# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Medical technology guidance scope

# Peezy Midstream for midstream urine collection

## 1 Technology

### *1.1 Description of the technology*

Peezy Midstream (Forte Medical) is a medical device for midstream urine collection in children and adults. The device kit includes a genital wipe, the Peezy Midstream collection funnel, and either a 30 ml or 10 ml tube which stores the urine sample and can be sent to the microbiology lab.

During urine collection, Peezy expels the first void urine stream into the toilet, midstream urine is captured in the collection tube, and any excess urine is diverted into the toilet once the tube is full. When collection is finished, the sample collection tube is detached from the Peezy Midstream funnel and sealed with a lid. A full bladder is needed to use Peezy Midstream effectively.

A midstream urine sample is usually collected to check for urinary tract infection. During urination, the early part of the urine stream may contain contaminant organisms that are picked up from the lower urinary tract during voiding. The middle part of the stream, however, is usually clear of contaminants and is therefore a more reliable sample in which to test for true urinary tract infection. Urine samples can be tested in clinic using a dipstick test or in a laboratory for microbiological analysis.

Peezy Midstream captures only midstream urine, without needing the person to interrupt urine flow. The technology meets Public Health England's UK Standards for Microbiology Investigations: Investigation of urine. The potential benefits of Peezy Midstream are that it is hygienic and easy to use and this

might increase the accuracy of midstream urine testing, reducing the need for repeat testing and rates of false-positive testing.

## *1.2 Relevant diseases and conditions*

Urinary tract infections are among the most common types of infection. In the most recent data set available, 2013/14 184,000 unplanned admissions to hospital were associated with a urinary tract infection, costing the NHS £434 million. 10–20% of women will have a symptomatic urinary tract infection at some point in their lives. In adult men, urinary tract infections are less common and can be complicated. People with a history of repeated urinary tract infections, multiple sclerosis, spinal cord injury, diabetes or obesity may also be at a higher risk of urinary tract infection.

During pregnancy, there is a 4% incidence of asymptomatic bacteriuria (persistent colonisation of the urinary tract without urinary symptoms). If left untreated or if treatment is delayed, there is an increased risk of preterm birth and pyelonephritis in around 20% to 40% of pregnancies.

Incidence increases with age; about 10% of men and 20% of women over the age of 80 have asymptomatic bacteriuria. Underlying health issues can make diagnosis difficult and make this group susceptible to resistant strains. Urinary tract infections may also be difficult to diagnose in children because the presenting symptoms are often non-specific.

Failure to diagnose and treat a urinary tract infection quickly and successfully may result in renal scarring and eventually loss of function. Urinary tract infections are a significant cause of mortality, especially in elderly people, with urinary tract infection related symptoms accounting for between 1–3% of all primary care consultations and being the main reason for 13.7% of community antibiotic prescriptions.

## *1.3 Current management*

Current methods for diagnosing a urinary tract infection include blood analysis, ultrasound and CT scans, and MRI imaging. The most commonly used method is to send a midstream urine sample for urinalysis and

microbiological testing. Midstream urine samples are most commonly captured using a clean-catch technique, where avoidance of contamination of the urine sample, for example from skin contact, is needed. This technique uses a standard plastic sample container designed to collect about 10ml of urine. In order to capture a midstream sample an individual must first void an initial flow of urine before filling the container with a sample and concluding by emptying any remaining urine from their bladder into the toilet bowl. The current method can result in soiled hands and containers, creating additional infection control risks. The sample may be associated with contamination by bacteria from the hands or genitals, which may grow on culture and be mistakenly identified as bacteria from the urine.

Pregnant women are routinely screened for gestational diabetes, pre-eclampsia and asymptomatic bacteriuria which can be done using midstream urine culture early in pregnancy. Midstream urine samples are mainly done in primary care.

## *1.4 Regulatory status*

The Peezy Midstream received a CE mark in July 2014 as a class 1 device for midstream urine collection.

## *1.5 Claimed benefits*

The benefits to patients claimed by the company are:

- More accurate or earlier diagnosis
- improved management
- higher patient satisfaction
- fewer complications
- treatment can be started or stopped earlier
- fewer repeat appointments/tests
- greater hygiene and dignity
- prevents deterioration of condition

The benefits to the healthcare system claimed by the company are:

- Fewer staff, lower grade of staff needed
- reduced length of stay
- reduced cost of lab services
- reduced admin time for clinical staff
- greater infection control

# 2 Decision problem

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| Population | People providing a midstream urine sample in a health service or self-care setting |
| Intervention | Peezy Midstream |
| Comparator(s) | 'Clean-catch' urine sample collection |
| Outcomes | The outcome measures to consider include:<br>• Correct diagnosis of urinary tract infection<br>• antibiotic use<br>• contamination rate<br>• proportion of mixed cultures and presence of skin cells<br>• number of repeat samples required<br>• staff time<br>• number of appointments<br>• ease of use<br>• patient satisfaction<br>• device-related adverse events |
| Cost analysis | Costs will be considered from an NHS and personal social services perspective.<br>The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared.<br>Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed. |
| Subgroups to be considered | • People at high risk of urinary tract infection, including those with a history of repeated urinary tract infections<br>• pregnancy<br>• children who are toilet trained |
| Special considerations, including those related to equality | Peezy Midstream may be difficult to use for some people with limited dexterity, mobility or vision. Using the technology may also be difficult for people with limited comprehension such as people with dementia, learning difficulties and mental health conditions. |

