BEST PRACTICES IN BOTULINUM TOXIN A (BoNT-A) TREATMENT



A REPORT BASED ON INTERVIEWS AND ROUND TABLE CONVERSATIONS WITH HEALTHCARE PROFESSIONALS IN THE NETHERLANDS ABOUT THE TREATMENT OF PATIENTS WITH SPASTICITY AND DYSTONIA.

SEPTEMBER 2022

20 YEARS OF IMPACT VINTURA

IPSEN Innovation for patient care

PROLOGUE July, 2022

The start of dystonia treatment with botulinum toxin around 1990 had a significant effect on the wellbeing of the patients. In the thirty years since this treatment came available, it did not change that much due to the highly effective blocking of the neuromuscular junction using botulinum toxin. However, new insights based on scientific research and development of best practises give us the opportunity to improve our daily practice of the botulinum toxin treatment for dystonia.

To do so, I would like to perform a thought experiment using the existing evidence- based research, the needs of our patients and combine these with the best practises as presented in this brochure.

In the first place one would need neurologists, physician assistants and/ or nurse practitioners, not only with proper knowledge and substantial experience in treating patients with dystonia with botulinum toxin, but also with an eye for the needs and wishes of their patients. This should lead to shared decision making and setting clear treatment goals.

One of these goals should be the optimisation of the individual treatment interval of the patient. This interval should be at least 12 weeks but can be longer if possible. To make these individual intervals possible, consultation hours need to be scheduled once a week or once every two weeks. Based on the presented best practises in this brochure, a dystonia treatment should take 10 to 15 minutes, resulting in about twenty sessions per morning/ afternoon. The capacity regarding the total number of treatments will then be around 500 or 1000 per year. In my opinion, based on efficiency, patient satisfaction and a mix of different dystonias, between 500 to 1000 treatments per year would be appropriate to build or keep the expertise that is needed to be an expert in botulinum toxin treatment of dystonia.

For medical staff performing these botulinum toxin treatments it is important that holidays and other schedule free days are covered. As a result, a minimum of two staff members is needed. This leads to a minimum of about one thousand treatments per year per expertise centre.

Besides the motor symptoms of dystonia, non-motor symptoms of dystonia such as anxiety, depression, persistent pain, and impaired sleep could be present. For some, but not all, patients non-motor symptoms are a significant burden. To address these non-motor issues 10 to 15 -minute treatment sessions are too short. So, in addition to treatment sessions there should also be separate consulting hours for the non-motor issues. These consulting hours could be conducted by a physician assistant or a nurse practitioner and in that capacity, they could take part in the treatment of the dystonia patients. Additional consulting hours could also be of value in patients with (complex) spasticity to add more time to determine which (motor or non-motor) factors are of additional importance to the botulinum toxin treatment.

Based on the above thought experiment (regional) botulinum toxin treatment centres can be created to facilitate in treating these patient volumes. To setup regional expertise centres for botulinum toxin treatment all stakeholders involved should be convinced of the necessity to create such regional centres in order to optimize the botulinum toxin treatment of patients in the most effective way. See this brochure. Although best practises between botulinum toxin treatment of patients with dystonia differ from the treatment of patients with spasticity in rehabilitation centres, both neurologists and rehabilitation physicians can learn from their knowledge and experience.

Dr. Jaco W. Pasman, neurologist

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IPSEN DEVELOPED THIS BEST PRACTICE OVERVIEW TO MAKE A CONTRIBUTION TO THE FIELD OF SPASTICITY AND DYSTONIA REGARDING BOTULINUM TOXIN A (BoNT-A) TREATMENT

Project ambition

- With this project Ipsen aims to support the optimization of treatment pathways and patient outcomes of patients who are being treated with BoNT-A for dystonia and spasticity.

- By collecting best practices regarding the treatment with BoNT-A, Ipsen wants to facilitate the sharing of knowledge and learning between hospitals and clinics.

