Improving outcomes following hospital discharge: An RCT examining two patient-centered intervention models for acute stroke patients

Paul P. Freddolino, Ph.D.

Michigan State University (USA) and

PSSRU, London School of Economics

Bio Notes

- Michigan State University
  - Large (47,000), public, Research-intensive
- School of Social Work
  - Undergrad, master's, and doctoral programs
- My roles – Professor, Director of Distance Education and Technology, research on technology and services
- The Michigan Stroke Transitions Trial (MISTT) team
  - Interdisciplinary, full-time faculty researchers

Leadership Team - MSU

- Mathew Reeves BVSc, PhD, FAHA
  - Professor, Epidemiology
  - PI. Responsibilities: Project concept, design, oversight, conduct, analysis.

- Paul Freddolino, PhD
  - Professor, School of Social Work
  - Co-I. Responsibilities: Technology based Intervention

- Anne Hughes, PhD
  - Associate Professor, School of Social Work
  - Co-I. Responsibilities: SCM Intervention

Leadership Team - MSU

- Amanda Woodward, PhD.
  - Associate Professor, School of Social Work
  - Co-I. Responsibilities: Outcome measures, caregivers.
- Michele Fritz, LVT, MS.
  - Department of Epidemiology
  - Project Manager
  - Responsibilities: Project development, conduct, communication, administration, etc, etc.
- Others acknowledged below

AGENDA

- Background on stroke and transitions
- Unique funding source – PCORI
- Research design details
- Initial focus group data
- Web site development
- Immediate priorities
- Questions

Stroke Statistics

- In the UK, 152,000 annual incidents

- In the US, 795,000 annually

- Stroke is the **fourth** single largest cause of death in the UK and **second** in the world.

- In the UK there are approximately 1.2 m stroke survivors; in the US, 7 million +

- Stroke is a leading cause of serious long-term disability.

Stroke and Stroke Transitions

- Stroke is an acute onset unexpected event

- Average time in hospital is short

- 50% of patients are discharged home

- Another 25% return home after spending time in a rehab facility

- Wide variation in stroke severity and   pre-stroke function

- Typical stroke recovery period >100 days
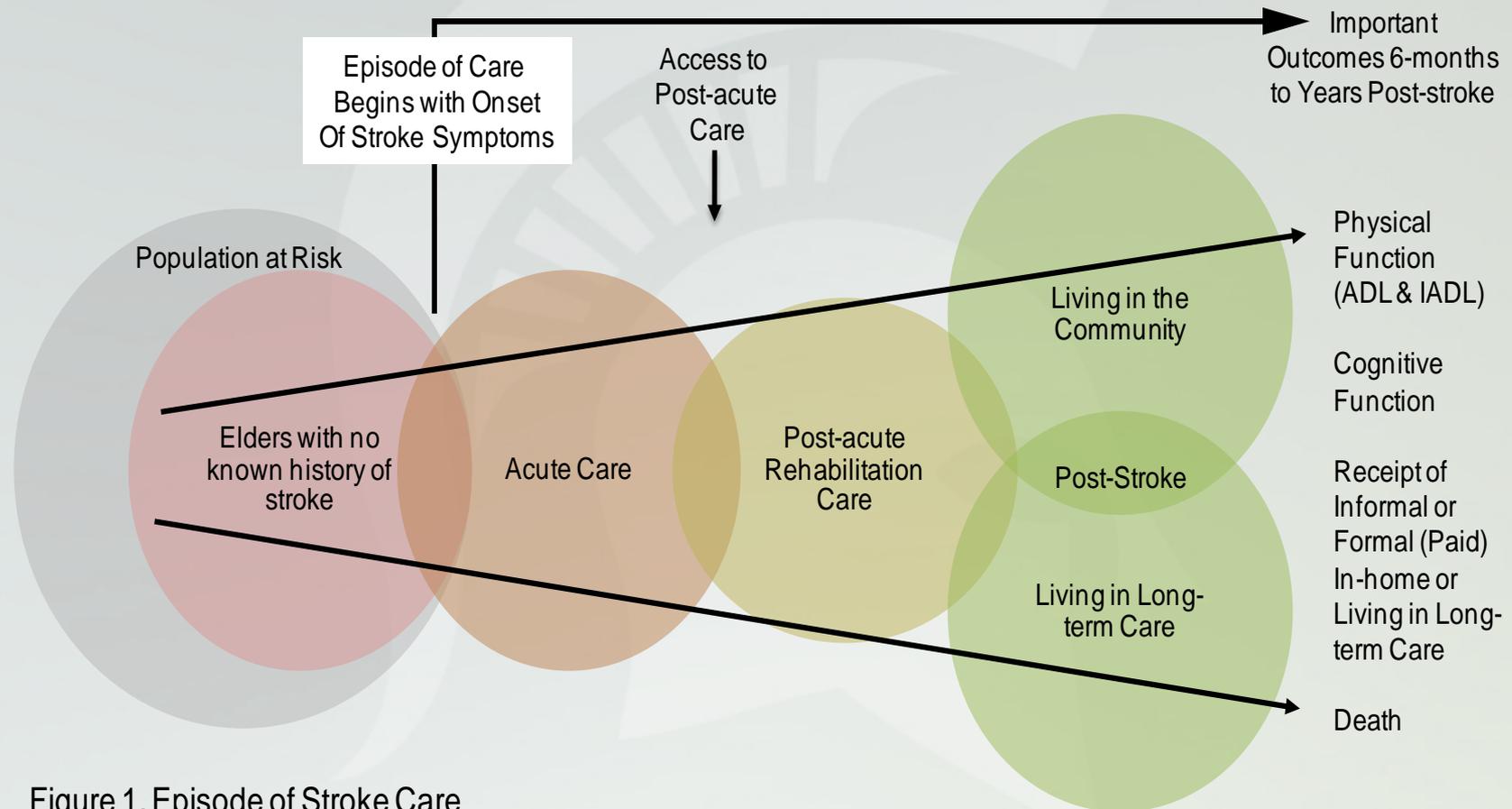
An Episode of Stroke Care......

