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### HEALTH ECONOMICS & DECISION SCIENCE

#### **Discussion Paper Series**

HEDS Discussion Paper 25.01

Title: Model estimation of the impact of delayed diagnosis of colorectal cancer and advanced adenomas on long term outcomes and costs

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## Model estimation of the impact of delayed diagnosis of colorectal cancer and advanced adenomas on long-term outcomes and costs

Sheffield Centre for Health and Related Research (ScHARR), Population Health, University of Sheffield

10 January 2025

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#### 1 Introduction

Diagnostic pathways for colorectal cancer (CRC (such as the former two week wait (2WW) standard, which has since been replaced by the Faster Diagnosis Standard (FDS), and the use of FIT testing within primary care) are important as they facilitate the early diagnosis and treatment of cancer which is crucial for improving survival rates. Reducing the length of time from the onset of cancer symptoms to presentation in primary care, receiving a diagnosis and starting treatment, may reduce the risk of disease progression. As CRC symptoms such as abdominal pain, rectal bleeding, change in bowel habit, and weight loss are non-specific, optimising diagnostic pathways to reduce the diagnostic interval within a service with capacity constraints is challenging.<sup>1</sup> Adenomas are generally asymptomatic but can be diagnosed incidentally during investigations for suspected CRC and are clinically important because adenomas (particularly high-risk adenomas (HRAs)) have the potential to develop into CRC.<sup>2</sup>

The health economic evaluation of cancer diagnostic pathways requires the quantification of: (1) resource use (such as numbers and costs of diagnostic procedures undertaken), and (2) the impact of reducing/increasing the diagnostic interval for persons with underlying disease (e.g., delayed diagnosis for persons receiving a false-negative test result).

Existing evidence on the association between the time to diagnosis and CRC outcomes is heterogeneous. A previous systematic review explored the association between shorter times to diagnosis and more favourable outcome and found that although many studies reported no associations, more studies reported a positive, rather than a negative, association.<sup>3</sup>

This study involved the development of a Markov model to quantify the impact of delayed diagnosis for CRC and HRAs on lifetime survival, QALYs and costs. This simple model utilises outputs from an existing CRC microsimulation model (MiMiC-Bowel).<sup>4</sup> The estimates

generated here provide key inputs for the evaluation of new diagnostic technologies or changes to existing CRC diagnostic pathways.

#### 2 Methods

#### 2.1 <u>Model perspective</u>

The model adopted a lifetime horizon to evaluate the long-term impact of delayed diagnosis on healthcare costs and health outcomes for CRC and HRAs. A discount rate of 3.5% was used to account for time preferences, in line with the NICE Reference Case.<sup>5</sup> The analysis was conducted from the perspective of the UK National Health Service (NHS) and personal social services (PSS), which included all costs and patient benefits associated with healthcare services and social care interventions. Direct costs associated with CRC diagnosis and treatment, including the costs of diagnostic tests, healthcare contacts, hospitalisations, medications, and palliative care, were considered. Health outcomes were measured in terms of life years (LYs) gained (or lost), and quality-adjusted life years (QALYs).

#### 2.2 Model structure

A health economic model was used to estimate the impact of a delayed diagnosis on patient outcomes. The current time to diagnosis is assumed to be the average time to diagnosis based on the most recent data available for the previous 2WW pathway. A delayed diagnosis with delay length zero reflects this average current time to diagnosis and results for delay periods >0 are compared incrementally against this.

The model structure is illustrated in Figure 1. For patients with CRC, the impact of delayed diagnosis is estimated by comparing the stage distribution of CRC at diagnosis without delay to the expected stage distribution of CRC at diagnosis with the delay. The change in stage distribution during the delayed diagnosis represents disease progression during this time period. For patients with HRAs, disease progression is represented by the proportion of individuals who develop CRC during the delayed diagnosis. These estimates of disease progression during the delayed diagnosis are combined with estimates of the differential health outcomes and costs by disease stage to produce an overall estimate of the impact of delayed diagnosis over a range of delay intervals.

