

Disposable female urinal bottle (the UniWee) improves patient experience for immobile women with lower limb fractures

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ABSTRACT

Background Female patients with lower limb fractures experience pain and loss of dignity when manoeuvred onto a bedpan. Poor bladder management, including urinary catheterisation for convenience, can lead to longer hospital stays and eventual loss of independence. Staff at Great Western Hospital Emergency Department modify disposable male urinal bottles to accommodate the female perineum without need to reposition the patient. These have not been used consistently and no formal evidence supported their use.

Methods This project was inspired by a patient who advocated widespread use of the 'female' urinal. We formalised the design of the urinal and spread use to other hospitals and an ambulance service in the South West of England over three improvement cycles. Feedback on utility and acceptability of this urinal was sought from the study group of female immobile patients (primarily hip fracture) and healthcare staff supporting them to use the urinal. Local feasibility studies were initiated in an emergency department and then extended to the emergency and trauma departments. The final cycle was a study in four hospital sites. Evaluation was conducted from January 2021 to February 2023.

Results The final study cohort included 103 immobile female patients and 118 healthcare professionals. 74% of patients (n=103) and 78% of healthcare professionals (n=118) in this trial would recommend the urinal. Patients felt they avoided pain because the urinal minimised movement and that it was a more dignified way to void their bladder. Healthcare professionals felt that the potential advantages were reducing the need for urinary catheters, and reducing lifting and log rolling patients.

Conclusion A disposable urinal that accommodates female anatomy and supplies the same advantage as the male urinal bottle in allowing the patient to void the bladder without repositioning, appears to be acceptable to patients and staff and would have value in many clinical settings.

INTRODUCTION

Hip fractures are the most common orthopaedic inpatient admission, with current UK incidence estimated at 76 000 per annum,¹ 75% of which are women.² Male patients who are immobile are offered commercially available disposable urinal bottles that can be used with minimal aid and little movement.³ Common practice for bladder voiding in female patients involves the use of a bedpan,⁴

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Female patients with lower limb fractures suffer pain and indignity when being moved onto bedpans to void the bladder, while men can use a male urinal bottle without being moved.

WHAT THIS STUDY ADDS

⇒ A female-specific urinal bottle was tested among patients and staff in several wards and hospitals in England and was found to be acceptable to both patients and healthcare staff. Patients reported minimal pain when using the female urinal and staff felt it created less work and avoided potential injury from the need to move patients onto traditional bedpans.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ A female-specific urinal bottle may reduce the use of urinary catheters for immobile women with reduction in catheter-associated infections and loss of independence. It anticipated that it would reduce lifting by healthcare staff (and injury from lifting) and reduce the number of staff required to assist patients.

which results in both pain and indignity during bladder voiding. Fractures are painful at the time of injury and any time the patient moves or is moved,⁵ for example, onto a bedpan despite optimal analgesia such as fascia iliaca block.⁶ Alternatively, voiding in immobile female patients is managed with an indwelling or intermittent urinary catheter with associated risk of infection, delirium and long-term impact on urinary continence and independence.^{7–8} For patients who cannot tolerate either, or soil themselves, incontinence pads are used with risk of associated dermatitis and urinary tract infections.⁹ Reluctance to use the bedpan can lead to avoiding fluid intake to prevent bladder filling,¹⁰ with resultant preoperative dehydration and post-operative kidney injury.¹¹ The use of bedpans also increases patient dependency,¹² and patients are often left waiting for assistance to void.^{13 14}

There is therefore inequity in bladder management for men and women in immobile patients. This project evaluates a disposable urinal that can be used by an immobile female patient when lying or sitting. Our project was inspired by a patient



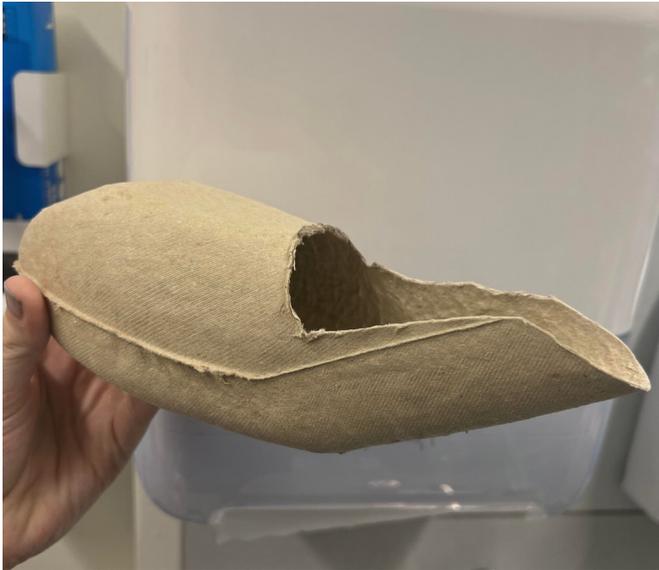


Figure 1 Photograph of the 'female' urinal.

