Evidence-Based Clinical Care Guideline for Physical Therapy Management of Single Event Multi-Level Surgeries for Children, Adolescents, and Young Adults with Cerebral Palsy or Other Similar Neuromotor Conditions Guideline (48)

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*Abbreviations, Definitions for terms marked with *, and How to Cite this Guideline may be found in the Appendices.*

INTRODUCTION / BACKGROUND

Cerebral Palsy (CP) is a disorder of movement and posture caused by a static, non-progressive, neurological incident, occurring in the fetal or infant brain. As a result, individuals often have secondary impairments including musculoskeletal pathologies consisting of abnormal muscle tone, loss of selective motor control, impaired balance, impaired posture, and impaired mobility (Narayanan, 2012 [5a]; Thomason, 2012 [*]). Single event multi-level surgery (SEMLS) is a preferred intervention amongst orthopaedic surgeons to promote improved lower extremity skeletal alignment and muscle efficiency with the ultimate goal of enhancing function (McGinley, 2012 [1b]). Allied health professionals commonly use the term SEMLS when referring to orthopedic surgeries; however, the definition may differ from one practitioner to another. For the purposes of this guideline, SEMLS is defined as a surgical intervention involving two or more joints and including three or more bony or soft tissue procedures. Single event multi-level surgery is effective when supported by physical therapy (PT) interventions (Kondratek, 2010 [5a]); however, there are large variations in PT management with this patient population (McGinley, 2012 [1b]). Functional outcomes following SEMLS are affected by age, type, and distribution of CP (Yu, 2015 [4a]; Shore, 2010 [1b]; Murray-Weir, 2003 [4b]; Rutz, Donath, 2013 [*]).

The purpose of this guideline is to provide evidence-based evaluation and intervention strategies for pre-operative and post-operative PT management for patients undergoing SEMLS. Recommendations were developed based on a systematic search, critical appraisal, and synthesis of the available literature. These recommendations will inform clinicians of best practice standards specific to the SEMLS population. In addition, an evidence-based algorithm is included as part of this guideline to assist with pre-operative, post-operative, and long-term PT management. A group of clinically experienced physical therapists generated consensus-based statements when evidence was insufficient. Clinical staff needs to be aware of PT recommendations, rehabilitation protocols, and the progression of strength and function following SEMLS (Karol, 2004 [5b]; Buckon, 2004 [3b]; Park, 2010 [4a]; Saraph, 2002 [4b]; Sung, 2013 [4b]; van der Linden, 2003 [*]; Amichai, 2009 [4a]; Spruit, 1997 [*]; Dobson, 2005 [4b]; Rutz, Passmore, 2012 [4b]; Dodd, 2003 [2a]; Steinwender, 2000 [4a]; Thomason, 2011 [2a]; Mitchlitsch, 2006 [4b]; Grecco, 2013 [2b]; Rodda, 2006 [4a]; Gupta, 2008 [4b]; Shore, 2010 [1b]; Rutz, Baker, 2013 [*]).

Objectives

Specific objectives for this guideline include:

- Decrease variation of PT management for individuals with CP and other like neuromotor conditions who undergo SEMLS
- Consistently use the International Classification of Function, Disability, and Health (ICF) framework and Gross Motor Function Classification System (GMFCS) when assessing and developing a PT plan of care
- Educate clinical staff

TARGET POPULATION

Criteria for Inclusion:

Children, adolescents, and young adults (5 years to 25 years old) with

- Diagnosis of CP or encephalopathy
- Any lower extremity orthopedic multi-level surgery
- Referred for PT services

Criteria for Exclusion:

- Surgery other than lower extremity orthopedic (i.e. upper extremity, spinal)
- Non- multilevel lower extremity orthopedic surgeries (i.e. slipped capital femoral epiphysis, avascular necrosis of the hip, lower extremity fractures, total hip replacements, selective dorsal rhizotomy)
- Diagnoses other than CP or other like neuromotor conditions

TARGET USERS FOR THE RECOMMENDATIONS

Target users include, but are not limited to:

- Occupational therapists
- Orthotists
- Other patient care staff
- Patients and families/caregivers
- Physicians
- Physical therapists
- Primary care providers
- Recreational activity personnel (i.e. wellness)

GUIDELINE RECOMMENDATIONS

Click on the **{Evidence Discussion and Dimensions for Recommendation #}** *hyperlink for the Discussion/Synthesis of the Evidence, the Table of Dimensions for Judging Recommendation Strength, and the Evidence Table of Included Studies related to individual recommendation statements.*

General Recommendations

Recommendation 1

Recommendation Strength
Moderate

It is recommended that the International Classification of Functioning, Disability, and Health (ICF) framework including the domains of body structure and function, activities, and participation be used to guide care when working with individuals undergoing SEMLS (Wilson, 2014 [1b]).

Note: This guideline is aligned with the ICF (WHO, 2001 [*]). The domains of the ICF include body structures and function (functioning at the level of the body); activities (functioning at the level of the individual); participation (functioning of a person as a member of society) and environmental factors (facilitators or barriers) (WHO, 2001 [*]). Researchers and clinicians have used the ICF to classify outcomes and develop rehabilitation programs (Wilson, 2014 [1b]; Dodd, 2003 [2a]; McGinley, 2012 [1b]; Thomason, 2012 [*]). Outcome measures that cross the ICF can quantify and identify gaps in care (Wilson, 2014 [1b]) and show improvements following SEMLS (Thomason, 2012 [*]).

{Evidence Discussion & Dimensions for Recommendation 1}

Recommendation 2

Recommendation Strength
Moderate

It is recommended that patients and caregivers be provided with specific education about:

- Pre-operative evaluation (Park, 2010 [4a] and goal setting (Rutz, Tirosh, 2012 [4b]).
- Post-operative expectations (Lee, Chung, 2009 [4a]; Park, 2009 [4a]; Park, 2010 [4a]).
- Functional prognosis based on CP distribution (Shore, 2010 [1b]).
- Use of orthotics and equipment throughout rehabilitation (Local Consensus, 2017 [5]).

Note: Pre-operative education is an important component of the PT evaluation as it provides patients and families with a better understanding of the recommendations for post-operative therapy related to dosing and realistic expectations of the rehabilitation protocol (Lee, Chung 2009 [4a]; Park 2009 [4a]; Cuomo 2007 [4a]). Prognostically, optimal timing of surgery has been discussed in the literature. Inconsistent evidence has been reported on best outcome of SEMLS in reference to pre-operative functional level and age at time of surgery (Noonan, 2000 [4b]; Shore, 2010 [1b]; Westwell, 2009 [4b]). Additionally, there is evidence to indicate that girls maintain long-term changes in gait following SEMLS to a greater degree compared to boys (Zwick, 2012 [4b]).

{Evidence Discussion & Dimensions for Recommendation 2}

Recommendation 3

It is recommended that a GMFCS level is confirmed pre-operatively by a physical therapist to inform post-operative prognosis (Godwin, 2009 [4a]; Rutz, Tirosh, 2012 [4b]; Harvey 2012 [4b]; Yu, 2015 [4a]) and goal setting (Rutz, Tirosh, 2012 [4b]).

Recommendation Strength
Moderate

Note: The GMFCS is a five-level scale used to classify gross motor function and mobility in children with CP (Palisano, 1997 [*]). An individual classified as GMFCS level I demonstrates greater voluntary control of movement, whereas an individual classified as GMFCS level V is the most functionally impaired (Godwin 2009). Clinicians have used the GMFCS and knowledge of the natural progression of CP to educate caregivers on prognosis (Rosenbaum 2002 [4a]; Rutz, Tirosh, 2012 [4b]; Svehlik, 2008 [*]; Harvey, 2007 [4a]; Godwin, 2009 [4a]; Bishay, 2008 [4]; Shore, 2010 [1b]; Zwick, 2012 [4b]) and to establish realistic and functional goals for PT interventions (Rutz, Tirosh, 2012 [4b]).

{Evidence Discussion & Dimensions for Recommendation 3}

Clinical Assessment

Recommendation 4

It is recommended that prior to and following SEMLS procedures, a standard PT clinical examination is conducted with assessments focusing on gait, functional skills, and quality of life measures (Wilson, 2014 [1b]).

Recommendation Strength
Moderate

Note 1: Table 1 provides clinical assessments across the ICF that physical therapists may use to assess patients prior to and following SEMLS procedures.

Note 2: Supporting articles (Harvey, 2007 [4a]; McMulkin, 2007 [4a]; Park 2009 [4a]; Shore, 2010 [1b]; Thomason, 2011 [2a]; and McGinley, 2012 [1b]) outside of the primary reference (Wilson, 2014 [1b]) were used for this recommendation. When Local Consensus was the only support for a recommended assessment, a reference for the assessment was provided.

Note 3: A PT examination including gait analysis and walking efficiency, when available, is supported to assist with surgical decision making (Wren, 2011 [*]; Wren, 2013 [*]).

{Evidence Discussion & Dimensions for Recommendation 3}

Table 1. PT Assessments across the ICF for Individuals with CP

ICF Domain	Clinical Assessments	Consideration for use	References
Body Structure and Function	Hypertonia Assessment Tool	Distinguishes between dystonia, spasticity, rigidity, or mixed muscle tone.	Local Consensus, 2017 [5]; Jethwa, 2009 [**]
Body Structure and Function	Modified Tardieu Scale	When spasticity is identified.	Local Consensus, 2017 [5]; Gracies, 2010 [**]
Body Structure and Function	Selective Control Assessment of the Lower Extremity	Differentiates between normal and abnormal motor control at hip, knee, ankle, foot, and toes.	Local Consensus, 2017 [5]; Fowler, 2009 [**]
Body Structure and Function, Activities	Gait Analysis – 3D and walking efficiency	3D and walking efficiency are preferred, if available and tolerated by patient.	Shore, 2010 [1b]; McGinley, 2012 [1b]; Wilson, 2014 [1b]
Body Structure and Function, Activities	Gait Analysis – 2D	When 3D is not available or feasible.	Shore, 2010 [1b]; McGinley, 2012 [1b]
Body Structure and Function, Activities	Gait Analysis- Visual	When 3D or 2D is not available or feasible	Local Consensus, 2017 [5]
Body Structure and Function, Activities	6-minute walk test, 1-minute walk test	For ambulatory patients. Use 1 minute if patient unable to complete 6-minute walk test.	Local Consensus, 2017 [5]; Maher, 2008 [**]; McDowell, 2005 [**]
Activities, Participation	Gross Motor Function Measure (GMFM)	Documents changes in gross motor function	Wilson, 2014 [1b]; Thomason 2011 [2a]
Activities, Participation	Functional Mobility Scale (FMS)	Documents change in mobility	McGinley, 2012 [1b]; Harvey, 2007 [4a]
Activities, Participation	Functional Assessment Questionnaire (FAQ)	Documents change in mobility and function	McGinley, 2012 [1b]; Park II, 2009 [4a]
Activities, Participation	Pediatric Evaluation Disability Inventory (PEDI)	Documents change in self-care, mobility and social function with and without caregiver assistance	Wilson, 2014 [1b]
Activities, Participation	Pediatric Outcome Data Collection Instrument (PODCI)	Documents change in function, mobility, and pain	McMulkin, 2007 [4a]
Participation	Canadian Occupational Performance Measure (COPM)	Assists in setting patient/caregiver-identified meaningful goals	Local Consensus, 2017 [5]; Law 2005 [**]
Participation	Quality of Life	Documents change in perception of quality of life	Wilson, 2014 [1b]; Thomason, 2011 [2a]

{Evidence Discussion & Dimensions for Recommendation 3}

Goal Setting

Recommendation 5

Recommendation Strength ***Weak***

It is recommended that patient-centered functional goals for post-operative PT intervention be identified with patients and caregivers using the following:

- GMFCS levels (Rutz, Tirosh, 2012 [4b])
- COPM (Local Consensus, 2017 [5])

Note 1: The GMFCS classification levels guide both gross motor prognosis and appropriate goal setting. (Rutz, Tirosh, 2012 [4b]). Use of the COPM can assist patients and caregivers in identifying meaningful, functional goals (Local Consensus, 2017 [5]).

