Summary table of responses from consultees on update to drug eluting stents

Consultee	Section	Comment	Action
RCN	**General**	The review of this appraisal feels as if it is too soon. The last guidance and its recommendations still enable Cardiologists to work within what they would feel are appropriate. With relation to Drug eluting stents, there is not a huge amount of new data yet available and many NHS trust are still struggling to implement the DES recommendations due to lack of funding. This is tied in to the HRG for PCI procedures which is way too low and making commissioning at levels of the original guidance very hard to achieve. New guidance is very likely to expand the use of DES and make this problem worse.	Information from other consultees indicates further data and products are available to inform a review at this time.
RCN	**General**	It is not clear, but it reads as if there will not be a look at any new evidence for the 2 DES endorsed in the last guidance. This would appear very limiting as it would usually be reasonable to re-assess any product that has new evidence base to it (as the 2 DES do).	Scope amended to allow for examination of all DES developments
RCP	**General**	Our overall comment is that data should be assessed not only on "new" drug eluting stents but also new data on older drug eluting stents. It is our belief that the 30% useage stated in the last guideline is an underestimate based on the "lesion guidelines" and this should be reviewed in the update. When the "lesion guidelines" are applied to a "real world" scenario we believe the true "appropriate" rate should be around 70%.	Scope amended to allow for examination of all DES developments
Boston Sci	**Objective**	We propose broadening of the scope **with additional new data relating to DES sub-populations and use**, as stated in Guidance No. 71 "Recommendations for further research." Support for the broadening is provided below in *Other Considerations*.	Scope amended to allow for examination of all DES developments
Cordis	**Objective**	We would first like to identify what we consider to be inconsistency within the draft scope. First, it is proposed that; "This scope of this appraisal is therefore restricted to those DES not included in Technology Appraisal 71" However the scope continues to indicate that; "If the evidence allows, sub-groups involving narrow arteries, long lesions, complicated lesions (such as bifurcation lesions), saphenous vein grafts, partial versus total occlusion, and people with diabetes should be investigated."	Scope amended to allow for examination of all DES developments. Evidence pertaining to original designs of a specific DES will only be accepted in support of modified designs providing equivalence has been adequately demonstrated.

		We do not feel that the original technologies from guidance 71 should be excluded from the scope of the proposed appraisal, since it would then be possible for the newer technologies to benefit unreasonably from more broad-ranging recommendations than those provided in guidance 71 for the older technologies. If the original technologies are to be excluded, then the review must restrict its assessment to reviewing the new technologies by the same hurdles and rigor as the original appraisal, and only to provide the same recommendations currently made in guidance 71. This is not, however, our preferred approach. Instead we feel that it would make better sense to include all the currently available technologies in the scope of the review and to allow the widest possible range of use of these, subject to license and to the evidence. The review of current technologies with respect to current guidance should in itself be relatively straightforward. Randomised trials of the Cypher stent have reported follow up to 2 or 3 years and these longer-term data are entirely consistent with the 9 to12-month results submitted during technology appraisal 71. The conclusion of cost effectiveness should therefore remain unchanged in the review, but the original guidance would be confirmed by the longer-term outcomes. Current devices should also be included because there are new data available which show benefit of the Cypher stent in more patient groups, and include a new indication. New devices however, should be appraised on their own merit and not on assumed equivalence with existing devices, particularly if the trial evidence for the new devices is not specific to the patient groups covered by the current guidance.	
Kiwimed	**Objective**	The appraisal objective and background are clear and concise. The only comment I would make is the use of (PTCA) as an abbreviation for percutaneous transluminal coronary angioplasty is now not often used and has been replaced with the term percutaneous coronary intervention (PCI) which is globally accepted.	Scope amended to PCI
LRiG	**Objective**	Paragraph 1: "*This scope of this appraisal is therefore restricted to those DES not included in Technology Appraisal 71*". We feel this would mean that we would not have the opportunity to explore important outcomes in the long-term or to add power to our analysis. We also	Scope amended to allow for examination of all DES developments.