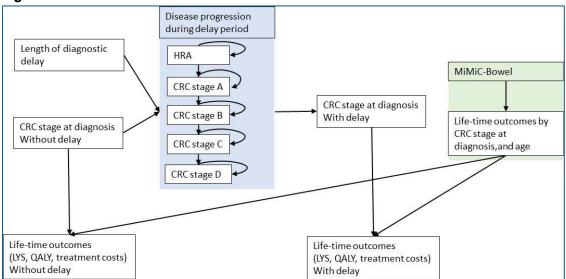


Figure 1: Model structure and estimation of outcomes

CRC - colorectal cancer; HRA - high-risk adenoma; LY - life year; QALY - quality-adjusted life year

#### 2.3 Population

The model population reflects patients referred under the 2WW system for suspected CRC in England<sup>6</sup> (subsequently replaced by the FDS in 2023). All individuals in the model have either CRC or HRAs. The age distributions applied for symptomatic patients with underlying disease (either CRC or HRAs) are shown in Table 1, based on data from the National Cancer Registration and Analysis Service (NCRAS).

The CRC stage distribution for the average current time to diagnosis was assumed to be the stage distribution of CRC in the 2WW population in England: 19.6%; 25.4%; 31.2%, 23.8% for Dukes' stages A-D, respectively.<sup>7</sup> This corresponds to patients diagnosed via symptomatic or chance detection (i.e., not via screening or surveillance). The model assumes that chance detection and symptomatic presentation are associated with the same stage distribution at diagnosis.

Table 1:	Age distribution assumed for persons with CRC or HRA diagnosed via
2WW referra	I

Age	CRC diagnos	ed via	HRA diagnose	ed age	Prevalence of
category	2WW age		distribution		CRC in 2WW
(years)					referrals
					population
	Frequency, N %		Frequency, N	%	
30-49	734	5%	49,251	13%	1.5%
50-59	1,814	13%	63,396	17%	2.9%
60-69	2,841	21%	85,690	23%	3.3%
70-79	4,274	32%	104,062	28%	4.1%
80-89	3,789	28%	73,564	20%	5.2%
All persons	13,452	100%	375,963	100%	3.6%

CRC - colorectal cancer; HRA - high-risk adenoma; 2WW - 2-Week Wait

#### 2.4 Modelling disease progression during delay period

Patients enter the model in one of five health states: HRA or CRC stage A, B, C or D. During the delay period, a proportion of patients will experience a stage shift. For undiagnosed HRAs, a proportion of patients will develop CRC stage A, and for CRC a proportion of patients will advance to the next stage. The probability of transitioning depends on the length of time over which diagnosis is delayed. The transition probabilities were taken from the existing MiMiC-Bowel model,<sup>4</sup> as detailed in Table 2. MiMiC-Bowel reports annual transition probabilities. In this model, it was necessary to convert the reported transition probabilities into rates to estimate transition probabilities for shorter periods of time.

The model assumes that individuals can only make one state transition during each 1-year period. This assumption is consistent with the assumptions made in MiMiC-Bowel. For predictions related to delays of >1 year, multiple transitions are included. It is assumed that all patients survive the delay period, i.e., there is no transition to "dead" in the model. This is a simplifying assumption but, is not expected to have a significant impact on the results given the short length of the delay period.

In MiMiC-Bowel, the preclinical patient population includes both asymptomatic and symptomatic patients; hence, the preclinical disease progression probabilities therefore relate to both asymptomatic and symptomatic individuals. It is plausible that a wholly symptomatic population may experience faster disease progression; this is a minor limitation of the analysis presented here.

Transition	Transition probability (1 year) from MiMiC- Bowel			
$CRC\;A\toCRC\;B$	0.293	0.347		
$\textbf{CRC B} \rightarrow \textbf{CRC C}$	0.554	0.807		
$\textbf{CRC C} \rightarrow \textbf{CRC D}$	0.350	0.431		
$\mathbf{HRA} \to \mathbf{CRC} \ \mathbf{A}^*$	0.027	0.028		

Table 2:Disease progression transition probabilities

CRC - colorectal cancer; HRA - high risk adenomas

\*Within MiMiC-Bowel the risk of progression is age dependent for HRA ->CRC. In this model, an average transition rate for age of 62 was applied for simplicity based on the midpoint average rate for ages 57 and 67.

