

## **Appendix B: Stakeholder consultation comments table**

2018 surveillance of Gallstone disease: diagnosis and management (2014)

Consultation dates: 10 to 23 July 2018

Do you agree with th	you agree with the proposal to not to update the guideline?				
Stakeholder	Overall response	Comments	NICE response		
Boston Scientific	Yes	We agree with the decision of NICE not to update the current guideline CG188 Gallstone disease: diagnosis and management. However, we would like to take this opportunity to ask NICE to take into consideration the updated Tokyo Guidelines 2018 (TG 2018) in the future review and in particular, we would like NICE to consider these guidelines when reviewing the paragraph "1.2.6 Reconsider laparoscopic cholecystectomy for people who have had percutaneous cholecystostomy once they are well enough for surgery" (NICE CG188).	Thank you for your comments.  Thank you for highlighting the ongoing study comparing endoscopic ultrasound-guided gallbladder drainage with percutaneous cholecystostomy as a definitive treatment in high risk acute cholecystitis patients. As the scope of the guideline covers the relative effectiveness of different types of interventions for the management of acute cholecystitis, including in people for whom surgery is not appropriate, we will monitor this study and once the results are published assess the impact on the recommendations in NICE guideline CG188.		
		According to the updated Tokyo Guidelines 2018 (TG 2018), they recommend that EUS-GBD could be considered in high-volume institutes when performed by	Thank you for providing a reference to the updated Tokyo Guidelines 2018: management strategies for gallbladder drainage in patients with acute cholecystitis. While we do not include other guidelines as evidence sources, any relevant studies on which the		

skilled endoscopists, as an alternative to PTGBD as a standard drainage method for surgically high-risk patients with acute colecystitis (AC).

EUS-GBD have been reported as novel, effective alternative gallbladder drainage procedures in patients with acute colecystitis. With the EUS-GB technique, a nasogallbladder drainage tube, a double pigtail plastic stent, a self-expandable metal stent, or the more recently developed lumen-apposing metal stents (LAMS), are inserted into the gallbladder to provide effective and safe drainage of its content. The internal drainage obtained with endoscopic gallbladder drainage results in less post-procedure pain than with the external drainage of PTGBD.

However, most likely because these internal procedures require difficult endoscopic techniques, and almost all reports regarding endoscopic drainage have been by skilled pancreatobiliary endoscopists from high-volume centers, those newer endoscopic techniques have not yet been established as standard procedures. Therefore, it seems logical to propose that EUS-GBD be considered as a viable alternative in these high-volume institutes when managed by skilled operators.

A prospective, randomized, head-to-head comparison of PTGBD and EUS-GBD using the LAMS device is currently in progress (Clinical trials registration number: NCT02212717), and will soon be able to provide the answer as to whether EUS-GBD will become the standard

guideline was based, that fit the original guidelines' review criteria would be included.

During the surveillance review no published studies were identified comparing different gallbladder drainage methods in the management of acute cholecystitis; but 1 study was identified comparing laparoscopic cholecystectomy (LC) with percutaneous cholecystostomy (PC), which indicated that LC was significantly superior to PC in a number of outcomes including mortality and length of hospital stay. As LC is the recommended approach for managing acute cholecystitis, there is no impact on the guideline; and gallbladder drainage techniques are not currently being considered as an area for update in NICE guideline CG188.

		of care in the treatment of acute cholecystitis in high surgical risk candidates.	
		References (attached document):  Yasuhisa Mori, Todd H. Baron et al. Tokyo Guidelines 2018: management strategies for gallbladder drainage in patients with acute cholecystitis. J Hepatobiliary Pancreat Sci (2018) 25:87–95.	
Department of Health and Social Care	No response provided.	I wish to confirm that the Department of Health and Social Care has no substantive comments to make, regarding this consultation.	Thank you for your comment.
Royal college of Nursing	No response provided.	Nurses caring for people with Gallstones have reviewed the proposal and have no comments to submit at this stage.	Thank you for your comment.
Royal College of Physicians	No response provided.	Just to confirm that the RCP (having liaised with the BSG) sees no need to update this guideline at present.	Thank you for your comment.

## Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Boston Scientific	No	No comments provided	Thank you for your response.

Do you have any comments on equalities issues?					
Stakeholder	Overall response	Comments	NICE response		
Boston Scientific	No	No comments provided	Thank you for your response.		
Do you have any comments on the timing of surgery in the management of acute cholecystitis, common bile duct stones or gallstone pancreatitis?					
Stakeholder	Overall response	Comments	NICE response		
Boston Scientific	No	No comments provided	Thank you for your response.		

© NICE 2018. All rights reserved. Subject to Notice of rights.