

# Newsletter

## A new start

In April 2005, the Bristol Urological Institute (BUI) was awarded £500,000 from the Department of Health, through the Health Technology Devices (HTD) programme, to set up the BioMed Healthcare Technology Cooperative (HTC) with 10 founding partners from government, industry and a patient user group. This BioMed HTC is a national collaboration, which brings together different organisations, groups or individuals interested in improving the health and quality of life of people with severe urinary dysfunction. The BioMed Centre, based in the BUI, acts as the focus for this activity. Meet the team and read why the HTC is needed. Whether you are a member of the public, health professional, researcher or industrialist, your involvement can make a difference, so please complete and return the enclosed BioMed Membership slip.

Towards the end of last year, two of the BioMed HTC partners, Professor Roger Feneley, founder of the BioMed Centre and Chairman of the BioMed HTC, and Dr Diana Hodgins

MBE, Managing Director of ETB Ltd., were awarded the degree of Honorary Doctor of Science. This accolade is in recognition of significant contributions in their field.

October 19, 2005 was a milestone for the Bristol Urological Institute. The new building was officially opened by HRH the Duchess of Gloucester. Commissioning of the BioMed Centre microbiology laboratories was also completed around this time and Dr Nicola Morris reports on the services that are now available.

We hope you enjoy our first BioMed HTC Newsletter. We welcome your feedback and encourage contributions that support our aims. So, if you have something you want to tell people, get writing! Please make your contributions short and concise and send them to Janice Hillier at the BioMed Centre. All articles are subject to editorial review and approval.

For copies of this Newsletter and for more information on the BioMed HTC please visit the website at [www.biomedhtc.org.uk](http://www.biomedhtc.org.uk)



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# Why do we need a BioMed Healthcare Technology Cooperative?



Readers will appreciate how little has changed in palliative care for patients with urinary dysfunction. In a highly technological

age we are still reliant on variations of the Foley catheter first introduced over 70 years ago, or on some type of absorbent pad, to address this condition.

One reason for so little progress is that the condition is embarrassing and thus not readily open to debate. Personal stories illustrating this point abound. In his recently released autobiography, Graham Webb, creator and owner of Wella, the third largest hair products company in the US, told of his undiagnosed spina bifida that left him with 'funny feet' and urinary incontinence. He was told by the experts that his problem was 'psychological' and was given endless therapies, all of them, not unsurprisingly, unsuccessful. For 32 years he wore pads in secret and even as a highly successful businessman suffered the indignity of 'discovery' in airport searches. That this did not deter him is a reflection of the strength of the human spirit, but that it happened at all is an indictment of our society.

Patients should be able to look to health and social care professionals to be advocates on their behalf. Generally, however, little is done to

meet their needs. The title of an audit published by the Royal College of Physicians in November 2005 says it all, "Inadequate and incomplete - continence care in the UK". It highlights the failure of health and social care services to meet the National Framework for older people's requirement for integrated continence services, noting the lack of policy in many hospitals and care homes, and the failure of professionals to adequately document continence care.

So, can industry provide the solution? The answer so far is 'no' since the perceived gains do not outweigh the calculated costs. The information needed to understand the market is sparse and the way in which healthcare needs are managed positively discriminates against technological advancement in this field.

However, to fully appreciate the reasons for the lack of progress, we must actually acknowledge the sheer attractiveness of the Foley catheter. Cheap and simple, it can be used almost universally. For some it offers a degree of freedom and control that alternatives do not. But, with over 70% of users experiencing complications, it remains an unsatisfactory solution in this day and age. Infection and encrustation leading to blockage and leakage are commonplace, and research and development efforts to date have rightly focused on addressing these issues. A number of new catheter designs are in prototype and clinical

trials in progress, bringing hope of improvement one step closer.

But much more needs to be done.

The BioMed Healthcare Technology Cooperative (HTC) aims to accelerate this development and to use new technologies, devices and procedures to improve health and quality of life.

*"By bringing together patients and carers, health professionals, industry, researchers, charities and government organisations we can focus efforts where they are most needed"*

All our partners are involved and have a say in how new products are developed. For patients and their carers, health and lifestyle needs are paramount. Healthcare professionals need to be confident that the advantages of using a new technology are based on sound scientific and clinical evidence. Research can provide the science underpinning new technologies that may revolutionise device design. Industry can then develop products with confidence in market potential and financial return.

