University Hospitals Birmingham NHS
NHS Foundation Trust

Expanded Practice Protocol for Performance of Percutaneous Tibial Nerve Stimulation (PTNS) by Colorectal Clinical Nurse Specialists

CONTROLLED DOCUMENT

CATEGORY:	**Procedural Document**
CLASSIFICATION:	**Clinical**
PURPOSE	**The purpose of this expanded practice protocol is to support colorectal clinical nurse specialists to perform PTNS treatment in patients with faecal incontinence**
Controlled Document Number:	TBC
Version Number:	**1** Draft 3
Controlled Document Sponsor:	**Executive Chief Nurse**
Controlled Document Lead:	**Clinical Nurse Specialist Functional Bowel Service**
Approved By:	**Executive Chief Nurse** **Executive Medical Director** **Associate Director of Nursing, Division B** **Matron** **Clinical Service Lead**
On:	
Review Date:	
Distribution: • **Essential Reading for:** • **Information for:**	 **All colorectal clinical nurse specialists who currently undertake the practice of PTNS and all colorectal clinical nurse specialists who wish to expand their practice to include this skill.** **All colorectal clinical nurse specialists and colorectal surgical team.**

EVIDENCE FOR PRACTICE

Faecal incontinence is a common and distressing problem which has a number of underlying causes affecting either the anatomy or function of the anal sphincter. Faecal incontinence is associated with a high level of physical disability and social stigma. Its true incidence may be under reported due to the embarrassing nature of the condition. Therefore it is difficult to know how common bowel incontinence is, but various research studies suggest that about 10% of adults soil their underwear regularly (Ahmed et al, 2010).
For understandable reasons, faecal incontinence has remained a largely hidden problem, with many patients feeling too embarrassed or ashamed to admit their symptoms to healthcare professionals, or even to family and friends.

Faecal incontinence has many possible contributing causes, including perineal injury during vaginal delivery, anal surgery, neurological disease, bowel impaction, congenital disorders, overflow incontinence due to faecal impaction and diarrhoea (NICE, 2007).

First line treatment is conservative to include dietary and medication optimisation. If these are not successful in controlling the symptoms, pelvic floor training and biofeedback may be used (NICE, 2007). If conservative treatments have been unsuccessful surgery may be recommended. Options include sphincter repair, sacral nerve stimulation and permanent colostomy.

Percutaneous tibial nerve stimulation (PTNS) is a 30 minute clinic based treatment for faecal incontinence which is NICE approved (NICE, 2011). This treatment is ideal to be offered in the treatment pathway as an option prior to considering surgery, as it has fewer complications and is more cost effective. The procedure is performed whilst the patient is seated or reclined. Initial treatment usually consists of 12 weekly sessions lasting 30 minutes each (Van Balken, 2007).

A needle electrode is inserted near the tibial nerve, which carries electrical impulses from a hand-held stimulator to the sacral plexus. A non-randomised comparative study of 52 patients treated by PTNS or sham treatment (placebo) reported that 53% (17/32) had ‘good’ results, 31% (10/32) had ‘fair’ results and 16% (5/32) had ‘poor’ results after treatment with PTNS. No clinical improvement was reported in the 20 patients treated with sham treatment (Shafik et al, 2003). In a prospective study of 31 patients 71% (22/31) had more than 50% reduction in leakage episodes and 65% (20/31) had an improvement in ability to defer defaecation (Allison, 2011).

The potential benefit of percutaneous stimulation is that it may achieve the same neuromodulatory effect as sacral nerve stimulation through a less invasive route which is more cost effective (Findlay et al, 2010).

PTNS is a minimally invasive treatment with few side effects which is ideally undertaken by the Clinical Nurse Specialist for functional bowel. Treatment by the Clinical Nurse Specialist in Functional Bowel is cost effective and enables holistic assessment of the patient. Also it enables a therapeutic relationship to develop as the same clinician is seeing the patient weekly. For a condition with such a social stigma this is an advantage as it allows the patient to have confidence and

therefore confide in the clinician thus ensuring better assessments and more specific treatment.

CONSENT

It is recommended in the NICE interventional procedure guidance (NICE, 2011) that formal written consent is required and this must be documented in the patient's notes. For further information regarding consent and mental capacity please refer to the following documents:

- Department of Health Reference Guide to Consent for Examination or Treatment (2009).
- The Trust's Policy and Procedural document for consent to examination or treatment (current version).
- *Mental Capacity Act (2005).*

INDICATIONS

PTNS is undertaken in patients with faecal incontinence, who have undergone assessment in a consultant led or nurse led colorectal clinic. Patients must already have tried a course of conservative treatment, as discussed above, which has failed to improve their symptoms.