advocate of this 'female' urinal and is in line with National Clinical Guidelines that promote minimising pain and postoperative delirium associated with hip fractures.^{15 16} This urinal is a simple modification of the disposable, round urinal bottle to accommodate female anatomy for patients to use while lying or sitting in bed (figure 1). Perceived benefits include minimising pain, maintaining patient dignity and autonomy, and reducing staffing needs and injury. This can be used with the patient lying or sitting and requires minimal or no movement of the patient. The intervention was advocated by a patient in the first instance and was, therefore, assumed to have a reasonable likelihood of success.

There is limited literature advocating the use of female urinals in hospitals^{4 17} and few equivalent products designed for female anatomy. A small number of staff, patients receiving palliative care and healthy volunteers were interviewed after using a female disposable urinal and concluded that female urinals should be available and offered to female patients in hospital.⁷ A conference abstract described use of non-disposable urinals for female orthopaedic patients and showed that the majority of patients found the female urinal more comfortable than a bedpan and would recommend its use.⁴ A further paper described methodology to scan the female perineum to optimise design of the opening of a female urination device, though generalisability was limited as the study cohort consisted of a small number of young Chinese women, who may not be representative of the wider population.¹⁸ There is a vast array of commercially available female urinals, some of which are disposable, most of which are designed for use while standing, some can be used sitting, but none is fit for purpose in a hospital setting or when lying down. At the time of our study, one pulp female urinal was commercially available; however, this is significantly more expensive than its male counterpart and is used in a manner similar to a bedpan.

The modified male urinal bottle has been used for many years in Great Western Hospital's (GWH) Emergency Department (ED), its provenance is unclear. In the past, it has only been made by a small number of staff. A patient attended GWH ED in January 2021 with a periprosthetic femur fracture and was adamant that she did not want to be moved onto a bedpan. She was grateful for and satisfied with the modified male urinal

bottle that she was able to use independently. She asked to be shown how to make the female urinal. She took a sample to the Trauma Department and subsequently taught her care givers how to make the urinal. She has been into hospital since her 2021 admission and continues to use this design and teach her care givers how to make it. This patient's enthusiasm inspired us to consider that the female urinal might have a more general application beyond our department and potential to benefit many patients while also addressing an inequity in bladder management.

METHODS

Study design

The Institute for Healthcare Improvement's Model for Improvement process with sequential Plan, Do, Study, Act (PDSA) cycles¹⁹ was used to evaluate utility and acceptability of the urinal to patients and healthcare professionals in EDs and Trauma and Orthopaedic (T&O) departments in district general hospitals in the South West of England (figure 2) between January 2021 and February 2023. This project required healthcare staff to use and make a non-commercial product to assist patients' toileting. The urinal is fashioned by cutting around the neck of the pulp urinal bottle to create a wider mouth with a posterior section that can be slid under the perineum. The urinal was offered as an alternative to patients with female anatomy who were over the age of 18, had capacity to verbally consent, were not in acute urinary retention, were immobile (primarily those who had sustained lower limb fractures such as hip fractures), were unable to use a male urine collection bottle, needed to void the bladder. These patients were invited to provide feedback. All healthcare professionals providing a urinal to a patient were invited to participate. The questions addressed were (1) is the modified male pulp urinal bottle useful for patients without male anatomy and (2) is it acceptable to that cohort of patients, and healthcare professionals supporting them. Our aim was to develop an acceptable product that could be more widely used and/or made available commercially by the end of 2023.

Problem definition

A driver diagram was used to present ways in which patient experience could be improved for immobilised patients prior to surgery and identified the need to minimise pain, maintain dignity and avoid catheter use. The female urinal has the potential to address these issues. We identified our study population as those providing bladder management for female immobile patients as well as the patient. The perceived advantages for staff included less lifting and reduced numbers of staff to assist with toileting. Questions that would allow us to assess utility and acceptability to patients and staff were identified.

Implementation team

The initial team leading the first cycle of this project (figure 2) in January 2021 at GWH was an Emergency Department Assistant, Paramedic and Registrar with advice from the patient advocate.

