**Supplemental data - Health Economic analysis**

**Unit Cost data**

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| **Resource Item** | **Cost** | **Source** |
| GP surgery visit | £37 | PSSRU (2017) p165- Including direct care staff costs with qualification; Per participant contact lasting 9.22 minutes |
| Nurse at GP surgery | £6.45 | PSSRU (2017) p163 - £42 per hour (cost including qualifications). Per patient contact lasting 9.22 minutes |
| District nurse visit house | £77.35 | £75 PSSRU (2015) p172 Nurse specialist (community) £75 per hour with qualification of patient related work [not updated in latest publication]  Inflated to 2017 cost year |
| Walk in centre | £32.94 | £28 (23)  Inflated to 2017 cost year |
| Hospital A&E Department | £63 | Department of Health (DoH). NHS Reference Costs. 2017-18 Tariff information spreadsheet – index. London: DH; 2017. URL: https://improvement.nhs.uk/uploads/documents/Copy\_of\_Annex\_A\_-\_National\_tariff\_workbook.xlsx (accessed 16 January 2018). |

Table HE1: Summary of participant- reported health care use and associated unit costs

**Unit costs of patient-reported prescriptions**

Almost all of the entries could be allocated to either antibiotics, painkillers, or dressings. Given that the price of dressings was negligible, it was assumed that amongst participants who reported receiving one or more prescriptions, 50% received painkillers and 50% received antibiotics

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| --- | --- | --- |
| **Drug Name** | **Price** | **Source** |
| Metronidazole  400 mg every 8 hours for 7 days | £4.10  (21 tablets) | BNF (2018) (24) |
| Co-codamol 15mg/500mg 3 times a day for 5 days | £4.93  (100 tablets) | BNF 2018 |

Table HE2: Summary of participant-reported medication use (prescriptions) and associated unit costs.

**Operation associated costs**

Given that no information was collected on the staff members present during the operations, it was assumed that the following health-care staff were present at the procedure - anaesthetist, anaesthetic assistant, surgeon, assistant surgeon, scrub nurse, and a circulating nurse.

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| **Item** | **Cost** | **Source** |
| Biodesign® Surgisis® anal fistula plug | £780 |  |
| Theatre time / hr | £1,144 | IDS Scotland figures (<http://www.isdscotland.org/Health-Topics/Finance/Costs/Detailed-Tables/Theatres.asp>) (accessed 16 January 2018) |
| Elective inpatient excess day | £392 | (NHS reference costs, 2017) FZ22E Intermediate Anal Procedures, 19 years and over, with CC Score 0 |
| Surgeon | £107 | PSSRU (2017) P213 Hospital based doctors – Consultant Surgeon |
| Assistant Surgeon | £107 | PSSRU (2017) P213 Hospital based doctors – Consultant Surgeon |
| Anaesthetist | £107 | PSSRU (2017) P213 Hospital based doctors – Consultant Surgeon |
| Assistant Anaesthetist | £54 | PSSRU (2017) P209 Hospital based nurses – grade 7 |
| Scrub Nurse | £54 | PSSRU (2017) P209 Hospital based nurses – grade 7 |
| Circulating Nurse | £54 | PSSRU (2017) P209 Hospital based nurses – grade 7 |
| Perioperative antibiotics- Metronidazole 500mg/100ml infusion 100ml bags - 1 dose 500mg | £62  (20 bags) | BNF (2018) |
| Post-operative antibiotics Oral Co-Amoxiclav (Augmentin) 250/125 mg every 8 hours 3 times /day for 7 days | £1.59  (21 tablets) | BNF (2018) |
| *Bowel Preparation* |  |  |
| Phosphates enema (Formula B) 128ml long tube | £27.93 | BNF (2018) |
| Oral Preparation - Moviprep oral powder One pair of sachets | £10.36  (4 sachets) | BNF (2018) |
| *Analgesics* |  |  |
| Morphine sulfate 10mg/10ml solution for injection ampoules | £15  (10 ampoules) | BNF (2018) |
| Co-codamol 15/500mg 2 tablets | £4.93  (100 tablets) | BNF (2018) |
| Lactulose 10g/15ml oral solution 15ml sachet sugar free | £2.52  (10 sachets) | BNF (2018) |
| Bulking Fybogel Mebeverine effervescent granules sachets orange (Reckitt Benckiser Healthcare (UK) Ltd) | £2.72  (30 sachets) | BNF (2018) |
| Tinzaparin sodium 3,500units/0.35ml solution for injection pre-filled syringes | £27.71  (10 pre-filled disposable injections) | BNF (2018) |