Figure 1. Episode of Stroke Care
(Adapted *Patient-Focused Episodes of Care* Framework, National Quality Forum 2010)

Challenges of Hospital based Stroke Care

- Average hospital LOS is 4 days
- Stroke patients are in a "state of shock"
  - Post stroke stress disorder (PSSD)
- Little time to absorb information
- Patients and caregivers are not in the right frame of mind to absorb information
- Patients report receiving information but are not able to process it.
- They "*don't know what they don't know*"
- On returning home they can face many unexpected challenges

9

Critical Role of Transitions

- Studies in US show this is a time of great vulnerability across health conditions
- Several intervention models show positive results but no clear best/standard practice
- Recent N.I.C.E. report also found little conclusive evidence for a best practice, presented guidelines, and suggested areas for further research
- Minimal research involving stroke patients in transition

10

Our Proposed Solution

- Successful models generally included a coordinated case management program implemented by: Registered nurses, social workers, and community navigators

- Local experience with Community-based Care Transitions Program (CCTP)

- BRIDGE model (http://www.transitionalcare.org/the-bridge-model/)
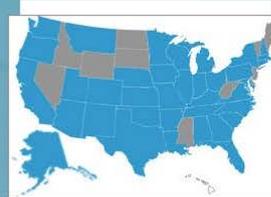
pcori.org

What is PCORI?

- **Patient-Centered Outcomes Research Institute**
- www.pcori.org
- Funded as part of the **Affordable Care Act**, but not a federal agency
- Focus of PCORI is **patient-centered care** and **shared decision making**
- Overall goal is to have greater involvement of patients and caregivers in common and important clinical decisions

PCORI: Focus on patient engagement
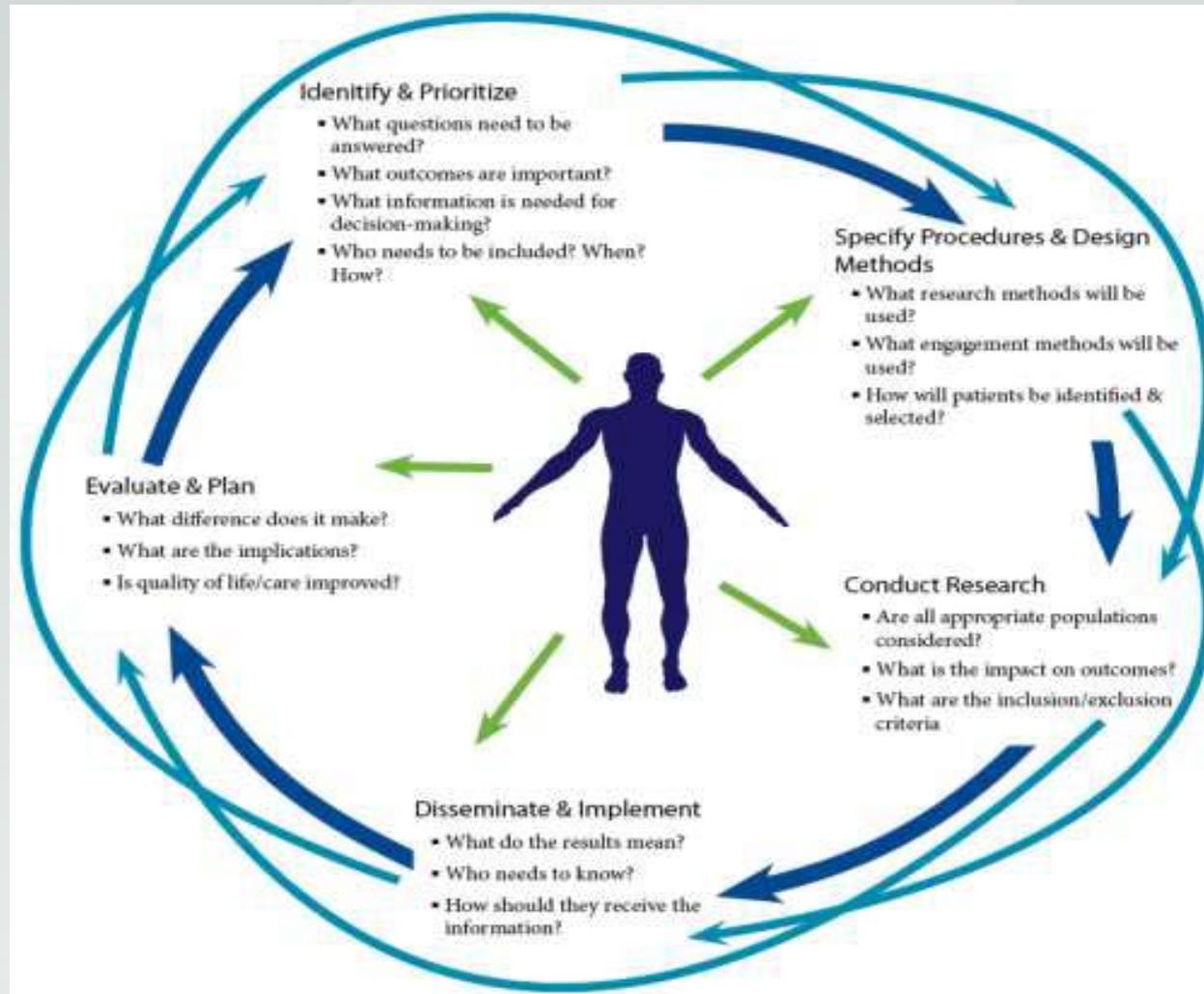
PCORI definition of Patient-centered Outcomes Research (PCOR)

- **Research needs to answer 4 key patient-centered questions:**

  - "Given my personal characteristics, conditions and preferences, what should I expect will happen to me?"
  - "What are my options and what are the potential benefits and harms of those options?"
  - "What can I do to improve the outcomes that are most important to me?"
  - "How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"

15

PCORI Funding Announcement: Improving Healthcare Systems

- PCORI seeks research comparing *the effectiveness of alternate features of healthcare systems* that:
  - compares alternative system-level approaches to improving patients' access to care; receipt of appropriate evidence-based care; quality of care; decision-making based on personal values; and self-care.
  - *compares alternative models of care delivery and approaches to coordination of care across healthcare settings, especially for patients with complex, chronic, and/or multiple conditions. The emphasis is on comparing alternate approaches' effects on patients and their caregivers in ways that they think are important.*
  - compares alternative system-level approaches that aim to improve the efficiency of healthcare delivery.
- Awarded 3-year $1.5 million grant, beginning October 2014

Aim 1: Stakeholder Panels

- "*Stakeholder groups **must** be fully involved in design, planning, implementation, and dissemination of study results*".

