



# QuickChange Incontinence Wrap for urinary incontinence in men

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# Summary

- The **technology** described in this briefing is QuickChange Incontinence Wrap. It is for men with urinary incontinence.
- The **innovative aspects** are that it prevents contact between urine and the skin and can be changed in under 30 seconds without lifting or rolling the person.
- The intended place in therapy would be as an alternative to catheters and adult briefs.
- The main points from the evidence summarised in this briefing are from 1 study
   (1 observational study) including a total of 30 men in hospital. It shows that
   QuickChange Incontinence Wrap is more effective than current incontinence care for
   men, including adult briefs and Foley catheters.

- Key uncertainties around the evidence or technology is that QuickChange was only
  piloted in 1 hospital and not in any care homes or home care settings. Also, evidence
  came from 1 observational pilot study done in the US, which was only a conference
  abstract.
- The **cost** of QuickChange Incontinence Wrap is between £0.77 and £1.08 per unit (excluding VAT). The **resource impact** would be as an alternative to standard care, which costs between £0.42 and £1.27 for adult briefs, and between £5.40 and £11.57 for catheters. There are indirect costs associated with adult briefs and catheters that are not relevant to QuickChange Incontinence Wrap.

# The technology

QuickChange Incontinence Wrap (UI Medical) is an absorbent, disposable, cloth-like material designed to wrap around the penis to collect and absorb urine. It is used for men with incontinence who are unable to leave the bed. The device is circular and encloses the penis. There is a seal that fits the base of the penis, which is intended to prevent leaks. The top of the wrap remains open for heat and moisture to escape. Once folded into place the device has a fan like shape and a hook fastener, which ensures it stays attached. The company expects that between 4 and 6 wraps per day would be needed.

#### **Innovations**

The company says that with QuickChange, the urine is absorbed immediately after voiding without urine ever touching the skin, unlike with briefs. Also, QuickChange can be changed with minimal disturbance to the person wearing it, with no lifting or rolling needed. It can be done by 1 person in less than 30 seconds.

## Current care pathway

Treatment for urinary incontinence depends on the type and severity of symptoms. The first line of treatment includes lifestyle changes, pelvic floor muscle training and bladder training. If these treatments do not work, medicines and surgery are considered. Incontinence products are not a treatment for urinary incontinence but can be used to manage the condition while waiting for a diagnosis or for the treatment to work. A wide range of products and devices are available for urinary incontinence and the most popular option are pads and pants (adult briefs). Other options include bed and chair protection,

catheters and penile sheaths, skincare and hygiene products and specially adapted clothing and swimwear.

The following publications have been identified as relevant to this care pathway:

- NICE guideline on lower urinary tract symptoms in men: management
- NICE guideline on urinary incontinence in neurological disease: assessment and management.

## Population, setting and intended user

QuickChange Incontinence Wrap is for men with urinary incontinence who are unable to leave the bed. It is not suitable for men with high pressure urine streams.

The technology is likely to be used in acute care hospitals, care homes and home care by technical staff lower than band 5 (non-nurses), carers and potentially by family members.

Training is not needed but highly recommended. The company provides 3 forms of training for professionals, which are all free of charge:

- Onsite training in almost all hospitals, and per-case determination in care homes.
   Typically, 2 days are spent in each facility.
- Virtual training over Zoom or other platforms. These are open to everyone and can be personal or team scheduled. The virtual training takes 30 minutes: 15 minutes of training and 15 minutes for questions.
- Videos that cover training and frequently asked questions. These videos are available
  on the website and can be downloaded and reuploaded for future use and referencing.

#### Costs

#### **Technology costs**

The technology is available in packs of 10 and 25, which are available in 2 cases. Case UIM1010 has 10 packs including 10 wraps each. These are for short-term acute care hospitals where patient stays are measured in hours and days. Case UIM1025 has 4 packs

including 25 wraps each. These are for long-term facilities like care homes and home care where patient stays are measured in weeks, months and years.

- UIM1010 costs between £93 and £108 per case and between £0.93 and £1.08 per wrap.
- UIM1025 costs between £77 and £89 per case and between £0.77 and £0.89 per wrap.

