The State of Spasticity in U.S. Adults: An Evidence-Based Synopsis

American Academy of Physical Medicine & Rehabilitation's Spasticity Summit

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The State of Spasticity in U.S. Adults:

Spasticity causes significant functional and quality-of-life impairment, yet access to care continues to be a hurdle for those who are or may suffer from it. As the treatments for spasticity advance, so too must the U.S. healthcare's collective response to ensure individuals are receiving the care they deserve.

Physical Medicine and Rehabilitation (PM&R) most often are the leaders in spasticity assessment and treatment and lead rehabilitation care teams. As such, The American Academy of Physical Medicine & Rehabilitation (AAPM&R) is taking a leadership role to address this crucial issue in healthcare, by taking the initial step of convening key stakeholders.

This document summarizes the current citable, evidence-based knowledge of spasticity and acknowledges areas in which evidence is lacking in the literature. This document is not intended to include the insights from healthcare stakeholders on their experiences.

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Introduction

Spasticity is a motor disorder characterized by hypertonia and a velocity-dependent increase in muscle tone or tonic stretch reflexes.[1] The presentation can range from subtle neurological manifestations to joint immobility.[2,3] Complications include interference with comfort, contractures, problems with daily function, difficulties with hygiene, trouble delivering nursing care, and pressure ulcers with or without complicating, subsequent infections. There also may be an increased risk of subluxation and/or dislocation and heterotopic ossification.[3,4] Spasticity may, however, help some patients with weakness to bear weight, stand or ambulate—which may aid circulation, improve mental health, and decrease osteoporosis risk.[3,5]

Background

In the United States, approximately 795,000 people have a stroke each year, of which about 610,000 are new strokes.[6] Of people who have had a stroke, 25–43% will develop spasticity in their first post-stroke year.[7] Spasticity affects approximately 35% of people who have had a stroke, 50% of people with traumatic brain injury, 40% of patients with spinal cord injury, more than 90% of people with cerebral palsy, and 37–78% of people with multiple sclerosis.[3,8]

The COVID-19 pandemic has also contributed to this landscape. A study published in 2021 using data from 54 healthcare facilities showed that 103 of 8,163 COVID-19 patients (1.3%) developed acute ischemic stroke.[9] These people may also go on to develop spasticity.

Some populations are more at-risk for strokes, and the disability that can accompany them, than others. African Americans have a first-stroke risk that is twice as high as that of White people,[6] and African Americans have the highest stroke-related death rate.[10] There has been an increase in stroke-related death for Hispanic people since 2013.[10]

People’s geographical location can also impact their chances of being affected by a stroke, and possibly also spasticity. Residents of Alabama, Arkansas, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee and Virginia are in what is known as the “stroke belt.”[11] While the reasons behind the elevated incidence of strokes in this area have not been definitively proven,[12-15] hypotheses include diet, lifestyle, healthcare-facility quality, hypertension, infections, low socioeconomic status and smoking.[16]

Treatments for Spasticity

Treatment generally starts with conservative methods and may progress to more invasive approaches if conservative treatment is not entirely successful. Initially, patients can be taught to recognize and avoid triggers such as deep venous thrombosis,

heterotopic ossification, ingrown toenails, infection, pain, pressure ulcers, and urinary retention or stones.[3] If avoidance of noxious stimuli doesn't satisfactorily improve the condition, treatment can move on to physical modalities and therapeutics including direct tendon pressure, application of heat and cold, stretching, splinting, serial casting, functional electrical stimulation, vibration and biofeedback.[17] Additionally, physical therapy and occupational therapy can help.[18] If these treatments also fail to provide adequate relief, medications and interventional treatments are available.

Oral Medications

Centrally Acting

Baclofen

Baclofen is a gamma aminobutyric acid (GABA) B agonist that works pre- and postsynaptically at the spinal level.[18,19] It is a first-line treatment for spasticity, especially in people with spinal cord injury.[20] Oral baclofen improves quadriceps flexion and subjective functioning when compared with placebo in patients with multiple sclerosis.[21,22] Furthermore, it also prevents deterioration in body musculature.[23] Adverse effects of using oral baclofen include fatigue, sedation and systemic muscle relaxation.[19,24,25] It can be hepatotoxic, so liver function should be monitored.[26] Also, it should not be used in the elderly because it can cause excessive sleepiness.[27]

Alpha-2 Agonists

Clonidine

Clonidine is an alpha-2 agonist that decreases spasticity by inhibiting excessive afferent sensory transmission below the injury level.[28] Outcomes have not been consistent with its use,[29] and because of its problematic side-effect profile, including bradycardia, hypotension and drowsiness, it is rarely used as a single agent.[30]

Tizanidine

Tizanidine decreases tone by increasing the presynaptic inhibition of motor neurons, which decreases spinal interneuron release of excitatory amino acids.[31] It is often used with other medications for additive effects.[25] It requires frequent dosing due to a short half-life,[20] but muscle weakness is less of a problem than with most other oral medications.[32] Side effects include hallucinations, hypotension, muscle weakness, sedation and xerostomia.[31,33] Tizanidine should be used with caution in people taking antihypertensives.[31] It may also prolong the QT interval.[26]

Anticonvulsants

Benzodiazepines

Diazepam works postsynaptically on $GABA_A$ receptors, which depresses central nervous system (CNS) action.[18] Benzodiazepines such as diazepam and clonazepam are quite sedating, so their use for nighttime spasticity can also help with sleep.[25]

Diazepam acts primarily on flexor reflexes, making it better suited for spinal spasticity than for cerebral spasticity.[34] Because benzodiazepines are dependence- and tolerance-inducing, they are not well suited for long-term use.[35,36]