- Assemble two panels:

    - **recent stroke survivors and their caregivers**

    - **health care providers** (i.e., nurses, therapists, social workers, discharge planners, physiatrists, neurologists)

- Goal: to identify **informational needs, preferences, and patient-oriented outcomes** of stroke patients and their caregivers relevant to the transitional care period. [Timeline: 1-6 months]

Aim 2: To incorporate the experiences, needs, and preferences of stroke survivors and caregivers into the design of an intervention

- 1) *Social Work Case Managers* **(SWCM)** program that includes home visits and telephone follow-up over a 60-day period following return to home; based on the Bridge Model

- 2) **V***irtual Stroke Support Portal* **(VSSP)** - a patient-centered online communication, information and support resource (a.k.a. **the** *Website*) [Timeline to develop: months 6 – 12]

The VSSP (Study Website)
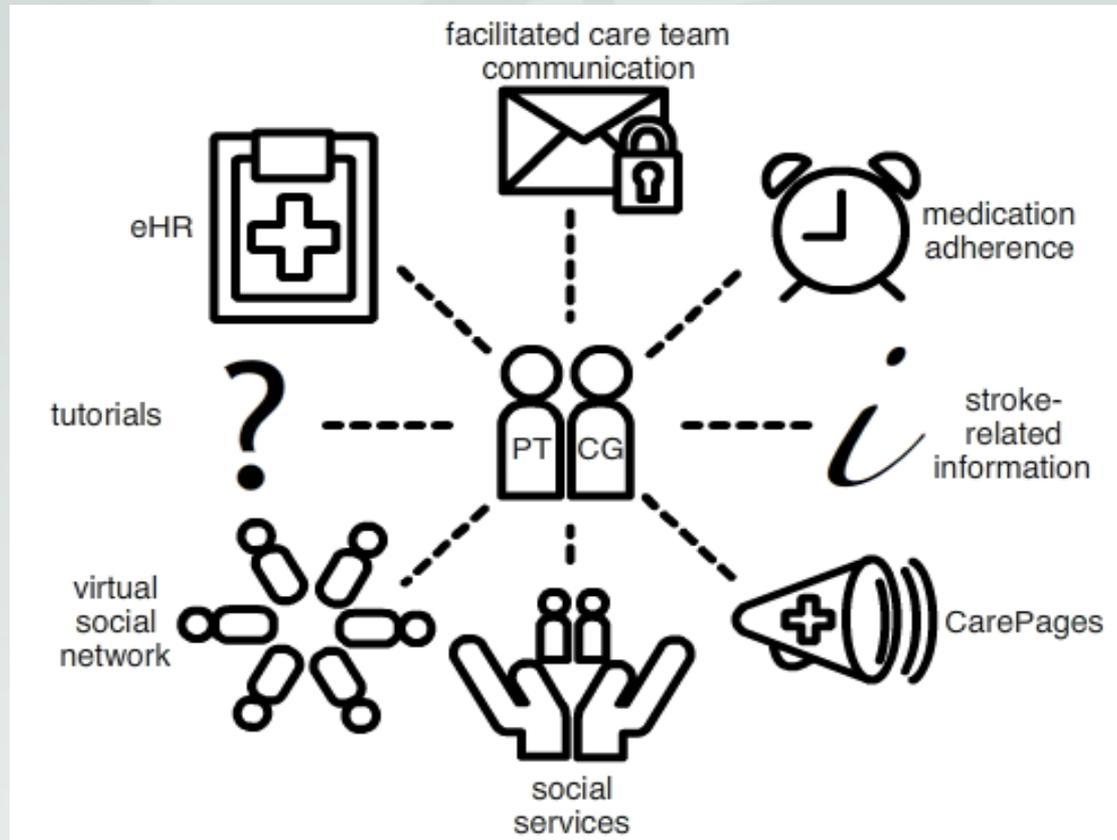
Aim 3: The Intervention (RCT)

- Test the two complementary interventions against usual care by enrolling 480 acute stroke patients discharged from 4 Michigan hospitals in a **pragmatic, randomized, open clinical trial**.

- The 3 group parallel design will compare:
  - Usual care.
  - Social Work Case Manager (SWCM) program **only**.
  - Social Work Case Manager (SWCM) program, **plus** the Virtual Stroke Support Portal (VSSP) (Website).

- 4 Hospitals (Ingham and Washtenaw counties) [Timeline for intervention: months 15 – 36]

Trial Inclusion Criteria

- Acute ischemic or hemorrhagic stroke
- Adult, living at home prior to stroke
- Must have stroke symptoms on presentation (NIH Stroke Scale >= 1).
- Must have moderate disability at discharge (modified Rankin Scale >=1).
- Discharged home, OR
- If discharged to a rehabilitation facility (Inpatient Rehab Facility or Skilled Nursing Facility) then must have expectation of return to home within 4 weeks.
- Will use proxy respondent if patient consent not possible (e.g., aphasic, cognitive impaired)

Trial Exclusion Criteria

- Live > 50 miles from the hospital (home visits).

- Discharged to hospice care, nursing home for long term care, or long term care hospital.

- No proxy respondent available(aphasic, mci).

- Fail cognitive screening (Abbreviated Mental Test Score (AMTS) score <=6) and no proxy respondent.

- Enrolled in another acute stroke intervention trial that has impact on the post-acute period (i.e., intensive data collection required of patient during follow-up).

- Limited life expectancy (< 6 months) or significant medical comorbidity likely to impact completion of the study (e.g., mental illness, drug/alcohol abuse).

- Does not speak English.

