Catastrophic Spinal Cord Injury and Spasticity Management:

Recognizing factors that influence volatility, functional outcomes and costs

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OUTCOMES

Indira S. Lanig, MD - Paradigm Medical Director

Julie Fawson, BSN, RN – Paradigm Associate Vice President, Clinical Services

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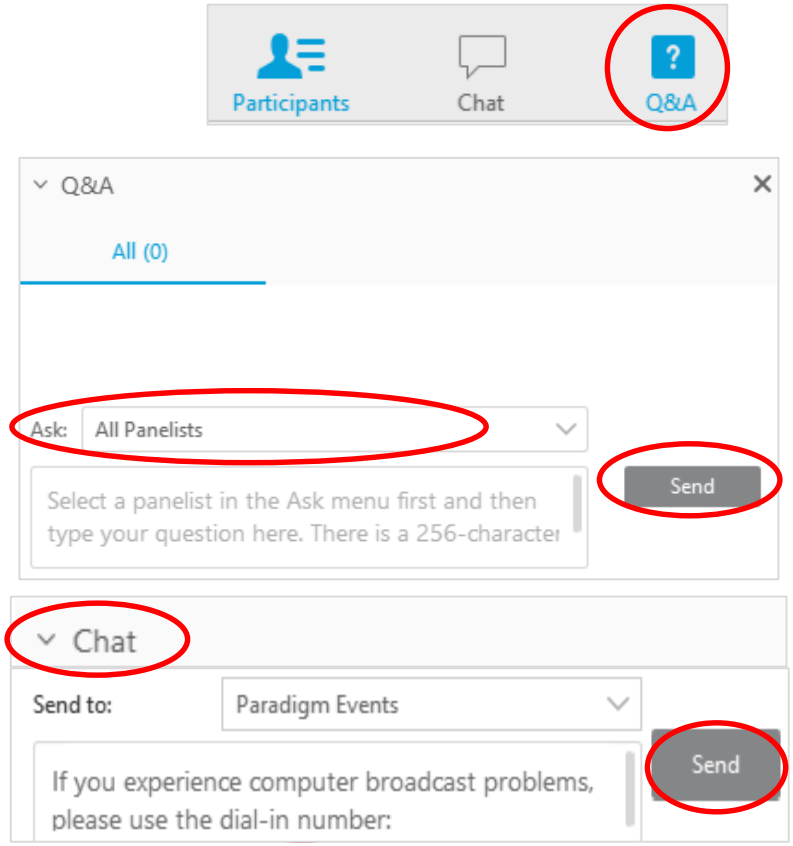

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Our Speakers Today

Indira S. Lanig, MD
Paradigm Medical Director

- Board Certification in Physical Medicine and Rehabilitation with Subspecialty Certification in SCI Medicine
- Past Chief of SCI Service Houston VAMC, Baylor College of Medicine, Houston Texas
- Past Attending Physician at Craig Hospital , Rocky Mountain Regional Model System of Care
- Current Chairwoman of the NIH Advisory Board on Medical Rehabilitation and Research (2018)

Julie Fawson, BSN, RN
Paradigm AVP Clinical Services

- Director of Clinical Services for Paradigm since 2000
- Over 30 years of experience in clinical management, operations management, product development and management, sales and marketing, and team development
- She has worked in all levels of the catastrophic injury healthcare continuum including acute care, outpatient, rehabilitation, home health, and home and community based healthcare

Our Conversation Today Centers on Four Objectives

Summarizing the demographics, prevalence, and features of spasticity that contribute to uneven recognition and management by providers

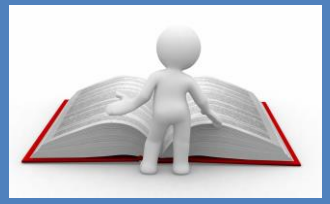
Describing effective case management strategies to address common barriers to the optimized management of problematic spasticity

Delineating the value of referencing of a SCI-specific Clinical Pathway algorithm to support clinical decision-making that optimizes both financial and functional outcomes

Reflecting on opportunities to encourage treating providers to incorporate best practice into their particular setting

1

Recognition, Evaluation and Treatment



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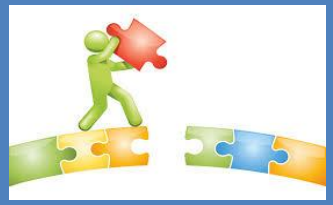
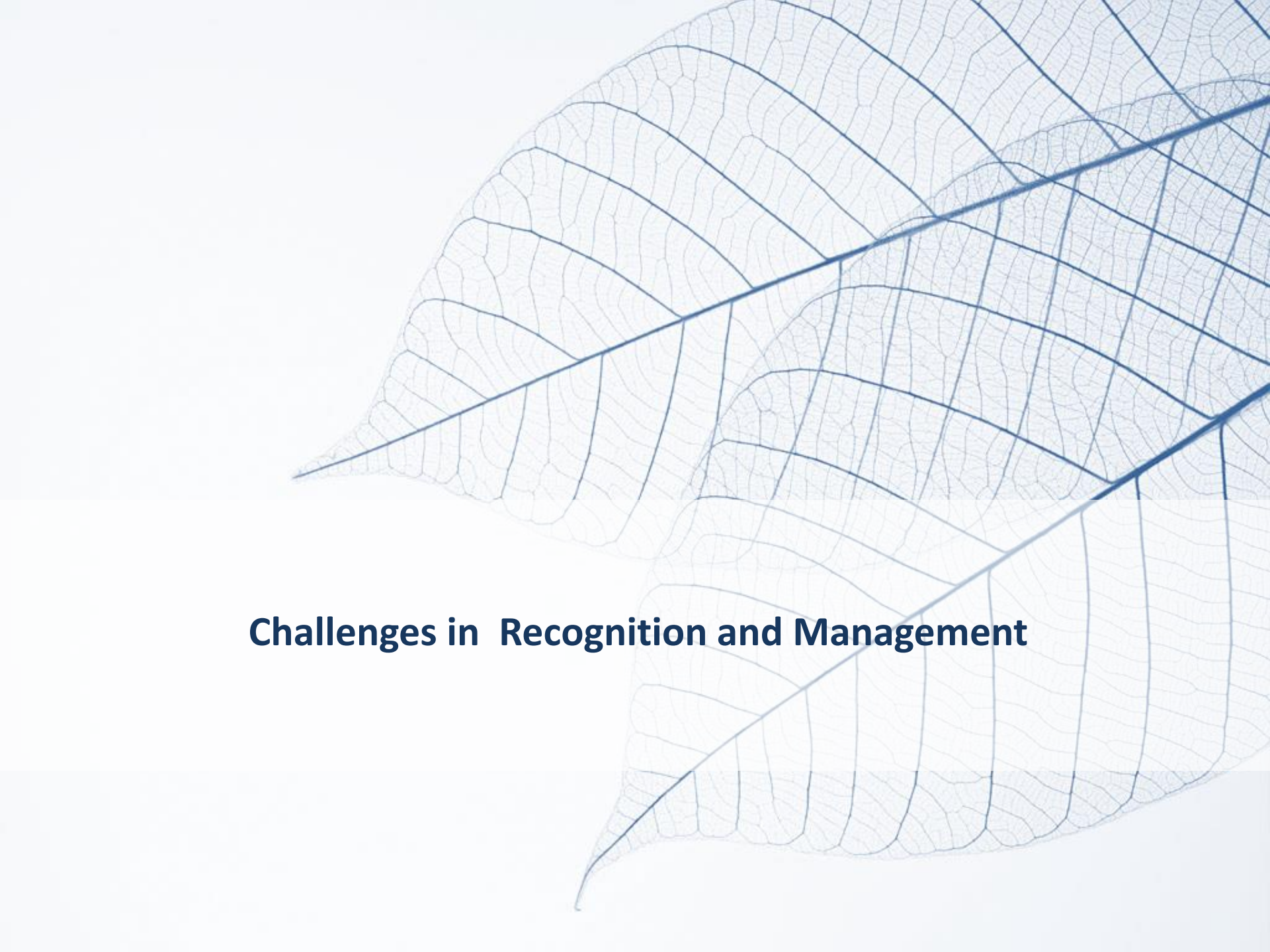
A Clinical Pathway for Clinical Decision-making Support



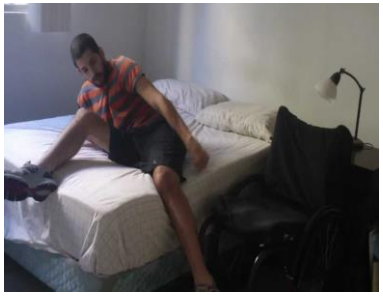


Challenges in Recognition and Management

The Nature of Spasticity

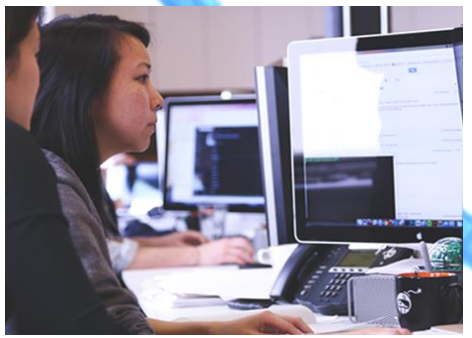
Spasticity evolves

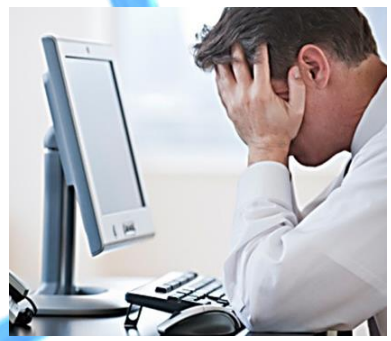
Spasticity is interactive with other stimuli



