Drug-eluting stents:

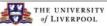
a systematic review & economic evaluation

5′ Addendum

Confidential: not for release

No commercial in confidence data have been included in the preparation of this report June 1, 2007





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2nd Addendum - additional evidence and analyses requested by Appraisal Committee

Sensitivity Analysis Tables for Drug-Eluting Stent Appraisal including Additional Use of Clopidogrel

Recent controversy in cardiology conferences and journals has centred on claims by some researchers of accumulating evidence of increased rates of late stent thrombosis with associated sequelae (possibly including mortality) arising from use of drugeluting stents. Although the issues are not yet resolved, the FDA have suggested that extended use of anti-thrombolytics should be considered, and the American Heart Association has issued precautionary guidelines that clopidogrel should be prescribed for at least 12 months post-PCI. It is likely that similar advice will be adopted in the UK.

NICE have indicated that it is important to explore the implications of these developments for the cost-effectiveness of drug-eluting stents in the UK, prior to issuing updated guidance. To this end NICE requested that the analyses previously provided to the Appraisal Committee in Addendum 3 to the LRiG Technology Assessment Report be updated on the assumption that clopidogrel use would be extended in patients receiving drug-eluting stents from 3 months to 12 months post-intervention.

Clopidogrel is normally prescribed as a single daily oral dose of 75mg costing £35.31 per 28 tablet pack (BNF 52, February 2007). This is equivalent to £460.61 per year, and results in an extra cost per DES patient of £345.45 for an additional 9 month period.

Selected updated tables from Addendum 3 are shown below (using the same identifiers to allow ready comparison with the earlier results). In addition, the initial descriptive Table A from Addendum 3 is repeated at the request of NICE.

This second addendum reproduces the analysis previously reported in the first addendum but with a revised additional cost of clopidogrel on the assumption that 44% of patients will already be receiving clopidogrel therapy prior to

undergoing PCI (because of a diagnosis of Acute Coronary Syndrome). This has the effect of reducing the additional cost of clopidogrel per patient to £257.94 per year, or £193.45 per patient for an additional 9 month period.

Explanatory Notes

Initial Descriptive Table A

- 1. The descriptive table has been prepared using Liverpool CTC audit patient-level data, and the multi-variate model using conventional factors described in the Addendum. This is necessary as no equivalent IPD unselected dataset is currently available to LRiG on which the required analysis could be performed. Readers should bear in mind that none of the three factors in this multi-variate model achieved conventional significance so that the individual relative risks have wide confidence intervals and should be considered as only illustrative.
- 2. Results for absolute risks and average numbers of stents are simple unadjusted means for all relevant patients. Minor differences from figures previously published are due to the exclusion of some non-elective patients not considered eligible for this review (those for whom PCI was primary treatment for AMI), and to bias adjustments required to previous estimates which made use of non-linear regression techniques.
- 3. Sub-groups are ordered by increasing size of the relative and absolute risks. The average risks obtained in CTC data set are shown as an additional bold column (marked Base Case) for information.

Tables (B, C, F & G)

- 4. The tables have been prepared on the basis of the adjustments identified in the Addendum:
- stent wastage rates of 1%;
- alternate disutility estimates for PCI (0.00304 per patient) and CABG (0.03808);
- adjustments, for reduced numbers of non-fatal AMIs, to costs (saving of £13 per patient) and utility (gain of 0.00055 per patient) when DES are used.
- 5. For Tables B and F, the mean number of stents used, and the mean repeat intervention rate for the whole patient group are used. However, in Tables C and G, the emboldened absolute risks are calculated specifically for the sub-groups of CTC patients in whom only one index stents was deployed.

- 6. The threshold premium in the final column of the tables is the maximum value of the price premium which would yield an ICER of £30,000 per QALY gained or less.
- 7. The final row shows the effect on estimated cost-effectiveness for the Base Case of including a direct benefit from reduced mortality associated with performing repeat interventions. These calculations are made on the following assumptions:
- average CTC proportions of reinterventions by CABG apply (9.0% elective, 17.9% non-elective);
- additional mean life expectancy for patients surviving without reintervention of 10 years;
- mean utility value of patients in such additional life-years of 0.66.

