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RACP Position Statement on the Therapeutic Use of Botulinum Toxin in Rehabilitation Medicine for spasticity and dystonia

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Australasian Faculty of
Rehabilitation Medicine



The Royal Australasian
College of Physicians

**Position Statement on the Therapeutic Use of Botulinum Toxin in
Rehabilitation Medicine for
spasticity and dystonia**

For some years now there has been strong evidence for the use of botulinum toxin type A (BoNT-A) in the treatment of spasticity/dystonia (for example, muscle overactivity). Whilst BoNT-A has been shown to be of benefit in reducing activity limitation and improving participation and quality of life for individual patients, it has also been shown to have the potential to reduce the overall costs for ongoing care of patients. At this stage there is not strong evidence for function or for cost benefit. In those circumstances where treatment of muscle overactivity is required, the Australasian Faculty of Rehabilitation Medicine (AFRM) recognises that appropriate use of BoNT-A is one of a number of treatment options. The AFRM also recognises that the use of BoNT-A should be seen as one option in a broader approach to the management of muscle overactivity. BoNT-A should not be used in isolation, but as part of a coordinated multidisciplinary approach.

The AFRM believes that the following points constitute some (but not necessarily all) of the considerations relevant for 'appropriate use' of BoNT-A in the treatment of spasticity and dystonia. The decision to treat should be based on the potential to reduce limitations in activity and participation, improve the lives of patients and their families, and to use scarce health care resources most efficiently:

Patient Selection:

- a. That the S100 accredited practitioner/team selecting patients for potential BoNT-A injections do so with the clear understanding that there are a range of treatment options for the management of spasticity and dystonia, and that all of these other options have been carefully considered for that patient.
- b. That the S100 accredited practitioners selecting patients for BoNT-A have appropriate experience in patient assessment, spasticity assessment, functional assessment, as well as having a clear understanding of the potential outcomes of BoNT-A injections.
- c. That the S100 accredited practitioners offering BoNT-A injections to patients have an appropriate level of expertise in patient selection, muscle selection, indications, precautions, exclusions and dosage of various forms of BoNT-A.

Patient Preparation:

- a. Indications, and patient and treating team goals should be identified and recorded prior to the procedure. Goals should be agreed upon by both the patient (and/or parent/guardian) and the S100 accredited practitioner.
- b. Once BoNT-A injection is offered, the patient has every opportunity to seek answers to questions about the drug, the indications, the procedure, the

- potential side effects and complications, as well as the experience of the injectors.
- c. Written informed consent should be completed and signed prior to the procedure.
 - d. Outcomes of the BoNT-A injection should be measured via patient interview and/or examination at an appropriate time, by an appropriately trained S100 accredited practitioner. Measures should be undertaken pre and post injection.
 - e. It should be determined that the patient will be available to undergo therapy (e.g. physiotherapy or occupational therapy) during the time when the BoNT-A is active in order to maximise the functional gains.

The Procedure:

- a. BoNT-A injections should be carried out or supervised by an appropriately trained, 'accredited' S100 practitioner.
- b. The environment should be appropriate for a number of considerations, including (but not limited to) privacy, confidentiality, comfort, and cleanliness. There should be appropriate lighting, and adequate space and equipment for effective patient transfers, and patient positioning for purposes of the procedure. There should be adequate staffing.
- c. In certain circumstances (e.g. children, patients with intellectual disability) it is appropriate to use some form of analgesia/sedation/anaesthetic for safe and effective injection of BoNT-A. In these cases, it is recommended that there needs to be appropriate preparation space (e.g. theatre space or anaesthetic bay) as well as appropriately trained staff, and support equipment.
- d. In addition to anatomical surface landmarks, the injector should use muscle localisation techniques (e.g. electrical stimulation or ultrasound guidance) when appropriate.
- e. Care must be taken with dosage and dilution, taking into account factors such as body weight and co-morbidities.
- f. A record should be kept for each muscle injected, the dose, dilution and the type of BoNT-A used. The BoNT-A batch number and expiry date should be recorded for each ampoule used.
- g. Any unexpected events or complications should be recorded.
- h. After the procedure, the patient should be able to ask further questions.
- i. After the injection, appropriate follow-up plans should be provided clearly to the patient, including instructions for the patient for ongoing rehabilitation management, and contacts in case of questions or concerns.

Other Considerations:

Multidisciplinary Team Management

- The AFRM strongly recommends the involvement of a multidisciplinary team as part of the therapeutic process.
- Whilst it is feasible for individual S100 accredited practitioners to take on all of the roles of assessor, patient selector, proceduralist, and follow-up practitioner, the evidence suggests that better patient outcomes are achieved through the use of a multidisciplinary team (e.g. inclusion of a physiotherapist, occupational therapist, nurse and/or other allied health professionals). This has the potential to provide better outcomes for the patient.

