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Overcoming Practical Challenges to Conducting Clinical Research in the Inpatient Stroke Rehabilitation Setting

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Abstract

There is a shortage of published empirical studies conducted in acute inpatient stroke rehabilitation, though such studies are greatly needed in order to shed light on the most efficacious inpatient stroke rehabilitation interventions. The inherent challenges of inpatient research may dissuade researchers from undertaking this important work. This paper describes our institution's experience devising practical solutions to research barriers in this setting. Our efforts facilitated five simultaneous inpatient stroke rehabilitation studies, and led to several benefits, including increased effectiveness of research participant identification and enrollment, novel collaborative projects, innovative clinical care initiatives, and enhanced emotional and practical support for patients and their families. We provide recommendations based on lessons learned during our experience, and discuss benefits of this collaboration for our research participants, clinical staff, and the research team.

Keywords

Stroke; Rehabilitation; Research Design

Of the nearly 800,000 Americans experiencing a new or recurrent stroke annually, approximately 60% will survive;[1] three-fourths of survivors will enter inpatient rehabilitation. Early, intensive inpatient rehabilitation is associated with improved functional outcomes[2,3] after stroke, but there have been few trials to identify the most efficacious inpatient rehabilitation interventions.[4,5] More clinical studies are needed[6,7] to decipher the "black box" of inpatient stroke rehabilitation.[4,6–8]

The shortage of inpatient stroke rehabilitation literature may stem from practical challenges inherent to this setting.[9] For example, cognitive impairments among nearly 50% of post-stroke patients [10–13] and communication impairments among 30% or more of stroke survivors[14,15] can decrease enrollment by making obtaining informed consent difficult.

Diminished physical or emotional tolerance after neurological injury[16] can also decrease research participation, especially if studies are perceived to be intense or lengthy.

Other considerations impeding inpatient research include conflicting clinical staff priorities and institutional or regulatory constraints. Conquering these challenges requires creative solutions. Inpatient stroke research challenges and possible practical solutions have not been well documented in the literature. This paper describes our experience overcoming practical and methodological challenges in designing and conducting inpatient stroke rehabilitation clinical trials, and highlights unanticipated benefits that occurred through resolving identified challenges.

Setting

Studies informing this paper were conducted on the inpatient stroke rehabilitation service of a large, university-affiliated hospital system in western Pennsylvania. The UPMC Rehabilitation Institute (RI) is an academic-practice partnership between the University of Pittsburgh Schools of the Health Sciences and the post-acute care services of UPMC Health System, comprising 10 inpatient rehabilitation units at seven hospitals, and a network of outpatient rehabilitation clinics. Stroke is the largest diagnostic group at RI. The RI accommodates interdisciplinary research supporting advanced, evidence-based care for persons requiring physical rehabilitation services.

The therapeutic day at the RI stroke unit begins at 7 am and lasts into the evening. Daily patient activities include direct care; patient-caregiver teaching; supervised therapeutic meals; 3 to 5 hours of physical, occupational, and speech therapy; stroke education classes; sessions with psychologists, orthotists/prosthotists, and case managers; and physician rounds. Evenings include direct care, patient/caregiver teaching, reinforcement and carryover of skills acquired in therapy, community reintegration events, and diversional activities.

Studies

All studies informing this paper (Table 1) were approved by the University of Pittsburgh Institutional Review Board (IRB). Decisionally capable participants provided written informed consent; decisionally impaired individuals provided assent and a participant-designated proxy provided written consent. Studies occurred concurrently, utilizing shared recruitment and data collection resources and a collaborative recruitment strategy that matched patients to all studies for which they were eligible.

Challenges

Our experience with recruitment and retention challenges secondary to impaired cognition and communication is similar to that of other researchers.[13,16,17] We encountered additional practical challenges that may influence study implementation as well as reliability and validity of research data. These challenges include patient/caregiver considerations, clinical staff priorities, and institutional and regulatory constraints.

