NICE National Institute for Health and Care Excellence

Molecular testing for Lynch syndrome in people with colorectal cancer

Diagnostics Assessment Report (DAR) - Comments

Stakeholder	Comment no.	Page no.	Section no.	Comment	EAG Response
Lynch Syndrome UK	1	General	General	We LSUK would like to thank you for the comprehensive and helpful study and look forward to the recommendations for standardised screening for all colorectal patients being implemented soon.	Comment noted. No response.
Bowel Cancer UK	2	General	General	Bowel Cancer UK is the UK's leading research charity for bowel cancer. Improving the identification and management of high risk patients for bowel cancer is one of our top policy priorities and we welcome this opportunity to comment on the NICE DAR on molecular testing for Lynch syndrome in people with colorectal cancer. People with Lynch syndrome are likely to develop bowel cancer at a much younger age than the rest of the population – the average age of being diagnosed with bowel cancer in someone with Lynch syndrome is 43 years old. Lynch syndrome can increase a patient's risk of developing bowel cancer by as much as 80% but only 5% of known carriers have so far been identified. This is because testing to identify people with Lynch syndrome is not carried out systemically across the country despite guidelines from the Royal College of Pathologists (RCPath). Carrying out systematic molecular testing for Lynch syndrome in people diagnosed with bowel cancer across England has been proven to be a cost effective	Comment noted. No response.

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				use of NHS resources and would meet the NICE QALY threshold (Snowsill et al, 2014).This is because by knowing if a person has Lynch syndrome they can be placed in a surveillance programme to receive regular colonoscopy. This can help detect bowel cancer at an earlier stage when it is less costly to treat, compared to treatment costs for people diagnosed at a later stage of bowel cancer.	
	3	53	1.1.4.1	In July and August 2016 we carried out a patient experience survey to better understand the experience of being diagnosed and managed for Lynch syndrome. [redacted]	Comment noted. No response.

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	4	55	1.1.44	Family history is a useful tool to assist in the identification of people with Lynch syndrome, but should not be used solely as an identification tool due to its lack of sensitivity. In Hampel et al *'Underutilization of Lynch syndrome screening'* they have estimated that one in four individuals with Lynch syndrome will be missed by the use of family history or age based screening criteria.	Comment noted. The systematic review of diagnostic test accuracy study includes some studies which do use family history or other clinical criteria to identify the study population, but every effort was made to also identify studies which were based on an unselected population with CRC (one such study was included in the systematic review). Family history is not assumed to form a part of the diagnostic pathways in the economic evaluation.
	5	65	1.4	In June 2016 we submitted a Freedom of Information (FOI) request to every hospital trust in England, health board in Scotland and Wales, and health and social care trust in Northern Ireland. This was a follow up to the FOI we submitted in 2015 and aimed to establish whether adherence to the RCPath dataset, which mandates that all bowel cancer patients under the age of 50 are tested, automatically, for Lynch syndrome at diagnosis, had increased. We found that 69% of hospitals in England carry out testing for Lynch syndrome in all patients diagnosed	Comment noted. No response.

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				with bowel cancer under the age of 50, compared to 49% in 2015. However, only 54% perform this test automatically as a reflex test. Whilst more hospitals in England are offering molecular tests for Lynch syndrome there is still variation in the referral pathway. There needs to be a consistent approach to enable testing to take place automatically, as a reflex test, at diagnosis of bowel cancer. We believe that NICE guidelines on molecular testing for lynch syndrome in people with colorectal cancer could help to establish a consistent approach to identifying these individuals and ensuring all hospitals are carrying out this test.	
	6	152	5.1.2.1	From our FOI we found only 7 hospitals in England perform this test at diagnosis with the majority (77%) performing it post-treatment. Testing at diagnosis is important as Lynch syndrome can affect a patient's treatment options.	Comment noted. Following discussions at the scoping workshop (January 2016) it was assumed in the economic evaluation that diagnosis of Lynch syndrome would not affect a patient's treatment options.
	7	183	5.1.4.1.2	Data from our patient survey [redacted]	Comment noted. No response.

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				[redacted]	
	8	256	6.1	Our 2016 FOI briefing found that the barriers to testing identified in the 2015 FOI still existed. These barriers relate to finances, resources and capacity. In addition, two hospitals mentioned that they are awaiting NICE guidance before carrying out systematic testing. Some hospitals stated they have overcome these barriers through developing regional approaches that streamlines testing via the use of a singular pathology department. This type of approach could alleviate the pressures smaller hospitals face.	Comment noted. No response.
Roche diagnostics	9	General	General	Roche Diagnostics Ltd welcomes the report and its recommendations on the use of molecular testing for Lynch Syndrome in people with colorectal cancer. We feel it adds valuable evidence to a medical condition that is not currently well understood. As test manufacturers, we would have been able to advise on test specifications, had we been invited to do so. However, we broadly concur with the assumptions on test specifications contained within the report, and on the overall recommendations on test strategy.	Comment noted. No response.