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Cost-effectiveness of long-term intermittent catheterisation with hydrophilic and uncoated catheters in traumatic spinal cord injury in Australia

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ABSTRACT

Aims: To model the cost-effectiveness of hydrophilic coated intermittent catheters (HCIC) compared with uncoated catheters (UC) for intermittent catheterisation in Australians with neurogenic bladder from traumatic spinal cord injury (SCI).

Methods: A published probabilistic Markov model was adapted for Australia to compare lifetime costs and quality-adjusted life years for the two catheter types in SCI Australians who intermittently catheterise. The primary analysis was from the Australian healthcare perspective with a supplementary societal perspective analysis that incorporated costs from lost productivity.

Results: Lifetime UTI events were reduced by 10% with HCIC use. If every Australian with SCI who undertakes self-catheterisation used HCIC over their lifetime, the modelled decrease in UTI incidence would result in a cost saving of approximately $299,000,000. The incremental cost-effectiveness ratio (ICER) of $48,542 was below the threshold of $50,000 to $60,000 cost per quality-adjusted life year (QALY) informally interpreted as showing cost-effectiveness of medical technologies and pharmaceuticals in Australia. When the societal perspective was taken, HCIC use produced superior clinical outcomes at a lower total cost compared with UCs.

Conclusion: UTI was the most common complication leading to readmission in the 2 years following traumatic SCI, hence reducing UTI incidence has a significant impact on both an individual's quality of life and on total healthcare costs. The ICER results from the base case and sensitivity analyses suggest that use of HCIC in Australia is cost-effective.

1. Introduction

It is estimated that about 20,800 Australians are living with a spinal cord injury (SCI) with 23% under 35 years and majority 65 years and younger (alpha beta Australia, 2020) [1]. The impact of an SCI is devasting with debilitating health consequences which includes loss of bladder control. Social continence, reduction in urinary tract infections (UTI) and protection of the upper tracts have remained key tenets of the urological management of patients with SCI [2]. Effective bladder management with low pressure filling and adequate emptying has been shown to preserve renal function in patients with SCI [3]. Intermittent catheterisation (IC) (European Association of Urology (EAU) and American Urological Association (AUA) guidelines) where possible, is considered a standard treatment for patients who are unable to spontaneously void [2]. IC is most commonly undertaken with either uncoated catheters (UC), which must be coated with a lubricating gel before use, or hydrophilic-coated ready to use catheters (HCIC).

An Australian study showed that UTI was not only the most frequent cause of presentation to Emergency Departments and hospital readmission, but it was also the most expensive secondary condition in people

Abbreviations: AIHW, Australian Institute of Health and Welfare; AR-DRG, Australian National Diagnosis Related Groups; HCIC, hydrophilic coated intermittent catheter; IC, intermittent catheter; ICER, incremental cost-effectiveness ratio; QoL, quality of life; UC, uncoated catheter; UTI, urinary tract infection

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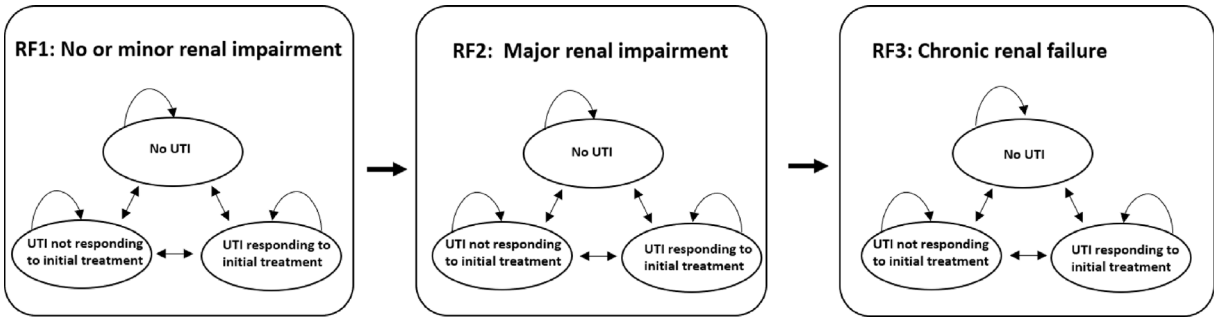

Fig. 1. Schematic of the Markov decision model. The three boxes represent the renal function health states (RFI-1 to RF-3) that include 3 UTI-related health states. Arrows illustrate either progression or maintenance in the same health state.

with an SCI [4]. The cost per admission of a UTI was AUD$19,617 (± AUD$26,985), with an estimated total cost of AUD$2,216,681 over a two-year period [4]. This study is considered an under-representation of the true cost.