Patients are referred by members of the colorectal surgical team.

CONTRAINDICATIONS

PTNS is contraindicated if:

1. The patient has capacity but does not give consent for PTNS treatment.
2. The patient is under 16 years of age.
3. The patient is pregnant.
4. The patient has a pacemaker or an implanted defibrillator.
5. The patient has bleeding problems.
6. The patient has neurological disease.
7. The patient has had back surgery.
8. The patient has central nerve damage.
9. The patient has allergies to any of the components used.
10. The patient has a needle phobia.

11. If the patient has leg sores/ulcers which do not heal.

LIMITATIONS TO PRACTICE

PTNS should be used with caution and after discussion with the colorectal consultant surgeon in the following:

1. Patients with diabetes.

2. Patients with swollen ankles.

3. Patients with foot problems.

4. Patients who have had previous gynaecological surgery.

5. Patients who have ongoing back problems.

6. Patients who are on anti-coagulant treatment.

If the patient develops a side effect to the treatment this must be documented in the patient's records and also recorded on the NICE audit tool (NICE, 2011) which must be completed for each patient.

Minor side effects include:

Transient discomfort around the needle site
Redness or inflammation around the needle site
Transient toe numbness
Minor bleeding at needle site
Aching calf muscle

Any serious side effects must be reported on an incidence form to the company (Uroplasty Ltd).

If the Clinical Nurse Specialist for functional bowel is concerned about the patient's condition they must refer the patient to the appropriate medical practitioner for advice on any further action to be taken, and this must be recorded in the patient's notes.

The appropriate Health and Safety risk assessments must have been completed for the clinical area.

CRITERIA FOR COMPETENCE

1. Colorectal Clinical Nurse Specialists must be of band 7 or higher to undertake PTNS.

2. Colorectal Clinical Nurse Specialists must have undertaken relevant post graduate training as recognised by the matron for colorectal nursing.

3. Evidence of satisfactory supervised practice must be provided by the Colorectal Nurse Specialist as witnessed by a practitioner who is already competent in PTNS treatment. (Appendix 1). In addition evidence of supervised practice as witnessed by a representative of the company (Uroplasty Ltd) must also be provided.

4. The number of supervised practices required will reflect the individual Colorectal Nurse Specialist's learning needs.

5. Evidence of competence, as assessed by a practitioner who is already competent in PTNS treatment must be provided and a copy kept in the Colorectal Nurse Specialist's personal file and in the ward or department where the skill is practised. (Appendix 2). Additionally evidence of competence, as assessed by a representative of Uroplasty Ltd, must also be provided. Evidence of competence will also be kept by Uroplasty Ltd.

6. The Colorectal Nurse Specialist must provide evidence of competence in the safe handling, use and maintenance of Urgent PC Neuromodulation system (Uroplasty Ltd.).

7. The Colorectal Clinical Nurse Specialist must adhere to the NICE guidance for PTNS treatment and maintain the NICE audit of all patients treated (see appendix 4)

8. Colorectal Clinical Nurse Specialists new to the Trust, who have been performing the skill elsewhere, must read and understand this protocol. Evidence of appropriate education and competence must be provided and checked by the Colorectal Nursing team leader before undertaking this expanded practice at the Trust. The decision whether the Colorectal Clinical Nurse Specialist needs to complete Trust training and competence will be at the discretion of the Colorectal Clinical Nurse Specialist's line manager.

9. In accordance with codes of professional practice, the Colorectal Clinical Nurse Specialist has a responsibility to recognise, and to work within, the limits of their competence. In addition, the Colorectal Clinical Nurse Specialists has a responsibility to practise within the boundaries of the current evidence based practice and in line with up to date Trust and national policies and procedural documents. Evidence of continuing professional development and maintenance of skill level will be required and confirmed at the Colorectal Clinical Nurse Specialist's annual appraisal by the Colorectal Clinical Nurse Specialist's line manager.

A list of Colorectal Clinical Nurse Specialists competent to perform this skill must be kept by the line manager.

PROTOCOL AND SKILLS AUDIT

The Clinical Nurse Specialist for Functional Bowel will lead the audit of the protocol with support from the Practice Development Team. The audit will be

undertaken in accordance with the review date and will include:

- Adherence to the protocol
- Any untoward incidents or complaints
- Number of colorectal nurse specialists competent to perform the skill
- Completion of NICE audit (NICE, 2011, Appendix 5)

All audits must be logged with the Clinical Governance Support Unit.

