

Peezy Midstream for urine collection

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is Peezy Midstream. It is used for collecting a midstream urine (MSU) sample.
- The **innovative aspect** is that Peezy Midstream captures only MSU, without needing the patient to interrupt the flow of urine.
- The **intended place in therapy** would be as an alternative to standard urine collection containers for MSU samples in people needing a urine test.
- The **main points from the evidence** summarised in this briefing are from 6 studies (1 clinical audit and service review, 1 cross-sectional review, 3 observational studies and 1 usability questionnaire study) including a total of 1,350 adults in a community and outpatient hospital setting. They show that Peezy Midstream is easy to use and could potentially reduce sample contamination rates.
- The **key uncertainty** is that there is limited published evidence.
- The cost of Peezy Midstream is £0.87 per kit (exclusive of VAT). The resource impact would be a small increase in cost which may be offset against a reduction in contamination rates of MSU collection and subsequent retesting.

The technology

Peezy Midstream (Forte Medical) is a medical device for midstream urine (MSU) collection for children and adults. There are other types of methods for getting a urine sample, such as bag, pad,

catheter, prostate massage or secretions, clean catch, suprapubic aspirate, cystoscopy, ureteric, ileal conduit, urostomy and nephrostomy urine. Peezy Midstream is used when collecting a sample which needs collecting during urination. The device kit includes a genital wipe, the Peezy Midstream funnel collection device and either a 30 ml or 10 ml tube which stores the urine sample and is then sent to the microbiology lab (and can accommodate a bar code label). During urine collection, the first void urine is automatically expelled into the toilet, MSU urine is captured in the collection tube, and 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.

An MSU sample is primarily collected to check for infection. A sample of urine from the middle of a person's bladder does not normally carry contaminants that may mean the specimen is unreliable. If bacteria are found in the sample, it means that the urine is infected. Urine samples can be tested in clinic using a dipstick test or in a laboratory if a more complex urine analysis is needed.

Innovations

Peezy Midstream captures only MSU, without needing the patient to interrupt urine flow. The device is the only urine collection method that 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 to collect MSU. This could increase the accuracy of MSU testing, reducing the need for repeat tests and rates of false-positive dipstick samples.

Current care pathway

Currently, people with a suspected urinary tract infection (UTI) need to provide a urine sample. MSU samples are recommended for routine urine collection. MSU samples are commonly captured using a clean-catch technique, where avoidance of contamination of the urine sample (for example from skin contact) is needed. Patients are usually given a standard container only and must empty the first part of the urine then while continuing flow, collect about 10 ml (in a CE-marked leak proof container) to provide an MSU specimen. The current method also results 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 in the urine.

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

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

- [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.

Population, setting and intended user

Peezy Midstream would be used for MSU collection. Urine samples are often taken to diagnose UTIs. UTIs are among the most common types of infections, with an estimated 145,132 people admitted as an emergency in 2010/11, at an estimated cost of £316 million per year (about £2,177 per patient; [Bardsley et al. 2013](#)). This trend is increasing, in 2013/14 there were 184,000 unplanned admissions associated with UTI at a cost of £434 million (about £2,358 per patient) to the NHS ([Unplanned Admissions Consensus Committee](#), accessed 30 January 2019).

In children, UTIs are common bacterial infections that cause illness and can be difficult to diagnose because the presenting symptoms are often non-specific. Failure to diagnose and treat a UTI quickly and successfully may result in renal scarring and eventually loss of function. About 10% to 20% of women will experience a symptomatic UTI at some point during their life time. The incidence of UTI is highest in young women. In adult men, most infections are complicated and related to abnormalities of the urinary tract. However, there is a low incidence of spontaneous UTIs in otherwise healthy young men.

In the elderly population, the incidence of UTIs increase with age for men and women and are 1 of the most common infections associated with this age group. 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.

Urine samples are also taken for routine antenatal screening (gestational diabetes, pre-eclampsia and asymptomatic bacteriuria), diabetic screening (routine screening for ketones and metabolites) and diagnostic screening for sexually transmitted diseases. 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 affecting maternal and fetal outcome. About 20% to 40% of pregnant women with untreated bacteriuria will develop pyelonephritis ([UK Standards for microbiology investigations: general information](#), accessed 19 February 2019).