The clinical value of the hydrophilic technology is its ability to impose lower friction force during catheterisation, reduce risk of urethral trauma [5,6], reduce risk of urinary tract UTIs [7–10] increase quality of life (QoL) [11,12], and possibly increase compliance and long-term adherence to treatment [8,9,13,14].

Economic evaluation internationally has shown that HCIC can be considered cost-effective compared to UC in traumatic SCI patients [15–18]. A cost and benefit analysis of IC use in people with SCI in Australia has demonstrated [19] improved bladder management resulted in substantial morbidity improvements and cost savings [4]. Limited financial resources dictate the need for economic evaluation to maximise outcomes and minimise costs.

The objective of this study was to assess the cost-effectiveness of HCIC compared with UC for people with SCI in Australia with particular focus on the cost of long-term sequelae from UTIs and renal impairment. A supplementary analysis was performed from a societal perspective which, included productivity loss.

2. Materials and methods

2.1. Design of decision model

In 1983, Beck and Pauker described the use of Markov models for determining prognosis in medical applications [20]. The Markov model provides a far more convenient way of modelling prognosis for clinical problems with ongoing risk. This provides a framework to model recurring events in the lifetime of a patient. Timing of the events recurrence rates are considered [21]. The model assumes that the patient is always in one of a finite number of states of health referred to as Markov states. All events of interest are modelled as transitions from one state to another. Each state is assigned a utility, and the contribution of this utility to the overall prognosis depends on the length of time spent in the state [21,22].

An established Markov decision model [15–18] was adapted and validated by a panel of Australian clinical experts to evaluate the cost effectiveness of HCIC use in the Australian Healthcare system over a lifetime compared with UC use. The model included long-term sequelae of UTIs, plus an additional scenario analysis of the adverse impact of UTIs on productivity.

The model includes 3 health states related to renal function (RF): RF1 “no or minor renal impairment”; RF2 “major renal impairment”; and RF3 “chronic renal failure” (Fig. 1). Nested within each of these 3 health states are 3 UTI health states: “no UTI”, “UTI responsive to initial treatment” and “UTI not responding to initial treatment”. All patients commence in RF-1 and can then transition to RF-2 and RF-3, with no backward movement in RF state allowed. Death was considered a possible outcome from all RF- and UTI-related health states.

In keeping with the demographics of the Australian SCI population [35], a hypothetical cohort of 80% males:20% females were simulated over a lifetime horizon to estimate costs and benefits of using HCIC and UC.

2.2. Data inputs

Clinical Evidence

A literature search was conducted using PubMed, Medline, Embase and the Cochrane library to identify comparative studies of the effectiveness of HCIC and UCs in SCI for inclusion in the model. Search terms included hydrophilic, catheter, spinal cord injury, randomised controlled trial and meta-analysis. A total of 5 relevant meta-analyses were identified all of which showed a treatment benefit for HCIC over UCs in reducing UTI incidence in SCI [7,24,26,27,29,37–39]. The treatment effects of HCIC were taken from a recent meta-analysis of adult studies by Rognoni and Tarricone that reported HCIC versus UC UTI treatment benefit as a risk ratio suitable for use in this evaluation [7].

Baseline risk of UTI

Baseline risks and the risk of transition between health states is presented in Table 1. No Australian specific data on baseline risk of UTIs in the community was identified. A retrospective Australian audit of all new inpatient SCI cases found a rate of symptomatic UTI of 1.1 starts/100 days in patients undergoing a 6-hourly nursing-administered IC protocol [28,40]. Self-reported data from a Canadian community survey of 2.6 UTIs per year was reviewed by the local clinical expert panel and contextualised to reflect Australian practice. The clinical expert panel also took into consideration Australian specific data from the acute setting, which showed that 41% of new acute SCI admissions experience a symptomatic UTI during admission (2.08 per person on average) [41]. A mean baseline risk of 28.1% was used in the model, as discussed, and agreed to by the expert panel.

