

**Justification Documentation for the Implementation of the Non Invasive Cuff Test into Clinical Practice at A.N. Other Hospital Urology Department**

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## 1. Executive Summary

### 1.1. Background

Lower urinary tract symptoms (LUTS) are a common complaint of the ageing male and there has been a rise in the number of men seeking advice regarding these symptoms.

Even though LUTS can be caused by a variety of urinary tract pathologies, men with voiding symptoms are often presumed to have bladder outlet obstruction (BOO) caused by an enlarged prostate.

In order to select those that would most benefit for surgical re-section of the prostate invasive Urodynamics is normally undertaken as this investigation has been shown to provide the greatest accuracy in diagnosing Bladder Outlet Obstruction. However invasive Urodynamics is expensive and carries a significant risk of morbidity and small risk of post test urinary tract infection. An alternative non-invasive test which can provide information on which men have bladder outlet obstruction and pre-screen those men which would actually benefit from invasive Urodynamics would be seen as an advantageous way forward.

The Non invasive cuff test is based on a technique which was first described in 1995 and involves placing an inflatable cuff around the shaft of the penis in a manner analogous to that used for blood pressure measurement [4]. It is totally non-invasive and carries none of the risks associated with invasive Urodynamics.

An evidence review of the non invasive cuff test machine was undertaken by the Centre for Evidence-based Purchasing and it concluded that the technique has significant potential. [6].

As part of the NHSTAC evaluation and implementation project the use of the non invasive cuff test has recently been evaluated at St. James University Hospital and the Bristol Urological institute. The results from the evaluation demonstrated that the investigation correctly identifies which men are obstructed and if used clinically in the appropriate diagnostic pathway it could result in a 10-25% reduction in the number of invasive Urodynamics studies being performed. Patient feedback was also collected as part of the evaluation comparing the penile cuff test non invasive cuff test with invasive Urodynamics. The feedback demonstrated that patients preferred the non invasive cuff test and felt far less embarrassed by the investigation.

### 1.2. List of options for implementing the non invasive cuff test into clinical service

- Do Nothing
- First line diagnosis at a GP health centre
- Adjunct to Uroflowmetry as part of initial secondary care LUTS clinics.
- Replacement for pressure flow studies (Invasive Urodynamics) in selected patients

**1.3. Preferred options**

The two preferred options are either ‘Do Nothing’, option 1 or use the non invasive cuff test as a replacement/screening tool for pressure flow or invasive Urodynamic studies - option 4.

**1.4. Benefits**

The potential benefits of introducing the non invasive cuff test as part of option 4 are as follows:

- It is a non-invasive diagnostic test
- Has an excellent positive predictive value even when compared to invasive Urodynamics.
- Avoids the risk of catheter related urinary tract sepsis
- Reduced embarrassment and discomfort compared to invasive Urodynamics.
- Can be integrated into current Urology outpatient services to provide a shorter diagnostic pathway and potentially reduce waiting times.
- Possible cost savings for the Urology Department by reducing the number of invasive Urodynamics in men with suspected BOO.

**1.5. Costs of preferred options**

**Table 1 Example Cumulative Cost savings achieved through the use of the non invasive cuff test over seven years**

Scenario	0% Reduction in Urodynamics (The Do nothing Option)	X% Reduction in Urodynamics (Worst Case)	Y% Reduction in Urodynamics (Most Likely)	Z% Reduction in Urodynamics (Best Case)
Cumulative cost savings over 7 years (-) denotes net loss	£0			

The costs identified in the table 1 above include those that can be achieved in both primary and secondary/tertiary care provided that the protocol in Appendix 4 is followed.

**1.6. Preferred Option**

[Summarise the preferred option based on benefits and costs.](#)

**1.7. Timescales and implementation pathway**

[Summarise the implementation pathway for the non invasive cuff test.](#)

## 2. Background

Lower urinary tract symptoms (LUTS) are a common complaint of the ageing male and there has been a rise in the number of men seeking advice regarding these symptoms probably as a result of health promotion campaigns raising awareness about prostate cancer. Voiding symptoms are a subset of LUTS experienced when passing urine and comprise a slow stream, hesitancy, intermittency, straining, terminal dribbling and a feeling of incomplete emptying [1]. The prevalence of voiding symptoms increases with age and in a population based survey published in 2006 it was shown to be highest for males aged 60 years and over (37.2%) [2].

