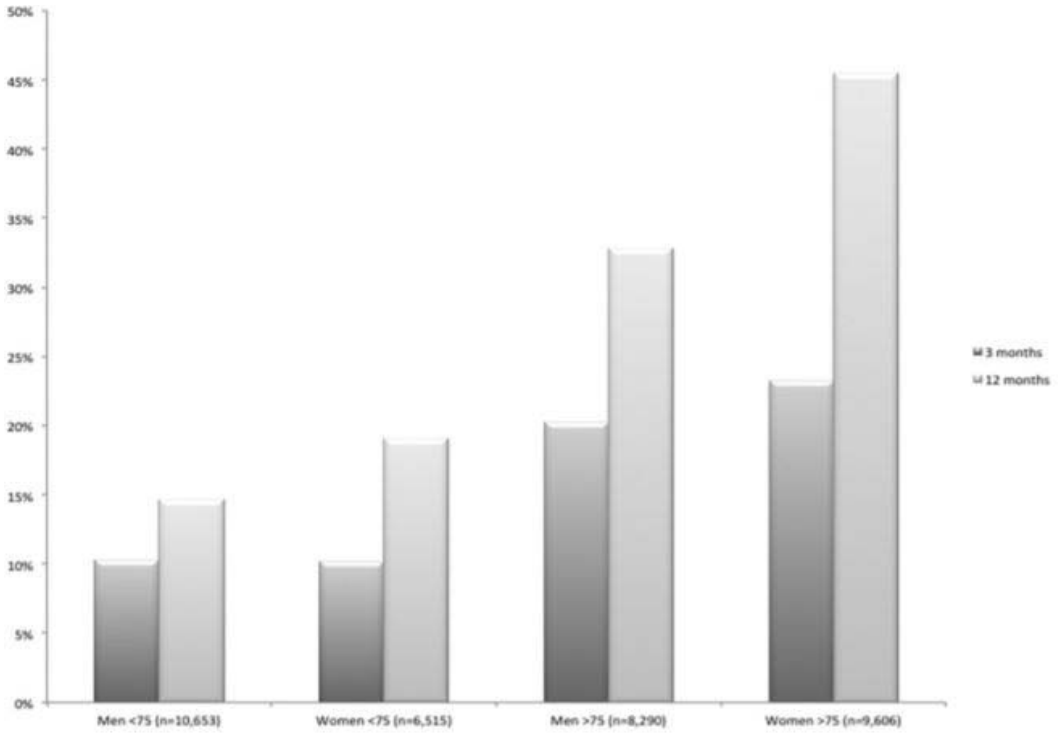


Figure 2. Proportions of patients who were ADL (activities of daily living)-dependent at 3 and 12 months.

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 tranlated
    - 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

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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