Costs

Technology costs

Peezy Midstream costs £0.87 per kit. There are possible savings through a reduction in urine samples being sent for culture because of a reduction in false-positive dipstick results.

Costs of standard care

A standard plain white universal container without an additional collection product costs between £0.05 and £0.09. Red boric acid containers cost about £0.06 each. Microbiological culture and microscopy of an MSU sample costs between £6.97 and £7.62.

Resource consequences

Peezy Midstream is currently used in 2 NHS trusts. There are no anticipated practical difficulties or changes in facilities and infrastructure associated with adopting this technology.

Regulatory information

Peezy Midstream kit is a CE-marked class I medical device.

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.

No equality issues have been identified. Peezy Midstream may promote equality of opportunity by making it easier for some groups to collect an MSU sample.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). 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

Six studies are summarised in this briefing. The 6 studies included 1,350 adults. [Table 1](#) summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

There is limited published evidence on Peezy Midstream. The evidence available is helpful to see the potential of the technology, particularly the potential reduction in urine samples sent for culture as a result of a reduction in false-positive dipstick tests. However, a well-conducted randomised control trial would be helpful to gain more certainty in terms of contamination rates and potential savings.

Table 1 Summary of selected studies

Southworth et al. (2019)	
Study size, design and location	Cross-sectional pilot cohort study (n=62). USA.
Intervention and comparator(s)	Peezy Midstream (n=21). Peezy Midstream with cleansing wipe (n=21). Standard method of urine collection (n=20).
Key outcomes	The authors used EQUC to compare microbial abundance and diversity of paired periurethral swabs and urine samples for each woman. Bacterial profiles of urine samples collected by Peezy Midstream differed substantially by multiple diversity indices and had substantially reduced colony-forming units compared with the paired periurethral swab. However voided urine using the standard clean-catch method had higher abundance and richness than paired periurethral swabs.
Strengths and limitations	Small study. Provides insight into the potential for Peezy to reduce cross contamination and shows that the standard clean-catch method may be contaminated by periurethral bacteria not present in urine.
Collier et al. (2014)	

Study size, design and location	Observational study. Female renal transplant recipients compared with matched historical controls. UK.
Intervention and comparator(s)	Peezy Midstream (n=420). Standard method of urine collection (n=424).
Key outcomes	Peezy Midstream statistically significantly increased the rates of epithelial cells (p=0.008). There was also a non-significant (p=0.1) increase in mixed growths in the urine samples (when compared with the historical controls).
Strengths and limitations	Statistically significant baseline differences between the 2 groups (eGFR, p=0.002 and underlying renal diagnosis, p<0.001), which could have affected the results. Historical matched controls used, which alongside potential baseline differences between the 2 groups could lead to decreased power or type I error rates. The study is also at risk of selection bias. This study used a previous version of the device which has since been modified.
<u>National Institute for Health Research (2017) Usability Study</u>	
Study size, design and location	Usability study, 17 adults recruited on an opportunistic basis, with consideration of providing equal male/female balance. UK.
Intervention and comparator(s)	Peezy Midstream. No comparator.
Key outcomes	Overall, Peezy Midstream had positive feedback from both males and females. The results showed the ease-of-use of the device compared with current methods of MSU collection. Most people felt the device was more hygienic than current standards, however a small number highlighted that Peezy Midstream caused a mess and it was suggested that a glove or extra wipes could be included in the package. The most substantial negative aspect of the technology both in scores and comments, was the packaging and the integrated instructions. People highlighted that the bag would tear open unpredictably, causing the instructions to become unreadable or for contents to spill on the floor.