Spasticity must be evaluated and interpreted in relationship to space, time, other stimuli, symptoms, and patient goals

The Nature of Our Healthcare System and Our Silos



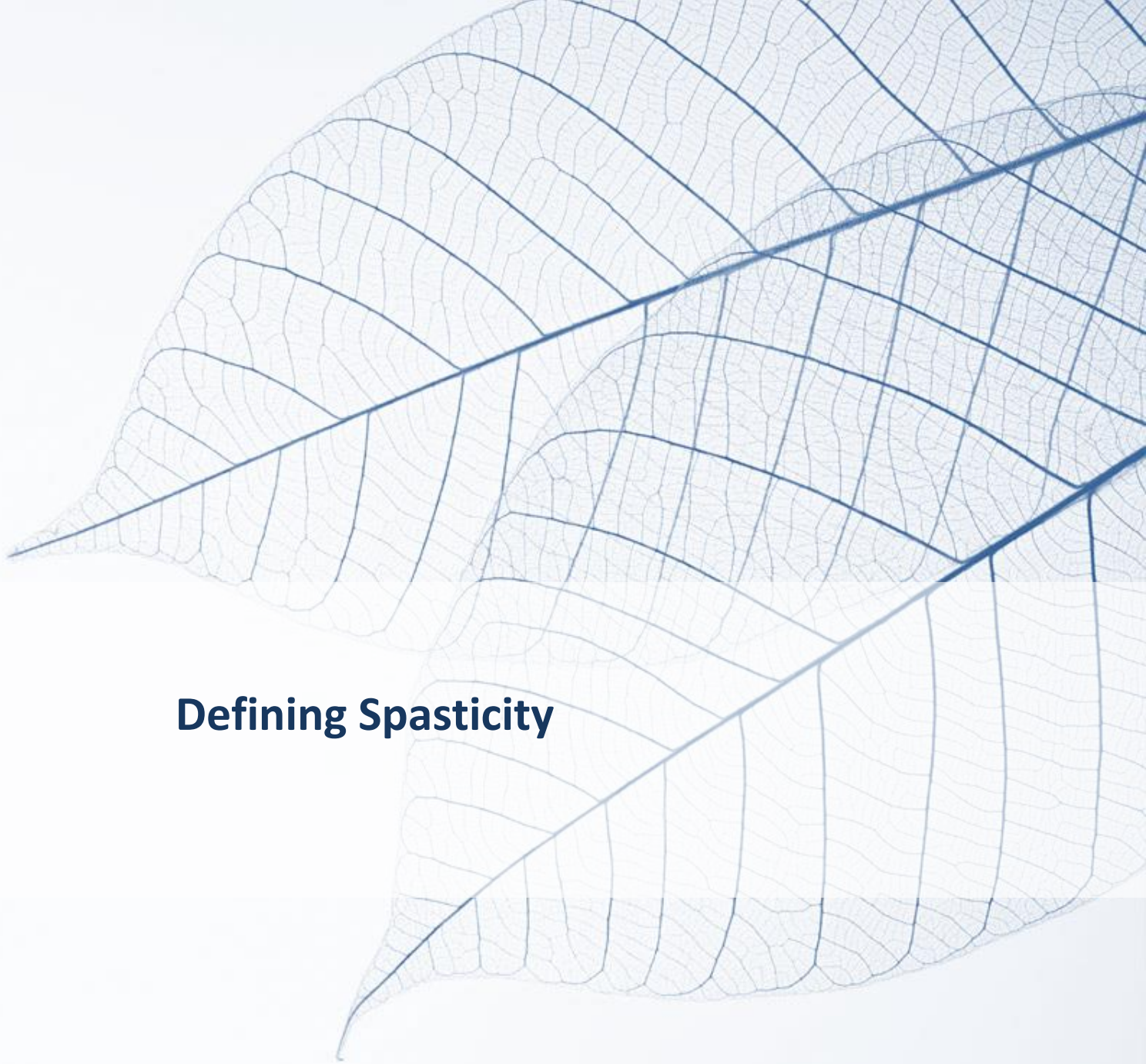


Spasticity in Spinal Cord Injury

- 65-78% of persons with SCI
- Problematic in 28-43%
- Medications needed in 43-49%
- An important factor that can decrease quality of life

Spasticity in Spinal Cord Injury

- Incomplete injuries > complete injuries
- Tetraplegia > paraplegia
- Legs > arms
- Extension > flexion



Defining Spasticity

Many Definitions of a Complex Circuitry Problem

Table 2 Summary of definitions of spasticity found in the literature

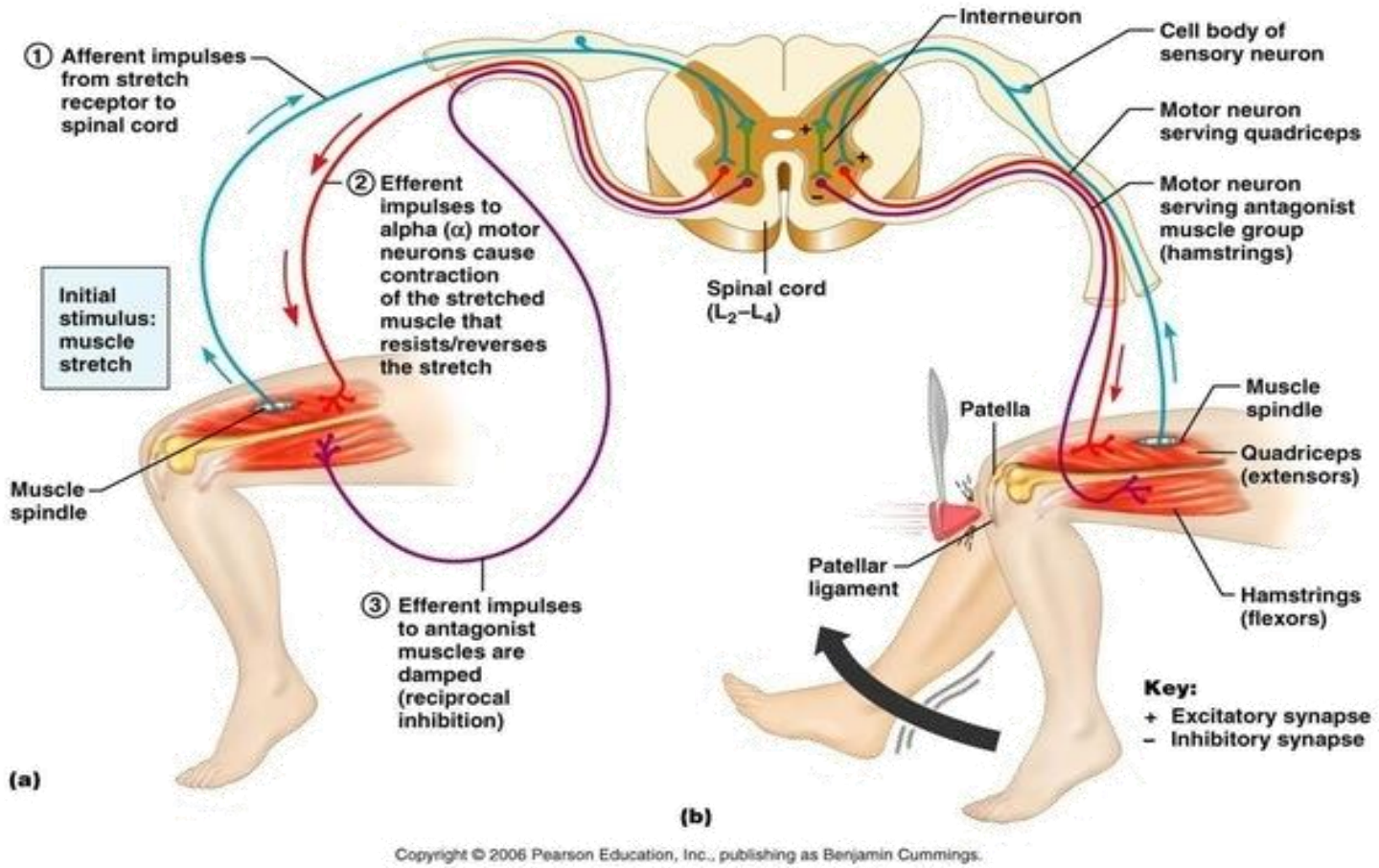
Definition	Author, Year
"[...] the presence of a soft yielding resistance that appears only towards the end of passive stretch, and is associated with increased amplitude of tendon reflex."	Denny-Brown,[30(p129)] 1966
"A velocity-dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motor neurone syndrome"	Lance,[31(p485)] 1980
"A motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes that result from abnormal intra-spinal processing of primary afferent input"	Young,[32(p513)] 1994
"Muscle hypertonia, hyperactive deep tendon reflexes, clonus, and velocity dependent resistance to passive stretch"	Engsberg,[33(p223)] 2002
"Hypertonia in which 1 or both of the following signs are present: 1) resistance to externally imposed movement increases with increasing speed of stretch and varies with the direction of joint movement, and/or 2) resistance to externally imposed movement rises rapidly above a threshold speed or joint angle"	Sanger,[34(pe91)] 2003
"An unusual tightening of muscles that feels like leg stiffness, jumping of legs, a repetitive bouncing of the foot, muscle cramping in the legs or arms, legs going out tight and straight or drawing up"	Rizzo,[29(p590)] 2004
"An involuntary muscle overactivity, which may have several harmful effects such as pain, deformity, and impaired function"	Ward,[35(p35)] 2003
"Disordered sensori-motor control, resulting from an upper motor neuron lesion, presenting as intermittent or sustained involuntary activation of muscles"	Pandyan,[36(p5)] 2005
"Spasticity is defined as a motor disorder characterized by an involuntary, velocity-dependent increase in muscle tone (hypertonicity) that is associated with neurologic conditions or injury to the brain or spinal cord."	Mullarkey,[37(pS14)] 2009
"Velocity dependent (increasing with faster movement of the limb) and varies in terms of direction of the stretch (with arm flexors and leg extensors being more affected)"	Ostrem,[38(p44)] 2010
"Velocity dependence: [...] the faster the stretch, the greater the muscle resistance"	Kheder,[39(p290-1)] 2012
"Clasp-knife" phenomenon: [...] the limb initially resists movement and then suddenly gives way [...]"	
"Stroking effect: stroking the surface of the antagonist muscle may reduce the tone in spasticity [...]"	
"Distribution: [...] differential distribution with antigravity muscles being more affected"	

