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ORIGINAL RESEARCH

Assessing the Value of PureWick™ for Female Urinary Incontinence in Non-Acute Settings: Multi-Country Cost-Effectiveness and Budget Impact Analyses

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ABSTRACT

Introduction: Urinary incontinence (UI) imposes a substantial clinical and economic burden. The PureWick™ device is a non-invasive alternative for women to pads/diapers and indwelling catheters, but its value has never been assessed internationally. We aimed at estimating the cost-utility and budget impact of introducing PureWick in nursing-home and home-care settings in Belgium, France, Germany, Italy, The Netherlands, Spain and the UK.
Methods: A 1-year decision model compared PureWick + pad with pad alone from the payer perspective (National Health Service-NHS/Personal Social Services). Model inputs were derived from a targeted literature review, national tariffs and manufacturer data; gaps were filled by expert judgement. The expected outcomes included quality-adjusted life years (QALYs), costs for each strategy and incremental cost-utility ratios (ICURs). Parameter uncertainty was explored with both deterministic and probabilistic sensitivity analyses. A dynamic budget-impact model projected per-patient costs over 3 years considering an increasing uptake (from 5 to 15%) of PureWick over pads.
Results: Relative to pads alone, PureWick + pad provided more QALYs (0.7792 vs. 0.7790) at lower cost, resulting in a cost-saving strategy in all country-setting combinations. In these countries, budget-impact modelling predicted

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per-patient savings of 29–1071€ and 77–2354€ in nursing home and home-care settings, respectively. The probabilistic sensitivity analysis confirmed the robustness of the model results across different countries and settings. The most influential parameters were unit cost and daily usage rate of the devices, nursing time requirements and the associated cost of nursing care.

Conclusion: Across the countries and care settings analyzed, PureWick combined with pads was a dominant strategy compared with pads alone. Policy makers should consider its inclusion in continence-care pathways while supporting real-world evidence collection to confirm long-term effectiveness, usage patterns and uptake assumptions.

Keywords: Female urinary incontinence; External urinary device; PureWick; Pad; Nursing home; Home care; Cost-effectiveness; Budget impact

Key Summary Points

Why carry out this study?

Urinary incontinence in women, particularly in non-acute settings, is highly prevalent and associated with substantial clinical and economic burden.

Female external urinary devices such as PureWick represent technological innovations able to improve urinary incontinence management, but robust economic evidence to inform reimbursement and adoption decisions across countries is limited.

The study assessed whether PureWick combined with pads is cost-effective and affordable compared with pads alone in nursing home and home-care settings in seven European countries.

What was learned from the study?

PureWick plus pads were cost-saving and slightly improved quality of life in all country-setting combinations, with savings up to 2354€ per patient over 3 years, considering increasing uptake (from 5% to 15%) of PureWick over pads. Reduced nursing time was the main driver of value for PureWick.

The findings support the potential inclusion of female external urinary devices in continence-care pathways and highlight the need for further real-world evidence to confirm long-term effectiveness, utilization patterns and uptake assumptions.

INTRODUCTION

Urinary incontinence (UI) is the involuntary leakage of urine, commonly affecting women and the elderly [1]. Epidemiological studies indicate that the prevalence of UI ranges from 25–45% in women and 5–35% in men, with an estimated 37.1% of women aged ≥ 55 years affected worldwide [1, 2]. Types include stress urinary incontinence (leakage during pressure on the bladder), urgency urinary incontinence (sudden, intense urge to urinate), overflow incontinence (constant dribbling due to incomplete bladder emptying), disability-associated incontinence (inability to reach the bathroom in time due to physical or mental impairments) and mixed urinary incontinence (combination of types) [3]. UI represents a substantial and growing challenge in healthcare, but its true scale is likely underestimated. From an economic perspective, in 2023, the economic burden of UI in Europe was €69.1 billion without caregiver costs, with women bearing quadruple the burden compared with men.

UI is a multifactorial condition influenced by gender, age, lifestyle and comorbidities. Women are at greater risk due to anatomical and obstetric factors, while advancing age leads to pelvic tissue degeneration and reduced muscle strength, increasing prevalence. Obesity contributes by elevating intra-abdominal pressure, and

smoking further weakens pelvic support through chronic cough and connective tissue damage. Medical conditions such as diabetes, hypertension, neurological disorders and recurrent urinary tract infections also play a significant role [4]. Among chronic disorders, UI represents one of the most bothersome diseases affecting physical and emotional dimensions and quality of life in general [5].

