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Abstract

Aims and objectives: This study explored whether a female urinal is an acceptable, safe and effective product to meet the toileting requirements of women receiving palliative care on oncology wards in hospitals. Background: There is minimal evidence on how urinary incontinence should be managed in women receiving palliative care. Female urinals may present an option. There have been two general reviews of products available but no formal evaluation since 1999. Methods: This qualitative interview study used semi-structured interviews. 11 healthy volunteers, 9 patients and 7 staff members used (or assisted with) a VernaFem (Vernacare) female urinal and were subsequently interviewed. Directed content analysis was used to analyse the interviews. Results: User testing confirmed that the VernaFem is an acceptable, safe and effective product. Design improvements were suggested. Conclusions: While unlikely to be suitable for all patients, hospitals should consider offering a female urinal to patients in receipt of palliative care.

Key words: ● Continence ● Urination ● End-of-life ● Qualitative Toileting

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rinary incontinence is a significant issue for patients with cancer approaching the end of life (Twycross, 2003; Glare et al, 2011), but there is minimal evidence as to how this should be managed (Farrington et al, 2013).

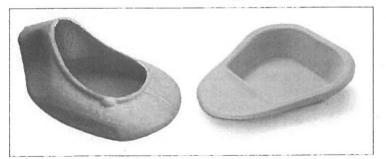


Figure 1. The VernaFem disposable female urinal made by Vernacare (left) and a Vernacare slipper bedpan (right), designed to be used inside a reusable plastic holder.

A recent study found nursing staff relied on 'practical wisdom' rather than evidence-based guidance to care for patients with urinary problems approaching the end of life (Farrington et al, 2015). A local audit revealed that a number of patients (over half), who died in two hospital wards and a hospice, died with an indwelling urinary catheter in situ (Farrington et al, 2014). There are strong arguments to reduce the number of indwelling urinary catheters used in acute care, largely due to infection risk (Health Protection Agency, 2011; King et al, 2012), as well as patient preference (Pfisterer et al, 2007). While alternatives to catheter insertion are available, there are many options for men (including bottles and urinary sheaths) and few for women. Bedpans are often used but patients can find them uncomfortable and embarrassing (Gattinger et al, 2013). Female urinals may present an alternative for women. There are two general reviews of the types of products available (McIntosh, 2001; Macaulay et al, 2006), but no formal evaluation of their suitability has been carried out since Fader et al (1999). There is no published investigation of the potential for use of the female urinal in palliative patients.

Background

A variety of female urinals are available (Continence product advisor, 201). These are mostly made from reusable plastic, and can be designed for use sitting, standing or lying down (Abrams et al, 2013). The multicentre evaluation by Fader et al (1997) tested 13 products with community-based women. They were mostly successful (easy to use without spillage) when standing or crouching, or when sitting on the edge of a bed or chair. Few were used successfully when the woman was supine. No one product was found to be suitable for all women, and women who had a higher level of dependency found fewer suitable products.

Women with cancer who are receiving palliative care in hospital have a varying degree of X .

X

dependency. Mobility may be impaired by pain, breathlessness, fatigue or neurological factors. Some women may be able to sit on the edge of a bed or chair without assistance, while others may be restricted to lying flat, for example in cases of spinal cord compression (National Institute for Health and Care Excellence, 2008). They will therefore have varying toileting requirements. This study aimed to assess whether the VernaFem female urinal (see Figure 1, alongside a Vernacare slipper bedpan) is an acceptable, safe and effective product to meet some or all of these requirements. The VernaFem was chosen as it is currently the only single-use female urinal available that can be pulped and is therefore suitable for use in hospital. This disposable system has a capacity of 900ml when flat (400ml when used at a 20° angle). It can be used with Vernagel (an absorbent powder designed to prevent spillages). The VernaFem had already been trialed with some success in acute settings (Medilink News, 2013).