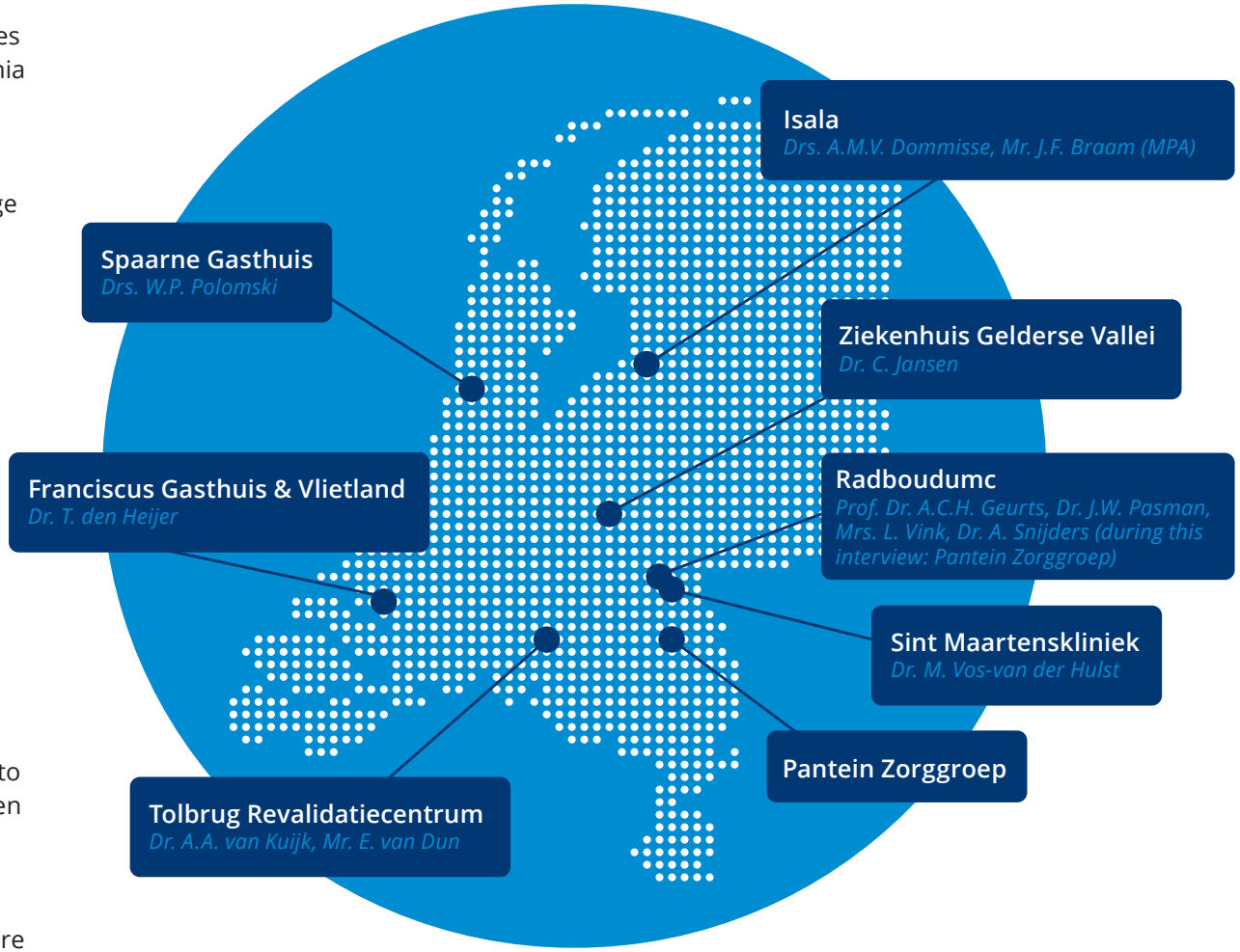
Methods

- Ipsen and Vintura have set up this explorative research to identify the most impactful best practices in the treatment with BoNT-A.

- During interviews **with rehabilitation physicians, neurologists and other involved healthcare professionals** from 8 clinics and hospitals in the Netherlands (see map) best practices were collected, focussing on:
  - Treatment logistics
  - Business operations
  - Patient-relevant outcomes

- In addition, two round table discussions were organised to validate findings and facilitate knowledge sharing between interview participants.

- Based on the interviews and round table discussions, 8 key best practices were identified. These best practices are shared in this brochure.



