

CONCISE GUIDANCE TO GOOD PRACTICE

A series of evidence-based guidelines for clinical management

This series is intended to cover less common disorders that are not covered by the major guideline producers but which are likely to be encountered in several specialties. They are designed to allow clinicians to make rapid informed decisions based on up-to-date and systematically reviewed and accessible evidence. Where such evidence does not exist, consensus will be used to complete the clinical pathway.

Guidelines for the use of botulinum toxin (BTX) in the management of spasticity in adults

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Clinical Effectiveness
& Evaluation Unit



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Botulinum toxin (BTX) is a powerful neurotoxin which blocks cholinergic transmission at the neuromuscular junction. Judiciously applied, it can reduce local muscle overactivity while maintaining the strength in other muscles.

To date, BTX has not been licensed for use in spasticity in the UK, and literature pertaining to clinical practice is still relatively scant. However, controlled trials have provided evidence for the effectiveness of BTX, both in reducing spasticity itself and achieving functional gain.

The guidance given here to clinicians involved in the management of spasticity covers patient suitability for treatment using BTX, maximum recommended dosage and the necessary follow-up procedures and documentation.

Background

What is spasticity and why does it matter?

Spasticity is overactivity in the muscles which follows damage to the brain or spinal cord, eg following stroke, trauma or hypoxic insult. It may take the form of sustained high tone, intermittent spasms or a mixture of the two. Uncontrolled spasticity leads to permanent shortening (contracture) in the muscles and soft tissues.

Spasticity matters because it causes pain and deformity which:

- increase disability (reduced mobility, self care, ease of hygiene etc)
- increase complications, eg pressure sores
- feed into a vicious cycle of poor posture which in turn exacerbates the spasticity.

However, spasticity is not always harmful. Patients with upper motor neurone weakness may rely on the increased tone to maintain their ability to stand and walk.

How is spasticity treated?

The mainstay of treatment is physical and involves:

- active treatment of exacerbating factors such as infection, pain, constipation and other nociceptive influences
- careful positioning throughout 24 hours to maintain muscle length and reduce deformity
- a regular physiotherapy programme, which may include stretching and splinting.

In addition, medical and surgical intervention may be required:

- Antispasmodic drugs (eg baclofen, tizanidine, diazepam or dantrolene) may be used to reduce spasticity. However, they also produce generalised weakness, so tone reduction may be at the expense of lost function.
- Where there is already contracture, surgical release may correct deformity and facilitate better postures (eg standing) to prevent further spasticity.

What can Botulinum toxin do?

BTX is a powerful neurotoxin which blocks cholinergic transmission at the neuromuscular junction. Injected into spastic muscles, it produces localised paralysis of the selected muscle(s). Judiciously applied, it can reduce muscle overactivity, while maintaining the strength in other muscles. Deformity can be corrected without generalised weakness, and function is maintained.

The direct effect of BTX itself is relatively short-lived (about 3–4 months). However, if the muscle can be stretched or active function regained during this window, continued physical management may then be sufficient to manage spasticity, so the benefits can be long-lasting.

In post-acute stroke or brain injury, spasticity may mask the return of voluntary muscle movement. If permanent contracture develops, this function may be lost for ever. There is a window of opportunity, therefore, when active spasticity management can improve muscle control and may

reduce long-term disability. Timing and the clinical expertise to recognise the underlying potential for motor recovery become critical.

Management of spasticity therefore requires the co-ordinated input of a highly specialist team of therapists, nurses and doctors to provide the best results.

Why are guidelines needed for the use of BTX in spasticity management?

In the light of emerging evidence for its effectiveness, at the time of publication a UK licence application is underway for the use of BTX in the management of spasticity. Currently, three different preparations of botulinum toxin are available: two of type A and one of type B. They have different potencies and the doses are not interchangeable.

BTX, although potentially extremely useful in the management of spasticity, is relatively expensive and potentially dangerous in the doses that may be required. Moreover, repeated administration may result in the development of neutralising antibodies so that further injection has no effect. **It is therefore important that its use is confined to practice which ensures the maximal effect.**

What is the evidence that BTX works?

