

Drug-eluting stents:

a systematic review & economic evaluation

6'

Addendum

***Confidential:
not for release***

No commercial in confidence data have
been included in the preparation of this report
July 6, 2007

Report commissioned by:

NHS R&D HTA Programme

On behalf of:

The National Institute for Health and Clinical
Excellence (NICE)

Produced by:

Liverpool Reviews and Implementation Group
Sherrington Buildings
University of Liverpool
Ashton Street
Liverpool, UK
L69 3GE

Tel: +44 (0) 151 794 5682/5541/5067

Fax: +44 (0) 151 794 5585

Email: LRiG@liv.ac.uk

Additional evidence and analyses requested at the Appraisal Committee meeting (July 4, 2007)

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

This addendum provides further sensitivity analysis tables based on parameters adopted by the NICE Appraisal Committee meeting on 4th July 2007. The principal changes from previous analyses are:

- the Committee wished to consider the combined results of all patients (elective and non-elective) based on an overall 12-month risk of repeat revascularisation when BMS are used of 11% (equivalent to 10% for elective patients and 13% for non-elective patients)
- the committee wished to consider results for all patient sub-groups defined by the conventional risk factors (small vessels, long lesions and diabetes)
- the committee wished to consider two additional possible parameter values for the relative risk reduction associated with DES use (55% and 65%).

Results for these combinations were generated during the meeting as the basis for its deliberation. This paper summarises the results of applying these assumptions in addition to previously described additional costs for extended clopidogrel use.

The layout of the addendum mirrors that of the earlier addenda, and reproduces some of the analyses previously reported in the first addendum. Table A now summarises the key parameter values for the adopted assumptions regarding revascularisation risk with BMS. Two versions of Table B are shown for the aggregated elective/non-elective results based on the two requested values for the DES relative risk reduction.

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.

Tables (B1 & B2)

3. The tables have been prepared on the basis of the adjustments identified in the first 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.

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

Elective & Non-elective patients combined

Conventional risk factors			Share of caseload	Mean stents used	Reintervention rate at 12 months	
Long lesion	Small vessel	Diabetes			Relative risk	Absolute risk for adopted overall risk of 11%
No	No	No	59.8%	1.54	1.00	9.7%
Yes	No	No	22.8%	1.53	1.20	11.7%
No	No	Yes	8.4%	1.56	1.19	11.6%
No	Yes	No	3.4%	1.66	1.95	19.0%
Yes	No	Yes	4.1%	1.73	1.43	13.9%
Yes	Yes	No	0.8%	2.24	2.33	22.7%
No	Yes	Yes	0.5%	2.57	2.20	21.4%
Yes	Yes	Yes	0.1%	2.63	2.63	25.6%
Overall			100.0%	1.571		

Patients affected by factor

27.9%	4.9%	13.1%
-------	------	-------

Appraisal Committee adopted scenario: 10% risk elective patients / 13% risk non-elective patients.
 Combined risk of 11% based on 67.65% elective patients & 32.35% non-elective patients

Table B1: All Patients combined, using assumed value of 55% relative risk reduction