Burns AS, Lanig IS, Grabljevec K, et al. Arch Phys Med Rehabil 2016;97:2222-8.

Spasticity Defined

"A motor disorder characterized by a velocity-dependent increase of tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motor neuron syndrome."

(Lance, 1980) *Lance JW. Symposium synopsis. In: Feldman RG, Young RR, Koella WP, editors. Spasticity: disorder of motor control. Chicago: Year Book Medical Publishers: 1980. p 485-94.*



“Spasticity is like love.

You know it when you feel it.

It is gripping and all encompassing.

It is centrally mediated but with important peripheral consequences.”

-Warwick Peacock, MD

Spasticity is a Continuum

Spasticity –

Disordered sensori-motor control, resulting from an upper motor neuron lesion, presenting as intermittent or sustained involuntary activation of muscles. (Pandyan AD et al. Disabil Rehabil 2005;27:2-6)

Disabling Spasticity –

Spasticity which is perceived by the individual or caregivers as hindering body function, activities, and/or participation

Burns AS, Lanig I, Grabljevec K, New PW, Bensmail D, Ertzgaard P, Nene AV. Optimizing the Management of Disabling Spasticity following Spinal Cord Damage – The Ability Network – An International Initiative. Arch Phys Med Rehabil 2016; 97(12): 2222-2228.

Functional Effects of Spasticity

Positive Effects

- Stability in sitting/standing
- Increases venous circulation
- Improves cough
- Improves functional capabilities
  - ADLs (i.e. handgrip; dressing)
  - Mobility (i.e. transfers, ambulation)

Can be a warning system to health problems

Negative Effects

- Medical (pain, stiffness, spasms, positioning, contractures)
- Physical (mobility, ADL, hygiene, cosmesis)
- Psychological (sleep, self esteem, mood)
- Social impact, Recreational impact
- Vocational impact , sexual health impact

"Positive" & "Negative" Symptoms of Disabling Spasticity

Positive Symptoms

Abnormal Movements

- Hyperreflexia
- Clonus
- Co-contractions
- Postural abnormalities
- Disorder of voluntary movements
- Increased muscle stiffness

Positive symptoms – easy to see & treat.

Negative Symptoms

Performance Deficits

- Muscle weakness
- Incoordination
- Fatigue
- Pain

Negative symptoms – more functionally limiting.

Common Noxious Stimuli

Bladder

- UTIs
- Bladder stones

Bowel

- Impaction
- Hemorrhoids

Ingrown Toenail

Other Important Causes:

- Fractures
- Heterotopic ossification
- Menstruation
- Venous Thrombosis
- Pressure Ulcers
- Intra-abdominal pathology (appendicitis, cholecystitis, uterine fibroids etc.)
- Syringomyelia/post traumatic progressive cystic myelopathy

Recognizing and Assessing Disabling Spasticity

Recognition

Consider the nature of spasticity

- Dynamic and evolutionary
- Interacts with other stimuli
- Focal, multisegmental or generalized

Assess the severity

- Clinical measures of presence and extent of spasticity

Evaluate the impact

- Functional impact: physical abilities, independence, burden of care
- Quality-of-life impact: patient-reported outcomes

Clarify functional goals with patient/therapists

- What will spasticity reduction allow the individual or caregivers to do more optimally?

Select appropriate outcomes measures

- Evaluate functional status before and after treatment.
- Did treatment result in improvements? Were pre-stated goals achieved?

Initial Assessment

Penn Spasm Frequency Scale

Composed of 2 parts:

Penn Spasm Frequency Scale:

0 = No spasm
1 = Mild spasms induced by stimulation
2 = Infrequent full spasms occurring less than once per hour
3 = Spasms occurring more than once per hour
4 = Spasms occurring more than 10 times per hour

Spasm Severity:

1 = Mild
2 = Moderate
3 = Severe

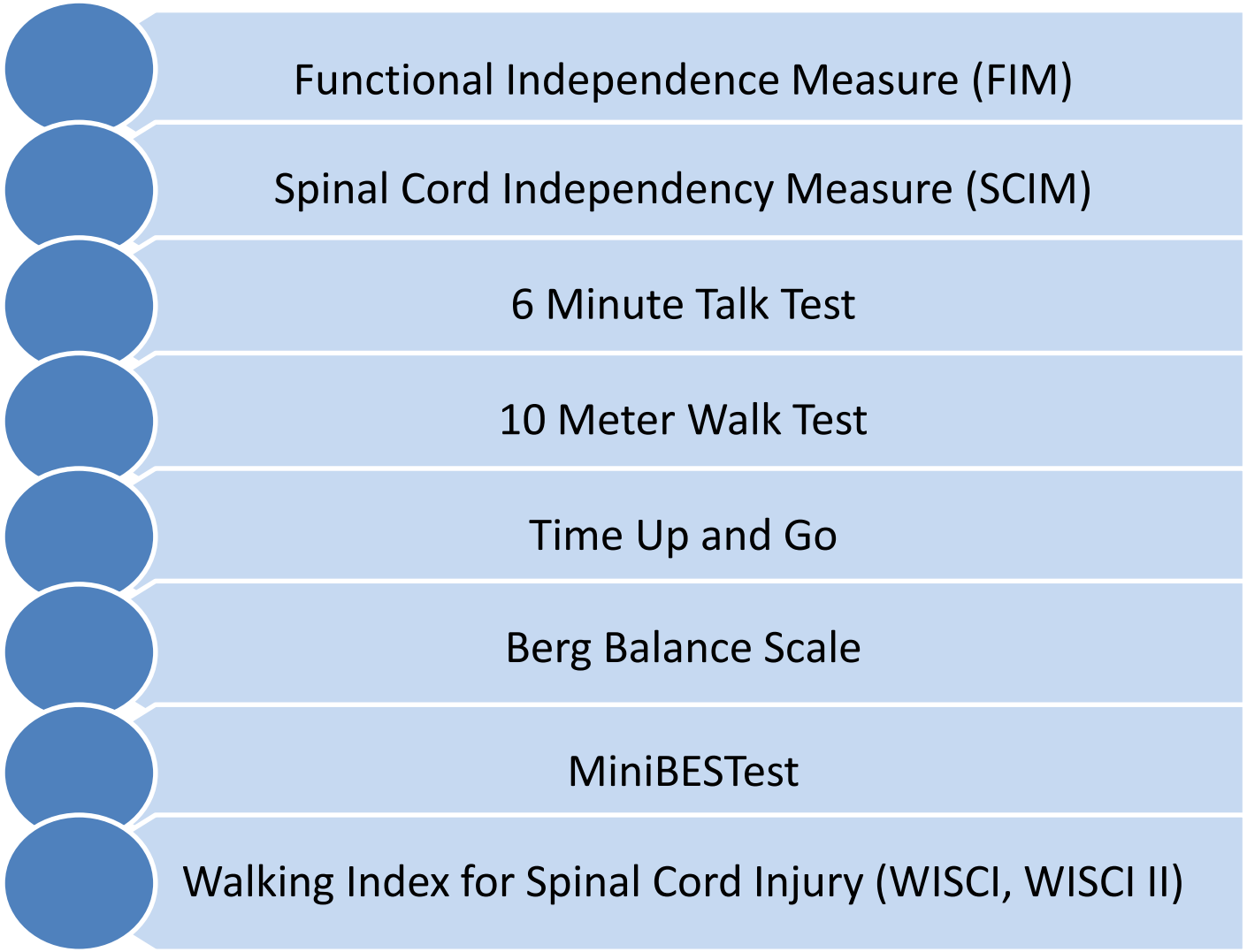
If the patient indicates no spasms in Part 1, then they do not proceed to Part 2.