Patient/Caregiver Considerations

Common stroke-related sequelae such as aphasia, fatigue, and caregiver protectiveness can impede full engagement in research participation and decrease the reliability and validity of research assessments.

Aphasia—In addition to difficulty ensuring truly informed consent,[16,18] aphasia may limit participants' ability to accurately complete research assessments that depend on intact verbal skills.[19,20] Inaccurate assessment findings can obscure distinctions between communication deficits and true cognitive dysfunction when interpreting research findings, so patients with aphasia are often excluded from research. Initially, we excluded a high proportion of patients using our initial language screening (the Boston Naming Test), even though clinicians and research team members had observed several excluded patients using basic functional language skills sufficient to permit research participation. After consulting with our research neuropsychologist, we adopted the repetition task of the Boston Diagnostic Aphasia Exam to better identify persons with intact functional communication. This change improved recruitment, although our final exclusion rate due to language deficits remained 30%, mirroring the aphasia prevalence in stroke.[14,15]

Physical and emotional fatigue—Physical fatigue after stroke is prevalent, not well understood,[21–23] and associated with diminished participation in rehabilitation.[24] In our experience, some patients perceived research participation as an undesirable energy demand. Fatigue sometimes prompted poor research engagement, incomplete research sessions, or withdrawal from participation. Emotional fatigue, expressed by patients as feeling stressed, worried, or overwhelmed, may have also deterred research participation. Despite valuing research, some patients felt that research participation would be an additional obligation and verbalized feeling unable to "take on one more thing."

Caregiver protectiveness—Families, friends, and significant others exhibited extraordinary protectiveness regarding patients' health and emotional well-being, serving as gatekeepers for the recruitment process. Consistent with the literature,[16] some families felt that research participation would be overwhelming, tiring, or frustrating for their loved one. In contrast, some families actively encouraged patients to participate, especially with intervention studies, citing the possibility of assignment to the intervention group.

Clinical Staff Priorities

With their primary focus on providing care in an increasingly complex environment, clinical staff may lack investment in research. Inpatient rehabilitation units' therapy schedules are full, with little latitude for participants or clinicians to participate in research activities. Some clinicians may perceive that research activities hinder patient care routines, and may resent researchers' presence on the unit. Some staff may be interested in research but have little time to participate because of full patient treatment schedules. Clinical staff may also misunderstand the goals of research or believe that it lacks direct benefit to their clinical practice, and may actively discourage patients from research participation. In our experience, though many staff welcomed our presence on the unit, some initially felt that research was an unnecessary patient burden and perceived few practice benefits of research.

A few actively discouraged patients' participation until the research team became integrated with the unit.

Institutional/Regulatory Constraints

Research barriers may occur because of inherent institutional or regulatory constraints. The environmental and space restrictions common in most hospitals, and the increasingly complex regulations with which rehabilitation facilities must comply are two potential deterrents to research.

Lack of privacy/space—Lack of privacy and inadequate on-unit space for research activities is common in inpatient rehabilitation. In our experience, lack of privacy interfered with accurate completion of research testing. Semi-private patient rooms allowed interruption by hospital staff and visitors; roommates' visitors or personal care needs also contributed distraction. Conference room space is often limited, as all available space may be in use for therapeutic activities. At the RI, unit lounges are used for therapy treatments (to practice mobility in a homelike setting or to perform kitchen skills); unit conference rooms are occupied for shift report, team conferences, low stimulation treatment, or family meetings. An alternative is transporting research participants to off-unit conference rooms, wasting valuable time.

Changing rehabilitation admissions regulations—Recent federal regulations[26] that tighten rehabilitation admission and reimbursement policies may decrease the number of potential participants and allow little time for patient-related research activities. Current admissions guidelines[26] have narrowed the available pool of research subjects by excluding persons at either end of the functional spectrum. Severely compromised patients unable to tolerate three or more hours of therapy daily and persons with minor impairment who fail strict 'medical necessity' criteria embraced by payors may no longer qualify for coverage of inpatient rehabilitation services.