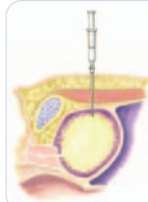
The ingredients are there, it is in the recipe that success will be found.

**Adele Long**, Director of BioMed HTC

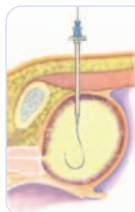
# A less traumatic way of introducing Suprapubic Urinary Catheters

Although generally a safe procedure, initial insertion of a suprapubic catheter can carry a small risk of bowel puncture particularly in patients with a contracted bladder. Most can be done under local anaesthetic (LA), but potentially difficult cases are usually done under general anaesthetic (GA). To increase safety and to reduce the number of insertions done under GA, Mediplus Ltd. and the BioMed Centre have developed a new catheter insertion kit that overcomes many of the disadvantages of other methods.

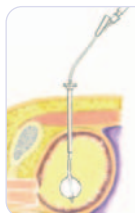
By using the Seldinger technique much of the guesswork, and thus danger, of introducing the catheter with a trocar type device has been removed. The three stage guide wire process gives the surgeon a superior level of control by ensuring that the catheter introducer is accurately inserted, so reducing the risk of bowel perforation and bladder transfixation. The Introducer Set thus offers increased safety, superior ease of use and, in some circumstances, can reduce the number of insertions carried out under GA, which in turn improves patient safety, comfort and convenience and potentially reduces the cost of the procedure by approximately £1,000 per patient.



The anaesthetised tract is created in the normal way, however the needle is left in the patient...



...the guide wire is then inserted through the needle into the bladder. It will curl up on the posterior wall preventing the trocar from being pushed in too far. The needle can then be removed...



...the trocar is then inserted in a controlled manner that causes less anxiety with the user and ensures it enters the bladder.

*"By first inserting a guide-wire into the bladder, one can be confident that the trocar and cannula will follow this and thus the catheter will be passed correctly into the fundus of the bladder"*

Professor Roger Feneley, Emeritus Consultant Urological Surgeon, BUI, Bristol

One of the other advantages of the kit is the design of catheter used. A considerable amount of effort has gone into developing a low profile all silicone catheter, which, in the opinion of Mr. Sunil Mather, Specialist Registrar, Royal Cornwall Hospital, Truro "is much better for the patient as it cuffs less, and thus causes less discomfort for the patient". It also has benefits when changing a patient's catheter as it is easier to introduce.

Mediplus is working with a number of centres throughout Europe on further proving the benefits of the Silicone Suprapubic Foley Catheter with Introducer Set (Order Code 5754) and would welcome the opportunity to work with you and your colleagues. We are in the process of making the catheter available on prescription as a result of the feedback and demand we have received.

**James Urie**, Technical Director, Mediplus Ltd  
[www.mediplus.co.uk](http://www.mediplus.co.uk)

## Fact Sheets for Industry

The BioMed Centre's services to industry are being promoted through BioMed HTC's partner, the BITECIC. A series of fact sheets have been published to advertise the microbiology testing, clinical trials and educational services. For further information, contact John Egan on **0113 284 0225**.



## Encrustation and catheter blockage: its not all in the pH

About half of people who use long-term catheters suffer from encrustation and blockage. We know that a bacterium, *Proteus mirabilis*, is the main culprit and we understand how it does it. Put simply, the organism causes crystals to form in the urine, these become tangled in a biofilm of bacteria that sticks to the catheter and this eventually leads to blockage. These crystals form in urine above a certain pH, known as the nucleation pH.