It should be borne in mind that this adjustment depends upon a strong presumption of effect for which there is no direct evidence. It is LRiG's view that such an adjustment is unwarranted and probably involves 'double-counting' of deaths already included in aggregate trial results.

Table A: Parameter values for risk-based subgroups, derived from Liverpool CTC audit data

Elective patients

						Reintervention rate at 12 months											
Conve	entional risk	factors						Absolute risk									
			Share of	Mean													
Long	Small		elective	stents			Relative	6%	7%	7.43%	8%	9%	10%	11%	12%	13%	
lesion	vessel	Diabetes	caseload	used	LCL	UCL	risk										
No	No	No	59.7%	1.54	1.49	1.58	1.00	5.3%	6.1%	6.5%	7.0%	7.9%	8.8%	9.7%	10.5%	11.4%	
Yes	No	No	22.5%	1.63	1.55	1.72	1.20	6.3%	7.4%	7.8%	8.4%	9.5%	10.5%	11.6%	12.6%	13.7%	
No	No	Yes	8.5%	1.56	1.43	1.69	1.38	7.3%	8.5%	9.0%	9.7%	10.9%	12.1%	13.3%	14.5%	15.8%	
No	Yes	No	3.8%	2.30	2.11	2.48	1.52	8.0%	9.3%	9.9%	10.7%	12.0%	13.3%	14.7%	16.0%	17.4%	
Yes	No	Yes	4.0%	1.72	1.52	1.91	1.66	8.7%	10.2%	10.8%	11.6%	13.1%	14.5%	16.0%	17.5%	18.9%	
Yes	Yes	No	0.9%	2.53	2.19	2.87	1.82	9.6%	11.2%	11.9%	12.8%	14.4%	16.0%	17.6%	19.2%	20.8%	
No	Yes	Yes	0.6%	2.67	2.23	3.11	2.10	11.1%	12.9%	13.7%	14.7%	16.6%	18.4%	20.3%	22.1%	23.9%	
Yes	Yes	Yes	0.1%	3.00	ne	ne	2.52	13.3%	15.5%	16.4%	17.7%	19.9%	22.1%	24.3%	26.5%	28.7%	
	Overall		100.0%	1.615	1.580	1.650				Base case							

Patients affected by factor

27.4% 5.4% 13.2%

ne not estimable

Non-Elective patients

							Reintervention rate at 12 months										
Conve	entional risk	factors						Absolute risk									
			Share of non-	Mean													
Long	Small		elective	stents			Relative	8%	9%	10.04%	11%	12%	13%	14%	15%	16%	
lesion	vessel	Diabetes	caseload	used	LCL	UCL	risk										
No	No	Yes	8.0%	1.52	1.34	1.69	0.90	6.5%	7.3%	8.2%	9.0%	9.8%	10.6%	11.4%	12.2%	13.0%	
No	No	No	60.1%	1.43	1.37	1.50	1.00	7.2%	8.1%	9.1%	10.0%	10.9%	11.8%	12.7%	13.6%	14.5%	
Yes	No	Yes	4.5%	1.54	1.29	1.79	1.07	7.8%	8.7%	9.7%	10.7%	11.6%	12.6%	13.6%	14.5%	15.5%	
Yes	No	No	23.7%	1.42	1.33	1.52	1.19	8.6%	9.7%	10.8%	11.9%	12.9%	14.0%	15.1%	16.2%	17.2%	
No	Yes	Yes	0.2%	2.00	ne	ne	2.36	17.1%	19.2%	21.4%	23.5%	25.6%	27.8%	29.9%	32.0%	34.2%	
No	Yes	No	2.5%	2.00	1.51	2.49	2.62	19.0%	21.4%	23.8%	26.1%	28.5%	30.8%	33.2%	35.6%	38.0%	
Yes	Yes	Yes	0.2%	2.00	ne	ne	2.81	20.3%	22.9%	25.5%	27.9%	30.5%	33.0%	35.6%	38.1%	40.7%	
Yes	Yes	No	0.7%	2.50	1.40	3.60	3.12	22.6%	25.4%	28.3%	31.1%	33.9%	36.7%	39.5%	42.3%	45.2%	
	Overall		100.0%	1.467	1.415	1.518				Base case			_				

