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iMEDicare

Economic Evaluation of Men's Liberty Acute External Urinary Catheter for Use in an Acute Care Setting

Final Report

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Abbreviations

AE	Adverse event
CAUTI	Catheter-associated urinary tract infection
HCSA	Health care supply association
IAD	Incontinence-associated dermatitis
JFC	Joint formulary committee
LoS	Length of stay
NHS	National health service
NICE	National Institute for Health and Care Excellence
PSS	Personal social services
PSSRU	Personal social services research unit
PU	Pressure ulcers
UK	United Kingdom
YHEC	York Health Economics Consortium

About YHEC

York Health Economics Consortium (YHEC) is a health economics consulting company owned by the University of York. It provides a range of services, including economic modelling, literature searching, systematic reviews, network meta-analyses, patient-reported outcomes, service review and applied research and training to the NHS and the pharmaceutical and health care industries. YHEC also carries out work for a range of clients outside the health sector, including Local Authorities and the voluntary sector. Current clients include: NHS England, the National Institute for Health and Care Excellence (NICE), a range of local NHS trusts and several large multi-national pharmaceutical, device and nutrition companies.

YHEC is one of a group of Health Economics departments at York, which is the largest and most active group in the United Kingdom. It is the main consultancy provider of Health Economics expertise at York, combining rigorous research standards with efficient project delivery. As well as its own multidisciplinary staff, YHEC often draws on the specific expertise of staff in related academic departments.

1 Introduction

1.1 Background

Urinary incontinence affects an estimated 30% of patients on acute NHS wards [1]. Some of this population will be given indwelling catheters to manage this incontinence. A urinary catheter can be used to empty the bladder and collect urine. Between 12 and 26% of hospitalised patients in the UK are reported to be catheterised during their stay [2]. This catheter utilisation is higher in males, with an average catheterisation rate in hospital of 15.7% compared with 10.7% for females [2].

A common complication of catheterisation is catheter-associated urinary tract infections (CAUTIs). A CAUTI is caused by bacteria entering the urinary tract through an indwelling catheter [3]. CAUTIs can lead to further complications, such as sepsis or further infection that can consequently extend the patient's length of stay (LoS) in hospital [4]. CAUTIs and their associated complications can also result in increased hospital resource use and associated costs to the NHS.

Other people with incontinence will be given urinary pads to manage their urinary incontinence. For a substantial number of people with urinary incontinence, indwelling catheterisation is considered unsuitable and they may also be unsuitable for the less invasive condom catheter. This can be due to a variety of contraindicators such as urethral stricture or required frequent monitoring of urinary output [5]. In these cases, alternative urinary management solutions include urinary pads. Urinary pads are a non-invasive and easy to apply. However, they are also associated with adverse events (AEs) such as such as incontinence-associated dermatitis (IAD) and pressure ulcers (PU) [6].

iMEDicare offers a glands-adherent urinary management device, BioDerm XLS Oval (referred to as Men's Liberty Acute). Men's Liberty Acute uses a petal-shaped sheath to adhere directly to the penile glands, offering an alternative for patients unsuitable for condom catheters. This external device diverts urine immediately away from the urethral area, reducing the risk of AEs from traditional management methods [3]. iMEDicare has requested an early economic evaluation to assess the cost-effectiveness of Men's Liberty Acute within acute care settings in the UK.

1.2 Objectives

YHEC has developed an early cost-comparison pathway model to evaluate the cost and health impacts of the Men's Liberty Acute for adult males with urinary incontinence in UK acute care settings. The model incorporates three different populations to explore variation in impact for the general, immunocompromised and vulnerable populations.

This technical report provides details of the modelling approach, structure, inputs, and main results of the model.

2 Methods

2.1 Decision Problem

The model has three populations to choose between. All populations are acute care male patients in need of incontinence management who have no medical reason to be using an indwelling catheter and cannot use a condom catheter. Costs were applied from the perspective of the NHS and personal social services (PSS) for a 2023/24 cost-year. A time horizon of 30-days was used, including the length of the hospital stay. Only short-term outcomes were considered so discounting was not applied since our time horizon does not extend beyond a year. The details of the decision problem are summarised in Table 2.1.

Table 2.1: Decision problem

Model element	Description
Population	▪ General population: All acute care male patients with urinary incontinence. ▪ Vulnerable population: Acute care male patients over the age of 60 with urinary incontinence. ▪ Immunocompromised population: Acute care male patients who are immunocompromised. It is assumed that this population are more susceptible to infection, have a higher risk of mortality, and are unsuitable for an indwelling catheter.
Intervention	The intervention for all populations is the Men's Liberty Acute Urinary Catheter. This is a glands-adherent external catheter.
Comparator	▪ General population: A coated or uncoated indwelling catheter. ▪ Vulnerable population: Either a coated or uncoated indwelling catheter, or urinary pads and barrier cream. ▪ Immunocompromised population: Urinary pads and barrier cream.
Outcomes	Number of adverse events (CAUTIs, IAD and PU), mortality, Length of stay (LoS), Total cost, and Incremental cost.

CAUTI - catheter-associated urinary tract infection; LoS - length of stay; PU - pressure ulcers.

2.2 Model Structure

The model was made up of two pathway models for either the indwelling catheter or urinary pad comparator. A time horizon of one month has been used to capture short-term AEs and acute care costs. This model does not discount any costs since the time horizon is less than a year. The selected population informs the chosen comparator of either an indwelling catheter or a urinary pad with barrier cream or liquid. All populations were modelled using the Men's Liberty Acute Urinary Catheter as the intervention.

The modelling of the indwelling catheter comparator captured the incidence of CAUTIs as the AE, whereas modelling of the urinary pad comparator captured the incidence of IAD and PU. The costs captured in each treatment arm included the incontinence management resources, AE treatments and LoS. Mortality was also included in the model to present the impact on clinical outcomes from using Men's Liberty Acute.

The model also has two optional scenarios. The first scenario includes the cost of staff time to change or apply the different incontinence managements systems. This was included as a scenario to model the cost impact of differing staff time required for the application or changing of different incontinence management systems. However, this has not been included in the base case as it may be double counting staff time already accounted for in LoS costs and some AE treatment costs. Furthermore, there is little published evidence on staff time and numbers required as part of incontinence management.

