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Clean pulp versus sterile plastic for mid-stream urine collection: a paired equivalence study comparing the microbiological performance of a novel low carbon collection device with the standard of care

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ABSTRACT

Objectives To determine whether a novel urine collection device (the 'Pee-in-Pot (PiP)') produces the same rates of reportable urine culture results as standard of care (SOC) urine collection. To determine whether the PiP produces comparable microscopy results to SOC urine collection. To estimate the carbon footprint of the PiP compared to SOC urine collection.

Design A prospectively designed, single-centre, paired comparison study.

Setting A district general hospital in Southwest England, including antenatal clinical, accident and emergency, medical and surgical ward environments.

Participants Adults aged 18 or over.

Interventions Urine passed through the PiP device before being decanted into a 10 mL boric acid tube for microscopy and culture, compared with the same urine contained only in a sterile plastic vessel before being decanted into a boric acid tube for microscopy and culture.

Primary outcome measure The proportion of positive urine culture results.

Secondary outcome measures The proportion of heavy mixed growth culture results. Comparison of particle counts: all small particles, bacteria, red blood cells and white blood cells.

Results Microscopy was performed for 1353 paired samples, of which 808 paired samples both underwent culture. Overall, urine cultures were positive in 9.3% (75/808) and 10.0% (81/808) of PiP and control cases, respectively. Overall matching between PiP and control arms for reportable positive culture results was 98.5% (796/808), with a Cohen's Kappa test coefficient (κ) of 0.9149 (almost perfect agreement). There was no significant difference in the rate of positive urine culture results between testing arms for any organisms (margin of non-inferiority prospectively defined as ±2.5% for *Escherichia coli* positive cultures). For microscopy, there was agreement in meeting culture thresholds for 1308 of 1353 paired samples with a difference in culturing rates of 0.00517 (95% CI −0.0045 to 0.015, ie, high level of agreement). The estimated base case carbon footprint of PiP testing was 95g CO2e compared to 270g CO2e for SOC testing.

Conclusions This study found the PiP to be non-inferior for routine urine microscopy and culture testing and to have a lower carbon footprint compared with SOC urine testing.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This pragmatic prospectively designed non-inferiority study used routine urine testing pathways across a range of clinical secondary care settings.
⇒ The life cycle carbon footprint assessment used a broad range of parameters in sensitivity analysis.
⇒ The Pee-in-Pot (PiP) was used as an intermediate vessel rather than as the primary collection device, differing from how it would be used in routine practice.
⇒ Analysis was performed with a smaller sample size than originally intended.

INTRODUCTION

Urinary tract infections (UTIs) are a common cause of morbidity and mortality among patients and represent a large proportion of patients admitted to hospital, with an increasing burden observed in high-income countries.[1] UTIs can substantially affect patients' quality of life and are a costly burden on health services.[2–5] Urine microscopy, culture and sensitivity (MC&S) testing is performed very frequently as part of UTI management, as well as for antenatal care and routine preoperative screening for

urological surgery.[6–8] Despite the importance of gaining reliable results from this common test, there is currently a high degree of variation in how mid-stream urine (MSU) specimen collection is performed. This risks inaccurate results, and the addition of unnecessarily wasteful and expensive practices.

The development of environmentally sustainable ways of delivering routine clinical care is hugely important, as health services transition towards lower carbon emitting practices to mitigate climate change.[9] Single-use plastic products are a particularly large source of healthcare's greenhouse gas emissions, and therefore reducing reliance on these is a priority.[10–12] Transitioning to lower carbon products should involve questioning the necessity of environmentally harmful practices that have evolved in the absence of evidence.[13] Where evidence is lacking but there is a potential opportunity to introduce more sustainable alternatives in clinical care, we should investigate these possibilities. Excessive use of sterile plastic equipment is one of the foremost areas requiring this type of enquiry.