UI can be managed through various approaches, depending on the context (acute or non-acute), the type and the severity of the condition. Indwelling urinary catheters are indicated only in specific clinical circumstances, such as retention of urine (acute or chronic), monitoring of urine output during acute illness, during or post-surgical immobilization for some procedures or bedridden status to preserve skin integrity when other methods have failed, whereas absorbent products (pads/diapers) are more commonly used for ongoing containment in patients with some mobility impairment or when active treatment is not feasible or has failed [6]. Moreover, current clinical guidelines recommend minimizing the use of indwelling urinary catheters because of their well-established link with catheter-associated urinary tract infections (CAUTIs); consequently, absorbent products such as diapers and pads are commonly employed as an alternative approach for managing urinary incontinence in older patients and individuals with chronic illnesses [7]. Absorbent products help contain urine but require frequent changes and proper barrier protection to prevent moisture-associated skin damage and pressure ulcers [8]. Despite their widespread use, prolonged reliance on diapers without proper skincare measures can increase the risk of skin breakdown and infections.

A recently developed device, namely the PureWick™ system (from now on, PureWick), offers a non-invasive option for managing UI in women (Fig. 1). The system includes a soft, single-use external female device connected via flexible tubing to a reusable urine collection system comprising a suction unit and collection canister. The single-use external device is designed with a soft, conformable outer layer and an absorbent core that rests externally between the labia and along the perineal area. Its shape allows it to adapt to female anatomy while remaining entirely external, without entering the urethra. The device itself does not require electricity to function; when connected to the electrically powered suction unit, low continuous suction gently draws urine away from the body through the absorbent core and tubing into a sealed collection canister. By continuously diverting urine from the perineal skin, the system is intended to maintain dryness, reduce moisture exposure and minimize the need for frequent pad changes.

Fig. 1 Picture representing PureWick

Compared with diapers or pads, an external female device reduces prolonged skin contact with urine and moisture, which can cause rashes, dermatitis and pressure sores, lowers the risk of urinary tract infections associated with leakage and dampness, decreases discomfort and sleep disruption due to frequent nighttime changes and may reduce the risk of falls at night by lessening the requirement to get out of bed for toileting. Moreover, compared with indwelling catheters, PureWick is likely to reduce the risk of CAUTI and UTI [9, 10]. However, its effectiveness depends on correct placement and on whether the patient's anatomy and mobility are suitable. It may be less effective in individuals with very high urine output, severe mobility limitations or urinary retention. Continence management in hospitalized or bedridden female patients presents significant challenges, including skin integrity preservation, infection prevention and patient comfort. Selecting the appropriate continence

management device is crucial for minimizing complications, while ensuring effective urinary management. While innovative devices such as the PureWick System are increasingly being introduced into clinical practice and have shown potential to be cost-neutral or cost-saving [11], evidence to guide decision-makers on their economic value outside of the acute care environment remains limited. In particular, no cost-effectiveness studies are currently available to inform whether and how health systems should allocate resources to support their adoption. A comprehensive evaluation should consider multiple dimensions, including long-term sustainability, the workload on healthcare professionals and the environmental impact. Traditional continence management strategies, especially absorbent pads and briefs, generate substantial waste, require frequent disposal and contribute to the environmental footprint of healthcare facilities through both manufacturing and waste-processing emissions. By reducing pad usage, external urinary management systems such as PureWick may offer opportunities to lower waste volumes, decrease the use of single-use plastics and reduce the carbon and resource burden associated with transport and disposal. Understanding these potential environmental benefits is essential, as healthcare systems increasingly prioritize greener, more sustainable models of care.

However, the absence of robust economic evidence, including analyses of environmental externalities, poses a barrier to rational decision-making and the equitable integration of innovative solutions into care pathways. Comprehensive assessments are therefore needed to determine not only the clinical and financial value of new technologies, but also their contribution to sustainability goals in modern healthcare. From a gender-medicine perspective, female-specific external urinary devices such as PureWick represent a relatively recent innovation compared with the longstanding availability of male external urinary systems, highlighting the importance of evaluating their clinical and economic value also within an equity-focused framework of continence care.

To address the mentioned gaps, the aim of the present study was to conduct a cost-effectiveness analysis (CEA) and a budget impact analysis (BIA) to compare the use of the PureWick system and pads in non-acute (both nursing home and home-care settings). Pad-based management was selected as the primary comparator, as it represents the most widely used standard-of-care approach for urinary incontinence management in non-acute settings [12–15]. The analyses considered the payer perspective in Belgium, France, Germany, Italy, The Netherlands, Spain and the UK.

METHODS

The Model

A decision model was chosen for the health economic evaluation. This model was designed to project health outcomes (quality-adjusted life years, QALYs) and economic consequences related to female patients with UI managed with pads or PureWick + pad over a short-term horizon (1 year) in non-acute settings (nursing home and home care).

Pad-based management alone reflects standard practice in non-acute settings across the countries included in the analysis. Each pad change requires active nursing involvement and typically includes removal of the soiled pad, thorough perineal cleansing, inspection of skin integrity, placement of a clean pad and appropriate waste disposal.