*†Rates were calculated using the formula: rate, r=-ln [1-annual\_trans\_prob], then to estimate the transition probabilities relating to shorter time period the formula p(t) = 1 - e^{-rt}, where <i>r* is the rate and *t* is the time period was used. We note that this conversion formula has weaknesses and is most reliable for a model in which a person can experience only one type of event in a single cycle.<sup>8</sup>

#### 2.5 Lifetime outcomes without a diagnostic delay for CRC

Lifetime outcomes for CRC without delayed diagnosis were estimated by undertaking new analyses using the existing MiMiC-Bowel simulation model.<sup>4</sup> The model was set up to best reflect current practice in CRC screening and diagnosis, i.e., individuals in the model were eligible for screening by FIT at the age of 56 years. MiMiC-Bowel records diagnoses and outcomes separately for individuals diagnosed via screening or via symptomatic presentation. Only outcomes for individuals diagnosed symptomatically were used, as this best represents individuals in the NHS 2WW pathway.

MiMiC-Bowel was run for a population of 169,975 individuals based on 25 loops of the Health Survey for England (HSE) population. For each individual diagnosed via symptomatic/chance presentation in the model, the LYs, QALYs, and healthcare costs from the point of diagnosis until death were recorded. These outcomes were then subdivided according to the age group and stage at diagnosis, and the mean outcomes per age and stage at diagnosis were calculated. Details on how these outcomes are estimated by MiMiC-Bowel are reported in full in the relevant published model documentation.<sup>4</sup> As the costs in MiMiC-Bowel correspond to 2018 prices, aggregate costs were uplifted to 2023 values using the NHS Cost Inflation Index (NHSCII).<sup>9</sup>

#### 2.6 Lifetime outcomes without a diagnostic delay for HRAs

It was implicitly assumed that individuals diagnosed with HRAs have these removed via polypectomy. It is possible that individuals with HRAs removed via polypectomy might have slightly poorer health outcomes and higher costs than the general population. This modelling exercise made a simplifying assumption that lifetime outcomes for individuals with HRAs which are removed via polypectomy would be the same as for the general population. Life expectancy for the general population was taken from ONS life tables for England (2017-2019)<sup>10</sup> and age- and sex-adjusted HRQoL was based on EQ-5D-3L estimates from Hernández Alava *et al.*<sup>11</sup>

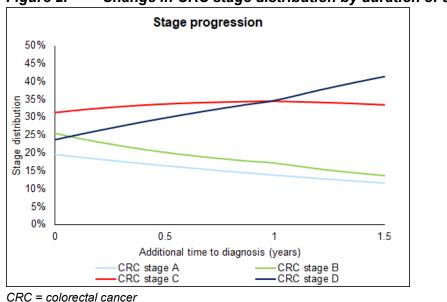
#### 2.7 Lifetime outcomes with a diagnostic delay

The two interim sets of results: (1) disease stage with delay, and (2) lifetime outcomes by disease state, were combined to provide an estimate of lifetime outcome for different lengths of diagnostic delay (up to 3 years). Estimates for different age groups were generated and these were combined to produce estimates which were specific to a 2WW population cohort. In addition, results for the age 60-69 years age group are presented as these data were used to inform the economic analysis of colon capsule endoscopy (CCE).

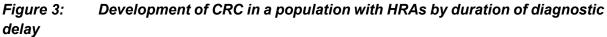
#### 3 Results

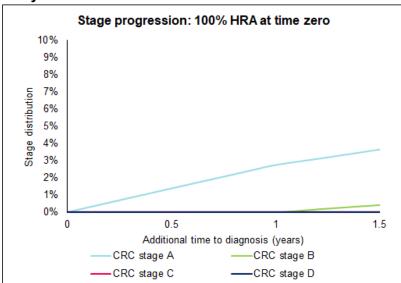
#### 3.1 Interim results: Model estimates of disease progression

Figure 2 and Figure 3 show the impact of disease progression during the diagnostic delay period on underlying disease state which is estimated by the Markov component of the model. For CRC, we see that with a longer diagnostic delay more individuals progress to late-stage CRC (stage C and D) and fewer are diagnosed in early stages (stages A and B). For HRA with a longer diagnostic delay, more individuals develop CRC.



*Figure 2: Change in CRC stage distribution by duration of diagnostic delay* 





CRC - colorectal cancer; HRA - high-risk adenoma

#### 3.2 Interim results: Costs and health outcomes by age and disease stage

Table 3 shows expected lifetime outcomes by age group and underlying disease state generated by undertaking re-analyses using MiMiC-Bowel. These results suggest lower expected LYs and QALYs for older age groups and more advanced stages of disease.