The second scenario allows the user to adjust the model cohort for the urinary pad comparator pathway to explore the impact of Men's Liberty Acute for a cohort who already have PU or IAD. This also includes an assumed reduction in LoS, able to be varied by the user, for those using Men's Liberty Acute rather than a urinary pad. There is assumed to be no difference in LoS in the base case. The model diagrams of the pathway model structures for both the indwelling catheter and urinary pad comparators can be found in Figure 2.1 and Figure 2.1: Model diagram (indwelling catheter comparator)

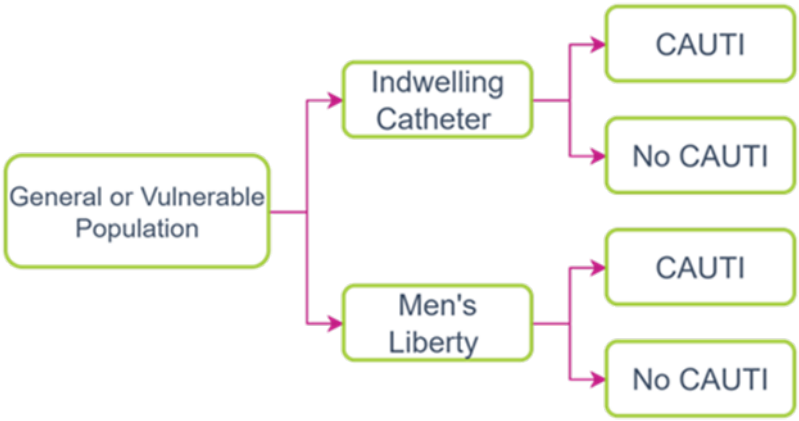


Figure 2.2 respectively.

Figure 2.1: Model diagram (indwelling catheter comparator)

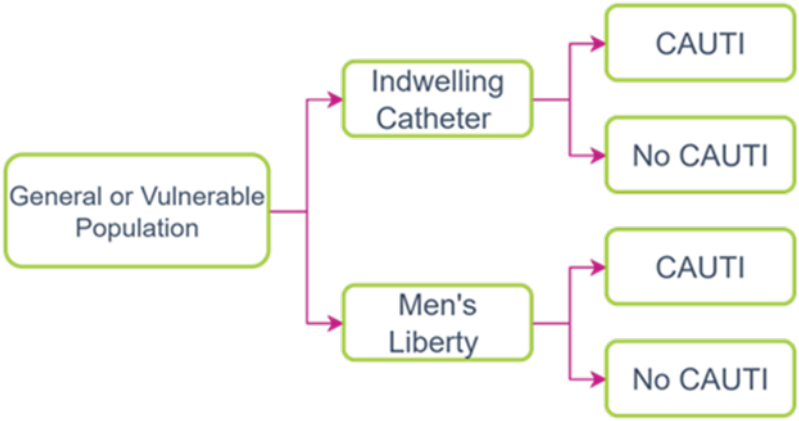
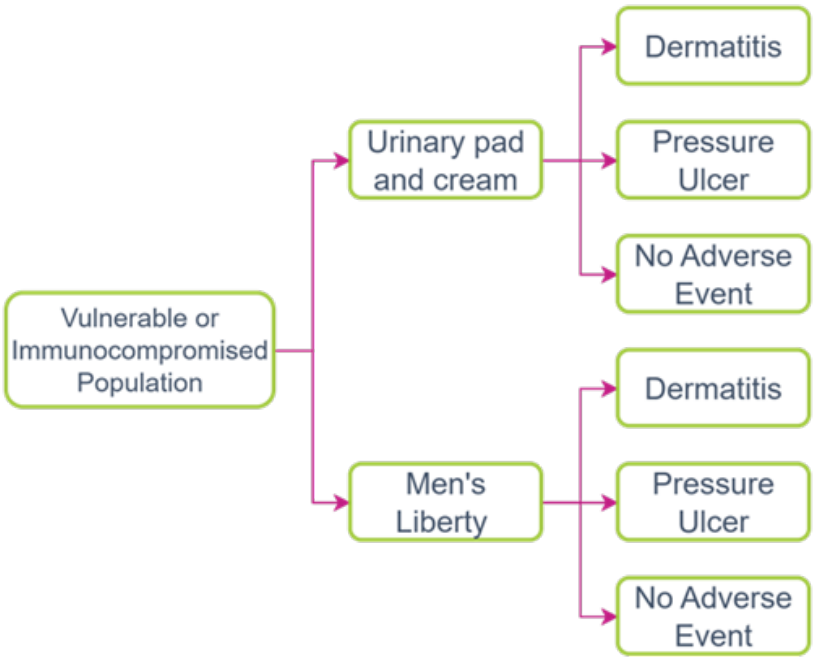


Figure 2.2: Model diagram (urinary pad comparator)



2.3 Model Assumptions

The following clinical and structural assumptions were made in the modelling process:

- Where statistics for males could not be sourced, general population statistics were assumed to be constant across genders.
- All modelled populations were assumed to have urinary incontinence only. Where possible, sources which separate faecal and dual incontinence were chosen, but otherwise the data were assumed to be for urinary incontinence only.
- Any evidence identified for the vulnerable population was taken from studies with average ages over 60.

2.4 Model Parameters

Data used to populate the model were taken from various sources. These include informed assumptions provided by Men's Liberty Acute as well as a range of published sources identified through targeted literature searches. The early nature of the analysis means that some evidence was based on mixed populations, which may not exactly match the modelled population from the decision problem.

2.4.1 Clinical inputs

2.4.1.1 CAUTI prevalence

The CAUTI prevalence for populations using Men's Liberty Acute was assumed to be 0%. This was an assumption informed by iMEDicare based on the mechanism of action associated with Men's Liberty Acute, as described in Section 1.

The CAUTI prevalence for those on the indwelling catheter comparator arm can be found in Table 2.2. As part of the modelling approach, the difference in CAUTI risk is captured for those using an uncoated catheter compared to a coated indwelling catheter.

Table 2.2: CAUTI prevalence with comparators

Model parameter	Value	Source
CAUTI prevalence for the general population with indwelling catheters	3.80%	Smith et al., 2019 [7]
CAUTI prevalence for the vulnerable population with indwelling catheters	4.70%	Smith et al., 2019 [7]
Relative risk of CAUTI for coated catheters compared to uncoated	0.82	Gauhar et al., 2022 [8]

CAUTI - catheter-associated urinary tract infection.

2.4.1.2 IAD prevalence

The IAD prevalence for populations using Men's Liberty Acute was assumed to be 0%. This was an assumption informed by iMEDicare based on the mechanism of action associated with Men's Liberty Acute, as described in Section 1.

Clark et al. reported aggregated IAD prevalence that included community care data. However, due to lack of available data this source has been used as a proxy for IAD prevalence for the general population in an acute care setting. A relative risk was then applied to the general population prevalence to estimate the prevalence for the vulnerable and immunocompromised populations. The upper bound of the relative risk for the vulnerable population was used as a proxy for the relative risk of the immunocompromised population. These inputs can be found in Table 2.3.