Note 2: Shared decision making between the patient, family, and therapist is helpful for goal setting during the rehabilitation process following SEMLS. (Local Consensus, 2017 [5]).

{Evidence Discussion and Dimensions for Recommendation 5}

Consults/Referrals

Recommendation 6

Recommendation Strength ***Moderate***

It is recommended that physical therapists consider consults/referrals to other disciplines to ensure that excessive pain (Blumetti, 2012 [4b]; Park, 2010 [4a]), increased muscle tone (Blumetti, 2012 [4b]), difficulties with activities of daily living (McMulkin, 2007 [4a]), nutritional limitations (Minhas, 2015 [4b), and postural impairments (Blumetti, 2012 [4b]; Dreher, Vegvari, 2012 [4a]) do not interfere with the attainment of optimal functional outcomes.

{Evidence Discussion and Dimensions for Recommendation 6}

Post-Operative Physical Therapy Interventions

Recommendation 7

Recommendation Strength ***Weak***

It is recommended that post-operative PT intervention includes but is not limited to transfer training (Local Consensus, 2017 [5]), range of motion (Local Consensus, 2017 [5]), scar management (Local Consensus, 2017 [5]), strengthening (Seniorou, 2007 [2b]; Patikas, 2006 [2b]), standing program (Local Consensus, 2017 [5]), gait training (Grecco, 2013 [3b]), treadmill training (Grecco, 2013 [3b]), positioning, endurance training, balance training, postural training, aquatic PT, electrical stimulation, adaptive equipment, and orthotic management (Local Consensus, 2017 [5]).

Note 1: Table 2 provides interventions that physical therapists may use to treat patients following SEMLS procedures.

Note 2: Supporting articles (Saraph, 2002 [4b]; Buckon, 2004 [3b]; Amichai, 2009 [4a]; Ganjwala, 2011 [4a]; Thomason, 2011 [3b]; Sung, 2013 [4b]) outside of the primary references (Patikas, 2006 [2b]; Seniorou, 2007 [2b]; Grecco, 2013 [3b]; Local Consensus, 2017 [5]) were used for this recommendation. Supporting articles described post-operative rehabilitation protocols related to PT interventions following SEMLS, however, the interventions were not specifically studied as in the primary references. Supporting articles are indicated following primary articles or Local Consensus in Table 2.

{Evidence Discussion and Dimensions for Recommendation 7}

Table 2. PT Interventions across the ICF for individuals with CP

ICF Domain	Intervention	Consideration for use	References
Body Structure and Function	Range of motion	Comfort and positioning	Local Consensus, 2017 [5]; Grecco, 2013 [3b]; Thomason, 2011 [3b]; Ganjwala, 2011 [4a]; Amichai, 2009 [4a]; Saraph, 2002 [4b]
Body Structure and Function	Scar management	Comfort and positioning, as well as pain	Local Consensus, 2017 [5]
Body Structure and Function	Strengthening	Strength for functional mobility, mobility related activities of daily living, transfers, and active range of motion	Seniorou, 2007 [2b]; Patikas, 2006 [2b]; Grecco, 2013 [3b]; Sung, 2013 [4b]; Ganjwala, 2011 [4a]; Thomason, 2011 [3b]; Amichai, 2009 [4a]
Body Structure and Function, Activities, Participation, Environmental Factors	Positioning	Obtain optimal alignment	Local Consensus, 2017 [5]; Amichai, 2009 [4a]
Body Structure and Function, Activities, Participation	Postural training	Static control of postures in sitting and standing	Local Consensus, 2017 [5]; Grecco, 2013 [3b]
Body Structure and Function, Environmental Factors	Splints/orthoses	Positioning for optimal alignment	Local Consensus, 2017 [5]
Body Structure and Function	Electrical stimulation	Neuromuscular re-education recruitment techniques	Local Consensus, 2017 [5]
Activities, Participation	Transfer training	Assist with position changes, as well as functional mobility	Local Consensus, 2017 [5]; Buckon, 2004 [3b]
Activities, Participation, Environmental Factors	Standing program	Upright posture, use of lower extremities in good alignment, endurance	Local Consensus, 2017 [5]; Saraph, 2002 [4b]; Grecco, 2013 [3b]
Activities, Participation	Gait training	Improve gait efficiency, components of gait, and functional strengthening	Grecco, 2013 [3b]; Sung, 2013 [4b]; Amichai, 2009 [4a]; Saraph, 2002 [4b]
Activities, Participation	Treadmill training	Upright mobility, endurance, gait training, and strengthening	Grecco, 2013 [3b]
Activities, Participation	Endurance training	Mobility and gait, tolerance to upright, and cardiovascular health	Local Consensus, 2017 [5]; Ganjwala, 2011 [4a]
Activities, Participation	Balance training	Dynamic control of sitting, standing, walking/mobility, and transitions	Local Consensus, 2017 [5]; Thomason, 2011 [3b]
Activities, Participation	Aquatic PT	Mobility, range of motion, and strengthening using the properties of water for therapeutic exercise	Local Consensus, 2017 [5]
Environmental Factors	Adaptive Equipment	Alignment and support for functional activities	Local Consensus, 2017 [5]; Amichai, 2009 [4a]