In the majority of cases men with voiding symptoms are often presumed to have bladder outlet obstruction (BOO) resulting from an enlarged prostate. However, a subset of these patients will have poor bladder contractility as a cause for their symptoms.

Invasive Urodynamics or pressure flow studies offer the best accuracy for diagnosing BOO, but there is associated expense, morbidity and risk of urinary tract infection [3]. It is therefore clear that a simple non-invasive test would be an invaluable adjunct or in some cases replacement to invasive Urodynamics. The non invasive cuff test is one such investigation.

## 3. The Non Invasive Cuff Test

The non invasive cuff test is based on a technique that involves placing an inflatable cuff around the shaft of the penis in a manner analogous to that used for blood pressure measurement. During voiding the cuff is inflated to obstruct flow temporarily and then released to allow flow to resume. It theoretically allows a low flow rate due to obstruction to be distinguished from a low flow due to bladder muscle under-activity.

By plotting the non invasive cuff test pressure generated when flow is obstructed against maximum flow rate on a chart, patients can be categorised into obstructed, non-obstructed and equivocal groups [5].

As part of the NHSTAC evaluation and implementation project the use of the non invasive cuff test has recently been evaluated at St. James University Hospital and the Bristol Urological institute. The results from the evaluation demonstrated that the investigation correctly identifies which men are obstructed and if used clinically in the appropriate diagnostic pathway it could result in a 10-25% reduction in the number of invasive Urodynamics studies being performed. Patient feedback was also collected as part of the evaluation comparing the non invasive cuff test with invasive Urodynamics. The feedback demonstrated that patients preferred the non invasive cuff test and felt far less embarrassed by the investigation.

An evidence review of the non invasive cuff test has also been undertaken by the Centre for Evidence-based Purchasing and it concluded that the technique has significant potential [6].

#### 4. Options Appraisal

There are a number of different options that are potentially available for the implementation of the non invasive cuff test into the diagnosis of men with Bladder Outlet Obstruction. These include the following.

##### 4.1. Non financial options appraisal

###### 1. Option 1: Do Nothing

The non invasive cuff test is not used in the diagnosis of men with Bladder Outlet Obstruction. All men will continue to be referred for invasive Urodynamics or pressure flow studies as per the current diagnostic protocol.

###### 2. Option 2: First line diagnosis at a GP health centre

The cuff test would be used in male patients presenting at primary care with LUTS and testing would take place in GP surgeries, Health Centres and community hospitals. Compared to centralisation of services, this may duplicate costs as more than one non invasive cuff test may need to be purchased and the corresponding additional staff will need to be trained in the use of the system and the interpretation of the results it yields. A blanket approach to the use of the test will require a set-up with enough capacity to cope with the demand. Such an approach will yield a higher level of non-conclusive cuff results thus prompting further investigation.

Non-specialists would perform the patient assessment and consequently this may be less focused and thorough than would be the case in a specialist clinic. This raises the possibility that other causes of LUTS may be overlooked and that a potentially sinister aetiology may be missed. For example, it seems logical that a urologist's assessment of prostate size and normality may be more accurate than that of a GP. Measurement of post void residuals is another indicator of lower urinary tract function and one which is used in planning the management of patients with LUTS. This parameter is not assessed with non invasive cuff testing.

A single cuff test may also lead to inaccuracies as patients may find it difficult to void 'normally' in an unusual environment.

For the reasons described above this not considered to be a viable option.

###### 3. Option 3: Adjunct to Uroflowmetry

The cuff test would be used in male patients referred to secondary care with persistent bothersome LUTS after unsuccessful first line management in primary care. Testing would take place in specialised flow clinics and the cuff test would be performed after the patient has produced 2 to 3 free flows with assessment of post void residuals. This will ensure that the flow rate produced during the cuff is representative

and will make it less likely that results yielded are uninterpretable due to a low voided volume.