Table HE3: Operation related costs.

**Within trial cost-effectiveness analysis**

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| --- | --- | --- | --- | --- |
| **Cost Type** |  | **Fistula plug**  **(n=87)** | **Surgeon’s preference (n=90)** | **Difference**  **P-value of**  **t-test** |
| Surgery related costs | Mean  (SD) | £2,306  (610) | £1,728  (502) | 0.0000 |
| Hospital-based costs due to readmissions | Mean  (SD) | £159  (412) | £89  (363) | 0.2330 |
| Health and social services use | Mean  (SD) | £267  (777) | £484  (1014) | 0.1092 |
| Total Costs | Mean  (SD) | £2,738  (1,151) | £2,308  (1,228) | 0.0174 |

Table HE4: Costs of health care resources (not imputed)

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| --- | --- | --- | --- | --- |
| **Time point** |  | **Fistula plug**  **(n=87)** | **Surgeon’s preference (n=90)** | **Difference**  **P-value of t-test** |
| Baseline | Mean (SD)  Median  (min-max) | 0.810 (0.238)  0.796  (-0.594-1.000) | 0.750 (0.220)  0.796  (-0.016-1.000) | 0.0818 |
| 6 weeks | Mean (SD)  Median  (min-max) | 0.791 (0.222)  0.796  (0.082-1.000) | 0.780 (0.229)  0.796  (-0.181-1.000) | 0.7330 |
| 6 months | Mean (SD)  Median  (min-max) | 0.837 (0.210)  0.883  (0.082-1.000) | 0.775 (0.287)  0.796  (-0.239-1.000) | 0.0998 |
| 12 months | Mean (SD)  Median  (min-max) | 0.856 (0.195)  1.000  (-0.181-1.000) | 0.836 (0.236)  0.924  (-0.331-1.000) | 0.5372 |
| Total QALYs | Mean (SD)  Median  (min-max) | 0.829 (0.174)  0.852  (0.043-1.000) | 0.790 (0.212)  0.832  (-0.102-1.000) | 0.1820 |

Table HE5: EQ-5D-3L index scores at baseline and follow-up and total QALYs by treatment arm (not imputed).

|  |  |  |
| --- | --- | --- |
|  | **Fistula plug**  **(n=87)** | **Surgeon’s preference**  **(n=90)** |
| Total QALYs (SD) | 0.829 (0.174) | 0.790 (0.212) |
| Total Cost £ (SD) | £2,738 (1,151) | £2,308 (1,228) |

Table HE6: Total costs and QALYs by treatment arm (deterministic, non-imputed)

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| Strategy | Total Cost  Mean (SD) | Incremental Cost  Mean (SD) | QALY  Mean  (SD) | Incremental. QALY  Mean  (SD) | ICER  Mean  (SD) | Inc.  NB  Mean (SD) |
| Surgeon’s preference | £2,308 (129) |  | 0.790 (0.022) |  |  |  |
| Fistula plug | £2,738 (123) | £430  (178) | 0.829 (0.183) | 0.039 (0.029) | £10,993 (478,666) | £352  (622) |

Table HE7: Probabilistic cost-effectiveness results (non-imputed)



**Figure HE1: Cost-effectiveness acceptability curve showing the probability that the fistula plug will be cost-effective compared to surgeon’s preference across different willingness to pay values for the QALY using the bootstrap analysis of the imputed data adjusted for the baseline EQ-5D-3L.**