Treatment algorithm

For the management of adult patients with disabling spasticity.

European expert consensus on improving patient selection for the management of disabling spasticity with intrathecal baclofen and/or botulinum toxin type A.[1]

> "This algorithm is a practical and easy to use tool that by simply identifying the spasticity distribution your patient has, will guide you to consider the most effective treatment option for them."
>
> **Dr Valerie Stevenson**

Study objective

To develop an algorithm to aid clinicians in the management of adult patients with disabling spasticity who are potential candidates for treatment with **intrathecal baclofen (ITB) and/or botulinum toxin type A (BoNT A).**

Method

An **Advisory Board** of 8 specialists (4 neurologists and 4 rehabilitation specialists) from 8 European countries, with experience in spasticity management, were assembled to **evaluate current knowledge** and to **share experience on patient selection** and the **optimal treatment pathway** for patients with disabling spasticity.

4-step approach was implemented:

Step 1

A **literature review** on recent evidence of ITB and BoNT A treatments for patients with disabling spasticity was conducted.

Step 2

A **survey** was designed and finalized after debating the results of the literature review. Furthermore, **an algorithm** for the management of adult patients with disabling spasticity was proposed based on the evidence and on the expert opinion of the advisory board.

Step 3

The survey was sent to 138 external experts in total (125 European physicians and 13 non physician specialists) via Qualtrics electronic platform. **Consensus was reached when ≥75% of respondents agreed with or were neutral** on the question response (<25% disagreed).

Step 4

The results of the survey were presented and discussed by **the advisory board,** who then **revised the algorithm based on external expert responses.**

Results

Algorithm development

The best candidates for ITB

Patients with multi-segmental or generalized disabling spasticity refractory to oral drugs (consensus 96.1%).

Good candidates for ITB

Patients with bilateral disabling spasticity affecting lower limbs only (consensus 97.4%), bilateral (consensus 100%) or unilateral (consensus 90.9%) disabling spasticity affecting lower limbs and trunk, and unilateral or bilateral disabling spasticity affecting upper and lower extremities (consensus 96.1%).

The ideal candidates for BoNT A

Patients with focal/segmental disabling spasticity (consensus 98.7%).

Conclusions

Based on the current literature, a comprehensive survey and the consensus process, **this study provides an algorithm for the management of adult patients with disabling spasticity who are potential candidates for ITB and/or BoNT A treatments -** hoping that it is a useful tool to guide treatment choice and help the patients and their families understand and engage in shared decision-making.

Further studies focusing on goal attainment, functional benefit, Quality of Life, and the role of combined ITB and BoNT A treatment are needed to accurately define which patients could benefit most.

Shared decision

It is important to have a **'shared decision approach'** in the patient management strategy, where patient's and caregiver's preferences are taken into consideration **at every stage of the treatment decision process (agreement 96.1%).**

Treatment algorithm

Patients with disabling spasticity.

Focal, multi-focal or segmental disabling spasticity

Bilateral disabling spasticity affecting **upper extremities only.**

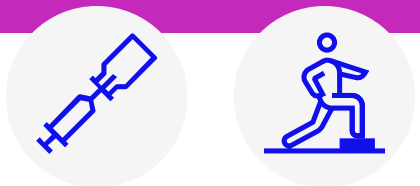
Unilateral disabling spasticity affecting **both lower and upper limbs.**

Bilateral disabling spasticity affecting **both lower and upper limbs.**

Treatment goals not reached with max BoNT recommended dose

BoNT + adjuvant treatments

(including rehabilitation and orthosis)



Patient/caregiver preference must be considered at every stage (shared decision approach).

Multidisciplinary input essential at times to optimize physical management programme and manage spasticity trigger factors.

Strong consensus

Weak consensus
(includes neutral answers to reach >75% consensus)

Multi-segmental or generalized disabling spasticity refractory to oral drug treatment.