By examining the initial free flows, the use of the p non invasive cuff test could be more targeted to avoid an unnecessary waste of consumables and time. For example, cuff testing could be avoided in patients who consistently produce low voided volumes, as the results in such patients are likely to be uninterpretable. Patients who are medically unfit for surgical intervention may also be excluded from testing as the result of cuff testing is unlikely to alter the patient's management. Careful selection of patients should aim to reduce the number of equivocal cuff results.

Nursing staff who perform the flow clinics often find cuff testing more time consuming than a free flow. Consequently, the reduced capacity of a flow clinic undertaking cuffs must be taken into account.

For this reason this option is considered to be un-workable and the additional costs and facilities required to operate additional flow clinics do not warrant the introduction of the non invasive cuff test

4. Option 4.: Replacement for pressure flow studies (Invasive Urodynamics) in selected patients

The cuff test would be used in male patients who are being considered for surgical intervention to treat their LUTS. Patients will have been referred to secondary care with persistent bothersome LUTS and will have already been assessed. Patients are also likely to have received medical treatment for their symptoms with limited or no benefit.

Non invasive cuff testing would be aimed at diagnosing the presence of BOO in patients complaining of voiding symptoms when reviewed 3 to 6 months after initial presentation. It would therefore only be able to replace a proportion of the invasive studies which would normally be carried out, as routine invasive Urodynamics.

This option is considered a viable way forward for implementing the non invasive cuff test into clinical practice. It is estimated that the non invasive cuff test will replace invasive Urodynamics in 10-25% of men referred for this investigation.

**4.2. Preferred options**

The two preferred options are therefore either 'Do Nothing', option 1 or use the non invasive cuff test as a screening test for pressure flow studies, option 4.

**5. Financial Options appraisal**

A new non invasive cuff test device will need to be purchased and there will be associated capital charges associated with the purchase of the device.

It is estimated that it will take approximately **A** hours of staff time to perform each non invasive cuff test. This is considered a worst case scenario and the time to perform the test will be considerably less once the process has been fully integrated.

These factors have been included as part of the costing model shown in Appendices 1 to 3.

The financial appraisal for the two preferred options are compared and the results/breakdown shown in Appendices 1, 2 and 3. Example scenarios shown for option 4 are:

- a. **X** %of men are still referred for invasive Urodynamics (Worst Case Scenario).
- b. **Y** % of men are still referred for invasive Urodynamics (Most likely scenario).
- c. **Z** % of men are still referred for invasive Urodynamics (Best case scenario)

Please use the scenarios which best reflect those for the local hospital and input this data into the costing model spreadsheet.

The cumulative costs over seven years for each of the options in the scenarios described above are shown in Table 2.

**Table 2: Comparison of Costs for options 1 and 4**

	The Do Nothing Option Option 1	Different Scenarios for Option 4 – Cumulative Costs savings over seven years		
Scenario	0% Reduction in invasive Urodynamics	X% Reduction in Urodynamics (Worst Case)	Y% Reduction in Urodynamics (Most likely)	Z% Reduction in Urodynamics (Best Case)
Cumulative cost savings over 7 years (-) denotes net loss	£0			

The costs identified in the table 2 above include those that can be achieved in both primary and secondary/tertiary care provided that the protocol in Appendix 4 is followed.

## 6. Benefits of implementing non invasive cuff test into diagnostic pathway

The benefits of implementing the non invasive cuff test into the diagnostic pathway are shown in Table 3 below:

**Table 3: Potential benefits of non invasive cuff test compared to invasive Urodynamics**

	Benefits of CT3000 non-invasive bladder analysis
<b>Patients</b>	<ul style="list-style-type: none"> <li>• Non-invasive diagnostic test</li> <li>• Avoids the risk of catheter related urinary tract sepsis</li> <li>• Reduced embarrassment and discomfort compared to invasive Urodynamics – better patient dignity</li> <li>• Can be integrated into current Urology outpatient services to provide a shorter diagnostic pathway and potentially reduce waiting times</li> </ul>
<b>Clinical Staff</b>	<ul style="list-style-type: none"> <li>• Test quick and simple to perform</li> <li>• Minimal patient morbidity</li> <li>• Training requirements needed to use the CT3000 cuff machine are minimal</li> <li>• Test results are easy to interpret</li> <li>• May be used to assess patients who are difficult to catheterise</li> </ul>
<b>Service/Trust Managers</b>	<ul style="list-style-type: none"> <li>• Cost savings generated by reducing the number of invasive Urodynamic studies performed</li> <li>• A relatively inexpensive diagnostic test</li> <li>• Reduced post-investigation complications</li> <li>• Improved risk management</li> <li>• Greater productivity</li> <li>• Impact on waiting lists</li> <li>• Improved compliance with access targets</li> </ul>
<b>Influencers/Other key stakeholders</b>	<ul style="list-style-type: none"> <li>• Improved patient outcomes</li> <li>• Enhanced patient experience</li> <li>• Improved capacity and demand management</li> </ul>