Caregiver Eligibility

- ## Inclusion Criteria
  - Any person identified by the stroke patient as the primary caregiver
    - Individual primarily responsible for assisting with the patient's care
  - Patient has consented
 - Age 18 or over
- ## Exclusion Criteria
  - Does not speak English

Focus Groups – Major Themes

- Unprepared for discharge home
- Understanding medications
- Concern about stroke recurrence
- What caused me to have a stroke? How do I prevent a second stroke?
- Caregiver stress
- Need to access reliable information

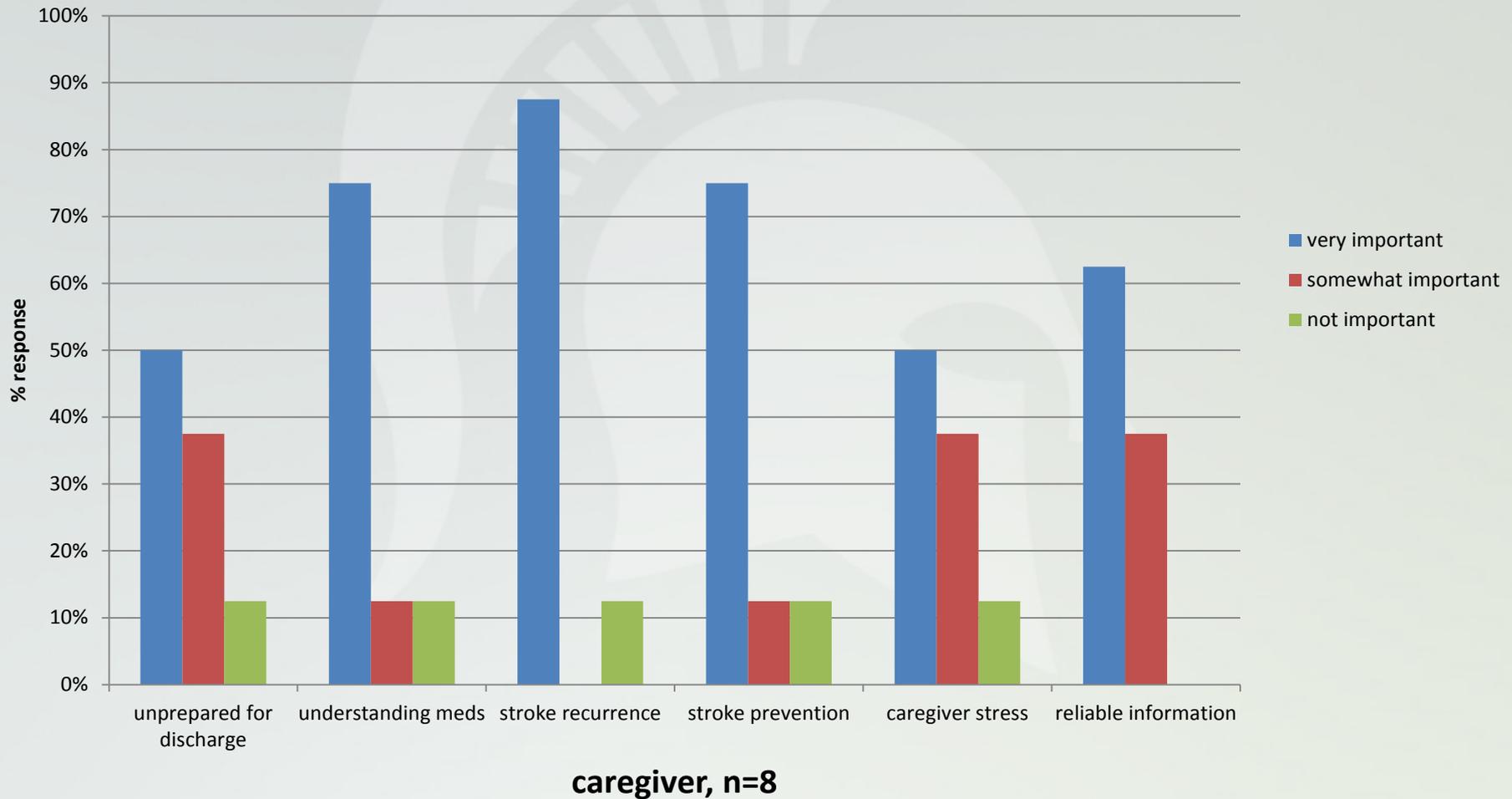# **Patient** Themes of Concern during transition home

Rate the importance of each transition Theme of Concern
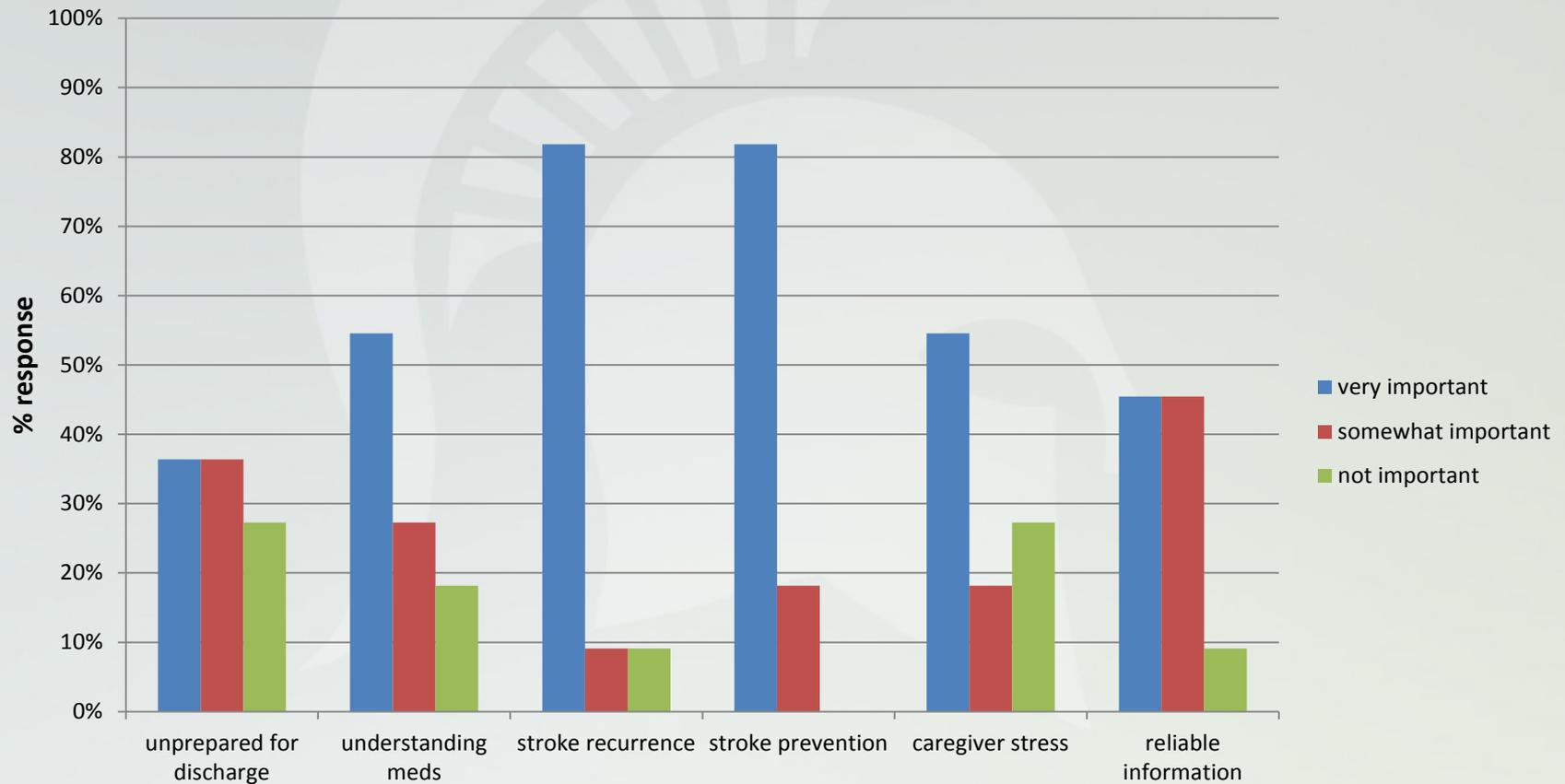
patient, n=11