Comment [sg1]: Insert sentence on relating evidence

		feel that there would be value both in exploring Cypher versus Taxus comparisons and adding-in further data on Cypher and Taxus to our economic evaluation. In general, this update (as described in the draft scope) would not take up many of the recommendations for future research included in our preceding TAR – such as exploring long term follow-up or developing tools to assist in identifying high risk patients. More specifically, we feel that updating our analyses of Cypher/Taxus DES is necessary as further economic analysis conducted by our Group (after completion of the previous TAR) suggests that disease categories selected in Guidance 71 for targeting use of DES may be inappropriate and that in fact other factors are more important and require exploration. As any significant mortality differences between devices would have pivotal effect on the cost-effectiveness of DES, the Cypher/Taxus trials may be the only source of this long-term data on survival.	Evidence pertaining to original designs of a specific DES will only be accepted in support of modified designs providing equivalence has been adequately demonstrated.
RCP	**Objective**	We are unclear as to the definition of "newer" drug eluting stents and believe that new data on old drug eluting stents should also be included.	Scope amended to allow for examination of all DES developments.
RCP Edinburgh	**Objective**	1 There are few prospective randomised efficacy trials of Cypher Select, Costar and Xience DES and so perhaps the appraisal might be a little premature in terms of the likelihood of finding either a clear benefit or an adequately powered negative result. 2 Until the efficacy data is available it will be difficult to undertake a meaningful cost-benefit analysis, more so because pivotal trials are often in selected patient groups where the outcomes may be more positive that the general population. 3 The development of commercial competition in the supply of these products is desirable to reduce NHS costs, assuming the efficacy and risk:benefit data is available.	Information from other consultees indicates further data and products are available to inform a review at this time
RCP	**Background**	We believe the term PTCA is dated and the term PCI (percutaneous coronary	Scope changed to PCI

		intervention…which includes stents) should be used	
RCP	**Background**	In the last paragraph of the background section we believe it is important to differentiate between restenosis as a process and re-intervention (TLR: target lesion revascularisation) which is a clinical procedure relevant to the patient. The rates quoted in this paragraph are much more like those of angiographic restenosis rather than clinical restenosis. In order that the “expectation of change" will be appropriate we believe it should be made very clear whether angiographic or clinical restenosis are being discussed. It is our view that both processes are reduced by drug eluting stents.	Clarification made in background
Kiwimed	**Technology**	I am in agreement with the general description of two basic types of stents being the bare metal and drug eluting stent (DES) however there are merging technologies that do not rely on a polymer to bond the drug to the stent and there should be provision made for this especially in light of growing concern as to the longer term effects of polymers. We represent the Translumina DES system which relies on a nano-porous surface to absorb the drug which is coated onto the stent using a validated device within the cath-lab itself. Like other evolving manufactures, the Germany based Translumina company developed this system to allow physicians to tailor their treatment depending on the patient cohort being treated. The Physician is able to prescribe different doses and vary the drug therapy depending on individual patient requirements. Once the drug has eluted the stent remains in place as a standard stainless steel stent with a surface clinically proven to endothelialise well. There is no polymer involved. Translumina received CE mark approval for the device in March of 2004 and have a large registry of data from Prof. Albert Schömig’s group at the German Heart centre in Munich where they have now implanted over 800 Translumina Yukon DES stents. The latest data evaluating Sirolimus (Rapamycin) coating of the stent will be presented at the PCR meeting in Paris in May of this year and clearly shows that the system is safe, with clinical outcomes comparable to other DES’s on the market. Further studies are now underway globally including the HiDRAR study being conducted by Prof. Martin Rothmans group at the London Chest Hospital. This is a randomised, blinded study looking at dose dependant effects in Diabetic patients. The system is also starting to be used routinely at other NHS centres in the UK as an economically viable alternative to others presently available. The Yukon DES device and coating system was presented to the MHRA medical	Scope amended to allow for examination of all DES developments.

