

# Efficiency and Safety of Aftercare With Intrathecal Baclofen on Location

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**Objectives:** Patients with intractable spasticity treated with intrathecal baclofen (ITB) need regular evaluation and aftercare in an outpatient clinic or pain clinic setting. Logistically, this can be challenging. A solution could be to perform treatment at the patient's home setting. In the Netherlands, a project of the Dutch Healthcare Authority was initiated to deliver ambulatory ITB-related services via a home-based Ambulant Care Clinic. This aftercare is performed by nurse practitioners (NP) with support from a medical specialist. The scope of the study was to investigate the efficiency and safety of ITB-care for patients with severe disabling spasticity in their home setting.

**Materials and Methods:** A retrospective analysis of prospectively collected data. Patients with congenital or acquired spasticity were treated with ITB (1st April 2011 to January 1st 2016) using an implanted programmable pump system were referred to the home-based Ambulant Care Clinic by various neuromodulation centers in the Netherlands. All study parameters were a part of the standard intake and follow-up documentation.

**Results:** Of the 900 patients treated with ITB in the Netherlands, 239 were referred to the home-based Ambulant Care Clinic and included in this study. Mean age was 45.5 (range 7–82) years; 52% lived at home; the average satisfaction score was 9 (scale 0–10); and 0.29% had (serious) adverse events (60% of clinical manifestations were prevented by remote double-check control). Certifications for patient safety and quality standards were obtained.

**Conclusions:** The concept of ITB aftercare on location demonstrated efficacy and safety in the described setting. For troubleshooting, close collaboration with a neuromodulation center is necessary and can be arranged in chain-based care.

**Keywords:** Efficiency, home-based ambulant care clinic, intrathecal baclofen, safety, spasticity

**Conflict of Interest:** Dr. Delhaas reports personal fees from Medtronic Inc., as a previous consultant. Dr. Frankema reports a personal fee from Medtronic as previously an invited speaker (ITB complication session). Dr. Huygen reports advice reboard Abbott, advice reboard Grunenthal, educational grants from Abbott and Saluda, and a Dutch patent application N 2022004. Simone Goslinga-van der Gaag has no conflicts of interest to report.

## INTRODUCTION

It has been shown that the administration of intrathecal baclofen (ITB) via an implantable drug delivery system provides a reduction of intractable severe spasticity. Regarding long-term use only data from observational studies are available; these studies showed secondary benefits including fewer side-effects, improvement in activities of daily living, less sleep disturbance, and fewer care needs (1–9).

Until now, long-term follow-up of ITB has only been performed in a hospital setting. However, this is often inconvenient for severely immobilized patients and sometimes makes it impossible to provide therapy. Despite the advantages of ITB therapy, this inconvenience may be one of the reasons for the substantial undertreatment and/or an often “too late” initiation of ITB (5). These problems might be reduced by performing ITB aftercare in the patient's own surroundings (e.g. at home, in a nursing home or in disabled community). Therefore, we developed a home-based Ambulant Care Clinic to provide high-level standard care in a close cooperation with some of the neuromodulation centers.

We obtained recognition as a home-based Ambulant Care Clinic of the Ministry of Health, Wellbeing, and Sport. For the provision of home-based specialized medical care, no regular

financial reimbursement was available. However, since the Ministry offers financial support for new projects to stimulate innovations in healthcare, our “home-based Ambulatory Care Clinic Neuromodulation” activity was accepted as an innovation project. One of the requirements for approval of this project was the demonstration of quality and safety.

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## MATERIALS AND METHODS

We performed a retrospective analysis of prospectively collected data, investigating the efficacy and safety of delivery of home-based ITB aftercare in the period of 1st April 2011 to January 1st 2016.

The study was approved by the local Medical Ethical committee (2018–1221). After referral to the home-based Ambulant Care Clinic, patients gave consent for the treatment at the initial visit. Due to the retrospective character of the study, the local Medical Ethical committee waived away the requirement to obtain informed consent.