Measures

- The AFRM recommends that pre and post injection measures may include (but not be limited to):
 - I. Objective measures of change, e.g.:
 - a. Range of movement
 - b. Degree of spasticity (e.g. Modified Ashworth Score, Tardieu)
 - c. Degree of dystonia
 - d. Speed of movement
 - e. Quality of movement
 - II. Measures of function/goal attainment, e.g.:
 - a. Goal Attainment Scale
 - b. Canadian Occupational Performance Measure
 - c. Timed Up and Go
 - d. Walking distance/tolerance
 - III. Measures of patient /carer satisfaction, e.g.;
 - a. Measures of pain
 - b. Examples of improved participation
 - IV. Duration of effectiveness of injection(s)

Research, Education and Training

- More research continues to expand our knowledge about the indications, potential benefits, and complications of BoNT-A in the management of spasticity. The AFRM believes that S100 accredited practitioners who take on the responsibility for establishing BoNT-A injection clinics should also give strong consideration to participation not only in their own professional development in this arena, but also to undertake responsibility for training other S100 accredited practitioners, and participating in research activities. There continue to be changes in product availability, recommendations for procedures, and indications. As the use of, and the indications for, BoNT-A expand, so too does the need for more workforce supervised by accredited medical practitioners trained in pharmacotherapy, delivery and management of complications associated with BoNT-A.

Adherence to government requirements

- Australian and New Zealand Governments have a set of regulations regarding the appropriate use and monitoring of BoNT-A injections. The AFRM supports full compliance with these regulations but notes there may be sound clinical indications for BoNT-A injection that do not fall within current funding guidelines.

Background to Consensus Process:

- This position statement is the result of consideration of an Expert Working Committee appointed by the NeuroRehabilitation Special Interest Group and Policy and Advocacy Committee of the AFRM. It is based on the experience of this committee, with reference to:
 - o The international consensus statement for the use of botulinum toxin treatment in adults and children with neurological impairments (European Journal of Neurology 2010, 17 (suppl.2)
 - o Spasticity in adults: management using botulinum toxin. National Guidelines. Royal College of Physicians, January 2009
 - o Botulinum toxin assessment, intervention and after-care for lower limb disorders of movement and muscle tone in adults: international consensus statement (European Journal of Neurology 2010, 17 (suppl.2)
- Participating members of the Expert Working Group included:

A/Professor Ian Baguley
Dr Stephen de Graaff
A/Professor Steven Faux
Professor John Olver
A/Professor Michael Pollack (Lead Writer)
A/Professor Barry Rawicki
A/Professor Adam Scheinberg

APPENDIX:

GLOSSARY OF TERMS

Botulinum Toxin – Several forms of botulinum neurotoxin are available, e.g.: Botulinum neurotoxin type A - trade names Botox and Dysport are primarily used in Rehabilitation Medicine.

Botulinum neurotoxin type B - trade names Myobloc and Neurobloc.

Other serotypes of botulinum neurotoxin are under investigation as potential therapeutic agents and include types C, D, E, F, and G.

Dystonia - Involuntary movements and prolonged muscle contraction that result in an abnormal posture and twisting of involved body part.

S100 accredited practitioner – Source: Australian Government, Department of Health and Ageing (February 2013), **MBS Reviews Botulinum Toxin Injections Protocol**¹ “a medical practitioner who is registered by Medicare Australia to participate in the arrangements under Section 100 of the *National Health Act 1953* relating to the use and supply of Botulinum Toxin”. “Only medical practitioners who hold specialist qualifications (and who have been approved to inject botulinum toxin) are eligible to prescribe BotoxTM and DysportTM. These include approved specialists within: ophthalmology, neurology, plastic surgery (not cosmetic surgery), otolaryngology (head and neck surgery), rehabilitation medicine, paediatrics, dermatology, orthopaedic surgery and geriatric medicine. A medical practitioner who wishes to use S100 botulinum toxin under the arrangements for the botulinum toxin program must apply in writing to Medicare Australia and are only added to the program after assessment by the Pharmaceutical Benefits Advisory Committee”.

Spasticity – Lance (1980) 'a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes with exaggerated tendon jerk, resulting from hyper-excitability of the stretch reflex'

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The RACP trains, educates and advocates on behalf of more than 14,300 physicians – often referred to as medical specialists – and 6,500 trainees, across Australia and New Zealand. It represents more than 32 medical specialties including paediatrics and child health, cardiology, respiratory medicine, neurology, oncology and public health medicine, occupational and environmental medicine, palliative medicine, sexual health medicine, rehabilitation medicine, geriatric medicine and addiction medicine. Beyond the drive for medical excellence the RACP is committed to developing health and social policies which bring vital improvements to the wellbeing of patients. www.racp.edu.au.

¹ Australian Government, Department of Health and Ageing (February 2013), **MBS Reviews Botulinum Toxin Injections Protocol**, p. 32 and p.39. Online, available: [http://www.health.gov.au/internet/msac/publishing.nsf/Content/B0765AC67F291E27CA25792600788B69/\\$File/Botulinum.docx](http://www.health.gov.au/internet/msac/publishing.nsf/Content/B0765AC67F291E27CA25792600788B69/$File/Botulinum.docx) (last accessed 18/11/2013).