Women's Health and Urinary Tract Infection (UTI)

FACT SHEET WITH SOURCE LINKS The scandal of ignored guidelines

Global guidance specifies midstream urine (MSU) for Urinary Tract Infections (UTI)¹ and prenatal screening, yet there is **no protocol available to ensure guidelines are met** leading to unreliable samples, contaminated with bacteria and flora washed from the skin into the urine sample creating an unreliable diagnostic outcome.

- 1. Peezy Midstream captures MSU² but requires healthcare policy and budgets to support preventative practice. Until this happens, a device like Peezy Midstream will struggle to gain traction or deliver exponential improvements to women's urological healthcare.
- 2. Antimicrobial guidance stipulates identifying bacteria before prescribing: see Antimicrobial Stewardship³

Who suffers from UTI?⁷

- Acute UTI occurs in up to 50% of women with 20-30% having a recurrance⁴
- UTIs account for up to 10m primary care visits by women annually⁵

Women are given a narrow tube or small cup into which they are told to startstop-start their urine stream to provide a "clean-catch" urine sample. This is messy, unreliable and undignified. **34-60% of UTI antibiotic prescribing is given** without urine culture adding to risk of unnecessary antibiotic use, arguably putting women on the frontline of antimicrobial resistance (AMR).⁶





Peezy Midstream is the evidence-based⁶7 future of accurate, right-first-time, hygienic and dignified urine specimen collection to promote targeted prescribing. Works for women and men, children, the elderly and less able

Clean hands, clean loo, clean you.

Why is guideline-specific midstream specimen collection important?

- Urine is rich with information and has diagnostic parity with blood, yet is treated with less diligence
- Current recommended start-stop-start collection method cannot guarantee midstream and is difficult if pregnant
- First-void urine can wash flora and bacteria from the skin into the sample, creating contamination
- Contaminated specimen is harder to analyse due to creation of "mixed growth" bacteria
- Unreliable specimens lead to high volumes of retesting and false-positive results
- Repeat testing at frontline is costly (HCP time to recall patients followed by clinician and lab time)
- Unreliable specimens leads to unnecessary prescribing (poor antibiotic / AMR stewardship) potentially putting women on the frontline of antimicrobial resistance
- Untreated UTI leads to chronic conditions, kidney disease and unplanned hospital admissions
- Hygiene: soiled patient hands can spread pathogenic bacteria and viruses found in urine and on the perineum into the environment (toilet flush, door handles, taps). The list of microorganisms is long but can include E-coli, Streptococcus, Staphylococcus, Proteus, Enterococcus, Gonorrhoea, Chlamydia, Hepatitis B, HIV, and more

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The wider impact of unreliable diagnostic urine collection

- Urinary tract infections (UTI) are among the most common bacterial infections leading to clinic visits and can cause serious sequelae, such as renal damage and urosepsis. In 2019, the global incident cases of UTI were 400 million, an increase of 60.40% from 1990⁸
- Nearly 25% of sepsis cases originate from the urinary tract⁹
- UTI is a significant cause of death accounting for 4835 deaths in England and Wales in 2012¹⁰
- Unplanned hospital admissions for UTI cost the NHS nearly £400m to treat¹¹
- For 34-60% of people diagnosed with UTI, antibiotics are prescribed before their diagnosis can be confirmed by the laboratory¹²
- 7 million antibiotic items were prescribed in primary care in 2019/20 to treat lower UTI at a cost of £47.6 million, and 41% (2.73 million) of these antibiotics were prescribed to people aged 70+ years¹³

EVIDENCE to support efficacy of Peezy Midstream for reliable diagnoses and reduced antibiotic prescribing

Real world evidence generated on the frontline of Primary and Maternity Care has garnered excellent results:

- Public Health Wales: Peezy Midstream in Primary Care, real world study delivered 0% contamination¹⁴
- NHS West Hertfordshire Antenatal real-world study demonstrated reduced retesting and significant improvements to women's care¹⁵
- Barts Health NHS Trust: small study showing dramatically reduced retesting¹⁶
- The device has struggled to gain traction across the NHS due to silo budgets and vested interests. More detail within Imperial College MedTech Innovation¹⁷ report (Page 29 and Appendix 2)

Academic papers have produced evidence that relied upon unmet protocols. Full detail in the links:

- Contrary to protocol, the Royal Free study did not send ALL Peezy Midstream samples to the lab for analysis on
 negative dip, thereby discarding all positive evidence that should have been verified in the lab. Correspondence
 between the study lead and Forte Medical can be provided to confirm this;
- The Oxford study did not ensure patients had the required full bladder prior to use for successful outcomes and have declined to confirm that they provided verbal instructions, thereby denying required study parity with the comparative group. Study Lead correspondence with Dr Vincent Forte via the RCGP website can be seen here: https://bjgp.org/content/bjgp/72/717/157.1.full.pdf

What about the money? Peezy Midstream can deliver huge cost and efficiency savings

Peezy Midstream is a simple collection device which is shown to cut repeat tests and associated indirect costs to deliver estimated savings of:

- £3.6m in reduced retesting
- o £160m including significant indirect costs of time and resources attached to recalling patients

Independent cost benefit model produced by M-Tech Access¹⁸ (available for scrutiny) Direct savings

 •	Introduction	Population	Calculator	Summary	Indirect costs	Reference	s 💷 C'
Calculator							
Total urine samples analysed per annum				7,000,000	Edit unit costs	<u>dı.</u>	
			Peezy Midstri	eam Universal con	tainer Savings		
Cost of specimen o Total for initial su Total for re-samp Cost of other con Total for all speci	amples ling	other consumables	£14,000,00 £210,000 £0 £14,210,00	£126,00 £4,200,0	0 -£84,000 00 £4,200,000		
Cost of laboratory a Total for initial sa Total for re-samp Total for all labor	amples ling		£70,000,00 £1,050,00 £71,050,00	0 £14,000,0	00 £12,950,000		
Total cost for samp	le collection & testing		£85,260,00	10 £88,956,0	60 £3,696,000		
Average cost per re	equired sample		£12.18	£12.71	60.53		
Alternative study a	ussessing the impact of f	alse-positives	Fals	e-positives case study			

Author: Giovanna Forte, CEO, Forte Medical Limited

Indirect (efficiency) savings

introduction	Population Calculator	Summary	Indirect costs	References IFU					
Potential budget impact of Peezy midtream including indirect costs									
Total urine samples analysed per annum	7	,000,000		<u>dı.</u>					
	Peezy midstream	Universal container	Savings						
Total direct costs	£85,260,000	£88,956,000	£3,696,000						
Adminstration costs Opportunity cost of a Urology outpatient appoin Office administration costs Total indirect costs	tment £11,340,000 £1,399,650 £12,739,650	£151,200,000 £18,662,000 £169,862,000	£139,860,000 £17,262,350 £157,122,350						
Total indirect costs	£12,739,650	£169,862,000	£157,122,350						
Total costs	197,999,650	£258,818,000	£160,818,350						

Important patient centric collection: hygiene and dignity for all

Pee into this with messy start-stop-start method and later sample decanting in lab?

- Brit



Or pee straight into this,

with lab-compatible tube?

Clean, hygienic, dignified.

Easy assisted use for elderly / less able patients. Clean, kind, dignified – and importantly, no genital exposure.



MADE IN THE UK WITH RECYCLABLE CREDENTIALS

Peezy Midstream is made in the UK from recyclable Polypropylene Manufactured under license by Boddingtons Plastics¹⁹

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