Strengths and limitations	Small study using an opportunistic sample. Provides insight into ease of use.
<u>Chow and Hussain (2013)</u>	
Study size, design and location	106 (76 males, 30 females) consecutive patients who attended a urology clinic were given the new Peezy Midstream device for standard collection of an MSU sample. Patient questionnaire and examination of the exterior surface of the specimen bottle was recorded. Microscopy and microbiological culture reports were obtained subsequently. UK.
Intervention and comparator(s)	Peezy Midstream. Standard MSU collection.
Key outcomes	55% of all patients (male 28%, female 80%) reported problems mainly in spillage with existing method of MSU collection. 90% of patients found the device instructions clear, 21% experienced problems with Peezy Midstream. Spillage happened in 6% of patients. Although the device was new to 99% of the patients, 89% of them would prefer to use Peezy Midstream in the future instead of the previous methods. MSU bacteriology suggested possible contamination in only 7 specimens (6.5%) compared with 22.9% of reported incidence in the local laboratory.
Strengths and limitations	Study published as a poster presentation, so it is difficult to assess the quality of the study. Study done in the NHS so the results are generalisable.
<u>Jie et al. (2018)</u>	
Study size, design and location	A retrospective review of MSU samples taken using standard collection. Inclusion criteria: pregnancies booked before 12 weeks gestation and continued their care, ending in delivery at study hospital. 100 most recent deliveries from 8 September 2019. Variables examined: MSU samples sent in total, positive MSU samples, antibiotics administered to protocol, contamination rate. A service evaluation study on Peezy (n=40) for MSU collection. UK.

Intervention and comparator(s)	Peezy Midstream. Standard MSU collection.
Key outcomes	5% positive culture rate for standard MSU collection with a 95.5% false-positive rate and treated unnecessarily, resulting in a possible £25,847 per year spent on contaminated dipstick samples. Peezy Midstream showed a reduction in laboratory contamination to 2.5% and 70% of patients found Peezy Midstream user friendly.
Strengths and limitations	Study published as a poster presentation, so difficult to assess the quality of the study. Study done in the NHS so the results are generalisable.
<u>Lewis (2019)</u>	
Study size, design and location	Observational study n=281. UK.
Intervention and comparator(s)	Peezy Midstream (n=158). Standard MSU collection (n=123).
Key outcomes	The results showed that the introduction of Peezy increased the rate of negative culture from 115/158 (73%) to 106/123 (86%), decreased the rate of E. coli from 10/158 (6%) to 4/123 (3%), decreased the rate of faecal streps (enterococci) from 6/158 (4%) to 1/123 (1%), decreased the rate of mixed cultures from 20/158 (13%) to 8/123 (7%).
Strengths and limitations	Study published as a blog, so difficult to assess the quality of the study. Study done in the NHS so the results are generalisable.
Abbreviations: eGFR, estimated glomerular filtration rate; EQUUC, expanded quantitative urine culture; MSU, midstream urine.	

Recent and ongoing studies

- Watford General Hospital Antenatal Trial, manuscript being prepared for submission to a midwifery journal The Practising Midwife and website [All4Maternity](#).
- [Oxford University primary care and Nuffield department of primary care health sciences CONDUCT study](#). Completed in September; the database is being closed soon with the data

- analysis expected in May. Publication is estimated to be December 2019.
- Public Health Wales: the antenatal and out-of-hours strands are completed. The final primary care strand has completed, and the findings are expected to be reported in 2019.
- PEEZY Midstream urine device compared to catheterized urine sample (PEEZY).
ClinicalTrials.gov identifier: NCT03729336. Status: currently recruiting.

Specialist commentator comments

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

Three specialists were familiar with and 2 had used this technology before.

Level of innovation

Specialist commentators indicated that this technology is an innovative and novel solution to collecting a high-quality midstream urine (MSU) specimen. Ease of use (patients do not need to start-stop-start), reduced incidence of user spillage, reduction in contamination of urine specimens for culture, resulting in more accurate diagnosis of urinary tract infection were highlighted as the key patient benefits.

Potential patient impact

Peezy Midstream may be of particular benefit for heavily pregnant women because it is potentially easier to use. It may be beneficial in screening for asymptomatic bacteriuria in antenatal care and pre-operative care because positive results have a substantial effect on the care pathway. Peezy Midstream would also be of benefit for people with poor balance or manual dexterity, because they may find it difficult to control their urinary stream.

Potential system impact

Peezy Midstream has the potential to improve clinical outcomes and reduce system costs because it reduces the number of samples sent for laboratory testing and unnecessary use of prophylactic antibiotics.

Specialist commentators

The following clinicians contributed to this briefing:

- Sylvia Bone, clinical lead midwife ANC/MDAU, West Hertfordshire Hospitals NHS Trust, did not declare any interests.
- Marcus Drake, professor of urology, North Bristol NHS Trust, interests declared, none relating to the topic in question.
- Tom Lewis, consultant microbiologist, Northern Devon Healthcare NHS Trust, did not declare any interests.

Development of this briefing

The [interim process and methods statement](#) 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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