“Objective” Assessments

Clinical/Qualitative Assessments

- Modified Ashworth Scale
- Tendon Taps
- SCATS, SCI-SET
- Pendulum Test
- Functional Assessments

Functional Assessments



Problems with the different scales & tests:

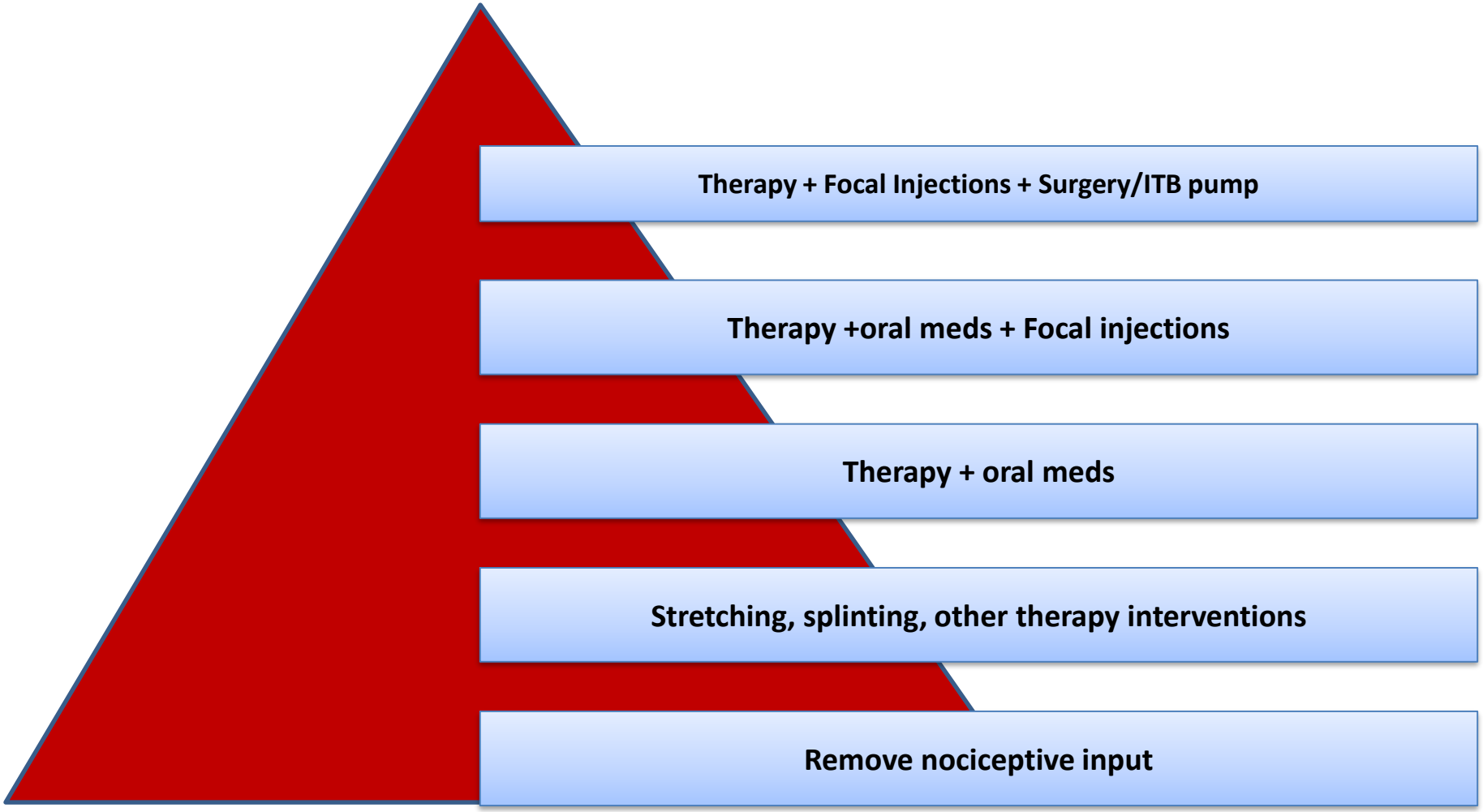
- Static tests for a dynamic process
- Test positions usually are not the positions of function
- Poor correlation between scales
- Discrepancy between self-rated and clinical scores
- A decrease in score does not necessarily correlate with improved function
- There is still no measure that addresses the specific impact of spasticity in limiting activity or participation

Therapeutic Interventions

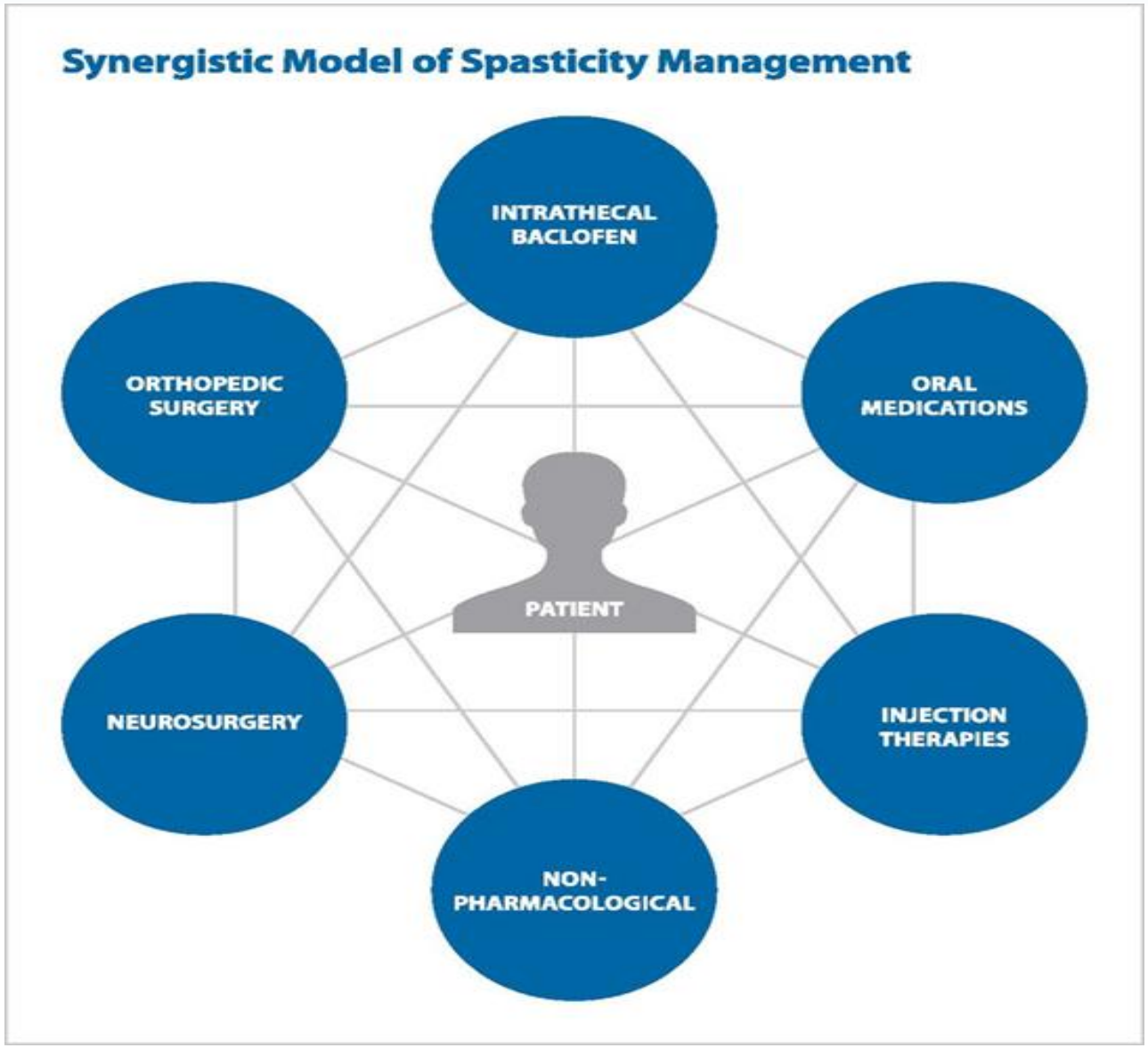
Indications for Treatment

- Does the spasticity cause pain?
- Does it affect safety and independence? Burden of care?
- Is it leading to contracture? Skin breakdown?
- Does it interfere with function? Sleep? Breathing?
- Does it impair hygiene/ personal care?
- Is clonus a dominant feature?
- Does it affect quality of life?