Monitoring

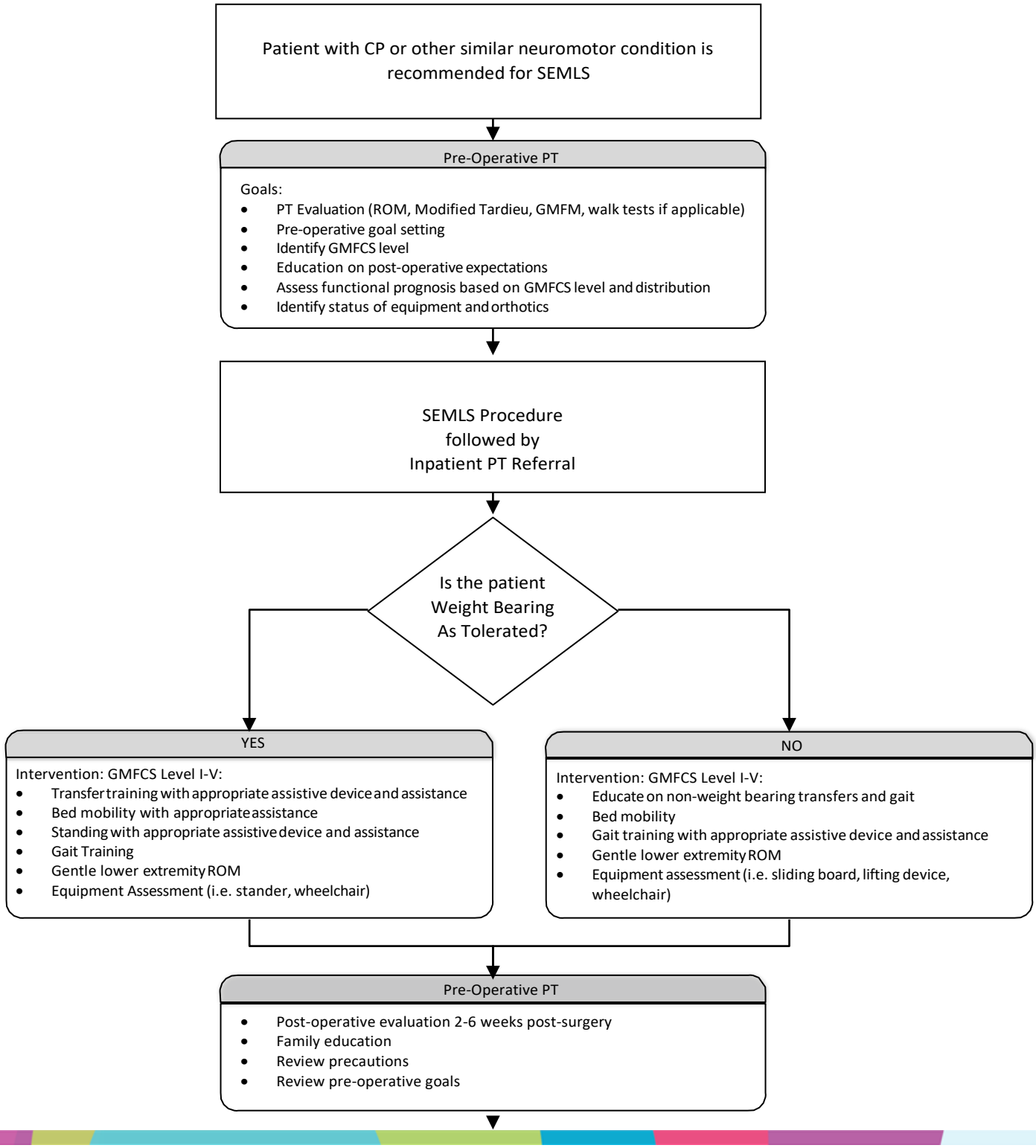
Recommendation 8

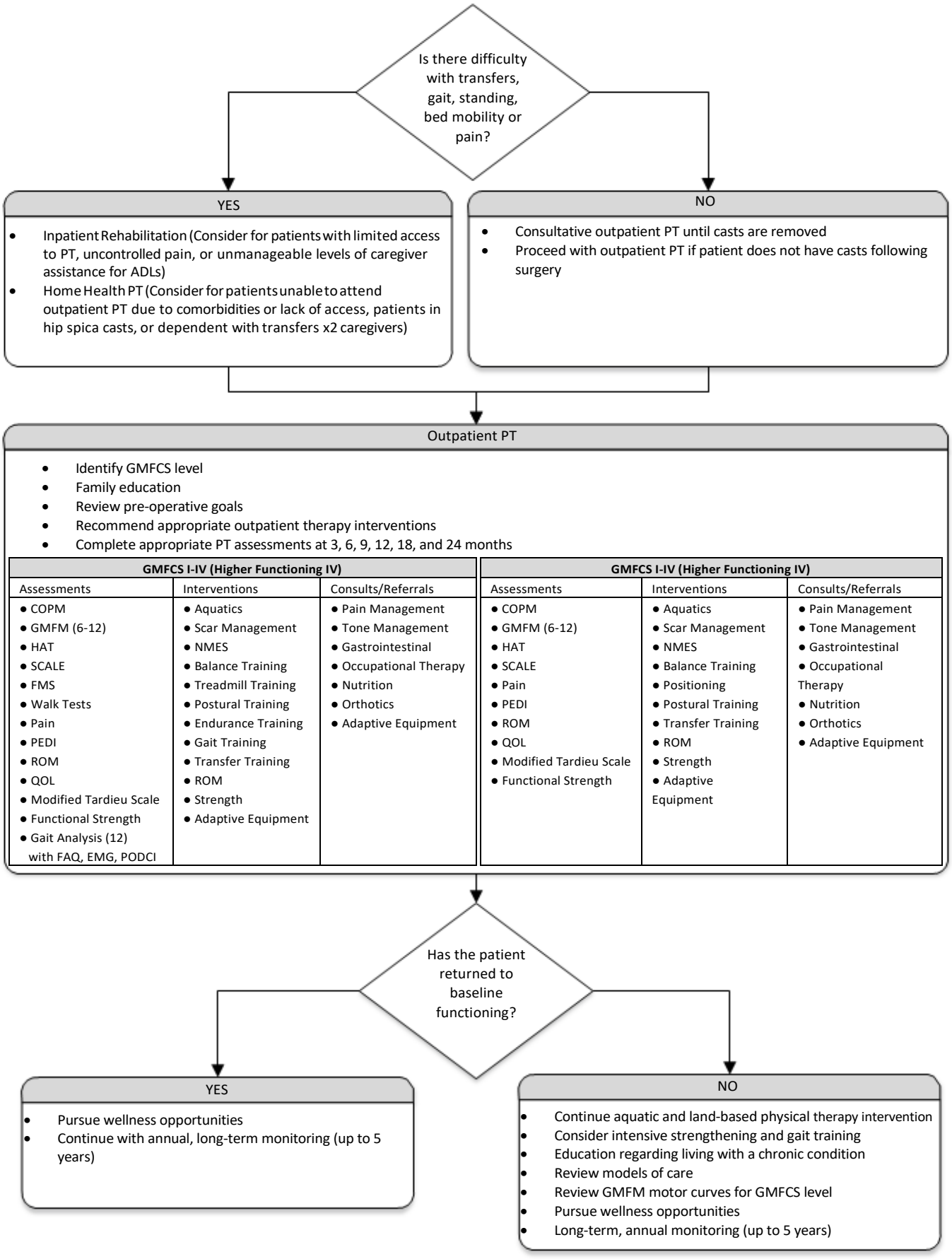
It is recommended that annual, comprehensive PT evaluations occur for up to 5 years following SEMLS (Thomason, 2013 [3b]; Rodda, 2006 [4a]; Zwick, 2012 [4b]; Dreher, Buccoliero, 2012 [4a]).

Recommendation Strength
Moderate

{Evidence Discussion and Dimensions for Recommendation 8}

Suggested Algorithm for Delivery of Physical Therapy Services for Patients Recommended for SEMLS Procedure





Algorithm Legend:
ADL = Activity of Daily Living
COPM = Canadian Occupational Performance Measure
EMG = Electromyography
FAQ = Functional Assessment Questionnaire
FMS = Functional Mobility Scale
GMFCS = Gross Motor Function Classification System
GMFM = Gross Motor Function Measure
HAT = Hypertonia Assessment
LE = Lower Extremity
NMES = Neuromuscular Electrical Stimulation
OT = Occupational Therapy
PEDI = Pediatric Evaluation of Disability Inventory
PODCI = Pediatric Outcome Data Collection Instrument
PT = Physical Therapy
QOL = Quality of Life
ROM = Range of Motion
SCALE = Selective Control Assessment for the Lower Extremity
WBAT = Weight Bearing as Tolerated

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*Evidence Level in [ ], Table of Evidence Levels in **Appendix 7***

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APPENDICES

APPENDIX 1
ABBREVIATIONS AND DEFINITIONS

Abbreviations

- CP – Cerebral Palsy
- COPM- Canadian Occupational Performance Measure
- CPQoL – Cerebral Palsy Quality of Life
- GMFCS – Gross Motor Function Classification System
- GMFM- Gross Motor Function Measure
- FAQ- Functional Assessment Questionnaire
- FMS- Functional Mobility Scale
- ICF – International Classification of Function, Disability, and Health
- PEDI- Pediatric Evaluation of Disability Inventory
- PODCI – Pediatric Outcomes Data Collection Instrument
- PT – Physical Therapy
- SEMLS – Single Event Multi-level Surgery

APPENDIX 2
IMPLEMENTATION

Applicability & Feasibility Issues

This clinical practice guideline is applicable due to the variation in PT management for individuals with CP undergoing SEMLS. An estimate of 50 patients are seen for PT management per year following SEMLS at Cincinnati Children's Hospital Medical Center.

Clinicians will be educated on this clinical practice guideline to reduce variation of care. Their education will include:

1. Test of competency following knowledge translation lectures
2. Individual clinical mentoring
3. Ongoing communication amongst clinicians and physical therapy care coordinators who monitor this patient population

Barriers to implement this clinical practice guideline:

1. Lack of integrating information offered to clinicians following knowledge translation lectures
2. Adequate communication and coordination of care among healthcare professionals
3. Insurance coverage during the rehabilitation process for physical therapy and durable medical equipment
4. Lack of patient and parent education and compliance to rehabilitation process

Relevant Cincinnati Children's Tools

1. Algorithm for PT management for individuals with CP following SEMLS
2. Knowing Notes and checklist for patient and parent education prior to SEMLS; distributed by nursing and physical therapists
3. Clinical documentation templates will be developed to support clinical practice guideline recommendations
4. Email contact for clinicians to reach care coordinators: OPPTSEMLS@cchmc.org

Outcome Measures and Process Measures

Assessment of the clinician's compliance of the following process measures are important to insure adherence to the recommendations and algorithm related to evaluation and interventions for individuals undergoing SEMLS.

For Clinicians:

1. The percent of individuals with CP following SEMLS who receive a pre-operative evaluation according to the clinical practice guideline.
2. The percent of individuals with CP following SEMLS who receive a post-operative assessment according to the clinical practice guideline.
3. The percent of individuals with CP following SEMLS who receive interventions indicated within the clinical practice guideline.

Pain, mobility, satisfaction, education, and community participation are outcome measures used to ensure progression of function within an adequate time frame for individuals following SEMLS.

For Patients:

1. The percent of individuals with CP following SEMLS for who pain does not limit function at the beginning of post-operative, outpatient physical therapy.
2. The percent of individuals with CP following SEMLS who resume pre-operative GMFCS level within 24 months of surgery.
3. The percent of individuals with CP following SEMLS who resume baseline mobility according to the FMS within 12 months of surgery.
4. The percent of individuals with CP following SEMLS who report increased COPM satisfaction scores at 12 months compared goals set pre-operatively.
5. The percent of individuals with CP following SEMLS who are provided with resources to encourage participation in community wellness programs within 12 months of surgery.

APPENDIX 3
DISCUSSION / SYNTHESIS OF THE EVIDENCE, TABLES OF DIMENSIONS FOR JUDGING RECOMMENDATIONS STRENGTH, AND EVIDENCE TABLE OF INCLUDED ARTICLES *(i.e., articles meeting inclusion criteria)* BY RECOMMENDATION

Given the dimensions below for each recommendation and that more answers to the left of the scales indicate support for a stronger recommendation, the recommendation statements reflect the strength of each recommendation as judged by the development group. *(Note that for negative recommendations, the left/right logic may be reversed for one or more dimensions.)*

Recommendation 1

It is recommended that the ICF framework including the domains of body structure and function, activities, and participation be used to guide care when working with individuals undergoing SEMLS (Wilson, 2014 [1b]).

> **Note:** This guideline is aligned with the ICF (WHO, 2001 [*]). The domains of the ICF include body structures and function (functioning at the level of the body); activities (functioning at the level of the individual); participation (functioning of a person as a member of society) and environmental factors (facilitators or barriers) (WHO, 2001 [*]). Researchers and clinicians have used the ICF to classify outcomes and develop rehabilitation programs (Wilson, 2014 [1b]; Dodd, 2003 [2a]; McGinley, 2012 [1b]; Thomason, 2012 [*]). Outcome measures that cross the ICF can quantify and identify gaps in care (Wilson, 2014 [1b]) and show improvements following SEMLS (Thomason, 2012 [*]).

Discussion/Synthesis of the Evidence and Dimensions for the Recommendation

One systematic review (Wilson, 2014 [1b]) supported this recommendation to use the ICF to guide the plan of care for individuals with CP undergoing orthopedic surgeries. Assessments for each domain of the ICF were identified to reduce gaps in care for children with CP undergoing lower limb orthopedic surgery (Wilson, 2014 [1b]). The ICF is a tool used to guide care and potentially reduce cost. It does not pose safety threats or risks. The ICF can be used to address the unique needs of each individual patient following orthopedic surgery. Effective use of the ICF can improve quality of care and help determine appropriate interventions to reach maximum outcomes for individuals with CP undergoing orthopedic procedures. There is no known burden with using the ICF, however, practitioners have not consistently utilized the ICF in the past to determine any secondary implications. The rating of strength for this recommendation is moderate.

Dimensions of Judging the Recommendation Strength for the ICF Framework

1. Safety / Harm *(Side Effects and Risks)*	☒ Minimal		☐ Moderate		☐ Serious
2. Health benefit to patient	☐ Significant		☒ Moderate		☐ Minimal
3. Burden on population to adhere to recommendation	☐ Low		☒ Unable to determine		☐ High
4. Cost-effectiveness to healthcare system	☒ Cost-effective		☐ Inconclusive		☐ Not cost-effective
5. Directness of the evidence for this target population	☒ Directly relates		☐ Some concern of directness		☐ Indirectly relates
6. Impact on quality of life, morbidity, or mortality	☐ Positive		☒ Moderate/Neutral		☐ Negative
7. Grade of the Body of Evidence *(See Evidence Table below; *GNA – Grade Not Assignable)*	☐ High ⊕⊕⊕⊕	☒ Moderate ⊕⊕⊕◯	☐ Low ⊕⊕◯◯	☐ Very Low ⊕◯◯◯	☐ GNA* ◯◯◯◯
Overall Strength of the Recommendation:	☐ **Strong**		☒ **Moderate**		☐ **Weak**

Evidence Table of Included Studies

First Author & Year	Purpose	Methods	Results	Evidence Level
Wilson, 2014	Review of the literature to identify and quantify outcome measures used to assess lower limb orthopaedic surgery in children with CP. Each outcome measure would be mapped using the ICF to determine gaps in the current usage of tools.	Systematic review	The authors recommended a combination of the GMFM and/or PEDI, PODCI, and CPQoL to cover the International Classification of Functioning Disability and Health.	1b

{Back to Guideline Recommendation 1}

Recommendation 2

It is recommended that patients and caregivers be provided with specific education about:

- Pre-operative evaluation (Park, 2010 [4a] and goal setting (Rutz, Tirosh, 2012 [4b]).
- Post-operative expectations (Lee, Chung, 2009 [4a]; Park, 2009 [4a]; Park, 2010 [4a]).
- Functional prognosis based on CP distribution (Shore, 2010 [1b]).
- Use of orthotics and equipment throughout rehabilitation (Local Consensus, 2017 [5]).

Note: Pre-operative education is an important component of the PT evaluation as it provides patients and families with a better understanding of the recommendations for post-operative therapy related to dosing and realistic expectations of the rehabilitation protocol (Lee, Chung 2009 [4a]; Park 2009 [4a]; Cuomo 2007 [4a]). Prognostically, optimal timing of surgery has been discussed in the literature. Inconsistent evidence has been reported on best outcome of SEMLS in reference to pre-operative functional level and age at time of surgery (Noonan, 2000 [4b]; Shore, 2010 [1b]; Westwell, 2009 [4b]). Additionally, there is evidence to indicate that girls maintain long-term changes in gait following SEMLS to a greater degree compared to boys (Zwick, 2012 [4b]).