The PureWick + pad strategy was assumed to employ 1.5 units of PureWick per day in combination with one backup pad per day. This combination reflects real-world practice in nursing home and home-care settings, where sporadic leakage, brief device downtime and occasional replacements occur, ensuring a conservative base case estimate. Conversely, the comparison strategy (pad) only accounts for pads.

In the PureWick + pad strategy, nursing activities include positioning or replacing the external device, performing hygiene as required, checking the suction system, disposing of used components and periodically replacing the canister collection and tubing. Pad-related care activities (e.g., removal, cleansing, skin inspection and

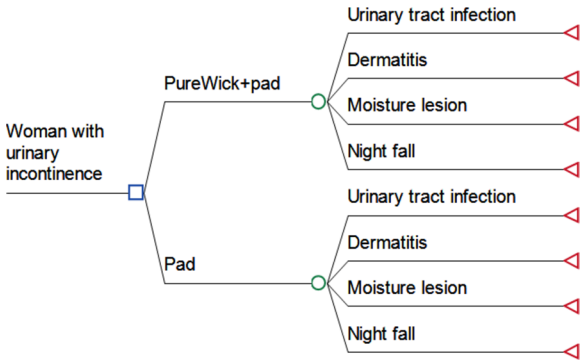

Fig. 2 Model representation

disposal) are performed only during the periods in which the backup pad is used and were therefore modelled proportionally to the time covered by pad use within the combined strategy.

A 1-year time horizon was adopted because the clinical outcomes and costs associated with urinary incontinence in nursing home and home-care settings occur within short timeframes, and longer horizons would add unnecessary uncertainty. This period aligns with annual budgeting cycles used by payers and reflects the typical duration of care episodes in these settings. It therefore provides a pragmatic and methodologically robust basis for evaluating the economic impact of continence management technologies.

The model (Fig. 2) compares two strategies according to the possible main complications (urinary tract infection [UTI], dermatitis, moisture lesion, night fall).

Night-time falls were included in the model based on evidence that urinary incontinence is an independent predictor of falls in older adults, beyond the effect of age alone [14]. Mechanisms such as urgency, nocturia, mobilization to manage saturated pads and rushing to the toilet can contribute to increased body instability, particularly at night.

The study population included women with any type of UI managed in non-acute settings. Population characteristics and patient's pathway management are assumed to be similar across the different countries considered in the analysis. The model incorporates the estimation of mean number of UTIs per patient and year to give a more precise estimate of costs and patients' quality of life. The model was developed and analyzed in Microsoft Excel®.

The analysis has been reported according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) [15, 16]. This study is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

Preliminary Data Collection via a Literature Review

To support the development of the economic model, a preliminary literature review was conducted to identify existing evidence on key outcomes associated with the use of the devices considered in the analysis, namely PureWick and pads. Distinct search queries were developed for each outcome of interest, namely infections, falls and skin problems (dermatitis and moisture lesions). In addition, the search also included nursing time (to account for the time needed to change and/or clean UI devices) and the environmental impact (to account for the waste generated daily with both PureWick and pads).

Each search strategy was structured around four blocks of keywords: (1) UI, (2) female incontinence, (3) continence devices and (4) the specific outcome of interest. Table 1 presents a summary of the key blocks and terms used in each search, while the detailed search strings are reported in Supplementary Table 1.

The searches were performed in two scientific databases, PubMed and Web of Science, and were launched in late November 2024. Searches were limited to studies published in the last 10 years (2014–2024). Furthermore, searches were restricted to title and abstract fields only, and to English language.

Articles were considered in scope when they presented data that were granular enough on the relevant outcomes (i.e., infections, skin problems, falls, nurse time and wastage) for female patients. Conversely, articles were considered out of scope if only devices' characteristics were discussed, when incontinence was treated with devices other than PureWick or pads, when

Table 1 Search strategy

Search blocks (linked with AND)	Specific keywords (linked with OR)
(1) UI	Incontinence, urine*, bladder control, leakage, dysfunction
(2) Female incontinence	Female*, woman, women, feminine
(3) Continence devices	PureWick, wicking device*, pad, pads, diaper*, pant*
(4) Outcome of interest	(4.1) Infections: infection*, UTI, CAUTI
	(4.2) Falls: fall*, drop*, sleep quality, sleep hour*
	(4.3) Skin problems: skin, cutaneous, derma, cutis, dermis
	(4.4) Nurse time: nurse*, APN, personnel, plus: time, timing, hour*, minute*, nurse-driven protocol
	(4.5) Environmental impact: waste*, environment*, carbon, CO_2, greenhouse gas, water consumption, pollution, Life Cycle Cost*, Life Cycle Assessment, LCA, sustainability, ESG, Environmental Social Governance, toxicity

APN, advanced practice nurse; *CAUTI*, catheter-associated urinary tract infection; *CO_2*, carbon dioxide; *ESG*, Environmental, Social and Governance; *LCA*, life cycle assessment; *UI*, urinary incontinence; *UTI*, urinary tract infection

outcome data were aggregated for male and female population or when outcome data were missing.

