NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1747 Botulinum toxin injections into the urethral sphincter for idiopathic chronic non obstructive urinary retention**

Your information

Name:	Click here to enter text. Jalesh N. Panicker
Job title:	Click here to enter text. Reader and Consultant Neurologist in Uro-Neurology
Organisation:	Click here to enter text. The National Hospital for Neurology and Neurosurgery and UCL Queen Square Institute of Neurology
Email address:	Click here to enter text. j.panicker@ucl.ac.uk
Professional organisation or society membership/affiliation:	Click here to enter text. I am a member of the Association of British Neurologists
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text. **GMC 6164983**

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

X☐ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	Yes
	Have you used it or are you currently using it?	Yes- regularly
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	Limited use
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	Urology and Neurology
	− If your specialty is involved in patient selection or referral to another	Women with chronic urinary retention where there is evidence for a primary disorder of urethral sphincter relaxation

	specialty for this procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. X I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. X I have published this research. X I have had no involvement in research on this procedure. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Novel repurposing of an approved agent A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. .
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Addition to existing standard of care in women who either decline or unable to undergo standard care (sacral neuromodulation)

Current management

5	Please describe the current standard of care that is used in the NHS.	At community level- Catheterisation (IC or IDC) At tertiary care level- Sacral neuromodulation after MDT discussion , Catheterisation (IC or IDC)
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Newer sacral neuromodulation devices Considerably

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Minimally invasive Effects (and side effects) reversible Outpatient procedure requiring only local anaesthesia Quick procedure
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	This procedure if pertinent to only women with chronic idiopathic urinary retention who have evidence for a primary disorder of urethral sphincter relaxation (elevated UPP and/or abnormal urethral sphincter EMG) (roughly 40% of women presenting with chronic idiopathic urinary retention- Panicker JN, Game X, Khan S, Kessler TM, Gonzales G, Elneil S, Fowler CJ. The possible role of opiates in women with chronic urinary retention: observations from a prospective clinical study. J Urol. 2012 Aug;188(2):480-4. doi: 10.1016/j.juro.2012.04.011. Epub 2012 Jun 15).
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	In a cohort for whom sacral neuromodulation is not possible- Less reliance on catheterisation Less UTIs and less acute retention episodes- thereby less A&E visits Less requirement for catheters- cost saving
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Difficult to say, however as botulinum toxin is available at all major centers and the procedure can be delivered as an outpatient procedure using local anaesthesia there it is possible that there will be cost savings
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about	Beneficial impact because of reduced costs and less visits to A&E, hospital and GP practices from less catheter use, less UTIs

	same-in terms of staff, equipment, and care setting)?	Alternative to the more resource intense sacral neuromodulation
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Outpatient room
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	None Reversible stress incontinence (<2% from our data) Discomfort during the procedure (uncommon) A degree of oozing of blood (uncommon) Limited duration of effect (12-16 weeks)
15	Please list the key efficacy outcomes for this procedure/technology?	Reduced frequency of catheterisation/becoming catheer free Ease of catheterisation Pain associated with catheterisation
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Long term risk for stress incontinence is uncertain, however we are closely monitoring our patient cohort

17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	None Two routes of delivery: Periurethral EMG guided vs cystoscopy guided delivery of the product
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK. yes (because the condition is so uncommon)

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Panicker JN, Seth JH, Khan S, Gonzales G, Haslam C, Kessler TM, Fowler CJ. Open-label study evaluating outpatient urethral sphincter injections of onabotulinumtoxinA to treat women with urinary retention due to a primary disorder of sphincter relaxation (Fowler's syndrome). BJU Int. 2016 May;117(5):809-13. doi: 10.1111/bju.13342. Epub 2015 Nov 8. PMID: 26435296. Kao YL, Huang KH, Kuo HC, Ou YC. The Therapeutic Effects and Pathophysiology of Botulinum Toxin A on Voiding Dysfunction Due to Urethral Sphincter Dysfunction. Toxins (Basel). 2019 Dec 13;11(12):728. doi: 10.3390/toxins11120728. PMID: 31847090; PMCID: PMC6950422.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not aware