Fewer lifetime QALYs are accrued by individuals with CRC than with HRAs, and within CRC, fewer QALYs are accrued by individuals diagnosed at later stages than at early stages. Within each stage, individuals in older age groups accrue fewer lifetime QALYs than those diagnosed in younger age groups. Expected QALY estimates are lower than the corresponding LY

estimates for people without CRC, reflecting the impact of the disease and treatment on HRQoL.

Lifetime treatment costs indicate a more complex pattern. Treatment costs for individuals with CRC are much higher than for individuals with HRA. For CRC, individuals diagnosed with stage D cancer have the lowest treatment costs (likely due to such individuals having much shorter life expectancy, and more likely to be offered only palliative treatment). The pattern across the other age groups and stages is influenced by the interactions between life expectancy and treatment options.

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Age	Expect	ed discou	inted lifetii	me LYs		Expect	Expected discounted lifetime QALYs				Expect	ed discoun	ted lifetime	treatment of	costs
group	HRA	CRC A	CRC B	CRC C	CRC D	HRA	CRC A	CRC B	CRC C	CRC D	HRA	CRC A	CRC B	CRC C	CRC D
30-49	22.05	21.74	20.00	18.89	4.02	18.58	16.91	14.65	12.94	2.80	£574	£34,191	£33,168	£44,315	£14,780
50-59	18.32	17.72	17.11	14.57	3.63	14.89	12.80	12.00	10.60	2.57	£581	£34,205	£33,410	£44,320	£14,033
60-69	14.59	14.62	13.00	11.54	2.39	11.50	9.80	9.21	8.06	2.25	£521	£34,818	£33,599	£38,324	£10,938
70-79	10.40	9.58	8.65	6.83	1.53	7.88	6.66	6.09	5.02	1.76	£385	£31,693	£30,289	£31,357	£7,438
80-89	6.30	4.98	4.49	3.50	1.28	4.53	3.67	3.53	2.93	1.54	£95	£25,306	£24,391	£24,940	£5,155

 Table 3:
 Expected discounted LYs, QALYs, and inflated treatment costs by age and stage at diagnosis (excluding delay)

LY - life year; QALY - quality-adjusted life year; HRA - high risk adenoma; CRC - colorectal cancer

#### 3.3 Impact of delayed diagnosis

Table 4 and Table 5 present the estimated impact of delayed diagnosis for individuals with CRC and HRAs. Table 4 presents the estimated outcomes absolute values by duration of diagnostic delay, whilst Table 5 presents incremental outcomes compared to no delay.

For CRC, a longer diagnostic delay is associated with worse health outcomes (LYs and QALYs) but lower treatment costs (due to more individuals being diagnosed in stage D which is associated with lower treatment costs). At WTP thresholds of £30,000 per QALY, the QALY loss outweighs the treatment cost savings, resulting in lower NMB with longer diagnostic delays.

For HRAs, a longer diagnostic delay is associated with lower expected LYs and QALYs. This reflects the disease progression to CRC in some individuals and the lower HRQoL with CRC stage A compared to HRAs. Treatment costs are higher which reflects the higher treatment costs for CRC versus HRAs.

Table 4:	Estimated outcomes absolute values by duration of diagnostic delay	,
(discounted a	rate of 3.5% per year)	

Additional	CRC expec	ted outcomes	, absolute: by	by HRA expected outcomes, absolute: b		
time to	time to diagr	nosis		time to diagr	nosis	
diagnosis	Expected	Expected	Expected	Expected	Expected	Expected
(months)	discounted	discounted	discounted	discounted	discounted	discounted
	LYs	QALYs	lifetime	LYs	QALYs	lifetime
			treatment			treatment
			costs			costs
0.0	7.93	5.81	£26,222	13.41	10.63	£417
0.5	7.88	5.78	£26,121	13.41	10.63	£451
1	7.83	5.75	£26,020	13.41	10.63	£484
2	7.74	5.69	£25,823	13.41	10.63	£551
4	7.53	5.55	£25,353	13.41	10.62	£718
6	7.37	5.45	£24,998	13.41	10.61	£851
8	7.21	5.34	£24,621	13.40	10.61	£1,000
10	7.04	5.24	£24,228	13.40	10.60	£1,165
12	6.94	5.17	£23,968	13.40	10.59	£1,280
14	6.70	5.01	£23,350	13.39	10.58	£1,448
16	6.56	4.92	£22,962	13.39	10.58	£1,559
18	6.39	4.81	£22,505	13.38	10.57	£1,698
20	6.24	4.71	£22,076	13.38	10.56	£1,836
22	6.10	4.62	£21,674	13.38	10.55	£1,973
24	5.97	4.53	£21,297	13.37	10.55	£2,110
26	5.79	4.42	£20,800	13.36	10.54	£2,250
28	5.64	4.31	£20,335	13.36	10.53	£2,388
30	5.49	4.22	£19,899	13.35	10.52	£2,526
32	5.35	4.13	£19,491	13.35	10.51	£2,662
34	5.23	4.04	£19,110	13.34	10.50	£2,798
36	5.11	3.97	£18,753	13.33	10.49	£2,932