Only patients with severe disabling spasticity were eligible, and these were treated with ITB using an implanted programmable pump system (SynchroMed II, Medtronic Inc., Minneapolis, MN, USA) and referred to the home-based Ambulant Care Clinic by neuromodulation centers. Patients had to have achieved a stabilized dose for at least 3 months before their referral.

After referral for aftercare, there followed an initial visit from a specialized physician and nurse practitioner (NP). During the visit, the ITB aftercare on location concept was explained, and informed consent and medical history were obtained, followed by a physical examination and a read-out of the pump settings.

In addition to this, in the first 3 years for the initial visit, we used a standard questionnaire where patients were asked about the burden of traveling to the center for their ITB aftercare. At the following visits, we gathered information and entered it in the electronic patient file including the reason for the visit, performed activity, printouts of the programming pump, any (serious) adverse events, complaints, annual patient satisfaction scores, and travel time/distance to the center. We recorded the number of pump refill visits during the study period, as well as the additional visits for dose adjustments.

Via an annually applied anonymous questionnaire, patients provided their feedback on the ITB management service and their satisfaction level with the service. In case of official complaints, we started a complaints procedure.

In our setting, we have chosen to work with nurse practitioners (NP: Master's Degree in Advanced Nursing Practice). In our country, NP's are allowed to perform medical tasks independently. They are obliged to follow training every year. A reregistration will follow after 5 years only if all of the training requirements have been met. In the first 3 months working with ITB, the NP's are trained on the job by a medical specialist and an experienced nurse practitioner and work on an observer basis. During the next year, they receive intensive supervision. In addition, weekly multidisciplinary patient meetings and three monthly intervision sessions are held. During their work, the NP's are supervised by a medical specialist or a (colleague) NP10. The team is available on call 24/7. For percutaneous pump refills, patients were visited at least every 90 days as well as, if necessary, for dose adjustments and/or troubleshooting. We performed visits at the patient's home, a nursing home, a community for disabled persons, or (in case of a temporary stay) in the rehabilitation center or hospital.

One week before the appointment, a nurse practitioner prepared the visit. The NP prescribed a baclofen solution and (after being checked by a second nurse practitioner or medical supervisor) and digitally sent the prescription to the pharmacy. After receiving the medication, the NP checked the prescription and medication label and stored the medication at room temperature. Two to three days before the visit, the NP telephoned the patient or caregiver to enquire about the clinical status of the patient; if this was not stable, the condition was discussed with the

medical supervisor. On location, the NP made a brief note of medical history (focusing on spasticity treatment), performed a physical examination, and used telemedicine (encrypted bi-directional video connection via the 3G or 4G-broadband, Cisco Jabber Video Telepresence software version 4.7, Visions Connected, Amsterdam, The Netherlands). The screen-to-screen connection gives the supervisor and another NP or medical specialist access to communicate with the patient and the NP on location, as well as remote visual control of the prescription and the syringe label. After this, the connection was terminated and the NP performed the refill and/or dose adjustments and programming procedures. After refilling the pump under aseptic conditions, the NP made another telemedicine application for remote visual control of the pump programming printout. If the supervisor observed an error in programming, an immediate correction was made. Occasionally, we video-recorded the procedure either at the request of a physician or for training purposes. The NP documented the results in the electronic patient file. The patient received a printout of the pump programming session. Finally, the NP sent a consultation letter to the patient's physician(s). If requested, a brief consultation letter was left behind after the visit (Fig. 5).

The equipment included a synthetic, washable three-compartment trolley, separating sterile and nonsterile material, a box for medication storage during transport, a pump programmer (N'Vision, Medtronic), a mobile printer, a laptop, and a mobile telephone. The small laptop computer had an integrated camera and a built-in dongle device allowing wireless broadband access. Also, the supervisor (based at the headquarters of the ambulant clinic) was provided with a computer with identical features.

### Data Records

For safety management, we followed the Dutch Technical Agreement 8009 'Safety management system for hospitals and organizations which administer hospital care. This embeds patient safety in healthcare practices. It enables risk identification, the implementation of improvements and evaluations, and modification of policies. It also includes the '5 rights', that is, the "right patient, right action, right time, right cues, right reason" (10). The team adhered to these rights: that is, used the appropriate concentration of medication and the appropriate pump programming. Throughout the study, all serious adverse events (SAE) were recorded at each visit and discussed at our 6-weekly multidisciplinary team progress meetings. A sub-heading was made of the (S)AE that occurred due to surgery, as well as hospital-related and long-term related complications.