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an	Difficult to say- ??10-40 per year

	estimated number, or a proportion of the target population)?	
22	Are there any issues with the usability or practical aspects of the procedure/technology?	None
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	None except for the need to gain experience with this treatment
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	RCT- however considering the heterogeneity of the population and lack of interest amongst funders (industry) we were unable to set up a study
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Frequency of catheterisation Ease of catheterisation Pain associated with catheterisation Adverse outcome measures: Short term (days/weeks) Reversible stress incontinence Discomfort during the procedure A degree of oozing of blood

		Long term (years) stress incontinence

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	This treatment is pertinent to only a small cohort of women with chronic idiopathic urinary retention who have evidence for a primary disorder of urethral sphincter relaxation (elevated UPP and/or abnormal urethral sphincter EMG) and therefore the service should be closely audited

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	Coloplast (catheter company)- Speaker Honorarium and Advisory Board member	**2/2021**	**ongoing**
Direct - financial	AbbVie (onabotulinumtoxinA manufacturer)- Advisory Board member	**5/2021**	**7/2021**
Direct - financial	Wellspect (catheter company)- Speaker Honorarium	**6/2021**	**6/2021**

X☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Click here to enter text.** **Jalesh N Panicker**
Dated:	**Click here to enter text.** **1 December 2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1747 Botulinum toxin injections into the urethral sphincter for idiopathic chronic non obstructive urinary retention

Your information

Name:	Ms Mahreen Pakzad
Job title:	Consultant Urological Surgeon
Organisation:	University College Hospital NHS FT
Email address:	Mahreen.pakzad@nhs.net
Professional organisation or society membership/affiliation:	BAUS
Nominated/ratified by (if applicable):	BAUS
Registration number (e.g. GMC, NMC, HCPC)	4412744

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Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please	I am very familiar with its use and regularly use botox. I imagine uptake would be high if approved by NICE for HTNRSO

	indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure- yes I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers- yes I have published this research- abstracts and paper in progress I have had no involvement in research on this procedure. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Novel use of drug WHICH HAS a well studied EXISTING SAFETY AND EFFICACY PROFILE Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. YES Definitely novel and of uncertain safety and efficacy. The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	addition

Current management

5	Please describe the current standard of care that is used in the NHS.	SACRAL NERVE STIMULATION
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	NO

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Could be offered under LA as opposed to GA
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Young women with a primary disorder of urethral sphincter relaxation
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	yes
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Same/possibly slightly less
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Same / possibly slightly less
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No change required
13	Is any specific training needed in order to	Yes, for safe delivery

	use the procedure/technology with respect to efficacy or safety?	

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Stress urinary incontinence Flu-like illness All known side effects of administration of botulinum toxin
15	Please list the key efficacy outcomes for this procedure/technology?	Render patients able to void
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	nil
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	no
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	**Most or all district general hospitals.** A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	audit IN MY UNIT at UCLH.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	200
22	Are there any issues with the usability or practical aspects of the procedure/technology?	no
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your	no

	organisation or across the wider NHS?	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Long-term efficacy
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: USP questionnaire Flow rate PVR Reduction in need to self catheterise Rendering patient catheter free Adverse outcome measures: SUI Botulinism

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I have found it to be a useful addition to the armamentarium in treatment of voiding dysfunction in young women

NICE National Institute for Health and Care Excellence

Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

x ☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Mahreen Pakzad**
Dated:	**22.02.2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1747 Botulinum toxin injections into the urethral sphincter for idiopathic chronic non obstructive urinary retention

Your information

Name:	Sara Simeoni
Job title:	Consultant Neurologist
Organisation:	UCLH
Email address:	sara.simeoni@nhs.net
Professional organisation or society membership/affiliation:	GMC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	7548912

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	Yes – I perform it 2-3 times/month
	Have you used it or are you currently using it?	Yes
	– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	Few centres in the UK are performing this procedure
	– Is this procedure/technol	Yes, by Urologists

	ogy performed/used by clinicians in specialities other than your own? - If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	I am involved in patient selection for this procedure – I run a weekly uro-neurology clinic and I take part in a weekly MDT discussion within the uro-neurology department for the selection of patients for this treatment
I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). **X I have done clinical research on this procedure involving patients or healthy volunteers. (I have been doing with my colleagues an audit with regard to long-term follow up of patients that have undergone this treatment. An abstract has been sent for the INUS**	- Please indicate your research experience relating to this procedure (please choose one or more if relevant):	