For each included article, the following data items were retrieved:

- Article information: title, abstract, authors, publication year and country where the study was conducted.
- Study design: type of study, setting of care (i.e., nursing home or home care), device of interest (i.e., PureWick, or pads), type of patient population (e.g., patients with chronic incontinence), number of (female) patients, mean age.
- Outcome of interest: specific outcome object of study, measure, unit of measure, frequency.
- Costs: costs of devices and of the management of complications (if available).
- Quality of life: quality of life instruments and measure.

Overall, after duplicate removal, the searches retrieved 1908 records (i.e., 1385 for infections, 172 for skin problems, 135 for environmental impact, 123 for nurse time, 93 for falls). After title and abstract screening, 96 records were selected for full-text read, and 19 were ultimately considered in scope and potentially useful for the analyses. Furthermore, 14 other potentially relevant articles were identified through citation chaining of the records selected for a full text read, of which 4 were considered in scope and deemed potentially useful for the analysis, leading to a total of 23 articles identified through the review. Of these, four were ultimately included in our model [9, 17–19]. Given the consideration of multiple care settings (nursing home, home care) and multiple countries, the evidence collected as part of the literature review was complemented with several additional country-specific sources, from both the scientific and the gray literature, the synthesis of which is reported hereafter.

Healthcare Resource Consumption and Costs

The model assumed an average use of four pads per day [20], with each change requiring active nursing involvement. Nursing time for pads (18.59 min per change [21]) includes removal of the soiled pad, perineal cleansing, skin inspection, positioning of a new pad and waste disposal. In contrast, for the PureWick + pad strategy, the model considers 1.5 PureWick devices per day combined with one backup pad. Nursing

Table 2 Healthcare resource consumption data and frequency of events, by device

Item	PureWick	Pad
N devices used per day	1.50 [22]	4.00 [20]
Frequency of change of PureWick canister + tubing (days)	60.00**	–
Nursing time for replacing the device (minutes)	8.50§	18.59 [21]
Nursing daily time for additional device-related activities (minutes)[1]	0.08§	–
Frequency UTI per year	0.41^	0.41 [23]
Frequency dermatitis per year	–	0.06 [24]
Frequency moisture lesion per year	–	0.24 [25]
Frequency night fall per year	–	0.03 [26]
Weight consumable kg (1 piece)	0.18**	0.36 [21]
Weight PureWick canister + tubing (kg)	0.43**	–

UTI, urinary tract infection

[1]Considers canister and tubing change for PureWick every 60 days

§Validated by healthcare professional (AY). ^Assumed for PureWick the same UTI frequency of pads due to lack of specific studies in nursing home/home setting on PureWick. **Manufacturer internal data

time for PureWick replacement (8.5 min, validated by clinical expert input) reflects device repositioning/replacement, basic hygiene as required, system checks and disposal. In addition, a minimal daily time (0.08 min) was included to account for canister/tubing replacement every 60 days, prorated on a daily basis. Because PureWick continuously diverts urine away from the skin, the frequency of full perineal cleansing and pad changes is reduced compared with pad-only management. Healthcare resource utilization for model inputs is reported in Table 2.

Since the analysis was conducted from the payer's perspective in all countries, costs included device acquisition, healthcare personnel (particularly nursing staff) and complication management. Table 3 reports values in euros for all countries except for the UK (where pounds are used), updated to 2025. In case country-specific cost data could not be retrieved, assumptions were made. Specifically, cost data for Belgium on the management of UTIs, dermatitis and moisture lesions were unavailable; therefore, corresponding cost estimates from The Netherlands were applied given the similar care pathways, provider mix and unit-tariff structures in non-acute settings across the two systems. Sensitivity analyses (±30%) around these inputs were conducted to confirm that conclusions are robust to plausible Belgian cost variation.

Event frequencies for complications associated with pad-based care were derived from published literature. The annual incidence was estimated at 0.41 urinary tract infections per patient [23], 0.06 episodes of incontinence-associated dermatitis per patient [24] and 0.24 moisture lesions per patient [25]. Moreover, the model assumes that PureWick may reduce the need for night-time mobilization associated with pad changes, thereby potentially reducing the fraction of falls attributable to incontinence management. The annual fall rate applied in the pad arm (0.03 per year) was conservatively derived from the literature [26] and represents the risk of night-time falls associated with urinary incontinence that result in fracture. These estimates were conservatively applied to the pad arm and are reported in Table 2.