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| | Peezy Midstream requires a minimum of 100ml of urine to separate a midstream sample. This means it may not be suitable for people with very low volumes of urine and young children. Peezy Midstream is unlikely to be suitable for people with urinary incontinence (including very young children who are not toilet trained). | |
| Special considerations, specifically related to equality | Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic? | No |
| | Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality? | No |
| | Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance? | No |
| Any other special considerations | Use of Peezy Midstream is likely to lead to increased 'yellow bag' plastic waste, however this impact may be reduced by fewer samples needed overall. | |

# 3 Related NICE guidance

**Published**

- Urinary tract infections (2018) NICE Pathway.
- UK Standards for microbiology investigations (2019) Public Health England.
- Urinary tract infection: diagnostic tools for primary care (2018) Public Health England.

# 4 External organisations

## *4.1 Professional*

The following organisations have been asked to comment on the draft scope:

- Association for Clinical Microbiologists
- Association for Continence Advice
- Association of Renal Industries

- Association of Renal Technologists
- British Association of Urological Nurses
- British Infection Association
- British Maternal and Foetal Medicine Society
- British Menopause Society
- British Prostate Group
- British Renal Society
- British Society for Paediatric Endocrinology & Diabetes
- British Society of Urogenital Radiology
- British Society of Urogynaecology
- British Urological Foundation
- British Uro-Oncology Group
- European Association for the Treatment of Addiction UK
- Medical Foundation for AIDS & Sexual Health
- National Substance Misuse Non-Medical Prescribing Forum
- Renal Association
- Royal College of General Practitioners
- Royal College of Midwives
- Royal College of Nursing
- Royal College of Obstetricians and Gynaecologists
- United Kingdom Continence Society
- Association for Clinical Biochemistry and Laboratory Medicine

## *4.2 Patient organisations*

NICE's Public Involvement Programme contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- Kidney Cancer UK
- Kidney Research UK
- Bob Champion Cancer Trust
- Everyman
- Movember Foundation
- Orchid - Fighting Male Cancer

- Pelican Cancer Foundation
- Prostate Cancer UK
- Prostate Help Association
- Tackle Prostate Cancer
- Diabetes Research & Wellness Foundation
- Diabetes UK
- Foot in Diabetes UK
- InDependent Diabetes Trust
- Juvenile Diabetes Research Foundation
- Daisy Network
- Endometriosis UK
- FEmISA (Fibroid Embolisation, Information, Support and Advice)
- Pelvic Pain Support Network
- Verity
- Women's Health Concern
- Gransnet
- Menopause Exchange
- Menopause Self Care
- Abortion Rights
- Action on Pre-Eclampsia
- Ante-natal Results and Choices
- Association for Improvements in the Maternity Services
- Baby Lifeline
- Best Beginnings
- Birthrights
- Bliss
- Congenital Diaphragmatic Hernia UK
- Disability, Pregnancy & Parenthood international
- LIFE
- Maternity Action (Maternity Alliance)
- Multiple Births Foundation
- PANDAS Foundation

- The Miscarriage Association
- The Pelvic Partnership
- Tommy's - The Baby Charity
- Twins and Multiple Births Association
- WellBeing of Women
- National Childbirth Trust
- Group B Strep Support
- BabyCentre UK
- Mumsnet
- Netmums
- British Association for Sexual Health and HIV
- English Collective of Prostitutes
- National Health Education Group
- National Ugly Mugs
- Sexual Advice Association
- British Liver Trust
- National AIDS trust
- National Chlamydia Screening Programme
- ADFAM
- Alcohol and Drugs Action
- Hope UK
- Mentor UK
- Northern Ireland Community Addiction Service
- Release
- Re-Solv
- The Forward Trust
- Transform
- UK Harm Reduction Alliance
- Bladder and Bowel UK
- Bladder Health UK
- International Children's Continence Society
- Kidney Cancer Support Network

- Kidney Care UK
- Kids Kidney Research
- National Kidney Federation
- Pelvic Pain Support Network
- Polycystic Kidney Disease Charity
- Stomawise
- Urology User Group Coalition
- Al-Anon Family Groups
- Carers Federation Limited
- Carers Trust
- Carers UK
- CAUSE (NI)
- Crossroads Caring for Carers - NI
- The Relatives and Residents Association
- Alzheimer's Research UK
- Alzheimer's Society
- Dementia Action Alliance
- Dementia UK
- Age UK
- Beth Johnson Foundation
- British Red Cross