

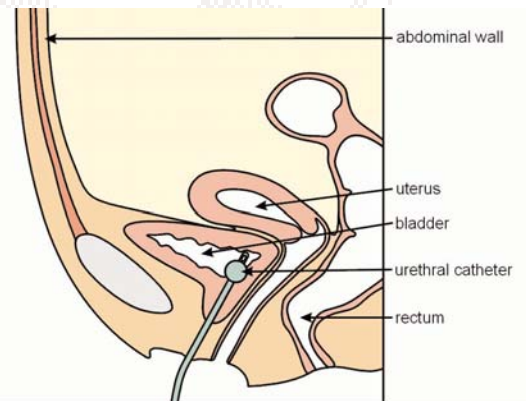
BITEOutcomes: Urological Clinical Trials

BioMed HTC, through its unique partnership and infrastructure, aims to accelerate the production of new devices, technologies and procedures designed to improve the health and quality of life of patients with urinary incontinence.

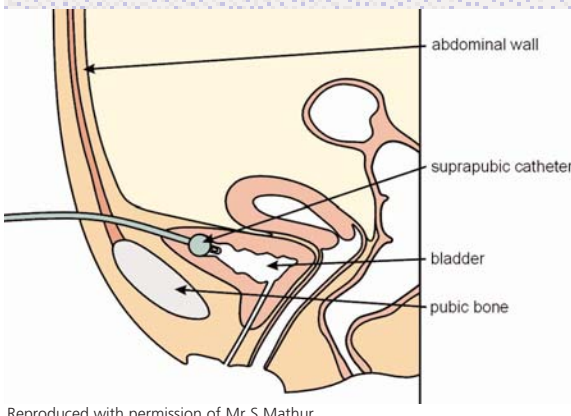
An estimated 3 million people in the UK suffer from some loss of urinary control and the cost of management to the NHS amounts to almost £500 million per annum¹. This distressing, socially unacceptable problem affects many elderly and young disabled people, restricting activities of daily living. It has become a common reason for many older people to seek residential care, and up to 40% of this group have continence control issues. The prevalence of urinary incontinence increases with age. Demographic trends indicate that people are living longer with those over 80 the fastest growing section of the population².

Methods of restoring bladder control vary according to the cause and severity of the condition and complicating factors. Despite a high level of morbidity, long-term catheterisation (LTC) is a common form of management for many people disabled by conditions such as strokes, spina bifida, multiple sclerosis and spinal injuries. These individuals are fitted with a Foley catheter, a tube designed to passively drain the bladder, avoiding the need for normal bladder and urinary sphincter function.

Catheters can be inserted into the bladder through the urethra, or suprapubically through a surgical tract in the anterior abdominal wall. The design of the urinary catheter has not changed fundamentally since 1937 and its shortcomings have still to be successfully addressed.



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LTC is invariably delegated to nursing staff in the community and presents a heavy burden, accounting for 4% of Community Nurses' workload³.

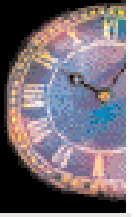
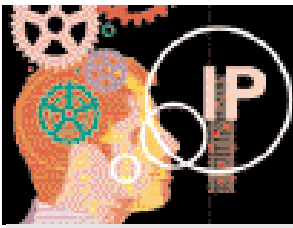
- A survey on 467 patients in the Bristol region reported 506 emergency calls for catheter-related problems during a six-month period.
- In a more detailed 12 week study, 72% of patients experienced some complication, 48% with blockage problems and 39% with bypassing of urine around the catheter⁴.
- The need for further research in this field has been repeatedly advocated, including improvements in catheter design⁵.

Clinical trials are an essential component of the introduction of any new procedure, intervention or medical device. They help ensure patient safety and measure the efficacy of the new technology either against a placebo or the current gold standard treatment. The BioMed Centre supports industry and other research groups to facilitate and conduct clinical studies and trials that explore ways of improving the healthcare and quality of life of people with long term indwelling catheters.

References

1. Making the case for Investment in an Integrated Continence Service: 12. Cost of Incontinence to the NHS: The Continence Foundation; April 2000
2. Greengross, S., Murphy, E., Quam, I., Rochon, P., Smith, R. Aging: a subject that must be at the top of the world agendas Editorial British Medical Journal 1997; 315 : 1029-1030.
3. Getliffe K. Catheter blockage in community patients. Nurs Stand 1990; 21: 33-36
4. Kohler-Ockmore J., and Feneley RCL. Long-term catheterisation of the bladder: prevalence and morbidity. Brit. J. Urol. 1996: 77: 347-351
5. Morris NS, Stickler DJ, Winters C. Which indwelling urethral catheters resist encrustation by Proteus mirabilis biofilms? Br J Urol 1997; 80: 58-63

Through BITECIC, BioMed HTC represents a valuable expert resource with a range of specific validated test programmes, ensuring commercial integrity in the important areas of 'confidentiality, intellectual property, quality and project management'.



Clinical Studies and Trials Facilities and Services

Complementing our *in-vitro* pre-clinical testing services, the BioMed Centre offers the planning and execution of early stage clinical trials for pilot testing new technologies.

Facilities

- A dedicated clinical facility within the BioMed Centre to treat patients with complications associated with indwelling catheters
- Clinical and administrative staff experienced in running clinical trials
- Access to the research and clinical resources and expertise of the North Bristol NHS Trust
- An extensive network of Community Nurses and General Practices from whom we can mobilise patients for trials
- A database of patients that enables us to identify suitable candidates for trials
- Access to a national network of experts from the clinical, scientific, industrial and user group communities
- Access to people with urinary problems and their carers through our partnership with Promocon
- Links with the NHS
 - National Institute for Health and Clinical Excellence (NICE)
 - Purchasing and Supplies Agency (PaSA)
 - National Institute for Innovation and Improvement and the NHS Innovations Hubs
- Links with other networking bodies through our partnership with the Medical Devices Faraday and MediWales

All trials conducted by BioMed Centre are run to ICH-GCP standards and comply with NHS Research Governance regulations. In line with regulatory requirements we are keen to publish the results of all trials. All steps are taken to protect intellectual property rights through confidentiality agreements, and we can offer advice on patenting and design rights.

Services

- Prepare clinical research protocols that meet individual study requirements
- Obtain clinical and user feedback as part of the trial design
- Prepare and submit applications to the Central Office for Research Ethics Committees (COREC) and the Local Research Ethics Committee (LREC)
- Conduct early stage clinical studies on device prototypes
- Analyse the results and prepare reports
- Submit new technology applications to the Medicines and Health Regulatory Agency



What our customers say:

"The assistance of the BioMed Centre in conducting early stage trials enabled us to focus on the design aspects of product development. The close collaboration afforded good communication and prevented us from going up blind alleys "
Geoffrey Andrews, CEO Ranier Technology Ltd.

For further information visit the Biomed HTC website : www.biomedhtc.org.uk

If you are interested in using any of the facilities or services listed above contact:

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BITECIC represents Biomed HTC as the UK centre of excellence for the assessment of urological devices

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