Patients affected by factor

29.1% 3.7% 12.9%

ne not estimable

Table B: All Elective Patients, using mean number of stents implanted

Elective In	dex PCI	1.615	stent per pa	atient														
										•								Threshold
Absolute	Incremental						e premium								f price premi			premium
risk	utilty	£100	£200	£300	£400	£500	£600	£700	£800	£100	£200	£300	£400	£500	£600	£700	£800	(£30000)
4%	0.00162	£282	£444	£605	£767	£928	£1,089	£1,251	£1,412	£174,600	£274,500	£374,300	£474,200	£574,000	£673,900	£773,700	£873,600	-£45
5%	0.00188	£267	£428	£589	£750	£911	£1,072	£1,233	£1,394	£141,800	£227,200	£312,700	£398,200	£483,700	£569,200	£654,700	£740,200	-£31
6%	0.00215	£252	£412	£573	£733	£894	£1,055	£1,215	£1,376	£117,000	£191,700	£266,400	£341,100	£415,800	£490,500	£565,200	£639,900	-£17
7%	0.00242	£236	£397	£557	£717	£877	£1,037	£1,197	£1,358	£97,800	£164,100	£230,300	£296,600	£362,900	£429,200	£495,400	£561,700	-£2
7.43%	0.00253	£230	£390	£550	£710	£870	£1,030	£1,190	£1,350	£90,700	£153,900	£217,100	£280,300	£343,500	£406,600	£469,800	£533,000	£27
8%	0.00268	£221	£381	£541	£700	£860	£1,020	£1,180	£1,339	£82,400	£141,900	£201,400	£261,000	£320,500	£380,000	£439,500	£499,100	£4
9%	0.00295	£206	£365	£524	£684	£843	£1,002	£1,162	£1,321	£69,700	£123,700	£177,700	£231,700	£285,700	£339,800	£393,800	£447,800	£12
10%	0.00322	£190	£349	£508	£667	£826	£985	£1,144	£1,303	£59,200	£108,600	£158,000	£207,400	£256,800	£306,200	£355,600	£405,000	£41
11%	0.00348	£175	£334	£492	£651	£809	£967	£1,126	£1,284	£50,300	£95,700	£141,200	£186,700	£232,200	£277,700	£323,200	£368,700	£56
12%	0.00375	£160	£318	£476	£634	£792	£950	£1,108	£1,266	£42,600	£84,700	£126,900	£169,000	£211,200	£253,300	£295,500	£337,600	£71
13%	0.00402	£144	£302	£460	£617	£775	£933	£1,090	£1,248	£36,000	£75,200	£114,400	£153,700	£192,900	£232,200	£271,400	£310,700	£86
14%	0.00428	£129	£286	£444	£601	£758	£915	£1,072	£1,230	£30,100	£66,800	£103,500	£140,200	£176,900	£213,700	£250,400	£287,100	£101
15%	0.00455	£114	£271	£427	£584	£741	£898	£1,055	£1,211	£25,000	£59,500	£93,900	£128,400	£162,800	£197,300	£231,800	£266,200	£116
16%	0.00482	£98	£255	£411	£568	£724	£880	£1,037	£1,193	£20,400	£52,900	£85,400	£117,800	£150,300	£182,800	£215,200	£247,700	£131
17%	0.00508	£83	£239	£395	£551	£707	£863	£1,019	£1,175	£16,400	£47,000	£77,700	£108,400	£139,100	£169,700	£200,400	£231,100	£146
18%	0.00535	£68	£223	£379	£534	£690	£846	£1,001	£1,157	£12,700	£41,700	£70,800	£99,900	£129,000	£158,000	£187,100	£216,200	£161
19%	0.00562	£53	£208	£363	£518	£673	£828	£983	£1,138	£9,400	£37,000	£64,600	£92,200	£119,800	£147,400	£175,000	£202,600	£177
20%	0.00588	£37	£192	£347	£501	£656	£811	£965	£1,120	£6,300	£32,600	£58,900	£85,200	£111,500	£137,800	£164,100	£190,400	£192
21%	0.00615	£22	£176	£330	£485	£639	£793	£947	£1,102	£3,600	£28,600	£53,700	£78,800	£103,900	£129,000	£154,100	£179,100	£207
22%	0.00642	£7	£160	£314	£468	£622	£776	£930	£1,083	£1,000	£25,000	£49,000	£72,900	£96,900	£120,900	£144,900	£168,800	£223
23%	0.00668	-£9	£145	£298	£452	£605	£758	£912	£1,065	-£1,300	£21,600	£44,600	£67,600	£90,500	£113,500	£136,400	£159,400	£239
24%	0.00695	-£24	£129	£282	£435	£588	£741	£894	£1,047	-£3,500	£18,600	£40,600	£62,600	£84,600	£106,600	£128,600	£150,600	£255
25%	0.00722	-£39	£113	£266	£418	£571	£724	£876	£1,029	-£5,500	£15,700	£36,800	£58,000	£79,100	£100,200	£121,400	£142,500	£270
26%	0.00748	-£55	£97	£250	£402	£554	£706	£858	£1,010	-£7,300	£13,000	£33,400	£53,700	£74,000	£94,300	£114,700	£135,000	£286
27%	0.00775	-£70	£82	£233	£385	£537	£689	£840	£992	-£9,000	£10,500	£30,100	£49,700	£69,300	£88,900	£108,400	£128,000	£302
28%	0.00802	-£85	£66	£217	£369	£520	£671	£823	£974	-£10,600	£8,200	£27,100	£46,000	£64,800	£83,700	£102,600	£121,500	£319
29%	0.00828	-£101	£50	£201	£352	£503	£654	£805	£956	-£12,200	£6,100	£24,300	£42,500	£60,700	£78,900	£97,100	£115,400	£335
with Proced	dural mortality	estimate																