Daily therapy requirements—Stringent regulations dictate inpatient rehabilitation daily therapy requirements. Patients must receive at least 180 minutes of skilled therapy services for five consecutive days out of seven during rehabilitation for insurance to accept and reimburse the claim. Pressure on clinical staff to meet these regulations intensifies the logistical challenges of scheduling research sessions. Regulatory demands for therapy intensity and duration may also contribute to the confounding effect of fatigue on cognitive testing.[20]

Practical Solutions to Identified Research Challenges

The practical research challenges we encountered are not unique; constraints we describe could be expected in most inpatient stroke rehabilitation programs in the United States. Challenges may stem from stakeholders' concerns that research conflicts with their own needs and priorities. For example, our patients and their family caregivers were concerned that research participation would be physically and emotionally taxing or would interfere with their rehabilitation care. Clinicians were concerned that research activities would interfere with patient care, causing additional patient burden more work for clinicians.

Hospital administration needed assurance that the current standard of care would be met for all patients regardless of research participation, and that all legislative and accreditation requirements were met. Below, we summarize global solutions that addressed multiple challenges and concerns simultaneously. Selected specific strategies we implemented to achieve these global solutions are provided in Table 2.

Cultivating collaborative relationships

Clinicians and researchers may pursue disparate goals within the same physical space. We focused on partnering with the clinical team to develop collaborative relationships built on mutual respect while cultivating shared goals. To demonstrate that patient care was our ultimate concern, we became a nearly constant presence on the unit, immersing ourselves in unit procedures and routines. We were careful to avoid intruding on clinical care, and approached staff respectfully and conveyed that we wanted to learn from them. We helped unit staff when appropriate (e.g., transporting patients). We also provided periodic “research update” sessions where we shared study progress and sought clinicians’ feedback about our processes. As our understanding of the multiple demands faced by patients and clinicians increased, we refined our research procedures to accommodate the clinical team’s concerns. Such practices meant that we invested time in non-research activities, but this investment quickly brought rewards as we became incorporated into the stroke clinical team. Prioritizing both research and clinical goals quickly became part of the unit climate.

Scheduling

Cultivating trusting, collaborative relationships facilitated dynamic scheduling, which solved multiple research challenges including patient fatigue, privacy concerns, and concerns about meeting daily therapy minutes regulations. Once administration and clinicians trusted our desire to prioritize clinical care, clinical supervisors provided access to the clinical team’s daily scheduling meetings. As collaborative relationships grew, clinical staff began to voluntarily seek out researchers for scheduling concerns and to alert researchers to changes in patients’ condition that might impact our research assessments. Patients also participated in the scheduling process; patient preferences for research and clinical scheduling were discussed during daily scheduling meetings. The research team never exceeded our allotted time, encouraged patients’ attendance at therapy, and ensured that patients arrived at therapy as scheduled. Clinicians in turn respected and safeguarded scheduled research sessions, ensuring that personal care needs were met prior to research activities and closing patients’ room doors to minimize interruptions. Clinicians began to reassure patients and their families that fatigue could be managed and would not preclude research participation, and that research activities could be paced or rescheduled according to patients’ needs.

Capitalizing on unanticipated benefits

Identifying and developing unanticipated opportunities for mutual benefit also addressed multiple challenges. We identified collateral benefits to research participation for clinicians and patients and actively highlighted them when interacting with clinicians, administrators, and patients, to further establish ourselves as a positive presence on the unit.

Participant benefits—Though we could not guarantee direct benefits of research participation, several indirect benefits proved attractive to many participants. For example, several studies included post-discharge follow-up for up to six months. The additional in-home clinical monitoring after inpatient discharge was appealing to many participants and caregivers, as well as to the clinical team. Our study team identified several acute medical or psychiatric illnesses during research follow-up visits and intervened to obtain needed care. We linked several participants with supplementary services such as vestibular rehabilitation, driving rehabilitation, and rehabilitation engineering when those needs arose during research follow up after inpatient discharge.