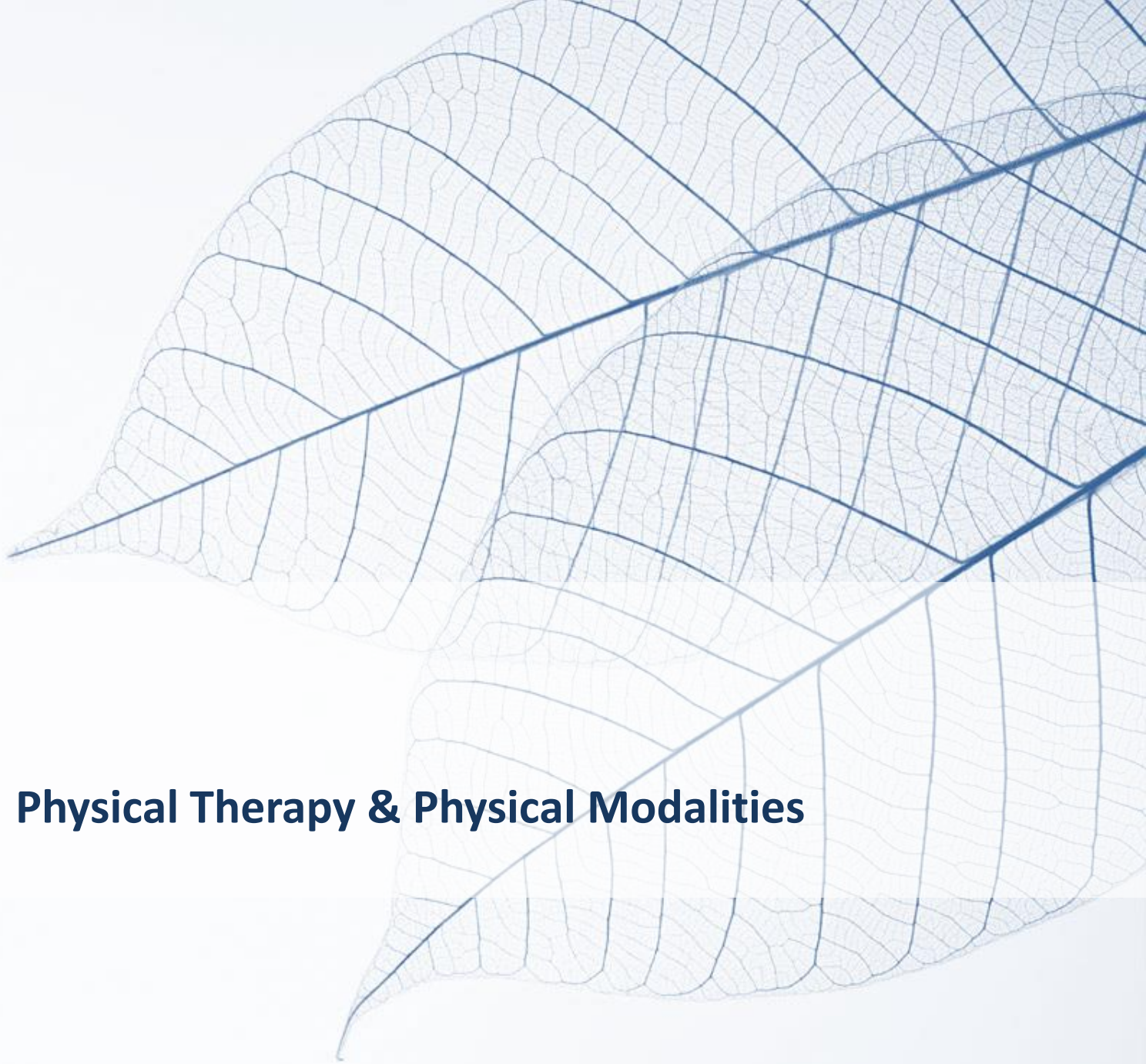
Treatment:
The “Classic” Pyramid



Spasticity Treatment Is Nonlinear & Synergistic



Saulino M., Ivanhoe C.B., McGuire J.R., Ridley B., Shilt J.S., Boster A.L. 2016. Best Practices for Intrathecal Baclofen Therapy: Patient Selection. Neuromodulation 2016; 19: 607 - 615



Physical Therapy & Physical Modalities

Stretching

- Dynamic and evolutionary
- Reduces motor neuron excitability and tone
- Focuses on muscles at risk for contracture
- Superficial heat may help tolerance, but doesn't change tone
- Standing provides prolonged stretch and may improve spasticity in some

Posture and Positioning

- Lumbar support in wheelchairs
- Good flexibility of hamstrings
- Avoid sling seats
- The "Dump" and "Squeeze" of the wheelchair encourage upright posture and reduce extensor tone

Orthotics / Splinting

- Static or dynamic splinting
- Serial casting
- An adjunct to pharmacologic intervention, chemodenervation
- Can aid in gaining range of motion
- Timing is important

Modalities

- **Cold**
  20 minute application required for short lived benefits (~1 hour)
- **Biofeedback**
- **Electrical stimulation (FES, NMES)**
- **Vibration (whole body or local)**

Oral Drug Treatments

Most Common Oral Medications for Spasticity

Medication	Usual Dosage	Considerations & Common Side Effects
Baclofen	5mg TID – 40mg QID	Sedation, ataxia, muscle weakness. Abrupt withdrawal may result in seizures & hallucinations.
Diazepam	5mg q day – 10mg QID	Sedation, impaired memory & attention, impaired motor coordination. Dependence
Dantrolene	25mg q day – 100mg QID	Nausea, diarrhea, malaise , generalized muscle weakness. May cause hepatotoxicity. Liver enzymes should be monitored.
Tizanidine	2mg q day – 36mg/day in divided doses. Better tolerated as a QID dosing	Dry mouth, drowsiness(41-46%), dizziness, mild hypotension, elevated liver enzymes. Avoid use with Cipro
Clonidine	0.1-0.3mg transdermal	Orthostasis, bradycardia, dry mouth, constipation, ankle edema, drowsiness.
Gabapentin	100mg TID – 1200mg TID	Sedation, ataxia, tremor, dyspepsia, constipation

Injectable Drug Therapies

Botulinum Toxins (A and B)

Mechanism: binds at the neuromuscular junction to inhibit release of acetylcholine

- FDA approved use: both upper and lower extremity muscles
- Onset (3 days), peak (3 weeks), duration (3 months)
- Dose: total max dose/visit: varies with type of toxin used

Botulinum Toxin Dosing Guidelines

Muscle	Onabotulinumtoxin A (Botox) & Incobtulinum toxin A dose (Xeomin) (units)	Abobotulinumtoxin A dose (units) (Dysport)	Rimabotulinumtoxin B Dose (units) (Mycobloc)
Pectoralis	75-150	150-300	2,500-5,000
Biceps	50-200	100-400	2,500-5,000
Triceps	50-200	100-400	
Flexor Carpi Radialis	25-100	150	1,000-3,000
Flexor Carpi Ulnaris	20-70	100-150	1,000-3,000
Flexor Digitorum Superficialis	20-60	150-300	1,000-3,000
Flexor Digitorum Profundus	20-60	150-200	1,000-3,000
Hip Adductors	200-400	500-1000	5,000-10,000
Quadriceps	50-200		5,000-7,500
Gastrocnemius	50-250	250-1000	3,000-7,000
Posterior Tibialis	50-150	200-500	3,000-7,5000
Anterior Tibialis	50-150		2,500-5,000

Motor Block Points:

- Focal treatment for a systemic problem
- Phenol (4-6%) or ethanol (35-60%)
- Results: rapid reduction, variable duration of action (3-12 months)
- Side effects: pain, edema, DVT, permanent degeneration of the axon

Nerve Blocks:

- Perform on mostly motor nerves (i.e. Obturator, Musculocutaneous, etc.)
- Phenol or ethanol
- Lasts longer than botulinum toxins (~6-12 months)
- Monitor for dysesthesias (from incomplete block)

Surgical Interventions

Surgical Interventions

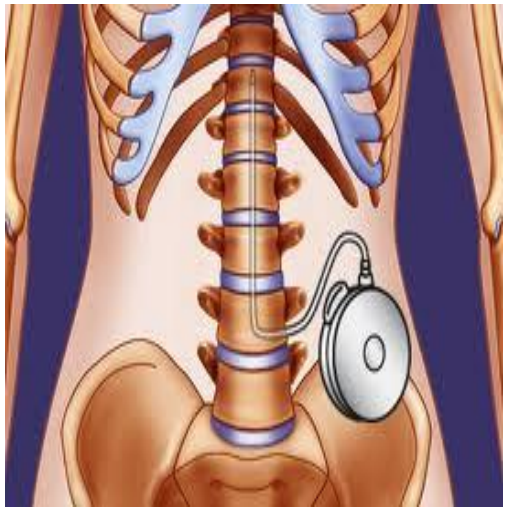
Intrathecal Baclofen Pump

Other Surgical Options (Irreversible)

- Peripheral Ablative Procedures
  - Selective dorsal rhizotomy, peripheral neurectomy
- Central Ablative Procedures
  - Myelotomy, cordectomy

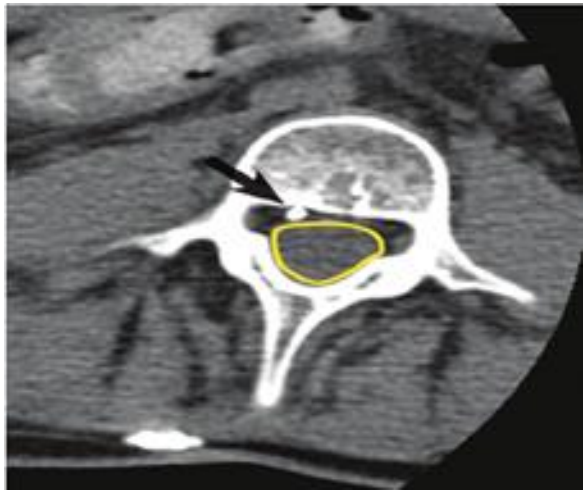
Indications

- Severe spasticity of spinal or cerebral origin (97% efficacy in SCI)
- Refractory to oral medications or side-effects are intolerable
- Patient responds to intrathecal bolus of <100ug (screening trial)



Considerations

- Reversible
- Programmable dosing
- Intrathecal delivery is 100x more potent than oral delivery
- Patient selection process



ITB Test Dose/Screening Trial

- If severe disabling spasticity is present, it is appropriate not to wait to do a screening test dose
- A successful screening dose provides valuable information for decision-making (by both the patient and the provider) and is noncommittal
- If you do a screening test, do it right

Screening Trial ("Test Dose")

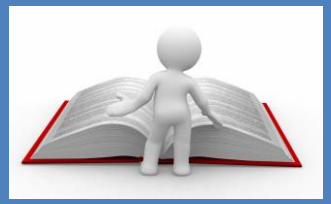
- Assess spasticity
- Administer 50-100ug via lumbar puncture
- Onset is within 30-60 minutes
- Peak effect is 4 hours
- Monitor response for a minimum of 4-6 hours. Document accurately per protocol.
- If response less than desired, perform 2nd bolus with 75ug 24 hours later.
- A 3rd bolus of 100ug may be tried 24 hours after the second bolus.