CLINICAL INCIDENT REPORTING AND MANAGEMENT

Any untoward incidents and near misses must be dealt with by the appropriate management team. An incident form must be completed and in addition the Risk Management Team must be notified by telephone of any Serious Incidents Requiring Investigation (SIRI).
Any serious side effects of PTNS treatment must be reported on an incidence form to the company (Uroplasty Ltd).

REFERENCES

Ahmed M McCallum IJD Mercer-Jones M (2010) Management of faecal incontinence in adults. **British Journal of Medicine**.340 1350-5

Allison M (2011) Percutaneous tibial nerve stimulation for patients with faecal incontinence. **Nursing Standard** 25(24) 44-48

Department of Health (2009) **Reference Guide to Consent for Examination or Treatment** 2nd edn. HMSO London

Findlay JM Yeung JM Robinson R Greaves H Maxwell-Armstrong C (2010) Peripheral neuromodulation via posterior tibial nerve stimulation – a potential treatment for faecal incontinence? **Annals of the Royal College of Surgeons of England** 92(5) 385-390

Mental Capacity Act 2005,
http://www.legislation.gov.uk/ukpga/2005/9/contents
(accessed 3/4/13)

National Institute of Clinical Eexcellence (2007) **Faecal Incontinence: The Management of Faecal Incontinence in Adults.** Clinical guideline no. 49 NICE: London

National Institute of Clinical Excellence (2011a) **Percutaneous tibial nerve stimulation for faecal incontinence.** Interventional procedure guidance no. 395. NICE: London

National Institute of Clinical Excellence (2011b) **Percutaneous tibial nerve stimulation for faecal incontinence: Audit support.** NICE:London

Shafik A Ahmed I El-Sibai O Mostafa RM (2003) Percutaneous peripheral neuromodulation in the treatment of fecal incontinence. **European Surgical Research** 35 103-107

University Hospitals Birmingham NHS Foundation Trust (current version) **Policy for consent to examination or treatment**, University Hospitals Birmingham NHS Foundation Trust http://uhbpolicies/Microsites/Policies_Procedures/consent-to-examination-or-treatment.htm
[accessed 3/4/13]

University Hospitals Birmingham NHS Foundation Trust (current version) **Procedure for consent to examination or treatment**. University Hospitals Birmingham NHS Foundation Trust http://uhbpolicies/Microsites/Policies_Procedures/consent-to-examination-or-treatment.htm
[accessed 3/4/13]

Van Balken MR (2007) Percutaneous tibial nerve stimulation: the Urgent PC device. **Expert Review of Medical Devices.** 4 (5) 693-698

BIBLIOGRAPHY

Lindsey I Nugent K Dixon T (eds) (2011) **Pelvic Floor Disorders for the Colorectal Surgeon.** Oxford University Press: Oxford

Norton C Chelvanayagam S (eds) (2004) **Bowel Continence Nursing.** Beaconsfield Publishers Ltd: Oxford

University Hospitals Birmingham NHS Foundation Trust Risk Assessment Documentation http://uhbhome/Resources/RiskAssessmentDocs/Home.aspx
[accessed 12/4/2013]

PROTOCOL SUBMISSION DETAILS

Protocol prepared by:

Yvette Perston	Clinical Nurse Specialist for Functional Bowel
Kaori Futaba	Colorectal Consultant Surgeon
Belinda Wadwell	Practice Development Nurse

Protocol submitted to and approved by:

Executive Chief Nurse ……

Date: ……

Executive Medical Director ……

Date: ……

Associate Director of Nursing, Division B ……

Date: ……

Matron ……

Date: ……

Clinical Service Lead ……

Date: ……

Appendix 1

UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST

EVIDENCE OF SUPERVISED PRACTICE

To become a competent practitioner, it is the responsibility of each Colorectal Clinical Nurse Specialist to undertake supervised practice in order to perform Percutaneous Tibial Nerve Stimulation for Faecal Incontinence in a safe and skilled manner.

Name of Colorectal Clinical Nurse Specialist : …….

DATE	DETAILS OF PTNS	SATISFACTORY STANDARD MET	COMMENTS	PRINT NAME, SIGNATURE & DESIGNATION
		Yes / No		
		Yes / No		
		Yes / No		
		Yes / No		
		Yes / No		
		Yes / No		

UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST

CRITERIA FOR COMPETENCE

END COMPETENCE: Performance of Percutaneous Tibial Nerve Stimulation for Faecal Incontinence

Date(s) of Education and supervised practice: …….