£1,350 £60,300 £102,300 £144,300 £186,300 £228,300 £270,300 £312,300 £354,300

£51

7.43% 0.00381

£230

£390

£550

£870

£710

£1,030

£1,190

Table C: Elective patients receiving a single stent

Elective Index PCI 1.	0 stent per patient
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													Threshold					
Absolute	Incremental					evels of price				Incremental cost per QALY by levels of price premium								premium
risk	utilty	£100	£200	£300	£400	£500	£600	£700	£800	£100	£200	£300	£400	£500	£600	£700	£800	(£30000)
4%	0.00162	£220	£319	£419	£518	£617	£717	£816	£915	£136,200	£197,600	£259,000	£320,500	£381,900	£443,300	£504,700	£566,200	-£74
5%	0.00188	£205	£304	£403	£502	£600	£699	£798	£897	£108,800	£161,300	£213,800	£266,300	£318,800	£371,300	£423,800	£476,300	-£51
5.53%	0.00202	£197	£295	£394	£493	£591	£690	£789	£887	£97,200	£145,900	£194,600	£243,400	£292,100	£340,800	£389,500	£438,300	-£38
6%	0.00215	£190	£288	£386	£485	£583	£682	£780	£879	£88,200	£133,900	£179,700	£225,500	£271,300	£317,100	£362,900	£408,700	-£27
7%	0.00242	£174	£272	£370	£468	£566	£664	£763	£861	£72,100	£112,700	£153,200	£193,800	£234,400	£274,900	£315,500	£356,100	-£4
8%	0.00268	£159	£257	£354	£452	£549	£647	£745	£842	£59,200	£95,600	£132,000	£168,400	£204,700	£241,100	£277,500	£313,900	£20
9%	0.00295	£144	£241	£338	£435	£532	£630	£727	£824	£48,700	£81,600	£114,600	£147,500	£180,500	£213,400	£246,400	£279,300	£44
10%	0.00322	£128	£225	£322	£419	£515	£612	£709	£806	£39,900	£70,000	£100,000	£130,100	£160,200	£190,300	£220,400	£250,500	£68
11%	0.00348	£113	£209	£306	£402	£498	£595	£691	£787	£32,400	£60,100	£87,700	£115,400	£143,100	£170,700	£198,400	£226,100	£92
12%	0.00375	£98	£194	£290	£385	£481	£577	£673	£769	£26,000	£51,600	£77,200	£102,800	£128,400	£153,900	£179,500	£205,100	£117
13%	0.00402	£82	£178	£273	£369	£464	£560	£655	£751	£20,500	£44,300	£68,000	£91,800	£115,600	£139,400	£163,200	£186,900	£141
14%	0.00428	£67	£162	£257	£352	£447	£542	£638	£733	£15,600	£37,800	£60,000	£82,200	£104,400	£126,600	£148,800	£171,000	£166