Titrating Dose After Implantation

- Initial dose is based upon response to trial
  - Can increase 10 – 15% once every 24 hrs
- Lowest dose with an optimal response should be used
- Range: Most common – 300 to 800 micrograms daily (can go higher if clinically benefitting)
- Therapy and oral medication wean are undertaken concurrent with dose titration

1

Recognition, Evaluation and Treatment



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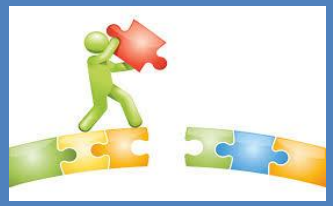
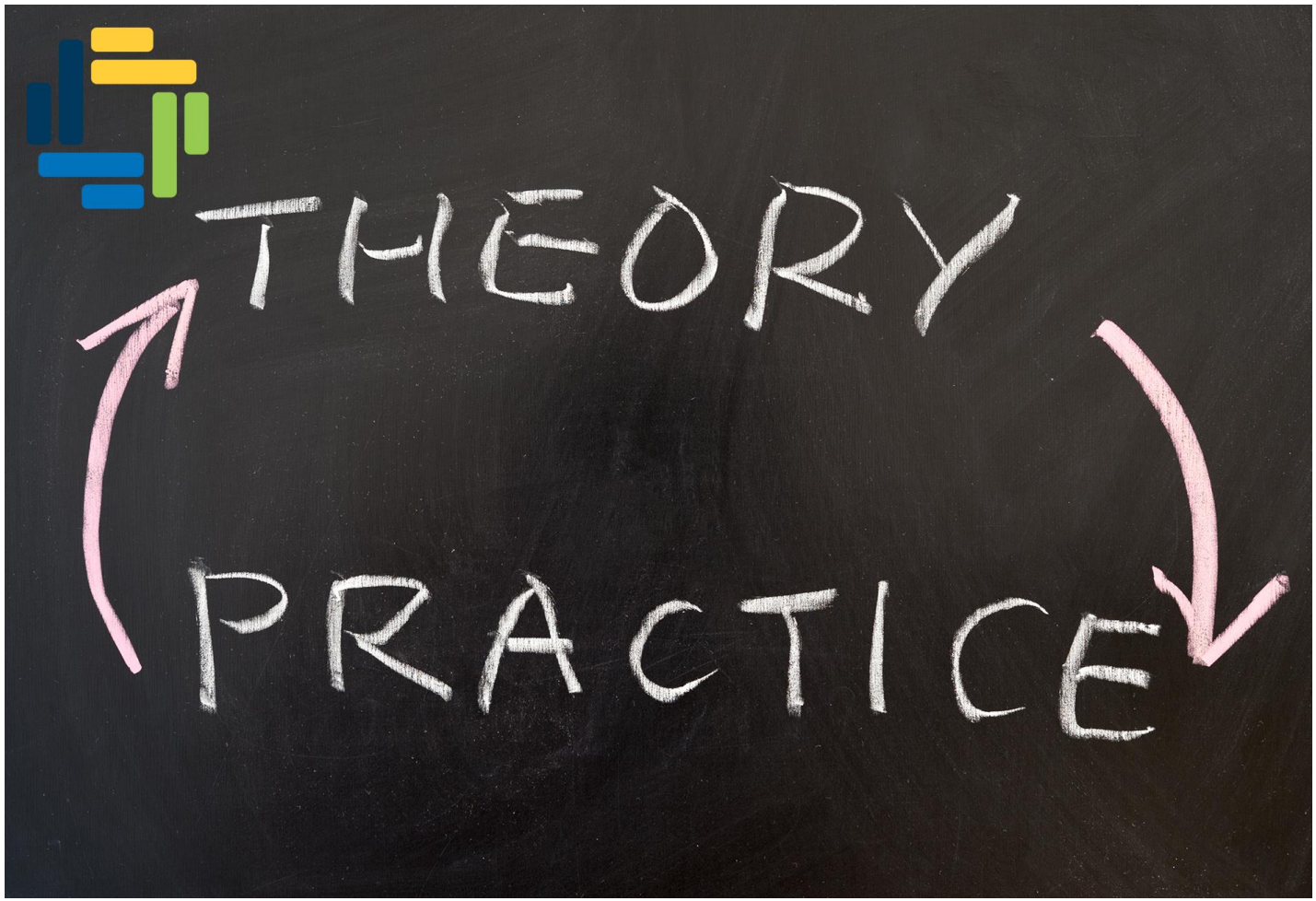
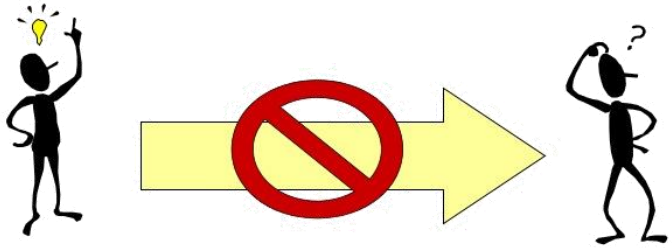
A Clinical Pathway for Clinical Decision-making Support





Barriers to Effective Decision Making

What are some barriers to successful knowledge management?



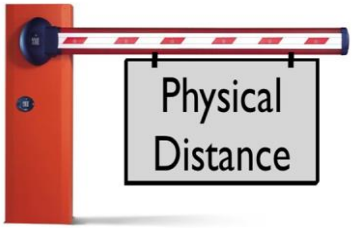
KNOWLEDGE gap

- Knowledge is power
- Lack of understanding
- Lack of incentive
- Time constraint