IPSEN THANKS THE FOLLOWING HEALTHCARE STAKEHOLDERS FOR THEIR ACTIVE PARTICIPATION IN THIS EXPLORATIVE RESEARCH

Rehabilitation physicians

Drs. A.M.V. Dommisse	Isala
Prof. Dr. A.C.H. Geurts	Radboudumc
Dr. A.A. van Kuijk	Tolbrug/JBZ
Drs. W.P. Polomski	Spaarne Gasthuis
Dr. M. Vos-van der Hulst	Maartenskliniek

Neurologists

Dr. T. den Heijer	Franciscus Gasthuis
Dr. C. Jansen	Ziekenhuis Gelderse Vallei
Dr. J.W. Pasman	Radboudumc
Dr. A. Snijders	Pantein/Radboudumc

Other involved healthcare professionals

Mr. J.F. Braam – physician assistant	Isala
Mr. E. van Dun – physiotherapist	Tolbrug/ JBZ
Mrs. L. Vink – nurse	Radboudumc

IN THIS EXPLORATIVE RESEARCH WE FOCUSED ON THE BoNT-A TREATMENT OF PATIENTS WITH SPASTICITY AND DYSTONIA

Spasticity



Treating doctor:
rehabilitation
physician

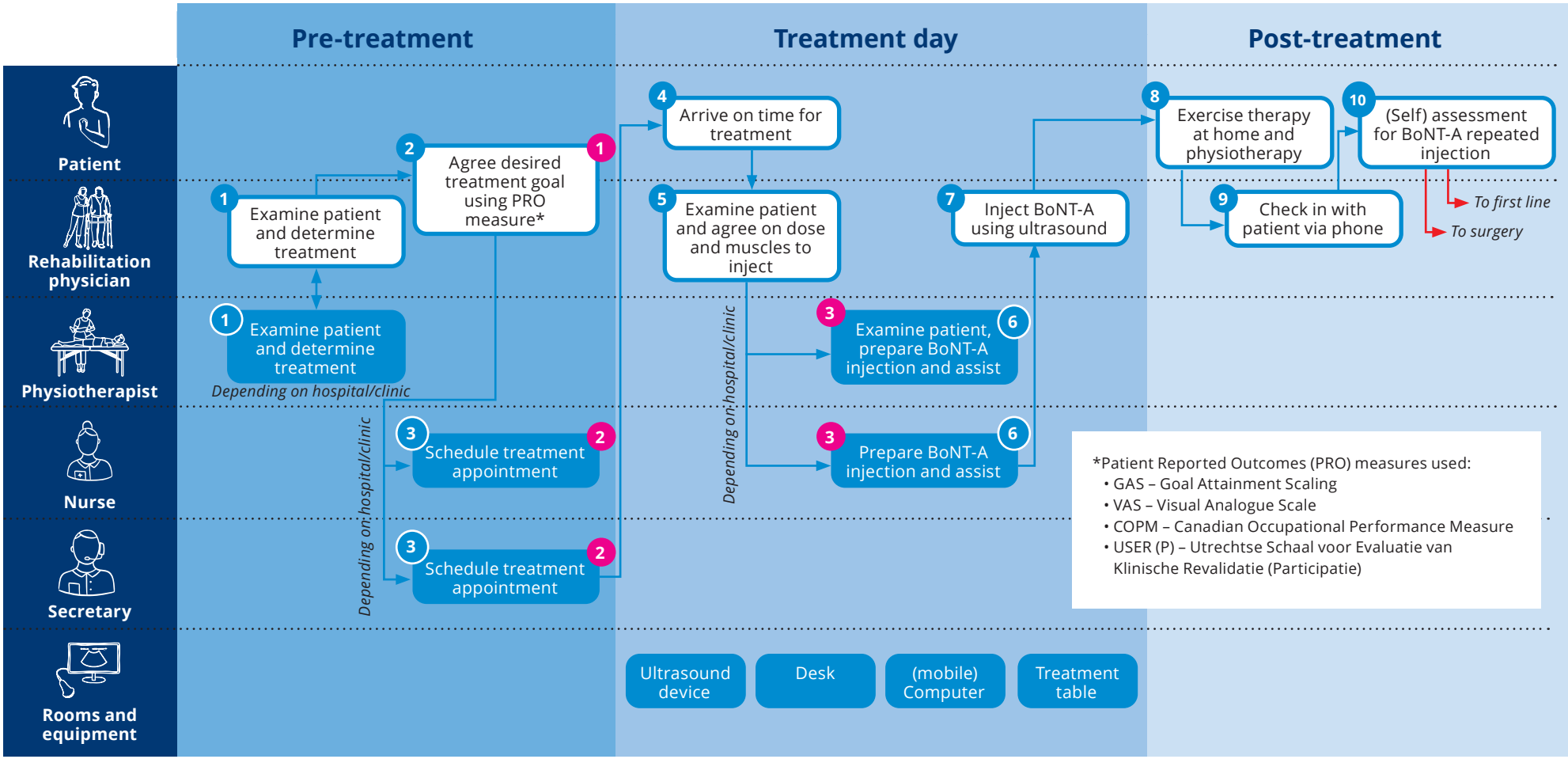
Dystonia



Treating doctor:
neurologist

TREATMENT PATHWAY - SPASTICITY

Different pathways to treat patients with spasticity with BoNT-A were identified. The results are summarized below.



