How Nurses Can Partner With National Institutes of Health StrokeNet to Deliver Best Research and Care to Stroke Patients

Jamey Frasure, PhD; Judith Spilker, BSN

The National Institutes of Health (NIH) StrokeNet is a cooperative research network supported by National Institute of Neurological Disorders and Stroke and was established to facilitate maximization of efficiencies in stroke treatments. The main components include the National Coordinating Center at the University of Cincinnati, the National Data Management Center at the Medical University of South Carolina, and 25 Regional Coordinating Centers across the United States. Site selection is based on many criteria, a few being strong stroke research abilities and geographical location. The network was NIH funded and began building its infrastructure in 2013. Centers are submitting competitive renewal applications in the fall of 2017 for a second 5-year award. Benefits of the stroke research network are beginning to come to fruition.

Nursing and Clinical Stroke Research of the Past

For decades, bedside and clinic nurses have inadvertently been exposed to clinical research involving alteplase and other investigational interventions to improve stroke outcomes. Nurses’ learning has likely been enhanced by working with various treatments and the need to acquire keen assessment skills. Benefits of first-hand involvement have increased understanding of processes, such as urgency of treatment times and risks of bleeding. These components are now recognized as stroke care standards. Guideline development by a group of experienced research nurses has facilitated knowledge dissemination. It is difficult to imagine that even indirect exposure to investigational treatments does not benefit nurses and ultimately patients.

Being at the forefront of stroke research continues to have potential to expose nurses to the next generation of clinical practice. Comprehensive stroke centers are required by The Joint Commission to demonstrate use of evidence-based care stroke guidelines and participate in research. Nurses play a significant role in research and in strategies to limit bias and enhance objectivity of an investigation. However, there are times when nurses may struggle ethically with placebo treatments. Clinical scenarios can make caregivers uncomfortable with randomized blinding because they feel potential benefits of receiving certain treatments are already known. It is widely accepted in clinical research that a blinded design is the gold standard for determining effective treatments. Pursuit of improved stroke therapy, as in neuroprotective trials, has had some false starts, and randomized blinded trials are a critical step in the process.

It has long been recognized that nurses have a pivotal role in patients’ care. In the research process, as in clinical settings, nurses’ presence needs to be acknowledged as an advantage and needs to be leveraged. Patients’ clinical changes can be subtle, yet significant, and may only be detected with vigilant surveillance. Nurses are best situated to make these observations because they spend the most time with patients. It is essential to know when a patient’s condition changes: timing is key. Necessary patient activities can disrupt accurate assessments, possibly creating temptations to score items the same, such as when using the NIH Stroke Scale. It is difficult to know if a patient is drowsy from clinical changes or from interrupted sleep for monitoring purposes. With frequent assessments, nurses can identify and document trends in the patient’s status.

Nurses’ Involvement in Clinical Trials and Its Benefits

Being exposed to direct research processes can have educational benefits for nurses. Providing care to research subjects allows nurses to be one step ahead of colleagues who have not had similar exposure to cutting-edge treatments. They have experiential insight when it comes to observations to identify risks or complications. Nurses being knowledgeable about current treatments can potentially translate into improved patient outcomes.

Early alteplase trials did not directly address nursing care as being associated with positive results. Researchers derived bedside assessments and interventions from actual clinical protocols. Nurses’ experiences during the pivotal National Institute of Neurological Disorders and Stroke rt-PA Stroke Trial (recombinant tissue-type plasminogen activator) was initially described by nurse coordinators in a special edition of The Journal of Neuroscience Nursing.
December, 1997. Nursing care guidelines were developed after primary and secondary publications of the pivotal research were made available. Guidelines about posttreatment care of patients with acute ischemic stroke have since been updated to include published secondary experiences based on the evolution of evidence-based practice. One example is the recommendation for intervals of assessment necessary for recognition of intracerebral hemorrhage, initially described in the aforementioned Journal of Neuroscience Nursing special edition. Current guidelines incorporate basic principles proven to be advantageous to identifying this complication, but new findings alter the previous schedule of assessments.

As clinical trials continue to advance, researchers are more focused on limiting what is needed to prove hypotheses for implementation and data collection strategies. These efficiencies, because of limited funding and prior trial experiences, have led to the need for more pragmatic trial designs. Adaptive trial designs have been introduced to maximize gained knowledge. These trials may be challenging to bedside providers because treatments may change rapidly. For instance, trials with ≥2 arms could plan to drop one of the arms based on results from a preplanned interim data analysis. Nurses are positioned to provide valuable input on the feasibility and the balance needed in trials. Regardless of research participation status, best practice and institutional standards still need to be provided to all patients.

Building an Ideal Environment for Future Clinical Research

Researchers have to be able to present studies as a team to advance practice by improving care and treatment of patients with stroke. Study teams need to stress significance of research methodologies and the use of study controls and to advocate for the highest level of evidence in trials. The US Food and Drug Administration has rigorous requirements for protocol approvals, and the NIH has similar standards for grant funding. Nurses and other caregivers need to be part of the process to obtain desired research goals.

