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1 EXECUTIVE SUMMARY

The S-Cath™ is a supra-pubic catheter introduction set that is manufactured by Mediplus Ltd. The system helps to reduce the number of complications associated with supra-pubic catheterisation, is safer for patients and can produce cost savings for NHS Trusts. The transfer of the procedure from an inpatient to an outpatient setting can benefit patients and can dramatically reduce the associated length of stay.

This Briefing Pack looks at the S-Cath™ System, how it works, the evidence available, the clinical and system benefits and the financial case. It also presents the findings of two trusts where the technology has been used.

Findings from the contributing Trusts, detailed in Section 10, include:

- the technology is safe in use, especially for more junior staff, and that it produces a clean and neat incision compared to the previously used system. Patients have responded positively to the technology and are, on the whole, pleased with the results.
- the Trust has seen a reduced length of stay, reduced complications, a reduction in healthcare associated infections and has benefitted from realising savings.

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INTRODUCTION

The NHS Technology Adoption Centre (NTAC) has been commissioned by the Department of Health to formulate this Briefing Pack, which is a summary of the information provided to the Department of Health by Mediplus Ltd. The technology has been identified by the Innovative Technology Adoption Procurement Programme (iTAPP) as being significant to the NHS Quality, Innovation, Productivity and Prevention (QIPP) agenda and its benefits have been explored at a local, regional or national level in consideration of the benefit of a wider health economy. It is recognised that technology is an enabler of the step-change innovation needed to make the necessary and significant impact and improvements in healthcare service delivery.

This technology Briefing Pack is designed to provide comprehensive information and data required to demonstrate how the S-Cath™ Supra-Pubic Foley Catheter Introduction Set can be introduced into local healthcare services to yield real, significant and sustainable benefits to its patients and the healthcare system.

As part of this work, NTAC has consulted with Sheffield Teaching Hospitals NHS Foundation Trust and Taunton and Somerset NHS Foundation Trust and feedback from these Trusts is included in Section 10.

THE TECHNOLOGY AND PRODUCT

The S-Cath™ is a Supra-pubic Foley Catheter introduction set that has been developed by Mediplus Ltd. It offers a safe and cost effective method to insert a supra-pubic urinary catheter.

The S-Cath™ employs the ‘Seldinger Technique’, a catheter insertion technique that uses a guide wire, dilator and peelable sheath and is well known for placement of central venous catheters. The key difference when using this technique for Supra-pubic catheter insertion is that a novel guide wire has to be used as traditional guide wires kink when attempting to progress the dilator over them due to the tough, fibrous tissue surrounding the bladder.

The S-Cath™ pack contains a Foley Catheter with integrated balloon, a scalpel, two syringes, a dilator/peelable sheath and a novel, patented, three-stage guide wire.

The S-Cath™ is made and supplied by Mediplus Ltd, was CE marked in 2005 and is a class IIb device.
There are two groups of patients who can benefit from this technology:

1. Patients who have long term Foley catheters to drain urine from the bladder
2. Patients in urinary retention where urethral catheterisation is difficult or complex

Patients in group one usually start treatment with an indwelling urethral catheter. Over time the urethra may become damaged so supra-pubic catheterisation (SPC) becomes indicated. Many patients may also prefer SPC because it is seen as more hygienic, is removed from the genital area where infection has an easy passage to the bladder via a urethral catheter, is easier to change and less embarrassing for the patient and relatives. Long term urethral catheterisation may also cause pressure areas to occur and sexual activity can be inhibited. SPC is also electively indicated in patients unable to tolerate a long-term urethral catheter due to bladder spasm/ discomfort/ bypassing, and in patients with neurological diseases such as multiple sclerosis and spina bifida.

Patients in group two undergo supra-pubic catheterisation as a treatment for the acute retention of urine. Supra-pubic catheterisation (SPC) is a surgical procedure traditionally performed in the operating theatre and is routinely used in urology to decompress the bladder in patients who present as an emergency with bladder outlet obstruction (BOO) and where a urethral catheterisation is unsuccessful, or undesirable, because of an enlarged prostate or urethral stricture. Supra-pubic catheterisation alleviates this situation directly and the S-Cath™ does this in a safe and cost effective way.