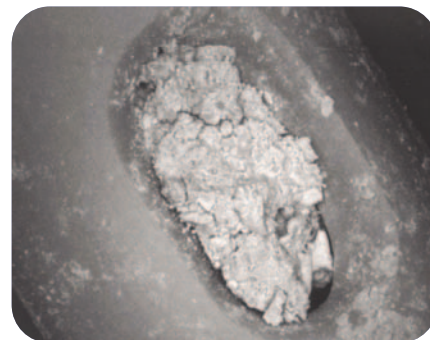
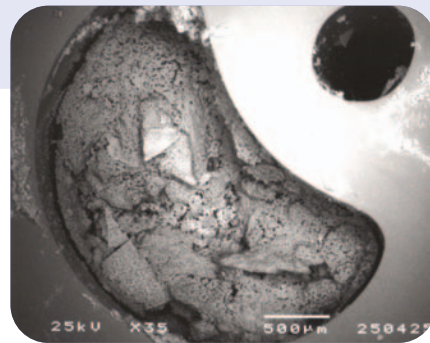
What we didn't know was, why the rate of catheter blockage varied between individuals, whether or not it was possible to have *Proteus* infection but not catheter blockage, or if catheter users with the worst encrustation had more alkaline urine or a lower nucleation pH than those that rarely blocked or blocked more slowly?

To answer these questions, we conducted a study on twenty patients with long-term catheters and whose urine was infected with *Proteus*, and followed them up for about 12 weeks.

Weekly urine samples were analysed for bacteria, voiding pH and nucleation pH. The length of time catheters took to block was noted and the catheters were collected for examination.

We found that while some catheters blocked within just 2 days, others were still draining freely after 10 weeks. The people whose catheters took longer to block tended to have a higher nucleation pH than those whose catheters blocked rapidly, but there was no difference in urinary pH. One patient had such a high nucleation pH that she didn't block her catheter even though she had very alkaline urine. Other people had very frequent blockage even though they didn't even have alkaline urine, but because they had very low values of nucleation pH.

The study concluded that the rate of catheter encrustation in patients colonized with *Proteus* varies according to the difference between the pH of the voided urine and the nucleation pH. It appears that nucleation pH is not fixed



for an individual and so could possibly be manipulated with treatment. If the value of the nucleation pH could be raised, this would hopefully slow down the encrustation process so catheters would take longer to block.

**Reference:** Sunil Mathur, Marc TE Suller, David J Stickler and Roger CL Feneley. Prospective study of individuals with long-term urinary catheters colonized with *Proteus* species. *BJU Int* 2006; **97**: 121-8

**Sunil Mather**, Research Fellow, BioMed Centre

## Catheter design with patients in mind: a new clinical study



Patients with long term indwelling catheters are, like everyone else, a mixed bunch. Yet, often the choice of device or product for managing continence is limited or doesn't meet a patient's individual needs. This is a problem for everyone, from the patient using the product to the company that supplies it. The BioMed Centre has been successful in obtaining a research grant of £29,600 from the Wright Bequest to undertake a study to characterise the needs and capabilities of patients with intractable urinary incontinence so that devices can be designed and health professionals can prescribe the product that best meets patient's (and their carer's) needs.

If you are a patient, carer or healthcare professional and would be interested in helping us with this study please contact **Azhar Khan at the BioMed Centre**.

## The BioMed Centre Microbiology Laboratory

The BioMed Centre Microbiology Laboratory became fully operational on the 1 October 2005 prior to the official opening of the BUI by the Duchess of Gloucester.

Funding from the Wolfson Foundation has provided a fully equipped, purpose built microbiology laboratory enabling research into the problems associated with long-term catheterisation. Basic bacteriological analysis of catheters and urine samples taken from patients during routine clinics or clinical trials can be processed rapidly to allow the identification of bacteria that are responsible for causing infection and subsequent complications.

In addition to the basic bacteriology, the laboratory uses glass models of the catheterised bladder to simulate encrustation and blockage. The bladder model protocols, developed by Dr David Stickler, Director of Research in the BioMed Centre, provide an essential proof of principle test in the design and development of new devices and treatment regimes. Examples of tests performed in the bladder model include:

- Comparison of the abilities of currently available catheters to resist encrustation;
- Evaluation of novel catheter designs;
- Assessment of the efficacy of novel catheter coatings in inhibiting the encrustation process;



- Testing the effect of manual and automatic valves on the catheter encrustation process;
- Development and assessment of the value of novel strategies for inhibiting crystalline biofilm formation on catheters.

Any company or research group interested in using the services of the laboratory, please contact Dr Nora Sabbuba on **0117 959 5540**.

