

**Clinical
Commissioning
Policy: Selective
Dorsal Rhizotomy
(SDR) for the
treatment of spasticity
in Cerebral Palsy
(children aged 3-9
years)**

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Clinical Commissioning Policy: Selective Dorsal Rhizotomy (SDR) for the treatment of spasticity in Cerebral Palsy (children aged 3-9 years)

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**Prepared by NHS England Specialised Services Clinical Reference Group for
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Policy Statement

NHS England will commission selective dorsal rhizotomy for the treatment of spasticity in Cerebral Palsy in children aged 3-9 years in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary

About Selective Dorsal Rhizotomy (SDR) for treatment of spasticity in Cerebral Palsy

Selective dorsal rhizotomy (SDR) is an operation used to reduce spasticity (muscle stiffness) in cerebral palsy. Cerebral palsy is a descriptive term for a problem of motor control caused by an irreversible structural difference or damage to the brain that happens before birth, around the time of birth or in the first 2 years of life.

Although the brain injury does not get any worse as the child gets older, the difficulties it causes can change in the growing child. The problems of movement can often be accompanied by other clinical, functional and developmental challenges.

The pattern of movement problems are dependent on which part of the brain has been damaged. Sometimes the main problems can be stiffness (spasticity), sometimes weakness and sometimes a problem with controlling patterns of movement (dystonia).

How large the area of brain damage is usually determines the severity of movement problems. The severity of the child's motor problems is described on a scale of one to five (one the least and five the most) using the Gross Motor Functional Classification System (GMFCS). As with any child movement changes with growth and stiffness in the muscles this can lead to pain and tightness over time and can impair the child's ability to walk.

For children with cerebral palsy who have spasticity mainly affecting their legs and with not much weakness and with no 'dystonia' and who can walk but have problems with their pattern, SDR can be considered. We used to describe this group of movement disorder as spastic diplegia, but it is now referred to as bilateral spastic cerebral palsy GMFCS levels II and III.

SDR involves cutting carefully selected sensory nerves inside the spine of the lower back.

About current treatments

There are a number of other available treatments to help reduce the effects of spasticity to improve function and movement that may be used together with or instead of SDR. These include medication, long-term physiotherapy, occupational therapy and splints (orthotics), targeted botulinum toxin injections into the muscles as well as a variety of orthopaedic procedures.

About the new treatment

SDR surgery involves cutting nerves in the lower spine that are responsible for muscle stiffness in order to ease muscle spasticity and improve mobility in people with cerebral palsy.

Before considering children for this operation, brain scans are taken as well as x-rays of a child's hips to confirm that they are stable.

Following surgery regular physiotherapy is necessary to obtain the best results after SDR and children and their families need to be motivated and show that they are able to cooperate with the therapy.

What we have decided

NHS England has carefully reviewed the evidence to treat spasticity in cerebral palsy mainly affecting the legs, in children functioning at Gross Motor Function Classification System (GMFCS) levels II & III with SDR. The evidence review also included the Commissioning through Evaluation of Selective Dorsal Rhizotomy Kings Technology Evaluation Centre (KiTEC) Interim Report (22 March 2018). .. We have concluded that there is enough evidence to make the treatment available at this time. This interim decision will be reviewed once the full findings of the Commissioning through Evaluation scheme are available, towards the end of 2018.

1 Introduction

SDR is a complex specialised neurosurgical procedure for the treatment of spasticity (muscle stiffness) associated with cerebral palsy. The treatment also includes post-operative physiotherapy. The level of physiotherapy is linked to the severity of the child's motor problems and physiotherapy teams will review children at 6 months, 12 months and 24 months. Subsequent physiotherapy frequency may be adjusted linked to review outcomes.

Cerebral palsy describes a group of permanent brain disorders originating during foetal development, birth or early childhood. It is associated with abnormalities of movement, balance and posture.

SDR involves the irreversible division of some of the sensory nerves in the dorsal lumbar spinal cord, performed under general anaesthesia. It aims to reduce spasticity by decreasing sensory stimulation whilst preserving voluntary movement. Patients receive intensive physiotherapy for several months after SDR.

The GMFCS is a standardised classification system that describes the gross motor function of children and young people with cerebral palsy on the basis of their self-initiated movement with particular emphasis on sitting, walking, and wheeled mobility. Distinctions between levels are based on functional abilities, the need for assistive technology, including hand-held mobility devices (walkers, crutches, or canes) or wheeled mobility, and to a much lesser extent, the actual quality of movement.