When modelling the clinical and economic impact of PureWick compared with pad-based urinary continence management, it is both

Table 3 Costs, by device and countries

Costs	Belgium (€)	France (€)	Germany (€)	Italy (€)	The Netherlands (€)	Spain (€)	UK (£)
Cost PureWick (1 piece)[1]	8.99	8.99	8.99	8.99	8.99	8.99	6.51
Cost PureWick canister + tubing[1]	44.99	44.99	44.99	44.99	44.99	44.99	31.00
Cost PureWick suction unit[1]	449	449	449	449	449	449	341
Cost pad	0.31**	NH 0.94 HC 1.28 [27]	0.25**	0.92^	0.31**	0.57 [28]	0.205**
Cost ordinary wastage Kg[2]	0.02 [29]	0.27 [30]	0.27 [30]	0.30 [30]	0.14 [30]	1.40 [30]	1.14 [30]
Cost invasive wastage kg[2]	1.00 [31]	0.72 [30]	0.72 [30]	1.30 [30]	0.69 [30]	1.40 [30]	3.93 [30]
Nurse cost per minute	NH 0.724 HC 1.217 [32]	0.275 [33]	0.500 [34]	0.412 [35]	NH 0.724 HC 1.217 [32]	0.320 [36]	NH 0.238 [37] HC 0.450 [38]
Cost UTI	2889.95 [39]	1305.18 [40]	1395.79 [41]	286.50 [42]	2889.95 [39]	2225.00 [43]	1066.00 [44]
Cost dermatitis	123.54 [45]	144.45 [46]	92.75 [3]	45.50 [3]	123.54 [45]	238.02 [4]	144.22 [47]
Cost moisture lesion	123.54 [45]	144.45 [46]	107.75 [3]	161.00 [3]	123.54 [45]	238.02 [4]	144.22 [47]
Cost fall	2285.06 [48]	5000.00 [49]	6019.00 [50] [5]	2131.50 [51] [6]	2725.10 [52]	7934.40 [53]	3317.24 [54]

HC, home-care setting; *NH*, nursing home setting

[1]*Source*: Purewick Price Guidance EMEA. [2]Cost of ordinary/invasive wastage is not considered in the home-care setting as waste management is typically absorbed into household municipal services and does not generate direct, measurable costs for the healthcare payer or provider. [3]Estimated considering skin product use for 2 weeks. [4]Approach based on micro-costing: it is assumed that 95% of dermatitis cases resolve on their own (cost €0.00), while 5% require hospital admission (L22: diaper dermatitis = €4760.36 [ICD-10]). [5]DRG 166C—hip fracture group. [6]Mean value DRG 235–236 (fracture). ^Estimated based on the use of Tena Flex Medium. **Manufacturer internal data

[§]Validated by healthcare professional (AY)

reasonable and clinically defensible to assume no moisture lesions, no incontinence-associated dermatitis (IAD) and no night-time falls associated with the device. This assumption is grounded in PureWick's mechanism of action, its influence on risk pathways known to drive these complications and the available real-world evidence. In particular, a recent randomized trial of PureWick in the community found negligible skin irritation with the device (mean Draize score across 1065 assessments in 107 subjects was 0.16) [55].

PureWick continuously diverts urine away from the skin, preventing prolonged moisture exposure, the primary cause of incontinence-associated dermatitis and moisture lesions commonly seen with absorbent pads. By keeping the perineal area dry, the device effectively removes the underlying risk pathway for these complications. PureWick also reduces night-time falls by eliminating the need for users to get out of bed to manage saturated pads or rush to the bathroom, which are frequent triggers of nocturnal injuries in older adults with urinary incontinence. Available nursing home and home-care studies describe improved dryness, fewer skin issues and reduced night-time disruptions, with no device-related dermatitis or falls reported [55, 56].

For the PureWick+pad combination, the model assumes that PureWick is used 63% of the time (each device lasting 10 h), while a pad is used for the remaining hours. Consequently, the rates of skin problems (dermatitis and moisture lesions) and night-time falls associated with pad use were applied proportionally to the time during which the pad is used.

For UTIs, the model assumed the same frequency for PureWick as for pads because of the absence of specific studies evaluating UTI rates associated with PureWick use in nursing home or home-care settings.

Quality of Life Data

Quality of life was assessed through the literature search as well. A utility value = 0.78 was applied for a female patient with UI [57], while disutilities of 0.09, 0.033 and 0.121 [21] were applied to UTI, dermatitis/moisture lesion and fall, respectively. The duration of these events was respectively 6 [58], 3.3 [59] and 30 days [60].

Cost-effectiveness Analysis: Methodological Details

Cost-effectiveness analysis was performed by estimating the incremental cost-utility ratios (ICURs) as the difference in the mean expected costs between PureWick + pad versus pad, divided by the difference in the mean expected QALYs between these options. Cost-effectiveness thresholds were chosen in accordance with the different country guidelines (Supplementary Table 2).