Discussion/Synthesis of the Evidence and Dimensions for the Recommendation

This recommendation was based on multiple cross-sectional studies (Park, 2010 [4a]; Park, 2009 [4a]; Lee, Chung, 2009 [4a]), one cohort study (Rutz, Tirosh, 2012 [4b], and one systematic review (Shore, 2010 [1b]) focusing on patient and caregiver education needed through the process of PT management leading up to and following SEMLS. Patients benefit from a pre-operative evaluation to determine baseline function (Park, 2010 [4a]) and inform patients and caregivers about details of post-operative expectations regarding function and cosmetic presentation (Lee, Chung, 2009 [4a]; Park. 2009 [4a]) and rehabilitation (Park, 2010 [4a]). Patient and caregiver education is important to discuss gross motor prognosis and goal setting expectations following surgery (Rutz, Tirosh, 2012 [4b]). Education provided on functional prognosis based on CP distribution also provides a means of understanding potential changes following SEMLS (Shore, 2010 [1b]). Patients undergoing SEMLS and caregivers should be educated on the use of orthotics and equipment throughout rehabilitation following SEMLS (Local Consensus, 2017 [5]).

Family education is recommended for patients undergoing SEMLS (Park, 2010 [4a]; Shore, 2010 [1b]; Local Consensus, 2017 [5]). Patient and family education can be completed during the pre-operative PT evaluation and continued during post-operative rehabilitation. Patient education can be delivered through verbal instruction and demonstration. Patients and families who received education are better prepared for SEMLS intervention and post-operative rehabilitation. Local Consensus, 2017 [5] believes education may help with compliance for post-operative care. Education empowers patients and families with increased knowledge and awareness. The rating of strength for this recommendation is moderate.

Dimensions of Judging the Recommendation Strength for Patient and Caregiver Education

1. Safety / Harm *(Side Effects and Risks)*	☒ Minimal	☐ Moderate		☐ Serious
2. Health benefit to patient	☒ Significant	☐ Moderate		☐ Minimal
3. Burden on population to adhere to recommendation	☒ Low	☐ Unable to determine		☐ High
4. Cost-effectiveness to healthcare system	☐ Cost-effective	☒ Inconclusive		☐ Not cost-effective
5. Directness of the evidence for this target population	☒ Directly relates	☐ Some concern of directness		☐ Indirectly relates
6. Impact on quality of life, morbidity, or mortality	☒ Positive	☐ Moderate/Neutral		☐ Negative
7. Grade of the Body of Evidence *(See Evidence Table below; *GNA – Grade Not Assignable)*	☐ High ⊕⊕⊕⊕	☒ Moderate ⊕⊕⊕◯	☐ Low ⊕⊕◯◯	☐ Very Low ⊕◯◯◯	☐ GNA* ◯◯◯◯
Overall Strength of the Recommendation:	☐ **Strong**	☒ **Moderate**		☐ **Weak**

Evidence Table of Included Studies

First Author & Year	Purpose	Methods	Results	Evidence Level
Lee, Chung, 2009	To analyze parent satisfaction and factors affecting satisfaction with SEMLS outcomes and ambulatory children with CP.	Cross-Sectional	Counseling by physician needs to be completed prior to SEMLS for appropriate expectations in function and cosmetic affects following the surgery, especially for GMFCS Level III patients.	4a
Park, 2009	The aim of this study was to investigate the issues of concerns to parents after SEMLS in ambulatory patients with CP.	Cross-Sectional	Mutual understanding should be established between parents and surgeons regarding surgical outcomes and limitations before SEMLS. Parents of diplegic children showed higher overall concern score compared with the parents of hemiplegic patients. Parents of hemiplegic patients were more concerned with unequal leg circumference and leg length discrepancy. Parents of diplegic patients were more concerned with surgical scars, play activity, anxiety about recurrence of tightness and need for re-operation, and running ability.	4a
Park, 2010	To analyze the issues of parental concern before SEMLS in consecutive patients with CP	Cross-Sectional	Surgeons need to address functional level expectations and surgical goals in pre-operative education with parents. Clinicians should assess pain and surgical goals prior to surgery. Parents identified issues of concern following SEMLS: post-operative rehabilitation, duration of rehabilitation, immediate post-operative pain, general anesthesia, medical cost, sporting activities, and poor compliance to wear ankle foot orthosis. Parent of younger children showed significantly higher concerns compared with older children.	4a
Rutz, Tirosh, 2012	To examine stability of the GMFCS in a large group of children with CP before and after SEMLS.	Cohort, retrospective	The GMFCS level is a tool appropriate to classify patients with CP for long-term gross motor prognosis and goal-setting with SEMLS. The GMFCS level remained unchanged in 95% of patients following SEMLS and 5% improved GMFCS levels.	4b
Shore, 2010	To examine the current evidence base for the surgical management of equinus deformity in CP	Systematic review	The type of CP matters a great deal and should be carefully considered when deciding type of surgery procedure and overall management. Topographical distribution of CP may be the strongest determinant of the outcome following surgery for equinus deformity.	1b
Local Consensus 2017	To generate consensus on the content of recommendation 2.	A consensus generation process was used through online polling and Skype conversation to obtain agreement of a group of 18 physical therapists specializing in pediatric developmental PT.	After a single round of discussion and voting, a consensus of 18/18 pediatric physical therapists was obtained for this recommendation statement.	5

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Recommendation 3

It is recommended that a GMFCS level is confirmed pre-operatively by a physical therapist to inform post-operative prognosis (Godwin, 2009 [4a]; Rutz, Tirosh, 2012 [4b]; Harvey 2012 [4b]; Yu, 2015 [4a]) and goal setting (Rutz, Tirosh, 2012 [4b]).

> **Note:** The GMFCS is a five-level scale used to classify gross motor function and mobility in children with CP (Palisano, 1997 [*]). An individual classified as GMFCS level I demonstrates greater voluntary control of movement, whereas an individual classified as GMFCS level V is the most functionally impaired (Godwin 2009). Clinicians have used the GMFCS and knowledge of the natural progression of CP to educate caregivers on prognosis (Rosenbaum 2002 [4a]; Rutz, Tirosh, 2012 [4b]; Svehlik, 2008 [*]; Harvey, 2007 [4a]; Godwin, 2009 [4a]; Bishay, 2008 [4]; Shore, 2010 [1b]; Zwick, 2012 [4b]) and to establish realistic and functional goals for PT interventions (Rutz, Tirosh, 2012 [4b]).

Discussion/Synthesis of the Evidence and Dimensions for the Recommendation

This recommendation is based on one cohort study (Rutz, Tirosh, 2012 [4b]) and three longitudinal studies (Godwin, 2009 [4a]; Harvey 2012 [4b]; Yu, 2015 [4a]) focusing on determining a patient's GMFCS level prior to SEMLS to inform post-operative prognosis and guide goal setting. The GMFCS has been identified as a tool to classify patients with CP for long-term gross motor prognosis and goal setting following SEMLS (Rutz, Tirosh, 2012 [4b]). Studies describe prognosis or changes in mobility following SEMLS based on GMFCS level (Godwin 2009 [4a]; Harvey 2012 [4b]; Rutz, Tirosh 2012 [4b]; Yu 2015 [4a]). The GMFCS level remained unchanged in 95% of patients following SEMLS and 5% improved GMCS levels (Rutz, Tirosh 2012 [4b]). Improvements by one or two GMFCS levels may occur in individuals with CP following SEMLS over a 5 year period (Godwin, 2009 [4a]; Harvey 2012 [4b]). Changes in functional mobility (Yu 2015 [4a]) or a reduction in assistive device (Harvey 2012 [4b]) by GMFCS level have also been identified following lower extremity orthopedic surgery. Determination of baseline GMFCS level would assist in selection of appropriate PT assessments and interventions for individuals with CP following SEMLS. The GMFCS is a tool used to guide care and does not pose safety threats or risks. Effective use of the GMFCS can improve quality of care and limit unnecessary services. The GMFCS can be used to address the unique needs of each individual patient following SEMLS. The rating of strength for this recommendation is moderate.

Dimensions of Judging the Recommendation Strength for GMFCS

1. Safety / Harm *(Side Effects and Risks)*	☒ Minimal	☐ Moderate	☐ Serious		
2. Health benefit to patient	☐ Significant	☒ Moderate	☐ Minimal		
3. Burden on population to adhere to recommendation	☒ Low	☐ Unable to determine	☐ High		
4. Cost-effectiveness to healthcare system	☒ Cost-effective	☐ Inconclusive	☐ Not cost-effective		
5. Directness of the evidence for this target population	☒ Directly relates	☐ Some concern of directness	☐ Indirectly relates		
6. Impact on quality of life, morbidity, or mortality	☒ Positive	☐ Moderate/Neutral	☐ Negative		
7. Grade of the Body of Evidence *(See Evidence Table below; *GNA – Grade Not Assignable)*	☐ High ⊕⊕⊕⊕	☐ Moderate ⊕⊕⊕◯	☒ Low ⊕⊕◯◯	☐ Very Low ⊕◯◯◯	☐ GNA* ◯◯◯◯
Overall Strength of the Recommendation:	☒ **Strong**	☒ **Moderate**	☐ **Weak**		

Evidence Table of Included Studies

First Author & Year	Purpose	Methods	Results	Evidence Level
Godwin, 2009	To determine what effect, if any, an intervention such as SEMLS might have on the relative stability of GMFCS levels for CP over a 5-year period.	Longitudinal, retrospective	Interventions, such as SEMLS, can affect the stability of GMFCS levels. Two raters with excellent agreement measured improvement by 1 or 2 GMFCS levels in children undergoing SEMLS.	4a
Harvey, 2012	To examine changes in mobility longitudinally following SEMLS in ambulant children with CP, focusing on individuals using assistive devices for functional mobility.	Longitudinal, before and after	Less assistance was required for mobility for the majority of the patients. Individuals with a GMFCS level III who used crutches pre-operatively in a home setting had a 75% chance of no change or independent walking at 5 years. If a walker was used preoperatively in the home, there was a 70% chance of using less assistance.	4b
Rutz, Tirosh, 2012	To examine stability of the GMFCS in a large group of children with CP before and after SEMLS.	Cohort, retrospective	The GMFCS level is a tool appropriate to classify patients with CP for long-term gross motor prognosis and goal-setting with SEMLS. The GMFCS level remained unchanged in 95% of patients following SEMLS and 5% improved GMFCS levels. No individuals deteriorated in mobility following surgery.	4b
Yu, 2015	To examine the long-term impact of lower extremity orthopedic surgery for gait improvement on ambulatory function in patients with CP enrolled in LA County CCS Medical Therapy Program. Questions included: (1) How much change in ambulation was seen over time? (2) Did ambulation change dependent on gross motor functional level?	Longitudinal, retrospective	Patients with GMFCS level I had less PT sessions/person-year and less procedures/person-year compared with those in other GMFCS levels. Most hip surgeries were performed for less functional walkers and foot procedures were performed with more functional walkers. Mobility changed significantly for GMFCS level I in community ambulation, but not home ambulation. Mobility changed significantly for GMFCS level II and IV at all distances. Mobility changed significantly for GMFCS level III at all distances with the greatest improvement in household distances.	4a

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Recommendation 4

It is recommended that prior to and following SEMLS procedures, a standard PT clinical examination is conducted with assessments focusing on gait, functional skills, and quality of life measures (Wilson, 2014 [1b]).