- Lack of awareness
- Not-invented-here
- Lack of incentive
- Time constraint

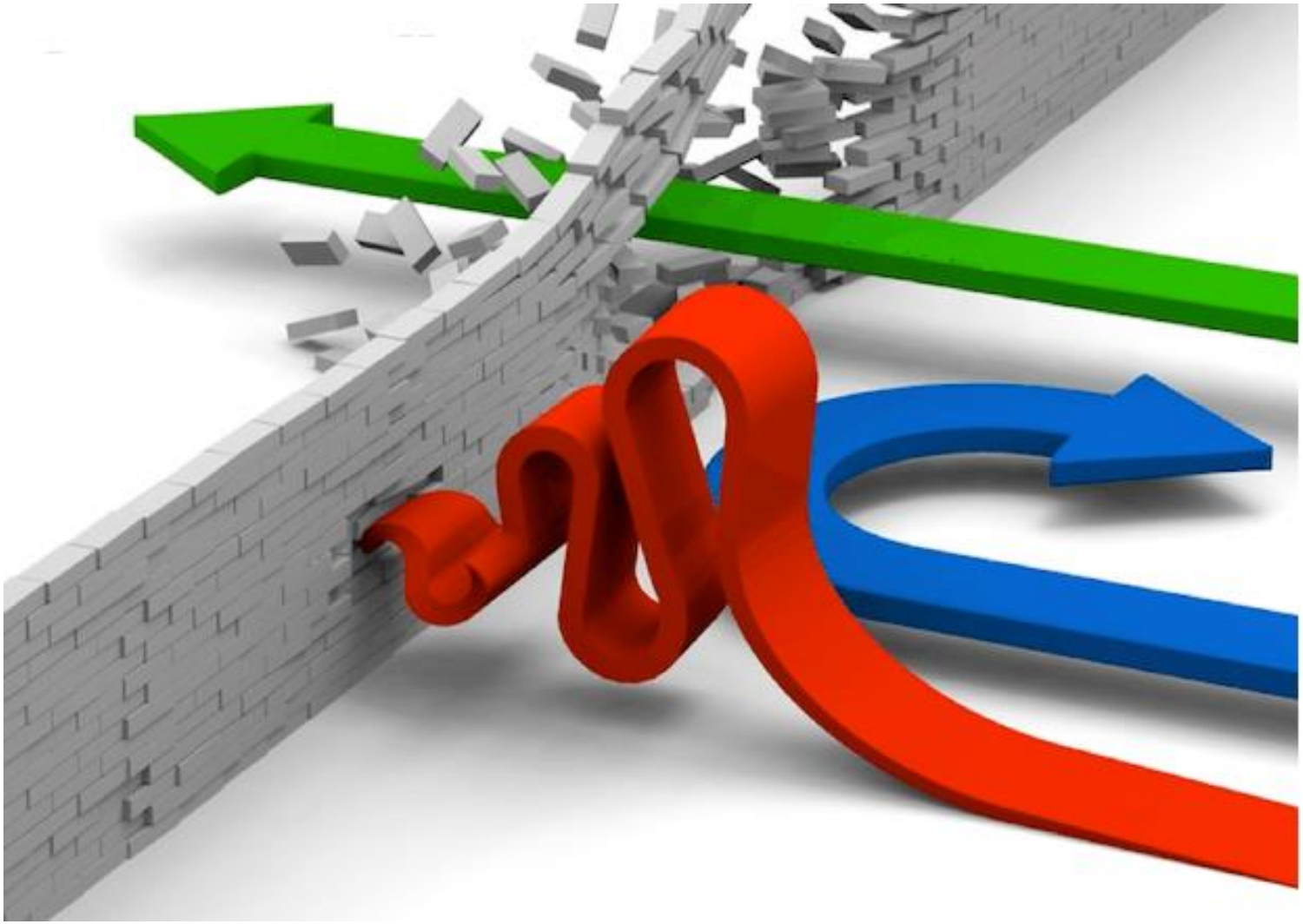
Scarce Resources

Incomplete Information



The Missing Piece

Breaking Barriers



Clinical Pathways *Help Translate* Clinical Practice Guidelines Into Local Settings

Criteria for an operational definition of a Clinical Pathway (CPW):

- Is it a structured multidisciplinary care plan?
- Is it used to channel the translation of guidelines or evidence into local structures ?
- Does it detail the steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol or other 'inventory of actions' (i.e. the intervention has time frames or criteria based progression)?
- Does it aim to standardize care for a specific clinical problem, procedure or episode of care in a specific population?

Adegboyega K. Lawal et.al What is a clinical pathway? Refinement of an operational definition to identify clinical pathway studies for a Cochrane systematic review. BMC Medicine201614:35

The Ability Network - Acknowledgments

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Kiekens, Carlotte: University Hospital Leuven, Belgium

Lanig, Indira S.: Northern Colorado Rehabilitation Hospital, Johnstown CO, USA

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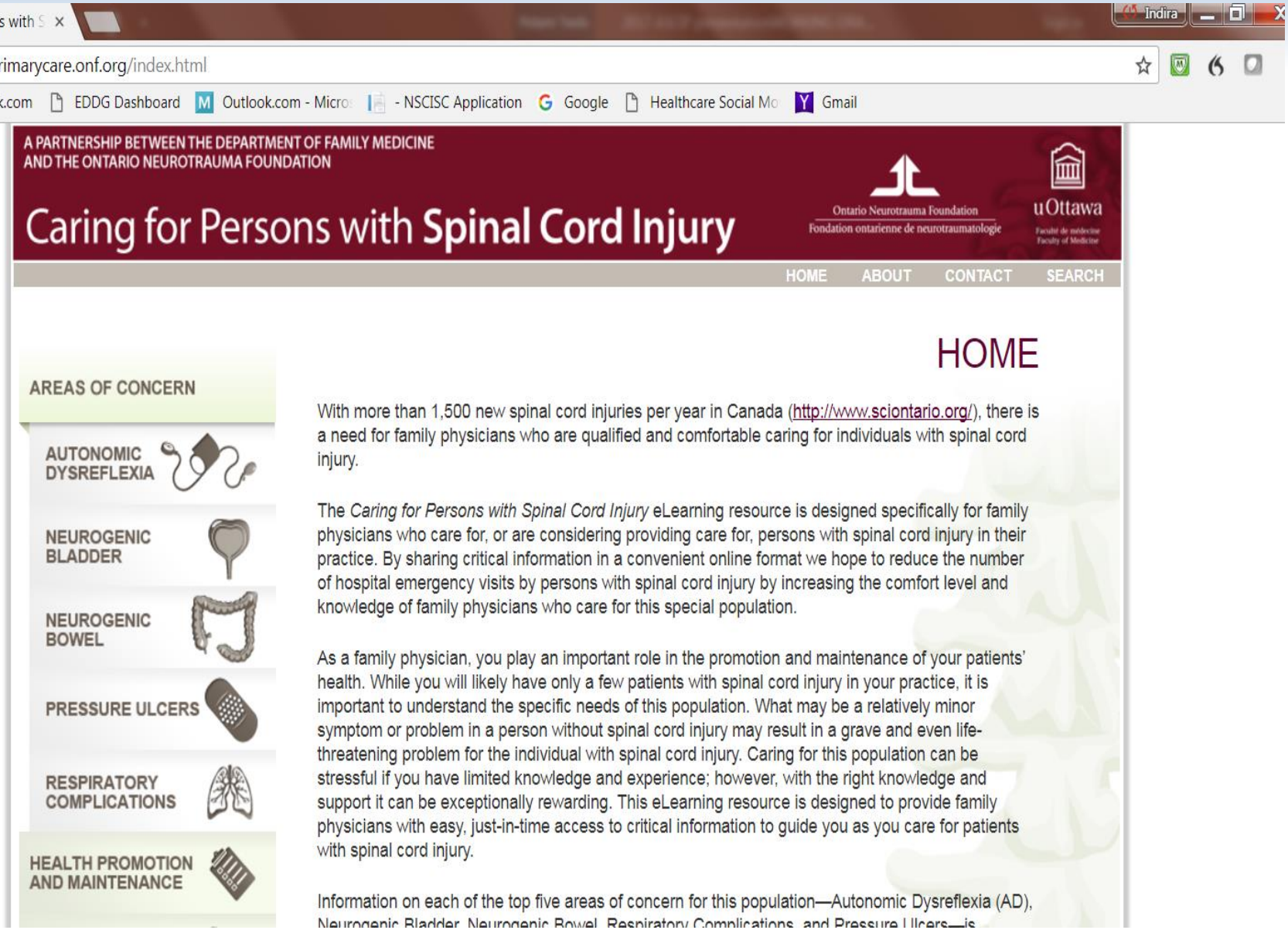
Rainha Campos, Alexandre: Hospital de Santa Maria, Lisbon, Portugal

Viaene, Annick: University Hospital, Ghent, Belgium

Yochelson, Michael R.: Shepherd Center, Atlanta, GA USA

Providers



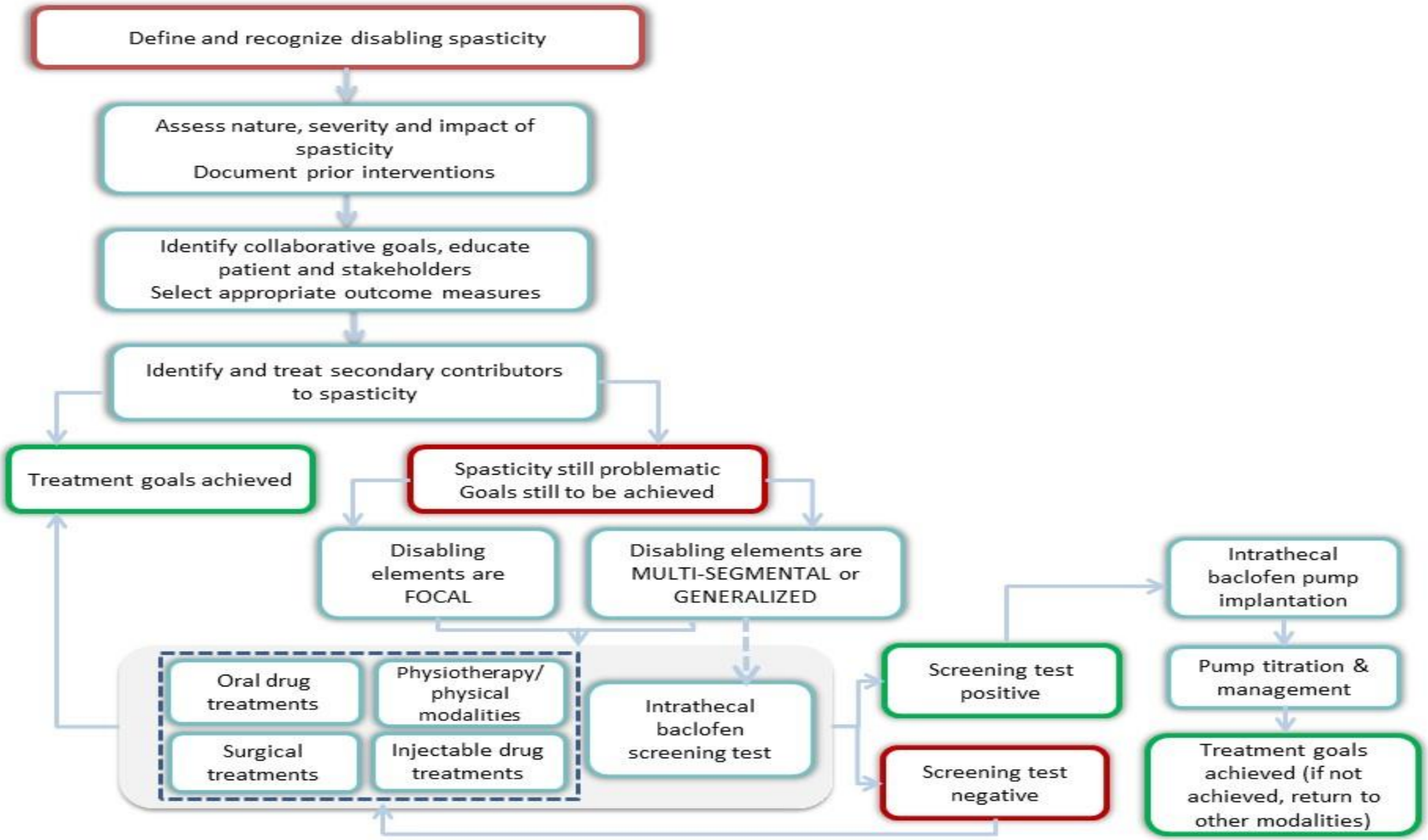
The first step in solving a problem is recognizing there is one.