There is growing evidence that the use of BTX in the management spasticity can produce clear functional gains.¹ Most of the research has been conducted in stroke. Double-blinded placebo-controlled trials have shown it to be safe and effective in the management of both upper limb^{2,3} and lower limb^{4,5} spasticity. Studies in multiple sclerosis^{6,7} have demonstrated functional benefits in the management of hip adductor spasticity. As yet, there are no definitive studies of the use of BTX in dynamic function (eg improving gait) in adults. However, several studies of the management of cerebral palsy in children demonstrate improvement of dynamic function with BTX injection.^{8–11}

Several studies on the effects of different doses,^{7,12} have demonstrated that large doses are often needed to achieve measurable functional gain, but as yet there is little clear evidence to inform precise management strategy or selection of appropriate cases. Although controlled evidence is lacking, the role of physiotherapy and occupational therapy are generally considered to be important.¹³ There is some controlled evidence for the use of splinting/casting to enhance the effects of BTX^{14,15} and also for the use of electrical stimulation.¹⁶

In the USA, there are some fairly well established algorithms for the use of BTX in management of adult spasticity.¹⁷ However, at the current time, specific recommendations for management must rely substantially on clinical opinion rather than research evidence.

The guidelines are presented with reference to the AGREE system for appraisal of guidelines.¹⁸

Scope and purpose of the guidelines

Overall objective

To provide practical advice on the use of botulinum toxin (BTX) in the management of spasticity in adults.

Clinical questions covered by the guidelines

The clinical questions covered by the guidelines are:

- Who should provide BTX services?
- What type of clinical experience is required?
- What type of facilities should be available?
- How should patients be selected for BTX?
- What requirements should be in place before using BTX?
- What is the maximum safe dose?
- What procedures should be in place for review and documentation?
- How should outcome, including adverse effects, be assessed?

The patients to whom guidelines apply?

The guidelines apply to adults with spasticity resulting from damage to the central nervous system, including:

- stroke
- brain injury resulting from trauma, hypoxia, inflammation or poisoning
- spinal cord injury
- progressive neurological conditions, eg multiple sclerosis
- cerebral palsy.

The process of development

The development group

The guidelines were developed by a group of clinicians (listed on page 7) who work in the field of neurological rehabilitation and are experienced in the management of spasticity. The group included doctors, physiotherapists and an occupational therapist. Sadly, it did not include any nursing staff. However, individuals in the group consulted regularly with their own local multidisciplinary teams during the guideline development, which included nursing staff and other therapy disciplines.

Patients and carers were not directly included in the development group because the guidelines principally concern the technical aspects of use of BTX. However, they are included in the consultation process, and their feedback will be important to the further refinement of the guidelines following the licensing of BTX for spasticity management and its more widespread use.

Evaluation of the evidence

An electronic search of the literature was conducted through the relevant databases – MEDLINE, EMBASE etc.

Because BTX has not been licensed for use in spasticity at the time of publication, the literature pertaining to clinical practice remains relatively

scant. As outlined above, there are a small number of controlled trials which provide evidence for the effectiveness of BTX, and some comparison of different dose regimens and the use of adjuncts such as electrical stimulation and splinting. However, as yet, there is no hard research evidence to indicate selection criteria, or the exact techniques for management which are the focus of these guidelines.

Patients presenting with severe spasticity form a rather small and heterogenous group. Spasticity can present a whole range of clinical problems that exist separately or in combination. Because of this wide variation in the clinical picture, it is impossible to be prescriptive about which muscles to inject, with what doses. It is a matter for clinical judgement for the treating team. Likewise, although it is agreed that all use of BTX should be accompanied by some validated measure of outcome, the exact choice of measure will depend on the agreed goals for treatment.

The recommendations can therefore indicate only in a broad sense the principles of good planning and practice, and the requirement for BTX to be administered by a team of clinicians with the appropriate skills and experience. At this stage they necessarily rely heavily on expert opinion and common sense.

Health benefits, costs and risks of BTX

It is estimated that the cost of a treatment with BTX (including assessment, physical aftercare, splinting and review etc over 3–4 months) is around £1,000. Set against this, however, there are major health benefits many of which have potential cost gains. These include:

- reduced pain and discomfort for the patient
- reduced physiotherapy time taken to reverse contractures
- reduced nursing time to provide basic care/hygiene
- avoidance of pressure sores
- increased independence in self care

- reduced carer burden, lost opportunity costs and health problems among family carers
- improved quality of life, cosmesis, and self-esteem, resulting in reduced depression.