Table 2.3: IAD prevalence with comparators

Model parameter	Value	Source
IAD prevalence for the general population	4.30%	Clark et al., 2017 [6]
Relative risk of IAD for the vulnerable population	2.48	Meirelles et al., 2020 [9]
Relative risk of IAD for the immunocompromised population	5.30	Meirelles et al., 2020 [9]

IAD - incontinence-associated dermatitis.

2.4.1.3 PU prevalence

The PU prevalence for populations using Men's Liberty Acute was assumed to be 0%. This was an assumption informed by iMEDicare based on the mechanism of action associated with Men's Liberty Acute.

Table 2.4 shows the PU prevalence for those using urinary pads and barrier cream. There are two sources available for the PU prevalence in the vulnerable population that can be selected in the model. The base case is an international study that gives the prevalence of PU specifically for those with just urinary incontinence. The alternative source is a UK based study, but the results are not stratified by type of incontinence, so it is a likely an overestimate since it includes the prevalence of PU due to faecal incontinence. The prevalence for the immunocompromised population uses the proportion of adults who develop pressure injury prior to ICU admission in UK hospitals as a proxy.
Table 2.4 also gives a relative risk of PU for those who have IAD. This is applied in scenario 2 when previously acquired IAD is selected to include a proportion of those people who will then develop PU.

Table 2.4: PU prevalence with comparators

Model parameter	Value	Source
PU prevalence for the vulnerable population	Base case: 3.69%	Lachenbruch et al., 2016 [10]
	Alternative: 8.90%	Clark et al., 2017 [6]
PU prevalence for the immunocompromised population	7.30%	Rubulotta et al., 2022 [11]
PU risk for those with IAD	32.30%	Gray & Giuliano, 2018 [12]

IAD - incontinence-associated dermatitis; PU - pressure ulcers.

2.4.2 Cost inputs

The model allows the user to choose the type of indwelling catheter due to the large variation in catheter costs. These have been sourced from a mix of the NHS drug tariff [13] and NHS local formularies. The uncoated catheter cost is used for the base case. The costs for each option included in the model can be found in Table 2.5. It has been assumed that all indwelling catheters use lubricating jelly, and a proportion will use anaesthetic gel (See Table 2.11). The costs for these can be found in Table 2.6.

Table 2.5: Indwelling catheter costs

Model parameter	Value	Source
Uncoated catheter	£2.36	NHS Drug Tariff, 2025 [13]
Biocath Hydrogel Coated (Bard) coated catheter	£9.12	South & West Devon Formulary and Referral, 2025 [14]
Lubri-Sil Aquafil Hydrogel Coated Silicone (Bard) coated catheter	£10.47	
Teleflex AQUAFLATE (PTFE Coated Latex)	£2.36	Somerset NHS Foundation Trust, 2025 [15]
Teleflex SYMPACATH AQUAFLATE coated catheter	£6.75	

NHS - National Health Service; PTFE - polytetrafluoroethylene.

Table 2.6: Indwelling catheter associated costs

Model parameter	Value	Source
Anaesthetic gel	£1.28	NHS Drug Tariff, 2025 [13]
Lubricating jelly	£0.17	

NHS - National Health Service.

The costs for the urinary pad and a variety of barrier creams that the model user can select from are given in Table 2.7. The cost provided per urinary pad includes the cost of staff time required to change it as well as including data from community care settings.

For all barrier creams, the largest option available was chosen to provide a conservative cost estimate and it was assumed 2g were used per application. The liquid dressing was used as the base case barrier cream. For all barrier cream options except the Liquid dressing, these are modelled to be re-applied with every change of pad. The liquid dressing should not be changed reapplied as frequently and a rate of change has been applied (see Table 2.11).

Table 2.7: Urinary pad and barrier cream costs

Model parameter	Value	Source
Urinary pad	£2.56	HCSA, 2023 [16]
Liquid Dressing Cavalon Advanced (per 0.7ml)	£6.99	NHS Drug Tariff, 2025 [13]
Cavilon Durable Barrier Cream (per 2g sachet)	£0.34	NHS, 2025 [17]
Drapolene cream (per 2g)	£0.05	JFC, 2025 [18]
Siopel cream (per 2g)	£0.19	
Sudocrem antiseptic healing cream (per 2g)	£0.05	
Conotrane cream (per 2g)	£0.04	

HCSA - Health Care Supply Association; JFC - Joint Formulary Committee; NHS - National Health Service.

The cost of the Men's Liberty Acute provided by iMEDicare was £8.78 per device.

The costs of CAUTI and PU treatment can be found in Table 2.8. The CAUTI cost has two sources available for the model user to choose from due to the wide variation in CAUTI treatment costs reported in literature. Both were inflated to a 2023/24 cost-year using the personal social services research unit (PSSRU) inflation indices [19].

The PU treatment cost is a weighted average of the costs of treating category 1 to 4 PU. These treatment costs from Dealey at al. [20] include bed days and were weighted using a distribution of observed PU from Parfit et al. [21] before being inflated to a 2023/24 cost-year using the PSSRU inflation indices [19].

Table 2.8 also an average hospital bed day cost since each AE is assumed to come with an increased Los (see Table 2.10). This cost is also applied to the average LoS (see Table 2.10) for all populations.

Table 2.8: Adverse event treatment costs

Model parameter	Value	Source
CAUTI treatment cost	Base case: £626	Smith et al., 2019 [7]
	Alternative: £904	Baker et al., 2023 [22]
PU treatment cost	£6,917	Dealey et al., 2012 [20] Parfitt et al., 2021 [21]
Cost per hospital bed day	£536	Jalilian et al., 2024 [23]

CAUTI - catheter-associated urinary tract infection; PU - pressure ulcers.

Table 2.9 shows the staff costs per working hour for bands 4 to 7, assuming all staff are hospital-based nurses. The model allows the user to vary the band of staff for the 3 roles whose staff time costs are modelled in scenario 1: inserting an indwelling catheter; applying Men's Liberty Acute; and changing a urinary pad and barrier cream. In the base case, it is assumed that these are all performed by a band 4 nurse.

Table 2.9: Staff time costs

Model parameter	Value	Source
Band 4	£37.00	Jones et al., 2025 [19]
Band 5	£45.00	
Band 6	£56.00	
Band 7	£67.00	

CAUTI - catheter-associated urinary tract infection; PU - pressure ulcers.

2.4.3 Resource inputs

LoS has been modelled as an average UK hospital stay duration, with an excess LoS added dependent on AEs experienced. The excess LoS due to CAUTI has two available sources for the model user to choose from due to the wide variation in reported figures. These values are reported in Table 2.10.