LY - life year; QALY - quality-adjusted life year

		-	•				
Additional			, incremental:	•		ncremental: by	
time to	by time to dia		I	time to diagnosis			
diagnosis	Expected	Expected	Expected	Expected	Expected	Expected	
(months)	discounted	discounted	discounted	discounted	discounted	discounted	
	LYs	QALYs	lifetime	LYs	QALYs	lifetime	
			treatment			treatment	
			costs			costs	
0.0	0.00	0.00	£0	0.00	0.00	£0	
0.5	-0.05	-0.03	-£102	0.00	0.00	£34	
1	-0.10	-0.06	-£202	0.00	0.00	£67	
2	-0.19	-0.12	-£399	0.00	-0.01	£134	
4	-0.40	-0.26	-£869	-0.01	-0.01	£301	
6	-0.56	-0.36	-£1,224	-0.01	-0.02	£434	
8	-0.72	-0.47	-£1,602	-0.01	-0.03	£583	
10	-0.88	-0.58	-£1,995	-0.01	-0.03	£748	
12	-0.99	-0.65	-£2,254	-0.02	-0.04	£863	
14	-1.22	-0.80	-£2,873	-0.02	-0.05	£1,030	
16	-1.37	-0.90	-£3,260	-0.03	-0.06	£1,142	
18	-1.53	-1.00	-£3,717	-0.03	-0.06	£1,280	
20	-1.69	-1.11	-£4,146	-0.03	-0.07	£1,419	
22	-1.83	-1.20	-£4,549	-0.04	-0.08	£1,556	
24	-1.96	-1.29	-£4,926	-0.04	-0.09	£1,693	
26	-2.13	-1.40	-£5,422	-0.05	-0.09	£1,833	
28	-2.29	-1.50	-£5,887	-0.06	-0.10	£1,971	
30	-2.44	-1.60	-£6,323	-0.06	-0.11	£2,109	
32	-2.57	-1.69	-£6,731	-0.07	-0.12	£2,245	
34	-2.70	-1.77	-£7,112	-0.07	-0.13	£2,381	
36	-2.82	-1.85	-£7,469	-0.08	-0.14	£2,515	

Table 5:Incremental outcomes (compared to no delay) by duration of diagnosticdelay (discounted at rate of 3.5% per year)

LY - life year; QALY - quality-adjusted life year; NMB - net monetary benefit; WTP - willingness-to-pay

#### 4 Conclusions

The results generated in this study can be used to inform the evaluation of the health economic impact of new diagnostic technologies or changes to the existing diagnostic pathways for CRC.

The use of a diagnostic test which is less sensitive (but perhaps more specific, less expensive, or less capacity constrained) than current care could result in additional individuals experiencing diagnostic delay. The duration of diagnostic delay for people who receive a false-negative test result will depend on what safety netting pathways are in place. We note that estimates of duration of diagnostic delay may be difficult to obtain so they may need to rely on expert opinion.

The evaluation of any change to diagnostic pathways for CRC should also consider the impact on patients with other potential underlying conditions. For example, non-cancerous conditions such as IBD, diverticulitis, irritable bowel syndrome (IBS), or haemorrhoids have symptoms which overlap with CRC symptoms, so these other conditions also need to be carefully considered in the design of diagnostic pathways.