THERE ARE FOUR KEY DIFFERENCES IN THE BoNT-A TREATMENT PATHWAY BETWEEN CLINICS THAT TREAT SPASTICITY

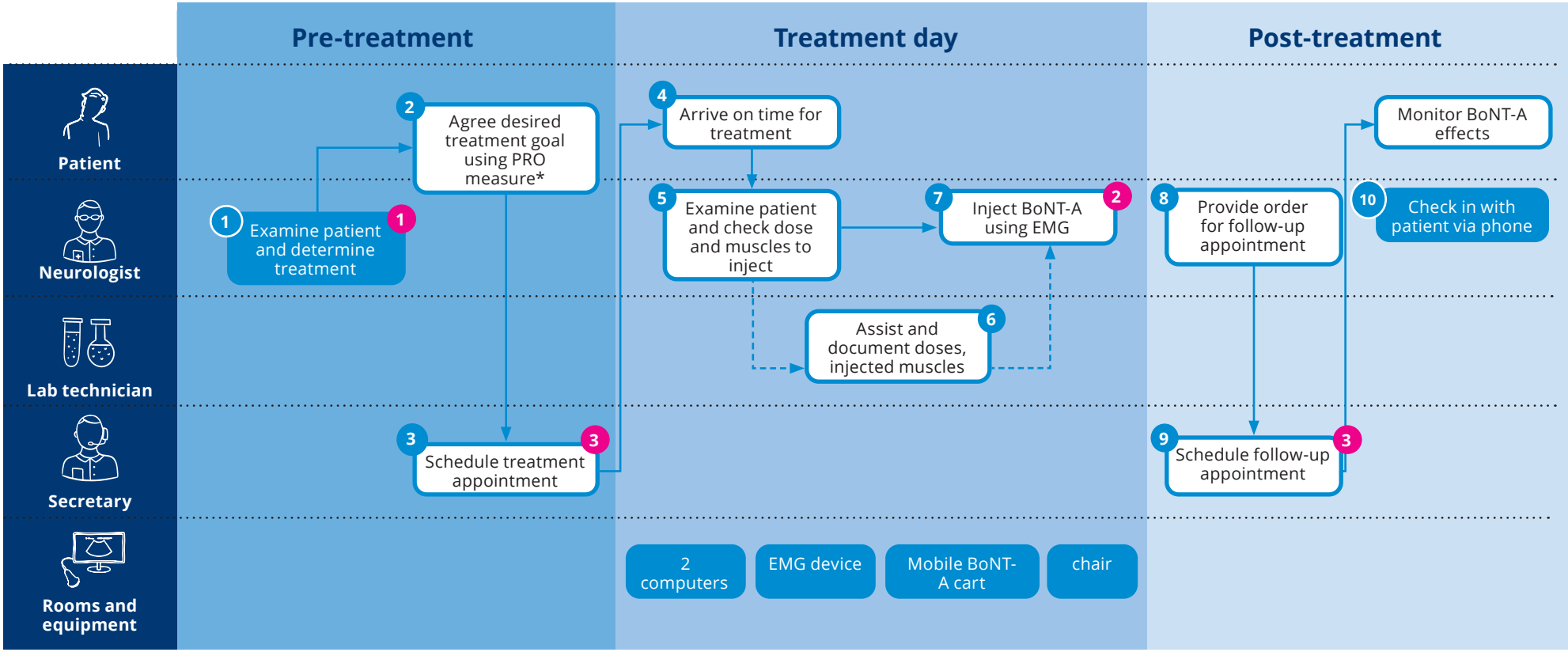
	1 Treatment goal setting	2 Administration and planning	3 Treatment assistance	4 Repeated injection