Note 1: Table 1 provides clinical assessments across the ICF that physical therapists may use to assess patients prior to and following SEMLS procedures.

Note 2: Supporting articles (Harvey, 2007 [4a]; McMulkin, 2007 [4a]; Park 2009 [4a]; Shore, 2010 [1b]; Thomason, 2011 [2a]; and McGinley, 2012 [1b]) outside of the primary reference (Wilson, 2014 [1b]) were used for this recommendation. When Local Consensus was the only support for a recommended assessment, a reference for the assessment was provided.

Note 3: A PT examination including gait analysis and walking efficiency, when available, is supported to assist with surgical decision making (Wren, 2011 [*]; Wren, 2013 [*]).

Discussion/Synthesis of the Evidence and Dimensions for the Recommendation

This recommendation is based on one systematic review (Wilson, 2014 [1b]) and supporting articles (Harvey, 2007 [4a]; McMulkin, 2007 [4a]; Park 2009 [4a]; Shore, 2010 [1b]; Thomason, 2011 [2a]; McGinley, 2012 [1b]; Local Consensus, 2017 [5]) to provide physical therapists with an array of assessments to complete during a clinical examination with an individual with CP prior to and following SEMLS; these assessments are identified within the ICF domains.

Outcome measures across the ICF were identified and recommended to assess individuals with CP undergoing SEMLS with a focus on gait, gross motor function, and quality of life (Wilson, 2014 [1b]). A clinical exam encompassing gait analysis, GMFM, PEDI, PODCI, and CPQOL were recommended outcome measures (Wilson, 2014 [1b]). Supporting articles recommended gait analysis be conducted pre-operatively, 1 year post SEMLS, and annually thereafter (Shore, 2010 [1b]; McGinley, 2012 [1b]). When 3D or 2D gait analysis is not feasible, Local Consensus (Local Consensus, 2017 [5]) agreed that a visual gait analysis is an appropriate means of assessing gait in this patient population. Supporting articles also recommended the GMFM (Thomason, 2011 [2a]) and PODCI (McMulkin, 2007 [4a]) as outcome measures for the activity and participation domain of the ICF. Furthermore, quality of life measures were recommended following SEMLS (Thomason, 2011 [2a]) but not specific to the CPQOL. In addition to the systematic review, additional body structure and function, activity, and participation outcome measures have been recommended. Local Consensus (Local Consensus, 2017 [5]) agreed that muscle tone, strength, and endurance measures, including the Hypertonia Assessment Tool, Modified Tardieu Scale, Selective Control Assessment of the Lower Extremity, and both 1 and 6 minute walk tests for body structure and function and activity domains of the ICF. Additional measures recommended for the activity and participation domains of the ICF included the FMS (Harvey, 2007 [4a]; McGinley, 2012 [1b]), Functional Assessment Questionnaire (Park 2009 [4a]; McGinley, 2012 [1b]), and COPM (Local Consensus, 2017 [5a]). Physical therapy assessments are required following SEMLS to guide appropriate therapeutic interventions and the plan of care to reach maximal outcomes and reduce potential adverse effects. Physical therapy assessments may be cost-prohibitive to some families. The rating of strength for this recommendation is moderate.

Dimensions of Judging the Recommendation Strength for PT Clinical Examination and Assessments

1. Safety / Harm *(Side Effects and Risks)*	☒ Minimal	☐ Moderate		☐ Serious
2. Health benefit to patient	☒ Significant	☐ Moderate		☐ Minimal
3. Burden on population to adhere to recommendation	☐ Low	☒ Unable to determine		☐ High
4. Cost-effectiveness to healthcare system	☐ Cost-effective	☒ Inconclusive		☐ Not cost-effective
5. Directness of the evidence for this target population	☒ Directly relates	☐ Some concern of directness		☐ Indirectly relates
6. Impact on quality of life, morbidity, or mortality	☐ Positive	☒ Moderate/Neutral		☒ Negative
7. Grade of the Body of Evidence *(See Evidence Table below; *GNA – Grade Not Assignable)*	☐ High ⊕⊕⊕⊕	☒ Moderate ⊕⊕⊕◯	☐ Low ⊕⊕◯◯	☐ Very Low ⊕◯◯◯	☐ GNA* ◯◯◯◯
Overall Strength of the Recommendation:	☐ **Strong**	☒ **Moderate**		☐ **Weak**

Evidence Table of Included Studies

First Author & Year	Purpose	Methods	Results	Evidence Level
Wilson, 2014	To 1) determine the range and frequency of outcome measures used to evaluate lower limb orthopaedic surgery in children and adolescents with CP, (2) identify outcome measures within the ICF domain to determine possible gaps in the usage of these tools, and (3) examine whether the outcomes measures have changed significantly over time.	Systematic review	Clinical exam and 3D Gait Analysis were the most commonly used measures of impairment within the body structure and function domain. The GMFM was used to assess impairments within the activity and participation domain. Quality of life was not measured until after 2001 and included the Child Health Questionnaire and Pediatric Quality of Life Inventory. It is recommended to administer a standard PT clinical exam, 3D Gait Analysis, GMFM, and quality of life measure.	1b
Harvey, 2007	To examine the sensitivity of the FMS in detecting change in children with CP undergoing SEMLS	Longitudinal, retrospective	The distance component of the FMS showed significant decline at 3 and 6 months post-operatively. Mobility returned to baseline by 12 months and improved further by 24 months post-operatively.	4a
McGinley, 2012	To evaluate the quality of evidence and develop recommendation for future research for children with CP undergoing SEMLS.	Systematic review	Recommendations were made to administer the Gillette FAQ, FMS, and a gait analysis.	1b
McMulkin, 2007	Assess the ability of the PODCI to (1) detect changes in function as perceived by the parents of children and adolescents with CP undergoing lower limb soft tissue and/or bony surgeries and (2) to determine the magnitude of these changes with varying levels of ambulation.	Longitudinal before and after	The PODCI detected improvements in upper extremity function, transfers and mobility, physical function and sports, and in the patients' overall score regardless of their GMFCS level.	4a
Park, 2009	To investigate parents' concerns after SEMLS in ambulatory patients with CP.	Cross-sectional	Gillette FAQ scores significantly improved post-operatively.	4a
Shore, 2010	To examine the evidence for the surgical management of equinus deformity in CP.	Systematic review	Studies reviewed completed gait analysis with a mean follow up of greater than 5 years.	1b
Thomason, 2011	To evaluate the change in gait, clinical examination, function, activity, mobility, and health-related quality of life following SEMLS in children with spastic diplegia.	Randomized controlled trial	Significant improvements in the GMFM scores were not found at 12 months post-operatively but were noted at 24 months post-operatively. The change in the social/emotional domain of the Child Health Questionnaire differed significantly between the groups at 12 months and may reflect enhanced self-esteem. The Child Health Questionnaire physical functioning domain was significant at 24 months.	2a
Local Consensus, 2016	To generate consensus on the content of recommendation 4.	A consensus generation process was used through online polling and Skype conversation to obtain agreement of a group of 18 physical therapists specializing in pediatric developmental PT.	After a single round of discussion and voting, a consensus of 18/18 pediatric physical therapists was obtained for this recommendation statement.	5

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Recommendation 5

It is recommended that patient-centered functional goals for post-operative PT intervention be identified with patients and caregivers using the following:

- GMFCS levels (Rutz, Tirosh, 2012 [4b])
- COPM (Local Consensus, 2017 [5])

Note 1: The GMFCS classification levels guide both gross motor prognosis and appropriate goal setting. (Rutz, Tirosh, 2012 [4b]). Use of the COPM can assist patients and caregivers in identifying meaningful, functional goals (Local Consensus, 2017 [5]).

Note 2: Shared decision making between the patient, family, and therapist is helpful for goal setting during the rehabilitation process following SEMLS. (Local Consensus, 2017 [5]).

Discussion/Synthesis of the Evidence and Dimensions for the Recommendation

This recommendation is based on one a cohort study (Rutz, Tirosh, 2012 [4b]) and Local Consensus (Local Consensus, 2017 [5]). The GMFCS levels guide appropriate goal setting following SEMLS. (Rutz, Tirosh, 2012 [4b]). The GMFCS provides information to assist with guiding an individual's plan of care including frequency and functional prognosis; therefore, limiting unnecessary therapy services. Shared decision making between the patient, family, and therapist is crucial for goal setting during the rehabilitation process following SEMLS. Use of the COPM can assist patients and caregivers in identifying meaningful, functional goals following SEMLS (Local Consensus, 2017 [5]). This recommendation statement was based on local consensus generated by the guideline development team. The rating of strength for this recommendation is weak.

Dimensions of Judging the Recommendation Strength for Goal Setting

1. Safety / Harm *(Side Effects and Risks)*	☒ Minimal	☐ Moderate	☐ Serious	
2. Health benefit to patient	☐ Significant	☒ Moderate	☐ Minimal	
3. Burden on population to adhere to recommendation	☒ Low	☐ Unable to determine	☐ High	
4. Cost-effectiveness to healthcare system	☒ Cost-effective	☐ Inconclusive	☐ Not cost-effective	
5. Directness of the evidence for this target population	☒ Directly relates	☐ Some concern of directness	☐ Indirectly relates	
6. Impact on quality of life, morbidity, or mortality	☒ Positive	☒ Moderate/Neutral	☐ Negative	
7. Grade of the Body of Evidence *(See Evidence Table below; *GNA – Grade Not Assignable)*	☐ High ⊕⊕⊕⊕	☐ Moderate ⊕⊕⊕◯	☐ Low ⊕⊕◯◯	☒ Very Low ⊕◯◯◯	☐ GNA* ◯◯◯◯
Overall Strength of the Recommendation:	☐ **Strong**	☐ **Moderate**	☒ **Weak**	

Evidence Table of Included Studies

First Author & Year	Purpose	Methods	Results	Evidence Level
Rutz, Tirosh, 2012	To examine stability of the GMFCS levels in individuals with CP before and after SEMLS.	Cohort, retrospective	The GMFCS level is a tool appropriate to classify patients with CP for long-term gross motor prognosis and goal-setting with SEMLS. The GMFCS level remained unchanged in 95% of patients following SEMLS and 5% improved GMFCS levels.	4b
Local Conensus, 2017	To generate consensus on the content of recommendation 5.	A consensus generation process was used through online polling and Skype conversation to obtain agreement of a group of 18 physical therapists specializing in pediatric developmental PT.	After a single round of discussion and voting, a consensus of 18/18 pediatric physical therapists was obtained for this recommendation statement.	5

Recommendation 6

It is recommended that physical therapists consider consults/referrals to other disciplines to ensure that excessive pain (Blumetti, 2012 [4b]; Park, 2010 [4a]), increased muscle tone (Blumetti, 2012 [4b]), difficulties with activities of daily living (McMulkin, 2007 [4a]), nutritional limitations (Minhas, 2015 [4b), and postural impairments (Blumetti, 2012 [4b]; Dreher, Vegvari, 2012 [4a]) do not interfere with the attainment of optimal functional outcomes.