		device division early last year shortly after receiving its CE mark approval.	
LRiG	**Technology**	*Two types of stent exist – bare-metal* Not sure if this it too specific. Many types of stent design strategies have been developed – for example the heparin or gold-coated stents trialled in the past and the potential new generation of stents coated in bioabsorbable material or constructed to be fully bioabsorbable. For the proposed appraisal it is possible that comparators to DES are not simply bare - but are polymer coated, without drug loading (for example the BiodivYsio phosphorylcholine coated, non-drug loaded stent maybe compared to DEXAMET stent from the STRIDE study). We have used the term 'non-DES' to be more inclusive.	Comparators amended to non drug eluting stents.
LRiG	**Technology**	*and drug-eluting stents (DES). DES are coated with a drug that is temporarily held in place with a polymer* Is it possible non-polymeric DES will be trialled again, perhaps utilising specially adapted surfaces or structure?	Scope amended to allow for examination of all DES developments.
LRiG	**Technology**	*that is 'painted'* Suggest: 'coated', 'applied' instead.	Scope amended to applied.
LRiG	**Technology**	Guidant is to seek CE marking for its everolimus-eluting [<<It would be helpful to highlight that this is their durable polymer stent, therefore suggest inserting: (durable polymer)] Xience stent	Scope amended to allow for examination of all DES developments
LRiG	**Technology**	*onto the bare metal. The drug is slowly released over a period of several months* We understand that some DES stents, for example the ENDEAVOR DES, reportedly release nearly all their loaded drug within 14 days and Taxus stents may retain a substantial proportion of drug indefinitely.	Sentence amend to " which are coated with a drug that is slowly released."
LRiG	**Technology**	Biotronik (not Biotronic?)	Amended accordingly
LRiG	**Technology**	We believe the dexamethasone-eluting stent is titled: 'Dexamet', therefore suggest: [Dexamet>>] BiodivYsio[<<-based] stent (manufactured by Abbott/Biocompatibles)	Amended accordingly
RCP	**Technology**	The second paragraph is not accurate. Not all drug eluting stents use a polymer. In addition the drug is generally released over a period of weeks rather than months. We are not convinced that this element of detail is useful.	Detail has been removed.
RCP	**Technology**	We believe that there are more developments in drug eluting stents; Boston Scientific are about to release their Taxus stent on the Liberte platform and Medtronic will have presented their "pivotal" Endevor 2 data at ACC 2005. In general we believe ALL NEW drug eluting stent data should be considered in the review.	Scope amended to allow for examination of all DES developments.

BCIA(Brit Cardio Ind Assoc)	**Intervention**	New data on existing devices should be considered in addition to new devices. Given the wealth of new and longer-term follow up data which has become available since the Technology Appraisal 71 was published, this review should consider new data on devices previously appraised otherwise there is the potential for new technologies to be reviewed in a wider range of sub-groups than existing devices. These new data may cover patient groups not included in guidance 71 and longer term follow up of the patients covered by guidance 71. A review of longer-term data for existing devices would confirm the robustness of the existing guidance. Data from randomised trials and registries should be considered.	Scope amended to allow for examination of all DES developments.
Boston Sci	**Intervention**	As the stated appraisal objective is related to newer drug eluting stents, we propose inclusion of the Taxus Liberté stent, a new platform structure for Taxus. CE mark for the Taxus Liberté stent is expected within the data deadline proposed by NICE. It offers clinical equivalency to the original Taxus stent, but with improved deliverability for the clinician.	Scope amended to allow for examination of all DES developments
Cordis	**Intervention**	The design of the Cypher™ stent has indeed been changed and the device marketed in the UK is now known as the Cypher Select™ Sirolimus-eluting Coronary Stent. The design philosophy for Cypher Select was: To improve deliverability (i.e. the ease with which the stent can be delivered to the target coronary artery lesion) by making a minor design modification to the stent architecture and using a state-of-the-art balloon delivery system. To use the same material specifications, drug and drug elution profile for Cypher Select as was employed for Cypher so that the clinical evidence that has already been obtained for Cypher is equally applicable to Cypher Select. The concentration of sirolimus per unit area of stent is thus the same for both Cypher and Cypher Select (approximately 140 µg/cm^2 after sterilisation). Cordis have validated this approach by conducting the prospective, randomised DOMINO trial, the rationale for which was to demonstrate non-inferiority of the Cypher Select versus Cypher. The primary endpoint of the study was angiographic in-stent late loss at 6-month follow-up as determined by Quantitative Coronary Angiography. The results of this trial will be made available to assure the Institute the clinical and cost effectiveness data for	Scope amended to allow for examination of all DES developments. Evidence pertaining to original designs of a specific DES will only be accepted in support of modified designs providing equivalence has been adequately demonstrated.