Table 2.10: Length of stay

Model parameter	Value	Source
Average LoS in hospital (days)	8.30	Cavallaro et al., 2023 [24]
Excess LoS due to CAUTI (days)	Base case: 2.75	Kilonzo, 2015 [25]
	Alternative: 0.63	Smith et al., 2019 [7]
Excess LoS due to IAD (days)	1.78	Choragudi et al., 2024 [26]
Excess LoS due to PU (days)	2.60	Theisin et al., 2012 [27]

CAUTI - catheter-associated urinary tract infection; IAD - incontinence-associated dermatitis; LoS - length of stay; PU - pressure ulcers.

Table 2.11 gives the resource use for comparators. It is assumed that only one urinary catheter is used per person within our time-horizon.

Table 2.11: Comparator resource use

Model parameter	Value	Source
Average number of urinary pads used per day	6	HCSA, 2023 [16]
Duration of use for liquid dressing (hours)	84	Brennan et al., 2017 [28]
Proportion of indwelling catheters that use anaesthetic gel	50.00%	Assumption based on clinical advice

HCSA - Health Care Supply Association.

The number of Men's Liberty Acute estimated to be required for an average patient for the first 2 days and then every day after has been provided by iMEDicare. These can be found in Table 2.12 and were combined to calculate an average number of Men's Liberty Acute required per day which was applied to the LoS.

Table 2.12: Men's Liberty Acute resource use

Model parameter	Value	Source
Number of Men's Liberty Acute used per day (days 1-2)	1.50	Provided by iMEDicare
Number of Men's Liberty Acute used per day (days 3+)	0.67	

IAD doesn't require any additional treatment except a more careful cleaning and reapplication process and more frequent pad changes. Ousey et al. [29] report a saving of 34 minutes of staff time per patient per day when pressure damage was reduced. This has been used as a proxy for staff time used to treat IAD and combined with the selected cost of staff time (see Table 2.9) to calculate a treatment cost for IAD.

Table 2.13 shows the time and number of staff needed to apply or change each intervention. These inputs are combined with staff time cost (see Table 2.9) to account for the variation in staff time needed for each treatment type when scenario 1 is selected.

The time taken to change an indwelling catheter has been assumed based on the 4-minute midpoint of a 3 to 5 minute range from anaesthetic gel guidance [30], combined with an assumption of 3 minutes insertion time for someone familiar with the device provided by iMEDicare.

Table 2.13: Scenario 1: Modelling staff time resource use

Model parameter	Value	Source
Average time taken to change an indwelling catheter (minutes)	7.00	Massey-Pawadyria et al., 2023 [30] combined with an assumption provided by iMEDicare
Average time taken to change Men's Liberty Acute external catheter (minutes)	5.00	Assumption provided by iMEDicare
Average time taken to change a urinary pad/barrier cream (minutes)	5.00	Assumption based on clinical advice
Number of staff needed to change a male indwelling catheter	1	
Number of staff needed to change a urinary pad	1	

For scenario 2, the number of Men's Liberty Acute used per day is assumed to be the same as the base case model. However, the option is included to alter this quantity in the model for those with IAD or PU. Given the lack of published evidence, no reduction in stay is applied for those using Men's Liberty Acute who have previously IAD or PU in the base case. However, the option is included since evidence suggests that moisture increase the risk of further injury and prevents wounds from healing efficiently [31]. It is assumed that an increased number of urinary pads are used per day for those with IAD and PU. These inputs can be found in Table 2.14.

Table 2.14: Scenario 2: Modelling previously acquired PU or IAD resource use

Model parameter	Value	Source
Reduction in LoS for people using Men's Liberty Acute	0.00%	Assumption able to be varied by the user
Average number of urinary pads used per day	8	
Number of Men's Liberty Acute used per day (days 1-2) for people with IAD or PU	1.50	Assumption provided by Men's Liberty Acute
Number of Men's Liberty Acute used per day (days 3+) for people with IAD or PU	0.67	

IAD - incontinence-associated dermatitis; LoS - length of stay; PU - pressure ulcers.

2.4.4 Mortality inputs

The number of events per selected cohort is calculated using the risk of mortality due to the AEs found in Table 2.15. This model captures the expected number of deaths per selected cohort but does not assign a cost to mortality. There are 2 sources available for risk of mortality due to CAUTI due to wide variation in the estimated risk found in published literature. The risk of mortality due to IAD is assumed to be 0% due to lack of evidence linking IAD to mortality. However, evidence links IAD to risk of PU so the risk of mortality will be implicitly capture through the mortality risk of PU.

Table 2.15: Scenario 2: Modelling previously acquired PU or IAD resource use

Model parameter	Value	Source
Risk of mortality from a CAUTI	Base case: 2.82%	Smith et al., 2019 [7]
	Alternative: 0.75%	Baker et al., 2023 [22]
Risk of mortality from IAD	0.00%	Assumption
Risk of mortality from PU	14.80%	Song et al., 2019 [32]

CAUTI - catheter-associated urinary tract infection; IAD - incontinence-associated dermatitis; PU - pressure ulcers.

3 Results

3.1 Base Case Results

The model base case uses the General population with an uncoated indwelling catheter comparator. A cohort size of 1,000 people was modelled.

3.1.1 General population

Table 3.1 shows the breakdown of cost per person, and the incremental costs. The analysis found an average cost saving of £19.76 per person when comparing Men's Liberty Acute external catheter to the uncoated indwelling catheter for the general population. The cost breakdown shows that the Men's Liberty Acute device is more costly than an indwelling catheter. However, this is outweighed by the cost savings due to reduced AEs and LoS.

Table 3.1: General population per person cost breakdown

Model parameter	Indwelling catheter cost per person	Men's Liberty Acute cost per person	Incremental cost per person
Incontinence management cost	£3.17	£63.22	£60.05
AE cost	£23.79	£0.00	-£23.79
LoS cost	£4,504.81	£4,448.80	-£56.01
Staff time cost	£0.00	£0.00	£0.00
Total cost per person	**£4,531.77**	**£4,512.02**	**-£19.76**

AE - adverse event; LoS - length of stay.

Table 3.2 shows the total clinical outcomes per 1,000 people for the model base case. Since the base case comparator is an indwelling catheter for the general population, IAD and PU are not modelled as AEs. A total of 38 CAUTIs and 1 additional death were estimated for the indwelling catheter compared to Men's Liberty Acute, per 1,000 people treated.

Table 3.2: General population clinical outcomes

Model parameter	Indwelling catheter	Men's Liberty Acute	Incremental outcome
Mortality	1	0	**-1**
IAD cases	0	0	**0**
PU cases	0	0	**0**
CAUTIs	38	0	**-38**

CAUTI - catheter-associated urinary tract infection; IAD - incontinence-associated dermatitis; PU - pressure ulcers.

