National Institute for Health and Care Excellence

IP1359 Aortic valve reconstruction with glutaraldehyde-treated autologous pericardium

IPAC date: 8th June 2023

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Company	1	Edwards Lifesciences welcomes the draft recommendations as these represent a reasonable conclusion based on the evidence reviewed and the uncertainties highlighted compared with treatment alternatives.	Thank you for your comment.
2	Consultee 1 Company	3.7	Given the uncertainties surrounding the evidence noted earlier in the guidance, the phrase "may be better than a mechanical or biological valve for young people" could be very misleading. In the absence of strong published evidence to support that statement and in particular as there isn't a perfectly clear (and largely endorsed by the scientific community) understanding of the underlying mechanisms for valve deterioration, we would recommend using the phrase "provides another alternative to mechanical or biological valves for young people."	Thank you for your comment. Section 3.7 was amended as suggested: The committee was told that glutaraldehyde- treated autologous pericardium provides another alternative to mechanical or biological valves for young people.'

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."