**Dr Nicola Morris**, Senior Research Manager, BioMed Centre

## Catheters top topic in Engineering Challenge Conference

The BioMed Team's session on urinary catheters was voted the most valuable by delegates at the fifth Engineering Challenge conference, hosted by the Institution of Mechanical Engineers on 30 Nov - 1 December 2005. The meeting brings together a multidisciplinary audience from clinical, scientific and industrial fields to address the demand for improved technologies for diagnosing, curing and managing incontinence.

Dr David Stickler, Director of Research at the BioMed Centre, and his research team Dr Nicola Morris, Dr Nora Sabbuba, Mr Sunil Mathur, Gareth Williams and Sheridan Morgan gave presentations on the most recent findings on the causes and modulation of catheter encrustation. Dr Siu Man Lee from the University of Durham talked about the valve system developed during the NuTap project, which can aid automatic emptying of the bladder via a suprapubic catheter.

# Catheter Management and Professionals' Education for the Future

That the health professional who undertakes catheter care is fully trained and competent to offer the best advice and treatment should go without saying, but is it true? We decided to put this to the test and, with the help and cooperation of fellow professionals, conducted an audit to assess the standard of care given to patients with indwelling catheters by district nurses in the Cardiff and Vale community. The purpose was to identify any skills gaps that could be addressed with some form of training and/or the introduction of robust standardised procedures.

The standards against which the audit was carried out were those set out in the NICE Guidelines Infection Control 2003, EPIC guidelines for infection control and the Essence of Care 2003/ Fundamentals of Care 2004 issued by the Department of Health and Welsh Assembly Government.

The audit looked at knowledge of insertion and infection control, rationale for insertion, management and interventions, documentation with regards to legal requirements and patient information. It also sought to identify the number of nurses competent to undertake urinary

catheterisation in line with the Knowledge and Skills Framework and to highlight any staff training needs that may be required.

The first audit, in 2003, showed a disappointingly high degree of variability in record keeping and large differences in deemed levels of competence between nurses. To address the situation, a compulsory training programme was introduced, along with a standardised Catheter Care Pathway form for recording catheter related episodes. The endeavours paid off, a re-audit the following year showed huge improvements. This was accompanied by a reduction in catheter associated problems and in the frequency and level of discomfort experienced by patients due to their catheter.

To ensure standards are maintained, we intend to conduct an annual audit, a 3 yearly clinical review of catheter skills and to establish a competence based education and assessment in catheter care for all health professionals who are responsible for continence care in the community.

**Ann Yates**, Director of Continence Services, Cardiff and Vales NHS Trust



## Community health professionals discuss catheter care

Over 40 delegates, including continence advisors, clinical nurse specialists, specialist urology nurses and care home managers, attended a study day entitled Catheter Care in the Community held in the BUI on 19 January 2006. A broad spectrum of topics was presented by

experts from the south west region, the most popular being one on catheter encrustation and bladder calculi. The event, organised by Sister Linda Fracyzk and chaired by Mr Sunil Mathur, was the first BioMed Centre study day and it received much positive feedback from the delegates.

## A Royal Visit

On Wednesday 19 October 2005 HRH the Duchess of Gloucester officially opened the Bristol Urological Institute building. Her host for the tour was Professor Paul Abrams, Director of the BUI.

Her Royal Highness was shown the BioMed Centre clinic and laboratories and was introduced to the Team.

In the Roger Feneley Seminar Room she unveiled a plaque, kindly donated by local film company Sounds Commercial, commemorating her visit.

On display for the first time was a newly commissioned installation depicting hot air balloons floating above the Bristol suspension bridge, each one marked with the name of a

donor for the building. We are very grateful to all who made this possible.

This ceremony indicated the importance of the BUI as one of the foremost urological education and research centres in the UK. In 13 years it has grown from a single desk in a shared office to a four storey state-of-the-art building with excellent clinical, laboratory and education facilities.



## Honourary Doctorates for BioMed HTC partners

Two of BioMed HTC's key players have been awarded Honourary Doctor of Science degrees.

