Department of Health & Social Care

Caroline Dinenage
Minister of State for Care

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Our reference: PFD 1138998

Ms L Hashmi
HM Area Coroner, Manchester North
Coroner's Service
Phoenix Centre
L/Cpl Stephen Shaw MC Way
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OL10 1LL

5th September 2018

Dear Ms Hashmi,

Thank you for your letter of 28 June to the Department of Health and Social Care about the death of Mr Stephen Whitehead. I am responding as Minister with portfolio responsibility for hospital care quality and patient safety.

I was extremely saddened to read of the circumstances surrounding Mr Whitehead's death. If you have the opportunity, please convey my sympathies to his family. I can appreciate this must be a difficult time for them.

Your report was issued to the British Society of Gastroenterology (BSG) and I understand the Society has provided a response. You will therefore be aware that after careful consideration, the Society is of the opinion that a national stent registry is not required, instead pointing to the existing guidance available and the need for clear communication between medical professionals and with the patient, as well as the clear recording of next steps in management plans.

This view is supported by the National Institute for Health and Clinical Excellence (NICE) which points out that in this case there appeared to be an intention to remove the stent but this did not happen due to an administrative

error. It is not clear how the establishment of a national stent registry would have avoided the sad outcome in this case where there were apparent shortcomings in the local arrangements for care.

I am informed that the Pennine Acute Hospitals NHS Trust has since established an ERCP (endoscopic retrograde cholangiopancreatography) biliary stent oversight meeting which has overseen an in-depth review of the current system of following up patients after having an ERCP and stent insertion. Amongst other actions, this learning is being shared across the Northern Care Alliance (the Salford and Pennine NHS trusts) to support a review of the management and follow up of all implantables.

This is encouraging to see and you will know that the BSG and its Joint Advisory Group are in discussion concerning the addition of a stent planning or recall database to the key performance indicators within the national standards framework, and incorporating it within the *Improving Safety and reducing Errors in Endoscopy* programme.

In addition, the BSG is proposing that a plan for a repeat ERCP (in for example, three to four months' time) is set at the time of the ERCP. While this appointment might need to be re-scheduled in light of circumstances, it may act as an important 'safety net'.

On your second matter of concern relating to the definition of 'short term' in clinical guidance, my officials have sought the views of NICE.

As you may be aware, NICE issued clinical guideline 188 on '*Gallstone Disease: Diagnosis and Management*'[1] in October 2014. This includes the following advice: '*If the bile duct cannot be cleared with ERCP, use biliary stenting to achieve biliary drainage only as a temporary measure until definitive endoscopic or surgical clearance*'.

NICE advises that the definition of 'short term' is understood in the field and appears to be been understood by the team caring for Mr Whitehead, as they had planned to remove the stent after a few weeks. NICE therefore considers that the recommendations in NICE guideline 188 remain appropriate.

In conclusion, I am satisfied that there is consensus that a national stent registry is not required and that best practice guidance is available. I am also assured that the BSG has carefully considered the matters raised in your report and will take forward action where it considers it appropriate.

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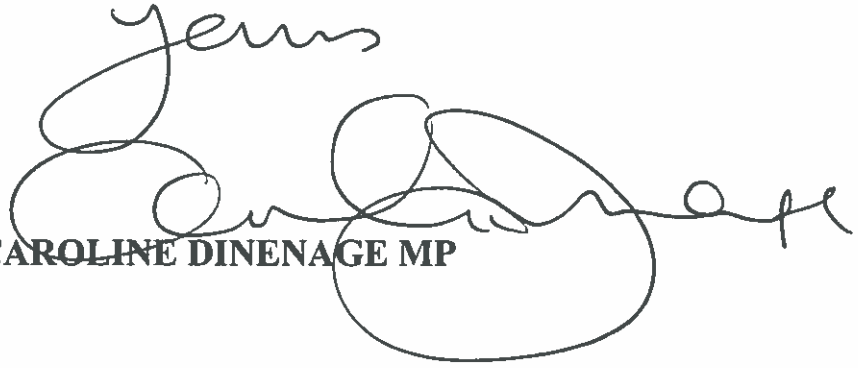
[1] https://www.nice.org.uk/guidance/cg188

Importantly, you will know from the BSG's response that there is a national initiative, *Getting it Right, First Time*[2], that aims to improve the quality of care through the reduction of unwarranted variations in practice. There is a gastroenterology workstream led by a clinical lead and the focus will be on disseminating best practice and reduce variations in clinical quality, efficiency and productivity. For completeness, NHS Improvement has brought the concerns in your report to the attention of the GIRFT clinical lead for gastroenterology, Dr Beverly Oates.

Thank you for bringing your concerns to our attention.



CAROLINE DINENAGE MP

[2] http://gettingitrightfirsttime.co.uk/