As yet there has been no opportunity for a detailed health economic analysis, but it is likely that once this is forthcoming, clear financial gains will be evident.

The risks from using botulinum toxin result mainly from use of a toxic agent at the upper limit of its therapeutic range. Transient dysphagia has been reported, and could pose significant risk if not managed appropriately. This underlines the requirement for treating clinicians to have adequate knowledge of the potential risks as well as the facilities for managing those problems – including access to hospital admission – if they occur.

Guidelines for the use of botulinum toxin (BTX) in management of spasticity in adults

1. Principles of co-ordinated spasticity management

- 1.1 Management of spasticity should be undertaken by a co-ordinated multidisciplinary team, rather than by clinicians in isolation.
- 1.2 Before using botulinum toxin (BTX) the team must ensure that appropriate physical management is in place and available post injection, and that remediable provocative factors have been excluded.
- 1.3 BTX must be injected only by clinicians with sufficient knowledge of functional anatomy, experience in diagnosis and management of spasticity, and knowledge of appropriate clinical dosing regimens.
- 1.4 BTX injection must be part of a rehabilitation programme involving post-injection exercise, muscle stretch and/or splinting, to achieve an optimal beneficial clinical effect.

2. BTX Injection

- 2.1 Patients should be selected for BTX on the basis of:
 - a focal spasticity
 - b dynamic spastic component
 - c clearly identified goals for treatment and anticipated functional gains.
- 2.2 Patients and their families/carers should be given appropriate information prior to treatment and should agree goals before treatment is given.
- 2.3 Informed consent should be obtained from patients prior to injection. If the patient does not have the mental capacity to consent, current trust policies for obtaining consent should be followed.
- 2.4 The maximum dose used in a single treatment should not exceed 1500mu Dysport® (Ipsen), 400U Botox® (Allergan) or 10,000u Neurobloc® (Elan Pharma).

3. Follow-up and documentation

- 3.1 Injections should be accompanied by a formal assessment of outcome. Appropriate measures

should be identified as part of the goal-setting process.

- 3.2 All injections should be followed by:
 - a therapy review in 1–14 days for assessment and, if necessary, splinting
 - b medical/MDT review at 4-6 weeks to assess effect, patient status and functional gains
 - c review at 3–4 months to plan future management.
- 3.3 Documentation for all injections should include:
 - a a clear statement of treatment goals
 - b baseline outcome measures appropriate to those goals
 - c BTX agent, dose, dilution and muscles injected
 - d follow-up treatment plan
 - e evaluation of outcome and repeat measures
 - f plans for future management.

4. Services

- 4.1 Services administering BTX should have access to staff with the relevant expertise and adequate space, facilities and equipment for splinting/orthotics.
- 4.2 Clinicians should have access to facilities to aid in assessment, selection and treatment planning, eg electromyography (EMG).
- 4.3 Ideally, clinicians should familiarise themselves with a single agent (see 2.4) to avoid confusion over dose.

5. Training

- 5.1 Training programmes should be in place to ensure that clinicians in all the relevant disciplines have the required knowledge and skill to use BTX.
- 5.2 Training can be provided through formal courses or on-the-job learning through observation of experienced clinicians.
- 5.3 Formal evaluation methods should be established to ensure the necessary knowledge, experience and skills to perform the technique and provide the service.

Where to from here?

Consultation

The guidelines have been fully endorsed by the British Society of Rehabilitation Medicine and are currently out to consultation with the bodies which represent the relevant patient groups and clinicians (medical, nursing, and therapies) working in this area. The present publication by the Clinical Effectiveness and Evaluation Unit of the Royal College of Physicians is also seen as part of the consultation process, stimulating debate amongst a wider clinical audience.

Updating the guidelines

Once BTX is licenced for use in the management of adult spasticity, it is expected that its use in the field will increase markedly, and more formal research evidence will soon be available to support or refute these guidelines. A formal review should be undertaken in January 2004.

Application of the guidelines

Target users

These guidelines apply to all clinicians who may be involved in the administration of BTX, including doctors, therapists and nurses. They are also relevant to managers who may be involved in the provision of services for management of spasticity in adults, whether in the hospital or the community. The specialties and services concerned are:

- neurology
- services for management of acute and chronic strokes
- care of the elderly
- rehabilitation
- services to support people with chronic disability.