The challenge becomes how to make nurses partners in clinical research. A recent observational study supports the concept that stroke research participants receive higher quality of care. Educating staff members about research concepts can reinforce the contributions which subjects provide through participation. Someone has to be able to answer questions for subjects and families, especially in the acute care phase when studies can be complex and researchers cannot be present. By teaching concepts such as equipoise, as well as procedural care, and adjudication of adverse events, research nurses can be an important resource while building rapport with staff, and ultimately with patients. The primary goal is to improve patient outcomes while respecting patients’ needs.

Nurses are frequently involved in difficult discussions with potential subjects on research participation. It is important that nurses understand there might not be a direct benefit for a current patient, but research might benefit future patients. Striving for transparency is important in building relationships. Patients can sense cohesiveness and respect among professionals. When research teams are done with enrollment and baseline data collection and exit the care unit, it is important to reinforce that staff nurses are part of the team.

Understanding the role of study coordinators is integral to staff and subject communication and education about research trials. Information about a research trial provided to bedside nurses can be invaluable. The challenge for research teams is to find ways to provide communication at all institutional levels. Investigational review board–approved trial handouts are one way to maintain study integrity and facilitate continuity of protocol requirements. Staff need to understand that materials targeted at professionals are appraised differently than materials for patients. Study coordinators must identify the best ways to make information accessible to subjects and caregivers.

Patients and families experience stress when a stroke is diagnosed. All involved care areas and research staff need to support families. Clinical Research Associates, another valued NIH StrokeNet partner, are frequently study coordinators in trials and might need to rely on experienced staff to provide psychosocial support for subjects and families who are experiencing stress from the recent health event. The Table shows some of the differences between Clinical Research Associates and research nurses. Clinical Research Associates’ training is primarily focused on the competencies needed to conduct clinical trials using good clinical practice guidelines. Investigators and nurses can support Clinical Research Associates by sharing knowledge and modeling caring behaviors.

Study coordinators visit clinical sites regularly to relay information and to keep trials prominent in the minds of those who facilitate subject recruitment. Staff members need to recognize the presence of researchers are often for a subject follow-up visit, and encounters may not mirror usual standards of care. Often protocol-driven assessments are canceled by personnel who do not realize certain evaluations are required for research. Staff do not understand incomplete or delayed data reflect on the quality of information collected and may diminish the value of research.

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<th>Table. Research Study Coordinator Qualifications and Skills</th>
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<td>Minimum educational requirement</td>
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<tr>
<td>Active nursing license</td>
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<td>Educational foundation</td>
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<td>Theoretical foundation</td>
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<td>Distinctive skills</td>
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It is well-known that electronic health records have replaced paper charts. Electronic health records have many advantages, but they are difficult to access for many study personnel. Credentialing and general security are a few of the challenges in multisite trials. Electronic health record systems are slow to allow and manage research requirements of standing orders. Merging standing orders to financial information for proper coding and billing provides institutions incentive to capture research participation. Centers for Medicare & Medicaid Services requirements have led to ways to flag charts for recognition of research patients to ensure correct reimbursement. Researchers need to make sure documentation gets into the electronic health records. Important paper forms tend to get lost when patients are transferred between units. Staff members need to be aware that a subject’s research participation needs to be clearly documented, and their assistance may be needed.

NIH StrokeNet Advantages

NIH StrokeNet is presently where all phase II and III stroke multisite trials, >5 sites, are processed to be NIH funded. The network provides an educational core that offers didactic and professional development webinars. Presentations addressing a variety of topics and clinical case studies are provided twice monthly. Recorded presentations are available on the NIH StrokeNet website for all healthcare disciplines.

The network is unique in its development and implementation of acute, prevention, and recovery stroke trials. Improving acute care facility connections with the recovery community may improve patient care. Research has the potential to facilitate a more cohesive care continuum through various phases. Some institutions are already good at this. Approved strategies for screening recovery patents in acute settings is a possible measure to help recruitment into trials. An objective of the NIH StrokeNet is to connect care phases, with one goal being better prevention that might decrease acute admissions. Patients can also benefit from rehabilitation being an integral part of the care continuum, hopefully by improving their quality of life sooner.

Experts are currently working together on different phases of stroke research. Practice change takes time because of well-established silos in the different stroke arenas and the need to evaluate referral patterns and physicians’ territories. Trial performance sites have the potential to begin change processes. Focusing on patient outcomes provides the impetus to find better ways to incorporate research within clinical practice. It is possible that care can become fragmented or plagued by unclear direction for patients. Research trials may facilitate patients feeling more empowered by their care decisions.

Discussion

Nurse researchers need to take advantage of the need for their involvement in stroke research. Experienced researchers possess the knowledge to address nursing care treatments and patient educational needs and other secondary outcomes, such as caregiver burnout or assessment tool refinement. Funding for clinical trials is limited, especially when trying to get primary questions answered. Nurses might consider using funding resources, such as the National Institute of Nursing Research, and partner with stroke physicians. This active role would contribute to the work of NIH StrokeNet and add a needed dimension to stroke research.

TAKE-HOME POINTS

- NIH StrokeNet is well supported and positioned to continue the research legacy established by passionate researchers during the past 4 decades.
- Dedicated researchers continue to develop innovative trials for funding.
- Patients with stroke remain the primary focus, and nurses will continue to grow professionally as they become more involved in research opportunities.
- To connect with the NIH StrokeNet hospital in your area, refer to http://nihstrokenet.org/the-network/about-us.

Disclosures

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References


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