The GMFCS is categorised into the following 5 levels:

Level I - Walks without restrictions: Children walk at home, school, outdoors and in the community. They can climb stairs without the use of a railing. Children perform gross motor skills such as running and jumping, but speed, balance and coordination are limited.

Level II - Walks without assistive devices: Children walk in most settings and climb stairs holding onto a railing. They may experience difficulty walking long

distances and balancing on uneven terrain, inclines, in crowded areas or confined spaces. Children may walk with physical assistance, a handheld mobility device or use wheeled mobility over long distances. Children have only minimal ability to perform gross motor skills such as running and jumping.

Level III - Walks with assistive devices: Children walk using a hand-held mobility device in most indoor settings. They may climb stairs holding onto a railing with supervision or assistance. Children use wheeled mobility when traveling long distances and may self-propel for shorter distances.

Level IV – Has limited self-mobility / may use powered mobility: Children use methods of mobility that require physical assistance or powered mobility in most settings. They may walk for short distances at home with physical assistance or use powered mobility or a body support walker when positioned. At school, outdoors and in the community children are transported in a manual wheelchair or use powered mobility.

Level V – Has severely limited self-mobility even with assistive devices: Children are transported in a manual wheelchair in all settings. Children are limited in their ability to maintain antigravity head and trunk postures and control leg and arm movements.

- GMFCS - E & R © Robert Palisano, Peter Rosenbaum, Doreen Bartlett, Michael Livingston, 2007

Background:

In 2013, NHS England published a clinical commissioning policy stating that SDR was not routinely commissioned due to the lack of evidence to support the procedure. This decision was also informed by the National Institute for Health and Care Excellence (NICE) review of the procedure.

NICE reviewed the use of SDR for spasticity in cerebral palsy and published interventional procedure guidance (IPG 373) in 2006. The guidance was part of the

NICE Interventional Procedures Programme and took into account safety and efficacy, but not cost-effectiveness.

The 2006 Guidance was updated and published in 2012 (CG145) as part of a review of the management of spasticity in children and young people with non-progressive brain disorders. The 2012 NICE Clinical Guideline CG145 recommended that SDR can be considered to improve walking ability in children and young people with spasticity at GMFCS level II or III but that further evidence was required about the efficacy of SDR and in particular that research should focus on whether SDR followed by intensive rehabilitation, performed between the ages of 3 and 9 years in children who are at GMFCS level II or III result in good community mobility as a young adult.

The Commissioning through Evaluation Programme for SDR:

In order to further assess the efficacy and safety of SDR surgery, NHS England launched a Commissioning through Evaluation (CtE) programme in 2014:

<https://www.england.nhs.uk/commissioning/spec-services/npc-crg/comm-eval/>

<https://www.england.nhs.uk/2014/07/cte-specialist-surgery/>

The aim of the NHS CtE programme for SDR was to evaluate the outcome of SDR and investigate whether there was improvement in gross motor function and quality of life after SDR at 6-months that was maintained or improved at 12 months and 2 years after SDR surgery. The evaluation also included the collection of information on adverse events to monitor the safety of the procedure.

2 Definitions

The key terms in this policy and their definitions are:-

Cerebral Palsy (CP) - describes a group of permanent brain disorders originating during foetal development, birth or early childhood. It is associated with abnormalities of movement, balance and posture.

Selective Dorsal Rhizotomy (SDR) - is complex neurosurgery operation involving the irreversible division of some of the sensory nerves in the dorsal lumbar spinal cord, performed under general anaesthesia. It aims to reduce spasticity by decreasing sensory stimulation whilst preserving voluntary movement. Patients usually receive intensive physiotherapy for several months after SDR.

Spasticity - is increased, involuntary, velocity-dependent muscle tone that causes resistance to movement.

Dystonia - is involuntary sustained or spasmodic muscle contractions involving co-contraction of the agonist and the antagonist. The movements are usually slow and sustained, and they often occur in a repetitive and patterned manner. They can be unpredictable and fluctuate in severity.

Ataxia/ataxic - is a term for a group of disorders that affect co-ordination, balance and speech.