Potential organisation barriers

The two most important barriers to application of these guidelines are a) time and b) separate working practice between therapists and doctors. There is temptation to provide a 'quick fix' to get the patient out of the clinic, rather than spend time planning the co-ordinated management of spasticity. Moreover, there is a general lack of awareness on the part of many doctors of the principles of physical management of spasticity.

Continuing medical education has an important role to play in improving understanding of the nature and pathophysiology of spasticity and the relevant skills of other professionals in its management.

Audit and tools for application

Goal-planning prior to use of BTX and assessment of outcome are the two crucial features stressed in these guidelines. They are essential for assessing the impact of treatment and for auditing outcome. Appendix 1 includes specific advice on the selection of outcome measures. Appendix 2 provides a draft proforma for documentation. This has been piloted in the North West Thames regional service.

Editorial independence

None of the working party members (see page 7) has any conflicting interests.

Direct financial costs of working party meetings were supported by Ipsen, but all meetings were planned and executed through an independent body, Radius Healthcare, to ensure editorial independence. The funding organisation had no input whatsoever into the drafting of the guidelines or recommendations.

References

1. Reichel G. Botulinum toxin for treatment of spasticity in adults. *J Neurol* 2001;248(Suppl 1):25–7.
2. Bhakta BB, Cozens JA, Chamberlain MA, Bamford JM. Impact of botulinum toxin type A on disability and carer burden due to arm spasticity after stroke: a randomised double blind placebo-controlled trial. *J Neurol Neurosurg Psychiatry* 2000;69:217–21.
3. Simpson DM, Alexander DN, O'Brien CF, Tagliati M, Aswad AS, Leon JM et al. Botulinum toxin type A in the treatment of upper extremity spasticity: a randomized, double-blind, placebo-controlled trial. *Neurology* 1996;46:1306–10.
4. Burbaud P, Wiart L, Dubos JL, Gaujard E, Debelleix X, Joseph PA et al. A randomised, double-blind, placebo-controlled trial of botulinum toxin in the treatment of spastic foot in hemiparetic patients. *J Neurol Neurosurg Psychiatry* 1996;61:265–9.
5. Hesse S, Lucke D, Malezic M, Bertelt C, Friedrich H, Gregoric M et al. Botulinum toxin treatment for lower limb extensor spasticity in chronic hemiparetic patients. *J Neurol Neurosurg Psychiatry* 1994;57:1321–4.
6. Snow BJ, Tsui JK, Bhatt MH, Varelas M, Hashimoto SA, Calne DB. Treatment of spasticity with botulinum toxin: a double-blind study. *Ann Neurol* 1990;28:512–5.
7. Hyman N, Barnes M, Bhakta B et al. Botulinum toxin (Dysport) treatment of hip adductor spasticity in multiple sclerosis: a prospective, randomised, double-blind, placebo-controlled, dose ranging study. *J Neurol Neurosurg Psychiatry* 2000;68:707–12.
8. Cosgrove AP, Corry IS, Graham HK. Botulinum toxin in the management of the lower limb in cerebral palsy. *Dev Med Child Neurol* 1994;36:386–96.
9. Koman LA, Mooney JF, 3rd, Smith BP, Goodman A, Mulvaney T. Management of spasticity in cerebral palsy with botulinum-A toxin: report of a preliminary, randomized, double-blind trial. *J Pediatr Orthop* 1994;14:299–303.
10. Gooch JL, Sandell TV. Botulinum toxin for spasticity and athetosis in children with cerebral palsy. *Arch Phys Med Rehabil* 1996;77:508–11.
11. Wong V. Use of botulinum toxin injection in 17 children with spastic cerebral palsy. *Paediatr Neurol* 1998;18:124–31.
12. Smith SJ, Ellis E, White S, Moore AP. A double-blind placebo-controlled study of botulinum toxin in upper limb spasticity after stroke or head injury. *Clin Rehabil* 2000;14:5–13.
13. Albany K. Physical and occupational therapy considerations in adult patients receiving botulinum toxin injections for spasticity. *Muscle Nerve Suppl* 1997;6:S221–31.
14. Reiter F, Danni M, Lagalla G, Ceravolo G, Provinciali L. Low-dose botulinum toxin with ankle taping for the treatment of spastic equinovarus foot after stroke. *Arch Phys Med Rehabil* 1998;79:532–5.
15. Boyd R, Graham HK. Botulinum toxin A in the management of children with cerebral palsy: indications and outcome. *Eur J Neurol* 1997;4:S15–22.
16. Hesse S, Reiter F, Konrad M et al. Botulinum toxin type A and short-term electrical stimulation in the treatment of upper limb flexor spasticity after stroke: a randomised, double-blind, placebo-controlled trial. *Clin Rehabil* 1998;12:381–88.
17. Brin MF. Dosing, administration, and a treatment algorithm for use of botulinum toxin A for adult-onset spasticity. Spasticity Study Group. *Muscle Nerve Suppl* 1997;6:S208–20.
18. Cluzeau F, Littlejohns P, Grimshaw J, Feder G, S. M. Development and application of a generic methodology to assess the quality of clinical guidelines. *Int J Qual Health Care* 1999;11:21–8.

