National Institute for Health and Care Excellence

Medical technologies evaluation programme

MT250 Endocuff Vision for assisting visualisation during colonoscopy

Consultation comments table

Final guidance MTAC date: 22 March 2019

There were 7 consultation comments from 2 consultees:

- 1 comment from a professional group
- 6 comments from the manufacturer

The comments are reproduced in full, arranged in the following themes:

- Draft recommendations (comments 1 to 3)
- Description of the evidence (comment 4)
- Critique of the evidence (comment 5)
- Cost modelling (comment 6)
- Other (comment 7)

#	Consultee ID	Role	Section	Comments	NICE response
Theme 1: Draft recommendations					
1	1	Healthcare Other	General	JAG response to NICE Endocuff proposal Responses received from [redacted] Comments collated and summarized by [redacted]	Thank you for your comment. The committee acknowledged the importance of JAG for supporting endoscopy services and maintaining clinical standards across the UK. The committee noted that technologies evaluated by MTEP are evaluated as single technologies and the use of other adjuncts and strategies aimed at improving ADR in a screening population

				Comments have been sought from the JAG committee members. To summarise: It is JAGâ€™s opinion that Use of Endocuff in Bowel Cancer Screening could be supported by NICE but should not be mandated in any patient group. Reasons for this statement include: â€¢ There are other technologies/strategies that have not undergone a similar level of scrutiny but might be equally effective (e.g. chromoendoscopy, high def kit, water-exchange, mandating an extubation time of e.g. 15 minutes, better prep) â€“ I feel these should be assessed with similar rigour before determining best approach â€¢ Data still a little mixed & even ADENOMA trial showed rather perplexing difference between screening & non-screening results â€¢ We donâ€™t know what the true benefit of additional adenoma yield is from an already high baseline ADR. â€¢ Endocuff changes scope handling characteristics and may be more uncomfortable for patients, may reduce terminal ileal intubation and can be problematic in diverticulosis â€¢ We need to be cognoscente of evolving equipment and would this device provide the same magnitude of effect with improved technology. â€¢ Additional cost (with a device) may not be best use of hard pressed funds. â€¢ The assumption that improvements in ADR seen with Endocuff in some studies but clearly not all (Bhattacharyya R. Endoscopy. 2017 Nov;49(11):1043-1050) then translates into fewer PCCRC. This has only been demonstrated for a training / feedback intervention by Michal Kaminski, and never for a device as far as we are aware. [Kaminski MF Gastroenterology. 2017 Jul;153(1):98-105. doi: 10.1053/j.gastro.2017.04.006. Epub 2017 Apr 17. Increased Rate of Adenoma Detection Associates With Reduced Risk of Colorectal Cancer and Death.]	have not been considered in this evaluation. The recommendations are on the use of Endocuff Vision only. The clinical expert advised that several other parameters can increase ADR and some of these were employed in the ADENOMA trial, in addition to Endocuff Vision. The committee agreed that the influence of other factors was sufficiently addressed in section 4.4 of the guidance. The committee agreed that the impact of a high baseline ADR and the variability in data have been sufficiently addressed in sections 4.5 and 4.1 of the guidance, respectively. The committee were advised by the clinical expert on the issues of handling with Endocuff Vision. The expert advised that the technology may increase the frictional resistance at the tip of the endoscope, making it more difficult in certain patients but this does not impact on quality metrics or patient discomfort scores. The committee also noted that terminal ileal intubation is not used as a quality indicator during screening and that caecal intubation is used instead. The committee agreed that the issue around handling is sufficiently addressed in section 4.8 of the guidance where patient selection is considered. The committee and EAC acknowledged that there is no evidence directly linking Endocuff Vision use to reduced interval cancer risk but noted that ADR is a well-recognised surrogate marker for cancer risk. The committee agreed that these assumptions have been clearly described in section 4.5 of the guidance. The cost savings estimated in the EAC's model are based on improved ADR leading to detection of cancers at an earlier stage and a reduction in cancer treatment costs. Therefore, any cost savings derive from improvements in clinical outcomes for patients. The EAC acknowledged the uncertainty in translating improvements in ADR to downstream impacts on stage at detection of cancer and the consequent costs of treatment. The committee considered the EAC's revised cost model reflected the most likely cost savings associated with the use of the technology and decided not to change the guidance.