Combined Elective & Non-Elective Index PCI

1.571 stents per patient on average

55% relative risk reduction at 12 months due to DES

Conventional risk factors			Absolute risk	Incremental utility	Incremental cost by levels of price premium								Incremental cost per QALY by levels of price premium							
Long lesion	Small vessel	Diabetes			£100	£200	£300	£400	£500	£600	£700	£800	£100	£200	£300	£400	£500	£600	£700	£800
No	No	No	9.7%	0.00400	£128	£274	£421	£567	£714	£861	£1,007	£1,154	£31,900	£68,600	£105,300	£141,900	£178,600	£215,300	£252,000	£288,700
Yes	No	No	11.7%	0.00467	£94	£245	£397	£549	£701	£853	£1,005	£1,156	£20,000	£52,500	£85,000	£117,500	£150,000	£182,500	£215,000	£247,400
No	No	Yes	11.6%	0.00467	£94	£243	£393	£543	£692	£842	£992	£1,141	£20,000	£52,100	£84,100	£116,100	£148,200	£180,200	£212,300	£244,300
No	Yes	No	19.0%	0.00724	£0	£212	£424	£636	£848	£1,060	£1,272	£1,484	£0	£29,300	£58,600	£87,900	£117,100	£146,400	£175,700	£204,900
Yes	No	Yes	13.9%	0.00549	£57	£217	£377	£537	£697	£858	£1,018	£1,178	£10,500	£39,600	£68,800	£98,000	£127,200	£156,300	£185,500	£214,700
Yes	Yes	No	22.7%	0.00855	-£46	£196	£439	£681	£923	£1,165	£1,407	£1,650	-£5,400	£23,000	£51,300	£79,700	£108,000	£136,300	£164,700	£193,000
No	Yes	Yes	21.4%	0.00812	-£23	£213	£448	£684	£920	£1,156	£1,392	£1,628	-£2,900	£26,200	£55,200	£84,200	£113,200	£142,300	£171,300	£200,300
Yes	Yes	Yes	25.6%	0.00961	-£89	£168	£424	£680	£936	£1,193	£1,449	£1,705	-£9,200	£17,400	£44,100	£70,800	£97,500	£124,100	£150,800	£177,500
Overall			11.0%	0.00409	£108	£261	£413	£565	£717	£870	£1,022	£1,174	£26,500	£63,700	£100,900	£138,100	£175,300	£212,500	£249,700	£286,900

Patients affected by factor

73.9%	88.8%	72.6%
-------	-------	-------

Table B2: All Patients combined, using assumed value of 65% relative risk reduction

Combined Elective & Non-Elective Index PCI

1.571 stents per patient on average

65% relative risk reduction at 12 months due to DES

Conventional risk factors			Absolute risk	Incremental utility	Incremental cost by levels of price premium								Incremental cost per QALY by levels of price premium							
Long lesion	Small vessel	Diabetes			£100	£200	£300	£400	£500	£600	£700	£800	£100	£200	£300	£400	£500	£600	£700	£800
No	No	No	9.7%	0.00462	£90	£236	£382	£527	£673	£818	£964	£1,110	£19,500	£51,000	£82,500	£114,000	£145,500	£177,000	£208,500	£240,000
Yes	No	No	11.7%	0.00542	£49	£200	£350	£501	£652	£802	£953	£1,104	£9,100	£36,800	£64,600	£92,400	£120,200	£148,000	£175,700	£203,500
No	No	Yes	11.6%	0.00542	£49	£198	£346	£495	£644	£792	£941	£1,089	£9,100	£36,500	£63,900	£91,300	£118,700	£146,100	£173,500	£200,900
No	Yes	No	19.0%	0.00846	-£73	£137	£347	£558	£768	£978	£1,188	£1,398	-£8,600	£16,200	£41,100	£65,900	£90,800	£115,600	£140,400	£165,300
Yes	No	Yes	13.9%	0.00638	£4	£163	£322	£480	£639	£798	£956	£1,115	£700	£25,600	£50,400	£75,300	£100,100	£125,000	£149,800	£174,700
Yes	Yes	No	22.7%	0.01000	-£133	£107	£347	£587	£827	£1,067	£1,307	£1,547	-£13,300	£10,700	£34,700	£58,700	£82,700	£106,700	£130,700	£154,600
No	Yes	Yes	21.4%	0.00950	-£105	£128	£362	£596	£830	£1,063	£1,297	£1,531	-£11,100	£13,500	£38,100	£62,700	£87,300	£111,900	£136,500	£161,100
Yes	Yes	Yes	25.6%	0.01126	-£187	£67	£321	£574	£828	£1,082	£1,336	£1,589	-£16,600	£5,900	£28,500	£51,000	£73,600	£96,100	£118,700	£141,200
Overall			11.0%	0.00474	£66	£218	£369	£520	£671	£822	£973	£1,125	£14,000	£45,900	£77,800	£109,800	£141,700	£173,600	£205,500	£237,400

Patients affected by factor

73.9%	88.8%	72.6%
-------	-------	-------