The Gross Motor Function Classification System (GMFCS) - is a standardised 5-level classification system that describes the gross motor function of children and young people with cerebral palsy on the basis of their self-initiated movement with particular emphasis on sitting, walking, and wheeled mobility. Distinctions between levels are based on functional abilities, the need for assistive technology, including hand-held mobility devices (walkers, crutches, or canes) or wheeled mobility, and to a much lesser extent, quality of movement.

The Gross Motor Function Measure (GMFM) - is a clinical tool designed to evaluate change in gross motor function in children with cerebral palsy. There are two versions of the GMFM - the original 88-item measure (GMFM-88) and the more recent 66-item GMFM (GMFM-66).

CPQoL - is an internationally designed and validated tool designed to assess the Quality of Life for children with cerebral palsy across a variety of domains including social wellbeing and acceptance, feelings about functioning, participation and

physical health, emotional wellbeing and self-esteem, access to services, pain and impact of disability, and family and parent health.

Magnetic resonance imaging (MRI) - is a powerful, accurate, non-invasive radiology scan used for diagnosing a variety of conditions such as cerebral palsy. It allows the doctors to obtain a high-quality scan of the brain to understand the reasons for a patient's condition.

Periventricular Leucomalacia (PVL) - or white matter damage of prematurity is the term given for changes in the brain beside the internal fluid spaces of the brain (the ventricles). It indicates that there has been an injury to that part of the brain due to lack of oxygen or poor blood flow either leading up to birth or around the time of birth itself. It is the most common abnormality found on an MRI brain scan of children with cerebral palsy and considered a diagnostic sign of cerebral palsy.

Basal ganglia –are the central grey matter structures of the brain responsible for the initiation and fluidity of movement (locomotor driving system). They include the Caudate, Putamen and Globus Pallidus that function to control the motor system. Damage in these areas leads to dystonic movement patterns.

Paralysis - is the loss of the ability to move (and sometimes to feel anything) in part or most of the body, including the legs and or arms.

Spinal deformity - involves a change in the normal curvature of the spine. This is a collection of terms that includes an abnormal forward bend of the spine (kyphosis) or abnormal sideways curvature (scoliosis).

Reimer's Index -is the measurement of the percentage migration of the hip joint, measuring whether there is any displacement of the hip bone (head of the femur) out of its socket.

3 Aims and Objectives

The aim of this policy is to define NHS England's commissioning position on SDR for the treatment of spasticity in cerebral palsy, mainly affecting the legs, in children

functioning at GMFCS levels II or III. These criteria are consistent with NICE Guidance (IPG 373). SDR is not usually recommended for children in GMFCS I as the possible benefits are not thought to outweigh the potential risks and there is very little research to support extending the criteria to cover GMFCS IV and V.

The objective is to demonstrate evidence based commissioning to improve outcomes for children with spasticity in cerebral palsy.

4 Epidemiology and Needs Assessment

The prevalence of cerebral palsy in developed countries is stable at around 2/1000 live births. Approximately 40% of cerebral palsy cases are children who have been born prematurely. With a birth rate of around 700,000 per year, 1 in 400 children will have a form of cerebral palsy.

Considering the breakdown of cerebral palsy subtypes, around 75% of children will have a predominantly spastic muscle tone of which one third will have a diplegic pattern (lower limb predominant). This constitutes around 1/1000 live births.

The current population for England is estimated at 53 million with 19% aged 0-15 years. This gives a total of about 10 million children under 15 years. The birth rate is around 700,000 per year.

Using the figures above, the estimated prevalence of children born with diplegia in England is therefore around 700/year. The GMFCS breakdown further suggests that around 20-30% will be at GMFCS levels of II and III.

Taking all these estimates together, the total number of children aged between 3 and 9 years who are likely to require SDR surgery is estimated at 200 per year.

5 Evidence Base

NHS England has concluded that there is sufficient evidence to support the routine commissioning of this treatment for the indication.

The evidence comes from:

- a. The evidence review commissioned by NHS England; and

- b. The King's Technology Evaluation Centre (KiTEC) Interim Analysis of the outcome data from the Commissioning though Evaluation study of SDR

Evidence review performed by Solutions for Public Health (SPH) on behalf of NHS England Specialised Commissioning

The evidence identified for SDR for spasticity caused by non-progressive brain disorders included five non-randomised controlled studies and one uncontrolled study.