Methods

Design

This small-scale, and exploratory qualitative interview study used semi-structured interviews to understand whether the participants found the VernaFem female urinal acceptable (comfortable and easy to use independently), safe (presenting no problems in terms of skin health) and effective (usable in a variety of positions without spillage). Interviews were employed to record data about the experiences of the women. The semistructured nature of the interview ensures that the same topics are addressed in each interview. but allows the interviewee to direct the conversation, ensuring that the participants' own experience is at the forefront of the data collected (Silverman, 2000; Patton, 2002). Use of this method ensures that the questions asked are both thematically appropriate (relevant to the knowledge we wanted to gain from the interviews) and dynamically appropriate (stimulates conversation and promotes a positive interaction) (Kvale and Brinkmann, 2009).

Participants and setting

Three groups of participants were interviewed:

- a) healthy volunteers (n=11);
- inpatients receiving palliative care on an oncology ward in hospital (n=9);
- healthcare professionals (nurses or healthcare assistants) caring for inpatients receiving palliative care on an oncology ward in hospital (n=7).

A relatively small sample size (total n=27) is acceptable using this methodology due to the rich

nature of the data collected, and the fact that in most qualitative research, new data tends not to occur after approximately 20 interviews (Green and Thorogood, 2009). Data collected from the patient and staff groups do not necessarily refer to the same incidents of use of the VernaFem. Some patients who used the VernaFem declined to be interviewed, while staff members who provided assistance to these patients were interviewed. In contrast, some members of staff declined to be interviewed when the patients they had assisted were interviewed. Usages of the VernaFem by patients and members of staff in the study are therefore treated as separate events, although in reality there was some overlap.

Healthy volunteers were recruited via an advertisement placed in the Faculty of Health Sciences, University of Southampton. All healthy volunteer participants were asked to use a female urinal and a bedpan at home, and were subsequently interviewed about this experience. The healthy volunteer cohort was included primarily to establish whether the VernaFem would be appropriate for patient use, and whether any caveats would need to apply in subsequent phases. To enable this, the healthy volunteers were interviewed in the first phase of the study, while interviews with patients and staff members took place in a second phase. Potential patient participants were identified by ward managers or nurses in charge of the three participating oncology wards in one NHS Trust, and asked to use a female urinal during their stay on the ward and be interviewed about their experience.

'Palliative' patients are deemed to be those with an advanced illness (here advanced or progressive cancer), who will not be 'cured' of their condition, who are approaching the end of their life, and who may have difficult or complex symptoms (World Health Organisation, 2002). Unlike the healthy volunteer cohort, patient participants were not required to use a bedpan in addition to the VernaFem, in order to reduce burden. However, all of the patients interviewed had used a bedpan previously, so their comparative experiences were discussed in the interviews. It was crucial to include patients judged to be in need of palliative care and those nearing the end of life in this research, in order to understand user experience and therefore improve the experience of this patient group. However, it was essential that measures were introduced to ensure sensitivity and to enable participation without undue burden. This included adhering to strict inclusion/exclusion criteria (see Table 1). Ward managers and nurses in charge also identified those members of staff

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Correspondence: n.farrington@soton.ac. uk The VernaFem was useful when patients were too tired to use a bedpan, in too much discomfort to roll, or were unable to stand due to pain?

who had assisted the patients in using the female urinal and were willing to be interviewed.

All participants received an information sheet prior to consenting, and established ethical principles of confidentiality and informed consent were followed. The study was approved by the Hampshire Research Ethics Committee (Reference: 15/SC/0017).

Data collection

Use of the female urinal and interviews occurred February 2015-March 2016. All participants were asked to use the VernaFem at least once-in addition healthy volunteers were asked to use the bedpan at least once-although the product was made available for them to try as many times as they wished. Interviews with healthy volunteers took place in the interviewer's office, those with healthcare professionals took place in a quiet space on the participants' home ward and, by necessity, interviews with patients took place on the ward on which they were receiving care. Efforts were made to ensure privacy. The interviews were recorded using a digital recording device and transcribed verbatim. Interviewing and transcription were conducted by NF and TH.