All visits, telephone calls and patient consultations were reported in an electronic patient dossier, including the referral letter, physical examination, treatment, medication, and printouts of the pump programming.

For prospective and retrospective risk management of near-incidents, we applied the "Healthcare Failure Mode and Effect Analysis" (HFMEA) of the "National Center for Patient Safety" (NCPS) (11). In case of a high risk of frequency and severity of consequences, we made an extensive PRISMA Medical analysis (Prevention Recovery Information System for Monitoring and Analysis) (12) to manage structural human errors in practice.

### External Audits

A quality and safety certification procedure was performed annually by an independent professional inspection institute (KIWA, Rijswijk, The Netherlands). The certificate demonstrates that the home-based

Ambulant Care Clinic met the necessary requirements for efficient and safe management and verifies that the related processes were correctly performed and in a way which enables the clinic to be sustainable. For the audit, the home-based Ambulant Care Clinic had to describe all protocols and procedure descriptions together with descriptive flow charts. The hygiene audit process included a “spot check” whereby the nurse practitioner (upon patient’s consent) was accompanied and observed by a hygiene auditor. As a part of the annual audit, the supervising pharmacist carried out an assessment of medication delivery and transportation.

## RESULTS

From 1st April 2011 to 1st January 2016, 239 patients of the current total population of 900 patients were referred to the home-based Ambulant Care Clinic. Table 1 presents the demographic and baseline characteristics. Multiple sclerosis (MS), cerebral palsy (CP), and spinal cord injury (SCI) were the most frequently reported etiologies of spasticity.

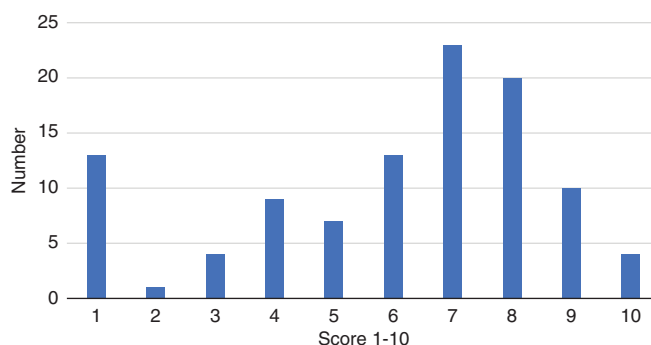
At the start of the home-based Ambulatory Care Clinic, nine hospitals in the Netherlands were treating patients with ITB. In addition to the hospitals, there were also satellite centers, for example, rehabilitation centers refilling and/or making dose adjustments. The majority of patients live at home: 28% live in a nursing home and 20.1% live in a community for disabled persons.

### Communications

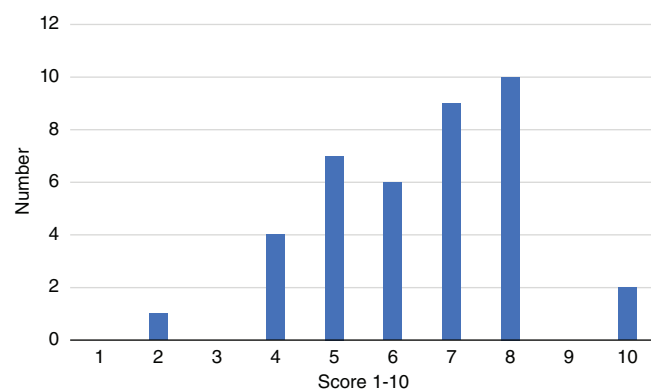
At the start of the study, 3G broadband was used for online videoconferencing. From 2014 onwards, 4G broadband was available and used. In the 3G broadband era, on 5 occasions, the connection was insufficient to establish a video feed. Three patients allowed the use of their own WiFi; for two patients, the only solution for control was a real-time telephone call. At the end of 2014, the telecommunication provider (KPN) delivered coverage to 98.4% of the inhabitants and 96% surface coverage throughout the Netherlands. Since then, very few connection problems have been encountered.