		Cypher also apply to Cypher Select. Furthermore, the fact that the drug itself, the dose per unit area, polymer and elution profile were unchanged was an important consideration in the CE marking of Cypher Select for use in both *de novo* lesions and in-stent restenosis. A third line of evidence was presented at the American College of Cardiology meeting in March 2004 in the form of the REDOX trial. This randomised trial showed that late loss, binary restenosis rate, in-stent pecentage volume obstruction and major adverse cardiac events were no different between patents who received a sirolimus-eluting stent with only 45% or 70% of the dose, as compared to 100% of the dose on the marketed Cypher/Cypher Select platforms. This shows that even a significant reduction in the amount of sirolimus on the stent is not detrimental to outcomes and speaks to the very flat dose-response relationship that exists with this product. . The Institute appear to have omitted to note that the design of the Taxus Paclitaxel-eluting Stent (manufactured by Boston Scientific) has also changed since technology appraisal 71, with the stent platform having moved from the NIR Conformer stent (used in the Taxus I, II and III studies) to the Taxus Express (used in the Taxus IV, V and VI studies). Boston Scientific have recently announced that the Taxus stent will move to the new 'Liberté' design.	
LRiG	**Intervention**	The 'new DES' selected are acceptable, but we note the potential for other new DES to be included. For example: Taxus Liberte (Boston) where we believe the CE Marking process has been initiated and ENDEAVOR (Medtronic) for which CE Marking has been applied for (and is expected Q1-2 this year). Existing DES Cypher and Taxus (reviewed in previous TAR to 2002) warrant ongoing review and are obvious comparators to the new-DES.	Scope amended to allow for examination of all DES developments Evidence pertaining to original designs of a specific DES will only be accepted in support of modified designs providing equivalence has been adequately demonstrated.
RCN	**Intervention**	The scope listed the new stents that would be assessed which is Biodiv Ysio, Costar and Xience which all have limited data and have left out the Sorin Janus stent that is already CE marked and in clinical use. There is not any mention of the Medtronic that is about to be CE marked and has a greater strength of data.	Scope amended to allow for examination of all DES developments
RCP		We believe all new data should be assessed. This will mean new DES and also new data on lesions not previously considered in the first appraisal. We believe	Scope amended to allow for examination of all DES

		there has been further data which should be considered in diabetics, saphenous vein grafts, chronic total occlusions, acute myocardial infarction and in-stent restenosis.	developments. In-stent restenosis not in scope of the update as per original.
BCIA	**Population**	Recent audit data from the British Cardiovascular Intervention Society shows that multivessel percutaneous coronary intervention (PCI) is growing as a proportion of total PCI, reflecting advances in the procedure, patient choice and indeed the availability of drug-eluting stents (DES). Where PCI and coronary artery bypass grafting (CABG) are both feasible and appropriate treatments, PCI may often be the patient's preferred option. Thus, the population defined as "people with coronary artery disease requiring PTCA" should be revised to "people with coronary artery disease requiring revascularisation and suitable for PCI". This would reinforce the importance of patient choice where PCI and CABG are both appropriate.	This point will be explored further at the Consultee meeting. Scope amended to "people with coronary artery disease requiring PCI".
Boston Sci	**Population**	Recent audit data from the British Cardiovascular Intervention Society shows that multivessel percutaneous coronary intervention (PCI) is growing as a proportion of total PCI, reflecting advances in the procedure, patient choice and indeed the availability of drug-eluting stents (DES). Where PCI and coronary artery bypass grafting (CABG) are both feasible and appropriate treatments, PCI may often be the patient's preferred option. In order to reflect current options for appropriate treatment of patients with a choice between PCI and CABG, we propose changing the wording from "people with coronary artery disease ***requiring PTCA***" to "people with coronary artery disease ***requiring revascularisation and suitable for PCI (percutaneous coronary intervention***)".	This point will be explored further at the Consultee meeting. Scope amended to "people with coronary artery disease requiring PCI".
Cordis	**Population**	The population definition of "people with coronary artery disease requiring PTCA" would be better revised to "people with coronary artery disease requiring revascularisation and suitable for PCI (percutaneous coronary intervention)". This would better reflect both the appropriateness of PCI versus CABG and patient choice. Review of data relating to patient flows through both PCI and CABG indicates that the availability of DES has changed the dynamics of the clinical pathway. This helps to explain why the proportion of patients presently considered appropriate for DES is higher that originally estimated in guidance 71. The ARTS II trial has shown that the Cypher stent reduces repeat revascularisation rates in patients with multivessel disease compared to bare metal stents in the original ARTS trial. These data should be considered in the review.	Scope amended to "people with coronary artery disease requiring PCI". This point will be explored further at the Consultee meeting.
Cordis	**Population**	Although, since the introduction of DES, the number of patients who suffer in-	Instent restenosis not part of