Gabapentin

Gabapentin's exact mechanism of action is not known.[18] It is used as an adjunct treatment, often in patients who have symptoms consistent with neuropathic pain in addition to spasticity.[25] Adverse side effects include nystagmus, somnolence and tremor.[34]

Peripherally Acting

Dantrolene Sodium

Dantrolene sodium acts on the muscles rather than the nerves. It inhibits calcium release at the sarcoplasmic reticulum, uncoupling excitation and contraction.[37] It is occasionally used in conjunction with other treatments in refractory spasticity,[38] but is not a first-line drug because of several serious adverse effects, including liver failure[19,37] and fatality.[35] It can also cause generalized muscle weakness.[25]

Interventional Treatments

Intrathecal Baclofen

Intrathecal baclofen (ITB) is the most common centrally acting intervention. The mechanism of action is the same as for oral baclofen, but the medication is delivered directly to the CNS at the spinal level.[18] Intrathecal delivery allows a higher concentration of the drug in the CNS at the spinal cord level at lower doses, which helps in avoiding the systemic side effects seen with oral baclofen.[18] People with lower limb spasticity benefit most from intrathecal baclofen because the medication concentration is thought to be higher at lower spinal levels.[35] The ability to vary intrathecal infusion is one advantage of this therapy.[31] This allows the amount of the medication to be adjusted according to the patient's activities, allowing for more flexibility in activities of daily living and helping with spasm control at night.[33,39] Intrathecal baclofen may also decrease bladder tone, improving neurogenic bladder.[40] Complications of intrathecal baclofen include problems with device placement and device failure.[18] Device failure can lead to either overdose or withdrawal, and placement problems include cerebrospinal fluid leak and infection.[18]

Botulinum Neurotoxin

Botulinum neurotoxin (BoNT) inhibits vesicular acetylcholine release from presynaptic nerve terminals at the neuromuscular junction.[41] There are two subtypes, A and B, which differ in immunogenicity and purity.[31] BoNT is the most common treatment for focal spasticity[20,26] and is tolerated better than oral treatments.[42] The effects of BoNT wear off within three to four months,[35] and immunoresistance can develop.[42] BoNT can also disseminate,[42] which can potentially cause dysphagia when it is used in the neck and upper limbs.[31]

Injection of Alcohol or Phenol

High-dose alcohol or phenol injections permanently destroy spasticity-causing nerves.[18] These injections are not a first-line treatment because they are nonselective[34] and because variable nerve regeneration can lead to decreased effectiveness within days to years.[20,31] They can, however, be useful in patients who have not responded well to other treatments[20,25] if limited to people with no functional movement in their lower body and complete sensation loss.[2] Such injections mainly help with gait, hygiene and posture.[43] Adverse effects include transient flushing,[31] neuropathic pain,[35] and possible loss of bladder, bowel and sexual function.[20] This treatment is becoming historical as BoNT injections become more popular.[34]

Who Treats Spasticity?

According to the Cleveland Clinic, optimal management of spasticity involves a team of healthcare professionals. Types of physicians ideally involved with spasticity management may include neurologists, neurosurgeons, orthopedic surgeons and physiatrists. Ancillary healthcare providers can include occupational therapists, physical therapists and speech pathologists.[44] However, primary care physicians, such as family practitioners, may be the first to see a person who has developed spasticity and may be responsible for diagnosing it and beginning treatment.[45]

Access to Care

Factors that Affect Successful Treatment

Shilt et al. developed the IDAHO criteria to assist with goal-setting in spasticity treatment as well as to account for the multiple factors that contribute to successful spasticity treatment.[46] The IDAHO criteria include:

Infrastructure: Full-time emotional and physical support give people with spasticity an advantage. It is also optimal for these people to have access to exercise equipment and to learn techniques for strengthening muscles to improve function and strength.

Desire: Desire refers to the patient's motivation to pursue treatment goals. People with spasticity and their caregivers also need to have realistic treatment goals, or they risk discouragement that can hinder treatment progress.[47]

Ability: A person's mental and physical characteristics, both before and after the condition that led to spasticity, also affect recovery. Cognitive impairment will hinder recovery, as will lesser degrees of motor control.

Hospital Access: This refers to how close a person with spasticity lives to professional care services. In the United States, one-third of African Americans and American

Indian/Alaskan natives and one-quarter of Hispanics do not live in metropolitan areas where suitable hospitals are located, and therefore don't get adequate care.[48]

Opportunity: Opportunity includes a person's financial ability to access care. Low-income people, who are less likely to be insured, are less likely to be able to access optimal care at appropriate hospitals.[48]

Barriers to Access

Availability of treating physicians also affects the quality of a spasticity patient's care. The United States has more than 10,000 board-certified physiatrists, yet there is a lack of physiatric services in some geographic areas of the country. There is also a growing need for physiatrists in skilled nursing facilities and other sub-acute rehabilitation settings because of payer preferences.[49]

A recently-presented abstract provided data from 2017 demonstrating that the region in which people with spasticity live affects their access to care. Urban areas have lower Medicare beneficiary-to-provider ratios than non-urban areas.[50] Furthermore, areas with less than 25% Hispanic population had a lower beneficiary-to-provider ratio than areas with 25% or greater Hispanic population.[50] As of 2017, the three areas with the lowest access were the non-urban areas of the middle Atlantic region, the northeast region and the western region.[50]

Cost and Reimbursement Issues

Further complicating matters, not all physicians who treat spasticity may offer the same treatments. The previously-referenced abstract provided data indicating that only 566 out of a total of 1,032,912 Medicare providers submitted more than 11 claims for chemodenervation in 2017.[50] A recent survey of AAPM&R members suggested that cost issues may be a problem for practicing physiatrists who offer BoNT treatment. Physiatrists in small or solo practices raised three main issues:

1. Ordering BoNT that might not ever get used is not cost-effective and is potentially wasteful.[51]
2. If the patient does not come in for the appointment after the product has been prepared, the product goes to waste, with a monetary loss to the practice.[51]

The list price for onabotulinumtoxinA is $1244 for a 200 Unit (U) vial.[52] Wholesale pricing information for abobotulinumtoxinA and incobotulinumtoxinA was not discoverable in a literature search. For spasticity, the recommended dose of onabotulinumtoxinA is up to 400 U per session for upper and/or lower limb spasticity,[53] meaning the potential cost to a practice for product alone for one patient could be as high as $2488. Spasticity doses of abobotulinumtoxinA range from 500 U to 1500 U depending on the limbs treated, with a maximum of 1000 U for one limb and 1500 U for two limbs.[54] IncobotulinumtoxinA is recommended is doses up to 400 U for upper limb spasticity.[55] Medicare will reimburse $2482.80 for 400 U of onabotulinumtoxinA, $2023.20 for 400 U of incobotulinumtoxinA, and $1704 for 200

U of abobotulinumtoxinA. The reimbursement for 400 U of onabotulinumtoxinA doesn't even entirely cover the cost of providing it.

Reimbursement for performing BoNT injections is a challenging issue as well. Currently, Medicare reimburses $141.21 for giving BoNT injections to four or fewer muscles in one extremity, and $166.42 for injecting five or more muscles in one extremity. For each additional limb, Medicare will pay $87.50 for four or fewer muscles, and $112.88 for five more muscles. This current reimbursement may allow practices to fully recoup the cost of providing the BoNT but doesn't leave much to cover overhead and staffing costs.[56]

As the above information illustrates, the monetary loss for unused or wasted product is not negligible, and reimbursement may not cover the total cost of providing the product and performing the procedure even if the entire amount of the product ordered for a patient is used. Furthermore, practices that use BoNT must have the capability to store it properly. Unopened onabotulinumtoxinA can be stored in a refrigerator (35.6°–46.4°F) for up to 36 months for the 100 U vial or up to 24 months for the 200 U vial. OnabotulinumtoxinA also needs to be used within 24 hours of reconstitution, during which time it also needs to be refrigerated.[57] AbobotulinumtoxinA and incobotulinumtoxinA also need to be stored in a refrigerator at these same temperatures and used within 24 hours once reconstituted,[54,55] although incobotulinumtoxinA does not need to be refrigerated prior to reconstitution.

3. Ordering BoNT for specific patients requires dedicated staff who will remember to place orders in time for the patients' visits.[51] Some practices rely on the patient to pick up their BoNT from the pharmacy and bring it to the appointment, but if the patient forgets to do so, then the appointment is unproductive for both the provider and the patient.[51]

AAPM&R members who work in skilled nursing facilities face different challenges. Performing an injection is billable under Medicare Part B if the toxin is prescribed for medically necessary reasons.[58] Currently, the FDA has approved onabotulinumtoxinA for 11 therapeutic indications, including axillary hyperhidrosis, blepharospasm, cervical dystonia, chronic migraine, spasticity, strabismus, overactive bladder and urinary incontinence due to a neurologic condition.[53] AbobotulinumtoxinA has been approved for cervical dystonia, glabellar lines and spasticity.[54] IncobotulinumtoxinA has been approved for blepharospasm, cervical dystonia, glabellar lines, chronic sialorrhea and spasticity.[55] While preparations of BoNT have been approved for spasticity, Medicare will not reimburse facilities for the injectate separately from the injection. Facility administration may be unwilling to provide BoNT for this reason.[51]

Intrathecal baclofen can also be financially problematic for practitioners who want to provide it to their patients. Reimbursement for implantation or replacement of pumps ranges from $332.57 to $447.46, depending on the type of pump used.[56] Compensation for pump removal is $303.50.[56] Reimbursement for analyzing and refilling pumps ranges from $25.61 to $112.82, depending on what is done during the procedure, where it is

performed, and the necessary skill level of the person doing the procedure.[56] The cost of baclofen itself is quite variable depending on the preparation used, but reimbursement from Medicare is $53.47 for a trial dose and $182.29 per 10 mg.[56]

Difficulties with Diagnosis and Management

According to recent studies, there is a 21–35% prevalence of spasticity in nursing facilities,[59,60] but only 13% had a diagnosis of spasticity in their medical records.[59] One of the problems may be that spasticity can result from many conditions. Spasticity is diagnosed commonly in people with cerebral palsy and multiple sclerosis.[61] However, it may be overlooked in other conditions such as stroke, spinal cord injury (SCI) and traumatic brain injury (TBI) because other potentially life-threatening and more immediate medical issues are prioritized.[61] Around 795,000 people have a stroke in the United States every year,[6] and as many as 1.4 million Americans may have stroke-related spasticity.[62] In the United States, approximately 259,000 people have SCI, and 68% may have some level of spasticity.[62] According to the CDC, approximately 2% of Americans have TBI, the majority from falls.[61] The lone small study done to determine the prevalence of spasticity in people with TBI found that 34% had spasticity one year after injury.[63]

Another issue with the diagnosis of spasticity may be the lack of a specific objective measurement tool for it,[64] although there are several scales used to assess aspects of it, including the Modified Ashworth Scale for muscle tone and the Tardieu scale for resistance to movement.[64] As stated in one recent paper: "…it is an accepted principle that if you cannot measure, you cannot manage".[64]