Decision Points And Stalling Out

Expert

Judgement

Clinical Care Pathway For The Recognition And Management Of Disabling Spasticity



IS Lanig, P New, AS Burns, G Bilsky, J Benito Penalva, D Bensmail, M Yochelson . Optimizing the management of spasticity in people with spinal cord damage: a clinical care pathway for assessment and treatment decision making from the Ability Network, an international initiative. Arch Phys Med Rehabil (In Press)
2 https://doi.org/10.1016/j.apmr.2018.01.017

Electronic Medical Record:
Data Collection and Reporting for Spinal Cord Injury – including International SCI Data Sets and Standards for Neurological Classification of SCI.

Fin Biering-Sørensen, MD, Clinic for Spinal Cord Injuries, Rigshospitalet, University of Copenhagen, Denmark; Gianna Maria Rodriguez, MD, Physical Medicine and Rehabilitation, University of Michigan Hospital System, Ann Arbor, Michigan, USA; Stacey Cohen, PT, Clinical Informatics, Mount Sinai Health System, New York, NY, USA

Introduction to Epic:

EpicCare Inpatient and EpicCare Ambulatory are two core applications in Epic. Encounters in each context differ, therefore care must be taken while setting up documentation tools in order to store and access data captured in both inpatient and outpatient contexts.

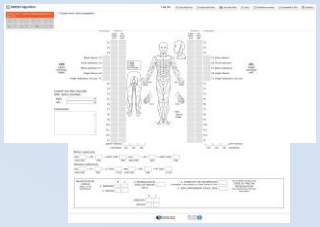
Flowsheets and SmartForms are two tools to enter information in a standardized manner and to capture discrete data. This information can be extracted for analysis through Epic's reporting infrastructure: Reporting Workbench, Clarity, and the Caboodle data warehouse, etc. Preparation is needed to design and create SmartForms and flowsheets to allow ease of storing, retrieving, and displaying data. **Flowsheets** are the backbone for most documentation. They offer integration of entered data across health professionals. They capture information as discrete data, and Epic-released flowsheets can be shared across institutions through Special Updates from Epic. Flowsheets capture longitudinal data better than SmartForms, as they can be filled out multiple times during an encounter.

SmartForms are highly customizable assessments to acquire problem or specialty-specific data. Answers to

SmartForm questions are recorded in **SmartData Elements** and are available across all applications. SmartData Elements are accessible for reporting purposes and can display information in print groups and notes via Epic SmartTools. Epic-released SmartData Elements and SmartForms can be shared across institutions through Special Updates from Epic. **SmartTools** help document information. **SmartTexts** and **SmartPhrases** generate text blocks or templates that can be used to write notes or frequently documented phrases, and they often contain **SmartLists, SmartLinks, and SmartBlocks**, which can display information captured elsewhere in the chart.

MyChart is Epic's **Patient Portal**.

With Epic one has access to all the information in clinical notes, orders, medications, results from diagnostic investigations, communications, etc. all in the same place.

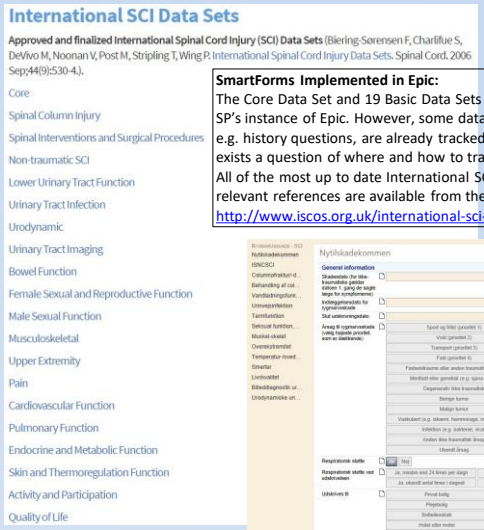


International Standards for Neurological Classification of SCI (ISNCSCI)
Available to access at:
http://isncscialgorithm.azurewebsites.net/
After filling in the form and making the calculation, we save the completed form as an image within the patient's chart in Epic.

In the future our goal is to work with Epic to create this assessment natively in Epic.

SCI specific instruments included in Epic:

Use of Epic in SCI rehabilitation for doctors, nurses, physio- and occupational therapists:



SmartForms Implemented in Epic:
The Core Data Set and 19 Basic Data Sets are implemented in SP's instance of Epic. However, some dataset data elements, e.g. history questions, are already tracked in Epic, so there exists a question of where and how to track this data.
All of the most up to date International SCI Data Sets and the relevant references are available from the ISCoS website:
http://www.iscos.org.uk/international-sci-data-sets

Functional Outcome Measures made as Flowsheets in Epic:
Spinal Cord Independence Measure (SCIMIII); Canadian Model of Occupational Performance (COMP); Gugging Swallowing Screen (GUSS); Forced Vital Capacity (FVC); Peak Expiratory Flow (PEF); Modified Ashworth Scale (MAS); Penn Scale; Grasp and Release Test; Timed Up and Go (TUG); Berg Balance Scale; Walking Index Spinal Cord Injury (WISCI); 6 Minutes Walk Test (6MWT); 10 Meters Walk Test (10MWT); Wheelchair Skills Test.

Tools for reporting in Epic:

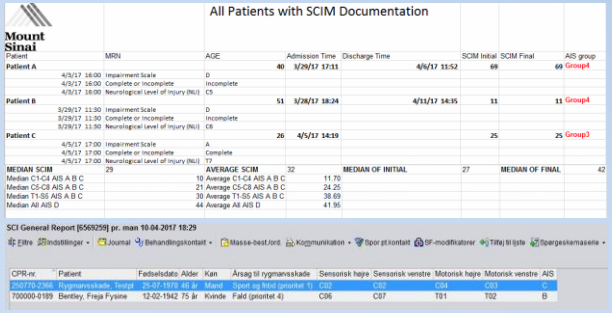
Registries group patients together based on identifying traits. *Epic's chronic disease and wellness registries* are collections of patients who match a specified definition, plus a list of relevant clinical information about those patients to simplify and speed reporting on population subsets. *Epic's contact-based registries* collect patient encounters of a specified type and gather information about documentation compliance and consistency across those encounters.

Radar provides a centralized location for reporting tools and metrics. Using home workspaces called dashboards, Radar users can view, access, and manipulate reports.

Caboodle, an enterprise data warehouse platform, can help more easily report on a variety of topics from allergies and procedure orders to hospital admissions. Caboodle can combine Epic and external data in reports, dashboards, and self-service reporting tools.

SlicerDicer is a self-service reporting tool allowing customizable data exploration abilities to sift through large populations of patients.

Reporting Workbench is a reporting tool available across Epic applications. Users can run administrator-created reports or build reports from templates. These reports can display discrete data captured in flowsheets and SmartData Elements via SmartForms, and these reports can be **exported into Excel files** for research purposes within and across institutions.



Interfacing with external registries and databases requires discussions with your Epic contacts and data infrastructure champions on the feasibility of such a data exchange.

Present development: Work is being done to build various SCI specific instruments and data elements into Epic's Foundation System. This will eliminate the need to use a different system to fill out and report on SCI data.

Take Aways

Utilizing a clinical pathway algorithm will support decision-making and improve access to clinical best practices.

Assessment of spasticity should capture both its severity and its impact on the individual.

Appropriate initial assessment is essential to determining efficacy of treatment.

Spasticity treatment is non-linear and synergistic.

Outcome assessment should document not only a reduction in spasticity but also its impact on function, burden of care, and/or quality of life.

It is important to weigh the cost/benefit of treatment versus the risk of complications from inadequate treatment.

Reminder Regarding CCMC Credit

In order to receive CCMC credit, after the closing comments, close out of the WebEx window.

Two surveys will pop up: 1) the WebEx feedback survey and 2) the CCMC credit survey.

Upon completion of the CCMC survey, you will be redirected to a copy of the CCMC Verification of Completion certificate.

If the CCMC survey does not pop up, you may access the survey from:
https://www.surveymonkey.com/r/SCIspasticity

Tip: If your work computer has blocked Survey Monkey, access the link via your home computer.

Question and Answer Session

Submit your questions in the Q&A panel on the right of your screen.

Indira S. Lanig, MD
Paradigm Medical Director

Julie Fawson, BSN, RN
Paradigm AVP Clinical Services

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