15%	0.00455	£52	£146	£241	£336	£430	£525	£620	£714	£11,400	£32,200	£53,000	£73,800	£94,600	£115,400	£136,200	£157,000	£192
16%	0.00482	£36	£131	£225	£319	£413	£508	£602	£696	£7,500	£27,100	£46,700	£66,200	£85,800	£105,400	£124,900	£144,500	£217
17%	0.00508	£21	£115	£209	£303	£396	£490	£584	£678	£4,100	£22,600	£41,100	£59,500	£78,000	£96,400	£114,900	£133,300	£243
18%	0.00535	£6	£99	£193	£286	£379	£473	£566	£660	£1,100	£18,500	£36,000	£53,400	£70,900	£88,400	£105,800	£123,300	£268
19%	0.00562	-£10	£83	£176	£269	£362	£455	£548	£641	-£1,700	£14,800	£31,400	£48,000	£64,500	£81,100	£97,600	£114,200	£294
20%	0.00588	-£25	£68	£160	£253	£345	£438	£530	£623	-£4,200	£11,500	£27,200	£43,000	£58,700	£74,400	£90,200	£105,900	£321
21%	0.00615	-£40	£52	£144	£236	£328	£420	£513	£605	-£6,500	£8,400	£23,400	£38,400	£53,400	£68,400	£83,300	£98,300	£347
22%	0.00642	-£56	£36	£128	£220	£311	£403	£495	£587	-£8,700	£5,600	£19,900	£34,200	£48,500	£62,800	£77,100	£91,400	£374
23%	0.00668	-£71	£20	£112	£203	£294	£386	£477	£568	-£10,600	£3,100	£16,700	£30,400	£44,000	£57,700	£71,400	£85,000	£401
24%	0.00695	-£86	£5	£96	£186	£277	£368	£459	£550	-£12,400	£700	£13,800	£26,800	£39,900	£53,000	£66,100	£79,100	£429
25%	0.00722	-£102	-£11	£79	£170	£260	£351	£441	£532	-£14,100	-£1,500	£11,000	£23,500	£36,100	£48,600	£61,100	£73,700	£456
26%	0.00748	-£117	-£27	£63	£153	£243	£333	£423	£513	-£15,600	-£3,600	£8,500	£20,500	£32,500	£44,500	£56,600	£68,600	£484
27%	0.00775	-£132	-£43	£47	£137	£226	£316	£406	£495	-£17,000	-£5,500	£6,100	£17,600	£29,200	£40,800	£52,300	£63,900	£512
28%	0.00802	-£147	-£58	£31	£120	£209	£299	£388	£477	-£18,400	-£7,300	£3,900	£15,000	£26,100	£37,200	£48,400	£59,500	£540
29%	0.00828	-£163	-£74	£15	£104	£192	£281	£370	£459	-£19,700	-£8,900	£1,800	£12,500	£23,200	£33,900	£44,600	£55,400	£569
										•							,	
	dural mortality		COOF	C20.4	C402	CEO4	cenn	C700	0007	000 400	000 200	C422 E00	C46E 600	C100 000	0000 000	COCE 400	0000 000	00
5.53%	0.00298	£197	£295	£394	£493	£591	£690	£789	£887	£66,100	£99,300	£132,500	£165,600	£198,800	£232,000	£265,100	£298,300	-£9