Deleted: As per the original appraisal, the update scope will not cover multi-vessel PCI.

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Deleted: Multi-vessel stenting not in scope: see above.¶

		stent restenosis (ISR) is a shrinking population, the scope should cover this indication because Cypher/Cypher Select is the only DES technology with a specific CE Mark for ISR available to those patients.	original DoH remit.
LRiG	**Population**	The NICE Technical Lead has clarified that we would not specifically be looking at the use of DES in the treatment of in-stent restenosis	Instent restenosis not part of original DoH remit
BCIA	**Comparators**	Given the above point, CABG should also be considered as a comparator for the treatment of multivessel coronary artery disease.	This point will be explored further at the Consultee meeting.
Cordis	**Comparators**	CABG should also be considered as a comparator for the treatment of multivessel coronary artery disease because as PCI equipment and technique have developed, some patients whose disease was previously best treated by CABG can now be treated by PCI. When either option is clinically appropriate, some patients are now choosing the less invasive PCI.	This point will be explored further at the Consultee meeting.
LRiG	**Comparators**	Non-DES – within trial comparison makes sense – pooling of new DES effects could be completed if appropriate.	Comparators amended to non-DES.
LRiG	**Comparators**	DES – comparison of DES versus DES would be interesting, but will be subject to data availability and appropriateness for statistical analysis.	Scope allows for comparisons to be made where evidence permits
LRiG	**Comparators**	Cypher and Taxus stents, being the main DES in use, should be included as comparators. A hierarchy of evidence will be applied, such that where RCT evidence is available, it will be used in preference to non-RCT data.	Scope allows for comparisons to be made where evidence permits
LRiG	**Comparators**	We note, however, that use of Cypher/Taxus as comparator stents appears inconsistent with the statement excluding Cypher/Taxus as discussed in 'response 2'.	Resolved by changes in scope to include all DES developments.
LRiG	**Comparators**	The Technical Lead mentioned 'looking' at the potential of use of DES in patients normally (or formerly) treated by coronary artery bypass graft. Resources permitting, we could describe (within the Budget Impact Analysis section of our TAR) trends in patient numbers/case mix in surgery or PCI and attempt to determine if there was evidence of expanded volume or transference from surgery to intervention with DES.	Agreed with Assessment Group. Should not proceed if capacity is absent to assemble evidence.
LRiG	**Comparators**	The Assessment Group would not, however, be in a position to make or support any recommendations about substitution of CABG by DES, as this would require separate appraisal/assessment in its own right	No action required
BCIA	**Outcomes**	The term "major adverse **coronary** events" should be amended to the standard term "major adverse **cardiac** events" (MACE).	Scope amended accordingly
BCIA	**Outcomes**	Adverse events of treatment" are distinguished from MACE events. We would like definition of which events, other than MACE, this may be referring to	Adverse effects of treatment are those relating to the stenting.

Deleted: Multi-vessel stenting not in scope as per original appraisal.