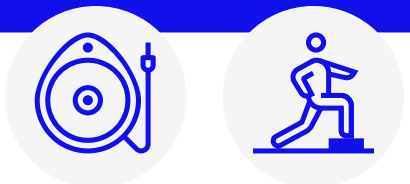
Bilateral disabling spasticity affecting **lower extremities only.**

Unilateral disabling spasticity affecting **lower limbs and back and/or abdominal muscles.**

Bilateral disabling spasticity affecting **lower limbs and back and/or abdominal muscles.**

Treatment goals not reached with ITB only

ITB + Rehabilitation



Combined BoNT and ITB + Rehabilitation

Patient cases*

Wheelchair user (SCI)

32 years old, injury resulting from a snowboarding accident in 2015

Patient history

Incomplete thoracic spinal cord injury

Muscle stiffness of Ashworth grade 2 in both legs (bilateral)

Severe flexor spasms at the hips and knees which interferes with sleep and causes difficulty when using standing frame

Transferring through a low pivot and dependent on a manual wheelchair for all mobility

Treatment history & strategy

Experiencing sedation from oral medication (baclofen and gabapentin) which limits the ability to concentrate when working

No clear triggers from bladder, bowel or skin

Intrathecal baclofen (ITB) discussed and trial of 50mcg completed. Resulting in elimination of spasms and spasticity reduced. Use of standing frame safer and less effortful

Decision to proceed to ITB pump implantation

Ambulant patient (MS)

56 years old with a history of MS dating back to 2006

Patient history

Struggles with walking, reliant on a stick

Significant spasticity in both legs (Ashworth 2's and 3's)

Uncomfortable and experiencing sleep disturbance

Bladder shows mild symptoms of overactivity, well managed with medication, no significant post void residual volume and urinary tract infections are infrequent

Bowels are opening regularly

Treatment history & strategy

Oral medication trialed and limited by side effects. Taking a combination of baclofen and tizanidine at maximum tolerated doses, also Clonazepam at night to try to help with sleep and nocturnal spasms

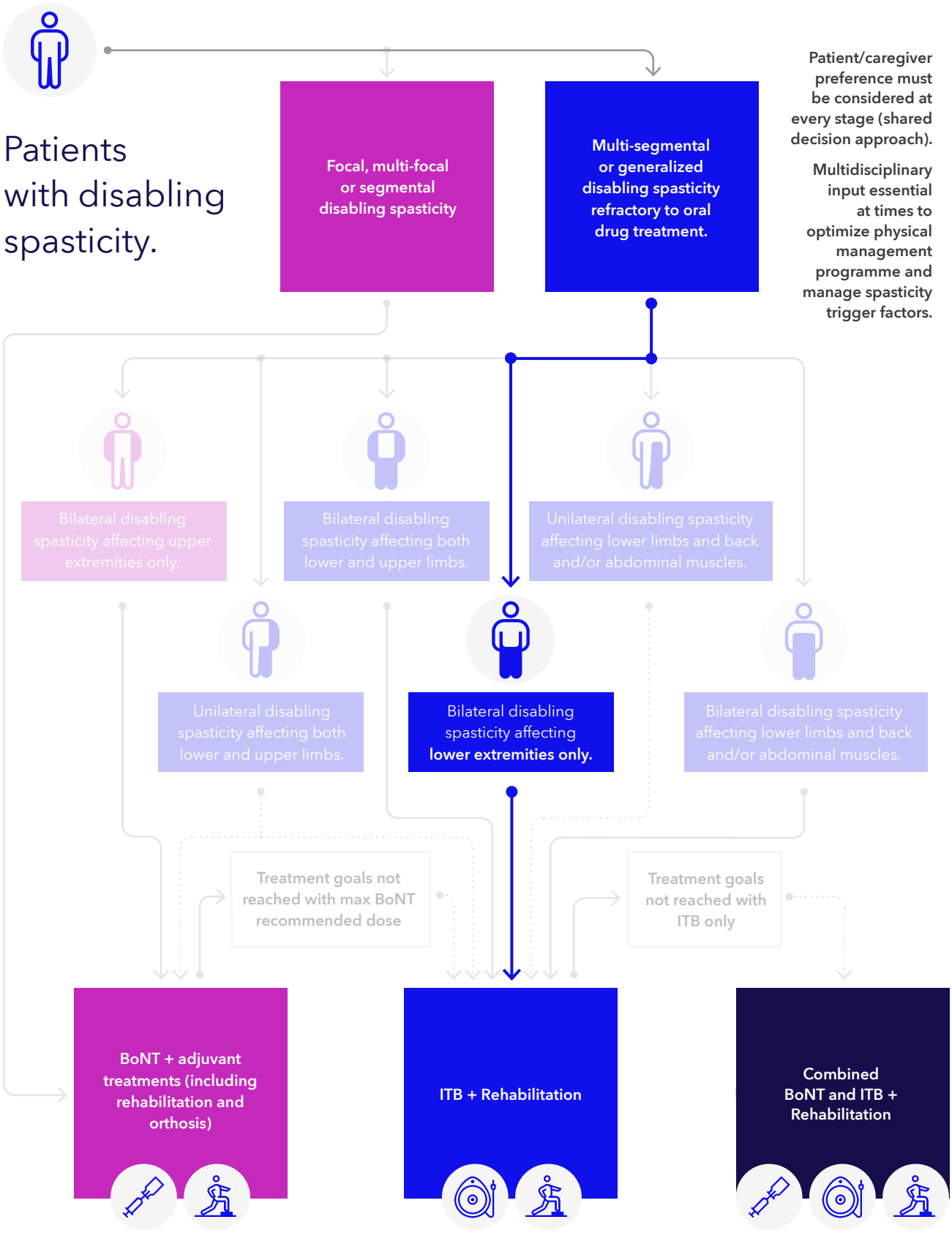
Intrathecal baclofen (ITB) discussed and trial of 25mcg completed. Resulting in spasticity reduction (Ashworth 1's and 2's), giving improved comfort. Now able to walk at a faster pace at peak dose effect