Missed diagnoses may also have something to do with the way people with stroke, SCI, and TBI are cared for in America. After the 1999 Olmstead act, more emphasis has been placed on caring for such individuals in the community rather than in institutions.[61] The National Alliance for Caregiving and American Association of Retired Persons (AARP) Public Policy Institute found that, in America, the prevalence of unpaid caregiving is 18.2%.[65] Of people who receive care, 83% get it in their own home or a relative's home from unpaid providers.[65] Caregivers with no medical training may not be able to recognize spasticity when it develops, hindering diagnosis.[61]

Successful rehabilitation involves getting patients the correct treatment at the correct time and promptly diagnosing and addressing new issues as they arise. As such, rehabilitation must be dynamic and involve frequent reassessment with a multi-disciplinary team over patients' entire course, including their time in the hospital, time spent in an inpatient rehabilitation unit, time at an outpatient rehabilitation clinic and home-based care.[64,66] A recent survey suggested that current spasticity management is falling short. Healthcare providers expressed that lack of formal guidelines for spasticity treatment, lack of access to treatment options such as BoNT, bureaucracy and referral delays hindered their ability to give care. Simultaneously, patients were frustrated because spasticity decreased their quality-of-life while they felt unclear about what symptoms are treatable and what their treatment options are.[64]

People with a recent stroke typically undergo a range of adjustment phases,[67] and not all patients with a recent stroke, TBI or SCI will develop spasticity immediately. Many such patients are discharged from the hospital without understanding that they may develop spasticity, what it is, or that it is treatable.[68] Since around 20% of people who have had a stroke will develop spasticity after three months, and as many as 40% may develop it after a year,[69] many stroke survivors will eventually develop spasticity. While resources that involve patients, caregivers and multidisciplinary teams exist, the survey demonstrated that patients still may not recognize their symptoms or understand the treatment options despite the available resources.[64] For optimum rehabilitation, patients and healthcare providers need to collaborate and communicate about goals clearly, using language that patients understand.[66] Rehabilitation plans in which patients and providers collaborate to set realistic goals are also more motivational than standard plans.[70]

Difficulty with Access to Treatment

Patients with spasticity are not just underdiagnosed for various reasons;[71,72] they're also undertreated. While some patients are discharged from the hospital with "rehabilitation prescriptions" that can help them arrange their outpatient treatment in America and the United Kingdom,[73] this is not a universal experience. One study found that only 30.7% of stroke survivors had outpatient rehabilitation, and theorized that lack of access to clinics and resources may be at fault.[74] BoNT is most helpful for spasticity when it is given early before complications such as contractures can develop.[75] However, the problems with gaining access to BoNT treatment, including lack of awareness on the part of patients and caregivers, as well as the lack of healthcare providers offering the treatment,[76] may force some people with spasticity to wait for more than a year before receiving the therapy.[77]

Reimbursement problems also affect patient access to appropriate therapy. A prospective cohort study analyzed the post-stroke course of 222 people using the Boston University Activity Measure for Post-Acute Care, which includes three assessment areas: basic mobility, daily activities and applied cognitive functioning. At six months post-stroke, patients who received care at an inpatient rehabilitation facility showed greater functional gains in all three domains compared with patients cared for at a skilled nursing facility. Their applied cognitive functioning was significantly better than that of patients who had outpatient home healthcare.[78] However, Medicaid does not reimburse for inpatient rehabilitation.[64] Also, another study found that decision-making constraints in the healthcare insurance environment of the United States resulted in diagnosis and treatment delays for patients.[79]

People with spasticity living in long-term care facilities may fare no better. A survey of medical directors at 11 long-term care facilities found that 55% reported access to neurotoxin injection, but only 18% reported access to intrathecal baclofen for their residents.[80] This may very well be at least partly a result of the cost and reimbursement issues noted above.

Ageing in Place

By 2050, an estimated 83.7 million Americans will be aged 65 years or older.[81] According to the CDC, one-third of elderly people fall each year.[61] In the elderly population, falls account for 74% of SCI and more than half of TBI.[82] Stroke reduces mobility in over half of stroke survivors aged 65 or older and is a leading cause of serious long-term disability.[6] More than 65% of people hospitalized for stroke are aged 65 and older.[83] It is therefore not unreasonable to hypothesize that the incidence and prevalence of spasticity will also increase as our population ages. Many of these people will likely also be cared for in the community by unpaid and untrained caregivers who are family members.

Stressors for Caregivers

Caring for an individual with spasticity can be difficult. Activities of daily living, such as personal hygiene and dressing, may be more difficult.[61] Decreased arm mobility affects activities of daily living, while lower-limb spasticity affects gait, which can, in turn, result in an increased risk of falls. Depressed mood and decreased social interactions may compromise relationships and result in an increased caregiver burden.[84]

Family caregivers are already doing many things that are beyond the scope of what people with no medical training should do. According to a 2019 study supported by the AARP, 20 million of the nation's 40 million family caregivers perform complex medical tasks. Of these 20 million, 82% manage medications (including giving injections and administering pain medications), 48% prepare special diets, 51% assist with mobility devices, 37% handle wound care and 30% manage incontinence.[85] These untrained family caregivers generally must teach themselves how to perform these tasks, and approximately half of them are concerned about possibly making a mistake.[85] Most of them feel like they have no choice[85] because of expectations from other family members and healthcare professionals.[86] Further complicating matters, socially-isolated caregivers or those who feel like they have no choice about caregiving, have a higher risk of experiencing difficulties with complex care.[86] The study calls for several ways to increase support for family caregivers.

Another study found that close intimacy with stroke survivors, fewer caregivers, longer duration of time since the stroke, and longer hours of daily caregiving all significantly increased ($P < 0.05$) informal caregiver stress. This study concluded that providing care had a significant negative influence ($P < 0.05$) on the emotional, financial, health-related, and social well-being of informal caregivers.[87] Family caregivers tend to be female, younger than the stroke survivors for whom they care and are aged in their late 40s to mid-60s.[88] This is an age range in which caregivers could also be balancing careers, childcare and possible health issues of their own. If this is indeed the case, such factors would further increase caregiver stress.