The Pee-in-Pot (PiP) is an innovation developed in the National Health Service (NHS) in Southwest England that has been intentionally designed to address several important issues. These include wide variation in how urine is collected, its relatively high cost and the substantial plastic waste and carbon footprint associated with current MSU testing techniques. The shape of the PiP provides a single-item solution for collection, dipstick testing and decanting of exactly 10 mL of urine into a 10 mL boric acid container for laboratory testing. Its composition from bamboo-derived cellulose thermofibre pulp makes it a more sustainable alternative to plastic, storing carbon from the atmosphere biogenically and undergoing disposal by maceration and flushing rather than incineration.[14] Its clean but non-sterile nature allows it to be manufactured, packaged and distributed more efficiently.

Local pilot work and observations of routine local practice where clean pulp was being routinely used to collect MSU samples have indicated that this material could provide non-inferior microscopy and culture results. Preliminary testing of the PiP in clinical areas has gained favourable feedback from patients and staff, and once again, no clear difference in urine culture results has been observed. This favourable early pilot work has led to the PiP receiving Small Business Research and Innovation Healthcare funding to undertake conclusive microbiological evaluation, and to scale production and rollout of the product across the NHS through an NHS-industry partnership between Somerset Foundation Trust and Polyco Healthline.[15] The PiP is a registered Class 1 in vitro diagnostic device for the collection of urine and is United Kingdom Conformity Assessed (UKCA) marked by the Medicines and Healthcare products Regulatory Agency (MHRA). A picture of the PiP is included in online supplemental appendix 1.

As a next stage in the evaluation of the PiP quality improvement innovation, this study was designed to assess the PiP against the standard of care (SOC) sterile plastic collection bowl. The study was designed to provide sufficient data to determine whether the PiP was non-inferior to SOC from a microbiological perspective.

Aim

To compare the performance of the clean pulp 'PiP' urine collection vessel against the current SOC for performing MSU microscopy and culture (M&C).

Objectives

- To determine whether a novel urine collection device (the 'PiP') produces the same rates of reportable urine culture results as SOC urine collection.
- To determine whether the PiP produces comparable microscopy results to SOC urine collection.
- To estimate the carbon footprint of the PiP compared with SOC urine collection.

Primary outcome

- The proportion of positive urine culture results.

Secondary outcome

- The proportion of heavy mixed growth culture results.
- Comparison of particle counts: all small particles, bacteria, red blood cells, white blood cells.

METHODS

Study design and setting

This was a prospectively designed, single-centre, paired comparison study of urine M&C results for MSU specimens that were passed through the PiP vessel (intervention), against those which were not passed through the PiP vessel but managed according to the SOC (control). This study was conducted within a larger quality improvement project to design and evaluate a urine collection and transfer device that is cheaper and with better environmental performance than current techniques.

An adult population (age >18 years) undergoing routine MSU testing in the following clinical settings was included: antenatal clinic, emergency department, inpatient surgical ward, surgical decision unit, day surgery ward, acute frailty unit and inpatient general medical ward. Catheter urine samples were not included. No other inclusion or exclusion criteria were applied. Indications included routine screening (eg, antenatal clinic) and testing in patients with potential UTI across a range of medical and surgical clinical presentations typical for an acute hospital.

One MSU sample was collected per patient into a SOC plastic sterile urine container. A non-clean catch technique was used, outlined in the Standard Operating Procedure in online supplemental appendix 2. Using this single specimen, 10 mL of urine was transferred into a boric acid tube container using a sterile 10 mL syringe in a manner practised in routine clinical care (control specimen). Using the same original sample, urine was transferred from the sterile bowl into a PiP. This was left for an equivalent time in the PiP to the SOC sample in the

plastic bowl, before being transferred into a second boric acid tube (PiP specimen). The control specimen was labelled according to trust policy and sent to the microbiology laboratory for standard M&C testing to inform the patient's care. The PiP sample was hand-labelled and sent with the control sample to the laboratory. Each sample was given a separate laboratory ID before undergoing independent processing and laboratory analysis. M&C results for the PiP sample were not uploaded to the patient record or used to inform their medical care. Intervention (PiP) and control sample tracking was performed using a separate pseudonymised database managed by the laboratory manager. Due to these measures, testing of the PiP sample had no impact on routine patient care. The microbiology technicians performing the MC&S processing and interpretation were blinded to the origin of the samples.