Data analysis

The transcribed interviews were organised using the qualitative analysis software QSR NVIVO version 10 (QSR International, Melbourne, Australia). Analysis was conducted by NF and TH. Directed content analysis was used to analyse the interviews. This is described by Hsieh and Shannon (2005) as a way of interpreting meaning from the content of textual data, that originates with a theory or previous research findings, as guidance for initial codes. This analytic method is popular in the field of end of life research (e.g. Blackford and Street, 2013; Bloomer et al, 2013). It is appropriate where some prior research exists

about a phenomenon but is incomplete (Hsieh and Shannon 2005). Directed content analysis begins by identifying key concepts or variables as initial coding categories.

The initial framework for exploring the potential usefulness of the VernaFem was based on the following categories/codes:

- Positioning: whether it is possible to use the female urinal in a supine position, and how this compares with other positions including sitting or standing;
- Spillage: whether the female urinal can be used easily without spillage of urine
- Ease of independent use: whether a nurse or care assistant is typically required to assist the patient using the female urinal
- Comfort: whether the female urinal is comfortable to use and how this compares with other methods of toileting they may have experienced
- Impact on dignity and privacy: whether the patient feels that using the female urinal allows them to maintain their dignity, and how this compares with other methods of toileting they may have experienced (including bedpans).

These were questions predetermined by prior research on toileting including Fader et al (1999), Farrington et al (2015) and Gattinger et al (2012). It was felt that these categories would help to determine if the VernaFem was acceptable, safe and effective.

In line with the directed content analysis method, interviews began with open questions, and then questions related to the above categories were asked. Analysis involved reading the interview text and categorising the participants' experiences and opinions using the predetermined codes, and any text that could not be categorised within these codes was given a new code, which was then further refined as a category or subcategory. While directed content analysis has limitations in that the data is approached with the preconceived categories in mind, and therefore may be subject to bias, the researchers employed strategies to improve the trustworthiness of the analysis (Lincoln and Guba, 1985 / firstly, TH and NF analysed the data separately before bringing the results together, and secondly, elements of the interview data that did not relate explicitly to the predetermined categories were rigorously coded and included in final analysis.

The results section describes the findings in relation to the predetermined codes, as well as relating significant findings that occurred outside these categories, including participants' perspectives on the success of the product, how

Table 1. Inclusion and exclusion criteria for patient participants.

Inclusion

- Adult women aged 18 or over
- Inpatient on participating oncology ward
- Receiving palliative care rather than curative treatment
- Able to understand the implications of the study and provide informed consent
- Able to communicate sufficiently well to be interviewed.

Exclusion

- Skin problems such as grade 3 or 4 pressure ulcers or wounds which may be damaged by the use of the VernaFem
- In receipt of curative treatment
- Unable to understand the implications of the study and provide informed consent, or communicate sufficiently to be interviewed
- In the terminal phase of life or deemed too unwell by nursing staff to participate.

the VernaFem compares with other methods of toileting and suggestions for improvement. *Table* 2 displays the number of times each participant used the VernaFem. Further numerical results are displayed in *Table 3*.

Results

Positioning

Basic guidance was provided to all participants only on positioning the VernaFem. Participants were told they could use the product in the position in which they felt most comfortable. They were advised that it could be used sitting in a chair, standing, or in bed, but asked to choose their own position. Interview data from healthy volunteers provided assurance that the VernaFem could be used in various positions. Over half of this group chose to use the product semi-supine lying in bed, propped up on pillows. Others sat upright in bed, sat in a chair, or even knelt on the floor. All but two of the healthy volunteers found the VernaFem easy to position, in contrast to the bedpan which was described as 'awkward' by three participants and found easy to position by only three participants. This suggested that the VernaFem would be at least as easy to position as the bedpan, and the research team felt confident in proceeding to test the product with patients.