## 7. The preferred option

Describe the preferred option in light of any potential cost savings and benefits for patients, staff etc as described in table 3.

## 8. Protocol for implementation

The protocol for proposed for implementing the non invasive cuff test into clinical practice is described in Appendix 4 and has been developed by the Bristol Urological Institute and St. James' University Hospital working in partnership.

## 9. Timescales and implementation pathway

Describe the local implementation pathway for integrating the non invasive cuff test into clinical practice.

## 10. Risks

Discuss the risks that may apply to using the non invasive cuff test.

## 11. References for main Business case

1. Abrams, P., et al., The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. *Neurourol Urodyn*, 2002. **21**(2): p. 167-78.
2. Irwin, D.E., et al., Population-based survey of urinary incontinence, overactive bladder, and other lower urinary tract symptoms in five countries: results of the EPIC study. *Eur Urol*, 2006. **50**(6): p. 1306-14; discussion 1314-5.
3. Porru, D., et al., Evaluation of morbidity of multi-channel pressure-flow studies. *Neurourol Urodyn*, 1999. **18**(6): p. 647-52.
4. McRae, L.P., M.R. Bottaccini, and D.M. Gleason, Noninvasive quantitative method for measuring isovolumetric bladder pressure and urethral resistance in the male: I. Experimental validation of the theory. *Neurourol Urodyn*, 1995. **14**(2): p. 101-14.
5. Griffiths, C.J., et al., A nomogram to classify men with lower urinary tract symptoms using urine flow and noninvasive measurement of bladder pressure. *J Urol*, 2005. **174**(4 Pt 1): p. 1323-6; discussion 1326; author reply 1326.
6. Evidence review Mediplus CT3000 cuff machine for diagnosis of bladder outlet obstruction; CEP 07010; Centre for Evidenced Based Purchasing; Purchasing and Supplied Agency.

## 12. References for data in Appendices 1-3 transferred from costing model.

Invasive urodynamic studies are well tolerated by the patients and associated with a low risk of urinary tract infection; Logadottir Y, Dahlstrand C, Fall M, Knutson Pecker R; *Scand J Urol Nephrol*. 2001 Dec; 35(6):459-62.

Patient experience with a urodynamic study: a prospective study in 208 patients; Ku JH, Kim SW, Kim HH, Paick JS, Son H, Oh SJ; *J Urol*. 2004 Jun;171(6 Pt 1):2307-10.

13. **Appendix 1 Comparison of the do nothing option and using the non invasive cuff test as a Replacement for pressure flow studies in selected patients (X % Reduction in Urodynamics studies)**  
Copy across the results from the modelling spreadsheet demonstrating costs implementing the non invasive cuff test into clinical practice with a reduction in invasive Urodynamics studies by X%

14. **Appendix 2 Comparison of the do nothing option and using the non invasive cuff test as a Replacement for pressure flow studies in selected patients (12% Reduction in Urodynamics studies)**

Copy across the results from the modelling spreadsheet demonstrating costs implementing the non invasive cuff test into clinical practice with a reduction in invasive Urodynamics studies by Y%

15. **Appendix 3 Comparison of the do nothing option and using the non invasive cuff test as a Replacement for pressure flow studies in selected patients (15% Reduction I Urodynamics studies)**

Copy across the results from the modelling spreadsheet demonstrating costs implementing the non invasive cuff test unit into clinical practice with a reduction in invasive Urodynamics studies by Z%

16. Appendix 4 Clinical pathway for the non invasive cuff test