Furthermore, the analysis found a reduction in LoS of 0.1 days per person for those using Men's Liberty Acute compared to using the indwelling catheter.

3.1.2 Vulnerable population

3.1.2.1 Indwelling catheter comparator

The following results use the base case settings as described above, but for the vulnerable population using the indwelling catheter comparator.

Table 3.3 shows the breakdown of cost per person, and the incremental costs. The analysis found an average cost saving of £38.66 per person when comparing Men's Liberty Acute external catheter to the uncoated indwelling catheter for the vulnerable population. The cost breakdown shows that the Men's Liberty Acute device is more costly than an indwelling catheter. However, this is outweighed by the cost savings due to reduced AEs and LoS.

Table 3.3: Vulnerable population per person cost breakdown

Model parameter	Indwelling catheter cost per person	Men's Liberty Acute cost per person	Incremental cost per person
Incontinence management cost	£3.17	£63.22	**£60.05**
AE cost	£29.43	£0.00	**-£29.43**
LoS cost	£4,518.08	£4,448.80	**-£69.28**
Staff time cost	£0.00	£0.00	**£0.00**
Total cost per person	**£4,550.68**	**£4,512.02**	**-£38.66**

AE - adverse event; LoS - length of stay.

The clinical outcomes for the vulnerable population shown in Table 3.4 show the 47 estimated CAUTIs and 1 estimated mortality per 1,000 people using the indwelling catheter compared to 0 AEs for those using Men's Liberty Acute. The analysis also found an estimated 0.13 days reduction in LoS per person for the vulnerable population using Men's Liberty Acute.

Table 3.4: Vulnerable population clinical outcomes

Model parameter	Indwelling catheter	Men's Liberty Acute	Incremental outcome
Mortality	1	0	**-1**
IAD cases	0	0	**0**
PU cases	0	0	**0**
CAUTIs	47	0	**-47**

CAUTI - catheter-associated urinary tract infection; IAD - incontinence-associated dermatitis; PU - pressure ulcers.

3.1.2.2 Urinary pad comparator

The following results use the base case settings as described above, but for the vulnerable population using the urinary pad comparator.

Table 3.5 shows the breakdown of cost per person, and the incremental costs. The analysis found an average cost saving of £473 per person when comparing Men's Liberty Acute external catheter to a urinary pad for the vulnerable population. The cost breakdown shows that the Men's Liberty Acute is cost saving for all aspects including device cost.

Table 3.5: Vulnerable population per person cost breakdown

Model parameter	Indwelling catheter cost per person	Men's Liberty Acute cost per person	Incremental cost per person
Incontinence management cost	£156.59	£63.22	**-£93.38**
AE cost	£277.76	£0.00	**-£277.76**
LoS cost	£4,550.66	£4,448.80	**-£101.86**
Staff time cost	£0.00	£0.00	**£0.00**
Total cost per person	**£4,985.01**	**£4,512.02**	**-£473.00**

AE - adverse event; LoS - length of stay.

Table 3.6 shows the clinical outcomes for the vulnerable population with a urinary pad comparator. The analysis found an estimated reduction of 5 mortalities, 107 IAD cases, and 37 PU cases per 1,000 people for those using Men's Liberty Acute compared to urinary pads. The analysis also found an estimated LoS reduction of 0.29 days per person.

Table 3.6: Vulnerable population clinical outcomes

Model parameter	Indwelling catheter	Men's Liberty Acute	Incremental outcome
Mortality	5	0	**-5**
IAD cases	107	0	**-107**
PU cases	37	0	**-37**
CAUTIs	0	0	**0**

CAUTI - catheter-associated urinary tract infection; IAD - incontinence-associated dermatitis; PU - pressure ulcers.

3.1.3 Immunocompromised population

The immunocompromised population results will similarly use the base case settings outlined above for an immunocompromised population with a urinary pad comparator.

Table 3.7 shows the breakdown of cost per person, and the incremental costs. The analysis found an average cost saving of £877.79 per person when comparing Men's Liberty Acute external catheter to a urinary pad for the vulnerable population. The cost breakdown shows that the Men's Liberty Acute is cost saving for all aspects including device cost.

Table 3.7: Immunocompromised population per person cost breakdown

Model parameter	Indwelling catheter cost per person	Men's Liberty Acute cost per person	Incremental cost per person
Incontinence management cost	£170.25	£63.22	**-£107.03**
AE cost	£553.08	£0.00	**-£553.08**
LoS cost	£4,666.48	£4,448.80	**-£217.68**
Staff time cost	£0.00	£0.00	**£0.00**
Total cost per person	**£5,389.81**	**£4,512.02**	**-£877.79**

AE - adverse event; LoS - length of stay.

Due to the higher risk of AEs associated with the immunocompromised population (See Table 2.3 and Table 2.4), Table 3.8 shows the highest incremental reductions in AEs. The analysis

predicts a reduction of 11 mortalities, 228 IAD cases and 73 PU cases per 1,000 people in the immunocompromised population using Men's Liberty Acute compared to urinary pads. This analysis also found an estimated reduction in LoS of 0.6 days per person.

Table 3.8: Immunocompromised population clinical outcomes

Model parameter	Indwelling catheter	Men's Liberty Acute	Incremental outcome
Mortality	11	0	**-11**
IAD cases	228	0	**-228**
PU cases	73	0	**-73**
CAUTIs	0	0	**0**

CAUTI - catheter-associated urinary tract infection; IAD - incontinence-associated dermatitis; PU - pressure ulcers.

3.2 Deterministic Sensitivity Analysis

Deterministic sensitivity analysis was run for each of the base case set ups. A tornado plot for each can be found in Appendix A (Figure 6.1 to Figure 6.4). These were built to display the impact on total incremental cost when parameters were individually varied. Parameters that have the most impact on the overall outcome can be seen at the top of the diagrams. For inputs with a confidence interval provided, these were varied between the lower and upper bounds. Where not otherwise indicated, all parameters were varied by 20% of their value.

For both the general and vulnerable population with the urinary pad comparator (Figure 6.1 and Figure 6.2), the CAUTI prevalence for those using Men's Liberty Acute was the most influential parameter when varied between 0% and 2%. It was also the only parameter whose variation resulted in Men's Liberty Acute becoming not cost saving, assuming all other parameters remain unvaried.

For the populations using the urinary pad comparator (Figure 6.3 and Figure 6.4) the key drivers were the relative impacts of AE (overall risk and cost). However, none of the parameters when varied individually caused Men's Liberty Acute to not be cost saving.

3.3 Scenario Analysis Results

This model contains multiple optional scenarios with the two main scenarios outlined in Section 2.2. The impact of these scenarios on the incremental cost per person can be found in Table 3.9.