Discussion/Synthesis of the Evidence and Dimensions for the Recommendation

This recommendation is based on multiple peer-reviewed articles (Blumetti, 2012 [4b]; Minhas, 2015 [4b]; McMulkin, 2007 [4a]) and Local Consensus (Local Consensus, 2017 [5]). After the initial PT assessment following SEMLS, additional consults and referrals should be considered to avoid interference with attainment of functional outcomes. Factors affecting outcomes may include pain (Blumetti, 2012 [4b]; Park, 2010 [4a]), unmanaged muscle tone (Blumetti, 2012 [4b]), reduced independence in activities of daily living (McMulkin, 2007 [4a]), difficulty gaining weight (Minhas, 2015 [4b]), constipation (Local Consensus, 2017 [5]), and reduced postural alignment (Blumetti, 2012 [4b]; Local Consensus, 2017 [5]). In attempt to mitigate secondary complications, these individuals may benefit from a referral to other healthcare providers to focus on management (Blumetti, 2012 [4b]; Park, 2010 [4a]), tone management (Blumetti, 2012 [4b]), occupational therapy (McMulkin, 2007 [4a]), nutrition (Minhas, 2015 [4b]), gastrointestinal (Local Consensus, 2017 [5]), adaptive equipment (Blumetti, 2012 [4b]; Local Consensus, 2017 [5]), and orthotists (Local Consensus, 2017 [5]). There are no adverse effects anticipated with referrals to other healthcare providers; however, additional referrals could lead to more appointments and increased costs. The rating of strength for this recommendation is moderate.

Dimensions of Judging the Recommendation Strength for Consult and Referrals following SEMLS

1. Safety / Harm *(Side Effects and Risks)*	☒ Minimal	☐ Moderate		☐ Serious
2. Health benefit to patient	☒ Significant	☐ Moderate		☐ Minimal
3. Burden on population to adhere to recommendation	☐ Low	☐ Unable to determine		☒ High
4. Cost-effectiveness to healthcare system	☐ Cost-effective	☒ Inconclusive		☐ Not cost-effective
5. Directness of the evidence for this target population	☐ Directly relates	☒ Some concern of directness		☐ Indirectly relates
6. Impact on quality of life, morbidity, or mortality	☒ Positive	☐ Moderate/Neutral		☐ Negative
7. Grade of the Body of Evidence *(See Evidence Table below; *GNA – Grade Not Assignable)*	☐ High ⊕⊕⊕⊕	☐ Moderate ⊕⊕⊕◯	☒ Low ⊕⊕◯◯	☐ Very Low ⊕◯◯◯	☐ GNA* ◯◯◯◯
Overall Strength of the Recommendation:	☐ **Strong**	☒ **Moderate**		☐ **Weak**

Evidence Table of Included Studies

First Author & Year	Purpose	Methods	Results	Evidence Level
Blumetti, 2012	To analyze the rate of complications and assess family and patient satisfaction with surgical outcomes.	Mixed methods	After SEMLS clinicians should refer for adequate tone control, comfortable feeding and positioning, and promotion of hip stability	4b
McMulkin, 2007	Assess the ability of the PEDI to detect changes in function with individuals undergoing SEMLS and to determine the magnitude of these changes.	Longitudinal before and after	The PEDI detected improvements in upper extremity function, transfers and mobility, physical function and sports, and overall score regardless of the GMFCS level. Improvement in upper extremity function supports an OT referral.	4a
Minhas, 2015	To examine the independent effect of body mass index on postoperative complications with respect to orthopeadics.	Retrospective cohort	Following SEMLS there is a higher risk of complications in underweight patients.	4b
Park, 2010	To analyze parental concerns of individuals undergoing SEMLS.	Cross-Sectional	Parents identified issues of concern following SEMLS including: immediate post-operative pain, general anesthesia, post-operative rehabilitation, duration of rehabilitation, medical cost, sporting activities, and poor compliance to wearing ankle foot orthosis. Clinicians should pay more attention to assessing and treating pain in patients with CP.	4a
Local Consesus, 2017	To generate consensus on the content of recommendation 6.	A consensus generation process was used through online polling and Skype conversation to obtain agreement of a group of 18 physical therapists specializing in pediatric developmental PT.	After 2 rounds of discussion and voting, a consensus of 18/18 pediatric physical therapists was obtained for this recommendation statement.	5

Recommendation 7

It is recommended that post-operative PT intervention includes but is not limited to transfer training (Local Consensus, 2017 [5]), range of motion (Local Consensus, 2017 [5]), scar management (Local Consensus, 2017 [5]), strengthening (Seniorou, 2007 [2b]; Patikas, 2006 [2b]), standing program (Local Consensus, 2017 [5]), gait training (Grecco, 2013 [3b]), treadmill training (Grecco, 2013 [3b]), positioning, endurance training, balance training, postural training, aquatic PT, electrical stimulation, adaptive equipment, and orthotic management (Local Consensus, 2017 [5]).

> **Note 1:** Table 2 provides interventions that physical therapists may use to treat patients following SEMLS procedures.
>
> **Note 2:** Supporting articles (Saraph, 2002 [4b]; Buckon, 2004 [3b]; Amichai, 2009 [4a]; Ganjwala, 2011 [4a]; Thomason, 2011 [3b]; Sung, 2013 [4b]) outside of the primary references (Patikas, 2006 [2b]; Seniorou, 2007 [2b]; Grecco, 2013 [3b]; Local Consensus, 2017 [5]) were used for this recommendation. Supporting articles described post-operative rehabilitation protocols related to PT interventions following SEMLS, however, the interventions were not specifically studied as in the primary references. Supporting articles are indicated following primary articles or Local Consensus in Table 2.

Discussion/Synthesis of the Evidence and Dimensions for the Recommendation

This recommendation is categorized across the ICF and is based on multiple peer-reviewed articles and Local Consensus, 2017 [5].

Body Structure and Function: Range of motion should be included in the post-operative PT protocol following SEMLS (Saraph, 2002 [4b]; Amichai, 2009 [4a]; Ganjwala, 2011 [4a]; Thomason, 2011 [3b]; Grecco, 2013 [3b]; Local Consensus, 2017 [5]). Individuals are often casted and placed in lower extremity orthoses or splints to maintain range of motion and adequate postural alignment during weight bearing (Saraph, 2002 [4b]; Amichai, 2009 [4a]; Local Consensus, 2017 [5]). Local Consensus also recommended scar management to reduce scar tissue thickening and tension, which could restrict mobility during post-operative rehabilitation (Local Consensus, 2017 [5]). Strengthening was recommended following SEMLS to regain strength, gait, and function (Seniorou, 2007 [2b]; Patikas, 2006 [2b]; Grecco, 2013 [3b]). Resistance strengthening was found to be more effective than active exercises (Seniorou, 2007 [2b]). A home exercise program for strengthening is not as effective as intensive strengthening during outpatient PT (Patikas, 2006 [2b]). Additional authors referenced strength training in post-operative rehabilitation following SEMLS. (Amichai, 2009 [4a]; Ganjwala, 2011 [4a]; Thomason, 2011 [3b]; Grecco, 2013 [3b]; Sung, 2013 [4b]). Electrical stimulation may be suggestive for but not exclusive to neuromuscular re-education techniques following SEMLS (Local Consensus, 2017 [5]).

Activities and Participation: Transfer training is recommended following SEMLS due to difficulty with movement in lower extremity casts (Buckon, 2004 [3b]; Local Consensus, 2017 [5]). Gait training was also cited as a component of post-operative rehabilitation in multiple studies (Saraph, 2002 [4b]; Sung, 2013 [4b]; Amichai, 2009 [4a]; Grecco, 2013 [3b]). Specifically, treadmill training was highlighted as a means of gait training to improve mobility and endurance (Grecco, 2013 [3b]). Proper positioning and adaptive equipment are necessary to promote adequate alignment gained from surgery (Amichai, 2009 [4a]; Local Consensus, 2017 [5]. For instance, a standing frame was used for some patients following SEMLS (Saraph, 2002 [4b]; Grecco, 2013 [3b]; Local Consensus, 2017). Postural training (Grecco, 2013 [3b]), balance training (Thomason, 2011 [3b]), and endurance training (Ganjwala, 2011 [4a]) lead to improved mobility and function following SEMLS and need to be incorporated within the course of rehabilitation (Local Consensus, 2017 [5a]). Likewise, aquatic PT can be an adjunct to improving range of motion, strength, posture, gait, balance, and endurance (Local Consensus, 2017 [5]).

Utilization of appropriate and timely PT interventions may decrease overall healthcare costs. The evidence of this recommendation directly relates to physical therapy intervention following SEMLS. The rating of strength for this recommendation is weak as many of the interventions are based on Local Consensus.

Dimensions of Judging the Recommendation Strength for Post-Operative PT Interventions

1. Safety / Harm *(Side Effects and Risks)*	☐ Minimal		☐ Moderate		☒ Serious
2. Health benefit to patient	☒ Significant		☐ Moderate		☐ Minimal
3. Burden on population to adhere to recommendation	☐ Low		☐ Unable to determine		☒ High
4. Cost-effectiveness to healthcare system	☐ Cost-effective		☒ Inconclusive		☐ Not cost-effective
5. Directness of the evidence for this target population	☒ Directly relates		☐ Some concern of directness		☐ Indirectly relates
6. Impact on quality of life, morbidity, or mortality	☒ Positive		☐ Moderate/Neutral		☐ Negative
7. Grade of the Body of Evidence *(See Evidence Table below; *GNA – Grade Not Assignable)*	☐ High ⊕⊕⊕⊕	☐ Moderate ⊕⊕⊕◯	☐ Low ⊕⊕◯◯	☒ Very Low ⊕◯◯◯	☐ GNA* ◯◯◯◯
Overall Strength of the Recommendation:	☐ **Strong**		☐ **Moderate**		☒ **Weak**

Evidence Table of Included Studies

First Author & Year	Purpose	Methods	Results	Evidence Level
Amichai, 2009	To examine the effect of femoral derotational osteotomy and rehabilitation on functional ambulation and energy cost in children with CP,		Significant improvement in hip rotation ROM at 6 and 12 months post-operatively; significant improvement in endurance at 12 months post operatively and significant gait improvements between 6 and 12 months post operatively.	4a
Buckon, 2004	To compare the efficacy of selective dorsal rhizotomy (SDR) and orthopedic surgery using multidimensional outcome measures.		The orthopedic group improved significantly in select quality of movement attributes on the Gross Motor Performance Measure (i.e. alignment, weight shift, and stability) at 6 months post-operatively, in standing skills on the GMFM at 1 and 2 years post operatively, and self-care skills on the PEDI at 1 and 2 years post-operatively.	
Ganjwala, 2011	To evaluate the effect of soft tissue orthopedic surgery on mobility and endurance.		Significant improvements in ROM values of the hip, knee, popliteal angle, and ankle DF with knee flexed at 1 and 2 years post operatively; significant gains in the FMS 500 and FAQ scores at 1 post operatively; significant gains in FMS 5, FMS 500, and FAQ scores at 2 years post operatively; signficant gains in walking speed and energy cost index scores at 1 and 2 years post operatively.	
Grecco, 2013	To determine the effect of treadmill training on gross motor function and functional mobility in children and adolescents with CP in PT following SEMLS.	Clinical controlled trial	It is beneficial to include treadmill training in conjunction with a typical PT regimen which includes ROM, muscle strengthening, postural training, standing, and gait training.	3b
Patikas, 2006	To investigate the effect of a post-operative strength training program on the walking of children with CP	Randomized controlled trial	Home programming for strength training helps with improving selective motor control. Better outcomes were achieved with home programming and outpatient PT services combined versus outpatient PT alone.	2b
Saraph, 2002	To analyze both physical examination and gait analysis data for a comprehensive assessment of outcome after gait-improvement surgery		Following SEMLS and post rehabilitation, improvements were noted in hip, knee, and ankle ROM.	4b
Seniorou, 2007	To quantify changes in lower limb muscle strength, gait and motor function in children with spastic diplegic CP following SEMLS, 2) To evaluate 2 different methods of	Randomized controlled trial	Significant decrease in strength after SEMLS was noted in knee flexors and hip flexors. Improved gait kinematics but decreases in motor function were noted at 6 months post operatively. Both strengthening groups	2b