Caregiver Themes of Concern
during transition home

Rate the importance of each Transition Theme of Concern

caregiver, n=8

Measuring stroke transitions

Satisfaction with care after return home

Quality of life

Stress

Ability to look after your own affairs

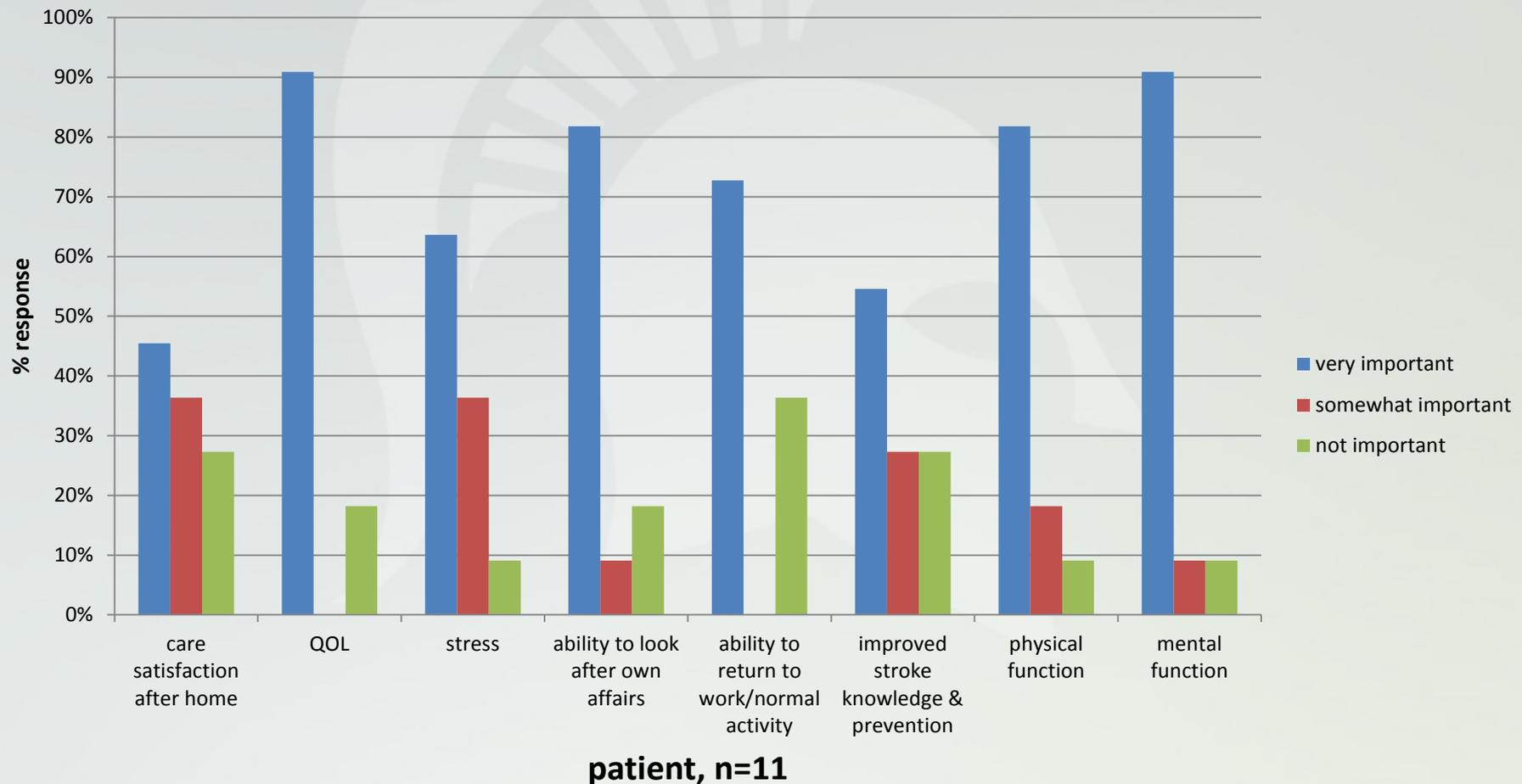**Ability to return to work/normal activities**