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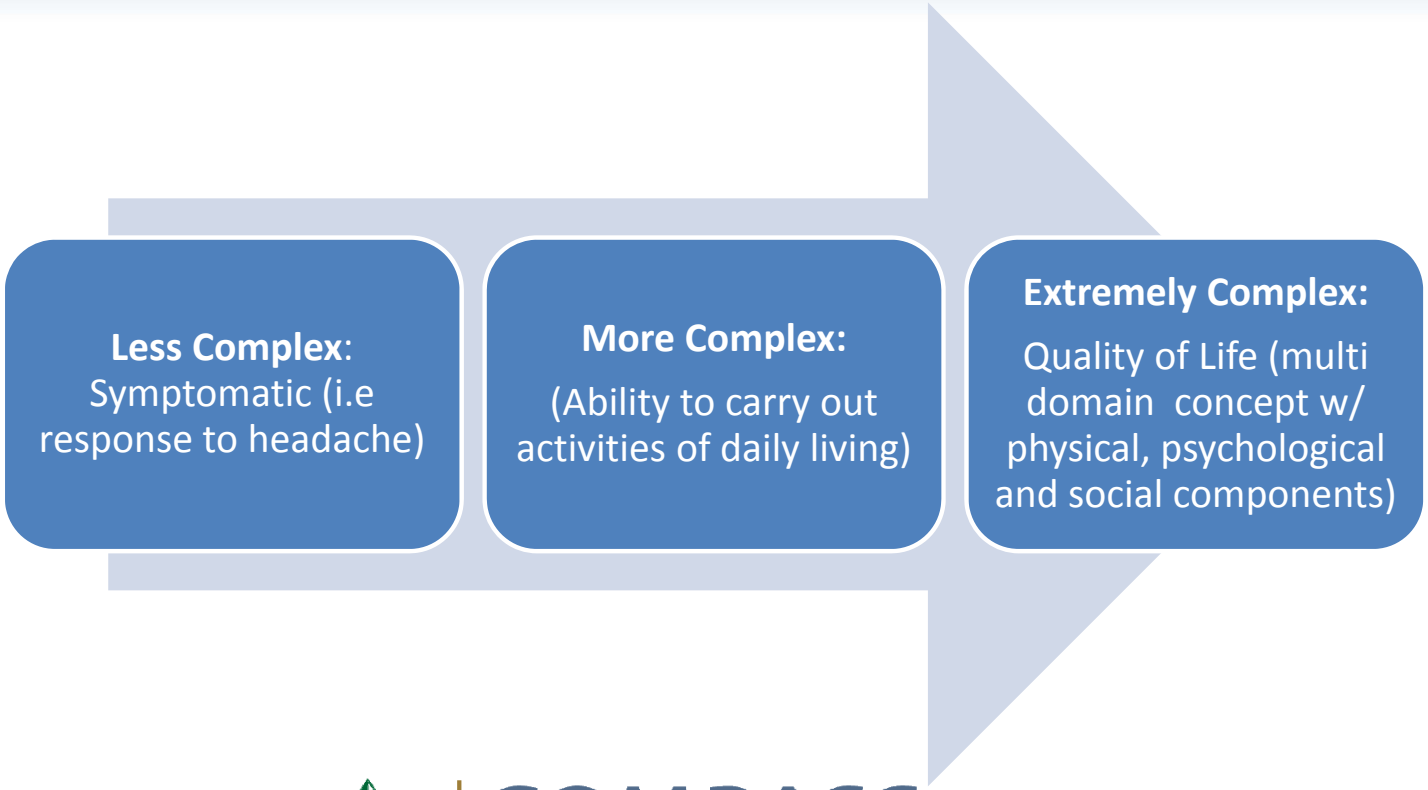
What is a PRO?



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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"** .

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CMS Mandates

- New Directions for Care for Complex Chronic Conditons

  - 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.

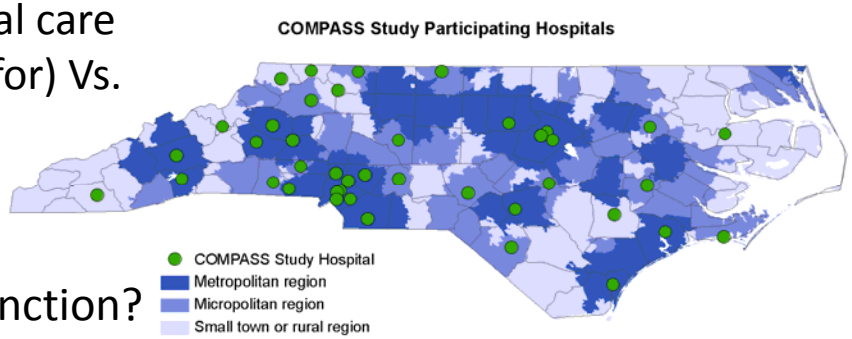
- Patient Reported Outcomes Should INFORM and Be Source of ACTIONS for Individualized Care
  - Patient Engagement
  - Patient Self Management

COMPASS Overview

Methods Paper:

*https://**bmc**neurol.**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

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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