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			Clarification added.
Boston Sci	**Outcomes**	The term "major adverse **coronary** events" should be amended to the standard term "major adverse **cardiac** events" (MACE). It should be noted by the appraisal committee that this definition varies between clinical trial programs which is of importance for any comparison between stents.	Scope amended accordingly.
Boston Sci	**Outcomes**	We would like to request clarification of the field "adverse effects of treatment." Specifically, to what is the appraisal committee referring and how does it differ from the outcome stated above.	Clarification added.
Cordis	**Outcomes**	The term "major adverse **coronary** events" would be better redefined as the standard term "major adverse **cardiac** events" (MACE). This is an important outcome which should be included because meta analysis may reveal differences in MACE rates between different DES.	Scope amended accordingly.
Cordis	**Outcomes**	The assessement team should take care to ensure 'like for like' comparisons of MACE because some stent trials specifiy all-cause mortality as a component of MACE whereas others specify only cardiac deaths. Conversely, some include target vessel revascularisation (TVR) and others target lesion revasularisation (TLR). Consideration of overall survival should also take this into account.	Comments noted. Have specified in the scope that care should be taken to distinguish MACE definitions that involve all-cause mortality from cardiac death, and target vessel revascularisation from target lesion revascularisation.
Cordis	**Outcomes**	Finally, when assessing the cost-effectiveness of the different technologies, the cost of the recommended duration of antiplatelet therapy with clopidogrel (6 months for the TAXUS stent versus 2 months for the Cypher stent, per the respective product instructions for use) should be included.	The products will be appraised as per their CE marking. The role of anti-platelet therapies will be explored.
LRiG	**Outcomes**	Clinical Effects: Adverse affects of treatment - - presumably stent related, and presumably to include thrombosis (AMI, SAT, LT); mal-absorption; 'incomplete stent apposition'; device failures/defects.	Clarification provided.
LRiG	**Outcomes**	Economic analysis: As expressed earlier, it is felt that later data on Cypher/Taxus warrant incorporation into the assessment.	Scope amended to allow for examination of all DES developments.
RCP Edinburgh	**Outcomes**	The primary efficacy variables are re-stenosis rates (usually binary rates, ie % above 50% at repeat angiography) and MACE (death, MI and rehospitalisation /target lesion revascularisation). Prospective randomised data is essential along with angiographic and IVUS follow up.	Section clarified

BCIA	**Other considerations**	The draft scope indicates that "If the evidence allows, sub-groups involving narrow arteries, long lesions, complicated lesions (such as bifurcation lesions), saphenous vein grafts, partial versus total occlusion, and people with diabetes should be investigated." The exploration of sub-groups is welcome and would be best served by widening the scope to include all new data since the publication of the previous guidance. Existing and new devices should be reviewed with equal rigour with respect to both current and potential new recommendations.	Scope amended to allow for examination of all DES developments.
Boston Sci	**Other considerations**	As one of the largest RCT and registry data sources, we propose the inclusion of Taxus in the appraisal. Specifically, we propose its inclusion based on Consideration of the second bullet point, as well as Guidance No. 71 Section 5.6, "*Studies to determine whether diabetes is a risk factor for increased rate of restenosis following PCI, independent of lesion length and artery calibre, are required. Much of this work could be performed by an analysis of patient-level data taken from trials already conducted."* We have patient level **subgroup analyses**, specifically for diabetic patients, as well as for long lesion and small vessel subgroups, and feel that inclusion of the analyses in the appraisal is necessary.	Scope amended to allow for examination of all DES developments. No restriction has been placed on the types of evidence that will be taken into consideration.
Boston Sci	**Other considerations**	The original appraisal was performed early in the DES life-cycle when only initial data was available (as highlighted by Guidance No. 71's suggestions for further research). Inclusion of Taxus RCTs and registries reinforces the committee's requirements for rigorous clinical data, as well as provides the bulk of patients needed to perform adequate sub-group analyses.	Scope amended to allow for examination of all DES developments.
Cordis	**Other considerations**	Section 3.3 of guidance 71 noted that "because the performance of a DES depends critically on the particular drug being used, each DES should be regarded as a separate technology". Emerging head-to-head DES trials such as ISAR DESIRE, SIRTAX and the Korean long lesion study indicate that there may be differences in DES effectiveness in some patient populations and as such, DES should not be appraised as a single 'class effect'. Similarly, sirolimus analogues or structurally related drugs such as tacrolimus should not be assumed to have the same benefit (or in the case of tacrolimus, the same mechanism of action) as sirolimus. Data comparing paclitaxel and sirolimus-eluting stents will be available. The exploration of sub-groups is welcome and should include outcome data from both controlled trials and registries to reflect trial and 'real world' populations.	The evidence for each technology will be examined. No restriction has been placed on the types of evidence that will be taken into consideration.
LRiG	**Other**	Concurrent therapies (e.g. antiplatelets or anticoagulants) could be presented as	No action required.