In general, participants found the VernaFem as easy as or easier to position than the bedpan:

'You can get it very easily between your legs. You can also sort of, on a sitting position on a bed, it's, because of the size of it you can very comfortably get it in the correct position without having to sort of get yourself in an awkward position.' (Healthy volunteer VF004)

'They [bedpans] seem a good idea but I think to heave yourself over the top of that when you're not feeling very strong. It's probably a bit harder than just sitting on [the VernaFem]' (Patient PVF005)

'It's definitely a lot easier to put [VernaFem] in than a bedpan. 'Cos you have to kind of roll them over and stuff whereas this you can kind of just, they just shuffle their bum up a bit and it's in.' (Staff member SVF006)

Spillage

Many of the healthy volunteers were concerned about spillage (both with the VernaFem and the bedpan), and spoke of their concerns in terms of 'fear' and 'anxiety'. One patient participant could not use the VernaFem at all as she was so concerned about spillage:

'It stopped me from having a wee. Normally I would just carry on but I couldn't cos I thought oh it's going to go all over the bed.' (Patient PVF003)

This patient had used bedpans many times before, and was happy with their use. Table 3 shows that none of the staff members assisting in the use of the VernaFem experienced spillage, but it is also notable that two staff members describe holding the VernaFem in position for the patient, indicating that their presence prevented spillage from occurring. In contrast, staff members describe spillage as occurring frequently when bedpans are used. One member of staff even stated that she 'assumed' spillage would occur with a bedpan, whereas she found that the more enclosed shape of the VernaFem made spillage less likely.

Ease of independent use

All of the healthy volunteers were expected to use the VernaFem independently, and all did so, stating that this was more suitable for independent use than the bedpan. Three mentioned that the handle on the VernaFem allowed for easier positioning and therefore independent use. They saw this as an advantage of the VernaFem:

'I think if I was a patient I would prefer to use the urinal because I could help myself' (Healthy volunteer VF008) *Some expressed surprise that there was not already such a product in use in hospital*

Healthy volunteers		Patients		Staff members	
Participant number	Number of uses	Participant number	Number of uses	Participant number	Number of uses
1	1	1	3	1	1
2	1	2	1	2	1
3	1	3	1	3	1
4	1	4	1	4	1
5	1	5	1	5	3
6	1	6	2	6	1
7	1	7	1	7	
8	1	8	1		
9	1	9	3		
10	1				

¹ To preserve the ethical principles of confidentiality and informed consent, when interviewing, patients were not asked which staff members had assisted them, and similarly, staff members were not asked which patients they had helped. Therefore although there was cross-over among the participants (in some cases both the patient and staff member from the same incident of use were interviewed), it is not possible to match the patient with the staff member.

of the VernaFem.			
Position	Healthy volunteers (n=11)	Patients (n=10)2	Staff (n=7)
Sat on edge of bed	3	4	1
Sat up in bed	6	5	5

Table 3: Patient and staff responses the potential usefulness

Position	volunteers (n=11)	Patients (n=10)2	Staff (n=7)	
Sat on edge of bed	3	4	1	
Sat up in bed	6	5	5	
Completely flat in bed	1	I	0	
Standing	0	0	1	
Kneeling	1	0	0	

Spillage	Healthy volunteers (n=11)	Patients (n=10) ²	Staff (n=7)
Spillage	5	2	0
No spillage	6	7	7
Did not use for fear of spillage	0	1	0

Independence	Healthy volunteers (n=11)	Patients (n=10) ²	Staff (n=7)
Totally independent	- 11	3	1
Independent but struggled	0	2	0
Assistance of I staff member	N/A	4	5
Assistance of 2 staff members	N/A	0	Г

Comfort	Healthy volunteers (n=11)	Patients (n=10) ²	Staff (n=7)
Comfortable	9	8 '	6
Uncomfortable	2	Î	1

² Note that although 9 patients were interviewed, this table shows 10 incidents of patient use for position and spillage, as one patient used the product twice (once sat on the edge of the bed and once sat up in bed), and experienced only one episode of spillage.