The technique used to collect the patient urine sample was the SOC recommended by the local infection prevention and control team and based on the Royal Marsden Manual of Clinical Nursing Procedures.[16] Patient and staff-facing instructional literature describing how to obtain study samples was developed by the study working group (online supplemental appendix 2). Guidance also included how to store the PiPs, which included being stored upside down within a closed container in a treatment room (not a dirty utility room). A healthcare assistant supported study management in enrolled clinical settings, visiting each setting on a weekly basis to ensure appropriate study compliance.

Microbiological laboratory testing

Urine samples were processed on an automated laboratory track system (Becton Dickinson (BD) Kiestra, Netherlands). Microscopy was performed by an automated particle recognition system (Beckman IQ200 Analyser, Beckman Coulter, Brea, USA). Culture was performed for all pregnant patients, or according to initial microscopy results based on meeting either leucocyte count $>45\times10^6$/L or all small particle count $>10\,000\times10^6$/L. Samples for culture were plated on BD BBL CHROMagar Orientation agar with plates automatically brought out of incubation for reading at 20–24 hours. Culture results were interpreted using guidance outlined in the UK Standard for Microbiology Investigation (SMI) B41, Investigation of Urine.[17] In general, pure or predominant organism culture was reported if the concentration was $>10^5$ colony forming units per millilitre (CFU/mL); however, with certain clinical details (symptomatic females or clinical suspicion of prostatitis) plus presence of white blood cells, we would report growth at 10^3–10^4 CFU/mL.

Categorisation of data

Categorisation of the M&C outcome measure for analysis is outlined in online supplemental appendix 3. Patient sex was recorded. Patient age categories were recorded according to whether they were aged 16–65 or>65 years old, except for those attending antenatal clinic, in which case an age category was not recorded. The clinical setting in which the urine sample was obtained was recorded.

Statistical planning

A sample size calculation was informed by the rate of positive *Escherichia coli* urine culture results identified during routine laboratory testing for the adult population at the study site over the prior year, which was 11.7%. A difference in the rate of *E. coli* positive cultures of 2.5% between PiP and control groups was therefore determined to be within the expected uncertainty of measurement in urine culture testing.[18] This required a sample size of 1350 (1350 PiP samples and 1350 control samples arising from 1350 unique patient urine samples). Independent consultation with an external statistician at the university of Exeter was sought during planning and data analysis.

Patient and public involvement and engagement

Patient feedback about the PiP was sought during innovation development. Patients typically viewed it favourably due to its reduced environmental impact, which was estimated using a process-based carbon footprinting approach. They also found the PiP straightforward to use, although of note, patients did not void directly into the PiP for this study in the way that they would in routine use. This was to achieve the paired urine samples in a manner that did not affect SOC testing.

Data management

All study data were stored on a password-protected study specific folder on the secure Somerset NHS Foundation Trust server. All data were collected and stored in compliance with data protection guidelines and Trust clinical governance policy. No interim data analysis was performed.

Study protocol and group

A prospectively designed study protocol was produced and filed at the study site—Somerset NHS Foundation Trust (online supplemental appendix 4). A multidisciplinary study group agreed the protocol. This group comprised urologists, microbiologists, microbiology laboratory managers, senior infection prevention and control nurses, nursing staff, healthcare assistants, statisticians, hospital management, hospital innovation executive staff and administrative staff.