First cycle

The initial cycle involved understanding the existing level of knowledge about the use of the 'female urinal' among GWH ED staff. Education was provided on fashioning the urinal through training videos, posters and leaflets (online supplemental material 1). Feedback was sought from patients who had used the 'female' urinal and from staff supporting patients using them. Feedback was collected in the form of paper-based questionnaires. We

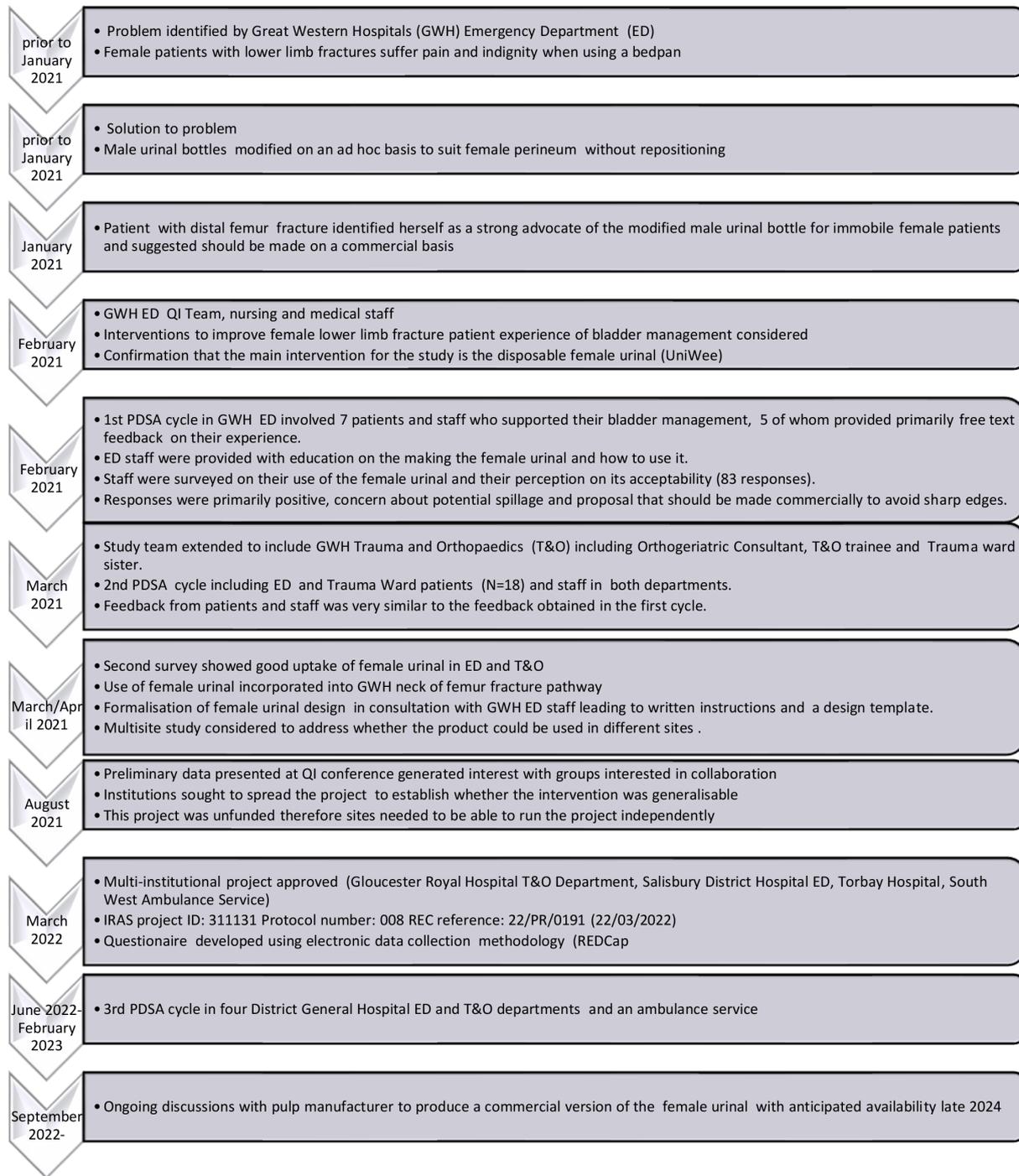


Figure 2 Time line of the sequential PDSA cycles used and the associated development of the female urinal project. PDSA, Plan, Do, Study, Act.

learnt that large scissors made a better product, that staff attitude influences patient perception.

Second cycle

The primarily positive outcomes from the first cycle encouraged us to extend our project to the T&O department at GWH. The study team was expanded to include an orthogeriatric consultant, the trauma ward sister and a T&O trainee. The second cycle (figure 2) involved providing education to the GWH trauma teams and reinforcing education in the ED. The study itself was not modified to ensure consistency. The essentially positive feedback encouraged us to spread the study to other sites in the South West of England.