### Feasibility

During the first 3 years, 143 patients referred to the home-based Ambulant Care Clinic were asked about the burden of traveling (Fig. 1). Of these, 104 were able to answer the questionnaire themselves; their mean score was 5.7 (out of 10, where a score of 10 indicates the highest burden); and 47 patients scored 7 or higher. Of the 39 patients who were unable to answer the questions themselves, their caregivers answered the question on burden of traveling with a mean score of 6.4 (Fig. 2). Data was missing for eight patients.



**Figure 1.** Burden of traveling. [Color figure can be viewed at wileyonlinelibrary.com]



**Figure 2.** Answer on burden of traveling for patients. N=39. [Color figure can be viewed at wileyonlinelibrary.com]

Patients were also asked: “If traveling is a burden, what kind of negative effect does it have lack of energy, fatigue, increase of spasticity, increase of pain, or something else, please describe” (Fig. 3).

Although 11 patients scored 1 for burden of traveling, all patients experienced one or more negative consequences. Most patients experienced a lack of energy: 67% of the patients who answered themselves (Fig. 3), and 64% of those whose caregivers gave the answers on their behalf (Fig. 4).

### Satisfaction

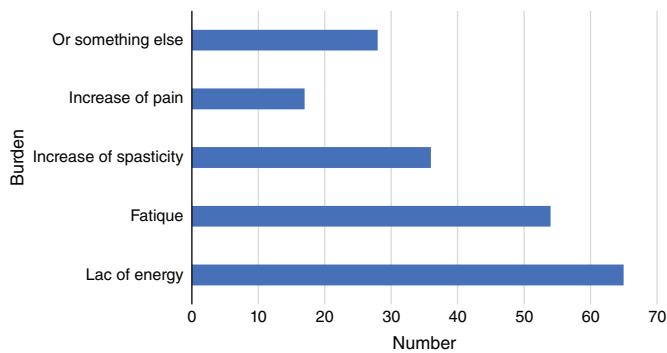
Patients and caregivers were positive about/satisfied with the ITB on location. All patients reported increased convenience from home-based Ambulant Care Clinic when compared to standard aftercare by visiting a medical center.

### Safety Evaluation

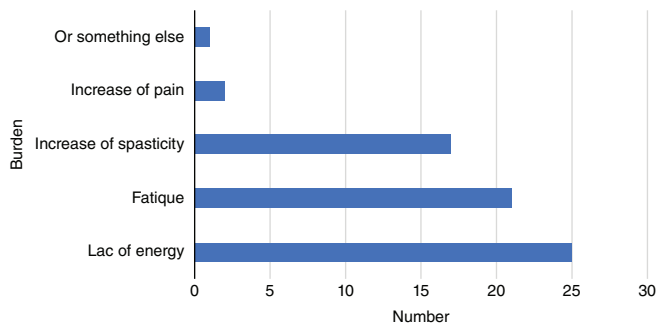
From a total of 6807 procedures, 11 adverse events (AE) and 9 SAE were registered. In one patient, a low reservoir alarm

**Table 1.** Demographic and Baseline Characteristics of the Aftercare Population (N = 239).

Disease	MS	SCI	Stroke	CP	CRPS	Other spinal	Other cerebral	Total
Male	26	31	7	44	0	8	18	134
Female	49	7	8	26	7	1	7	105
Total	75	38	15	70	7	9	25	239
Age (years)								
Mean	54.1	55.7	55	29.6	55.3	61.5	34.4	45.58
Range	(29–82)	(22–81)	(36–75)	(8–70)	(35–66)	(42–82)	(7–74)	(7–82)



**Figure 3.** Consequences of traveling, patients.  $N=104$ . [Color figure can be viewed at [wileyonlinelibrary.com](#)]



**Figure 4.** Caregivers' answer consequences on burden of traveling for patients. [Color figure can be viewed at [wileyonlinelibrary.com](#)]

created discomfort, but no harm. The wound management was adjusted because of postoperative deviant wound edges. After replacement of the pump, hematoma was reported postoperatively. One patient called in during duty hours with increased spasticity; earlier that day the patient had undergone an access-port procedure in the hospital. Investigation showed that, prior to discharge, the priming bolus had been omitted. We discussed the AE with the staff of the hospital, and an adaptation was made in the work process to prevent this in future.