Analysis

Data were managed using Microsoft Excel (Microsoft Corporation, 2023) and converted to CSV format and analysed using Python. The statistical analysis was conducted in Jupyter notebooks which are openly accessible via the Somerset NHS FT DS & Improvement GitHub account.[19] The Wald confidence method was used to estimate the difference between paired proportions for microorganism detection.[20]

Carbon footprint

The cradle-to-grave greenhouse gas (GHG) emissions associated with the PIP and control urine testing methods were calculated using a process-based life-cycle assessment method according to the Greenhouse Gas Protocol Product Standard.[14] An inventory of materials and energy flows for each testing pathway was compiled, and characterisation factors for greenhouse gas emissions sourced from Ecoinvent V.3.10, 2023 UK Government conversion factors and peer-reviewed life cycle assessment data on moulded pulp production in China.[21–23] No thermoform pulp moulding characterisation factors were identifiable in Ecoinvent; therefore, injection moulding of plastic was used as a surrogate activity of probable similar carbon intensity. GHG emissions from pulp vessel production were also adapted from Huo *et al* (substituting 2009 for 2022 Chinese electricity grid emissions factors) to create a range of estimates for PiP life cycle emissions.[23 24] Different maceration scenarios were also modelled using publicly available data describing water and electricity use for a commercially available macerator.[25] Biogenic carbon was accounted for in the emissions model. A full description of the life cycle assessment methods and results is in online supplemental appendix 5.

RESULTS

Sample collection ran from 17 October 2023 to 10 February 2024. 1569 paired urine samples were obtained and underwent microscopy. 216 PiP specimens were removed due to laboratory handling error (some PiP samples from antenatal clinic were not cultured whereas the SOC samples automatically were), resulting in 1353 paired samples which underwent microscopy, with 808 paired samples then undergoing culture on the basis of meeting standard laboratory criteria. The median patient age was 35 (IQR 29–50) and 81% were female. Table 1 shows the number of paired urine samples obtained from different clinical settings.

Following initial data analysis, it was apparent that the original sample size of 1350 culture specimens had not been reached because only 808 out of the 1353 collected samples met culture criteria based on standard laboratory thresholds. As a protocol deviation, a decision was made in consultation with an independent statistician who is not a study author to proceed to full analysis of 808 paired culture samples at this stage. This was on the basis that, if the observed differences were well within the prospectively defined clinically acceptable range, further testing was unlikely to change the result.

Table 1 Number of paired urine samples obtained from different clinical settings

Clinical setting	Number of paired urine samples
Antenatal clinic	527
Day surgery centre	283
Accident and emergency	260
Surgical decision unit triage	217
Surgical decision unit ward	22
Acute medical ward	19
Acute surgical ward	14
Acute frailty unit	11

Table 2 Stacked contingency tables for different reportable microorganisms and for mixed growths, identified on urine culture for PiP and control (sterile plastic container) specimens

Microorganism	Detected in control	Detected in PiP: 1	Detected in PiP: 0
Coliform (non-*Escherichia coli*)	1	11	0
	0	0	797
Enterococcus sp.	1	2	2
	0	0	804
E. coli	1	44	5
	0	1	758
Klebsiella pneumoniae	1	0	0
	0	1	807
Proteus sp.	1	4	0
	0	0	804
Pseudomonas aeruginosa	1	3	0
	0	1	804
Staphylococcus saprophyticus	1	4	1
	0	0	803
Streptococcus Group B	1	4	1
	0	0	803
All (excluding mixed growth)	1	72	9
	0	3	724
Mixed growth	1	80	19
	0	14	695

0, not detected; 1, detected; PiP, Pee-in-Pot; Sp, species.

Table 2 is a series of stacked contingency tables for different reportable organisms identified on urine culture, with mixed growths (reportable as likely non-significant contamination as per SMI) included. For significant reportable positive cultures, overall matching between PiP and control arms was 98.5% (796/808), with 89.6% (724) of paired samples returning no reportable growth in either the PiP or control cultures. Using Cohen's Kappa test to account for potential agreement by chance, the coefficient (κ) was 0.9149 (almost perfect agreement). Overall, urine cultures were positive in 9.3% (75/808) and 10.0% (81/808) of PiP and control cases, respectively.