Caring for a stroke survivor is also a considerable financial undertaking. One study found that 51.4% of elderly stroke survivors received help from a caregiver and that stroke survivors received 10 more hours of care weekly than controls matched for comorbidities and demographics.[89] Using an estimate of $11,300 as the annual cost of

providing care for an elderly stroke survivor, $5000 of which is stroke specific,[89] the extra hours caregivers spend with stroke survivors adds up in terms of time and money.

Furthermore, medical care for stroke survivors who experience spasticity is more expensive than care for those who do not. A Swedish study found that direct costs for hospital care, post-discharge primary care and community healthcare services amounted to four times more for stroke survivors with spasticity than for stroke survivors who do not develop spasticity.[90] This same study found a strong association between costs and functional ability after stroke, with increasing costs accompanying decreased functional ability.[90]

A Comprehensive Model of Care for Individuals with Spasticity in the United States

To develop and implement a comprehensive model of care for individuals with spasticity in the United States, several issues need to be addressed. The issues noted below are either evidenced by the current literature or lack of mention in current literature. More discussion, action and research must be done to fully address the needs of individuals with spasticity. The issues to be addressed based on the current evidence can be categorized into three areas: (1) Access to Care; (2) Patient and Caregiver Support; (3) Clinical Capacity and Capabilities.

During AAPM&R's 2022 Spasticity Summit, these issues will be addressed, and this list may be expanded.

Access to Care

- Define the scope of the access challenge
- Understand the heterogeneity of underinsured and uninsured individuals with spasticity to access care
- Improve access to appropriate care in geographic locations that lack enough providers who treat spasticity
- Improve access to appropriate care for underserved demographic groups
- Ensure a favorable regulatory and business environment that incentivizes all stakeholders (i.e., providers, payers, etc.) to help increase care access

Patient and Caregiver Support

- Provide those with spasticity greater access to appropriate physical support
- Optimize mental and emotional health for people with spasticity
- Increase ability for people with spasticity to follow their care plan, including those who are cognitively impaired
- Improve general awareness of spasticity
- Improve support and resources for untrained patients and caregivers of people who have spasticity
- Equip patients and caregivers to advocate for people with spasticity

Clinical Capacity and Capabilities

- Ensure a favorable regulatory and business environment that incentivizes providers
- Increase access to clinician education on how to assess and treat those with spasticity about the needs of those with spasticity (i.e., how to treat and manage cases in an outpatient vs. institutional setting)
- Increase the incidence of spasticity case follow-up by appropriate providers
- Clarify the roles and challenges of various health professionals in expanding care for those with spasticity
- Improve the diagnosis of spasticity in those with stroke, TBI, and SCI
- Improve implementing interventional treatment options (i.e., botulinum toxin injections, intrathecal baclofen pumps) into clinical workflows

References:

1. Lance JW. What is spasticity? *Lancet.* 1990;10:335. doi:10.1016/0140-6736(90)90389-m
2. Kheder A, Nair KP. Spasticity: pathophysiology, evaluation and management. *Pract Neurol*. 2012;12(5):289-98. doi:10.1136/practneurol-2011-000155
3. Rivelis Y, Zafar N, Morice K. Spasticity. In: Abai B, Abu-Ghosh A, Acharya AB, et al, eds. *StatPearls*. StatPearls Publishing; 2022. https://www.ncbi.nlm.nih.gov/books/NBK507869/
4. Escaldi SV, Cuccurullo SJ, Terzella M, Petagna AM, Strax TE. Assessing competency in spasticity management: a method of development and assessment. *Am J Phys Med Rehabil*. 2012;91(3):243-53.
5. Rekand T. Clinical assessment and management of spasticity: a review. *Acta Neurol Scand Suppl.* 2010;190:62-6. doi:10.1111/j.1600-0404.2010.01378
6. Tsao CW, Aday AW, Almarzooq ZI, Alonso A, Beaton AZ, Bittencourt MS, et al. Heart disease and stroke statistics—2022 update: a report from the american heart association. *Circulation*. 2022;145(8):e153–e639.
7. American Stroke Association. Let's talk about spasticity after stroke. Accessed August 15, 2022. https://www.stroke.org/-/media/stroke-files/lets-talk-about-stroke/life-after-stroke/ltas_spasticity_english_0419.pdf
8. Bochkezanian V, Newton RU, Trajano GS, Blazevich AJ. Effects of Neuromuscular Electrical Stimulation in People with Spinal Cord Injury. *Med Sci Sports Exerc*. 2018;50(9):1733-1739. doi:10.1 249/MSS.0000000000001637
9. Qureshi AI, Baskett WI, Huang W, Shyu D, Myers D, Raju M, et al. Acute Ischemic Stroke and COVID-19. *Stroke*. 2021;52:905-912. doi:10.1161/STROKEAHA.120.031786
10. Centers for Disease Control and Prevention. Underlying cause of death, 1999-2020. Accessed August 23, 2022. https://wonder.cdc.gov/ucd-icd10.html
11. Palermo, E. What is the stroke belt? *Live Science*. March 27, 2013. Accessed August 22, 2022. https://www.livescience.com/34465-what-is-the-stroke-belt.html
12. Casper ML, Wing S, Anda RF, Knowles M, Pollard RA. The shifting stroke belt. Changes in the geographic pattern of stroke mortality in the United States, 1962 to 1988. *Stroke*. 1995;26(5):755-760. doi:10.1161/01.str.26.5.755
13. Glymour MM, Avendaño M, Berkman LF. Is the "stroke belt" worn from childhood?: risk of first stroke and state of residence in childhood and adulthood. *Stroke*. 2007;38(9):2415-2421. doi:10.1161/STROKEAHA.107.482059
14. Department of Health and Human Services. HHS Announces Initiative to Reduce the Incidence of Stroke in Stroke Belt States. Accessed August 22, 2022. https://web.archive.org/web/20041031175118/http:/www.hhs.gov/news/press/2004pres/20040805.html
15. Brillman, D. The Mystery of the Southeast Stroke Belt. *Newsweek.* November 7, 2005. Accessed August 22, 2022. https://www.newsweek.com/mystery-southeast-stroke-belt-115515
16. Nainggolan, L. Hypertension may not be the whole story in the Stroke Belt. *Medscape.* February 9, 2005. Accessed August 22, 2022. https://www.medscape.com/viewarticle/538637
17. Gracies JM. Pathophysiology of impairment in patients with spasticity and use of stretch as a treatment of spastic hypertonia. *Phys Med Rehabil Clin N Am*. 2001;12(4):747-768.
18. Chang E, Ghosh N, Yanni D, Lee S, Alexandru D, Mozaffar T. A Review of Spasticity Treatments: Pharmacological and Interventional Approaches. *Crit Rev Phys Rehabil Med*. 2013;25(1-2):11-22. doi:10.1615/CritRevPhysRehabilMed.2013007945
19. Chou R, Peterson K, Helfand M. Comparative efficacy and safety of skeletal muscle relaxants for spasticity and musculoskeletal conditions: a systematic review. *J Pain Symptom Manage*. 2004;28(2):140-75. doi:10.1016/j.jpainsymman.2004.05.002
20. Stevenson V, Playford D. Neurological rehabilitation and the management of spasticity. *Medicine*. 2012;40(9):513-517.
21. Berger JR. Functional improvement and symptom management in multiple sclerosis: clinical efficacy of current therapies. *Am J Manag Care*. 2011;17(suppl 5):S146-153.