Improved knowledge about stroke/prevention

Physical function e.g., walking, ability to dress/toilet

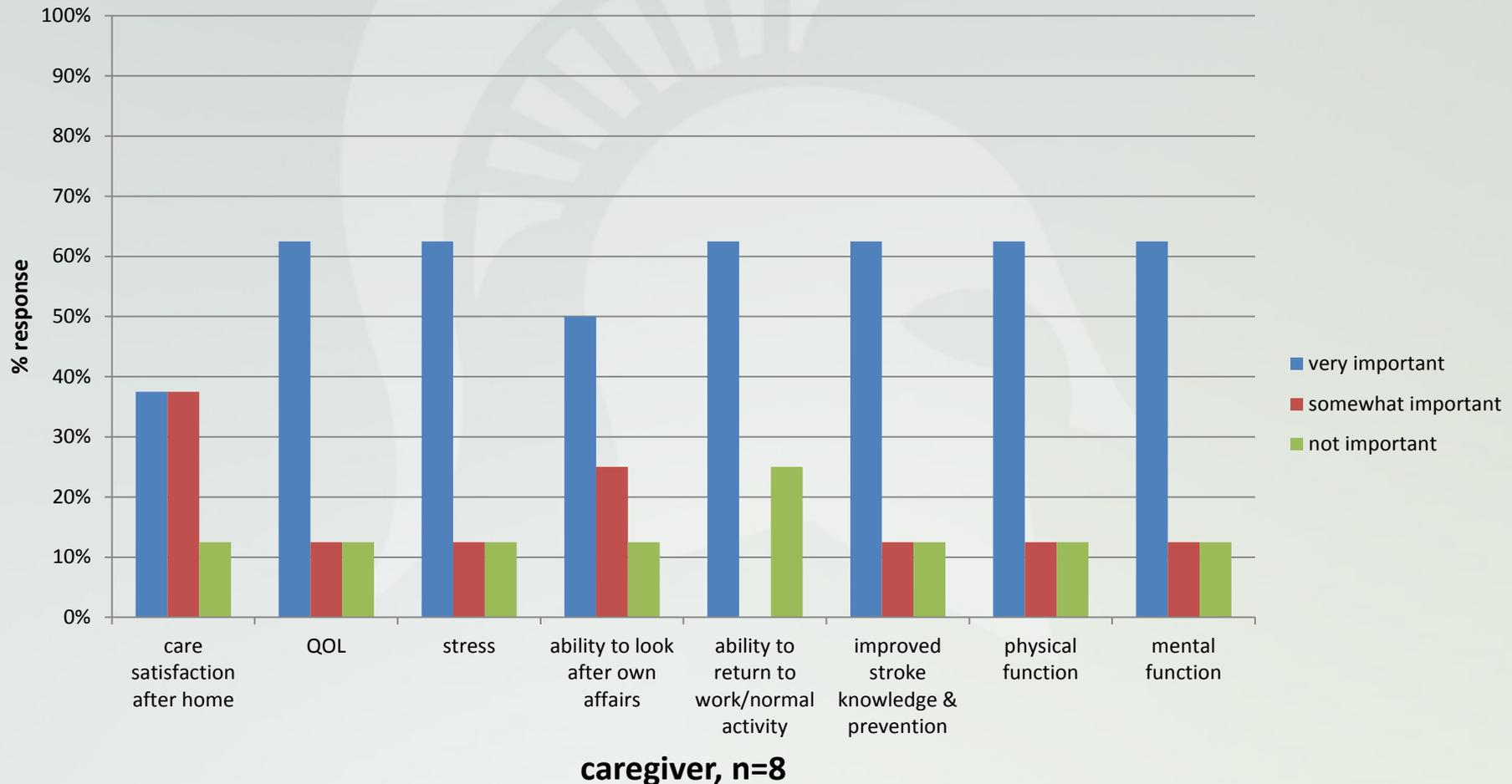**Mental function e.g., ability to think, good memory, not depressed**

Patient Importance of <u>Measures</u> during the transition period

Rate the 8 <u>Measures</u> in terms of their importance during the transition period

patient, n=11

Caregiver Importance of <u>Measures</u> during the transition period

Trial Outcomes

- Informed by the stakeholder focus groups.
- Measured by telephone at 7 and 90-days.

- <u>Primary Patient Outcomes</u>:
  - Patient Activation Measure (PAM)
  - PROMIS Global10 QOL scale

- <u>Secondary/Intermediate Patient Outcomes</u>:
  - PROMIS QOL self-efficacy scales (emotions, daily activities, social engagement, medication management)
  - PROMIS QOL support measures (informational, emotional, and instrumental).
  - Neuro QOL measures (anxiety)
  - Home time, stroke knowledge, hospital/ED visits, stroke recurrence.

30

Other Trial Measures

- Measured at baseline (hospital), and by telephone at 7 and 90-days.

- <u>Effect Modifiers/Sub-group Analyses</u>:
  - Demographics, hospital site
  - Stroke type, severity and disability (modified Rankin Scale [mRS].
  - Barthel Index [BI], ADL and IADL limitations, depression, Morisky, CTM-15, MoCA cognitive screen
  - Neuro QOL measures (communication, behav dyscontrol)
  - Technology aptitude measures