> Patients described using the VernaFem independently or with one member of staff to assist. The majority of staff reported that they assisted with the use of the VernaFem. In 2 cases this assistance took the form of helping to position the VernaFem, and then leaving the patient to use the product alone. However, 3 members of staff held the VernaFem in place during urination because the patient was very tired and/or because they felt the product would have shifted out of position if they released it. One member of staff suggested that the increased independence was an advantage of the VernaFem in comparison with the bedpan:

'Yeah, so after I was shown the first time I didn't need anyone else to come in cos obviously you don't have to roll the patient to get them in so also it's quite good for you

know, a busy ward 'cos it could just be done by one nurse which is really beneficial.' (Staff member SVF005)

She implied that this was beneficial for staff but also for patients, as arrangements for toileting could be made more quickly.

Comfort

Healthy volunteers were concerned with whether the VernaFem was 'comfortable' or not, and used this term to describe both psychological and physical comfort. Only one healthy volunteer stated that she found the VernaFem physically less comfortable than the bedpan, while others stated that they felt more comfortable or confident with the VernaFem:

'Far, far easier, far more flexible, I felt much more comfortable using that' (Healthy volunteer VF004).

Some felt 'safer' or 'more secure' with the VernaFem, although two healthy volunteers did describe having more confidence in the bedpan initially, as it is more tried and tested.

Of the patient participants, only one found the VernaFem uncomfortable, and stated that she was happier to use a bedpan. Most found the VernaFem reasonably comfortable, and certainly more comfortable than a bedpan. Where 'comfort' was not explicitly mentioned, participants did use positive words such as 'perfect', 'magic', 'robust' and 'secure'. These results were mirrored in the staff member data, with the majority stating that their patients found the VernaFem more comfortable than a bedpan:

'I was with her and she didn't complain of discomfort unlike with the bedpan which digs into people's bums and they always complain when you put it under them and you have to say sorry it's really uncomfortable' (Staff member SVF004)

However, one staff member described how the edges of the VernaFem protruded and were quite uncomfortable for her patient on removal.

Impact on dignity and privacy

Some of the healthy volunteers felt that, compared with the bedpan, the VernaFem had the potential for improving dignity, citing the potential for independent use:

'There's something, ah, better about doing it yourself and having a bit of control over your

own body really. You know? There's something dignified in that, isn't there?' (Healthy volunteer VF008)

Despite this potential, only one patient participant talked in terms of dignity and privacy, describing the VernaFem as 'discreet'. Their concerns focused on spillage and positioning instead. Only three members of staff discussed dignity and privacy in relation to the bedpan and the VernaFem. Their observations on this subject largely related to the fact that as the VernaFem led to less spillage, bed changes were not necessary so often, which was more dignified for the patient:

'So I think it's a good idea that it gives people the opportunity to try something a little bit more dignified than laying in a soaking wet bed.' (Staff member SVF001)

'I think it's a lot more discreet as well, a lot more comfortable and like I say you're not then changing them again afterwards which is very obvious. Especially when they're in a bay and you've gone in once with a bedpan you come out and then you go back in to change their bed they know what's happened.' (Staff member SVF006).

How successful is the female urinal?

The VernaFem was successful in a number of ways. One positive point was the positioning of the VernaFem: it did not require the patient to lift themselves onto the product, but rather to place it between their legs:

'Well, it was comfortable. And, it wasn't... I didn't have to lift myself, that was the main thing, you know. Sitting on those big things...' (Patient participant PVF001)

Staff members commented that the VernaFem was useful when patients were too tired to use a bedpan, in too much discomfort to roll, or were unable to stand due to pain. One staff member stated that being able to have the VernaFem pressed up against the patient's body was useful in 'catching' the urine, and other staff members saw the VernaFem as better in terms of the patient's skin integrity as the positioning means that the patient does not 'sit in' their urine, which is well away from the skin. Both patients and staff found the option of sitting up to pass urine with the VernaFem beneficial. One patient was pleased with being able to use the VernaFem at night: she found she could position the VernaFem herself, meaning she could avoid the painful

experience of getting up to go to the toilet.