Rate of symptomatic UTI

The rate of symptomatic UTI was sourced from a retrospective Australian audit, which demonstrated that of all new adult SCI cases found a rate of symptomatic UTI of 1.1 starts/100 days in patients undergoing a 6-hourly nursing-administered IC protocol [41].

Antibiotic resistance rate

The antibiotic resistance rate of 27.3% was sourced from the Australian Commissions on safety and Quality in Health Care (ACSQHC) 2019.

Recurrent UTI and renal impairment

There is a paucity of data regarding the event rates and ultimate cost of renal impairment resulting from recurrent UTI and poor lower urinary tract management. Data from published literature was used to support this input.

Utility values

Utilities for health states are based on preference weights of 0 (representing death) to 1 (denoting perfect health) for different health

Table 1
Key input parameters.

Parameter	Mean	Source/assumption
Monthly event rates (uncoated catheters)		
Baseline risk of UTI	21.8%	[23], Expert Panel
UTI not responding to initial treatment	0.32%	[24,25]
Bladder stones	0.12%	[24,26]
Kidney stones	0.12%	[24,26]
Urethral damage	0.19%	[24,26]
Major renal impairment	0.020%	Calculated using stage 3 and 4 from [16]
Renal failure	0.004%	[16]
Treatment effect (Hydrophilic-coated vs uncoated)		
UTI responding to initial treatment	0.84	[7]
UTI not responding to initial treatment	0.90	[16]
Bladder stones, kidney stones, urethral damage	0.90	[16]
Utility decrements		
Baseline utility of catheterisation (uncoated)	0.450	[27,28]
UTI responding to initial treatment	0.11	[27]
UTI responding to initial treatment (antibiotic resistant)	0.135	Assumed midpoint of UTI responding and not responding to initial treatment
UTI not responding to initial treatment	0.16	[29,30]
Major renal impairment	0.18	Assumed midpoint of UTI responding to initial treatment and renal failure
Renal failure	0.25	[30–32]
Kidney/bladder stones	0.11	Assumed same as UTI responding to initial treatment
Urethral damage	0.104	[29,30]
Utility benefits		
Using HCIC instead of UC	0.028	[12]
Mortality multipliers		
UTI responding to initial treatment	1	Assumed same as general population
UTI not responding to initial treatment	797.600	[16,33]
UTI responding to initial treatment (antibiotic resistant)	145.27	[16]
UTI responding to initial treatment, weighted[a]	40.894	Weighted average
Major renal impairment	18.000	Assumed 1/3 value of complete renal failure, consistent with [16]
Renal failure	54.000	[16]
All other health states or treatment-related adverse events	1	Assumed same as general population
Other parameters		
Proportion of cohort with antibiotic resistance	27.3%	[34]
Daily catheterisation frequency	4	Expert panel
Cohort starting age	48	Australian mean age of traumatic SCI; AIHW correspondence (No. 2018), data collected for [35]
Sick leave because of UTI responding to initial treatment	2.0 days	Expert panel
Annual sick days because of UTI with sepsis	26.0 days	[36], adjusted for SCI gender distribution in Australia
Length of admission for UTI unresponsive to initial treatment	3.9 days	Expert panel, [15]

[a]Calculation = Resistance rate * UTI responding to initial treatment (antibiotic resistant) + (1-resistance rate) * UTI responsive to initial treatment (not resistant) = 27.3%*145.27+ 81.8%*0 = 39.659.
All parameters are assumed to be gamma distributed, whereas utility parameters are assumed to be beta distributed.

states i.e., the more preferred health states will receive a greater weight and will, therefore, be favoured in the analysis [30,42].

Published literature showed a utility gain of 0.028 was associated with use of HCIC compared with UC [29,35,37]. As a comparison the calculated utility gain for cataract surgery is 0.023–0.028 [43,44].

A 0.11 utility reduction was reported by spinal cord injured patients experiencing a UTI in Australia [45]. This was greater than the published estimates of 6.0% [16] and 9.2% [15]. The 0.11 utility reduction was measured at the time of a UTI, in contrast to previous publications where participants were asked to recall the loss of utility from UTIs experienced over the last 12 months. This implies that lower values were a demonstration of the memory of utility loss rather than direct loss at the time [29].