Clinician benefits—Benefits to RI clinicians spurred their investment in research. Clinical staff can be wary of research due to perceived study burden, lack of time, and lack of understanding or interest in the research.[27] To minimize these perceptions, we met with staff prior to finalizing our study designs to ascertain their interests and incorporate their ideas when scientifically appropriate. We provided expert consultation on difficult treatment issues such as post-stroke depression, hemineglect, and falls. We provided formal and informal staff education sessions and hosted journal clubs to share evidence that informed clinicians' practice, and we regularly presented at RI interdisciplinary continuing education events that typically attracted more than 100 clinicians each month. Our team mentored clinical staff to begin grant-funded research or evidence-based practice initiatives that resulted in meaningful clinical practice changes and several co-authored publications. In accordance with our IRB's policies, we helped to streamline clinical care by sharing our neuropsychological research test results with the clinical neuropsychologists, thereby avoiding the time, expense, and practice effects of repeat testing. Some of these individuals thus received additional neuropsychiatric assessments that they would not have originally had, often resulting in referrals for additional services as pre-morbid behavioral health and substance abuse issues were identified. The research team also was able to facilitate improved clinical care in numerous instances, through our regular communication of patient problems and concerns to the team.

Research team benefits—As clinicians' regard for research grew, they began to identify potential participants and sought out study team members to make referrals. Clinicians also offered us their opinions regarding when potentially eligible patients were accustomed to the demands of rehabilitation, or had sufficiently improved functional communication who might be approached about opportunities for research participation. Clinicians offered valuable perspectives to investigators regarding variables of interest and operational considerations of conducting our studies in their facility. Moreover, immersion in the clinical rehabilitation environment enriched our understanding of issues facing people with stroke, especially during the early phases of adjustment and recovery.

Discussion

Overcoming the practical challenges inherent in integrating research with clinical care can enrich both activities. Benefits that may accrue to the clinical team include the availability of additional monitoring of study participants with complex medical needs and access to the research team's expertise for education and consultation. Researchers benefit from ongoing

exposure to the 'lived experience' of patients and clinical staff, allowing improvement of research content and methodologies. Researchers also benefit from the clinical staff's enthusiasm about research, which can encourage patients to consider research participation and facilitate obtaining informed consent and ongoing assent. Patients may ultimately benefit from future translation of evidence-based innovations into clinical rehabilitation practice. Previous authors[9] have detailed several methodological challenges inherent in rehabilitation research, such as patient selection and description, random allocation, and blinding. These practical challenges, as well as those we have described here, have direct implications for methodological integrity of rehabilitation research. We have identified several specific challenges that may affect the validity and generalizability of research conducted with inpatient stroke rehabilitation populations and make recommendations based on our experience in overcoming these challenges.

Power and recruitment

Recruitment difficulties are widely recognized among clinical researchers. Implications for statistical power and for the cost of conducting research in acute stroke care[17,28,29] and in rehabilitation[13,18,25] are well documented. We have described patient-specific characteristics (e.g. aphasia, cognitive impairment, fatigue) that affect research participation. Reliable, valid alternatives to lengthy gold standard research assessments must be found, to permit inclusion of persons with communication disorders and expansion of the potential subject pool. Eliminating such a high proportion of the recruitment pool likely introduces significant bias into research samples, decreasing the generalizability of the research findings to the target population. Stroke researchers need better ways to characterize and test those with aphasia, to enable informed consent and to ensure that research instruments and interventions are accessible to persons with communication deficits.

Recruiting cognitively impaired individuals is fraught with ethical concerns.[13,16] Simplifying the informed consent process could improve recruitment to stroke studies. Informed consent cannot be eliminated for intervention research, but rehabilitation sites could adopt commonly used research instruments as their standard of clinical care, permitting de-identified data collection directly from the clinical record[25] for observational studies. Efforts to integrate and standardize instrumentation for both clinical and research realms, such as the National Institutes of Neurological Disorders and Stroke's Common Data Elements project,[30] could facilitate large scale studies that were previously impossible. The ability to use reliable clinically available data could also reduce the need for burdensome research testing sessions.