Third cycle

The third/final cycle was a multi-institutional study (figure 2). Sites were identified through personal connections of the GWH team. Patients at Gloucester Royal Hospital were recruited from their ED and T&O departments, the project led by an orthopaedic consultant. Salisbury General Hospital recruited only from their ED. Torbay and South Devon Hospital included patients from T&O and ED and was initially run by a T&O trainee but subsequently run by Torbay Research Department. GWH recruited from ED, T&O and the local ambulance service (South West Ambulance Service NHS Trust). Each site of the multi-institutional study had an individual who led the study, including ED and Orthopaedic consultants, a T&O trainee, a

Research Nurse and Ambulance Service Research Lead. Each lead was supported by teams of nurses, healthcare workers, doctors and paramedics.

Outcome measures

The primary outcome measures were utility and acceptability to patients and healthcare professionals for all cycles. Utility was assessed by asking patients closed questions about the advantages of the urinal. Healthcare professionals were also asked closed questions about their perception of the utility of the urinal for patients and the impact on their working practices. Acceptability was addressed by asking patients and healthcare professionals whether they would recommend the urinal. Free text boxes were provided for patients and healthcare staff to describe anything they did not like about the urinal and for any other comments. Healthcare professionals were asked to provide limited demographic information about the patient. Patient position and body mass index (BMI) were collected by healthcare professionals in the final cycle as these variables may affect utility or acceptability (table 1). An online electronic survey tool was used in the final cycle.

Final cycle study size

A convenience sample was estimated from the expected attendances related to lower limb trauma. In the final multi-institutional study, each of the four sites sought to recruit as many participants as possible with a maximum of 40 patients and 40 healthcare professionals at each site between June 2022 and February 2023 to prevent dominance of any one site in the analysis.

Final cycle data sources

All data for the multi-institutional study were collected and managed exclusively using Research Electronic Data Capture tools,^{20 21} a secure, web-based software platform designed to support data capture for research studies. No patient identifiable data were collected. Surveys were considered complete if all questions were answered (except the free text field); incomplete responses were excluded from the analysis database. In some cases where patients were moved out of the ED before completion of the survey, they were contacted retrospectively and consented to participate and complete the survey. (Survey tool available as online supplemental material 2)

Final cycle data analysis

Kruskal Wallis test was performed to confirm no significant difference between the age data from the four sites. Free text comments from both patients and healthcare professionals were coded using inductive thematic analysis²² by the author (ST). After inductive coding of the feedback, the codes used were grouped into themes generated from the codes. The themes were 'negative' and 'positive' comments. The positive theme included codes of dignity, comfort and avoiding pain; the negative theme included codes of leaks and discomfort.

One-way analysis of variance (non-parametric data) of three groups followed by the Friedman test was performed to assess whether patient BMI influenced healthcare professional participants' view of whether they would recommend the urinal.

Statistical methods

Statistical tests were performed using GraphPad Prism V9.5.1 for Windows, GraphPad Software, San Diego, California USA, www.graphpad.com.

Table 1 Patient/staff questionnaire for UniWee study

Patient information	
How old is the patient (in years)?	
What position was the patient in?	<ul style="list-style-type: none"> ▶ Sitting ▶ Lying ▶ Other/what was this other position?
What was the patient's BMI*?	<ul style="list-style-type: none"> ▶ Low BMI (< 18.5) ▶ Normal BMI (18.5–29.9) ▶ High BMI (> 30)
Patient questions	
What reason(s) did you have for considering using a UniWee?	<ul style="list-style-type: none"> ▶ NOF† ▶ Other type of trauma ▶ Temporary immobilisation post-trauma ▶ Other/what was this other reason for using a UniWee
Have you used a UniWee before this hospital admission?	Yes/no
Would you recommend using a UniWee to another patient?	<ul style="list-style-type: none"> ▶ Strongly agree ▶ Agree ▶ Neither agree nor disagree ▶ Disagree ▶ Strongly disagree
What are the advantages of the UniWee?	<ul style="list-style-type: none"> ▶ Reduces pain from movement ▶ Privacy (able to manage on my own) ▶ More dignified than a bedpan
Was there anything you didn't like about using the UniWee?	
Any other comments	
Healthcare staff questions	
Have you used a UniWee for a patient before?	Yes/no
What reason(s) did you have for considering using a UniWee for this patient?	<ul style="list-style-type: none"> ▶ NOF ▶ Other type of trauma ▶ Temporary immobilisation post-trauma ▶ Other (please state why)
Did you use a UniWee for this patient? Yes/no	If no: What was the reason(s) for not using a UniWee for this patient? <ul style="list-style-type: none"> ▶ acute retention/catheter inserted ▶ cognitive status ▶ patient refused ▶ I was unsure how to make/use the UniWee ▶ Other/ what was this other reason for not using an UniWee?
Would you recommend using the UniWee for your patients	<ul style="list-style-type: none"> ▶ Strongly agree ▶ Agree ▶ Neither agree nor disagree ▶ Disagree ▶ Strongly disagree
Were there any advantages of using a UniWee?	<ul style="list-style-type: none"> ▶ Less pain ▶ More dignity ▶ Less work ▶ Avoid catheterisation ▶ Avoided log roll ▶ Avoided soiling ▶ Other/what were these other advantages? ▶ No, there were no advantage
*Body mass index (BMI)	
†neck of femur fracture (NOF)	