Table 3.9: Scenario analysis results

Scenario description	Base case description	Incremental cost per person
Base case	General population base case with an indwelling catheter comparator	**-£19.76**
	Vulnerable population base case with an indwelling catheter comparator	**-£38.66**
	Vulnerable population base case with a urinary pad comparator	**-£473.00**
	Immunocompromised population base case with a urinary pad comparator	**-£877.79**
Scenario 1: Including the cost of staff time to apply each incontinence management method	General population base case with an indwelling catheter comparator does not include cost of staff time to apply the incontinence management strategy	**-£20.99**
	Vulnerable population base case with an indwelling catheter comparator does not include cost of staff time to apply the incontinence management strategy	**-£39.89**
	Vulnerable population base case with a urinary pad comparator does not include cost of staff time to apply the incontinence management strategy	**-£489.30**
	Immunocompromised population base case with a urinary pad comparator does not include cost of staff time to apply the incontinence management strategy	**-£895.06**
Scenario 2: Assuming 100% have a previously acquired IAD with a proportion of those people having PU	Vulnerable population base case with a urinary pad comparator (no previous IAD)	**-£153.75**
	Immunocompromised population base case with a urinary pad comparator (no previous IAD)	**-£153.75**
Scenario 2: Assuming 100% previously acquired PU	Vulnerable population base case with a urinary pad comparator (no previous PU)	**-£161.98**
	Immunocompromised population base case with a urinary pad comparator (no previous PU)	**-£161.98**
Most optimistic scenario: See Appendix B for more details	General population base case with an indwelling catheter comparator	**-£35.34**
	Vulnerable population base case with an indwelling catheter comparator	**-£52.89**
	Vulnerable population base case with a urinary pad comparator	**-£938.24**
	Immunocompromised population base case with a urinary pad comparator	**-£1,000.82**
Most conservative scenario: See Appendix B for more details	General population base case with an indwelling catheter comparator	**£24.06**
	Vulnerable population base case with an indwelling catheter comparator	**£15.39**
	Vulnerable population base case with a urinary pad comparator	**-£420.93**
	Immunocompromised population base case with a urinary pad comparator	**-£832.08**

IAD - incontinence-associated dermatitis; PU - pressure ulcers.

4 Discussion

4.1 Model Results

The base case model results show Men's Liberty Acute is likely to be cost saving across all populations and comparators with cost savings ranging from £19.76 for the general population, to £877.79 for the immunocompromised population. Men's Liberty Acute has the greater cost saving when compared with the urinary pad comparator rather than an indwelling catheter. The cost savings with Men's Liberty Acute were driven by the reduction in AEs and their associated costs of treatment, as well as the reduction in LoS.

We looked at a range of scenario and sensitivity analyses. The key drivers were found to be the relative impact and costs of AEs, highlighting the value proposition of Men's Liberty Acute. As highlighted in the scenarios, there may be greater savings from Men's Liberty Acute than captured in the base case. For instance, the incremental cost saving is greater, if staff time is also incorporated into the model. There is minimal quantitative evidence to capture the difference in staff time. However, it is expected that the staff time will be less with Men's Liberty Acute, so not accounting for any change may underestimate the potential benefits. Furthermore, other scenarios highlighted showed that changes in the starting populations did not impact the direction of the results.

Our analysis also explored the most optimistic and most conservative scenarios. This analysis found that for the urinary pad comparator, even in the most-conservative scenario, Men's Liberty Acute was found to be cost saving. This was alongside benefits to patients with a reduction in IAD, PU, and mortality. The most-conservative scenario for the indwelling catheter comparator found Men's Liberty Acute to be cost-incurring with the key driver being the reduced CAUTI prevalence. This would suggest that for populations where the CAUTI rate due to indwelling catheters is very low, Men's Liberty Acute is less likely to be cost saving as an alternative to an indwelling catheter in the general population. However, it is likely to be cost saving for all populations with a urinary pad comparator.

One unquantified benefit of Men's Liberty Acute is the increase to patient comfort. This analysis suggests that Men's Liberty Acute is likely to decrease the occurrence of AEs for all populations, therefore improving patient welfare. For those patients already suffering from IADs and PUs, further treatment using urinary pads may exacerbate the issues, and cause greater suffering to patients, and in some cases, a higher risk of mortality. It is likely that by removing the need for urinary pads, Men's Liberty Acute will improve the quality of life of patients with IADs and PUs. The value to the patients' health-related quality of life is not fully quantified in this early cost-effectiveness model and should also be considered for future commissioning decisions.

4.1.1 Future evidence generation

Given the limited early-stage data available on the efficacy of Men's Liberty Acute, we recommend future evidence collection in this area. Existing studies on the efficacy of female external catheters have found significant reduction in CAUTI rate among female intensive care

patients [33]. However, there is little evidence for male external catheters that are not condom catheters or urinary sheaths. In order to further validate the model results, we therefore recommended to collect real-world data on the rate of AEs for patients using Men's Liberty Acute if it is rolled out further in NHS trusts. The exact study design may be decided based on available resource. However, it is important that comparative evidence is generated, between current standard of care practices. Comparative data should also be matched to account for population characteristics, which are likely to impact key clinical outcomes.

Furthermore, another important evidence gap is the number of staff and the staff time required to apply each incontinence management strategy. In order to validate the assumptions made in this model and apply quantitative differences in staff time, YHEC recommends observational evidence is collected on the duration of use and staff time required across the different populations and incontinence management strategies.

Finally, it is likely that for those using Men's Liberty Acute who have existing PU or IAD there would be a LoS reduction compared to those using urinary pads. Since Men's Liberty Acute is assumed to remove any moisture in contact with the skin, evidence suggests that time to heal would be reduced [31]. This could potentially impact the AE severity, treatment costs, and treatment duration. If evidence was collected to support this assumption and quantify a reduction in treatment costs and duration, the impact of this could be included in the model as another benefit of Men's Liberty Acute. We recommend collecting either trial or real-world data to support this value proposition. As with all data points in future evidence generation, we recommend that the data collected is comparative and can be controlled or matched on population characteristics.

4.2 Model Limitations

Due to lack of data availability, this early analysis has limitations that should be considered when interpreting the results.

The model is stratified by three different populations. These populations are reflected in the choice of comparator and type and risk of AE. However, there are factors included within the model that are not dependent on model population and would likely have some variation. For example, the costs of the AEs do not vary between populations due to lack of published evidence. We may expect a potentially higher cost for higher risk populations who may need extra medications or staff time.

This model has a time horizon of one month to capture the short-term impact of Men's Liberty Acute in an acute care setting only. It has therefore been assumed that for those on the indwelling catheter comparator arm, only one catheter is used per person. It is likely that this is an underestimate since factors such as blockages or malpositioning can cause catheters to fail and require replacement within one month.