To evaluate the robustness of the model, both deterministic and probabilistic sensitivity analyses (PSA) were performed. In the PSA, uncertainty was incorporated by assigning probability distributions to key model parameters. Beta distributions were used for utilities, while gamma distributions were applied to complication rates and cost variables. The variability of these parameters was defined by applying a ± 30% deviation from their baseline values. The model underwent 1000 Monte Carlo simulations, with parameters randomly drawn from their respective distributions. The results were visually summarized using cost-effectiveness acceptability curves (CEACs) for the ICUR. Additionally, one-way sensitivity analyses were conducted, applying the same parameter variations as in the PSA.

Budget Impact Analysis: Methodological Details

A dynamic budget impact analysis (BIA) model was developed to compare PureWick for managing patients with UI to hypothetical future scenarios that assume a gradual increase (+ 5% year 1, + 10% year 2, + 15% year 3) in the adoption of this device at the national level in the different countries.

To conduct the BIA, a sample of 1000 patients with UI in non-acute settings was considered across the different countries to allow meaningful comparisons.

The total costs for both the current and future scenarios were estimated by scaling the annual

Table 4 Mean costs per patient and cost-utility results, by country, device and setting

Country	Setting	Cost PureWick + pad strategy	Cost pad strategy	Difference	ICUR
Belgium	Nursing home	15,005 €	21,389 €	− 6384 €	PureWick + pad dominant
	Home care	20,653 €	34,767 €	− 14,114 €	
France	Nursing home	9539 €	9711 €	− 171 €	
	Home care	9599 €	10,061 €	− 462 €	
Germany	Nursing home	11,911 €	14,868 €	− 2957 €	
	Home care	11,848 €	14,725 €	− 2878 €	
Italy	Nursing home	10,653 €	12,893 €	− 2240 €	
	Home care	10,583 €	12,734 €	− 2152 €	
The Netherlands	Nursing home	15,039 €	21,468 €	− 6428 €	
	Home care	20,658 €	34,780 €	− 14,123 €	
Spain	Nursing home	10,608 €	11,486 €	− 878 €	
	Home care	10,279 €	10,745 €	− 466 €	
UK	Nursing home	7454 £	7939 £	− 485 £	
	Home care	9618 £	13,095 £	− 3477 £	

ICUR, incremental cost-utility ratio

per-strategy cost according to the proportion of the eligible population adopting each approach. To maintain a dynamic model, the calculation accounted for new incident cohorts entering the system each year. Financial projections were reported as undiscounted costs, as the analysis aimed to capture the expected budget impact at specific time points without adjusting for the time value of money [61].

RESULTS

For all countries and settings, QALYs were 0.7792 for PureWick + pad and 0.7790 for pads alone. Table 4 shows that introducing PureWick in combination with pads is economically favorable compared to using pads alone in all settings examined. Supplementary Fig. 1 presents the detailed breakdown of costs by category and shows that the main cost drivers are device costs, device utilization rates, and nursing time and associated costs.

The PSA confirmed the robustness of the model results in favor of PureWick + pad versus pad across all countries, with the exception of France, where cost-effectiveness appeared borderline (range 49.90–50.40% in the nursing home setting), while probabilities reached up to 96.10% in Belgium (home-care setting), across thresholds ranging from 0€ to 100,000€ or 0£ to 100,000£, depending on the country. The different acceptability curves are reported in Supplementary Fig. 2.

One-way sensitivity analyses (Supplementary Table 3) identified the key parameters that substantially influenced the incremental cost-utility

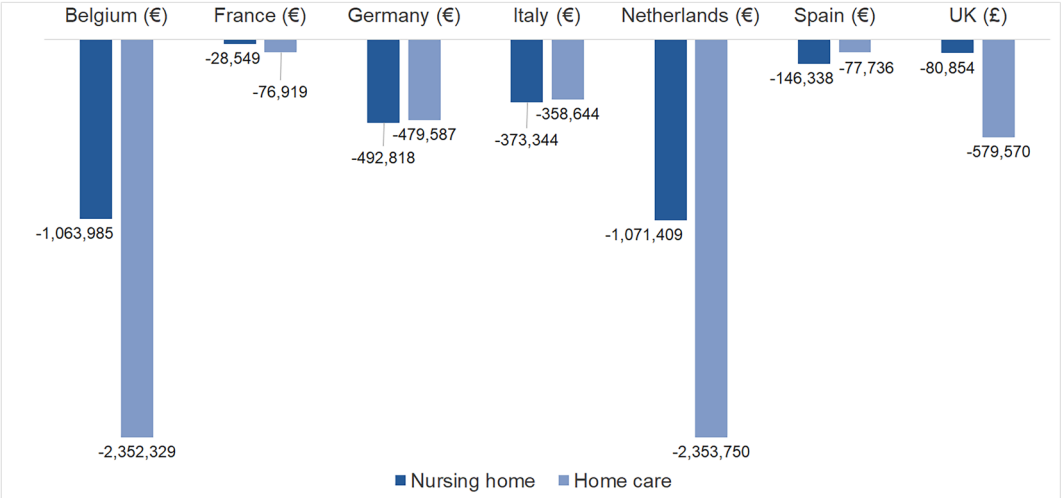

Fig. 3 Three-year budget impact by country and care setting, assuming an annual cohort of 1000 patients

ratios (ICURs) across all evaluated countries and care settings. The most influential parameters included the unit cost and daily usage rate of the devices, nursing time requirements and the associated cost of nursing care. Clinical outcomes, like the frequency, duration and disutility of urinary tract infections, did not report an impact on the results.