However, participants experienced several difficulties in using the VernaFem. Both patients and staff stated that their unfamiliarity with the product sometimes led to incorrect positioning and therefore spillage:

'I obviously didn't push it in, under far enough and when I pee, I pee a lot. It's like I sat on the front bit so it leaked back. So I did, I did get wet.' (Patient participant PVF006)

These issues may have been addressed if the participants had used the VernaFem for a prolonged period of time. In actual fact, healthy volunteers only used the product once, as did all but three patients and all but one staff member (see Table 2). Despite this, the general consensus was that when staff and patients become familiar with the product after practice, it would be easy to use. One member of staff and one patient suggested that the VernaFem was not appropriate for overweight patients. The patient found that the product 'squashed' underneath her weight, and the staff member found that she had to hold the VernaFem to stop it being pushed out of position by the patient's legs. Some patients also found that the VernaFem was not effective for too large a volume of urine:

'Like I said I am going like, nearly five hundred mils a go, I know you said it holds a lot but you know what I mean I still think that's pushing it' (Patient participant PVF006).

Comparison with other methods of toileting

Only two participants preferred the bedpan to the VernaFem. One healthy volunteer disliked the shape of the VernaFem, stating that it was 'less ergonomic', and one patient who was used to using bedpans was so concerned that the VernaFem was 'too small' that she was unable to bring herself to urinate in it. One staff member suggested that the bedpan was more appropriate for more dependent patients, but saw the benefits of the VernaFem for more independent patients. Another stated that she had initially been more comfortable using the bedpan due to familiarity, describing it as 'second nature'. In contrast, some participants were vehement in their criticism of the bedpan; a healthy volunteer and a patient described it as 'horrific' and 'horrendous' respectively.

Some patients' toileting habits were altered by the introduction of the VernaFem. One patient stated that she no longer used continence pads as a result: Despite these issues, the majority of patients and staff found the VernaFem an acceptable product for toileting.

The choice of toileting product should be made by patients, with the assistance of healthcare professionals, taking into account their individual needs.9

'So I don't make it to the toilet, you know. And I have to wear one of those big nappies which is quite hot, you know? So I don't do that if I've got [the VernaFem], 'cos I know that's nearby' (Patient participant PVF001)

When previously her only toileting option had been to use the bedpan, she had preferred to rely on continence pads. She did not feel the need to do this with the VernaFem. In another case, a staff member described how a patient was able to avoid having a catheter due to use of the VernaFem:

'And we were also thinking of whether she would be appropriate for a catheter... the bedpans were becoming a bit of an issue for her and she was...quite a palliative lady that whether to insert a catheter and obviously [the VernaFem] was recommended. I think that was a good thing 'cos it saves having for her to have a...catheter inserted 'cos she was still able to tell us when she needed to go to urinate and everything so it seemed more appropriate.' (Staff member SVF005)

This patient was still experiencing the urge to urinate, and still able to communicate this with staff, however she was struggling with using bedpans due to pain and weakness. The VernaFem was trialled and found to be an appropriate compromise.

Suggestions for improvement

Two main alterations were suggested by patient and staff participants. The first was to increase the volume that the product can hold. This suggestion was made by two staff members and two patients. One of the patients found that as she had been given diuretics, she was producing a large volume of urine. However, this participant did find that using 'Vernagel', a super absorbent powder which aims to prevent spillages by solidifying the urine collected, was helpful with this problem. The other patient, who was used to using bedpans, simply found the VernaFem 'too small'. She suggested that the product needed to be wider and longer, to 'give a sense of width and depth'.