An average in-hospital bed day cost is applied in order to cost LoS. Bed day costs are not linear, and costs tend to be front loaded in a patient's hospital stay. Therefore, bed day costs may be lower than estimated. It is also assumed that this cost includes staff time. However, it is unknown how much staff time has been accounted for within this cost. Consequently, applying

a cost for differing staff times is likely to be double counting this cost. For this reason, staff time is only included with an associated cost as an optional scenario. This allows the model user to explore the impact of this variation on overall cost, but it is not an accurate reflection of true cost.

The second scenario modelling previously acquired IAD or PU is also limited due to available evidence. This scenario assumes all patients on the urinary pad comparator arm have PU or, all have IAD (with a proportion of those assumed to have PU due to the increased risk of PU for people with IAD). The model incorporates the functionality to apply a LoS reduction for those with AEs using Men's Liberty Acute. This is to account for the removal of moisture likely reducing the healing time for an incontinence associated AE. The functionality to alter the number of Men's Liberty Acute required is also included to allow the user to explore the impact of more frequent changing. Since there is a lack of published evidence, these are assumed to have no change in the model base case.

5 Conclusion

This early cost-comparison analysis estimated Men's Liberty Acute to be a potentially cost saving alternative to standards of care for male incontinence management in acute care settings. It is most likely to be cost saving as an alternative for populations currently using urinary pads with potential cost savings found across device cost, LoS, and AE cost. It has been shown in all populations to reduce the number of AEs with extend hospital stays and impact a patient's health.

Due to the uncertainty of this early analysis, further evidence collection will improve the robustness of the model. This includes the collection of efficacy data in preventing AEs as well as typical resource use and staff time required for the intervention.

6 References

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Appendix A: Tornado diagrams

Figure 6.1: General population tornado diagram

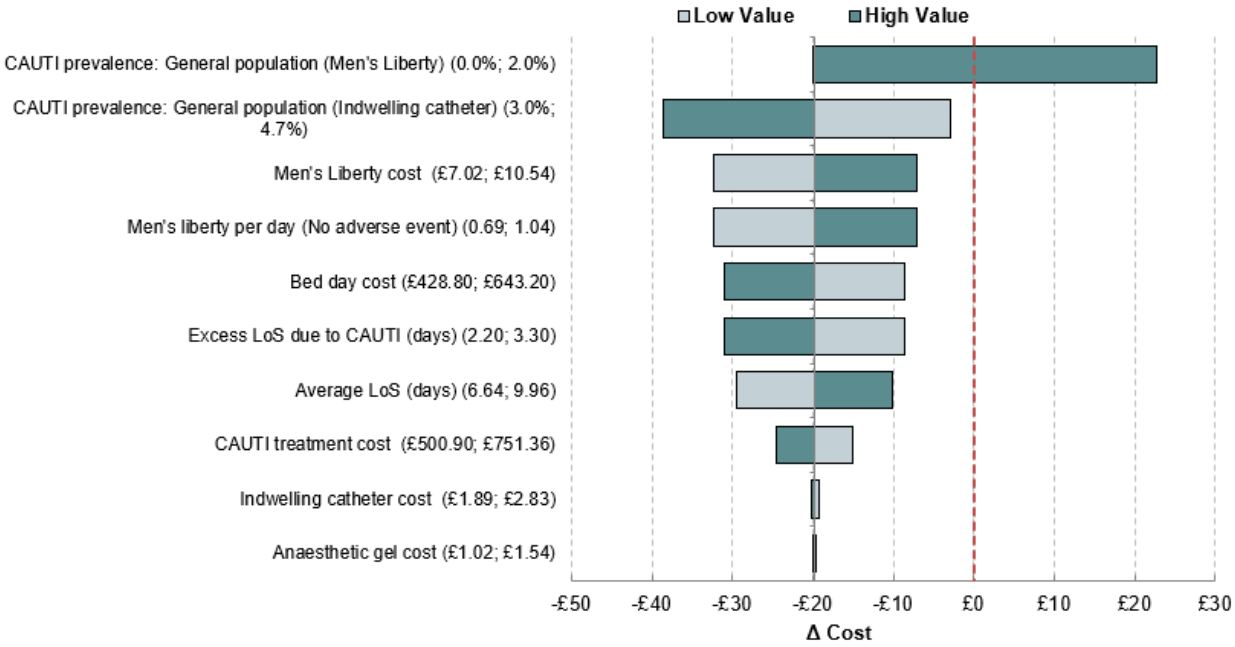


Figure 6.2: Vulnerable population (indwelling catheter comparator) tornado diagram