Name of Colorectal Clinical Nurse Specialist (print):…… Clinical Area / Department: ……

Name of Supervisor (print): ……

Element of Competence To Be Achieved	Date Achieved	Colorectal Clinical Nurse Specialist Sign	Supervisor Sign
Discuss and identify • indications, • contraindications • limitations for Percutaneous Tibial Nerve Stimulation for Faecal Incontinence according to this expanded practice protocol.			
Demonstrate an understanding of the aetiology of faecal incontinence and conservative treatments			
Demonstrate accurate history taking and assessment of patient			
Discuss accountability in relation to the NMC Code: Standards of conduct, performance and ethics for nurses and midwives (2008).			
Demonstrate maintenance of the patient's privacy and dignity throughout the procedure			

Element of Competence To Be Achieved	Date Achieved	Colorectal Clinical Nurse Specialist Sign	Supervisor Sign
Demonstrate a working knowledge of the Trust's policy for consent to examination or treatment.			
Demonstrate a working knowledge of the *Mental Capacity Act.*			
Demonstrate accurate provision of information pre and post the procedure in a way that the patient understands.			
Demonstrate an understanding of the normal anatomy of the ankle and lower leg.			
Demonstrate an understanding of the correct procedure for site selection and insertion of needle (see Appendix 3).			
Demonstrate an understanding of the expected sensations on stimulation.			
Discuss the need for referral to colorectal consultants.			
Demonstrate an understanding of the possible side effects of treatment and the management of them.			
Demonstrate involvement of the patient in decision making about their care and treatment.			
Demonstrate application of the Trust Principles for carers.			
Provide evidence of competence in the safe use of the Urgent PC PTNS stimulator.			
Demonstrate safe infection control practices throughout the procedure. To include: • Standard precautions • Aseptic Non-Touch Technique			

Element of Competence To Be Achieved	Date Achieved	Colorectal Clinical Nurse Specialist Sign	Supervisor Sign
Demonstrate accurate record keeping.			
Demonstrate safe removal and disposal of needle and leads.			
Demonstrate safe disposal of waste and cleaning of equipment			
Discuss any health and safety issues in relation to this expanded practice			
Demonstrate an understanding of the incident reporting process.			

I declare that I have expanded my knowledge and skills and undertake to practice with accountability for my decisions and actions. I have read and understood the protocol for Percutaneous Tibial Nerve Stimulation for Faecal Incontinence

Signature of Colorectal Clinical Nurse Specialist……Print name:……

Date: ……

I declare that I have supervised this Colorectal Clinical Nurse Specialist and found her/him to be competent as judged by the above criteria.

Signature of Supervisor: …….. Print name:……..

Date: ……..

A copy of this record should be placed in the Colorectal Clinical Nurse Specialist's personal file, a copy must be stored in the clinical area by the line manager, and a copy can be retained by the individual for their Professional

Procedure for Percutaneous Tibial Nerve Stimulation (PTNS) for faecal incontinence

Equipment

Trolley
Stimulator
Uroplasty pack containing 2 needle, leads and alcohol wipe
Apron
Gloves (if using)
Sharps Bin

Procedure

Action	Rational
At start of first treatment ensure patient has completed bowel diary, quality of life questionnaire and score him/her on the Vaizey score (see Appendix 4).	To obtain accurate assessment of patient's symptoms prior to treatment, as a baseline to assess effectiveness of treatment.
Wash hands, put on apron, put on gloves (if using).	To minimise cross infection.
Ask patient to expose relevant ankle and lower leg and sit with legs elevated (on chair or examination couch)	To allow for accurate positioning of needle and comfortable position for patient.
Prepare site with alcohol wipe	To ensure area is clean and enable good adhesion of earthing pad
Position needle electrode at 60 degree angle approximately 5cm (three fingers breadth) from the medial malleolus and 2cm (one finger breadth) posterior to the tibia	To ensure that needle is in correct position
Gently tap needle until it penetrates skin then remove needle guide and advance needle until 1.5cm of the top of the needle is exposed.	To ensure that electrode in inserted near to the tibial nerve.
Connect lead wire to needle electrode. Place a surface electrode under the arch of the foot and connect lead to stimulator	To enable stimulator to work.
Switch the stimulator on. Gradually increase current until a motor response is obtained (the toes fan or flex) or the patient describes a sensory response (a tingling under the foot or into the heel)	To ensure electrode is in correct position

Commence thirty minute treatment session	
Switch off stimulator on completion of treatment and remove needle. Safely dispose of in sharps box.	To ensure safe disposal of waste.
Remove apron and gloves and wash hands.	To minimise cross infection.
Document treatment and make further appointment (see Appendix 6). Complete NICE audit tool (Appendix 5).	Treatment requires 9-12 consecutive weekly or twice weekly treatments. To ensure written communication of patient care and as record for audit purposes.
At end of final treatment ensure patient has completed bowel diary, quality of life questionnaire and rescore on the Vaizey score.	To obtain accurate assessment of patient's symptoms at end of treatment, enabling comparison with baseline assessment.
At end of final treatment, make patient a follow up appointment, as appropriate (see Appendix 6).	To ensure appropriate follow up and management.