Decision to proceed to ITB pump implantation

"Intrathecal baclofen should never be seen as a last resort. It is much easier to keep someone walking than try and get them back on their feet."

Dr Valerie Stevenson

Treatment algorithm



Strong consensus

Weak consensus
(includes neutral answers to reach >75% consensus)

Patient case*

Stroke patient

63 years old with a history of hypertension

Patient history

Left basal ganglia bleed at 58 years old

Residual right hemiplegia with spasticity in both arm & leg (impacting hand function and walking)

Treatment history

Botulinum toxin type A (BoNT A) on several occasions (right calf, hamstrings, elbow flexors)

Combined with splinting of the arm and Functional Electrical Stimulation of the leg to improve footdrop (and potentially reduce plantarflexor tone)

Oral medication (baclofen & pregabalin)

Outcome

Effect of BoNT A was suboptimal (dose increases not possible due to reaching maximum dose limit)

Experienced sedative side effects on medication

Remains dissatisfied with his walking and discomfort due to ongoing spasticity in right arm & leg

Treatment strategy

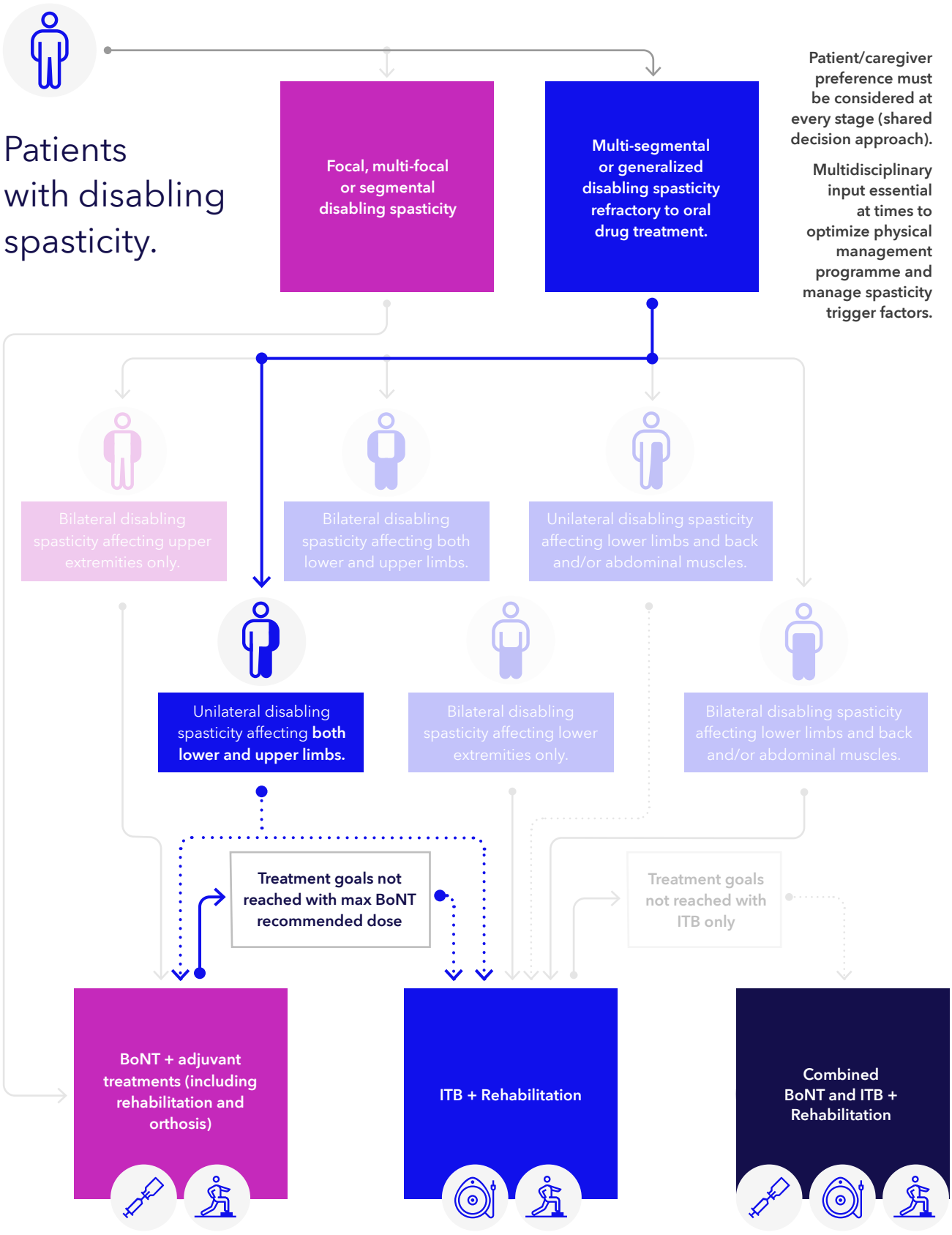
Intrathecal baclofen discussed and trial of 25mcg completed. Resulting in spasticity reduction and improved comfort, able to walk with less effort at peak dose effect

Decision to proceed to ITB pump implantation

> Trying BoNT A first is a reasonable strategy, however gaining control of spasticity in this many muscles is challenging particularly when involving large muscle groups such as the hamstrings.
>
> Once BoNT A has been tried and goals not achieved it is prudent to consider ITB, especially if the patient is at risk of developing contractures or function is compromised."