The local clinical expert panel assumed that a UTI not responding to initial treatment brings a utility decrement of 0.16. This increased value was considered a conservative estimate.

2.3. Resource use and cost data

The primary analysis perspective was the Australian healthcare system, with Australian cost data used and local clinical data included where possible. A supplementary analysis was performed from a societal perspective. This incorporated productivity impacts from lost salary contributions due to sick leave, early retirement, and death. Key cost inputs are listed in Table 2.

Direct healthcare costs

Each patient was assumed to use 4 catheters per day based on current practice and expert opinion. Catheter cost was based on an analysis of purchaser prices for the most used UC and HCIC brands weighted by purchaser (direct to consumer or government) volume.

The Pharmaceutical Benefits Scheme (PBS) dispensed prices were used for antibiotic costs (July 2021). Hospitalisation costs, including UTI hospitalisations [13] were adjusted for inflation using the Australian Institute of Health and Welfare (AIHW) health expenditure inflation index 2018/2019. General Practitioner (GP) visits and urine tests used Medicare benefit costs (July 2021).

Due to lack of publicly available data, hospital costs for treatment-related adverse events were provided by a private hospital (detailed in Table 2). A sensitivity analysis was undertaken to investigate using these private hospital-based costings.

Indirect healthcare costs

Societal costs from short- and long-term sick leave, early retirement and death were calculated. Data for wages and participation for the total Australian labour force was weighted for the gender mix used in the cohort. A sensitivity analysis considered the impact of a 30% lower

Table 2
Key cost inputs (in Australian dollars)

Healthcare cost	Mean	Source
Uncoated catheter	$1.20	Prices of most used straight catheters (Coloplast, Denmark) weighted by prices and usage rate by supplier (i.e. direct to consumer or via government funded accident compensation schemes)
Hydrophilic-coated catheter	$4.24	
Lubricant sachet cost (per day)	$0.53	Average price from 3 suppliers [46]
UTI responsive to initial treatment (including antibiotic resistant)[a]	$6,535.37	Calculated according to [16,29]
UTI not responding to initial treatment (with sepsis)	$8,248.02	Calculated according to [16]
Kidney stones[b]	$5,762.69	Total Procedure cost estimate [47]
Bladder stones[b]	$5,762.69	Total Procedure cost estimate [47]
Urethral damage[c]	$2,306.65	Total Procedure cost estimate [48]
Major renal impairment	$2,218.98	Calculated using Stage 3 & 4 [49]
Renal failure	$4,761.15	Calculated using [50], updated from 2008/2009 to current costs; dialysis modality/transplant rates according to [51]
Societal costs:		
Average weekly earnings (80% male/20% female)	$1,431.44	ABS Average Weekly Earnings (seasonally adjusted), November 2020

ABS, Australian Bureau of Statistics.

[a]Includes cost of GP visit, urine test, 1st line antibiotic treatment, non-elective hospital admission (based on [17]).

[b]Includes cost of GP visit, urine test, 1st line antibiotic treatment, hospital admission with procedure cost for removal of kidney/bladder stones (1-night hospital accommodation plus theatre fees, disposable, pharmacy and incidental costs).

[c]Includes cost of GP visit, urine test, 1st line antibiotic treatment, day hospital admission for bladder intermediate endoscopic procedure (day theatre fees, disposables and incidental costs).

Table 3
Cost-effectiveness results.

	Costs	QALYs	LYG	UTI events
Base case				
Uncoated catheters	$218,126	4.73	10.95	37
Hydrophilic-coated catheters	$248,003	5.35	11.60	33
Incremental values	$29,877	0.62	0.64	4
ICER		$48,542	$46,499	$8,282
Supplementary analysis including societal costs				
Uncoated catheters	$2,606,196	4.73	10.95	37
Hydrophilic-coated catheters	$2,277,869	5.35	11.60	33
Incremental values	−$228,327	0.62	0.64	4
ICER		Dominant	Dominant	Dominant

participation rate in those with SCI, compared with the total Australian population, to account for lower work participation rates reported for Australians following SCI [52–55]. Users of both HCIC and UC were assumed to have the same absence duration when a UTI or treatment-related adverse event was experienced. Work absence specific to the presence of renal impairment was not included in the model.