There were statistically significant improvements for children with cerebral palsy who had SDR compared to children with cerebral palsy who did not have SDR up to 22 years follow-up, for spasticity, self-reported function, and some gait kinematic variables; daily assistance was also significantly reduced as were subsequent orthopaedic procedures and injections. At 12 months follow-up there were statistically significant improvements in spasticity, function and mobility and significantly fewer orthopaedic procedures following SDR compared with intrathecal baclofen pump implantation (ITBP) in children with moderate to severe spasticity. Whether these improvements translate to clinically meaningful changes is unclear. No adverse events relating to the SDR procedure were reported.

There were no significant differences between SDR and non-SDR groups for functional mobility, ambulatory function, strength, selective motor control, most gait parameters, pain, fatigue, satisfaction, quality of life, extracurricular activities, cadence, velocity, stride, kinetics and BMI at one to 22 years follow-up.

In all studies of children who had SDR aged under 10 years there were no deleterious effects associated with SDR from one to 22 years follow-up for any reported outcome. The only exception was one study in which the non-SDR group had a statistically significantly higher gait deviation index than the SDR group. SDR in older children (mean age 15 years and four months at SDR) was associated with gross motor function declines compared with similar children who had no surgery.

Overall, the evidence found was limited to non-randomised mostly controlled studies

with a high risk of selection bias and confounding due, for example, to likely differences in the range and intensity of physical therapy/rehabilitation programmes between SDR and non-SDR groups. Other potential confounders include patient comorbidities, patient motivation after surgery and concurrent medical treatment. The severe limitations of the evidence limit the strength of any conclusions that can be drawn.

The review concluded that evidence is needed from studies with more robust designs that match participants with controls for all clinically important variables, in order to reduce heterogeneity, and with long-term data from a range of observed and self-reported outcomes, using well-validated tools specific to this patient group. Better quality reporting of participant characteristics, the SDR intervention and physiotherapy is also required.

Commissioning through Evaluation of Selective Dorsal Rhizotomy

Kings Technology Evaluation Centre (KiTEC) Interim Report. 22 March 2018

This register study has followed a cohort of children with cerebral palsy who underwent SDR through NHS England's Commissioning through Evaluation (CtE) programme. The CtE programme commissioned the procedure over a two-year period and the report presented the findings for all 137 eligible children.

The SDR CtE register data have shown that mean increase in GMFM-66 score is 3.2 per year with a reasonably narrow 95% confidence interval (2.9 to 3.5). The estimated increase was higher in those with GMFCS level II, 3.8 (95% CI: 3.3 to 4.4) compared to 2.8 (95% CI: 2.4 to 3.2) in those with GMFCS level III. All changes are highly significant statistically and are greater than the expected changes that would happen without SDR based on an extensive Canadian cohort study (Russell et al.2013) (see table one). They were also consistent with the findings of the meta-analysis of randomised controlled trials (RCT) that showed that the SDR group had a greater improvement in mean GMFM-66 than the control group (McLaughlin et al.2002).

Table One Mean change in GMFM-66 per year SDR and available normative and RCT data

Change in mean GMFM-66 per year	All children	GMFCS level	GMFCS level
		II	III
CtE SDR values: Random effect mixed model estimates	3.2	3.8	2.8
Weighted CanChild norms: [32]	2.1	2.5	1.8
Difference between SDR and control from the meta-analysis [15]	2.66 [*]		

Note * the inclusion criteria for the RCTS were broader than CtE.

The GMFM-66 centiles showed a similar trend towards an improvement from SDR to two-years post-operative. (A note of caution to these findings following comment from one of the reference centiles authors (Prof Peter Rosenbaum, McMaster) concerning the limited precision in the reference centiles and the view that raw GMFM-66 scores provided a more reliable measure of outcome).

The cerebral palsy Quality of Life (CPQoL) results using the parent-reported items, showed statistically significant improvement over time, in several domains. Specifically, there was improvement in mean scores for 'Feelings about functioning', 'Participation and physical health', 'Emotional wellbeing and self-esteem and 'Family health'. There was a reduction in mean reported pain score over time equivalent to a decrease of three units per year. This is small but statistically significant.

Twenty-eight adverse events were reported for 19 children with most having one event only. The most common event reported was wound infection of which just one was severe. All wound infections were resolved.