Daily usage of wraps depends on the nature of the person's condition, but typically for men with incontinence, it is between 4 and 6 wraps a day, which costs between £3.97 and £5.48 depending on which case is used.

#### Costs of standard care

The company states that adult briefs and catheters both have direct and indirect costs.

The costs for adult briefs depend on size, capacity and quality. Direct costs are as follows:

• large adult brief: £0.42

• bariatric diaper: £1.27

• wipes: £0.07 per change (includes 3 cleaning wipes)

• moisturiser: £0.23 per change

barrier cream: £0.62 per change

• gloves: depending on the protocol, more than 1 set of gloves may have to be used.

With an average of 4.6 changes a day, the cost of using adult briefs is estimated to be around £7.45 a day, including all additional costs (cleaning wipes, moisturiser, barrier cream and gloves).

Indirect costs for adult briefs include health issues, labour of changing the briefs, laundry and emotional impact. The company states that health issues include incontinence-associated dermatitis, which is a leading cause of pressure ulcers. The company states that treatment for incontinence-associated dermatitis is estimated to be between £116 and £154. The cost of pressure ulcers ranges from £1,157 to £15,431.

Short-term catheters can be left in for 3 weeks and long-term catheters for 3 months. With increased duration, there is an increased chance of bacterial infection. Catheters cost between £5.40 and £11.57.

The indirect costs are the same for catheters as they are for adult briefs, with 1 minor addition. Catheter users are highly susceptible to catheter-acquired urinary tract infections. The company states that the costs for treating these infections ranges from £1,543 to £6,173.

## Resource consequences

The company states that the technology is currently not used in the NHS.

The company states that the QuickChange Incontinence Wrap is cheaper than Foley catheters, condom catheters, hydrocolloid catheters and intermittent catheters. It also states that QuickChange is cheaper than adult briefs. Also, the company claims that QuickChange does not cause catheter-associated urinary tract infection and prevents incontinence-associated dermatitis and pressure ulcers associated with current incontinence care for men, reducing associated costs. The company claims that technical staff lower than band 5 can use QuickChange instead of a nurse.

# Regulatory information

QuickChange Incontinence Wrap is a planned CE mark class I scheduled for submission in September 2020. The device is expected to be available in the UK by the end of 2020.

# **Equality considerations**

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

QuickChange Incontinence Wrap is intended for men with urinary incontinence. Some people may not identify as men but have a penis. Urinary incontinence becomes more common in middle age and is very common in people who are 80 or older. Sex, physical disability, gender reassignment and age are protected characteristics under the Equality

Act (2010).

## Clinical and technical evidence

A literature search was carried out for this briefing in accordance with <u>NICE's interim</u> <u>process and methods statement</u>. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

#### Published evidence

One study including 39 people is summarised in this briefing.

This observational study was reported in abstract form only. It compares the QuickChange Incontinence Wrap to current incontinence care for men.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

#### Overall assessment of the evidence

The evidence is limited and of low methodological quality. The study is small in terms of patient numbers and was done in the US, not an NHS setting. The comparators chosen are representative of standard care in the NHS. The evidence shows that using QuickChange reduces hospital-acquired pressure ulcers and incontinence-associated dermatitis. The evidence came from 1 conference abstract so more high-quality research is necessary to evaluate QuickChange.

#### Famorca et al. (2019)

#### Study size, design and location

An observational study of 39 men with urinary incontinence in the US.

#### Intervention and comparators

Intervention: QuickChange Incontinence Wrap.

Comparators: current incontinence care for men (Foley catheter, condom catheter or adult briefs).

#### **Key outcomes**

Thirty people had the QuickChange wrap and 9 used adult briefs alone. None of the patients with QuickChange wraps developed any hospital-acquired pressure injury or incontinence-associated dermatitis. All patients using the adult briefs alone developed hospital-acquired pressure injury from incontinence. Nurses agreed that using QuickChange wraps assisted in managing urinary incontinence and helped preserve the skin. Also, nurses reported that changing a QuickChange wrap would take less time than using adult briefs or managing a Foley catheter.