Professor Roger Feneley, Chairman BioMed HTC, was awarded his degree by the University of the West of England on 24 November 2005. The ceremony, for the conferment of awards from the Faculty of Applied Sciences, was held in Bristol Cathedral and a well-deserved oration was delivered by Dr David Shaw.



Roger's grandfather was a Wesleyan Methodist minister who sailed to Africa in 1887 as a missionary, witnessing devastating cruelty, sickness and privation among the people. His belief in the right of all people to justice and decency drove him forward. Dr Shaw felt certain that Roger, as the grandson of this missionary, was driven by similar goals and ideals when he entered the Medical School at Cambridge University in 1952.

Dr Shaw spoke of the outstanding contribution Roger has made to medicine, "[Roger] has improved dramatically the quality of life of so many people in this area due to his skill as a urological surgeon and his determination to research the causes and treatments of urological diseases. In 1998 he founded the BioMed Centre within the Bristol Urological Institute, with the objective of improving the care of patients with intractable urinary incontinence. [...] Throughout his working life, Roger has served the medical profession with distinction...".



Dr Diana Hodgins, Managing Director ETB, was awarded her degree by the University of Hertfordshire on 16th November 2005. The ceremony for the conferment of awards from the Faculty of Engineering and Information Sciences was held in St. Albans Cathedral, and the Pro Vice Chancellor, Dr Denis Filer, conferred the award.

Diana wanted to become an 'inventor' from a very young age and has spent the last 15 years encouraging small companies across the UK to innovate, particularly in the medical sector.

# Meet the Team

The BioMed Centre provides several services to industry, academia and the NHS in addition to having its own collaborative research programme. Since June 2005 the Centre has been headed up by the Director of the BioMed HTC, Adele Long. Running the microbiology research programme and device testing is our very experienced team of microbiologists, Dr David Stickler, Research Director, Dr Nicola Morris, Research Manager and Dr Nora Sabbuba, Senior Research Assistant. Mr Anthony Timoney and Mr Marcus Drake, both Consultant Urological Surgeons at Southmead Hospital, lead the clinical team and a new device design and engineering programme. They are supported by a Clinical Advisory Group comprising medical and nursing staff. Mr Azhar Khan has recently been appointed as Clinical Research Fellow and he will



be involved in a number of clinical research projects such as testing a new sensor for conducting non invasive urodynamics, and new urinary catheter coatings and designs. All staff are ably supported by Janice Hillier, our team Administrator, and Karen Evely who looks after our website and donations.

The BioMed Healthcare Technology Cooperative, through its partnership and infrastructure aims to accelerate the production and use of new devices, technologies and procedures designed to improve the health and quality of life of patients with severe urinary incontinence. These are usually patients

for whom drugs or surgery alone do not offer adequate continence management. The Chairman of the BioMed HTC is Professor Roger Feneley and the Director is Adele Long. The founding partners are the BUI, HealthTecKTN (formerly the Medical Devices Faraday Partnership), MediWales, PromoCon, E-Tech Ltd, ETB Ltd, Mediplus Ltd, Ranier Technology Ltd, Coloplast Ltd, Limbs and Things Ltd and Principality Medical Ltd. A number of collaborations with academia and industry have already been formed, and we are seeking to partner and support individuals and groups, throughout the UK and worldwide, who share our aims.

## Launch of the BioMed HTC website

Visit our new website [www.biomedhtc.org.uk](http://www.biomedhtc.org.uk) On it you will find information on research and innovation, our latest news, notice of events, job vacancies and much more.



### *“Advancing Continence Products and Devices in the NHS”*

**Health Technology KTN Urology Special Interest Group Conference  
Friday 5 May, Southmead Hospital, Bristol**

Keynote speakers: Dr Alan Cottenden, Professor Kathryn Getliffe

Further information will be posted on the [website www.biomedhtc.org.uk](http://www.biomedhtc.org.uk) or go direct to <http://www.healthtechnologyportal.org.uk/> (you will need to register to enter this site).

#### **Contact us at:**

The BioMed Centre, Bristol  
Urological institute, Southmead  
Hospital Bristol BS10 5NB

T: 0117 959 5690

F: 0117 950 2229

E: [biomed@bui.ac.uk](mailto:biomed@bui.ac.uk)