				â€¢ There is concern that if endoscopists are poor performers we are likely better doing training / up skilling interventions which for similar or less cost produce larger increments (up to doubling ADR for worst quartile performers) [Rajasekhar PT et al. Endoscopy. 2015 Mar;47(3):217-24. doi: 10.1055/s-0034-1391563 . At Â£5 per device, this equates to Â£25K funds for example for upskilling which may produce more than just increased ADRs (5000 colons / year in average unit) â€¢ Additional funds maybe better used to extend screening to more individuals given that the quality of screening is already extremely high â€¢ It may be more logical t use this device is particularly high risk groups for example ALL men age 60-74 rather than a FIT/FOBT derived colonoscopy population â€¢ There is uncertainty around the cost analysis given that the increase in adenomas is seen in the low risk and very small cohort and cost may not translate into real clinical advantage.	
2	2	Manufacturer	Section 1.2 Page 2	The statement regarding the non BCSP population should be amended to indicate that this reflects the state of evidence at the time of publishing the guidance.	Thank you for your comment. The committee considered your comment but noted that all medical technologies guidance recommendations are made based on the available clinical and economic evidence at the time of development. Considering this, the committee regarded the suggested amendment as unnecessary and decided not to change the guidance.
3	2	Manufacturer	Page 3	The statement regarding ENDOCUFF VISION in non-screening populations should be amended to indicate that this reflects the state of evidence at the time of publishing the guidance.	Thank you for your comment. Please see response to comment 2.
Theme 2: Description of the evidence					
4	2	Manufacturer	Section 3.3 Page 6	This text should be amended to reflect that lower baseline ADRs were associated with greater benefit for ENDOCUFF VISION, however, all studies identified for ENDOCUFF VISION had ADRs greater than 50% at baseline and that, with the exception of the E-CAP study and the non-BCSP population in	Thank you for your comment. The committee discussed your comment carefully but agreed that committee considerations around the clinical effectiveness of Endocuff Vision and the impact of high baseline ADRs reported by the studies have been addressed in sections 4.1 and 4.11 of

				the ADENOMA study, all demonstrated a statistically significant benefit of ENDOCUFF VISION.	the guidance. They also noted that the reader is referred to the assessment report for full details and results at the end of section 3.3. The committee decided not to change the guidance.
Theme 3: Critique of the evidence					
5	2	Manufacturer	Section 4.11 Page 13	The inclusion of the conclusion from the Williet meta-analysis that ENDOCUFF VISION does not deliver a benefit for colonsocopists with a baseline ADR>45% is inappropriate: â€¢ This finding contradicts the results of the ADENOMA study which is the only study identified in this appraisal as being of high quality. In the ADENOMA study a statistically significant and clinically meaningful improvement in ADR in excess of 10% was observed for operators in the BCSP with an average baseline of 50.9% â€¢ This meta-analysis included three studies in the subgroups analysis that concluded no benefit of ENDOCUFF VISION over a baseline ADR of 45%. Of these: o Bhattacharyya R, 2017 (E-Cap study): a single centre study comparing ENDOCUFF VISION and standard colonoscopy, baseline ADR was very high in both groups (>60%). The draft guidance had previously concluded that this is not likely to be representative of practice in the NHS. o Van Doorn SC, 2017: This investigates the original ENDOCUFF, a different medical device. The publication acknowledged a flawed power calculation in its methodology. Extrapolation of these results to draw conclusions about the performance of ENDOCUFF VISION is inappropriate. o Cattau EL, 2015: This abstract did not report which distal attachment was used, nor specify the population as screening/surveillance colonoscopy. Please note that the ENDOCUFF VISION was not	Thank you for your comment. The committee considered your comment carefully and, whilst acknowledging the limitations of the meta-analysis, decided not to change the guidance. The committee agreed that Williet et al. 2018 helps inform on the association between an individual user's baseline ADR and ADR improvement with the use of Endocuff Vision. The EAC advised that the assessment report includes different sources of supporting evidence, including experts' views and individual studies such as the E-Cap and Geyer 2018, as well as Williet et al. 2018. The EAC also noted that the meta-analysis included only randomised controlled trials and excluded low levels of evidence. It also highlighted that the proposed cut off for high vs low ADRs in the assessment report is taken from the national audit by (Lee et al. 2012) and not from the Williet et al. 2018 meta-analysis. The committee acknowledged that the meta-analysis included both Endocuff Vision and its predecessor device but noted that this is clearly stated in both the assessment report and in section 4.11 of the guidance.

				launched until 2015. The conclusions reached by Williet et al should not be included in this guidance as they are based on studies that are not generalisable to practice in the UK BCSP. This is due to both high baseline ADR and inclusion of devices outside of the scope of this appraisal. â€¢ The inclusion of the Williet paper to suggest a threshold is even more pronounced given the results of the ADENOMA study and the results of both the Tsiamoulos paper and that by Rameshshanker et al which all provide evidence of a benefit in a cohort where baseline is greater than 45% â€¢ The findings of the Williet meta-analysis are inconsistent with the guidance (reported in Section 1.3) i.e. that ENDOCUFF VISION is cost-saving at a baseline ADR of 51% with this result being driven by the clinical benefit of ENDOCUFF VISION at this baseline It should be noted in this section that the ADR improvement in the ADENOMA study is greater than that needed to demonstrate cost-savings.	
Theme 4: Cost modelling					
6	2	Manufacturer	Section 4.1	It should be stated that the learning curve effect is reflected in the economic model that demonstrated ENDOCUFF VISION is cost saving to the NHS i.e. ENDOCUFF VISION is cost-saving to the NHS when accounting for time to realise benefits.	Thank you for your comment. The committee's considerations on the learning curve associated with Endocuff Vision use are summarised in section 4.10. The committee decided to include a statement at the end of this section to highlight that the learning curve with Endocuff Vision is represented in the cost analysis.
Theme 5: Other					
7	2	Manufacturer	General	We welcome the recommendation that ENDOCUFF VISION should be considered as an option for people having a colonoscopy as part of the bowel cancer screening programme.	Thank you for your comment.

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