There appears to be no accurate data on the current number of SPC procedures carried out by the NHS. However, Mediplus Ltd estimate the number of SPC procedures carried out by the NHS to be between 50,000 and 80,000 per year. In addition to the cases of SPC insertion above there is also the potential to have an impact upon the 2% mortality and 10% morbidity historically associated with the traditional SPC procedure.
TARGET ADOPTING SITES
All NHS hospitals and facilities where supra-pubic insertion of Foley catheters is undertaken. This will normally be limited to Acute Hospital Trusts but may also include Community Hospitals.

5 THE EVIDENCE

In the recent past, the Lawrence Add-A-Cath has been the most common device for introducing a supra-pubic catheter. However, accurate placement is difficult as there is no guide wire.

NTAC worked with three NHS Trusts to implement this technology and produced a ‘How to, why to Guide’ for the S-Cath™. The guide includes sections on an introduction to the technology, the evidence base, benefits v barriers, the implementation project, procurement, and policy and business case. Further details of this project can be found on the NTAC website here.

Other useful references detailing the evidence have been supplied by Mediplus:

- Supra-pubic catheter insertions is an Outpatient procedure: cost savings resultant on closing an audit loop. BJU Int volume 103 issue 5, p640 – 644, March 2009

The technology can affect key policy areas and performance, from its impact on out of hours care and compliance with access targets/cancelled operations, to important patient safety and satisfaction.

For a wider explanation of how this technology can affect local policy, see the Policy section of NTAC How to Why to guide here.
6 RELEVANCE TO NHS IMPROVEMENT AREAS

THE TECHNOLOGY ALIGNS WITH THE FOLLOWING DOMAINS WITHIN THE NHS OUTCOMES FRAMEWORK:

Domain 2: Enhancing quality of life for people with long-term conditions
Domain 3: Helping people to recover from episodes of ill health or following injury
Domain 4: Ensuring that people have a positive experience of care
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm

This product may be suitable for notification to the NICE Medical Technologies Evaluation Programme (MTEP). Technologies which are notified to MTEP and selected for guidance development are shown at www.nice.org.uk/guidance/mt/indevelopment/index.jsp which is updated regularly.

7 THE BENEFITS

The Seldinger Supra-pubic Catheter Kit, S-Cath™, offers a wide range of benefits to patients, clinical staff and trust managers – including lower risk of trauma and complication, improved comfort for patients, reduced demand on theatre capacity and lower overall hospital costs.

Key benefits of the technology are:

- **Greater control and accuracy** - a high degree of control allows accurate placement
- **Reduced risk** - low risk of trauma and tissue damage for the patient. The catheter rarely needs to be inserted under general anaesthetic - reducing the associated risks in an elderly and at risk group of patients
- **Greater confidence** - the bladder may be located with an 18G hypodermic needle, giving more confidence in inserting the trocar into the bladder, as the track has already been secured by the guide wire
- **Improved insertion and removal** - the safety guide wire improves insertion and removal, guaranteeing insertion of the trocar along the anaesthetised track
- **Reduced urethral catheter associated infections** – urinary infections caused as a direct result of urethral catheterisation will be reduced
- **Improved patient comfort** – use of SPC improves patient comfort and it relatively simple to manage
- **Reduces costs and hospital stay** - the procedure rarely needs to be undertaken as an inpatient, under general anaesthetic or in an operating theatre - reducing hospital stay for the patient from an average of 2.3 days to 27 minutes
- **Frees up consultants time and enhances out of hours services** - enables non-consultant grade clinical staff and suitably trained nurse practitioners to perform the procedure, thereby freeing up consultant time and allowing suitably trained staff to safely insert catheters during out of hours. In some hospitals, the procedure can be moved from Theatre to Outpatients.

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FINANCIAL CASE

Financial analysis has indicated that adoption of the technology would be expected to offer significant financial benefits to the NHS. The full financial analysis can be viewed on the NTAC web site or by contacting Mediplus Ltd.

