

National Institute for Health and Care Excellence
Medical technologies evaluation programme
MT396 Curoso for preventing infections when using needleless connectors

Consultation comments table
Final guidance MTAC date: 22 February 2019

There were 4 consultation comments from 3 consultees:

- 1 comment from an NHS professional
- 1 comment from the MHRA
- 2 comments from the manufacturer

The comments are reproduced in full.

#	Consultee ID	Role	Section	Comments	NICE response
1	1	NHS professional	General	Whilst the clinical actions of this device may be useful for lines which are not regularly accessed, consideration should be given to any potential effects if the device is lost in bedding or on the floor. Could it be a choking hazard and what would the ingestion complications be in the young or those with cognitive impairment if the bright green cap is swallowed? In addition, I agree that there is large scope for potential re-use.	Thank you for your comment. The committee discussed safety issues and heard from the clinical experts that although Curoso could be a choking hazard, nursing staff should be vigilant to ensure that it was not left within the patient's reach. The experts also noted that there were other parts of vascular access devices and other devices that are a possible choking hazard which must be managed by nursing staff. The experts did not think that Curoso posed any greater choking risk than other small parts of equipment used. The committee decided not to update the guidance.
2	2	MHRA	General	Dear Sir/Madam,	Thank you for your comment.

				<p>Thank you for giving MHRA an opportunity to review the draft medical technology consultation document on Curoc for preventing infections when using needleless connectors.</p> <p>Based on the information provided I have no additional comments on the draft document.</p> <p>As suggested, It is important for healthcare professionals to ensure that they use the device according to its intended use.</p>	
3	3	Manufacturer	3.4	<p>The EAC 'considered that nurses would use the 30-second drying time of alcohol wipes for other tasks (such as preparing the syringe or writing notes), and so this should not be considered as time saved when using Curoc.'</p> <p>In order to comply with Aseptic Non-Touch Technique (ANTT) the cleaning process requires the port to be held in one hand whilst scrubbed with an alcohol wipe using the other (Loveday et al 2014).</p> <p>Importantly, whilst drying the port it must be held to ensure it doesn't come into contact with a non-sterile field potentially leading to further contamination.</p> <p>To prepare for this response, 3M consulted with nurses who have experience of this process and asked for their view on whether there is a real time saving whilst the hub is drying:</p> <ol style="list-style-type: none"> 1. "Accessing any vascular access device requires the health care professional to maintain strict aseptic non-touch technique. In my opinion, the only other duty that the health care professional can do whilst waiting for 30 seconds for the hub to dry is to observe or talk to the patient. The health care professionals' gloved hands should be kept as sterile as possible throughout the procedure to 	<p>Thank you for your comment. The committee considered the testimony provided by the consultee and sought additional input from clinical expert advisers. The committee agreed that compliance with aseptic non-touch technique is likely to be very low in practice. However, due to the mixed clinical opinion as to whether Curoc would be time saving, the committee did not change its conclusion that further evidence would be needed to demonstrate this. The committee decided to update section 4.7 to clarify that clinical opinion was mixed about Curoc's potential for time-saving.</p>

			<p>prevent cross contamination which could cause health care acquired infections.” - District Nurse Community IV Team Leader</p> <p>2. “In my experience, after scrubbing the hub, whilst waiting for it to dry the nurse would need to ensure that the port of the intravascular device remains uncontaminated and therefore would not be able to carry out other duties” - Clinical Nurse Manager Vascular Access and Nutrition</p> <p>3. “In relation to time saving, I think it unlikely that anyone accessing a vascular access device would be able to perform any other task whilst waiting for the access port to dry as this would risk non-observation of the cleaned access port with an associated risk of contamination. My perception is that very few practitioners would spend 15 seconds cleaning a hub and allowing it to dry anyway (I do not however know of any high-quality research that supports this) and therefore in my opinion the best feature of the passive disinfection cap is that it mitigates this potential for substandard practice.” - Nurse Consultant Vascular Access</p> <p>4. "If these devices remove the necessity for the 30 seconds drying time they could prove beneficial to nurses working in the clinical area from this perspective. This time is very difficult to use elsewhere as the procedure requires the hub to be maintained in a sterile environment once scrubbed to prevent re contamination. Although it is possible that concordant patients may remain still, a sterile field would be required for the hub to rest on." - IV Resource Team Lead</p> <p>The cost impact of the drying time is highly significant because when a 30 seconds time saving is input to the EAC costing model and the base rate</p>	
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				for infections are set at zero (therefore isolating the time impact) Curoso becomes cost saving.	
4	3	Manufacturer	4.4	<p>'The committee acknowledged that using Curoso may increase compliance, but there was insufficient evidence for this.'</p> <p>Despite continual training and focus on scrub-the-hub, current compliance of IV access point disinfection in the UK is as low as 20%.The supporting evidence in past Curoso cap studies for increased compliance to infection prevention protocols may be confounded with training effects, however use of Curoso inherently improves compliance due to its binary nature (it's either on and compliance is high or it's not and compliance is low) removing user-technique variation to provide consistent disinfection of the IV access point every time.</p>	Thank you for your comment. While the committee agreed that Curoso has the potential to improve compliance with infection prevention protocols, it noted that there is a lack of evidence to demonstrate this. The committee decided not to update the guidance.

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