Annual Congress 2022) I have published this research. I have had no involvement in research on this procedure. **Other (please comment)**		
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	It is a novel approach to treat this condition, compared to intermittent catheterisation and sacral nerve stimulation (SNS). It could be beneficial to reduce voiding dysfunction in people who would not be suitable for SNS. Botulinum toxin injection is however an established treatment option as it is licensed for many other indications and has been regularly used in current practice for many years. Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. **Definitely novel and of uncertain safety and efficacy. (it has been used for many years and our audit suggests it is safe and effective, however there are no many studies in literature about efficacy of this treatment)** The first in a new class of procedure.
4	Does this procedure/technology	It would mainly be used as an addition to existing standard of care

	have the potential to replace current standard care or would it be used as an addition to existing standard care?	

Current management

5	Please describe the current standard of care that is used in the NHS.	Sacral nerve stimulation, intermittent urethral catheterisation
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	no

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Improvement of voiding dysfunction,
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients not suitable for SNS
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	It could lead to fewer hospital visits (due to reduced episodes of urinary retention); it is a less invasive treatment and, if effective for the patient, would be able to avoid or postpone the need for sacral nerve stimulation.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	The procedure is likely to cost less – it can be carried out as an outpatient procedure every 3-4 months. There is no need for specific equipment – the procedure involves the injection of botulinum toxin into the urethral sphincter.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	It is likely to cost less than standard of care in terms of staff, equipment and care setting
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No changes to existing facilities are needed.
13	Is any specific training needed in order to	Training by a physician with expertise in performing the procedure should be recommended

	use the procedure/technology with respect to efficacy or safety?	

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	No major risks or adverse events have been observed in our practice. Possible adverse events of botulinum toxin injections include transient stress urinary incontinence (2%), ecchymosis, flu-like symptoms, muscle weakness, pain at the injection site, infection; possible other side effects of botulinum toxin are reported in the BNF Stress urinary incontinence - seems to be transient and solve when the effect of botulinum toxin wears off. Possible side effects of botulinum toxin reported in the BNF. No long term side effects have been reported
15	Please list the key efficacy outcomes for this procedure/technology?	Reduction in the post void residual volume, reduction in the need to perform intermittent catheterisation
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	No concerns but there are no randomised controlled trials in literature
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. **X A minority of hospitals, but at least 10 in the UK.** Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	We are planning to present an abstract (Long term observational follow up study of women with Fowler's Syndrome undergoing transperineal urethral sphincter botulinum toxin injections for Urinary Retention - authors: Sara Simeoni., Prasad Malladi, Collette Haslam, Mahreen Pakzad, Jalesh N Panicker) at the INUS Annual Congress 2022 in June 2022
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	no

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	10-15 patients
22	Are there any issues with the usability or practical aspects of the procedure/technology?	no
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your	no

	organisation or across the wider NHS?	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Limited number of studies in literature – we are collecting data and carrying out an audit in our department
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Post void residual measurement before and 3-4 weeks after the procedure Clinical global impression of change 3-4 weeks after the procedure SF Qualiveen score before and 3-4 weeks after the procedure USP, IPSS questionnaires before and 3-4 weeks after the procedure Need for intermittent self-catheterisation (number of times daily) before and 3-4 weeks after the procedure NRS pain during catheterisation before and 3-4 weeks after the procedure Adverse outcome measures: Stress urinary incontinence (7-10 days after the procedure)

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Indirect	Non specific – I received one honorarium from Merz to give a talk about transition pathways and sponsorship for attendance of an expert meeting from Merz – I have never used Merz products when I performed botulinum toxin injections to the urethral sphincter	**Oct 2021**	**Oct 2021**
Choose an item.			
Choose an item.			

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Print name:	**Sara Simeoni**
Dated:	**10/12/2021**