Figure 1 shows the difference in proportions of positive urine cultures for PiP and control urine samples for

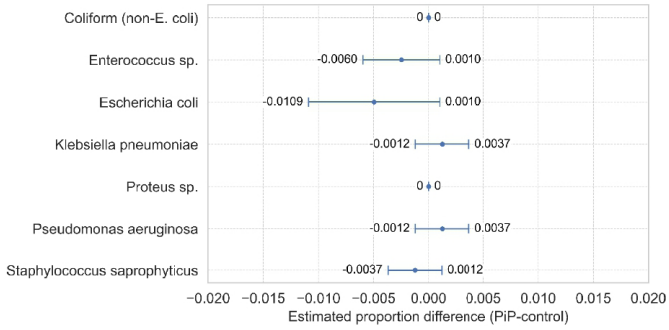

Figure 1 Difference in proportions of positive urine cultures for PiP and control urine samples (PiP minus control) for different microorganisms, and the Wald 95% CIs for these differences. A CI width of 0 indicates perfect agreement. PiP, Pee-in-Pot; Sp, species.

different microorganisms. The CIs for the differences in positive proportions between PiP and control groups all cross 0, suggesting differences in proportions are not significantly different to 0.

Figure 2A–D shows a Bland-Altman plot which is used to examine the differences between paired sample microscopy counts (PiP minus control) along with the mean of the two samples (log scale used to compress larger values). These data include all 1569 paired samples, with 2 sets of paired patient results excluded due to spuriously high readings and 10 due to imputation error (online supplemental table S6, appendix 6), which in routine practice would be re-tested on laboratory technical review. The Bland-Altman plot (figure 2A–D) demonstrates higher variability for larger magnitudes, although the symmetry present suggests that there is no constant bias between PiP and SOC related to this.

Figure 3A–D shows the distribution of the difference in microscopy counts for paired PiP and control urine samples. This shows a slight bias towards higher counts in PiP samples, particularly for red blood cell and all small particle counts, although this is not statistically significant for any type of small particle.

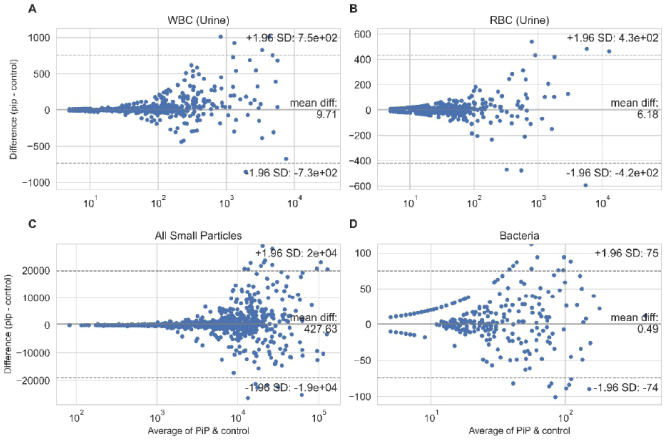

Figure 2 (A–D) Bland-Altman plot showing the difference (PiP minus control) against the average of microscopy counts (using a log scale). PiP, Pee-in-Pot; RBC, red blood cells; WBC, white blood cell.

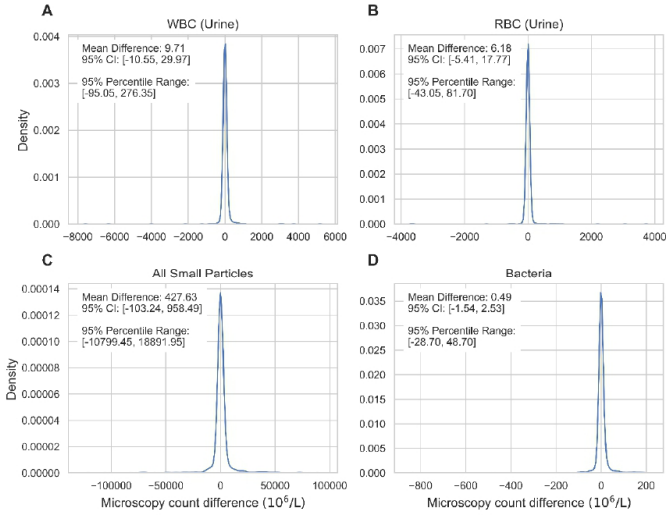

Figure 3 (A–D) Distribution (using kernel density estimate) of the difference in microscopy counts (PiP minus control) for paired PiP and control urine samples. PiP, Pee-in-Pot; RBC, red blood cells; WBC, white blood cell.