Timing of recruitment efforts may also influence accrual. The optimal time to approach patients for stroke or rehabilitation-related research is unclear. Opinions differ about whether approaching prospective participants soon after admission increases recruitment rates for stroke rehabilitation studies,[17] or whether waiting until patients and families begin to adjust to life with stroke before broaching research participation yields better results.[13,18] Our experience suggests that waiting to approach may be more effective. However, waiting to approach is not always feasible, especially for RCTs that evaluate effectiveness, dosing, or timing of inpatient rehabilitation interventions.

Blanton and colleagues[18] advocate increasing recruitment by offering compensation for participants' time and inconvenience. Several of our studies offered such compensation; we surmise that during the early post-stroke period, the minor compensation permitted by current ethical standards were inadequate to overcome participant concerns such as fatigue and feeling overwhelmed. Some patients were enticed by increased monitoring that they perceived would directly benefit them, and some participants were attracted by the behavioral or therapeutic components of some studies. Further investigations could elucidate patients' perspectives of motivators, facilitators, and barriers to enrolling in research during inpatient stroke rehabilitation.

Threats to internal validity

Fatigue, manifested as distractibility and slowed processing, can greatly affect the accuracy of research assessments[20] and can diminish responsiveness to research interventions, as does lack of quiet space for cognitive testing on the inpatient unit. Interruptions may affect participants' ability to properly attend to instructions or comprehend a task, especially if the stroke has caused cognitive impairment. Impaired vision or hearing can have similar consequences. Our team did not specifically screen for visual or auditory deficits, since these screenings are part of routine clinical care. We worked closely with clinicians to include appropriate interventions for visual and auditory deficits into the clinical plan of care and to all research sessions. Nonetheless, such deficits can affect the accuracy of the data, casting uncertainty on conclusions drawn.

We experienced a higher rate of missing data than might occur in other research settings, due in part to a burdensome (2.5 hour) baseline test battery that could not always be completed. Over 30% of our sample was missing data on key study variables (most frequently, cognitive assessments such as the Delis-Kaplan Executive Function System and the Repeatable Battery of Neuropsychological Status). Notably, data were not missing at random; participants with missing data were often older and more functionally impaired than those with complete data. Though participants with missing data can be omitted, the resulting implications for small sample sizes and statistical power make this an unattractive option, particularly in settings where recruitment is difficult and time consuming. In our studies, dropping participants with missing data on key variables would have resulted in a final *n* of 135 or less, far below the sample size needed to assure 80% power to detect statistically significant differences. To preserve sample size, the most acceptable method of handling missing data is multiple imputation,[31] whereby missing values are imputed by an algorithm in the statistical package (SPSS) using regression modeling with other variables as predictors. Several of our studies used multiple imputation to compensate for missing data; since multiple imputation is based upon probability estimates of missing data points' values, it may not provide "true" values upon which to base conclusions.

Threats to external validity

It is possible that the five studies' sample may not accurately represent the overall population of patients admitted for inpatient stroke rehabilitation. Regulations restrict the admission of patients who are too impaired or not impaired enough to be deemed medically appropriate for inpatient rehabilitation. Excluding patients at either end of the functional

spectrum from the potential research pool can artificially decrease the range of research assessment scores, affecting the validity of statistical inferences and decreasing generalizability. Statistical restriction of range[31] could also occur, obscuring true relationships and leading to Type II errors. Indeed, the generalizability of many rehabilitation studies, especially RCTs, has been questioned[25] because the rigorously controlled milieu required by most RCTs excludes many 'typical' persons with stroke, particularly individuals with aphasia. Self-selection may also compromise external validity, as patients who refuse research participation may differ considerably from those who enroll.[25,32]

A major threat to external validity stems from excluding patients with aphasia and other communication disorders, and from potential selection bias related to the need for informed consent. Developing objective outcome measures and improved research procedures that will include individuals currently excluded from research, such as those with aphasia, is crucial to improving the representativeness of research samples. Improving research inclusion across the continuum of care will also fill recognized gaps in rehabilitation research as noted by the Blue Ribbon Panel on Rehabilitation Research convened by the National Institutes of Health in 2012.[33] Efforts such as those currently underway by the Cognition Task Force of the American Congress of Rehabilitation Medicine's Stroke Special Interest Group to increase the accessibility of research assessments and interventions for individuals with aphasia will facilitate research participation by those to whom findings may be most applicable.