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Appendix 1. Goal setting and outcome evaluation

Spasticity can present a whole range of clinical problems and there may be many different goals for treatment and anticipated outcomes.

- Before injecting BTX, specific goals should be clearly established and agreed by the patient/carers
- All injections of BTX should be accompanied by a validated measure of outcome, but the choice of instrument will depend on the goals for treatment.

Ideally, outcomes should be assessed on the basis of functional improvement. However, when spasticity management is complex, the effects of individual injections may not be reflected at this level. Global measures such as the Barthel Index or Functional Independence Measure (FIM) are often not sensitive to this scale of change. For this reason it may be necessary to use measures of impairment or focal disability, closely targeted on the goals for treatment.

Goals for treatment

Table 1. Some common goals for treatment

Functional improvement	Improve mobility in terms of: <ul style="list-style-type: none"> ■ speed ■ quality or endurance of gait ■ endurance of wheelchair propulsion Improve ease and safety of transfers Dexterity and reaching
Symptomatic improvement	Decrease spasm frequency Pain relief Allow sexual intercourse
Enhanced appearance	Improve body image Fitting of clothes
Improve ease of handling/ rehabilitation	Reduction of generalised spasticity To facilitate sitting, positioning or standing To allow wearing of orthoses
Decrease carer burden	Positioning (eg for feeding) Care and hygiene, eg washing, catheterisation Dressing Decreased care time to allow quality time
Optimise service responses	Prevention of unnecessary anti-spasmodic and other medication. Prevention of complications, eg pressure sores, contractures. Prevention or delay of surgery

Outcome measurement

Measurement methods may include the use of:

1. Physical measures
2. Techniques to quantify individual symptoms or benefits, such as
 - Visual analogue scales
 - Verbal scales
3. Assessment of goal attainment
4. Formal standardised scales.

Physical measures

The most commonly used physical measures are:

- **goniometry** to determine range of movement
- **distance measurements** such as knee–knee distance (cm) in hip adductor spasticity
- **spasm frequency count**.

While these measures are at the level of impairment, rather than function, if there is no change in impairment it is unlikely that functional change will result.

Techniques to quantify individual symptoms

Self-report of symptoms is an important and widely used method for ascertaining the patient's view of the treatment. However, patients with cerebral damage (eg following stroke or brain injury) frequently have impaired language or visuo-spatial skills which affect their ability to complete questionnaires. Instruments should be kept short and simple, and ideally should offer questions in more than one format. Pre-screening of the patient's ability to complete different types of question may help interpretation of information gained through self-report.¹

Visual analogue scale (VAS)

On a VAS, the patient marks along a 10 cm line the severity of his/her target symptom. Recorded before and after treatment, this may provide an objective assessment of change in symptoms such as pain. Patients with visuo-spatial problems, may prefer to record on a numerical scale of 0–10.

Verbal scales

Some patients may find it easier to complete a verbal questionnaire. While this will offer fewer possibilities and is therefore less sensitive, it may be more reliable.

Simple verbal scales may take the form of:

- a direct description of the severity of symptoms, eg **None Mild Moderate Severe**
- or comparative severity, eg **Worse The same Better**

¹ Turner-Stokes L and Rusconi S, *Clinical Rehabilitation*, in press.

Measurement of goal attainment

As discussed above, clear goals for treatment should be documented in the medical records. Goals may be identified at the level of impairment, disability or handicap and will inform the measure used to assess outcome.