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COMPASS Care Model

2day Phone call	**7-14day Clinic Visit**	30day Phone call	60day Phone call

- **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

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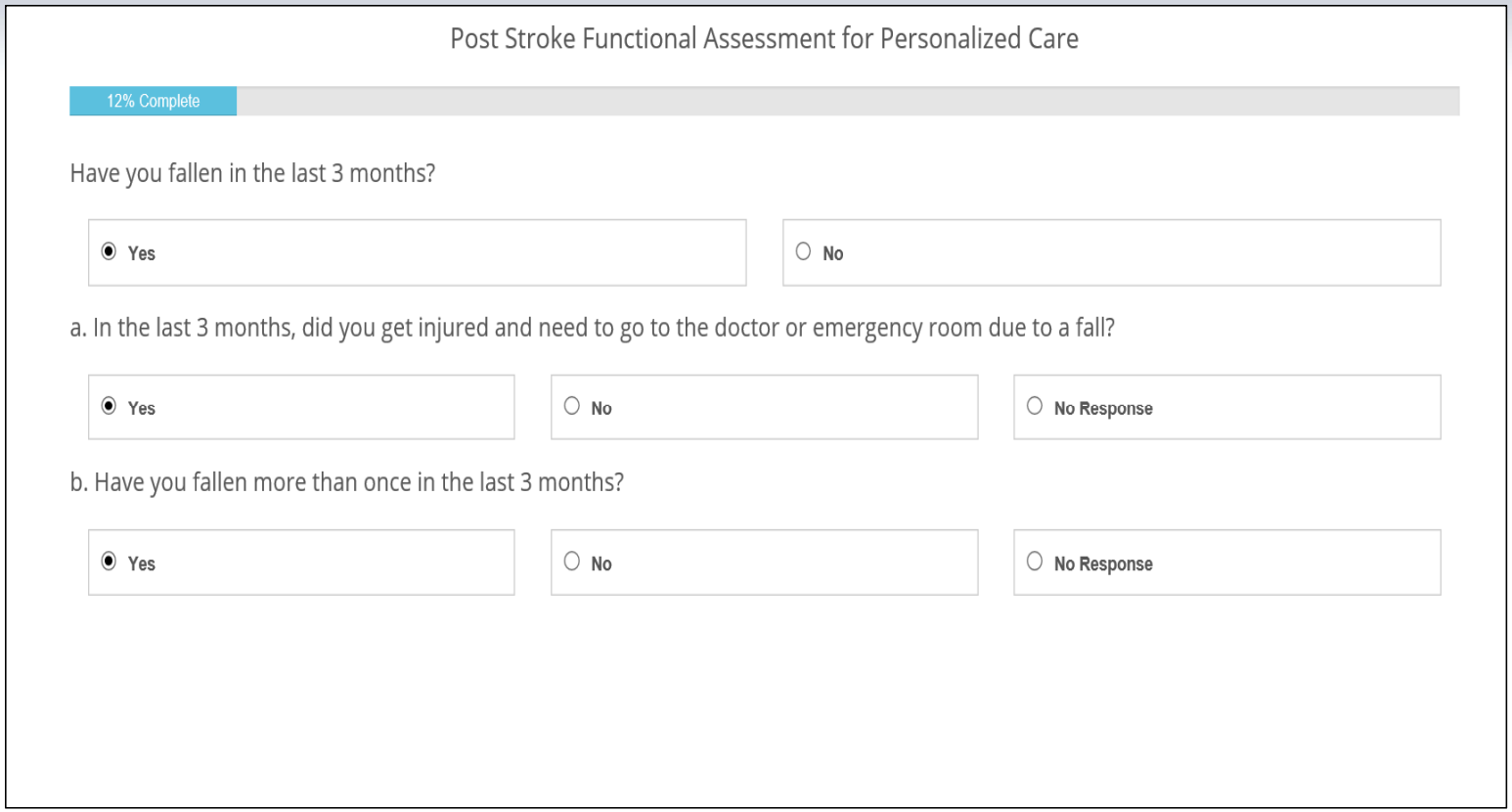
PRO example