Key differences	• Goal setting with patients can be done either through conversations (n=3) or with the help of various patient reported outcome (PRO) instruments (n=2)	• Planning and administration can be done by the:
		  • Nurse
		  • Specific secretary
		  • General secretariat
			• BoNT-A treatment is administered by the rehabilitation physician, either alone (n=1) or with help from a physiotherapist (n=1), nurse (n=3)
			• Physiotherapists (n=1) can support the rehabilitation physician in patient examination and treatment decisions. Nurse can assist the patient to be prepared for the injection.
				• Check-in with patients via phone 2 – 6 weeks following treatment
				• Treatment intervals of ~3-4 months or sometimes even longer, intervals vary per patient preference
				• Either fixed treatment interval over time or varying based on treatment evaluation
				• One clinic implemented an “on-demand” follow-up, where patients need to initiate the follow-up call

Implications	**Implications for patient outcomes** • Better follow-up conversation with use of PRO tools	**Implications for patient outcomes** • A dedicated person can better plan visits as she recognizes the specific needs for the patient	**Implications for patient outcomes** • Physiotherapist can add additional knowledge and another perspective • More comfortable for patient to have additional staff present, besides the doctor • Preferably a consistent person present during all treatments	**Implications for patient outcomes** • Always adequate treatment intervals, no “under” or “over” treatment
	Implications for efficiency • No impact on patient numbers per consultation hour	**Implications for efficiency** • Patient-dependent scheduling will allow for more patients per consultation hour	**Implications for efficiency** • More efficient treatment with assistance (no preferred help)	**Implications for efficiency** • Patient-dependent intervals allows for more room for new patients

TREATMENT PATHWAY – DYSTONIA*

Different pathways to treat patients with dystonia with BoNT-A were identified. The results are summarized below.



*focus is mainly on cervical dystonia, excluding dystonia in the extremities

THERE ARE FOUR KEY DIFFERENCES IN THE BoNT-A TREATMENT PATHWAY BETWEEN CLINICS THAT TREAT DYSTONIA

Key differences

1 Examine patient and determine treatment

- Treatment decisions are either made by the treating neurologist (n=2) or during multidisciplinary care (MDC) discussions (n=1)
- MDC teams consist of neurologists, neurology residents, and fellows for movement disorders (6-10 people)
- In MDC discussions, patients are evaluated based on videos of the patient's dystonia

2 Treatment using EMG

- In most cases treatment is always done under EMG guidance, however for some patients (e.g. facial dystonia) this is not used as it may be burdensome to the patient and adds additional costs (n=1)

3 Schedule (follow-up) appointment

- Scheduling of appointments is done by secretaries or KNF lab technician from 6 weeks to >3 months in advance
- In some cases patients have the possibility to plan their own appointments online (n=1)
- Multiple patients scheduled for one timeslot is the most time efficient (n=1)

4 Follow-up calls

- In most cases neurologist do not follow-up with patients via phone. In two cases all (n=1) or new patients only are called (n=1)
- Patients can reach out themselves via phone or hospital app (n=1)

Implications

Implications for patient outcomes

- Better treatment decisions when multiple people can provide their opinion on possible treatments

Implications for patient outcomes

- Less burdensome to patients when EMG not used
- Might impact outcomes when EMG is not used to find active muscles to inject

Implications for patient outcomes

- A structured planning will support individual patient-specific treatment intervals which lead to improved patient outcomes

Implications for patient outcomes

- It may be beneficial to check-in with patients between treatments

Implications for efficiency

- No impact on patient numbers per consultation hour

Implications for efficiency

- No impact on patient numbers per consultation hour

Implications for efficiency

- More efficient planning when scheduling 6 weeks ahead as patients per consultation are known

Implications for efficiency

- Not performing follow-up calls saves time
- More time may be needed during the next consultation to discuss the status of the patient to discuss the patient's status

OPTIMIZING TREATMENT LOGISTICS AND INCREASING PRODUCTIVITY CAN ENABLE TREATING AN INCREASING PATIENT POPULATION

1

Separation of evaluation and treatment



2

Specific consultation hour with time blocks



3

Teamwork and division of tasks



4

Ensure patient volume



SEPARATION OF EVALUATION AND TREATMENT TO ENHANCE EFFICIENCY IN THE TREATMENT HOUR

1

Separation of evaluation and treatment



Case – separating the roles of head practitioner and injection specialist

The Sint Maartenskliniek has a large patient volume. Every week, several BoNT-A treatment hours are reserved in the schedule. By separating the role of injection specialist and head practitioner, part of the practioner team has become specialists in BoNT-A treatment. This increases quality of care. In this clinic, a new care pathway was designed to enhance communication between injection specialist and head practitioner.