Some suggested types of measure which may be applied to assess the attainment of goals listed in Table 1 are given in Table 2 below.

Table 2. Examples of outcome measures which may be used to evaluate goal attainment

Goal	Suggested outcome measure
Improved mobility	Video-recording to assess quality of movement
■ Wheelchair mobility	Timed wheelchair course/timed transfers.
■ Gait pattern	Walking speed test/gait analysis.
■ Gait efficiency	Gait analysis with energy cost assessment.
Improved dexterity	Timed functional tasks, eg doing up 3 buttons.
Symptom improvement	
■ Pain reduction	Visual analogue scale/verbal scale of pain.
■ Spasm frequency	Spasm count.
Enhanced appearance	
■ Body image	Self report – patient’s perception.
■ Fitting of clothes	Photographic record.
Ease of handling	
■ Facilitate sitting/positioning	Photographic record – assessed by independent O/T. Carer rating of ‘ease’ on VAS/verbal scale.
■ Allow wearing of orthosis	Time taken to put on orthosis.
Decrease carer burden	
■ Positioning, eg for feeding	Timing of task, eg transfer from bed to satisfactory position in wheelchair/number of helpers required.
■ Maintaining hygiene	Assessment of skin condition/photographic record. Carer rating of ‘ease’ on VAS/verbal scale.
■ Dressing	Timing of care tasks/number of helpers.
Optimise service responses	
■ Avoid unnecessary medication	Analysis of medication records.
■ Prevention of complications, eg pressure sores, contractures	Complication rate.
■ Prevention or delay of surgery	Record of other interventions.

Formal standardised scales

Subjective symptom measures (eg the VAS and verbal scales described above) may be helpful in gauging individual response to treatment, but unfortunately provide little comparative information.

Standardised scales allow comparison between individuals and groups, although many of the recognised measures have limited applicability in this area. The choice of scale will depend on the goals for treatment. Some possibilities are listed below.

Impairment scales

The **Ashworth Scale** is the only widely used measure of spasticity. Both validity and sensitivity are acknowledged to be poor. However, it forms a useful baseline indicator of severity.

Focal measures of disability (activity)

Focal measures are applicable where the limb is functional, but the quality or speed of movement is affected by increased tone. Some useful focal measures include:

- the **Nine-hole peg test** and the **Frenchay arm test** for the upper limb
- **10m walking time** or **gait analysis** for the lower limbs.

Global functional ratings

Occasionally, spasticity management will provide critical benefits which change the global picture of disability – for example where it is instrumental in regaining the ability to walk or regain continence. The **Barthel Index** and the **FIM Motor Scale** are well validated and widely used measures of independence. They are divided into subscales and in some circumstances it may be appropriate to record the relevant sub-scale rather than the whole instrument.

Dependency and care needs assessment

For severely dependent patients with severe spasticity, two or more people may be needed for self-care, and handling tasks may take much longer than usual because of the need to undertake spasm-reducing manoeuvres prior to moving the patient. BTX can potentially make a critical difference to the number of people or the time taken to perform care tasks. It may also be necessary to put forward a strong argument that that the intervention will be cost-effective in terms of reducing care needs in the community.

The **Northwick Park Dependency Score** and **Care Needs Assessment** were devised for this purpose. The tool can be used to predict the likely impact of a reduction in dependency in terms of reduced care needs and costs of providing for them in the community.

Handicap (participation)

While health professionals may focus on impairment and disability as the direct indicators of successful treatment, patients and their families are more interested in handicap or quality of life. Because of the wide range of different goals and outcomes for BTX injection, there are currently no validated scales which are really applicable in this area. However, VAS and verbal scales can be applied to quality of life outcomes.

Appendix 2. Botulinum toxin/splinting management proforma

Name: _____ **Age:** _____ **Hospital No:** _____
Diagnosis: _____ **Main deficits:** Physical / Communicative / Cognitive
Date of onset: _____ **Physical deficits:** Hemiparesis / Tetra / Para / Other

Initial assessment	Date: / /	Doctor:
		Therapist(s):

Reason for referral/patient's problem(s) to be addressed

.....
.....
.....
.....