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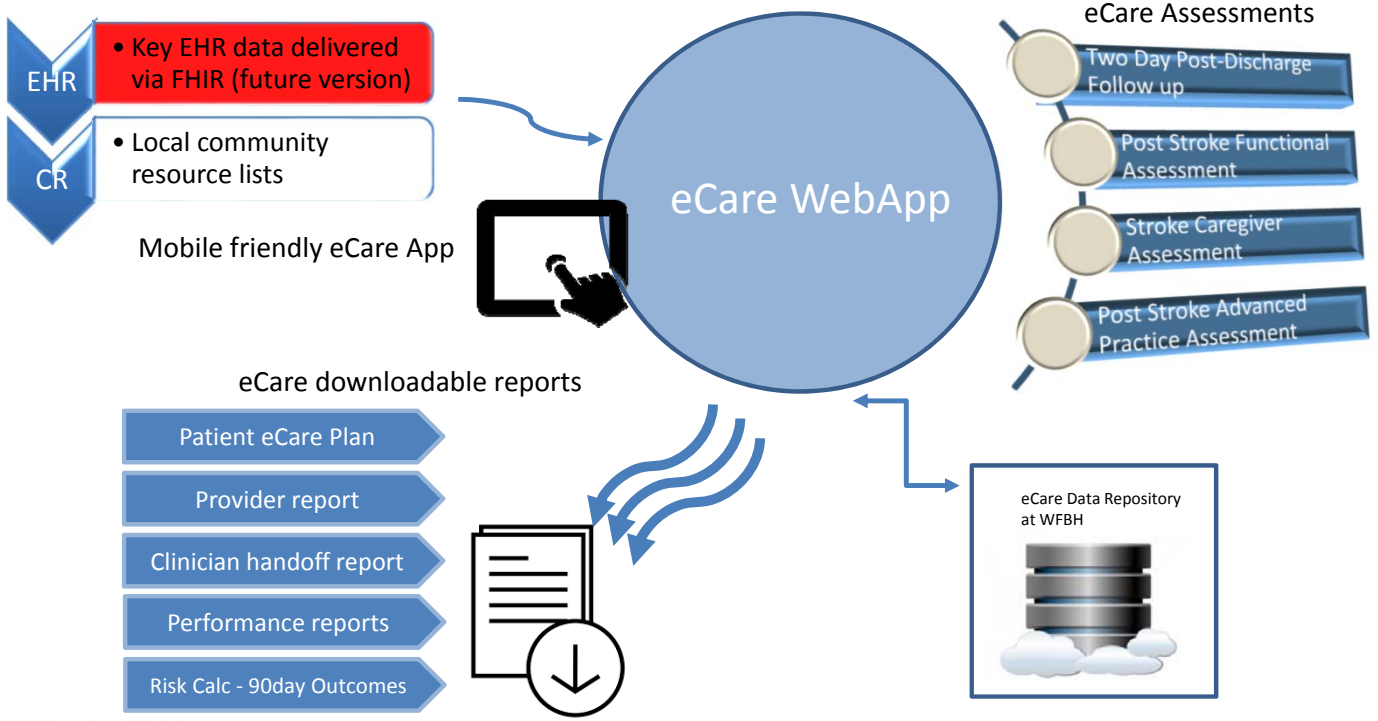

Patient Specific Care Plans

- 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

Medication Management Issues

If…..

- (MedDiff <=4) AND
- (MMAS2_SF = 0 OR 1) AND
- (MMAS1_SF = 0) AND
- (MedMng_SF = 1 OR -6) AND
- (Cogmed_SF = 1 OR -6) AND
- (Cogseq_SF = 1) AND
- (Cogdate_SF = 1 OR -6) AND
- (CogRcl_SF = 1 OR -6) AND
- (PurMed_SF = 1) AND
- (MedMny_SF =0)