#### Strengths and limitations

The QuickChange wrap was trialled in 3 hospitals. The decision to use QuickChange or current incontinence care for men was at the discretion of the nurses. This study is reported in conference abstract form only so is limited in detail.

## Sustainability

QuickChange Incontinence Wrap is a single-use device.

## Recent and ongoing studies

No ongoing or completed trials were identified.

# **Expert comments**

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Only 1 expert was familiar with the technology and none of the experts had used this technology before. Three experts noted that it is not available in the NHS.

### Level of innovation

Two experts said that QuickChange Incontinence Wrap is an innovative and new technology because it is not a full-piece incontinence pad or an all-in-one design. Two experts said that it is a minor variation compared with the current standard of care. Three experts agreed that no other similar technologies are currently available to the NHS. One expert said that it may be feasible to use a simple Inco-pad in the same way, which is currently available and the cost negligible. However, this application has never been studied.

## Potential patient impact

Two experts said that QuickChange Incontinence Wrap is easier to change than pull-up pants, for example. It can be done by fewer nurses and is less stressful for the patients. One expert also said that it will be kinder to the skin and is less invasive than other incontinence devices such as in-dwelling urethral catheters. Another expert noted a reduction in costs for patients. One expert said that it has the potential for patient benefits but that there are limited data to support this. One expert said that it has very little patient benefits.

One expert said that it has the potential to change the current pathway. For people who are immobile, long-term catheters in situ with risk of urinary tract infection are usually preferred over pads with risk of skin conditions. One expert said that it does not have the potential to change the current pathway. Another expert noted it is unlikely to change the current pathway and that there will still be a place for other incontinence products. One expert felt they could not comment because of the limited data.

Three experts agreed that the technology would benefit people with reduced mobility and who are unable to leave the bed. One expert stated that it would be for people in acute and community settings. Another expert said that it can also benefit nurses. One expert said that there are no groups of people who would particularly benefit from this technology.

## Potential system impact

Two experts said that the incontinence wrap is easy to change and can reduce skin deterioration, both leading to reduced nursing time. One expert did not comment, and another expert said that it is currently unclear because of a lack of evidence.

Experts had a varied view on the cost of the technology compared with current standard of care. Two experts said that it costs more, with 1 expert saying that the technology is likely to need more frequent changes. One expert said it costs less. Another expert said that it is about the same, cheaper than some options and more expensive than others.

Two experts said that the resource impact would be a reduction in time spent on incontinence care by staff. One expert said that it may allow people to be placed in a less intensive care setting, because some nursing homes do not accept people with catheters. Also, there may be fewer catheter complications. One expert noted that it is unlikely to have a significant benefit.

Three experts agreed that training is needed to use the technology. Three experts were unaware of any safety issues. One expert said that there were minimal data to understand the safety issues.

#### General comments

All experts agreed that the QuickChange Incontinence Wrap would be in addition to current standard care. One expert suspected that only a small minority of men with incontinence can use the technology, stating that QuickChange appears to be suitable for men who are immobile with mild incontinence. Experts were unaware of any issues that would prevent the use of this technology in the NHS, apart from 1 expert stating cost was a potential barrier. One expert noted that it cannot be used in all people, for example, men with faecal incontinence, obesity or oedema. Experts raised several concerns including determining how suitable the technology is for the person, how the technology will be held in place, if it needs changing after each void, potential leakage and the potential for cost and time savings. All experts agreed that further research including randomised controlled trials is needed to address the uncertainties in the evidence base.

# **Expert commentators**

The following clinicians contributed to this briefing:

- Ms Lisa Charlesworth, registered nurse, NHS supply chain: rehabilitation, disabled services, women's health and associated consumables. Did not declare any interests.
- Miss Charlotte Foley, consultant urological surgeon, East and North Hertfordshire NHS
  Trust. Did not declare any interests.
- Mr Mohammed Belal, consultant urological surgeon, University Hospitals Birmingham NHS Foundation Trust. Did not declare any interests.
- Mr Richard Parkinson, consultant urologist, Nottingham City Hospital. Did not declare any interests.

# Development of this briefing

This briefing was developed by NICE. <u>NICE's interim process and methods statement</u> sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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