Description

- *Spasticity:* During consultation, disease evaluation and injection are often combined. If the capacity of the BoNT-A treatment team is limited, this can take a significant amount of time. By separating disease evaluation (e.g. gait analysis and evaluating goal setting) and the injection moment itself, resources are used more efficiently. This is most relevant for clinics where the role of injection specialist is separate from the role of head practitioner
- *Spasticity:* relevant before every injection consultation as disease analysis and goal setting provides valuable insights needed for optimal treatment
- *Dystonia:* not relevant before every injection consultation, however valuable to plan recurring (quarterly/ yearly) evaluation, especially also for evaluation of non-motor symptoms

Impact

- Efficient use of time during injection consultation hour
- Dedicated time to evaluate disease and treatment
- More time during evaluation consultation to ensure in-depth disease assessment and evaluation

SCHEDULING ALL BoNT-A PATIENTS IN SPECIFIC TIME BLOCKS ON THE SAME DAY TO ENHANCE EFFICIENCY IN TREATMENT

2

Specific consultation hour with time blocks



Case – three ways of scheduling

Dystonia

1. *In both Radboudumc and Gelderse Vallei, dystonia patients receive their BoNT-A injection during a "pitstop" consultation, lasting only 10 minutes.*
2. *In Franciscus Gasthuis, multiple dystonia patients are scheduled at the same time, to allow time balance across patients.*

Spasticity

3. *In various hospitals, rehabilitation physicians can select various time blocks (e.g. 15, 30, 60 or 90 min) to best accommodate the time a specific patient with spasticity requires.*

Description

- Preparing for a BoNT-A injection takes time in terms of preparing the room, instruments and treatment. Scheduling patients requiring BoNT-A treatment on the same (part of the) day reduces the preparation time and allows for efficiency in actions, as the same action can be performed multiple times in a row

- Creating various time blocks for different types of patients (e.g. 10, 15, 30 and 60 minutes) ensures there is sufficient time per patient but no wasted time in-between patients. Patients can be segmented by
  - Injection location
  - Number of muscles to inject
  - New vs existing patients
  - Dystonia: Patients requiring ultrasound guidance

Impact

- Efficiency gain due to
  - Single time for medication preparation
  - Repetition in injection action
  - Limited time waste due to patient-tailored consultation times
  - Less waste of BoNT-A by more efficient use

TEAMWORK AND DIVISION OF TASKS TO ALLOW FOR SIMULTANEOUS ACTIVITIES AND ENHANCE EFFICIENCY IN TREATMENT HOUR

3

Teamwork and division of tasks



Case – from a helping hand to key player

In the Radboudumc the rehabilitation department hired a colleague with a distance from the labour market to support all four rehabilitation physicians during injection consultation hours. Over time, the collaboration strenghtened and the colleagues' support expanded from providing a helping hand during treatment but actually scheduling the appointments and being the main point of contact for patients.

Description

- Treatment with BoNT-A comes with a wide variety of tasks a doctors needs to perform. Dividing these tasks among a team during the injection consultation hour will allow for simultaneous performance of multiple tasks
- The team can consist of treating doctor in combination with, depending on the disease,
  - Nurse
  - Physiotherapist
  - KNF lab technician
- Tasks that can be divided or delegated can include preparation of patient, identification of the right muscles, preparation of medication, control of eacht other's work (also control on correct BoNT-A reconstitution and dosage), operating the EMG/ ultrasound device
- In many cases, a trained physician assistant can perform the injection treatment as well
- The better the team is trained, the more tasks can be delegated

Impact

- Time gain during consultation hour as actions can be performed simultaneously and team can support treating doctor during preparation and injection of patient
- Improvement in medical outcomes due to teamwork

ENSURING SUFFICIENT PATIENT VOLUME WILL ALLOW FOR OPTIMAL CARE DELIVERY AS WELL AS PROVIDE ROOM FOR TRAINING DOCTORS IN TREATMENT WITH BoNT-A

4

Ensure patient volume



Case – from a helping hand to key player

The rehabilitation physicians working in Spaarne Gasthuis, also facilitate BoNT-A injections in a rehabilitation clinic in the vicinity. This provides the treating doctors with a larger patient volume and ensures patients in the rehabilitation clinic have the possibility to receive BoNT-A on location from the best trained doctor.