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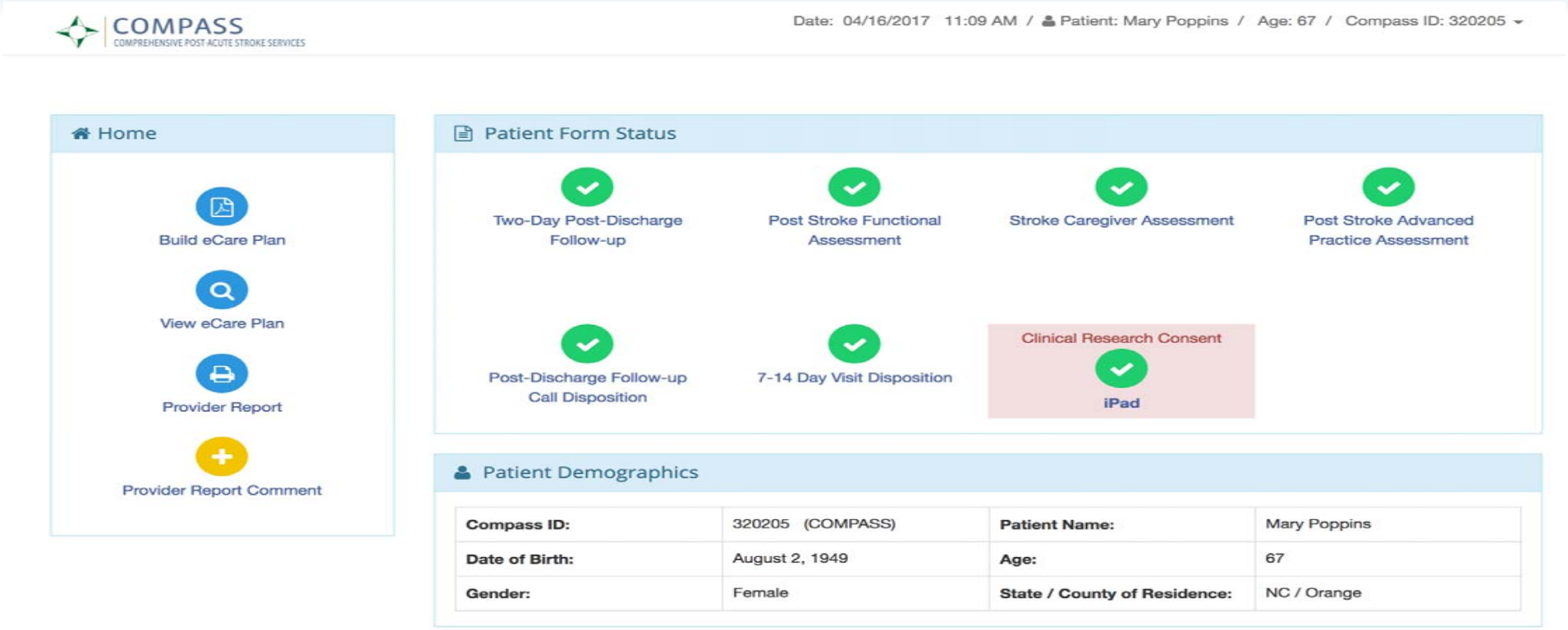
eCare App Patient Demo



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COMPASS: Finding my Way for Recovery, Independence, and Health

Name: Christina Condon ID: 7 January 19, 2016 Page 3

COMPASS COMPREHENSIVE POST-ACUTE STROKE SERVICES	What are my concerns?	Why is this important to me?	How do I find my way forward?
Engage: **Be engaged in my overall health and well-being** 	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

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Community Resources

Community Resources: Numbers

Piedmont Triad Regional Council Area Agency on Aging Extended Health Community Programs	
Organization and Program Information:	(336) 904-0300 1398 Carrollton Crossing Drive, Kernersville, NC 27284 http://www.ptrc.org/index.aspx?page=204
This program has a special referral process, please see website.	

NC DHHS Vocational Rehabilitation	
Organization and Program Information:	(919) 855-3500 101 Blair Drive Raleigh, NC 27603 https://www.ncdhhs.gov/divisions/dvrs/vr-local-offices
This program has special eligibility requirements, please see website.	