KiTEC's systematic review identified three RCTs and one meta-analysis which fitted the selection criteria. All three RCTs were included in the meta-analysis by

McLaughlin et al (2002). The meta-analysis is the most up to date summary of available evidence identified by KiTEC, and as described above, showed a greater improvement in GMFM-66 scores amongst SDR patients compared to controls.

A higher proportion of SDR CtE operations involved cutting approximately two thirds of the nerve rootlets with little suggestion of differences between centres. There was no notable difference in the mean percentage cut by GMFCS level. The average length of hospital stay post-SDR surgery varied between centres with the extremes being one centre where all children stayed 24 days and another that discharged all at four days.

The analysis of the small sample of cost data in SDR and non-SDR patients from an external source, suggests that while SDR may be associated with slightly higher costs in the short term, that in the longer term, costs are similar or may even be less for those receiving SDR.

Conclusion

The KiTEC interim analysis of the CtE SDR data found that after 2 years of follow up there were highly statistically significant improvements in motor function as measured by serial GMFM-66 assessments. These results were consistent with the KiTEC systematic review which identified a meta-analysis of RCTs that showed that the SDR patients had a greater improvement in mean GMFM-66 than the controls (McLaughlin et al 2002).

Whilst it is not possible to define a specific increase in the GMFM-66 score that can be regarded as "clinically significant", the finding of highly statistically significant improvements in the GMFM-66 in patients who also reported significant improvements in their quality of life (including a reduction in the mean reported pain score) provides objective evidence that SDR leads to practical benefits for patients with no evidence of major permanent adverse events.

Despite the limitations of the studies contained in the evidence review performed by SPH, it did re-inforce the NICE Guidance on SDR for Spasticity in Cerebral Palsy

(IPG373) that evidence of the efficacy of the procedure is adequate to support its use. In addition the evidence review did not find evidence of the “serious but well recognised complications” that were also cited in IPG373.

6 Criteria for Commissioning

SDR will be routinely commissioned for the treatment of spasticity in cerebral palsy, mainly affecting the legs, in children functioning at GMFCS levels II and III.

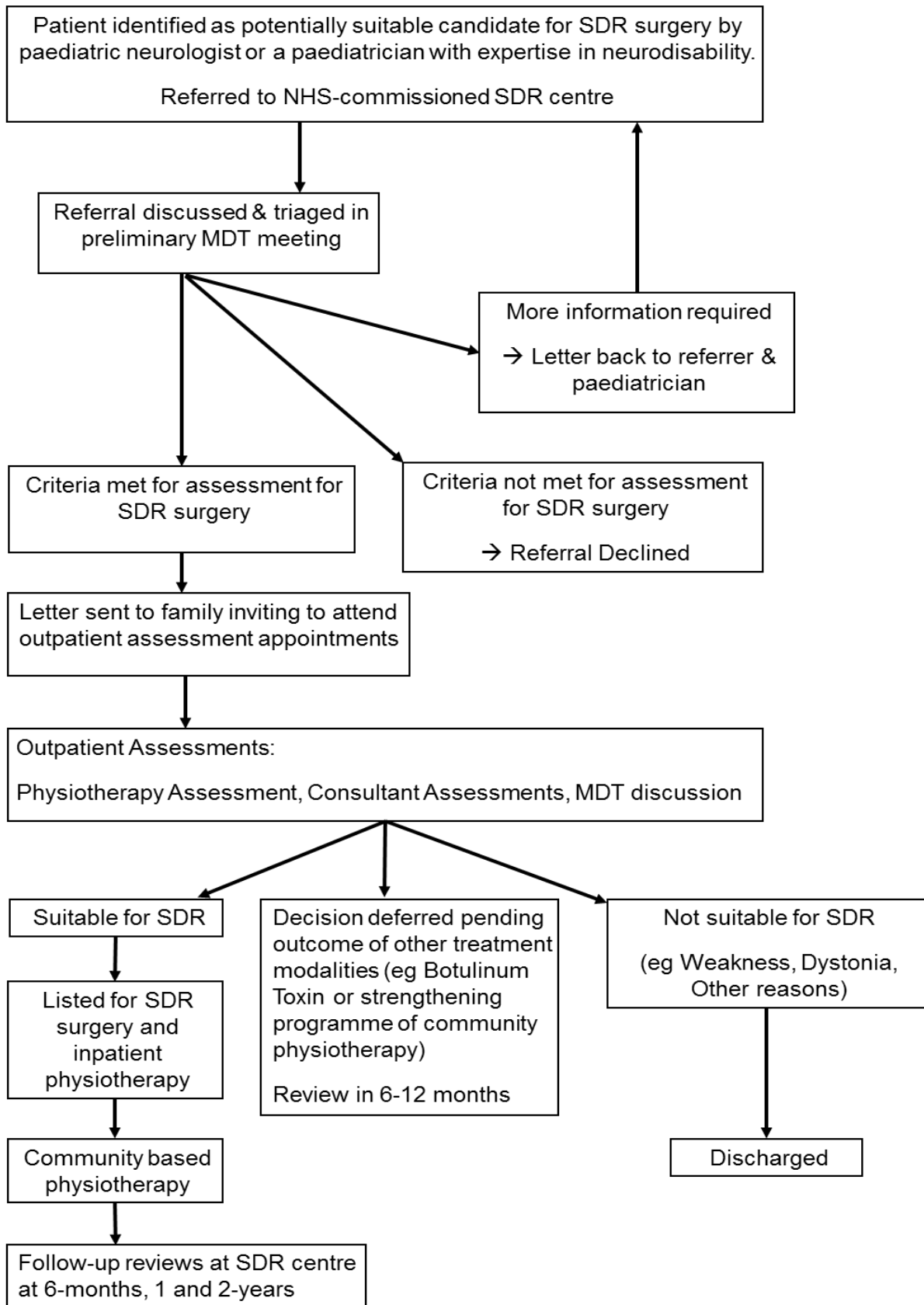
Patients must meet the following criteria:

- a) The child is aged 3 years to 9 years inclusive with a diagnosis of cerebral palsy with spasticity mainly affecting the legs;
- b) The child has dynamic spasticity in lower limbs affecting function and mobility and no dystonia;
- c) The MRI brain scan shows typical cerebral palsy changes and no damage to key areas of brain controlling posture and coordination; *
- d) The child functions at GMFCS level II or III;
- e) There is no evidence of genetic or neurological progressive illness;
- f) The child has mild to moderate lower limb weakness with ability to maintain antigravity postures;
- g) The child has no significant scoliosis or hip dislocation (Reimer’s index should be <40%)

* The typical MRI changes are those of white-matter damage of prematurity or periventricular leucomalacia (PVL).

* Lesions in basal ganglia or cerebellum are contra- indications to SDR, since they are associated with other cerebral palsy types (dystonia / ataxia).

7 Patient Pathway



8 Governance Arrangements

Each provider organisation treating children under this policy will be required to assure itself through its own internal governance arrangements that the referral criteria have been fulfilled and that appropriate assessments are completed before SDR is performed. NHS England can ask for documented evidence that these processes are in place.

This will involve the SDR centres collecting and recording the standardised pre-operative and post-operative assessments (as with CtE). Data would be recorded in a common format. The national network of SDR centres will meet on an annual basis to share outcome data and review clinical practice. This annual meeting would also be attended by NHS Specialised Commissioners.

9 Mechanism for Funding

NHS England is the responsible commissioner for SDR. Funding to the provider will be in accordance with NHS England Specialised Commissioning contracting and funding arrangements.

10 Audit Requirements

Centres providing SDR are required to collect and record the following data pre-operatively and post-operatively at 6 months, 1 year and 2 years post-procedure.

- Patient demographics including sex, age, height, weight
- GMFCS level
- Muscle tone – Modified Ashworth Scale
- Strength score – Modified Oxford
- Selectivity scale – Boyd and Graham
- Joint Range of movement – Goniometry
- GMFM-66
- 3-Dimensional gait analysis (pre-op and at 2-years post-operatively)
- CPQoL

- Hip x-ray – pre-operatively and at 2 years post -operatively in line with cerebral palsy integrated pathway (CPIP) protocol
- Spine x-ray – pre-operatively and at 2-years post-operatively

11 Documents which have informed this Policy

National Institute for Health and Care Excellence. (2012 (updated 2016)). *Spasticity in under 19s: management* (CG145) Clinical guideline, <https://www.nice.org.uk/guidance/cg145>

National Institute for Health and Care Excellence, (2010). *Selective Dorsal Rhizotomy for spasticity in cerebral palsy* (IPG373) Interventional procedures guidance, <https://www.nice.org.uk/guidance/ipg373>

12 Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

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