- <u>Caregiver Outcomes</u>:
  - Caregiver Strain index, Preparedness for Caregiving, mood, stroke knowledge, satisfaction, Dyad relationship scale.
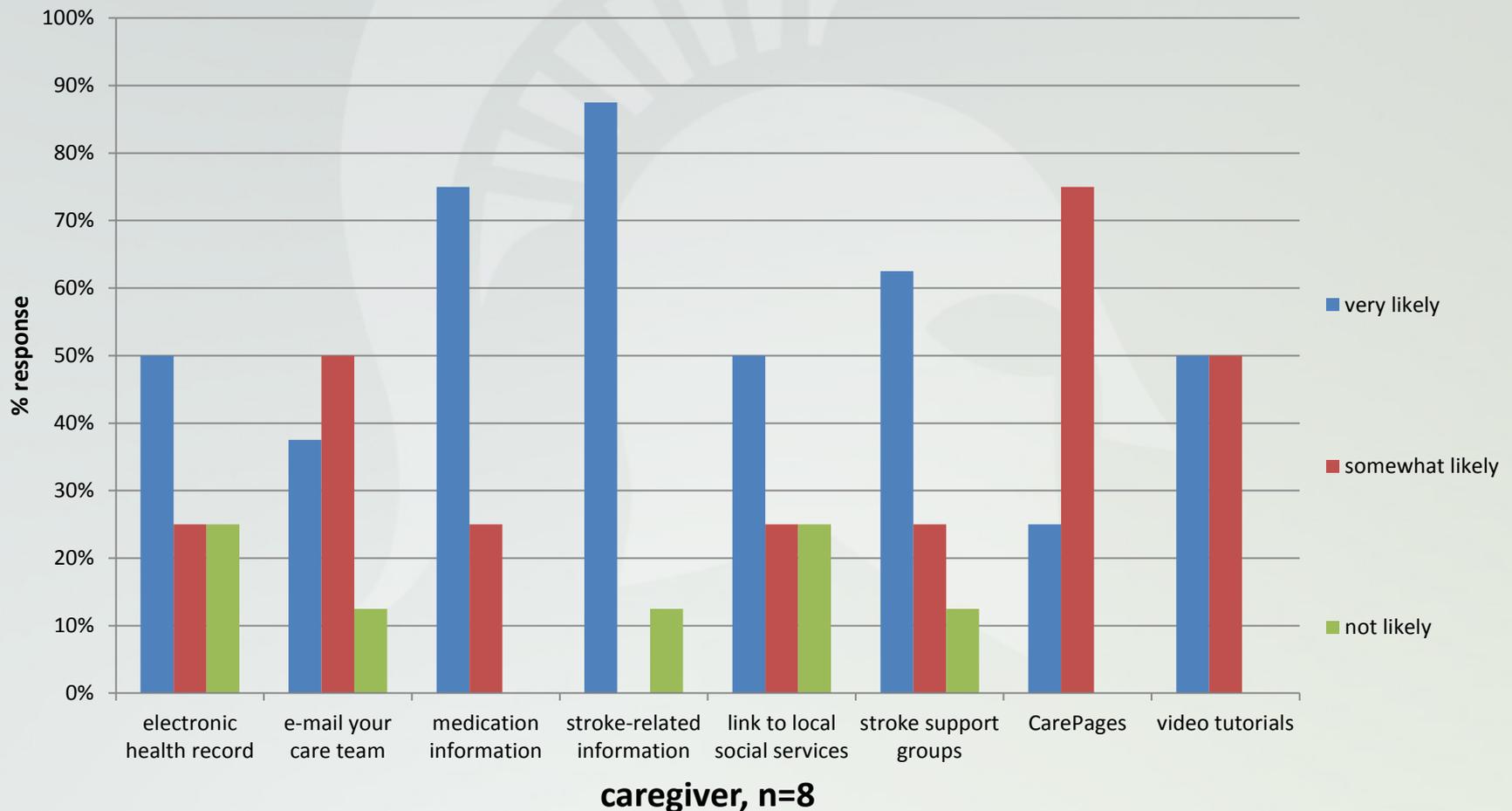
The VSSP (Study Website)
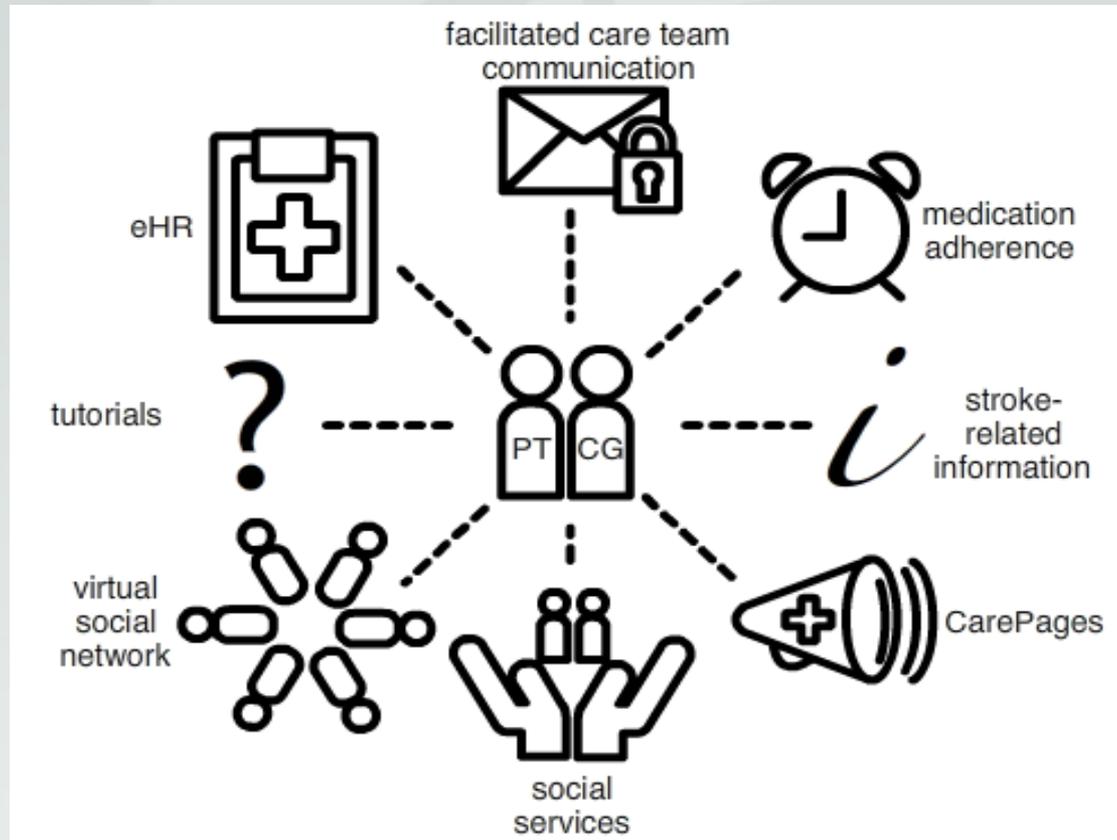
Patient Likelihood to use VSSP Components