STAKEHOLDER GROUP

The main stakeholder groups for this technology are all those staff members who work within Urology. It is also important when implementing any change that all staff who work in the patient pathway are involved. For example, this technology could have an impact upon nursing staff who could be trained to insert the S-Cath™ as part of an extended role.

It is also very useful to involve and consult patient groups and their representation should be sought on any local implementation teams.

There is also a requirement for staff to understand the technology, its underpinning theory and how to safely use it. Training is initially available from the company and this is then cascaded. Alternatively, training in the Seldinger Technique could be sourced within a trust as the technique is widely used for central venous catheter insertion.

ADOPTION CONSIDERATIONS

There are a number of adoption considerations that need to be taken into account when considering the use of this technology:

- Where Urology departments continue to carry out the procedure in the operating room, they will not achieve all the potential savings available.
- Silo budgeting, where the costs of the technology are paid by one budget whilst the benefits are seen in another, will need to be overcome.
- Experience at hospitals that have adopted the S-Cath™ indicates that there is minimal clinical risk. Indeed, the S-Cath™ reduces clinical risk associated with SPC.
- Adoption drives higher short term costs for medium or longer term benefits. The financial case would indicate there are financial benefits to be seen when using the S-Cath™. However the initial outlay for the product is higher and the project benefits may take a little time to realise.
- Deciding if the SPC procedure will remain in theatre or transferred to outpatients.
- Adoption may require a significant change in clinical practice. A decision will need to be made as to whether nursing staff should be trained to carry out the S-Cath™ procedure.
During the production of the briefing document, opinion was sought from two NHS Trusts, Sheffield Teaching Hospitals NHS Foundation Trust and Taunton and Somerset NHS Foundation Trust, who have used or who currently use this technology.

**Sheffield Teaching Hospitals NHS Foundation Trust** has used the S-Cath™ for a number of years and it is fully embedded within their routine service. They use the system for patients who have chronic retention of urine, neurological problems or who require emergency catheterisation due to a bladder outlet obstruction.

At present doctors undertake supra-pubic catheterisation at this Trust and there are currently no plans to extend this to other groups such as specialist nurses.

The Trust have found that the technology is safe in use, especially for more junior staff, and that it produces a clean and neat incision compared to the previously used system. Patients have responded positively to the technology and are, on the whole, pleased with the results.

Although no specific improvement data has been collected, the reported clinical and financial benefits have been realised at this Trust. The specific benefits noted are improved patient safety, improved patient acceptability and the reduced requirement for more complex training of juniors.

**Taunton and Somerset NHS Foundation Trust** have used this product since 2007 and it is fully implemented and embedded within their service. They currently use the product for anybody requiring a supra-pubic catheter. Specifically, this includes patients in acute retention of urine, neurological patients and those suffering with a bladder outlet obstruction.

They currently run two specific supra-pubic catheter clinics per month in outpatients. These clinics are staffed by a specialist nurse and a care assistant and they see approximately five patients per clinic. The implementation of these clinics has helped to reduce the patient’s length of stay from up to three days down to an average of 37 minutes.

Initially the Speciality Urology Nurse was initially trained to perform the procedure by the Consultant Urologist. Following many years of experience, the Specialist Nurse now undertakes the training of medical staff in the procedure.

The Trust has seen a reduced length of stay, reduced complications, a reduction in healthcare associated infections and has benefitted from realising savings. Angus MacCormick, Specialist Urology Nurse at the Trust says, “The main thing is it gives you more confidence in knowing that there is a reduction in serious complications”.
ACKNOWLEDGEMENTS

NTAC would like to thank Professor Chris Chapple (Consultant Urologist, Sheffield Teaching Hospitals NHS Foundation Trust) and Angus MacCormick (Specialist Urology Nurse, Taunton and Somerset NHS Foundation Trust) for their clinical input.

NTAC SUPPORT

NTAC have developed a Generic Adoption Process (GAP), which offers a stepped approach to successful adoption, with all of the necessary tools and resources available. For access, visit the NTAC website - www.ntac.nhs.uk which may be of help if you wish to adopt this technology.

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