Figure 3 summarizes the average budget impact associated with scaling up PureWick over the 3-year horizon. Overall, the results show that PureWick is cost-saving in all contexts and that cost savings are substantial in Belgium and The Netherlands (for these two countries, cost profiles are overall similar because The Netherlands' costs were also used for Belgium when country-specific cost items were missing), particularly in home care (up to 2354€ per patient over 3 years). In France, Spain, Italy and Germany, savings are modest but consistent across both care settings, with a minimum estimated saving of 29€ per patient over 3 years. In the UK, the model shows significant savings in home care (580£ per patient) and smaller savings in nursing homes (81£ per patient).

DISCUSSION

The present study assessed the cost-effectiveness and budget impact of PureWick combined with pads versus pads alone for the management of women with urinary incontinence in non-acute settings. Across the seven countries analyzed, the magnitude of cost savings associated with PureWick + pad varied substantially, reflecting differences in national cost structures and long-term care practices. Belgium and The Netherlands showed the highest levels of savings, partly due to shared assumptions where Belgian data were missing and Dutch cost profiles were applied, highlighting how higher baseline nursing costs amplify the economic benefit of adopting PureWick. A consistent finding across countries is that nursing time is a key cost driver in continence management. Technologies such as PureWick, which reduce the frequency and intensity of routine nursing tasks, can ease workload pressures, help preserve staff resources for higher-acuity care and indirectly support care quality, patient comfort and staff well-being. An optimized management of this condition aligns with the principles of value-based healthcare [62, 63], which prioritize interventions that deliver optimal outcomes for the resources invested. This is particularly relevant in healthcare systems constrained by

limited budgets. Additional dimensions of value associated with PureWick, while having a limited impact, include reduced complications (e.g., skin problems and nighttime falls) and a lower environmental footprint. Beyond economic considerations, recently the relevance of gender-specific innovation in continence care has been emphasized, highlighting that severe chronic urinary incontinence in older women has historically lacked dedicated technological solutions, in contrast to the long-standing availability of male external urinary devices [64]. This positions PureWick as a female-specific response to an unmet need, raising important considerations related to gender equity in access to appropriate continence technologies. This broader perspective links patient-centred outcomes (such as comfort and skin integrity) with resource utilization and sustainability, further reinforcing the value of PureWick in health-economic and policy decision-making.

Current literature highlights a significant gap in studies evaluating PureWick from a costing or cost-effectiveness perspective. More generally, robust data on the clinical, economic and quality-of-life burden of urinary incontinence are limited, hindering comprehensive economic assessment and leading to underestimation of its true impact. Existing evidence on PureWick comes mainly from observational and early clinical studies, which report reductions in pad use, nighttime awakenings and caregiver workload, as well as high urine-capture efficiency, ease of use and good patient tolerability [56, 65, 66]. Taken together, these findings suggest that PureWick is a non-invasive, user-friendly alternative that may enhance comfort, dignity and care efficiency for women with urinary incontinence, but its full economic value remained to be quantified.

Despite the rigorous adherence to CHEERS guidance [15, 16] and the use of country-specific inputs wherever possible, several limitations temper the confidence with which our findings should be interpreted. First, the model's structure, spanning seven health-care systems (i.e., Belgium, France, Germany, Italy, The Netherlands, Spain and UK) and two care settings (i.e., nursing home and home care), required an extensive evidence base that was not always uniformly available. Consequently, for some parameters (e.g., nursing time, complication rates in home care and country-specific device prices), we relied on proxy estimates or clinical judgment/validation, which may only partially capture local practice patterns. Second, cost data published only in national languages or embedded in grey literature could not always be retrieved, raising the possibility that important country-level tariffs or reimbursement schedules were missing and that device costs are under- or over-stated in specific jurisdictions. Third, our target population, namely women potentially affected by UI across nursing home and home-care contexts, is inherently heterogeneous in age, frailty, baseline risk of falls and skin integrity. While we attempted to model average risks, residual heterogeneity may attenuate the external validity of the results. Fourth, there is no internationally accepted core outcome set [67, 68] or harmonized definition of adverse events for UI technologies; variation in how source studies measured rates of falls, moisture lesions and UTIs may introduce additional uncertainty in the model results.