Dr Valerie Stevenson

Treatment algorithm



Strong consensus

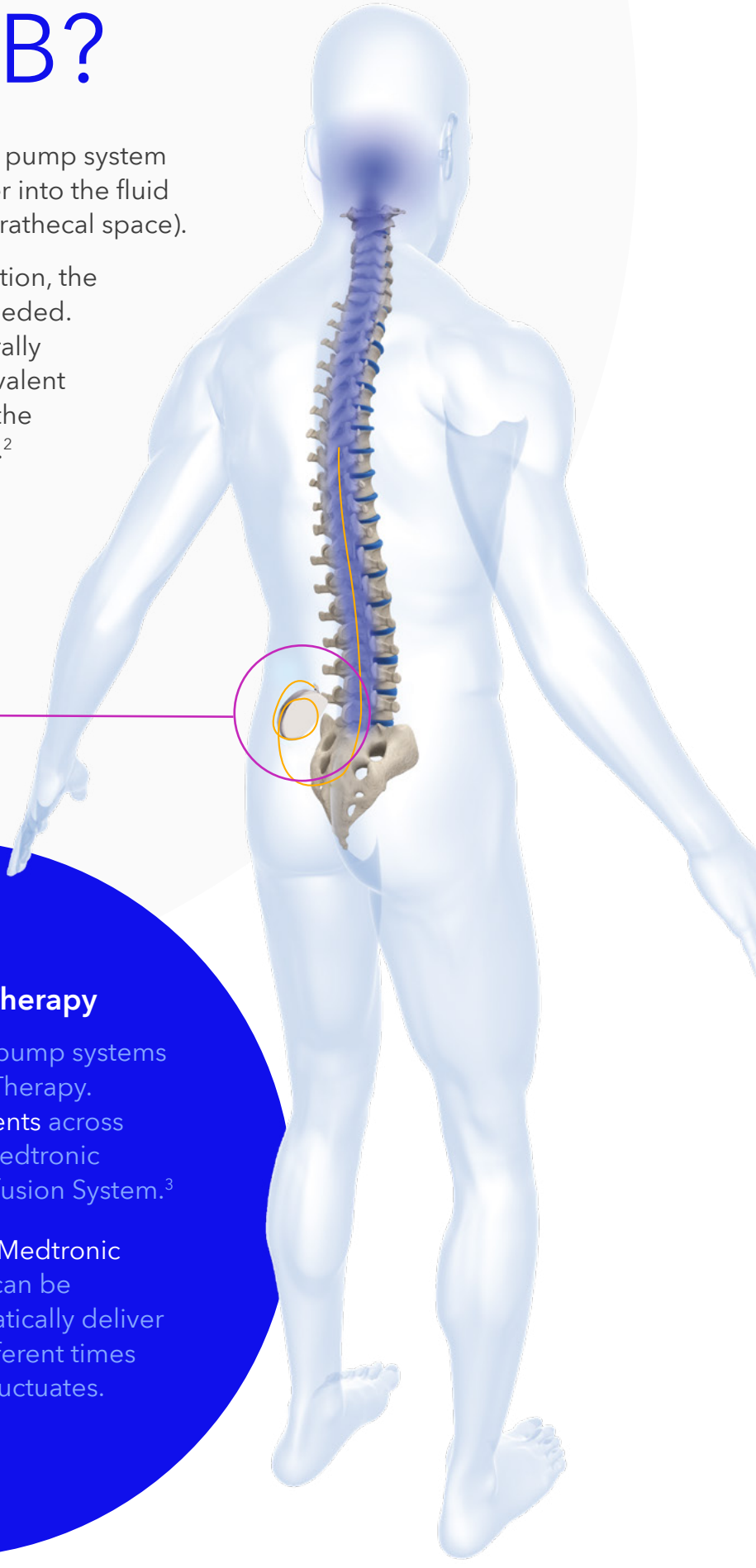
Weak consensus
(includes neutral answers to reach >75% consensus)

What is ITB?

An implanted, programmable drug pump system delivers baclofen through a catheter into the fluid surrounding the spinal cord (the intrathecal space).

Unlike other methods of administration, the drug is sent exactly to where it is needed. This means only small doses (generally 100 to 1000x smaller than the equivalent oral dose) are needed, minimizing the possibility of unwanted side effects.[2]

Targeted drug delivery (TDD) directly to the cerebrospinal fluid.