	considerations	a narrative analysis and commentary on comparability of evidence	
LRiG	**Other considerations**	Although we agree that analysis of subgroups is important, commitment to analysis of all listed subgroups in the clinical and economics sections of the assessment will require substantial review resources and likely be dependant on early access to patient level data.	This point will be explored further at the Consultee meeting.
LRiG	**Other considerations**	*Guidance will only be issued for DES that have been awarded an appropriate CE mark by September 30th 2005, and for which data have been supplied by 8th June 2005.* – We would appreciate support from NICE in 'plotting out' which stents are currently on/not on track for these dates?	Information has been obtained from consultees and will be shared with the Assessment Group.
RCP	**Other considerations**	We agree with further analysis of the subgroups stated but would reiterate this should also include the analysis of new data on the old DES.	Scope amended to allow for examination of all DES developments.
RCP Edinburgh	**Other considerations**	The acquisition of late safety data should be encouraged.	Data will be taken into account where available. This point will be explored further at the Consultee meeting.
RCP Edinburgh	**Other considerations**	In terms of the other considerations proposed in the appraisal remit, anticoagulation in this context has been largely superseded by anti-platelet therapy and may therefore be an unnecessary component of the work.	Anticoagulation omitted
BCIA	**Other**	The Institute should note that audit by a number of interventional cardiology centres has shown that over 70% of lesions currently treated by PCI meet the anatomical requirements for DES implantation defined in Technology Appraisal 71. The shift from CABG to PCI in some patient populations helps to explain why the proportion of patients presently considered appropriate for DES is higher that originally estimated in Guidance 71. However, the national tariff applied to PTCA under the introduction of HRG codes (code E15) for the year 2005/2006 assumes only 50% DES usage and is therefore inadequate to ensure full implementation of even the current guidance. Whilst this is not strictly within the remit of the Institute, it has a material impact on the ability of individual NHS Trusts to implement the Institute's guidance.	Comment noted-No action required.
Boston Sci	**Other**	We would like to bring to attention independent audits by IC centres that found up to 70% of lesions currently treated by PCI meet the anatomical requirements for DES implantation, as defined in Guidance No. 71. However, the national tariff applied to PTCA (code E15) for the financial year 2005/2006 assumes only 50% DES usage. This could lead to instances at a local level where NICE guidance	Comment noted-No action required. Scope amended to allow for examination of all DES developments.

		cannot be fully implemented. We feel that analyses of Taxus trial data may help to better elucidate the appropriate patient populations who benefit from DES use.	
Cordis	**Other**	Longer-term follow up of previously appraised devices should be reviewed to confirm guidance 71. This could be achieved relatively simply and quickly.	Scope amended to allow for examination of all DES developments.
Cordis	**Other**	Cypher Select is equivalent to Cypher, but with improved deliverability and should not be reviewed as a new device	Companies will be required to demonstrate equivalence and additional benefits.
Cordis	**Other**	New devices should be appraised on their own merits, not assuming equivalence with current devices. New devices should be considered according the same hurdles and rigor as was applied to current devices in technology appraisal 71	Companies will be required to demonstrate equivalence and additional benefits.
Cordis	**Other**	New multivessel disease data should be considered because there has been further shift from CABG to PCI in since technology appraisal 71.	This point will be explored further at the Consultee meeting.

Deleted: As per original appraisal, multi-vessel disease will not be considered.

No comment
BCHC Wales
Central Derby PCT
DoH
MedEx Medical
NCC for Acute Care
Terumo
PIU (only on consultees to be included)
Medtronic (will have a stent – Endeavour – up for appraisal)
RCS (suggestion for consultee to be included only)