Vaizey Score

Vaizey Score					
	Never	*Rarely*	*Sometimes*	*Weekly*	*Daily*
Incontinence for solid stool	0	1	2	3	4
Incontinence for liquid stool	0	1	2	3	4
Incontinence for gas	0	1	2	3	4
Alteration in lifestyle	0	1	2	3	4
		No		*Yes*	
Need to wear a pad or plug		0		2	
Taking constipating medicines		0		2	
Lack of ability to defer defecation for 15 minutes		0		4	
Never, no episodes in the past four weeks; Rarely, 1 episode in the past four weeks; Sometimes, >1 episode in the past four weeks but <1 a week; Weekly, 1 or more episodes a week but <1 a day; Daily, 1 or more episodes a day.					
Add one score from each row: minimum score = 0 = perfect continence; maximum score = 24 = totally incontinent					

Data collection tool for 'Percutaneous tibial nerve stimulation for faecal incontinence'

Complete one form for each procedure.

Patient identifier:	**Sex: M / F**	**Age:**	**Ethnicity:**
Date of procedure:			
Date(s) of follow up:			

Data item	**Criteria**	**Tick/complete box as indicated**			
Consent					
A	Written information on the procedure and any possible complications has been given to patient	Yes	☐	No	☐
B	Discussion with clinician about the procedure has been documented in the notes	Yes	☐	No	☐
C	Written consent to treatment has been obtained	Yes	☐	No	☐
Baseline data					
D	Number of patient-reported faecal incontinence episodes per week (change unit as necessary)				
E	Cleveland Clinic Florida Fecal Incontinence score (CCF-FI) (also referred to as the Wexner or Jorge-Wexner score)	Score:			
F	Rockwood score	Score:			
G	Faecal incontinence quality of life questionnaire (FIQL)	Score:			
H	Faecal Incontinence Severity Index (FISI)	Score:			
I	Short Form 36 Health Survey (SF-36)	Score:			
J	Other quality of life or health status instrument (please specify):	Score:			
Adverse events (please indicate in which session(s) the adverse event occurred)					
K	Discomfort or pain at the insertion site	Session:	Grade:		
L	Redness or inflammation at or around the insertion site	Session:	Grade:		
M	Toe numbness	Session:	Grade:		
N	Leg numbness	Session:	Grade:		
O	Gastrodynia	Session:	Grade:		
P	Other (please specify)	Session:	Grade: Detail:		

Effectiveness (post procedural – after the full course of treatment)					
Q	Improvement in faecal incontinence disease severity	Yes	☐	No	☐
R	Improvement in quality of life and emotional impact	Yes	☐	No	☐
S	Cleveland Clinic Florida Fecal Incontinence score (CCF-FI) (also referred to as the Wexner or Jorge-Wexner score)	Post procedural score:			
T	Rockwood score	Post procedural score:			
U	Faecal incontinence quality of life questionnaire (FIQL)	Post procedural score:			
V	Faecal Incontinence Severity Index (FISI)	Post procedural score:			
W	Short Form 36 Health Survey (SF-36)	Post procedural score:			
X	Other quality of life or health status instrument (please specify):	Post procedural score:			
Y	Improvement in physiological measurements	Yes	☐	No	☐
Z	Recurrence of symptoms	Yes	☐	No	☐
AA	Reduction of symptoms	Yes	☐	No	☐
AB	Number of patient reported faecal incontinence episodes per week (change unit as necessary)				
AC	Other (please specify)	Detail:			

Grade
0 - No adverse event
1 - Mild adverse event (minor no specific intervention)
2 - Moderate adverse event (minimal intervention)
3 - Severe and undesirable adverse event (significant symptoms)
4 - Life threatening or disabling adverse event (need for intensive care or invasive procedures)
5 - Death related to adverse event

Pathway for Patients with Faecal Incontinence undergoing Percutaneous Tibial Nerve Stimulation (PTNS)