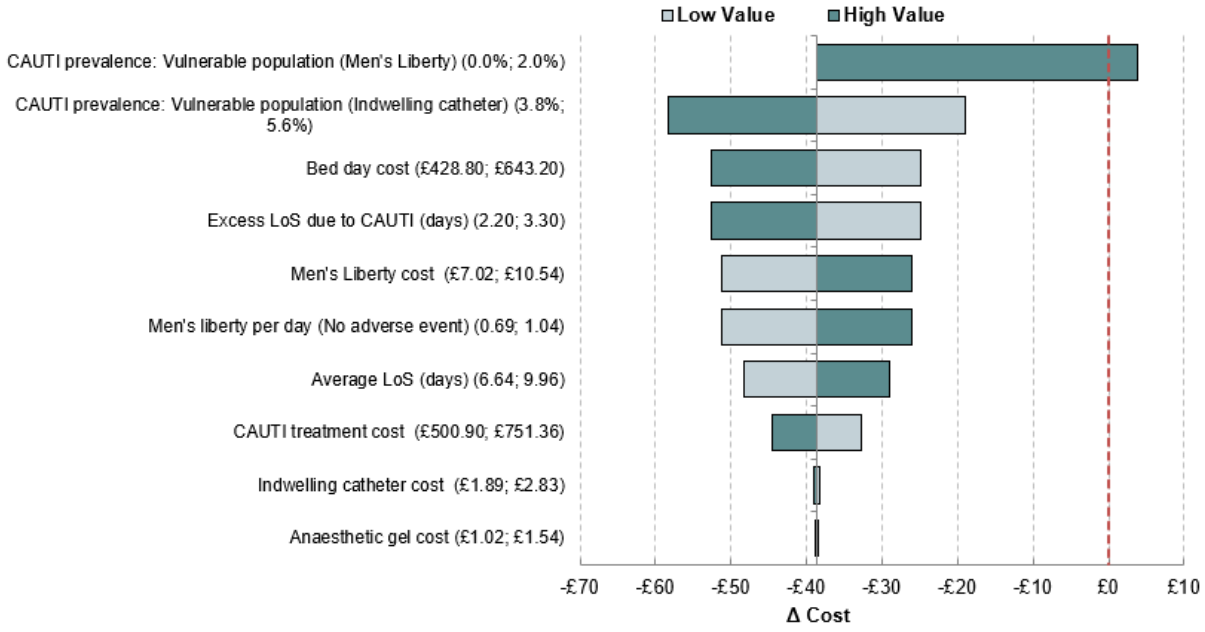


Figure 6.3: Vulnerable population (urinary pad comparator) tornado diagram

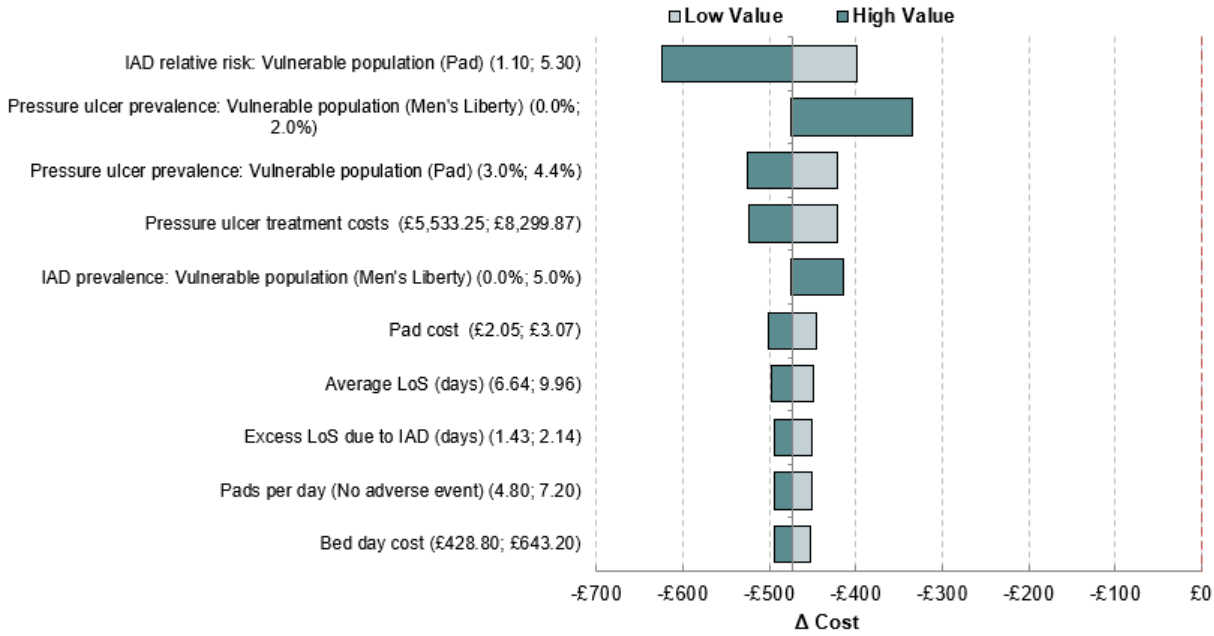
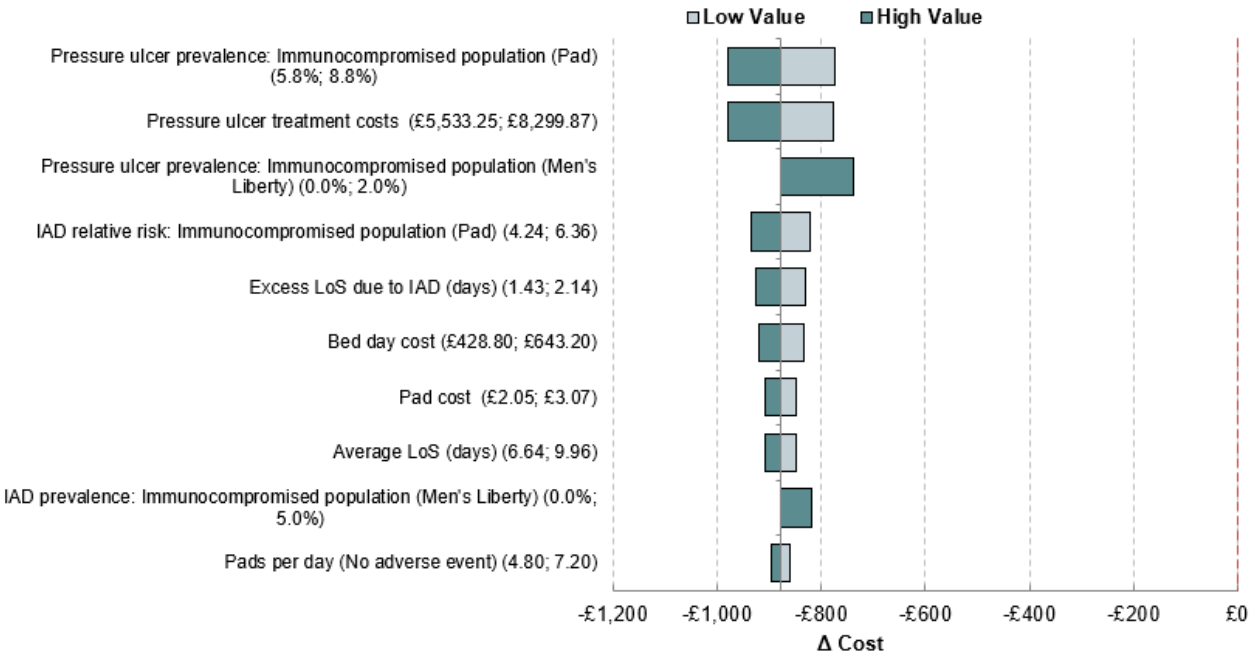


Figure 6.4: Immunocompromised population tornado diagram



Appendix B: Most optimistic/conservative scenarios

The most optimistic scenarios assumed the following model user inputs as well as selecting the options resulting in the maximum total cost-saving for any inputs with multiple options provided and applying scenario 1:

- The proportion of indwelling catheters using anaesthetic gel was assumed to be 100%.
- The number of staff required to change an indwelling catheter or urinary pad was assumed to be 2.
- The Cavalon advanced liquid dressing was assumed to be used all populations with the urinary pad comparator. However, the duration of use was assumed to be 48 hours rather than 84.

For any inputs with multiple options, the most conservative scenario used the option that minimised the total cost savings as well as the following model user inputs:

- The proportion of catheters using anaesthetic gel was assumed to be 0%.
- The frequency of use for urinary pads is assumed to be 4 per day rather than 6.