Table 3 shows the stacked contingency tables of agreement in meeting culturing thresholds from microscopy counts based on standard SMI thresholds. In addition to these thresholds, additional information such as pregnancy, immunosuppression and certain paediatric conditions is also considered when deciding whether to culture a sample.

Overall agreement in meeting culturing thresholds between PiP and control was 97%. The difference in culturing rates was 0.00517 (95% CI −0.0045 to 0.015). Removing the 527 antenatal samples (which are all routinely cultured and therefore had perfect agreement),

Table 3 Stacked contingency tables comparing microscopy counts exceeding culture thresholds between PiP and control

		Threshold passed in PiP	
	Threshold passed in control	**1**	**0**
ASP>10, 000	1	251	41
	0	54	1007
WBC>45	1	302	38
	0	50	963
Bacteria>5	1	217	33
	0	72	1031
Total	1	808	19
	0	26	500

Microscopy counts do not add up to the total because of clinical criteria for culture also applied by laboratory, for example, pregnancy and immunosuppression.
0, threshold not exceeded; 1, threshold exceeded; ASP, All small particles; PiP, Pee-in-Pot; WBC, White blood cells.

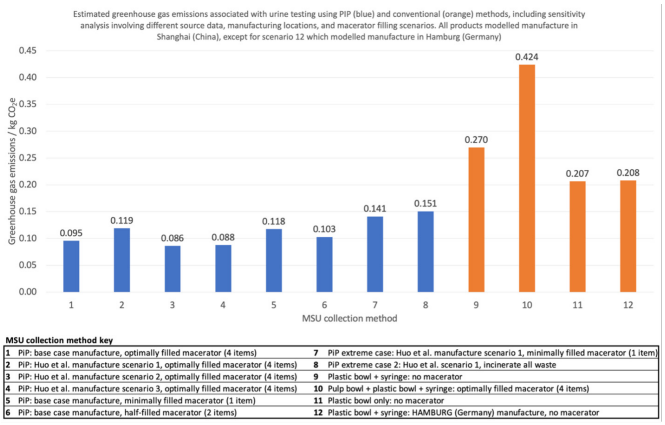

Figure 4 Estimated greenhouse gas emissions associated with urine testing using PiP (blue) and conventional methods (orange), including sensitivity analysis involving different characterisation factors for PiP pulp vessel manufacture, manufacturing locations and macerator filling scenarios. All products modelled as being manufactured in and transported from Shanghai (China), except for the last data point where manufacture and transport were modelled for Hamburg (Germany). CO_2e, carbon dioxide equivalent; MSU, mid-stream urine; PiP, Pee-in-Pot.

the agreement between PiP and control was 95%. The difference in culture rates for non-antenatal samples was 0.00847 (95% CI −0.0074 to 0.024) (online supplemental table S8, appendix 6).

Figure 4 shows the estimated carbon footprint of MSU collection using the PiP with direct decanting into a 10 mL boric acid tube (scenario 1, base case) compared with common current methods using sterile plastic. This figure includes sensitivity analysis exploring different assumptions pertaining to the emissions intensity of PiP manufacture, different filling scenarios for disposal of the PiP using a macerator, or by incineration, and different manufacturing locations for single use plastic products (Shanghai (China) and Hamburg (Germany)). In all modelled scenarios, MSU testing using the PiP results in lower GHG emissions than when using sterile plastic, even for improbable scenarios modelling higher carbon intensity PiP pulp manufacture and PiP disposal by incineration instead of maceration. We estimate that more than 2 million MSU tests undergo M&C in the UK annually. Assuming the average difference in GHG emissions between PiP and standard testing to be 174 g CO_2e (comparing scenarios 1 and 9, figure 4), an estimated 349 tonnes CO_2e of GHG emissions could be saved annually in the UK by adopting the PiP. This does not account for urine samples that undergo dipstick testing but are not sent for culture.