Impairment location: Upper limb / lower limb **Side:** Right / left
Pattern of spasticity: Focal / regional / generalised
Is the problem: Spasticity / spasms / dystonia / other
Are there fixed contractures? Yes / No
 Describe:

What is the target area for treatment?

Upper Limb	Muscle groups	Lower limb	Muscle groups
<input type="checkbox"/> Shoulder		<input type="checkbox"/> Hip	
<input type="checkbox"/> Elbow		<input type="checkbox"/> Knee	
<input type="checkbox"/> Wrist		<input type="checkbox"/> Foot	
<input type="checkbox"/> Hand		<input type="checkbox"/> Other	
<input type="checkbox"/> Other			

What are the functional goals of treatment?

.....

How will the effect of botulinum toxin be maintained? (Splinting, exercise etc.)

.....

Baseline measurement	Date: / /	Doctor:
Patient Name:		Therapist(s):
Patient Number: <input style="width: 100px; height: 20px;" type="text"/>		

Examples of suggested outcome measures:

- **Impairment related measures**

Spasticity	Modified Ashworth scale/pendulum test/Myometer/EMG
Range of movement	Goniometry/length measurement

- **Functional measures**

<i>Goal/Parameter</i>	<i>Suggested outcome measure</i>
Reduction of pain	Visual analogue scale/verbal scale
Ease of applying splint/orthosis	Timing of tasks/number of helpers/carer rating scale
Ease of maintaining hygiene	Timing of tasks/number of helpers/carer rating scale
Ease of dressing	Timing of tasks/number of helpers/carer rating scale/FIM
Improved seating position	Photographic record/measurement ie pelvis level
Improved gait pattern	Video analysis/10 meter walk test
Improved gait efficiency	Video analysis/patient rating/energy cost assessment

Please use at least one functional measure and one impairment based measure for each intervention:

Baseline Measures:

<i>Measure</i>	<i>Done</i>	<i>Score</i>
■ Impairment (Ashworth scale, ROM)		
1.		
2.		
■ Functional (Carers score)		
3.		
4.		

Add score sheets behind this page where applicable

Injection technique

Date: / /

Doctor:

Patient Name:

Patient Number:

Consent form signed Patient Doctor Explained to family

Information sheet given To patient To family/carers

Agent used: Dysport®/Botox®/Neurobloc® **Dilution:** units / ml saline

Active muscle identification: Palpation / EMG / Other:

<i>Muscle injected</i>	<i>Units</i>
.....
.....
.....
.....

Appointment date for splinting: Time:

Appointment date for review (4–6 wks): Time:

1–14 day review

Date: / /

Doctor:

(Splinting)

Therapist:

Response to injection: None / Some / Marked

Splints applied: YES / NO

(Please include more detail if not completing a splinting proforma domiciliary only)

■ **Type of splint:**

■ **Materials used:**

■ **Method of application:**

■ **Precautions:**

Appointment date for review of splinting: Time:

4–6 week review

Date: / /

Doctor:

Patient Name:

Therapist:

Patient Number:

Repeat Measures:

<i>Measure</i>	<i>Done</i>	<i>Score</i>
■ Impairment (Ashworth scale, ROM)		
1.
2.
■ Functional (Carers score)		
3.
4.

Add score sheets behind this page where applicable

What is the overall response? **None / Some / Marked**
Comments:

Has functional goal been achieved? **Yes / No / Partially**
Comments:

Is further injection needed at current time? **Yes / No**
Comments:

Review splints? **Yes / No**
Comments:

Symptom Scoring Sheet **Date:** / /

Patient Name:

Patient Number:

Symptom 1: *Specify:*

Visual analogue scale

Mark on the line how severe your is over the past 24 hours

None at all |-----| **Worst imaginable**

0 1 2 3 4 5 6 7 8 9 10

Verbal scale

Which of the following best describes the severity of your? (Circle one)

None Mild Moderate Severe

Compared with before the Botulinum toxin treatment, is this:

Worse? The same? Better?

Symptom 2: *Specify:*

Visual analogue scale

Mark on the line how severe your is over the past 24 hours

None at all |-----| **Worst imaginable**

0 1 2 3 4 5 6 7 8 9 10

Verbal scale

Which of the following best describes the severity of your? (Circle one)

None Mild Moderate Severe

Compared with before the Botulinum toxin treatment, is this:

Worse? The same? Better?