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Dear Members

You will probably be aware of recent controversies regarding a potential increase in mortality associated with the use of drug eluting stents/balloons.

An expert working group with the MHRA has made recommendations regarding the use of drug eluting technologies- with implications for duty of candour, in terms of patients previously treated. The link to the guidance can be found [here](#).

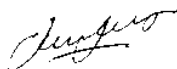
Recommendation 4 states:

‘Ensure local procedures, taking duty of candour into account, are in place for the continued management of patients who have already been treated with paclitaxel coated balloons and paclitaxel eluting stents. Consider the need for follow-up, which may include telephone consultation or review in the community, where appropriate. This should include reporting of serious adverse events and cause of death.’

Following that recommendation we have drawn up a template letter which could be used for Duty of Candour purpose, if your Trust decides to contact the patients previously treated. This is a revised version of a letter drawn up by the expert working group.

If the situation changes, based on further analysis of the current evidence and other international guidelines, we will issue a further statement.’

Regards,



Professor Ian Loftus  
President, the Vascular Society of Great Britain and Ireland