Reporting guidelines

Standards for quality improving excellence (SQUIRE) reporting guidelines were used.²³

Ethical considerations

The urinal is a minor modification of a well-established toileting aid that is used in most NHS hospitals. There was no modification to the patients’ surgical or medical management. Verbal consent was sought prior to use and patients without capacity were excluded from the study. Consent was also sought to complete the questionnaire and to use the data in the questionnaire. Data were anonymised prior to processing.

Patient and public involvement

This project arises from a patient’s wish for other patients to benefit from a urinal that does not require the patient to move. We have sought user and carer feedback throughout the project.

RESULTS

PDSA cycles (figure 2) allowed us to confirm the utility and acceptability of a female urinal and to refine the design with reference to comments received. The final cycle involved other institutions to ensure that the urinal was acceptable to staff and patients in other hospitals. Data from the third and final PDSA cycle are presented below:

Participants

A total of 103 patients and 118 healthcare professionals were recruited.

Patient characteristics

The age range of the patients was 19–102 years (mean=75, median=77, n=118). There was no significant difference between the age data from the four sites (p=0.15). Most patients (69% 81/118) had an estimated normal BMI (18.5–29.9), 12/118 (10%) a low BMI (<18.5), and 25/118 (21%) a high BMI (>30).

Most patients offered the urinal were immobile due to a hip fracture 73/118 (62%). Other indications included other lower limb trauma 23/118 (19%), temporary immobilisation post-trauma 16/118 (14%) and other issues including personal choice 6/118 (5.0%). 90% (106/118) of patients used the urinal in a lying position and 10% (12/118) were in a sitting position.

Patient feedback

Utility: the predominate patient-reported benefit (figure 3) was that the urinal avoided pain from movement (72/103), followed by it being more dignified than a bedpan (70/103) and increased privacy/ability to autonomously void their bladder (50/103).