#### 5 Appendix

Table 6:	Outcomes associated with additional time to diagnosis for the 60-69 age
group, for CH	RC OT

Additional	Absolute out	comes for 60-	69 age group	Incremental outcomes for 60-69 age group			
time to	Expected	Expected	Expected	Expected	Expected	Expected	
diagnosis	discounted	discounted	discounted	discounted	discounted	discounted	
(months)	lifetime	lifetime	lifetime	lifetime LYs	lifetime	lifetime	
	LYs	QALYs	treatment		QALYs	treatment	
			costs			costs	
0.0	10.34	7.31	£29,919	0.00	0.00	£0	
0.5	10.27	7.27	£29,812	-0.06	-0.04	-£107	
1	10.21	7.23	£29,706	-0.12	-0.08	-£213	
2	10.09	7.15	£29,499	-0.24	-0.16	-£420	
4	9.81	6.97	£29,001	-0.52	-0.34	-£918	
6	9.61	6.84	£28,624	-0.73	-0.47	-£1,295	
8	9.40	6.71	£28,222	-0.94	-0.60	-£1,697	
10	9.18	6.57	£27,801	-1.16	-0.74	-£2,118	
12	9.04	6.48	£27,523	-1.30	-0.83	-£2,396	
14	8.73	6.28	£26,855	-1.61	-1.03	-£3,063	
16	8.53	6.16	£26,437	-1.80	-1.15	-£3,482	
18	8.31	6.01	£25,941	-2.03	-1.30	-£3,978	
20	8.10	5.88	£25,476	-2.23	-1.43	-£4,443	
22	7.91	5.76	£25,039	-2.42	-1.55	-£4,880	
24	7.73	5.65	£24,628	-2.60	-1.66	-£5,291	
26	7.50	5.50	£24,088	-2.83	-1.81	-£5,831	
28	7.29	5.36	£23,581	-3.05	-1.95	-£6,338	
30	7.09	5.24	£23,106	-3.25	-2.07	-£6,813	
32	6.90	5.12	£22,660	-3.43	-2.19	-£7,259	
34	6.73	5.01	£22,243	-3.60	-2.30	-£7,676	
36	6.57	4.91	£21,852	-3.76	-2.40	-£8,067	

CRC - colorectal cancer; LY - life year; QALY - quality-adjusted life year

Table 7:	Outcomes associated with additional time to diagnosis for the 60-69 age
group, for HF	RA

Additional	Absolute out	comes for 60-	69 age group	Incremental outcomes for 60-69 age group			
time to	Expected	Expected	Expected	Expected	Expected	Expected	
diagnosis	discounted	discounted	discounted	discounted	discounted	discounted	
(months)	lifetime	lifetime	lifetime	lifetime LYs	lifetime	lifetime	
	LYs	QALYs	treatment		QALYs	treatment	
			costs			costs	
0.0	14.59	11.50	£521	0.00	0.00	£0	
0.5	14.59	11.49	£558	0.00	-0.00	£37	
1	14.59	11.49	£595	0.00	-0.00	£73	
2	14.59	11.49	£668	0.00	-0.01	£146	
4	14.59	11.48	£850	0.00	-0.02	£328	
6	14.59	11.47	£995	0.00	-0.02	£473	
8	14.59	11.46	£1,157	0.00	-0.03	£635	
10	14.59	11.46	£1,336	0.00	-0.04	£815	
12	14.59	11.45	£1,461	0.00	-0.05	£940	
14	14.58	11.44	£1,644	-0.00	-0.06	£1,122	
16	14.58	11.43	£1,765	-0.00	-0.06	£1,244	
18	14.58	11.42	£1,916	-0.01	-0.07	£1,395	
20	14.58	11.42	£2,066	-0.01	-0.08	£1,545	
22	14.58	11.41	£2,216	-0.01	-0.09	£1,695	
24	14.57	11.40	£2,365	-0.01	-0.10	£1,844	
26	14.57	11.39	£2,517	-0.02	-0.11	£1,995	
28	14.56	11.38	£2,667	-0.02	-0.12	£2,146	
30	14.56	11.37	£2,817	-0.03	-0.13	£2,295	
32	14.55	11.36	£2,965	-0.03	-0.14	£2,444	
34	14.55	11.35	£3,112	-0.04	-0.14	£2,591	
36	14.55	11.34	£3,259	-0.04	-0.15	£2,737	

HRA - high-risk adenoma; LY - life year; QALY - quality-adjusted life year

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