Medtronic and ITB Therapy

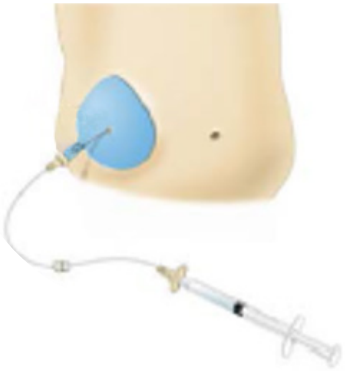
Since 1992, Medtronic pump systems have been used in ITB Therapy. Currently, 160,000 patients across the world are using a Medtronic Programmable Drug Infusion System.[3]

These systems, like the Medtronic SynchroMed™ II pump can be programmed to automatically deliver different dosages at different times of the day if spasticity fluctuates.

TDD procedure

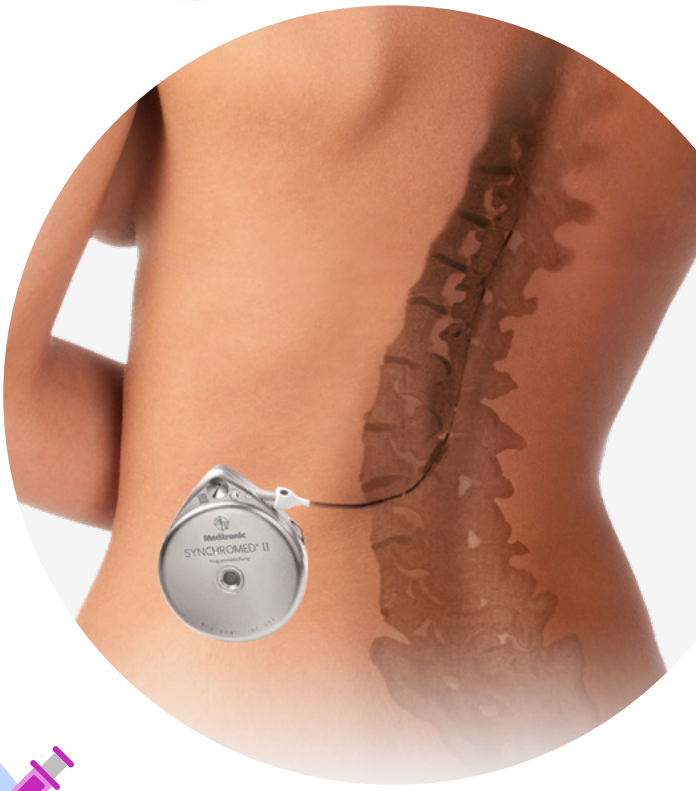
Patient selection

Trial



- Simple lumbar puncture
- Medications delivered via needle or catheter
- Evaluate therapy efficacy

Implant



- Time: 1-2 hours
- May be performed under general/local anesthesia
- Two incisions: Catheter and Pump

Titration and Refill

- 22 gauge needle
- No sedation required
- Dose optimization
- Programming via telemetry

Your Medtronic contact

Name:

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References:

1. Biering-Sørensen B, et al. European expert consensus on improving patient selection for the management of disabling spasticity with intrathecal baclofen and/or botulinum toxin type A. J Rehabil Med 2021; 53: jrm00236
2. Per Ertzgaard, Claudia Campo, Alessandra Calabrese. Efficacy and safety of oral baclofen in the management of spasticity: A rationale for intrathecal baclofen. J Rehabil Med. 2017 Mar 6;49(3):193-203."
3. Medtronic Product Performance Reports: https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance/neuromodulation-product-performance.html.

*Disclosure: Dr Valerie Stevenson acted as a paid consultant for Medtronic.

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information please contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

For applicable products, consult instructions for use on www.medtronic.com/manuals. Manuals can be viewed using a current version of major internet browser. For best results, use Adobe Acrobat® Reader in the browser.

When ITB is mentioned, we are considering Intrathecal baclofen (an antispasmodic) administered by an intrathecal drug delivery pump therapy. Medtronic provides only the intrathecal drug delivery pump and the catheter; the baclofen is provided by an external company.

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