Conclusion

Overcoming inpatient stroke rehabilitation research challenges can be addressed through strong collaboration between the research team and clinical staff. However, careful interpretation of research findings is needed, because data may have been obtained from a non-representative sample. Patient characteristics and constraints imposed by the setting raise additional logistical and methodological concerns. Nevertheless, the need for publishing high quality inpatient stroke rehabilitation research, combined with the potential for direct benefit for participants, clinicians, and researchers makes overcoming practical research challenges advantageous to all parties.

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Table 1

UPMC Rehabilitation Institute Stroke Studies

Title, Source of Support, PI	Design and Goals	Description
Enhancing Rehabilitation After Stroke (Enhance) **R01 HD055525** **PI: E. Whyte**	Double-blinded RCT Examines the effect of donepezil on functional and cognitive outcomes	Participants randomized to a medication group or placebo group Baseline functional, cognitive, and affective testing is completed before starting medication Participants followed for 6 months, receiving regular follow up testing throughout
Web-Based Stroke Education (Stroke Education) **R44 NS052948 (Grant PI: D. Fox)** **Study PI: E. Whyte**	Non-randomized effectiveness study Compares novel internet-based secondary prevention education program with 'standard of care' education (classes, informational brochures)	Participants assessed upon admission to inpatient rehabilitation regarding stroke knowledge and secondary prevention self-management practices Control and intervention groups receive standard clinical care; intervention group also receives the web- based program Both groups' stroke knowledge and risk-related behavior (e.g., smoking) re-assessed 2 and 6 weeks post-discharge
Neurobehavior and Activity Interactions After Stroke,' or Neuro ADL **K12 HD055931** **PI: E. Skidmore**	Prospective observational study Explores interactions among motor, cognitive and affective impairments after stroke, and the influences of these interactions on ADL disability	Consenting participants assessed upon admission Re-assessed 6 months post-stroke
Co-operative Training for Stroke Rehabilitation (CO-Op) **K12 HD055931 and the University of Pittsburgh Office of Research Health Sciences** **PI: E. Skidmore**	Two group RCT Examines effect of intensive cognitive strategy training on cognitive, affective, functional outcomes	Participants receive baseline cognitive, affective, functional testing Daily, one-hour structured problem solving intervention using therapist-guided self-instructional cognitive strategy training protocol supplements usual care inpatient therapy program; control group received a dose-matched attention control condition Participants followed for 6 months
Standing Tall After Stroke: Post-Stroke Cognition as a Fall Predictor during Inpatient Stroke Rehabilitation (Falls Study) **F31 NR01156, John A. Hartford Foundation, and Pittsburgh Pepper Center Pilot Grant Program** **PI: G. Campbell**	Prospective observational study Explores associations between functional, perceptual, and cognitive risk factors and the accidental falls during inpatient rehabilitation	Consented participants receive functional, perceptual, cognitive testing upon admission to inpatient rehabilitation Participants followed during inpatient rehabilitation for occurrence of accidental falls Fall circumstances collected via medical record review and participant interview when possible