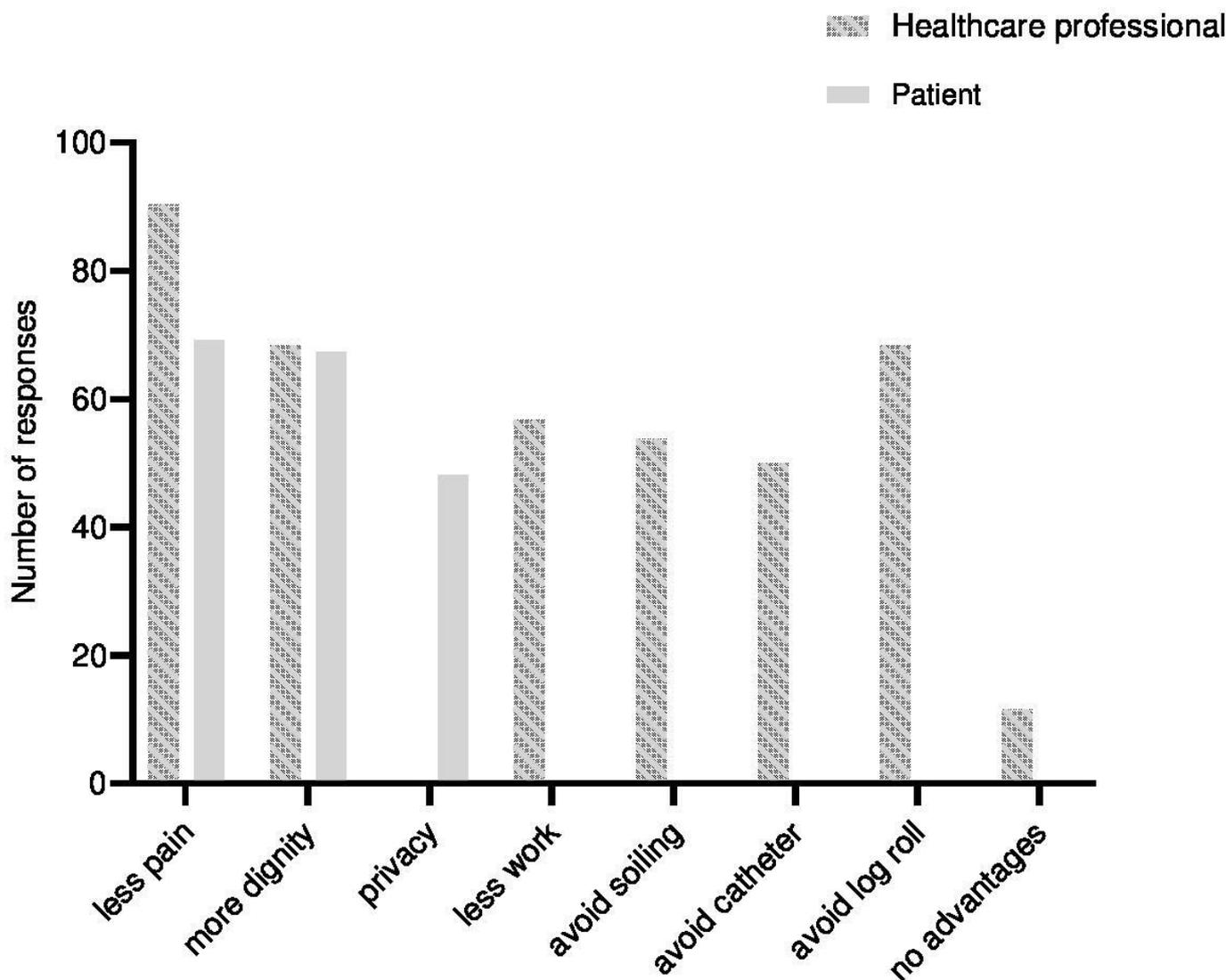


Figure 3 Survey feedback from patients (n=103) and healthcare professionals (n=118) on perceived benefits of using the urinal.