On two occasions, patients developed signs of underdosage (a mild increase of spasticity and some sweating) between the refill intervals. Our protocol for this situation involves aspiration of the reservoir content. In both instances, an empty reservoir was found, probably due to an inadvertent pocket injection. The pump was refilled and a reduced dose adjustment was made. Another patient was again initiated with oral baclofen, this happened after patient was relocated to another nursing home. The local geriatrician telephoned our team reporting that the patient was somnolent. Careful case history revealed double treatment, and the oral baclofen was immediately discontinued.

## SAE

In three other refills in obese patients, the pump was emptied normally and indicated a correct needle position; however, later on it appeared that the volume was injected outside the pump. Over time dyspnea occurred (in 2 patients); in one case, this was diagnosed as pneumonia and was not recognized by the patient's own geriatrician as a moderate withdrawal syndrome. Both patients were hospitalized and both recovered fully after refilling the pump and dose adjustment. In one patient, there was an increased discrepancy between the calculated and the actual

volume of the pump reservoir; this patient was referred to hospital and the pump was replaced. The older pump was returned to Medtronic for further investigation.

The remaining SAEs occurred during the postoperative stage of treatment, or after analysis of the patient's ITB system. Due to established collaboration with the neuromodulation centers, when the SAE occurred, the first contact with the patients was via the ambulatory care clinic. The SAEs included meningitis, withdrawal after incorrect pump programming, withdrawal after incorrect pump refilling with medication outside the pump, wound care, and liquor leakage. In one SAE, a patient received the incorrect dosage of oral medication from a caregiver in the nursing home, which led to hospitalization and temporary cessation of ITB.

In total, 81 mistakes were reported. In the first year, two incidents were related to availability during duty hours; for this, an immediate adaptation was made to the method of working. Seven incidents of pump programming errors were reported; in all cases, the double-check procedures prevented clinical manifestations. In two cases, no order was made to prepare the syringe before the pump was refilled, which necessitated a rush order. The highest number of incidents (21) was related to appointments, in particular when dose adaptations had to be made between the normal scheduled procedures. On six occasions, erroneous archiving of patients' information in the electronic patient dossier had to be corrected. On nine occasions, incidences were reported due to delivery of the medication via the cooperative pharmacist, and five incorrect preparations were found.