Table F: All Non-elective Patients, using mean number of stents implanted

Non-Electi	ve Index PC	I	1.467	stent per pa	atient												1	Threshold
Absolute	Incremental			Increment	al cost by le	evels of price	e premium					Incremental	cost per QAL	Y by levels o	of price premi	um		premium
risk	utilty	£100	£200	£300	£400	£500	£600	£700	£800	£100	£200	£300	£400	£500	£600	£700	£800	(£30000)
6%	0.00210	£231	£377	£523	£669	£815	£960	£1,106	£1,252	£110,100	£179,400	£248,800	£318,200	£387,500	£456,900	£526,300	£595,600	-£16
8%	0.00262	£199	£344	£489	£634	£779	£924	£1,069	£1,214	£76,000	£131,300	£186,700	£242,100	£297,400	£352,800	£408,200	£463,500	£17
10%	0.00314	£167	£311	£455	£599	£744	£888	£1,032	£1,176	£53,100	£99,100	£145,100	£191,100	£237,100	£283,000	£329,000	£375,000	£50
10.04%	0.00315	£166	£310	£454	£599	£743	£887	£1,031	£1,176	£52,800	£98,600	£144,500	£190,300	£236,100	£282,000	£327,800	£373,700	£51
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NICE SPECIFICATION FOR ADDITIONAL ANALYSIS

Extra analyses (2) for Ischaemic Heart Disease – Coronary Artery Stents– ACD meeting July 2007

Date: March 2007

Project Number	
Appraisal title	Coronary artery stents for the treatment of ischaemic heart disease (part review of NICE technology appraisal guidance no. 71)
Synopsis of the technical issue	Following the recent concerns over the issue of safety of drug-eluting stents (DES) and the recent conclusions of the FDA advisory panel, views have been expressed that the duration of use of anti-platelet therapy (aspirin and clopidogrel) should be extended in patients who have received a DES to 12 months, and in particular in those patients whose lesions are thought to be high risk. As a result of this, further work is requested to be undertaken to examine how the difference in the duration of clopidogrel use between bare-metal stents (BMS) and DES may affect the cost effectiveness.



Question(s) to be answered by the	What is the cost effectiveness of DES in the treatment of ischaemic heart disease, given that
Assessment Group	there is a difference in the duration of clopidogrel between patients receiving a DES and
	those receiving a BMS.
	 The base-case scenario should incorporate the cost (using BNF acquisition costs) of clopidogrel in BMS patients (3 months) and the cost of clopidogrel for DES patients (12 months)
	 Sensitivity analysis should be carried out around the number of stents used, for both the average number of stents and one stent only for both scenarios.
How will these questions be addressed	The Assessment Group will be asked to:
in an addendum?	re-run the model, containing these costs
	re-run the sensitivity analysis
	 present the analyses for the same range of absolute rates of revascularisation of BMS for mean number of stents and one stent only, for elective and non- elective patients as seen in tables B, C, F and G and include a copy of table A from addendum 3" (2006).
Date for delivery of report to Institute	10 th April 2007