Description

- Sufficient patient numbers requiring treatment with BoNT-A is necessary to deliver optimal care. Therefore, it is required to ensure optimal patient volume in each treating hospital/clinic and for each treating doctor
- To allow for sufficient patient volume, concentration of care in regions might be needed
- In addition to the delivery of optimal care, with sufficient patient volume increasing possibilities are created to train more specialists in the treatment with BoNT-A

Impact

- Sufficient volume will allow for efficient working due to clustering of patients in specific consultation hours
- More volume requires more treating doctors allowing for cover during holidays, illness or drop out
- Increased experience and knowledge of the physicians treating patients with BoNT-A

BY OPTIMIZING PATIENT LOGISTICS, THE NUMBER OF PATIENTS PER TREATMENT HOUR CAN BE INCREASED

Spasticity

Within the treatment of spasticity with BoNT-A, there are significant differences in treatment time. Consultation times between 30 minutes and 2 hours were reported during the interviews. This depends both on patient specific factors, like the severity of spasticity, and on logistics during the treatment hour.

By combining all best practices described, as much as 15 minutes per patients can be won. This means, in every injection consultation hour, one extra patient can be treated.

Dystonia

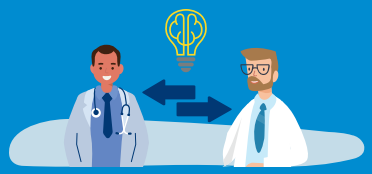
Decrease of treatment time per patient with 5 minutes, from 15 to 10 minutes, will increase the number of patients from 14 to 21 per injection hour (assuming 3,5 injection hours).

Given the current common practice of 15 minutes per patients, this will help accommodating growing patient numbers.

FOCUSING ON PATIENT OUTCOMES CAN HELP INCREASE THE VALUE OF BoNT-A TREATMENT FOR PATIENTS

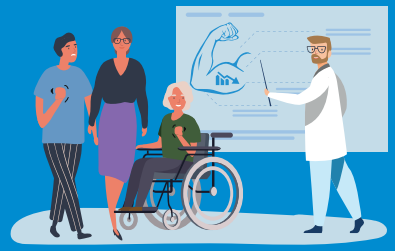
5

Knowledge sharing between disciplines



6

Patient education



7

Knowledge network with first line medical staff and carers



8

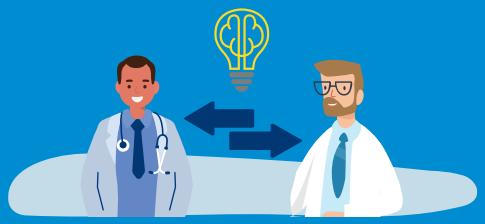
Leveraging patient-relevant outcomes for treatment evaluation



KNOWLEDGE SHARING BETWEEN BoNT-A TREATING DOCTORS TO IMPROVE PATIENT CARE

5

Knowledge sharing between disciplines



Case – Round table meetings

In March 2022, Vintura and Ipsen organised two round table discussions with rehabilitation physicians and neurologists to discuss treatment with BoNT-A. The main goal of these round table meetings was to facilitate knowledge sharing between disciplines regarding treatment logistics and patient outcomes. During lively discussions differences in treatment approach between disciplines was discussed and best practices were shared.

Description

- Treatment with BoNT-A is done by various physicians across various disciplines, and each have their own way of performing this treatment. Facilitation of knowledge sharing regarding treatment with BoNT-A between various disciplines allows discussion regarding differences in treatment of different diseases and patient types
- Sharing of knowledge and actions will allow determination of differences in treatment between various patient types and will help doctors identify key helpful insights applicable to own patients

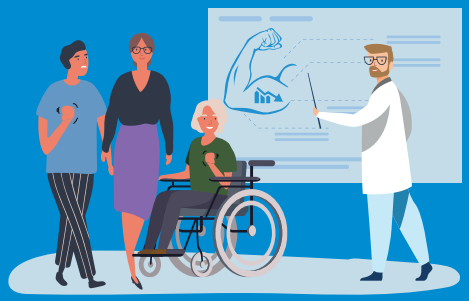
Impact

- Ensure all patients are treated according to the latest standards
- Ensure that any differences in the treatment of patients with BoNT-A are solely due to the differences in clinical picture and not due to the treating discipline

EMPOWERING PATIENTS THROUGH EDUCATION
TO IMPROVE THE VALUE OF TREATMENT WITH BoNT-A

6

Patient education



Case - patient empowerment

In both Tolbrug and Ziekenhuis Gelderse Vallei patients are able to schedule their own follow-up appointments for BoNT-A injections, depending on when they think it is time.