Another limitation of this study is the restricted comparator scope. Alternative device-based strategies exist, including indwelling catheters and other female external urinary collection devices (e.g., PrimaFit, UriCap). However, indwelling catheters are primarily used in acute care settings and for specific clinical indications, while their long-term use in non-acute contexts is generally discouraged because of the associated risk of complications [6, 7]. Similarly, although other external devices are available, the current evidence base on their use, effectiveness and costs in non-acute settings remains limited and heterogeneous, precluding their inclusion in a robust comparative economic model. Consequently, the analysis focused on the comparison with pad-based management, which reflects current standard practice. Future research could expand the range of comparators as more consistent and high-quality data become available, enabling a broader assessment of the relative value of different continence management options.

Patient choice and acceptability represent important considerations in continence care,

particularly in non-acute settings where comfort, dignity and individual preferences play a central role. As our analysis was conducted from a payer perspective, it focused primarily on clinical outcomes, quality-adjusted life years and direct healthcare costs. Experiential aspects, such as patient comfort, dignity, sleep quality and both patient and staff preferences, were not explicitly modelled, although some elements are indirectly captured through utility values and complication rates. Nevertheless, real-world uptake and sustained use may be influenced by patient and staff preferences, and heterogeneity in acceptability is expected. While available evidence suggests generally good tolerability and satisfaction with the device, future research incorporating patient-reported outcomes and preference-based measures would allow a more comprehensive assessment of value and better inform shared decision-making.

An additional limitation relates to potential implementation and training requirements associated with the introduction of a new device. The model did not explicitly account for initial staff training costs or temporary reductions in efficiency during the early adoption phase, including a possible learning curve as healthcare professionals become familiar with device placement and system management [69]. Although the device is designed to be intuitive and observational evidence suggests rapid familiarization in practice, a short transitional period with slightly longer handling times may occur. From a payer perspective, such training costs are typically one-off and distributed across a large patient population over time. Moreover, sensitivity analyses demonstrated that even substantial variations in nursing time did not materially alter the overall conclusions.

Another limitation concerns environmental assessment. Our analysis focused on solid waste generation from consumables, as this represents the most direct and measurable component from the healthcare payer perspective. Other dimensions, such as the electrical consumption associated with the reusable suction unit, were not explicitly modelled. This decision was based on the expectation that per-patient energy use of a low-suction device is relatively modest and that, in nursing homes, electricity costs are generally embedded within facility overheads. Moreover, reliable country-specific data on real-world energy consumption in non-acute settings were not available.

Finally, other generic limitations apply to our approach. The 1-year time horizon precludes assessment of long-term sequelae and device longevity, and indirect costs (caregiver time, productivity losses) were excluded. Although probabilistic and deterministic sensitivity analyses were performed, parameter uncertainty is magnified where evidence was poor. Taken together, these limitations suggest that the results should be interpreted with caution and highlight the value of further prospective, standardized, multi-country data collection to strengthen future economic evaluations of continence technologies.

Despite the insights provided, important evidence gaps remain. In particular, future research should include country-level prospective observational studies to validate the real-world performance of PureWick across diverse long-term care systems and patient populations. The field would also benefit from standardized definitions and measurement methods for UI-related outcomes to ensure comparability across studies and strengthen model inputs. Moreover, future research should quantify training needs and learning-curve effects to better inform implementation planning and economic evaluations and conduct full life cycle assessments to more comprehensively evaluate the environmental impact of continence management strategies. Finally, longitudinal data capturing device durability, adherence over time and patient-reported outcomes beyond 1 year are needed to assess the long-term value of PureWick and refine economic evaluations moving forward.

CONCLUSIONS

This study aimed to evaluate the value of an innovative continence management strategy across different care settings. The selection of an optimal management continence device should be guided by the clinical context, patient mobility, infection risk, skin integrity and environmental impact considerations.

Pads remain the first-line option for many patients but require proper skincare measures to prevent complications. Female external urinary devices, like PureWick, represent a promising alternative in select cases in non-acute settings, particularly for bedridden patients or patients with limited mobility, or mobile patients at high risk of falls, by offering a non-invasive cost-saving solution across diverse healthcare systems. From a gender-medicine and sustainability perspective, the evaluation of female-specific technologies also carries important policy relevance, as it addresses long-standing gaps in continence care while aligning with broader health system goals related to equity, environmental responsibility and value-based decision-making. A multidisciplinary approach, encompassing nurses, physicians and wound care specialists, is crucial to optimizing device selection and ensuring effective, dignified continence management.

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Data Availability. All data generated or analyzed during this study are included in this published article.

Declarations

Conflict of Interest. Carla Rognoni, Vittoria Ardito, Ann Yates and Rosanna Tarricone have nothing to disclose. The authors have not received any direct funding or assets from Becton Dickinson UK Limited.

Ethical Approval. The analysis has been reported according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) [15, 16]. This study is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

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