22. Shaygannejad V, Janghorbani M, Vaezi A, Haghighi S, Golabchi K, Heshmatipour M. Comparison of the effect of baclofen and transcutaneous electrical nerve stimulation for the treatment of spasticity in multiple sclerosis. *Neurol Res*. 2013;35(6):636-641. doi:10.1179/1743132813Y.0000000200
23. Gorgey AS, Chiodo AE, Gater DR. Oral baclofen administration in persons with chronic spinal cord injury does not prevent the protective effects of spasticity on body composition and glucose homeostasis. *Spinal Cord*. 2010;48(2):160-165. doi: 10.1038/sc.2009.105
24. Abbruzzese G. The medical management of spasticity. *Eur J Neurol*. 2002;9(suppl 1):30-34; discussion 53-61. doi:10.1046/j.1468-1331.2002.0090s1030.x
25. Keenan E. Spasticity management, part 2: choosing the right medication to suit the individual. *British Journal of Neuroscience Nursing.* 2009;5:419-424.
26. Brashear A, Lambeth K. Spasticity. *Curr Treat Options Neurol*. 2009;11(3):153-161. doi:10.1007/s11940-009-0018-4
27. Hulme A, MacLennan WJ, Ritchie RT, John VA, Shotton PA. Baclofen in the elderly stroke patient its side-effects and pharmacokinetics. *Eur J Clin Pharmacol*. 1985;29(4):467-469. doi:10.1007/BF00613463
28. Nance PW, Shears AH, Nance DM. Clonidine in spinal cord injury. *Can Med Assoc J*. 1985;133(1):41-42.
29. Stewart JE, Barbeau H, Gauthier S. Modulation of locomotor patterns and spasticity with clonidine in spinal cord injured patients. *Can J Neurol Sci*. 1991;18(3):321-332. doi: 10.1017/s0317167100031887
30. Rabchevsky AG, Kitzman PH. Latest approaches for the treatment of spasticity and autonomic dysreflexia in chronic spinal cord injury. *Neurotherapeutics*. 2011;8(2):274-282. doi:10.1007/s13311-011-0025-5
31. Simon O, Yelnik AP. Managing spasticity with drugs. *Eur J Phys Rehabil Med*. 2010;46(3):401-410.
32. Kamen L, Henney HR, Runyan JD. A practical overview of tizanidine use for spasticity secondary to multiple sclerosis, stroke, and spinal cord injury. *Curr Med Res Opin.* 2007;24:425-439.
33. Awaad Y, Rizk T, Siddiqui I, Roosen N, Mcintosh K, Waines GM. Complications of intrathecal baclofen pump: prevention and cure. *ISRN Neurol.* 2012;2012:575168. doi:10.5402/2012/575168
34. Lapeyre E, Kuks JBM, Meijler WJ. Spasticity: revisiting the role and the individual value of several pharmacological treatments. *NeuroRehabilitation.* 2010;27:193-200.
35. Kischka U. Neurological rehabilitation and management of spasticity. *Medicine.* 2008;36:616-619.
36. Verrotti A, Greco R, Spalice A, Chiarelli F, Iannetti P. Pharmacotherapy of spasticity in children with cerebral palsy. *Pediatr Neurol.* 2006;34:1-6.
37. Tilton A, Vargus-Adams J, Delgado MR. Pharmacologic treatment of spasticity in children. *Semin Pediatr Neurol.* 2010;17:261-267.
38. Ross J, Cook A, Stewart G, Fahy B. Acute intrathecal baclofen withdrawal: a brief review of treatment options. *Neurocrit Care.* 2011;14:103-108.
39. Bensmail D, Quera Salva MA, Roche N, et al. Effect of intrathecal baclofen on sleep and respiratory function in patients with spasticity. *Neurology.* 2006;67:1432-1436.
40. Stempien L, Tsai T. Intrathecal baclofen pump use for spasticity: a clinical survey. *Am J Phys Med Rehabil.* 2000;79:536-541.
41. Burchiel KJ, Hsu FP. Pain and spasticity after spinal cord injury: mechanisms and treatment. *Spine (Phila Pa 1976)* 2001;26(suppl 24):S146-S160.
42. Simpson DM, Gracies JM, Graham HK, et al. Assessment: botulinum neurotoxin for the treatment of spasticity (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology.* 2008;70:1691-1698.
43. Bakheit AMO. Chemical neurolysis in the management of spasticity. In: Barnes MP, Johnson GR, eds. *Upper motor neuron syndrome and spasticity: clinical management and neurophysiology*. 2nd ed. Cambridge University Press; 2001:150-164.
44. Cleveland Clinic. Spasticity. Accessed August 15, 2022. https://my.clevelandclinic.org/health/diseases/14346-spasticity
45. Milligan J, Ryan K, Lee J. Demystifying spasticity in primary care. *Can Fam Physician*. 2019;65(10):697-703.