2.4. Outcome measures

Definitions

- Life Year Gained (LYG) is the expected benefit in life span.
- Quality-adjusted life year (QALY) is a summary measure of health outcome, which incorporates impact on both the quantity and quality of life (QoL).
- Incremental cost-effectiveness ratio (ICER), expressed as cost/QALY is the incremental cost associated with 1 additional unit of the measure of the effect, and is calculated as below:

$$\frac{\text{Cost of HCIC} - \text{Cost of UC}}{\text{Effect of HCIC} - \text{Effect of UC}}$$

The outcome measures reported in this study are LYG, QALYs and ICER. A one-way deterministic sensitivity analysis was conducted to examine the effect of key parameters including number of catheters used per day and catheter price (Table 4).

3. Results

This economic evaluation measures two parameters — cost and outcome [56]. If a treatment provides relatively superior health outcomes at a lower cost, it is called a dominant treatment. If the treatment has superior health outcomes but at a higher cost, it can still be considered cost-effective. In this instance an ICER is used to help assess cost-effectiveness.

The utility of these calculations lies in the ability to ascribe benefit in a population setting and as such allow funding to support cost effectiveness and improvement of QoL. While there are no explicit willingness-to-pay thresholds published, reimbursement decisions made by the Australian Pharmaceutical Benefits Advisory Committee (PBAC) suggest an acceptable ICER threshold of $50,00 to $60,000/QALY [59–62].

The ICER for using HCIC compared with UC was $48,542/QALY in SCI patients, within the range considered acceptable to the PBAC.

Patients using HCIC gained an average 5.35 QALY. A gain of 0.62 QALY compared to UC. This would have to be balanced by the lifetime cost of $248,003 for HCIC, an increase of $29,877 compared to UC.

On adjusting the per catheter cost from the average cost to the cheapest catheter on the market resulted in an ICER of $9,738/QALY with a lifetime cost increase of only $4,118 in using HCIC. The threshold for funding is further supported in doing this.

The number of non-severe UTI decreased by 4 and severe UTI/sepsis events were reduced by 0.02 per patient lifetime with the use of HCIC.

The supplementary analysis which included productivity loss during a UTI support the use of HCIC over UC, implying lower lifetime costs of using HCIC compared to UC with improved outcomes. A sensitivity analysis, with 30% reduced workforce participation rates mirrored this result.

Detailed results for UTIs events, LYG, costs and QALYs are reported in Table 3.

Table 4
Key input parameters for the deterministic univariate sensitivity analyses.

Parameter	Base case value	Alternative values tested	ICER (Cost per QALY)	Reference
Base case	–	–	$48,542	For comparison
Catheters per day	4	5	$69,052	Assumption
Daily acquisition cost (UC)	$1.20	$0.65	$9,738*	Average of cheapest prices from 2 online sellers [57,58]
Daily acquisition cost (HCIC)	$4.24	$2.20		
Treatment effect (HCIC vs UC) in UTI responsive to initial treatment	0.84	0.75	$24,068	95% CIs for treatment effect from [7]
		0.94	$94,119	
Baseline risk of UTI	21.8%	17%	$56,865	Assumption (±5%)
		27%	$41,092	
Utility benefit (HCIC vs UC)	0.028	0	$100,169	Assumption
		0.05	$34,550	
Procedure costs for kidney/bladder stones and urethral damage halved	$5,762.69 and $2,306.65	$2,881.35 and $1,153.33	$48,632	Assumption (−50%)
Discount rate (costs and benefits)	3.0%	5.0%	$48,719	Assumption (as used by PBAC)
Productivity: workforce participation rate reduced by 30%	Australian population	30% reduction of base case	Dominant	[53]

*. Utility benefit of 0.011 for using HCIC instead of UCs applied, rather than the 0.028 benefit in the base case, as the HCIC catheters in the sensitivity analysis are not ready to use [12].

In a sensitivity analysis, the impact of renal dysfunction on the ICER was explored. The two inputs included in the economic model with regards to renal dysfunction resulting from recurrent UTI include complete renal failure and considerable renal impairment. With the probability of complete renal failure and considerable renal impairment occurring set to zero, the ICER reduces from $48,542 to $47,894/QALY. This demonstrates minimal impact of renal dysfunction on the ICER.