Case – patient education

In both Ziekenhuis Gelderse Vallei and RadboudUMC patients with dystonia are warned that after their intake, the consultation hours will be more like a pitstop, and will be less intimate as compared to the intake.

Description

- Patients should be educated on their disease and treatment (with BoNT-A) as this will empower them to play an active role in their disease and treatment. Patient education should cover the following topics/ questions

  - What to expect of treatment with BoNT-A
  - How BoNT-A works and medical outcomes
  - When is it time for the following injection
  - What patients can do in between injections (e.g. exercising/ monitoring)

- In addition to education, patients should be provided physiotherapy exercises they can perform in the time between injections to improve the treatment outcomes

- Patient empowerment also includes physiotherapy, stretching exercises at home and working on mental health

Impact

- Empower patients to take ownership of their disease and treatment
- Maximise treatment value by managing expectations
- Maximise treatment effect with the help of physiotherapy exercises

CREATION OF A KNOWLEDGE NETWORK WITH BoNT-A TREATING DOCTORS, FIRST-LINE MEDICAL STAFF AND CARERS TO COLLABORATIVELY IMPROVE PATIENT CARE

7

Knowledge network with first line medical staff & carers



Case – creating a spasticity network

In the region of Zwolle, rehabilitation physicians from Isala are setting up a spasticity network, including rehabilitation clinics and clinics for the mentally handicapped. As a starting point, the doctors have started to give presentations in various clinics to provide knowledge and training on different aspects in the treatment of spasticity, including regarding the use of BoNT-A.

Description

- Knowledge regarding patients that can benefit from BoNT-A treatment and ways to improve patient outcomes with BoNT-A treatment could be improved in the first-line setting. A knowledge network to facilitate collaboration of BoNT-A treating doctors and first-line medical staff can be a solution to close this knowledge gap
- In addition to medical staff, it will be valuable to include carers in this network as educating them will improve patients self knowledge and care.
- The following topics should be considered to collaborate on
  - Increase knowledge of first line medical staff on spasticity/dystonia and the treatment options, including BoNT-A, for better idenfitication of patients with an indication for BoNT-A treatment
  - Treatment of patients with BoNT-A
  - Combining BoNT-A with other forms of treatment

Impact

- Earlier identification and referral of patients who could benefit from BoNT-A treatment
- Maximise treatment value by educating first-line medical staff (e.g. physiotherapists) to help patients with exercise and self-care between injections
- Support carers in their task of caring for a patient with spasticity or dystonia closer at home
- Increase collaboration with first line

LEVERAGING PATIENT-RELEVANT OUTCOMES TO IMPROVE TREATMENT EVALUATION FOR PATIENTS BY PROVIDING INSIGHT IN DISEASE IMPROVEMENT

8

Leveraging patient-relevant outcomes for treatment evaluation



Case – EMG and video analysis

In the Radboudumc, during the intake of new dystonia patients neurologists can use both EMG analysis and video analysis. The use of EMG analysis helps to identify dystonic muscles allowing for optimal treatment. Video analysis is a valuable tool to help patients see the treatment effect by providing a baseline assessment.

Description

- Patient-reported outcomes (PRO) can provide valuable insight into the treatment effect for a specific patient. Leveraging applicable and relevant PRO measures along the treatment pathway can lead to improved patient care. Doctors should start with the PRO measures before injections and repeat the assessment before every following injections

- Various questionnaires can be considered including
  - GAS – Goal Attainment Scaling
  - VAS – Visual Analogue Scale
  - COPM – Canadian Occupational Performance Measure

- These questionnaires are not always relevant to the patient, so it is important to keep looking for a good outcome measure.

- Leveraging imaging/video can be considered to objectively assess baseline and subsequent improvement in disease and symptoms

Impact

- Using the results from PRO questionnaires to set treatment goals will provide insight in the treatment outcomes over time, and will help to assess whether a treatment is still working or that changes should be considered

- Taking photos and videos of the patient will allow for objective assessment of improvement and will help patients see improvements over time



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