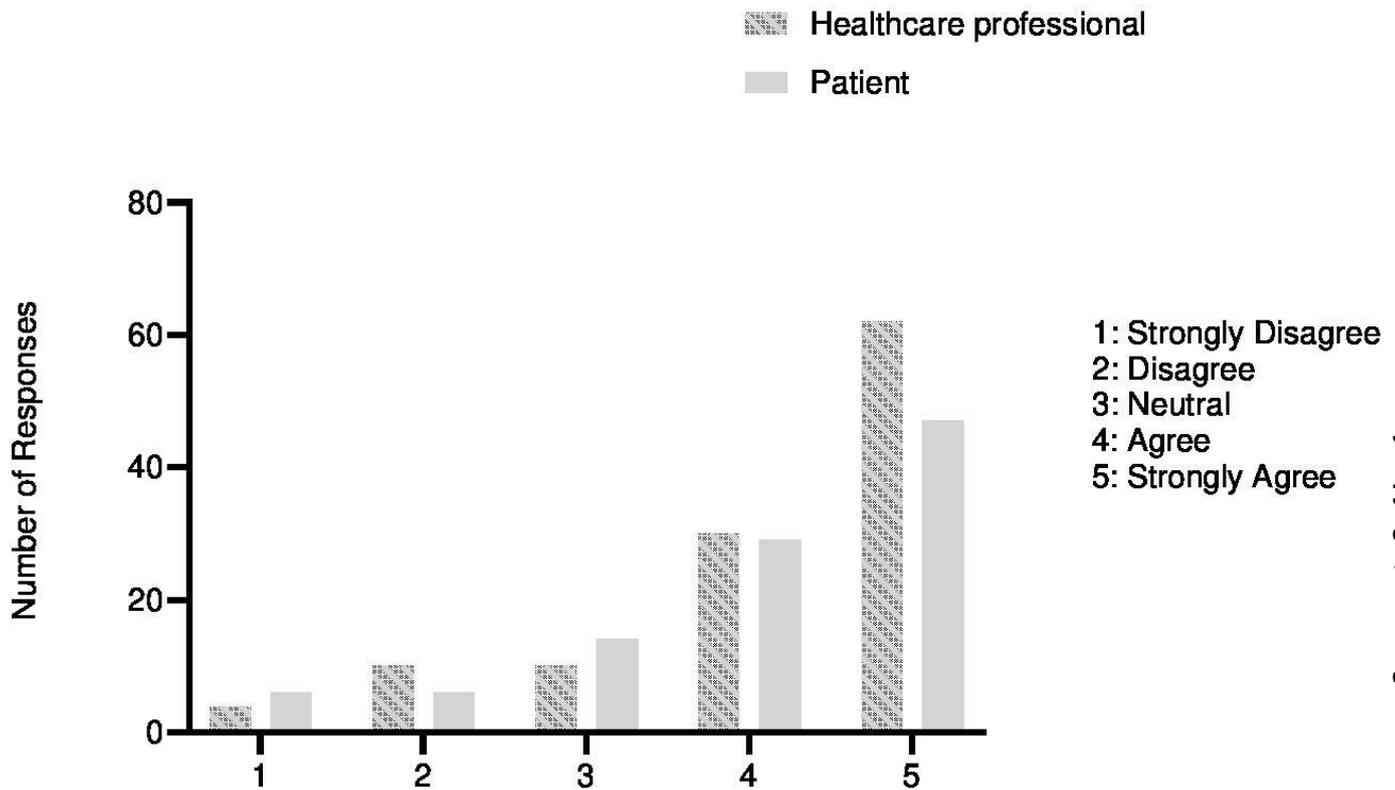


Figure 4 Survey feedback on acceptability of the urinal to patients (n=103) and healthcare professionals (n=118) using Likert scale.

Acceptability: 74% (76/103) of patients strongly agreed (47/103) or agreed (29/103) that they would recommend the urinal to a fellow patient (figure 4); 12/103 (12%) strongly disagreed (6/103) or disagreed (6/103) with this statement, and 14/103 (14%) provided neutral responses.

Healthcare professionals' feedback

Utility: healthcare professionals perceived benefits (figure 3) included avoiding pain for the patient (94/118=80%), avoiding the need to log roll a patient (71/118=60%) and increased dignity (71/118=60%). Other benefits included reduction in healthcare professional workload (59/118=50%), avoiding catheterisation (52/118=44%) and avoiding soiling (56/118=47%). 10% (12/118) stated that there were no advantages of the urinal over current practice.

Acceptability: 78% of healthcare professionals (92/118) strongly agreed or agreed that they would recommend the use of this urinal (figure 4); 13% (14/118) strongly disagreed or disagreed, and 9% (10/118) were neutral.

Free text feedback

Free text feedback was provided by 50% (52/103) of patients and 30% (35/118) of healthcare professionals.

Patient feedback included 26 positive and 23 negative comments.

- ▶ Negative comments included: *leakage, wet, uncomfortable.*
- ▶ Positive comments included: *easier/better than bedpan, brilliant, should be available in ED.*

Healthcare professional feedback included 17 positive and 9 negative comments.

- ▶ Negative comments included *wet, soiled, difficult.*
- ▶ Positive comments included *less pain, love this, easy to use, convenience.*

The data from healthcare professionals' feedback were analysed to assess whether estimated patient BMI influenced acceptability of the urinal to healthcare professionals (figure 5). One-way analysis of variance of the three groups followed by the Friedman test showed that BMI significantly ($p=0.018$) affected acceptability as perceived by healthcare professionals.

Sites with preprepared boxes of 10–20 urinals available weekly reported that these were all utilised, demonstrating actual usage was higher than the number of participants recruited.

DISCUSSION

This project was inspired by a patient using a design developed by nurses for patients. Most patients and healthcare professionals in this study would recommend the urinal. Patients felt they avoided pain due to movement, and that it was a more dignified way to void the bladder. Healthcare professionals felt that by using this urinal patients avoided pain related to movement, and that there were advantages related to patient urinary care management given reduced need for urinary catheters, and lifting and log rolling patients.

This majority of patient participants had hip fracture, and the outcomes are commensurate with the aspirations of a multidisciplinary approach to management of pain⁶ in hip fracture. If female patients feel that the urinal provides an option to void their bladders that does not involve pain and is dignified, this product could reduce the risk of infection, delirium and the longer term impact on independence associated with catheter use.^{8 9} It could also reduce the wait time for assistance and reduce fluid avoidance and associated dehydration or acute kidney injury.^{11 12 14}

The NHS Supply Chain purchased over 33 million disposable pulp male anatomy urinal bottles in 2022; however, only 381 624 bottles designed for female anatomy were purchased