The other suggestion made by one of the staff members was to reduce the ridge of cardboard that appears on the lip of the VernaFem. The patient she assisted found this small ridge quite uncomfortable as the product was placed in position and then removed. However, this staff member did state that the patient found the VernaFem overall more comfortable to use than the bedpan. Discussion: how acceptable, safe and

effective is the vernafem?

The patients participating in this study had various issues which made toileting in hospital a challenge, including: pain, general weakness and exhaustion, dyspnea and hemianesthesia. In conducting this study the researchers found that many of the patient participants had struggled with toileting in hospital, and were pleased to be offered the use of an alternative toileting product. The aim of this study was to determine whether the VernaFem is a safe, effective and acceptable product which meets the toileting requirements of women in hospital in receipt of palliative care. The following section discusses the acceptability, safety and effectiveness of the VernaFem based on the findings.

Acceptability: will patients and staff tolerate the female urinal?

In all 27 interviews conducted, only one participant found the VernaFem wholly unacceptable. This patient had various issues with the product: she found it too small, difficult to position, and structurally unsound (it squashed underneath her). She was unable to use it to void as she feared spillage. When asked to suggest improvements to the product, she asked for it to be made wider, longer and flatter - more like the bedpan with which she was familiar and comfortable. In contrast, the rest of the patient participants, and all of the staff members who assisted in using the VernaFem, would be content, if not eager, to use the product again. Some expressed surprise that there was not already such a product in use in hospital, one patient stating: 'Shame somebody hasn't come up with it a long time ago.'

The findings showed that the VernaFem is not without its problems: women still experienced spillage with this product, and some found positioning awkward. In addition, the fact that some staff members felt obliged to hold the VernaFem in place during use may have had a negative impact on privacy and dignity for the patient. Despite these issues, the majority of patients and staff found the VernaFem an acceptable product for toileting.

Safety: will patients be free from hurt or injury using the female urinal?

The principle safety concern of the research team was regarding skin integrity, as it is well known that palliative patients may be vulnerable to problems with skin integrity, which can be exacerbated by incontinence (Langemo, 2012). 'Skin integrity' was even considered as a possible predetermined coding

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category, although it was eventually decided that this category could be subsumed under other such as 'comfort' and 'spillage'. In actual fact, skin integrity concerns or related expressions such as 'wet' or 'moisture' were not mentioned by patients at all in the interviews. Two healthy volunteers expressed concern about urine coming into contact with their skin, both in the context of the bedpan. One stated: 'it felt like you were just sitting in urine after a while'. Only two staff members mentioned skin integrity, both stating that the VernaFem was preferable in this respect as urine was contained away from the patient's body. It seems therefore that our concerns regarding skin integrity were secondary to concerns of comfort and spillage for patients using the product.

In this study there were no safety concerns for patients or staff using the VernaFem. One staff member interviewed mentioned that the patient she helped with using the female urinal found the raised ridge on the product uncomfortable on insertion and removal. However, this would not stop her using the product again, particularly as the same discomfort occurs with the bedpan. Overall, the user experience showed that patients would not experience hurt or injury using the VernaFem.

Effectiveness: does the female urinal achieve the desired result?

The most common parameter used by all participants to determine whether the female urinal 'worked' was the level of spillage that occurred. Other factors, including comfort, were secondary. This was the case for the healthy volunteers, patients and members of staff. When participants referred to the product 'not working' they meant that spillage occurred or that urine was not contained properly.

As more participants experienced spillage with the bedpan than the VernaFem, it could be said that the VernaFem 'works' better than the bedpan for urinating for this patient group. However, spillage or leakage did occur with the VernaFem, ranging from a few drops of urine running over the outside of the product, to the entire voided volume leaking onto bedsheets. Where the latter occurred, this tended to be due to positioning errors, which the participants felt could be avoided with practice and adjustments. The majority of participants had more confidence in the effectiveness of the VernaFem to contain urine. However, this was not a universal experience, with one patient participant unable to use the product for fear of spillage. For this patient, the VernaFem did not achieve the desired

result, and she was far more confident in the effectiveness of the bedpan. This highlights that the choice of toileting product should be made by patients, with the assistance of healthcare professionals, in order to take into account their individual needs.