## HFMEA and PRISMA Medical Analyses

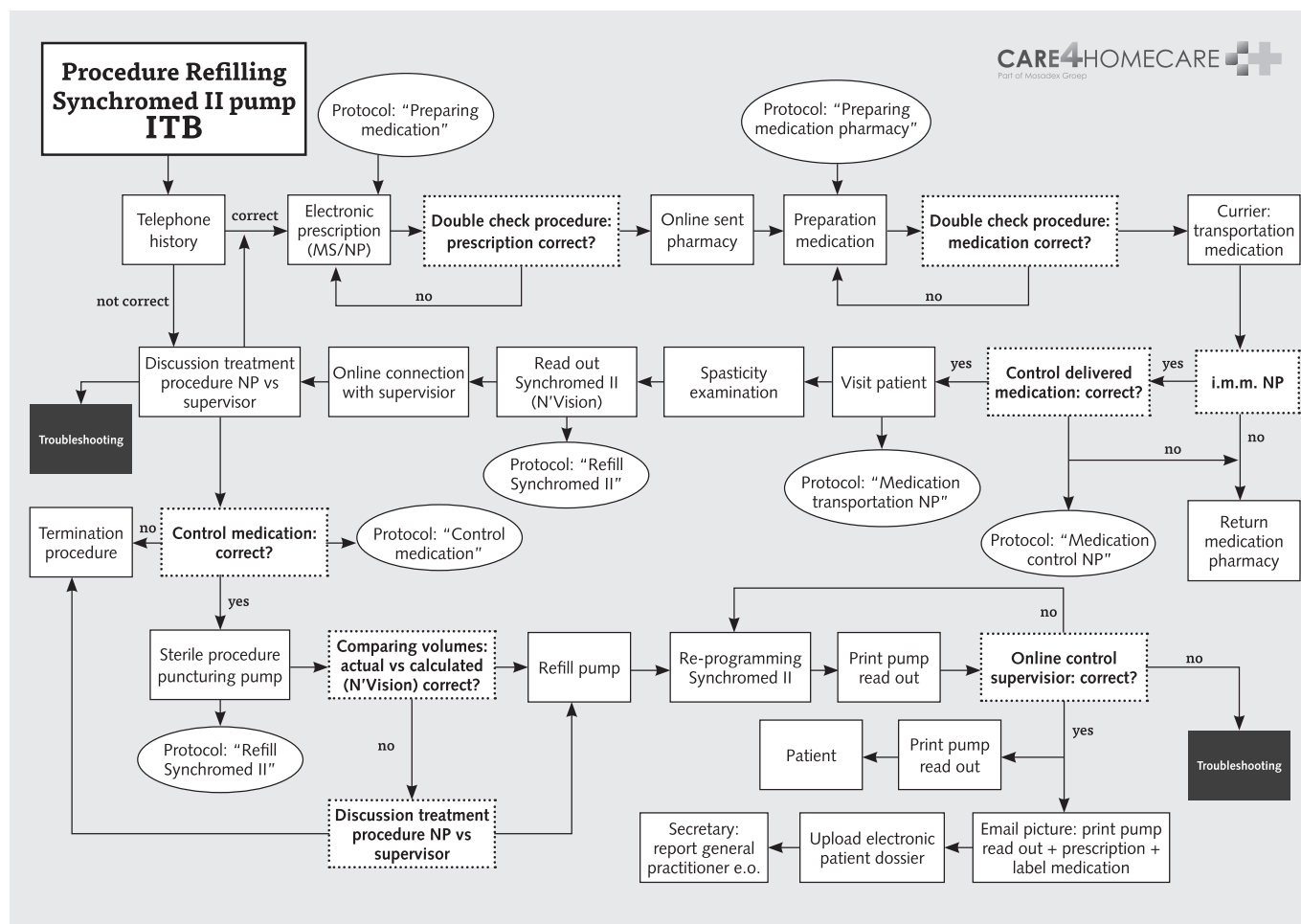
The retrospective HFMEA analyses included improvements in appointments, reporting delay, mistakes with patient data, and the labeling of medication syringes. As prospective subjects, we performed triage telephone call by the secretaries, transport, storage medication, on-line connections, pump refill procedure, and evaluation of the collaboration between Erasmus University Medical Center and Rehabilitation Center Rijndam adult rehabilitation population. For the PRISMA Medical analyses, we included; medication preparation and transport, motor stall pump device, and refilling outside the pump.

## External Audits

The annual quality and safety certification procedure performed by KIWA showed no nonconformances. The degree of involvement of the entire team was acknowledged. All 240 protocols and procedure descriptions (with related descriptive flow charts) were described. The audit of the hygienist and the supervising pharmacist also showed no deviations. The healthcare insurance company "Achmea" granted a quality and safety award.

## DISCUSSION

This study has shown the feasibility and safety of a home-based Ambulatory Care Clinic for ITB management in a domestic setting using telemedicine for real-time remote communication. Applying the concept prevents burdensome traveling to a medical center for severely handicapped patients. The importance of this was shown by the satisfaction scores. An important finding was that 51.9% of the patients were living at home, which has a considerable beneficial impact on the family's daily life. The majority of these patients received professional help for basic care. Routine



**Figure 5.** Procedure Refilling Synchronomed II pump, ITB.

aftercare in a home setting is very important, particularly since this avoids travel to an ITB center.

Telemedicine includes a growing variety of applications and services to provide equal access to medical support, irrespective of geographic circumstances (11). This term covers our activities and implies a more specific application using interactive video communication (13). The present study was performed in a small country with relatively short travel distances. In less densely populated countries with greater travel distances, the related problems might be more extensive.