DISCUSSION

This study evaluates the microbiological performance of a urine testing device that was innovated by frontline health staff in response to several recognised flaws with current testing: its over-reliance on single-use plastic, excessive waste and cost, a lack of standardised collection methods and the potential ability to avoid using sterile collection devices. The results indicate that MSU samples passed through the non-sterile but clean PIP device do not produce significantly different microscopy and culture results and would not change clinical or laboratory practices. This was the case for both reportable organisms and contaminated samples. These findings support the use of the PiP instead of sterile plastic as a means of urine collection.

There are no peer-reviewed consensus definitions of clinically important difference for urine culture results. The study group therefore prospectively selected a small difference of 2.5% across all reportable urinary organisms cultured, requiring a high standard of performance for the PiP compared with SOC, and which is within the range of expected uncertainty of measurement in urine culture.[18] This 2.5% difference was derived from consensus between microbiologists, infection control nurses and urologists. Microbiological performance of the PiP compared with SOC was well within the 2.5% limits for all organisms, and all CIs of the differences in positive culture result proportions crossed zero, indicating no significant differences. This provides confidence to use the PiP as a new SOC in obtaining MSU specimens. The fact that all results were well within the pre-defined 2.5% limits suggests that the decision to proceed with analysis with a reduced sample size was acceptable. A future research priority should be to define clinically meaningful differences in urine culture results that are agreed among the scientific community. This would ideally include validation against core outcome sets (COS) of patient-reported outcome measures. A COS for uncomplicated UTI in adults of both sexes has been developed, and there is one currently under development in antenatal populations.[26–28]

There is an increasing acknowledgement that we must understand how to safely adapt what are often excessive infection control and sterility measures in order to develop more environmentally sustainable and affordable models of care.[10] Wasteful and non-evidence-based personal protective equipment use is commonplace across healthcare, particularly since the COVID-19 pandemic, and single-use medical devices are commonly promoted on the basis of offering lower infection rates without there being any evidence to support this.[29 30] This study demonstrates the type of enquiry, study design and execution that is necessary to make progress in this domain. The non-inferior microbiological performance of pulp vessels for MSU testing has been demonstrated by the Academic Health Sciences Network in the UK. For the PiP innovation, the idea of clean pulp use for MSU collection was inspired by an antenatal clinic in Southwest England which was found to be already collecting routine urine specimens using clean, non-sterile pulp. Analysis of laboratory data identified no obvious difference in positive culture rates compared with a nearby antenatal unit using sterile plastic for urine collection. To improve reproducibility of our study findings in clinical practice,

adherence to the pragmatic storage and usage instructions that were used for the PiP throughout this study is necessary. This includes storing PiPs stacked upside down in a container with a closed lid and inside a clean storage area (not a dirty utility area/sluice).

We describe microscopy findings for paired samples as well as culture results. In this single centre study of adult patients our results show non-inferiority of PiP to SOC. We would welcome further studies from different healthcare settings, including paediatric patients, to further substantiate our findings.

Recent evidence has outlined the high negative predictive value of microscopy for UTI in MSU testing in adults.[31] The fact that the PiP does not significantly increase microscopy counts is therefore important. The material from which the PiP is manufactured is a Thermofibre white pulp derived from bamboo cellulose.[32] On this basis, one cannot necessarily assume that the microscopy findings in this study could be generalised to other forms of pulp, which may produce a greater number of small fibre particles that could influence automated small particle counts. The additional benefit of this type of pulp is that it can hold aqueous fluid for prolonged time periods, which is convenient in routine clinical practice and influenced the choice of material during product testing.