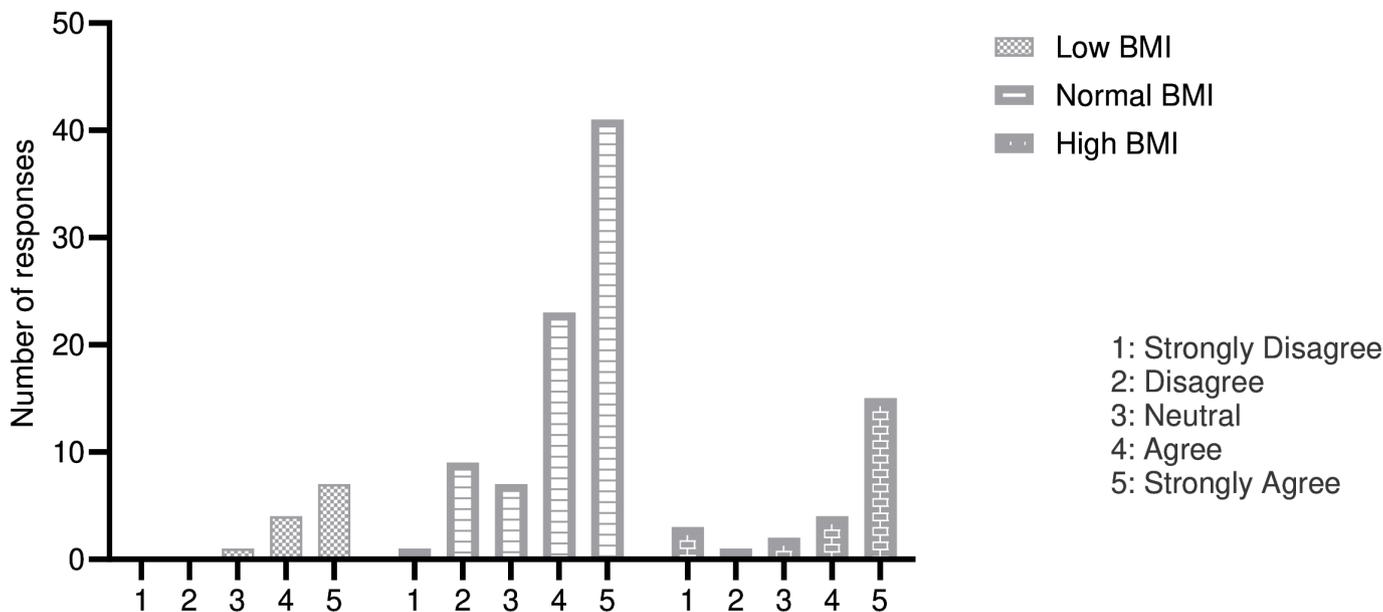


Figure 5 Acceptability of the urinal as a function of estimated body mass index (BMI) (Likert scale).

(personal communication, NHS Supply Chain), despite similar numbers of male and female patients.

Study limitations

This study did not compare different devices for bladder voiding directly. The healthcare staff who engaged in the study were self-selecting (those interested in using a non-commercial device) as were the study sites. It would be useful to measure outcomes such as staff time saved, reduction of catheter use, reduction of catheter-associated problems. The device was handmade and therefore may vary from person to person and have sharp edges.

The free text comments from patient and healthcare professionals were coded using inductive thematic analysis by the author ST and subsequently grouped into themes generated from codes. Codes and themes were not cross-checked.

Device limitations

There were negative comments relating to leakage and to sharp edges on this handmade device, and a lack of confidence in the integrity of the urinal under pressure. Patient-estimated BMI had a significant impact on acceptability to healthcare professionals and it was noted that some of the negative comments were related to the urinal not being as effective for patients with a higher BMI.

There was individual variability when making the urinal as it is reliant on tool availability (scissor size and sharpness) as well as staff skill, interest and time to ensure smooth edges. These could be addressed by the development of a commercially produced, machine-manufactured product.

Development of any future commercial product should recognise variation in habitus and need and be codeveloped with staff and patients.

CONCLUSION

The use of this type of urinal addresses an important health inequality for immobile women, has the potential to reduce NHS spend and releases staff time. It has potential to be used by any patient without male anatomy who is immobile; obstetric patients, postoperative patients in recovery, vascular patients pre/postlower limb amputation or patients with poor mobility.

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Contributors ST is the guarantor. ST designed the study, is fully responsible for the conduct of the study, had access to the data, analysed the data, is responsible for drafting this manuscript and controlled the decision to publish. SB, PE, SL, JP and ST lead the recruitment of participants and management of data in their respective departments. ML supervised the design of the data collection tool, provided advice on study design and contributed to manuscript writing. SB, PE, SL and JP have contributed to the final manuscript writing. All authors have read and approved the final version of the manuscript.

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Disclaimer Intellectual property is owned by Great Western Foundation Hospitals NHS Trust. Design protection is pending for this urinal. In the initial stages of this project the urinal was called an "EasyWee" however the name used now is UniWeeTM.

Competing interests Great Western Hospital Foundation NHS Trust are in discussion with OmniPac about commercialisation of this device, however, no funding support has been provided for this project or to the authors.

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 The third cycle multi-institutional study was approved by the Health Research Authority and Health and Care Research Wales (NHS) on 22 March 2022 (IRAS project number 311131) with Research Ethics Committee (22/PR/0191) approval. Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available upon reasonable request. Data are available on reasonable request. Requests to the corresponding author: Siân Thomas (sian.thomas9@nhs.net). De-identified participant data can be made available on request.

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