46. Shilt JS, Seibert PS, Kadyan V. Optimal management for people with severe spasticity. *Degener Neurol Neuromuscul Dis*. 2012;2:133-140. doi:10.2147/DNND.
47. Green NE, Swointkowski MF, eds. *Skeletal Trauma in Children.* 4th ed. Saunders, Elsevier; 2008.
48. First W. Overcoming disparities in US health care. *Health Affairs.* 2005;24:445-451.
49. Association of Academic Physiatrists. An Overview. Accessed August 23, 2022. https://www.physiatry.org/page/WhatIsPhysiatry?&hhsearchterms=%2210%2c000%22
50. Kazerooni R, Healy S, Verduzco-Gutierrez M. Disparities in Access to Spasticity Chemodenervation Specialists in the United States: A National Analysis of Medicare Data. Abstract Presented at: MDS Virtual Congress 2021; September 17-22, 2021; Virtual Congress. Abstract Number 352.
51. American Association of Physical Medicine and Rehabilitation. Reimbursement issues related to botulinum toxin for spasticity. Data on file. 2022.
52. Botox onabotulinumtoxinA injection. What will I pay for Botox? Accessed August 25, 2022. https://www.allerganpricing.com/botox
53. Botox. Prescribing information. UCB; 2017. Accessed August 25, 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf
54. Dysport. Prescribing information. UCB; 2020. Accessed August 25, 2022. https://www.ipsen.com/websites/Ipsen_Online/wp-content/uploads/2020/07/10002305/DYS-US-004998_Dysport-PI-July-2020.pdf
55. Xeomin. Prescribing information. UCB; 2021. Accessed August 25, 2022. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=ccdc3aae-6e2d-4cd0-a51c-8375bfee9458&type=display
56. American Medical Association. RBRVS DataManager Online. Accessed October 20, 2022. https://commerce.ama-assn.org/store/ui/catalog/productDetail?product_id=prod280002&navAction=push
57. Botox (onabotulinumtoxinA) Ordering and Storage Instructions. Accessed August 25, 2022.
58. Medical News Today. Does Medicare Cover Botox? Accessed August 25, 2022. https://www.medicalnewstoday.com/articles/does-medicare-cover-botox
59. Gill CE, Hacker ML, Meystedt J, Turchan M, Schnelle JF, Simmons SF, et al. Prevalence and Impact of Spasticity in a Single Nursing Home. *Archives of Physical Medicine and Rehabilitation*. 2008;89(11):e52.
60. Pfister AA, Roberts AG, Taylor HM, Noel-Spaudling S, Damian MM, Charles PD. Spasticity in adults living in a developmental center. *Arch Phys Med Rehabil*. 2003;84(12):1808-1812. doi:10.1016/s0003-9993(03)00368-x
61. Sayce L, Hudson T. (2016). Spasticity Diagnosis and Treatment in the United States-A Priority for our Aging Population. *International Journal of Neurorehabilitation*. 2016;3(3). doi:10.4172/2376-0281.1000216
62. McGuire J. Epidemiology of spasticity in the adult and child. In: Allison Brashear A, Elovic W eds. *Spasticity: Diagnosis and management*. 2nd ed. Demos Medical Publishing; 2015.
63. Wedekind C, Lippert-Gruner M. Long-term outcome in severe traumatic brain injury is significantly influenced by brainstem involvement. *Brain Inj*. 2005;19: 681-684.
64. Bowers D, Fheodoroff K, Khan P, Harriss JP, Dashtipour K, Bahroo L et al. Spastic paresis and rehabilitation – the patient journey. *Eur Neurol Rev.* 2016; 11(2):87. doi:10.17925/ENR.2016.11.02.87
65. The National Alliance for Caregiving; AARP Public Policy Institute. Caregiving in the U.S. 2015. Accessed August 23, 2022. https://www.caregiving.org/wp-content/uploads/2020/05/2015_CaregivingintheUS_Final-Report-June-4_WEB.pdf
66. National Stroke Association. Lack of Adequate Poststroke Care Unveiled. Accessed March 4, 2014. http://support.stroke.org/site/ DocServer/NSA_Stroke_Perceptions_Survey_Highlights_final. pdf?docID=1942
67. Brands IMH, Wade DT, Stapert SZ, van Heugten CM. The adaptation process following acute onset disability: an interactive two-dimensional approach applied to acquired brain injury, *Clin Rehabil*, 2012;26:840–852. doi: 10.1177/0269215511432018
68. Leathley MJ, Gregson JM, Moore AP, Smith TL, Sharma AK, Watkins CL. Predicting spasticity after stroke in those surviving to 12 months, *Clin Rehabil*. 2004;18:438-443. doi: 10.1191/0269215504cr727oa