Rate how likely you are to use each Online Resource

patient, n=11
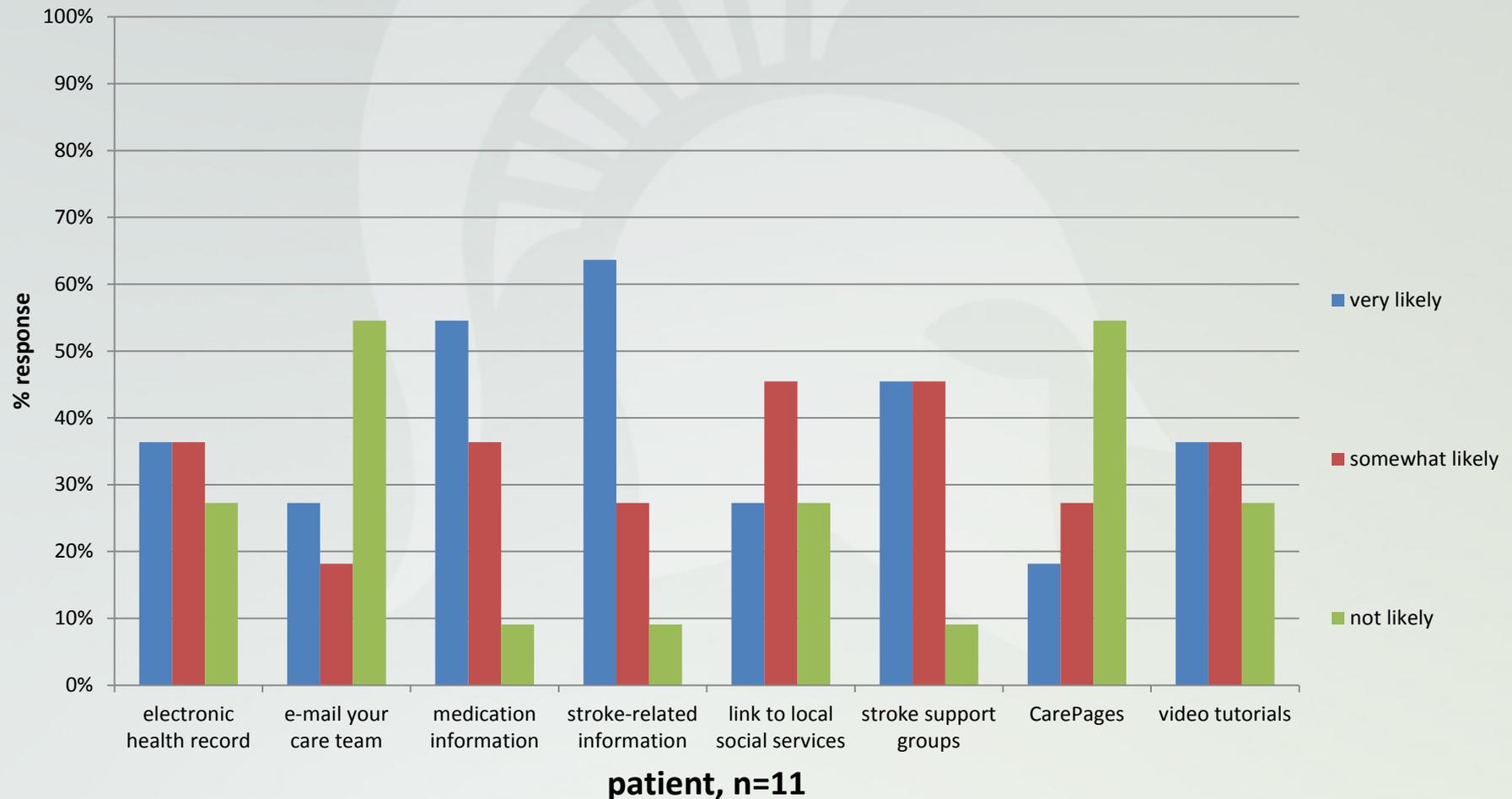
Caregiver Likelihood to use
VSSP Components

Rate how likely you are to use each Online Resource

caregiver, n=8

Challenges to tech solutions

- Cognitive challenges – brain fog, retention
- Physical challenges – manipulating the technology tools
- Skeptical attitudes – usefulness and value
- Privacy and security concerns
- Difficulties learning new technology without help

Web site development

- The current site – mistt.msu.edu

- Usability assessment – patients and caregivers – important feedback

  - Content must be simplified – common language, shorter sentences

  - Navigation in the site must be simpler

  - Improve or drop the 'search' function in the site

  - External links must be easier to distinguish

  - Pop-up warning about an external site is confusing

  - Navigation tools need refinement

Case management intervention

- Engagement
- Assessment
- Service planning
- Patient/caregiver education
- Short-term problem-solving
- Monitoring, follow-up, termination
- Documentation

Key difference between conditions

In case-management only group, discussions about technology must be initiated by patient or caregiver; e.g.:

- Is there information online that I can get in addition to these printed brochures?

- At the hospital they mentioned a patient portal. Can you help us sign up to that?

NO MENTION OF THE MISTT WEB SITE

Tech lessons learned already

- Adequate resources are needed
  - Tech tools take more time and cost more than you may have budgeted
- Locate the right experts
  - Not every university has what you need
  - Website developers, health communicators
- Don't let the perfect become the enemy of the good
  - Perfect will not necessarily be used more!

Immediate Priorities

- IRB (ethics) applications:
    - Two hospitals approved, two more in process
- Finalize the MISTT web page
    - Improvements based on usability testing
- Pilot Phase (in progress):
    - Enroll 20 patients at Sparrow hospital
    - Test case enrollment processes, SCM home visits, data collection, website access
- Launch in January

Social Workers/ Stroke Case Managers

LANSING AREA (1.5 FTE)

- Kristen Boeskool, MSW

- Deborah Montgomery, MSW

ANN ARBOR AREA (1.5 FTE)

- Ann Ripberger, MSW

- TBH

Other Personnel - MSU

- IT Support / Website Development
  - Nate Lounds
  - Joe Fitzgerald
    - Development, testing, maintenance of the website (VSSP portal)

- Usability/Accessibility Research and Consulting (UARC)
  - Sarah Swierenga
    - Website usability testing

- Constantinos Coursaris, PhD.
  - Associate Professor, Department of Media and Information
  - Co-I Responsibilities: Dissemination (Year 3)

- BRIC (Data System)
  - Nicole Jones, PhD

Key Personnel – Off Campus

- UofM
  - Lynda Lisabeth, PhD, SPH
    - Epidemiologist with interest in stroke and stroke care/outcomes
    - Site coordinator for UofM Hospital and AA activities
- MGH (Boston)
  - Lee Schwamm, MD, Department of Neurology
    - Clinical stroke neurologist, patient outcomes
    - Primary clinical consultant, interpreting focus group data, defining outcome measures

43

Other Key Personnel

- Four Hospitals
  - Stroke Coordinators at Sparrow, McLaren, U of M, St. Joseph Ann Arbor.
- BRIC (Data System)
  - Nicole Jones
- Project assistant (SSW)
  - Shelby Yeary
  - Daniel Cavanaugh
- Two data collectors (Epi)
  - TBN

Other Important Groups

- **Patient and Professional Healthcare Stakeholder groups (Lansing, AA)**
  - **10 Focus Groups (Year 1)**

- **Patient-Professional Advisory Panel**
  - **Years 2 and 3**

- **Capital Area Collaborative for Care Transitions (CACCT) – Susan Powell, Stephanie Ware, Carlton Nogle.**

Funding Notes

Questions?

paulfredd@gmail.com