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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. Cryptogenic stroke w/high suspicion of hypercoag state (... admission, she had stroke symptoms during her GYN visit to evaluate "pelvic mass" w/hysterctomy. She did not make it to surgery and came ... occlusion to her left MCA and was treated with IV tPA (... w/OB/GYN regarding her bleeding and pelvic mass). Post tPA her stroke score was 0-1. Her main concerns today centered around why she was feeling ... improving, yet her heart was racing and she couldn't ...

"... her anxiety was significantly reduced and she trusted our plan of care along w/appreciating both of us helping her navigate the multitude

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. (%)

Medication Management	
> 5 medications/day	253 (74.0)
Low Adherence	74 (21.6)
Financial Challenges	75 (21.9)
Cognitive / Psychosocial Factors	
Cognitive Deficits	141 (41.2)
Depression	128 (37.4)
Social Isolation	29 (8.5)
Limited Social Support	86 (25.1)
Lack of Risk Factor Knowledge	
Blood Pressure	125 (36.5)
Smoking	247 (72.2)
Diabetes	271 (79.2)
Atrial Fibrillation	320 (93.6)
Heart Disease	304 (88.9)
High Cholesterol	195 (57.0)
Physical Inactivity	288 (84.2)
Healthcare Utilization	
No PCP	23 (6.7)
ED Visit in last 3 mos	63 (18.4)
Hospitalized in last 3 mos	37 (10.8)

Results (continued)

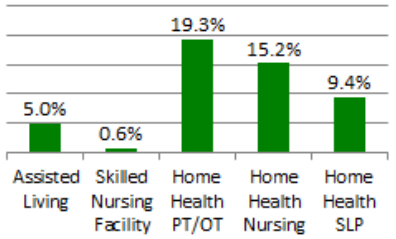
Table 1. (continued)

Functional Health	
Upper extremity difficulty	74 (21.6)
Spasticity	59 (17.3)
Physical mobility/safety	129 (37.7)
Poor/fair self-rated health *	75 (22.1)
Fall in the last 3 mos	80 (23.4)
ADL Limitations	83 (24.3)
IADL Limitations	59 (17.3)
Communication Deficits *	31 (9.8)
Caregiver Health *	
No Able/Willing Caregiver	25 (8.0)
Caregiver Stress	50 (30.7)
Caregiver Requires Help	18 (11.0)
Caregiver Health Limitations	28 (17.2)
Lifestyle Factors*	
Smoking	60 (19.0)
Alcohol Abuse	15 (4.7)
Recreational Drug Use	10 (3.2)
Physical Inactivity	147 (47.1)
Risk Factors *	
Systolic BP > 140	99 (31.3)
Diastolic BP > 90	23 (7.3)
LDL > 100	109 (50.7)
HgbA1c > 8.0	28 (20.7)

** Missing values excluded; Denominator <342*

Results (continued)

Figure 2. Selected eCOMPASS© Referrals, N=342



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.

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High User Satisfaction: 67% Very Satisfied

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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…

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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

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RVICES

A Tool for Clinical Trials : Assessment of Social and Functional Determinants of Health could support adherence for interventions (behavioral or medication)

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…

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

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

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More Information on eCOMPASS

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

- pduncan@wakehealth.edu

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- **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

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- Reference Slides

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COMPREHENSIVE POST-ACUTE STROKE SERVICES

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

Duncan, et al. Neurology 2003

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	Excellent	Very good	Good	Fair	Poor
Global 01	In general, would you say your health is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global 02	In general, would you say your quality of life is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global 03	In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global 04	In general, how would you rate your mental health, including your mood and your ability to think?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global 05	In general, how would you rate your satisfaction with your social activities and relationships?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global 09	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.)	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Completely	**Mostly**	**Moderately**	**A Little**	**Not At All**
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?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	In the past 7 days	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
Global 10	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		None	**Mild**	**Moderate**	**Severe**	**Very Severe**
Global 08	How would you rate your fatigue on average?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global 07	How would you rate your pain on average?	☐ 0 No Pain ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Worst Imaginable Pain				

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.

TOTALS	Raw Score	T-Score
Global Physical Health		
Global Mental Health		