The PiP promotes more environmentally sustainable urine testing in several ways. First, its shape allows excess urine to be discarded, leaving exactly 10 mL which can then be decanted directly into a 10 mL boric acid tube. This avoids the need for a syringe, pipette or other device to transfer urine from the collection vessel to the boric acid tube. Second, the PiP is made from organically derived material containing biogenic carbon.[33] We performed a cradle-to-grave assessment of greenhouse gas emissions associated with PiP use according to a range of manufacturing and disposal scenarios, and for typical current urine collection methods involving sterile plastic. In all modelled scenarios, the PiP performs more favourably than current testing methods, and our base PiP scenario demonstrated GHG emissions that were 65–77% lower than current common methods involving sterile plastic (figure 4, scenarios 9 and 10). The least favourable PiP life cycle scenario modelled, involving high carbon intensity pulp manufacture with three tonnes of coal combustion per tonne of pulp and one PiP being macerated at a time, still demonstrated GHG emissions lower than the most favourable scenario involving sterile plastic (−32%), which used one sterile bowl and no syringe or pipette to transfer urine (an approach likely to be technically difficult and result in spillage of urine). Based on this sensitivity analysis, we are confident that the GHG emissions associated with using the PiP are lower than for common alternative methods.

Strengths of this study include its pragmatic and prospectively designed nature, with input from multidisciplinary stakeholders. The life cycle carbon footprint assessment used a broad range of parameters in sensitivity analysis. The main limitation is that the PiP was used as an intermediate vessel rather than as the primary collection device. In theory, if the PiP were substantially more challenging to produce a urine sample into, one might find a higher rate of samples contaminated with perineal flora. In practice, extensive user feedback has not indicated increased difficulty in collecting specimens and so this is not felt to be a material risk. A further limitation is that we obtained relatively more samples from surgical, antenatal and emergency department populations compared with general medical settings. The decision to proceed with analysis before reaching the planned sample size is a deviation from protocol; however, it is felt to be justifiable given the tightly spaced CIs which were well within the prospectively defined 2.5% margins of clinically important difference. Lastly, the study authors would recommend that the microbiological performance of the PiP is monitored in other healthcare settings where it is adopted, in keeping with standard microbiology audit and governance processes. The PiP was used following specific storage and usage instructions and generalisability of our findings to other settings should therefore not be assumed without appropriate monitoring.

CONCLUSIONS

This study indicates that the novel PiP urine collection vessel has the same performance on microbiology testing of MSU samples as the SOC, while having a substantially lower carbon footprint. The data presented herein support the adoption of the clean, non-sterile PiP for MSU specimen acquisition in routine clinical practice for adult patients. This is an example of a sustainable and affordable innovation developed and refined within the UK National Health Service in response to unwarranted clinical variation and increasing awareness of the need to transition to more environmentally sustainable healthcare practices.

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Contributors All co-authors were part of the study group and co-designed the protocol. RP and LK advised on microbiology testing, TD on infection prevention and control, BH and AM provided advice on statistical design. NBC, NC, TD, YS, LK and AW were involved in the day-to-day running of the study. NBC is the study guarantor.

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Competing interests Somerset Foundation Trust has commercialised the PiP and owns its copyright and design rights. NBC, SS and JJ are co-innovators of the PiP and receive royalties. All other authors declare no conflicts of interest.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants. The study was registered as a quality improvement project at Somerset NHS Foundation Trust, ID SI-681. It was designed so that no elements of its conduct altered patient management in any way, with all patients receiving the SOC urine testing with a sterile plastic urine collection container. The PiP M&C results were not stored on the patient record. The study was run within a larger service improvement project. For these reasons, ethical approval and consent were not deemed to be necessary.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. The study data contain anonymised clinical information and are held by Somerset NHS Foundation Trust. Data sharing may be permitted upon reasonable request, subject to approval by the data-holding institution and compliance with relevant governance processes.

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