4. Discussion

The need for a cost effectiveness analyses to identify treatment approaches associated with both cost savings and improved outcomes in healthcare has been established. There are less health economic data informing decisions on bladder management [19].

In a society of limited resources with the need to maximise the health dollar, decision making would be dictated to by maintaining employment and societal involvement. Therefore, irrespective of governing body, productivity loss is arguably one of the most meaningful factors in decision making about funding for medical devices [63,64], highlighting the importance of including productivity benefits in cost-effectiveness analyses for the population and in this case, the SCI population.

Published literature suggests that UTI is the most common and expensive secondary condition in Australians with SCI, with a cost per admission of $19,617 (± AUD$26,985) in 2012 [4]. This episode cost is higher than that of admission to hospital for other UTIs estimated at $7,258(AR-DRG V10.0 L63 A). Thus, the cost savings from UTIs in this model are conservative and likely to be an underestimate.

The current economic analysis shows a reduction from 37 UTIs with UCs to 33 using HCIC which translates to approximately 10% reduction in UTI events in a lifetime. The model predicts that individuals using HCIC experience a 14% improvement, a QALY gain of 0.73. To put this in context, the Australian Government Department of Health QALY assessment of antiretroviral treatment for HIV patients demonstrated a QALY gain of 0.76 for patients on treatment [65].

The resultant ICER of $48,542/QALY in the Australian healthcare setting can be considered a cost-effective treatment option compared to UC in traumatic SCI patients. When a broader societal perspective including productivity loss is considered, HCICs are shown to be cost saving. With a 10% reduction in lifetime UTIs, a 14% improvement in QALY, people with SCI will maintain employment, take less days off work and maintain societal involvement.

The estimated cost of non-complicated UTI or a UTI responsive to initial treatment (including antibiotic resistant) is $6,535, which includes the cost of GP visit, urine test, 1st line antibiotic treatment, and non-elective hospital admission (for 27.3% of patients who have antibiotic resistance [34]) (Refer to Table 2 [16,29]). The use of HCIC reduces the number of UTIs by 4 over a lifetime. Applying this to the number of Australian SCI patients who intermittently catheterise, results in a cost saving of $299,041,600 over a lifetime (assuming 20,800 with SCI [1] and a self-catheterisation rate of 55% [23]).

There are limitations with the modelled analysis:

(1) Lack of published data on clinical complications of the use of HCIC and UC, for which expert input was sought. This warrants the need to conduct further studies to collect data on the clinical complications following use of HCIC and UC.

(2) Lack of Australian-specific data for some model inputs, thus data from international studies was used [15,16].

(3) Lack of Australian specific comprehensive cost data (i.e., day or overnight hospital admission, surgical costs, theatre fees, disposable costs, and pharmaceutical costs) for the treatment of complicated UTI-related adverse events including kidney and bladder stones, urosepsis and urethral damage. Estimates for these procedures were obtained from an Australian private hospital, which will under-represent costs such as intensive care admission, return to theatre costs, interventional radiology costs, prolonged hospital stay and other incidentals.

(4) The possibility that cross sectional studies such as this one, underestimates the ICER values compared to real world longitudinal studies.

This highlights the need to collect local resource utilisation data, which will enable a more accurate assessment of the cost effectiveness and total savings generated with the use of HCIC compared with UC in SCI patients.

5. Conclusion

The base case and supplementary analyses results suggest that HCIC provides a cost-effective treatment option with improvements in UTI event frequency, life years gained, productivity and QoL outcomes compared with UCs in people with SCI.

UTI was the most common complication leading to rehospitalisation in the 2 years following people with traumatic SCI [4]; hence reducing UTI incidence will have a significant impact on both an individual's QoL and on total healthcare costs.

Our study demonstrates a conservative estimate of the ICER for the base case analysis of $48,542/QALY. This is lower than the suggested

threshold range accepted by the PBAC supporting the argument for cost effectiveness for HCIC for SCI patients in the Australian setting.

The reduced healthcare costs and higher effectiveness (QALY gains) demonstrate significant productivity benefits with HCIC use compared to UC from the societal perspective. There would therefore be a strong argument to support government led funding to facilitate overall societal benefits, beyond the pure economic benefits to the healthcare system.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Dr M A P Couchman reports administrative support, statistical analysis, travel, and writing assistance were provided by Coloplast Ltd. She is am on the editorial board of Continence.

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