Table 2

Selected Research Challenges and Implementation Strategies

Challenge	Implementation Strategies	
Aphasia	**1**	Modified language screen to improve identification of appropriate patients for research studies
		a. Identify crucial communication skills needed for each study's purpose and measures
		b. Consult with neuropsychologist for best screening tool to assess crucial communication skills
	2	Followed patients whose aphasia initially prohibited research participation for signs of improving communication skills that would permit later enrollment
		a. Monitor Functional Independence Measure (FIM) comprehension and expression scores as part of IRB-approved screening activities
		b. Inform clinicians regarding potential participants and solicit input on improving language function
	3	Research team participated in clinical plan of care by incorporating adaptive communication devices into research sessions as appropriate
Fatigue	**1**	Clinicians took initiative to include education on post-stroke fatigue into their standard patient/family education program upon learning that fear of fatigue was dissuading patients' research participation
	2	Research team worked with clinical team to schedule research sessions at optimal times, e.g. scheduling neuropsychiatric assessments early in the day or after a rest period
	3	Research and clinical teams sought patient preferences for treatment scheduling, rest breaks, and research sessions; incorporated patient preferences into daily scheduling process
	4	Clinical staff reminded patients of research sessions during therapy and spoke positively about the patient's research engagement
	5	Researchers offered to reschedule sessions if patients appeared fatigued, upset, or not engaged in sessions
	6	Clinicians alerted the research team if patients were fatigued or ill and assisted with rescheduling research sessions
Caregiver protectiveness	**1**	Research and clinical team provided empathy, support, and education about stroke recovery to caregivers expressing concerns about their loved one's situation
	2	Clinicians spoke positively about the research team and ongoing studies to patients' caregivers
	3	Research team communicated caregiver concerns to clinical team as appropriate (with caregiver's assent)
	4	Research and clinical team assured caregivers that research activities would not interfere with clinical care
	5	Research team highlighted benefits of increased post-discharge medical monitoring included in research protocol to patients and caregivers when considering study participation
	6	Research team assisted with identifying appropriate outside resources and services (with approval of clinical team) when needs arose, e.g. substance abuse treatment and behavioral health services
Clinical staff priorities	**1**	Research team worked to develop collaborative, trusting relationships with clinical staff
		a. Research team met with clinical staff during study planning phase to solicit clinicians' research interests and clinical questions; incorporated clinicians' interests into study design when possible
		b. Research Update sessions held regularly to solicit staff concerns about the research process and logistics; research team addressed clinical staff s concerns through incorporating them into research standard operating procedures (e.g., checking with nurses and therapists before research sessions to receive updates on patient issues, changes in condition; reminding patients of upcoming therapy schedule at the beginning of research sessions; transporting patients from research sessions to therapy rather than waiting for unit staff to transport patients)

Challenge	Implementation Strategies
	c. Research team assisted with unit tasks as appropriate and within team members' professional competence (e.g., transporting patient to therapy or setting up meal trays or answering unit telephone if staff were not at the desk)
	2 Shared results of research testing (e.g. neuropsychological assessments) with clinical team as appropriate (and as approved by the IRB), avoiding duplication of services and to identify needs for additional clinical services
	3 Research team established itself as a valuable resource for clinical staff
	a. Consulted with clinical team about difficult patient issues such as hemineglect, fall risk assessment and fall prevention, neuropsychiatric issues, and poststroke depression
	b. Provided continuing education programs for rehabilitation staff
	c. Presented at unit journal clubs
	d. Mentored and provide technical assistance to clinical staff wanting to conduct evidence-based practice projects and clinician-led research initiatives
	e. Mentored clinical staff seeking program development and research grants
	f. Included clinicians as authors on manuscripts as appropriate
	4 Administrators and staff developed a Clinical-Research Integration initiative where administrators, researchers, and the interdisciplinary clinical team met monthly to discuss issues and problems and to develop collaborative practice projects
Administrative and regulatory concerns	**1** Research team volunteered to consult with administration and to participate on hospital work teams for key programmatic issues (e.g., development of evidence-based clinical practice guidelines; standardization of care processes across Health System rehabilitation units)
	2 Demonstrated the research team's commitment to meeting regulatory requirements for treatment duration:
	a. Worked with therapy supervisors and direct care staff to understand scheduling parameters
	b. Alerted clinical team when research sessions concluded early so additional therapy treatment could be provided if needed
	c. Never exceed allotted research time, even if additional research sessions had to be scheduled later to complete research activities
	d. Offered to postpone or shorten research sessions if patients lacked sufficient therapy minutes