	post-operative strengthening (e.g. progressive resistance strengthening versus active exercise)		(progressive resistance strengthening versus active exercise) showed improved muscle strength; however the resistance strengthening group showed significantly increased strength in more muscle groups compared to the active exercise group. Only the resistance strengthening group showed improvements towards normalized walking speed.	
Sung, 2013	To investigate the long term kinematic changes following SEMLS including distal hamstring lengthening		Significant improvements in temporal spatial gait parameters including both stride length and walking speed at 1 and 10 years post operatively; significant improvement in Gait Deviation Index scores at 1 and 10 years post operatively	4b
Thomason, 2011	To evaluate the magnitude of change between groups and over time on the basis of gait indices measures, physical measures, function, activity, mobility, and health-related QOL following SEMLS.		Significant between-group difference int eh social/emotional domain of the Child Health Questionnaire (parent form 50); significant difference with both Gillette Gait Index and Gait Profile Score scores at 12 months between groups, significant change in function (GMFM 66 and physical function domain of Child Health Questionnaire) for the surgical group at 25 months.	3b
Local Consensus, 2017	To generate consensus on the content of recommendation 7.	A consensus generation process was used through online polling and Skype conversation to obtain agreement of a group of 18 physical therapists specializing in pediatric developmental PT.	After 2 rounds of discussion and voting, a consensus of 18/18 pediatric physical therapists was obtained for this recommendation statement.	5

{Back to Guideline Recommendation 7}

Recommendation 8

It is recommended that annual, comprehensive PT evaluations occur for up to 5 years following SEMLS (Thomason, 2013 [3b]; Rodda, 2006 [4a]; Zwick, 2012 [4b]; Dreher, Buccoliero, 2012 [4a]).

Discussion/Synthesis of the Evidence and Dimensions for the Recommendation

This recommendation is based on the results of multiple peer-reviewed studies (Thomason, 2013 [3b]; Rodda, 2006 [4a]; Zwick, 2012 [4b]; Dreher, Buccoliero, 2012 [4a]). Annual evaluations may consist of gait analysis (Thomason, 2013 [3b]; Rodda, 2006 [4a]; Dreher, Buccoliero, 2012 [4a]; Zwick, 2012 [4b]), and clinical examination (Thomason, 2013 [3b]; Dreher, Buccoliero, 2012 [4a]), including range of motion (Dreher, Buccoliero, 2012 [4a]) strength (Rodda, 2006 [4a]; Dreher, Buccoliero, 2012 [4a]), and muscle tone (Dreher, Buccoliero, 2012 [4a]). Continued long-term follow-up is recommended for up to five years following SEMLS to assess for changes in gait (Rodda, 2006 [4a]; Zwick, 2012 [4b]) improvements in distal ankle strength (Rodda, 2006 [4a]), and progression of gross motor function (Thomason, 2013 [3b]). Ongoing assessments of patients in this population can identify potential comorbidities and assess for changes in function and quality of life. The rating of strength for this recommendation is moderate.

Dimensions of Judging the Recommendation Strength for Long Term Monitoring

1. Safety / Harm *(Side Effects and Risks)*	☒ Minimal		☐ Moderate		☐ Serious
2. Health benefit to patient	☒ Significant		☐ Moderate		☐ Minimal
3. Burden on population to adhere to recommendation	☐ Low		☒ Unable to determine		☐ High
4. Cost-effectiveness to healthcare system	☐ Cost-effective		☒ Inconclusive		☐ Not cost-effective
5. Directness of the evidence for this target population	☒ Directly relates		☐ Some concern of directness		☐ Indirectly relates
6. Impact on quality of life, morbidity, or mortality	☐ Positive		☒ Moderate/Neutral		☐ Negative
7. Grade of the Body of Evidence *(See Evidence Table below; *GNA – Grade Not Assignable)*	☐ High ⊕⊕⊕⊕	☐ Moderate ⊕⊕⊕◯	☒ Low ⊕⊕◯◯	☐ Very Low ⊕◯◯◯	☐ GNA* ◯◯◯◯
Overall Strength of the Recommendation:	☐ **Strong**		☒ **Moderate**		☐ **Weak**

Evidence Table of Included Studies

First Author & Year	Purpose	Methods	Results	Evidence Level
Dreher, Buccoliero, 2012	To provide long-term results after gastrocnemius-soleus intramuscular aponeurotic recession as a part of multilevel surgery.	Longitudinal, before and after	• PROM: Ankle PROM increased dorsiflexion at 1 year post-operatively; between 1 - 9 years post-operatively significant loss in dorsiflexion; no change in ankle plantarflexion at 1 year post-operatively; plantarflexion significantly decreased at 9 years post-operatively. • Strength: significant increase in ankle dorsiflexion at 1 year post-operatively and between 1-9 years post-operatively. • Tone: plantarflexor tone was significantly reduced at one, and nine year follow-up. • Gait: ankle dorsiflexion increased significantly at initial contact after surgery and for up to 9 years post-operatively; plantar flexion power significantly increased at 3 years post-operatively and was maintained for up to 9 years; global gait pathology was significantly reduced post-operatively and improvements were maintained for up to 9 years post-operatively.	4a
Rodda, 2006	To evaluate the functional and technical outcomes of SEMLS on severe crouch gait at 1 year post-operatively and determine if benefits were maintained at 5 years.	Longitudinal, time series	Improvements in ankle dorsiflexion and plantarflexion strength were noted with gait analysis at 1 and 5 years post-operatively. Improvements were also seen in FAQ and FMS. Reduced knee pain, increased function, and independence in the community were also noted.	4a
Thomason, 2013	To evaluate the outcome of SEMLS on gait, gross motor function, and functional mobility 5 years post SEMLS.	Cohort, prospective	Gait and gross motor gains were demonstrated at 5 years post operatively. The GMFM 66 showed a significant improvement at 5 years post-operatively. FMS scores were better for nearly 50% of the children, and no children were worse at 5 years post-operatively.	3b
Zwick, 2012	To test the hypothesis that boys with spastic diplegic CP would have a worse long-term outcome related to gait after SEMLS compared to girls.	Longitudinal retrospective	Gait improvement remained stable in girls following SEMLS but deteriorated continuously in boys.	4b

APPENDIX 4
CLINICAL QUESTIONS, CRITERIA FOR INCLUSION, EVIDENCE SEARCH STRATEGIES, AND SEARCH RESULTS

Clinical Question 1: In children, adolescents and young adults, aged 5 years to 25 years who are diagnosed with CP or other like neuromotor conditions and have had SEMLS, what are the most appropriate therapeutic assessments across the International Classification Functioning, Disability and Health (ICF) framework?

P	*(Population)*	Children, adolescents and young adults, aged 5 years to 25 years who are diagnosed with CPor other like neuromotor conditions and have had SEMLS
D	*(Diagnostic Test)*	most appropriate PT assessments across the International Classification Functioning, Disability and Health (ICF) framework

Clinical Question 2: In children, adolescents and young adults, aged 5 years to 25 years who are diagnosed with Cerebral Palsy or other like neuromotor conditions and have had SEMLS, what are the most appropriate therapeutic interventions to achieve optimal functional outcomes?

P	*(Population)*	Children, adolescents and young adults, aged 5 years to 25 years who are diagnosed CP or other like neuromotor conditions and have SEMLS
I	*(Intervention)*	most appropriate PT interventions
O	*(Outcome)*	optimal functional outcomes

Criteria for considering studies for this review

Types of Studies	Systematic reviews randomized controlled trials, clinical controlled trial, cross-sectional reviews, cohorts, longitudinal reviews, and mixed methods study
Types of Participants	Children, adolescents, and young adults diagnosed with CP, encephalopathy, or other like neuromotor conditions
Types of Interventions	SEMLS and PT
Types of Outcomes	Pain, mobility, patient/parent satisfaction, and education
Exclusion Criteria, *if any*	Surgery other than lower extremity orthopedic, non-multi-level lower extremity orthopedic surgeries, and diagnoses other than CP or other like neuromotor conditions

Search Strategy

Search Methods

All references were imported into an EndNote Library File representing evidence published prior to September 1, 2014. These articles were supplemented with an additional key word search designed to capture evidence from September 1, 2014 – September 15, 2015 (search terms by database and dates listed below). The articles identified through this search were also imported into EndNote. Duplicates were removed and articles from the selected pool of citations were evaluated for inclusion by two reviewers. This search strategy focused on answering clinical questions relevant to post-operative PT management for individuals undergoing SEMLS and employing a combination of Boolean searching and "natural language" searching on human-indexed thesaurus terms as well as "natural language" searching on words in the title, abstract, and indexing terms. During the course of the guideline development, additional articles were identified from other known references evidence and hand searching of reference lists.