Study limitations

The principle limitation of this study is the small sample size, meaning the results may not be generalisable beyond this patient group. Despite this, user testing in this exploratory study shows that for women in receipt of palliative care in the acute hospital setting, a female urinal may safely be offered as an alternative to a bedpan for urination.

It must be noted that after recruitment for this study ended, Vernacare changed the design of the VernaFem (changes made were incidental to this study). The new VernaFem (see Figure 2 below) has a larger lip and a more rounded base, as well as a less indented handle, in order to allow for a volume of 1200 ml when positioned flat, and with a 'usable capacity' of 525ml, when held at a 20° angle. This increased capacity addresses one of the main concerns of participants. However as this study did not trial this version of the VernaFem, it is not possible for us to say whether these alterations are favourable for this patient population. Further research would be needed to determine the impact of these changes. Nonetheless, due to the largely positive findings of this study, the authors have recommended that the female urinal be offered to patients in receipt of palliative care in the hospital in which they work alongside more traditional methods of toileting.

VernaFem was preferable to the bedpan for urination for all but one patient participant.

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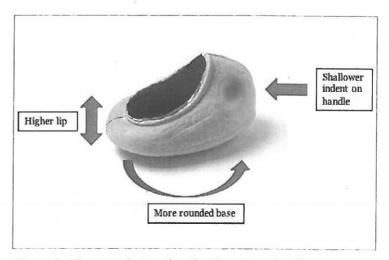


Figure 2. The new design for the VernaFem by Vernacare.

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Conclusion

This exploratory study has shown that the VernaFem has the potential to be a useful product to assist women in receipt of palliative care with toileting. In all the domains examined (positioning, spillage, ease of independent use, comfort and dignity), the VernaFem was preferable to the bedpan for urination for all but one patient participant. However, this product will not be appropriate for all patients, and nursing staff and patients would need to work together to assess the potential for use in individual cases; the important thing is that patients are provided with a range of options from which to choose. One of the healthy volunteers predicted this after trialing both the VernaFem and the bedpan:

'I think it's one of a number of strategies that should be put forward for people to have the option of using. I can imagine it may suit some and not others and so I guess it's useful to give people the opportunity to see what it is, try it, perhaps with support the first time, or depending on a person's preference.' (Healthy volunteer VF006)

The VernaFem is not the only female urinal available on the market; but it is the only one that is pulpable and therefore suitable for use in acute hospitals. As described, there are various types available from different companies, all of which are washable, which may suit different patient populations, particularly those living in the community. With the rise of the festival 'sheewee', the profile of the female urinal has been raised. Despite this, no one product will be suitable for all women. Further testing is necessary to compare the VernaFem with other female urinal designs, although at present a direct comparison is not possible as there are no comparable (pulpable) products available. Therefore, more research is needed that makes use of the expertise of engineers and materials scientists to produce effective products.

This study has provided some insights into the aspects of urinal use that could be measured in a future quantitative study or randomised controlled trial. While not all of the domains examined lend themselves easily to quantitative measurement, the primary concern of all participants in this study was spillage or leakage, and therefore a quantitative study of the effectiveness of female urinal designs could focus on this domain. This study also provides data that could inform a design specification for forthcoming female urinals. In particular, there

needs to be a focus on increased capacity, while retaining a shape which allows the product to be comfortably positioned between the legs.

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Contributions

Study design: MF, AR, NF; data collection and analysis: NF, TH; manuscript preparation: MF, AR, NF, TH.

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Conflict of interest

The authors declare that they have no conflicts of interest.

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