In our study, a lower incidence of complications was observed than in the subject literature. Whether there is a specific relationship between the treatment in the hospital or at home was not part of the scope of our study, so that we cannot comment on the matter.

Our concept could help to optimize the quality of life of patients who suffer severely. This was demonstrated by the extended growth of the test population; we performed aftercare in  $\geq 25\%$  of the entire ITB population in the Netherlands. The prevention of substantial adverse events demonstrated the value of the double-check procedures. We agree with Bradford et al. (14) that providing care at home should not involve a reduction of standards, implying that the double check should be included. The feasibility of the use of a laptop computer or tablet (14) to conduct double-checks using an e-health technique has been demonstrated without contravention of the existing standards. We found that obesity played an important role in the three adverse events during pump refill (15). Finding the small refill membrane and the risk of needle dislocation during syringe

changes are important parts of the process. Particularly in a 40-ml pump, a change of syringe could result in an (unrecognized) injection outside the pump. Good collaboration in case of trouble shooting with a medical center is indispensable. Direct referral of patients in case of problems is also very important. On the other hand, it is important that the patient stays as briefly as possible in a medical center; aftercare in their own surroundings is guaranteed by a home-based Ambulatory Care Clinic. Although time consuming, during a process of continuous improvement of treatment, the Ambulatory Care Clinic recognized that the HFMEA and the extended PRISMA Medical analyses should be conducted in routine practice.

A limitation of our study is that due to its retrospective character, we were not able to make a comparison of the adverse event data of the home-based ambulatory clinic with hospital-based data. This might have created a stronger argument that the home-based ambulatory group can be treated as safely as the hospital-based group. The problem is that the hospital-based patients are treated in different hospitals, and unfortunately, we do not possess the relevant data. Further research into this is therefore recommended.

## CONCLUSIONS

The concept of home-based Ambulatory Care Clinic has clearly shown its feasibility and safety and can prevent a patient's burdensome traveling to a medical center for pump refills and dose adjustments. The encrypted bidirectional videoconferencing with 4G connection

has proven its reliability and enabled communication with patients, and the performance of double checks on medication and procedures. Close cooperation with a neuromodulation center in case of problems is indispensable and can be arranged in chain-based care. In this way, clinical standards can be preserved for complex treatment. The method can be valuable for application elsewhere, particularly in countries with long traveling distances between care centers. The Dutch Healthcare Authorities are convinced about the research results and have included ITB-aftercare, performed by a home-based Ambulatory Care Clinic, as a fixed component in healthcare with associated reimbursement structure.

## Authorship Statement

Simone Goslinga-van der Gaag (SG) and Dr. Delhaas designed and conducted the study, including patient recruitment, data collection and data analysis. Dr. Frankema is the co-promoter of SG and helped her with preparing the draft version of the manuscript. Prof. Huygen is the promoter of SG and gave important intellectual input. All authors approved the final manuscript.

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## COMMENTS

The authors describe an interesting model for ITB follow-up care in a home-based setting, decreasing the burden for disabled patients who would otherwise have to travel long distances to a center. The program, implemented by medically-supervised nurse practitioners, demonstrated good outcomes and high patient satisfaction. It is a model that could be replicated in many settings.

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This is a very exciting study proving the safety and efficiency of utilizing NPs in the role of routine pump management in the outpatient/home setting.

Kristin Buxton, MS, RN, CPNP  
Boston, MA, USA

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The manuscript in the discussion and conclusion should reinforce that ITB is a safe therapy - the incidence of issues for all of the patient contacts are quite low - this would be helpful in debunking the "danger" of ITB and further addressing barriers to care and implementation (at home, can't travel, too many complications of ITB, if can't travel to office then more likely to have complications regarding management) - so many issues can be added in discussion to highlight safety, ability to refill or manage not in office but remotely.... access and awareness of efficacy and safety is key - this will help with that treatment barrier.

Mark Gudesblatt, MD  
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Comments not included in the Early View version of this paper.