69. Benchikh EY, Ottaviani J, McMurdo H, Cresswell K. Improving the patient journey towards enhanced management of spasticity. Presented at the 9th World Congress of the International Society of Physical and Rehabilitation Medicine, Berlin, June 2015.
70. Pradines M, Masson I, Portero R, Giroux C, Gracies JM. Muscle lengthening and structural changes in the muscle-tendon complex of triceps surae after 1 year of rehabilitation including a daily self-stretch program in patients with chronic hemiparesis. *Ann Phys Rehabil Med*. 2016;59(suppl):e73. doi: 10.1016/j.rehab.2016.07.170
71. Watkins CL, Leathley MJ, Gregson JM, Moore AP, Smith TL, Sharma AK. Prevalence of spasticity post stroke. *Clin Rehabil*. 2002;16(5):515-522. doi:10.1191/0269215502cr512oa
72. Rizzo MA, Hadjimichael OC, Preiningerova J, Vollmer TL. Prevalence and treatment of spasticity reported by multiple sclerosis patients. *Mult Scler*. 2004;10(5):589-595. doi:10.1191/1352458504ms1085oa
73. Irwin J, Carter A, Smith S, Dimarco P. Transforming trauma rehabilitation, recommendations for the north east region, Northern Trauma System Executive Group, 2013. Accessed July 30, 2014. https://www.nescn.nhs.uk/wp-content/uploads/2014/07/Final-Trauma- Rehab-report2.pdf
74. Ayala C, Fang J, Luncheon C, et al. Use of outpatient rehabilitation among adult stroke survivors — 20 States and the District of Columbia, 2013, and Four States, 2015. *MMWR Morb Mortal Wkly Rep*. 2018;67:575–578. doi: http://dx.doi.org/10.15585/mmwr.mm6720a2
75. Hesse S, Mach H, Frohlich S, Behrend S, Werner C, Melzer I. An early botulinum toxin A treatment in subacute stroke patients may prevent a disabling finger flexor stiffness six months later: a randomized controlled trial. *Clin Rehabil*, 2011;26:237-245. doi:10.1177/0269215511421355
76. Hubble J, Schwab J, Hubert C, Abbott C. Dysport (botulinum toxin type a) in routine therapeutic usage: a telephone needs assessment survey of European physicians to evaluate current awareness and adherence to product labeling changes. *Clin Neuropharmacol*. 2013;36:122-127. doi: 10.1097/WNF.0b013e318296e630
77. Barnes M, Kocer S, Fernandez MM, Balcaitiene J, Fheodoroff K. An international survey of patients living with spasticity. *Disabil Rehabil*. 2017;39(14):1428-1434. doi: 10.1080/09638288.2016.1198432.
78. Chan L, Sandel ME, Jette AM et al. Does postacute care site matter? A longitudinal study assessing functional recovery after a stroke. *Arch Phys Med Rehabil*. 2013;94(4):622-629. doi:10.1016/j.apmr.2012.09.033
79. Tritter JQ, Lutfey K, McKinlay J. What are tests for? The implications of stuttering steps along the US patient pathway. *Soc Sci Med*. 2014;107:37-43. doi: 10.1016/j.socscimed.2014.02.012
80. Gill CE, Taylor HM, Putman MS, Charles D. Spasticity in public developmental centers for adults with intellectual disability: A survey of medical directors. *Movement Disorders*. 2009;24:S452.
81. U.S. Census Bureau. Ortman JM, Velkoff VA, Hogan H. An aging nation: The older population in the United States. Accessed August 23, 2022.
82. Fassett DR, Harrop JS, Maltenfort M, Jeyamohan SB, Ratliff JD, et al. Mortality rates in geriatric patients with spinal cord injuries. *J Neurosurg Spine*. 2007;7:277-281.
83. Hall MJ, Levant S, DeFrances CJ. Hospitalization for stroke in U.S. hospitals, 1989-2009. NCHS Data Brief. 2012;(95):1-8.
84. Graham LA. Management of spasticity revisited. *Age and Ageing*. 2013;42(4):435–441.
85. AARP Public Policy Institute. Reinhard S, Young HM, Levine C, Kelly K, Choula R, Accius J. Home alone revisited: family caregivers providing complex care. Accessed August 23, 2022. https://www.aarp.org/ppi/info-2018/home-alone-family-caregivers-providing-complex-chronic-care.html
86. AARP Public Policy Institute. Reinhard S, Young HM, Levine C, Kelly K, Choula R, Accius J. Home alone revisited: at a glance. Accessed August 23, 2022. https://www.aarp.org/content/dam/aarp/ppi/2019/11/home-alone-revisited-at-a-glance.doi.10.26419-2Fppi.00086.001.pdf
87. Gbiri CA, Olawale OA, Isaac SO. Stroke management: Informal caregivers' burdens and strians of caring for stroke survivors. *Annals of Physical and Rehabilitation Medicine*. 2015;58(2):98-103.
88. May HL, Lui, Ross FM, Thompson DR. Supporting family caregivers in stroke care - a review of the evidence for problem solving. *Stroke.* 2005;36:2514-2522. doi: 10.1161/01.STR.0000185743.41231.85

89. Skolarus LE, Freedman VA, Feng C, Wing JJ, Burke JF. Care Received by Elderly US Stroke Survivors May Be Underestimated. *Stroke*. 2016;47(8):2090-2095. doi:10.1161/STROKEAHA.116.012704
90. Lundström E, Smits A, Borg J, Terént A. Four-fold increase in direct costs of stroke survivors with spasticity compared with stroke survivors without spasticity: the first year after the event. *Stroke*. 2010;41(2):319-324. doi: 10.1161/STROKEAHA.109.558619