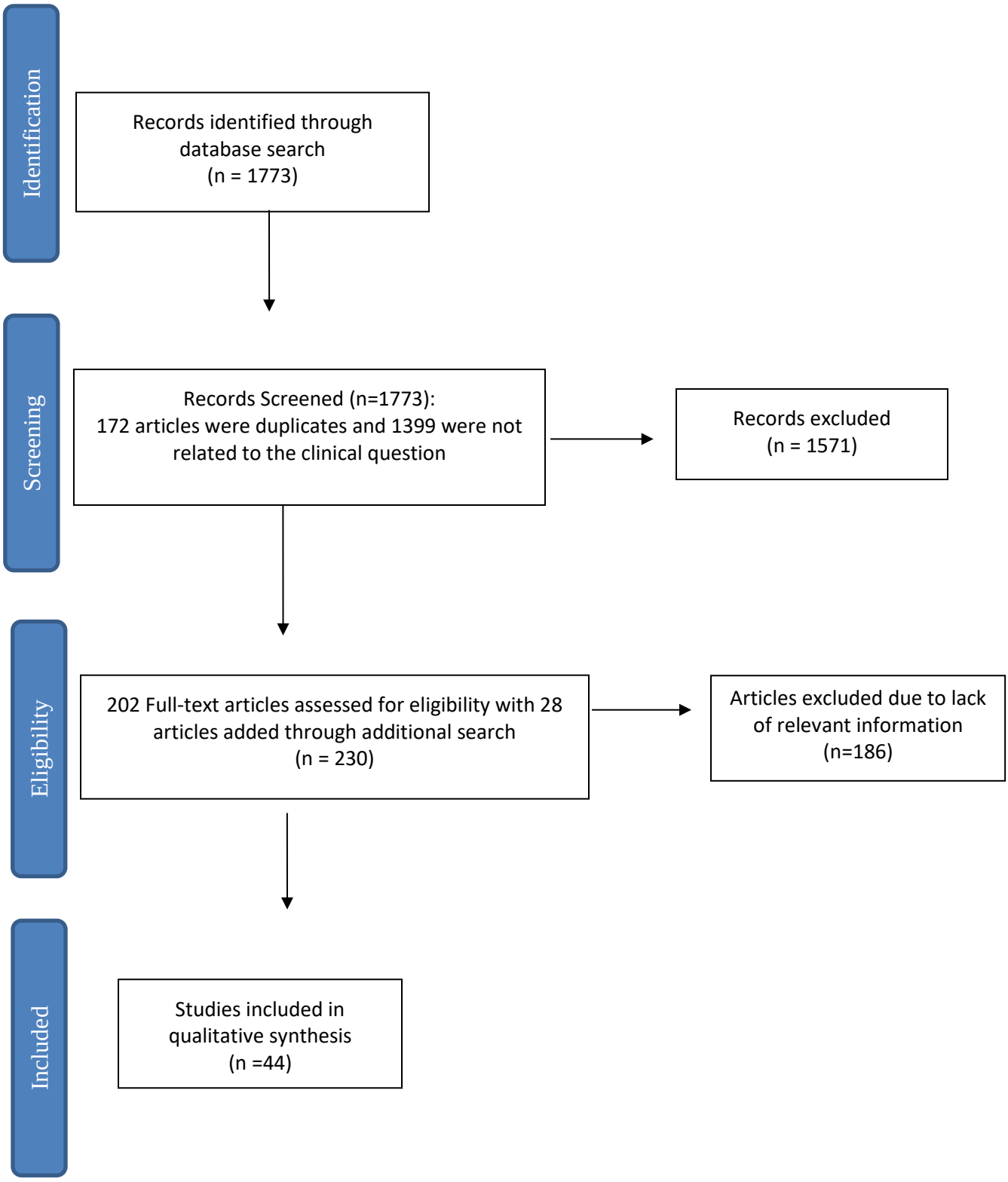
Search Databases	Search Terms	Limits, Filters, & Search Date Parameters	Date of Most Recent Search
☒ MedLine via PubMed or Ovid	• ("cerebral palsy" OR CP) AND ("single-event multilevel surgery" OR SEMLS OR "all american" OR "single-event multilevel ortho* surgery" OR "single event multiple level surgery" OR SEMS OR "orthop* surgery " OR "single-event multilevel orthopedic surgery") AND (physi* AND therapy OR Occupational therapy))) OR (("cerebral palsy" OR CP) AND ("single-event multilevel surgery" OR SEMLS OR "all american" OR "single-event multilevel ortho* surgery" OR "single event multiple level surgery" OR SEMS OR "orthop* surgery " OR "single-event multilevel orthopedic surgery"))) OR (("cerebral palsy" OR CP) AND ("single-event multilevel surgery" OR SEMLS OR "all american" OR "single-event multilevel ortho* surgery" OR "single event multiple level surgery" OR SEMS	Publication Dates or Search Dates: • 9/1/2014 to 9/15/2015 ☒ English Language ☒ Pediatric Evidence Only: ☐ Other Limits or Filters: • None	9/15/2015
☒ CINAHL	• ("cerebral palsy" OR CP) AND ("single-event multilevel surgery" OR SEMLS OR "all american" OR "single-event multilevel ortho* surgery" OR "single event multiple level surgery" OR SEMS OR "orthop* surgery" OR "single-event multilevel orthopedic surgery") AND (physi* AND therapy OR Occupational therapy) OR ("cerebral palsy" OR CP) AND ("single-event multilevel surgery" OR SEMLS OR "all american" OR "single-event multilevel ortho* surgery" OR "single event multiple level surgery" OR SEMS OR "orthop* surgery" OR "single-event multilevel orthopedic surgery") OR ("cerebral palsy" OR CP) AND ("single-event multilevel surgery" OR SEMLS OR "all american" OR "single-event multilevel ortho* surgery" OR "single event multiple level surgery" OR SEMS	Publication Dates or Search Dates: • 9/1/2014 to 9/15/2015 ☒ English Language ☒ Pediatric Evidence Only ☐ Other: • No Filters	9/15/2015

Search Results

The citations were reduced by: eliminating duplicates, review articles, non-English articles, and adult articles (e.g., limits/filters above). The resulting abstracts and full text articles were reviewed by a methodologist to eliminate low quality and irrelevant citations or articles. During the course of the guideline development, additional articles were identified from subsequent refining searches for evidence, clinical questions added to the guideline and subjected to the search process, and hand searching of reference lists. The dates of the most recent searches are provided above.

The initial search for evidence identified 1773 articles. One hundred seventy-two articles were duplicates and 1399 were not related to the clinical question of interest based on title or abstract review (n=1571). Two hundred two articles met the inclusion criteria above. Twenty-eight articles were added with an additional search ending 9/15/15. Two hundred thirty articles were reviewed in full text and critically appraised. One hundred eighty-six articles were excluded/discarded for the following reasons: lack of relevant information related to PT assessments or interventions or focus on surgical procedures. A total of 44 articles were used for recommendations within the clinical practice guideline.

PRISMA Flowsheet:



APPENDIX 5
FUTURE RESEARCH AGENDA

In children, adolescents and young adults with CP or other like neuromotor conditions and have had SEMLS:

1. What is the universal definition for SEMLS?
2. Does early tone management effect the recommendations and/or need for orthopedic surgery?
3. Does participation in a structured community wellness programs, including but not limited to swimming, horseback riding, and martial arts, impact the functional outcomes, quality of life, and overall healthcare costs?
4. Does implementation of a structured home exercise program while inpatient and continued until outpatient PT begins, impact overall functional outcomes of surgery and quality of life?
5. What is the optimal dosing for PT following orthopedic surgery related to GMFCS level to reach functional outcomes and quality of life?
6. How does 24 hour positioning affect outcomes in patients following SEMLS?
7. How does aquatic therapy affect outcomes in patients following SEMLS?
8. Is electrical stimulation effective in immediate post-operative rehabilitation following SEMLS?
9. Should there be a greater emphasis on family education for post-operative scar management in this patient population?
10. There is a need for long-term follow-up beyond 5-10 years in patients following SEMLS.
11. The use of quality of life measures need to be further assessed in patients following SEMLS to allow for greater consistency in clinical practice.
12. Could the use of lower extremity orthoses for a prolonged period in the post-operative phase assist in improving functional outcomes in patients following SEMLS?
13. Evaluate the efficacy of pre-operative PT evaluation and treatment in patients recommended for SEMLS.
14. How does adaptive equipment both pre-operatively and post-operatively effect functional outcomes and quality of life in children, adolescents and young adults with CP or other like neuromotor conditions and who have had SEMLS?

APPENDIX 6
TEAM MEMBERS & CONFLICTS OF INTEREST

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Conflicts of Interest were declared for each team member and:

☒ No financial or intellectual conflicts of interest were found.
☐ The following conflicts of interest were disclosed:

The guideline was developed without external funding.
Conflict of interest declaration forms are filed with the Cincinnati Children's EBDM group.

APPENDIX 7
LEGEND EVIDENCE EVALUATION SYSTEM *(LET EVIDENCE GUIDE EVERY NEW DECISION)*

Full tables of the LEGEND evidence evaluation system are available in separate documents:

- Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality *(abbreviated table below)*
- Grading a Body of Evidence to Answer a Clinical Question
- Judging the Strength of a Recommendation *(Appendix 3 – Evidence Discussion and Dimensions for Recommendations)*

Table of Evidence Levels *(see link above for full table)*:

Quality level	Definition
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5a or 5b	General review, expert opinion, case report, consensus report, or guideline
5	Local Consensus

†a = good quality study; b = lesser quality study

Table of Grade for the Body of Evidence *(see link above for full table)*:

Grade	Definition
High	Sufficient number of high quality studies with consistent* results
Moderate	A single well-done trial, Multiple lesser quality trials, or Multiple large, high-quality observational studies
Low	A single well-done study or Multiple studies of lesser quality or with some uncertainty
Very Low	Studies with insufficient quality including case reports, case studies, general reviews, and local consensus
Grade Not Assignable	There was insufficient evidence.

Table of Language and Definitions for Recommendation Strength *(see link above for full table)*:

Language for Strength	Definition
It is strongly recommended that… It is strongly recommended that… not…	When the dimensions for judging the strength of the evidence are applied, there is high support that benefits clearly outweigh risks and burdens. (or visa-versa for negative recommendations)
It is recommended that… It is recommended that… not…	When the dimensions for judging the strength of the evidence are applied, there is moderate support that benefits are closely balanced with risks and burdens.
It is suggested that… It is suggested that… not…	When the dimensions for judging the strength of the evidence are applied, there is weak support that benefits are closely balanced with risks and burdens.
There is insufficient evidence to make a recommendation…	

APPENDIX 8
EVIDENCE-BASED CLINICAL CARE RECOMMENDATION DEVELOPMENT PROCESS

The process by which this guideline was developed is documented in the Guideline Development Process Manual; relevant development materials are kept electronically. The recommendations contained in this guideline were formulated by an interdisciplinary working group which performed systematic search and critical appraisal of the literature, using the Table of Evidence Levels described with the references and in Appendix 4, and examined current local clinical practices. The guideline has been reviewed and approved by clinical experts not involved in the development process. The guideline has also been distributed to leadership and other parties as appropriate.

Recommendations have been formulated by a consensus process directed by best evidence, patient and family preference, and clinical expertise. During formulation of these recommendations, the team members have remained cognizant of controversies and disagreements over the management of these patients. They have tried to resolve controversial issues by consensus where possible and, when not possible, to offer optional approaches to care in the form of information that includes best supporting evidence of efficacy for alternative choices.

Review Process

This guideline has been reviewed against quality criteria by three independent reviewers from the Cincinnati Children's Evidence Collaboration.

The guideline was also externally appraised by three independent reviewers using the AGREE instrument *(Appraisal of Guidelines for Research and Evaluation)* and the results by domain are:

- Scope and Purpose 94%
- Stakeholder Involvement 83%
- Rigor of Development 95%
- Clarity and Presentation 72%
- Applicability 85%
- Editorial Independence 96%

Revision Process

The guideline will be removed from the Cincinnati Children's website, if content has not been revised within five years from the most recent publication date. A revision of the guideline may be initiated at any point within the five year period that evidence indicates a critical change is needed. Team members reconvene to explore the continued validity and need of the guideline.

Review History

Date	*Event*	*Outcome*
2/6/19	Original Publication	New guideline developed and published

Permission to Use the Guideline

This Evidence-Based Care Guideline *(EBCG)* and any related implementation tools *(if applicable, e.g., screening tools, algorithms, etc.)* are available online and may be distributed by any organization for the global purpose of improving child health outcomes. Website address: http://www.cincinnatichildrens.org/service/j/anderson-center/evidence-based-care/recommendations/default/

Examples of approved uses of the EBCG include the following:

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Notification to Cincinnati Children's (EBDMInfo@cchmc.org) is appreciated for all uses of any EBCG or its companion documents which are adopted, adapted, implemented, or hyperlinked.

Please cite as:

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For more information:

About this guideline, its companion documents, or the Cincinnati Children's Evidence-Based Care Recommendation Development process, contact the Cincinnati Children's Evidence Collaboration at EBDMinfo@cchmc.org.

Note/Disclaimer

This guideline addresses only key points of care for the target population; it may not be a comprehensive practice guideline. These care recommendations result from review of literature and practices current at the time of their formulations. This guideline does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this guideline is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding any specific care recommendation.