National Institute for Health and Care Excellence

Technology Appraisal

ID6683 Capsule sponge tests for detection of Barrett's oesophagus and early-stage oesophageal cancer and surveillance of Barrett's oesophagus

Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: The draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	NHSE	It is appropriate for NICE to consider Capsule Sponge technology as a diagnostic alternative for the surveillance of Barretts Oesophagus. However this should be within the context of the current NICE guidance regarding surveillance, rather than as a diagnostic test given that we don't know if the surveillance of Barretts, as currently undertaken, should be continued, given the results of the BOSS trial. (please see attached editorial with links to the original paper published last year). Therefore there is no point in using cytosponge to detect Barretts if we are not certain that subsequent surveillance improves patients outcomes and is cost effective. NHS-E Endoscopy transformation programme supports the use of cytosponge as an alternative to gastroscopy for the surveillance of BO. At the same time the strategy will encourage regions and Cancer Alliances to identify 1-2 centres of endoscopy to undertake any subsequent OGD for those patients identified as high risk from a cytosponge surveillance procedure undertaken in a community diagnostic centre.	Thank you for your comment. The detection use case was included in the assessment following feedback from multiple stakeholders that this should be considered and evaluated by NICE. The implementation of technologies with a recommendation by NICE is within the remit of NHS England and integrated care boards.

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		Regions and Cancer alliances will be required to collect data to demonstrate whether centres of excellence in surveillance can improve patient outcomes. Phased implementation will allow comparative data to be collected to demonstrate any improvements.	
	NHSE	The NHS CCoE (National Priority HealthTech) Team compiled a Commercial Intelligence Briefing in relation to this topic and has subsequently been supporting system preparedness activity. Whilst undertaking the tasks, we have noted that numerous stakeholders have raised concerns about the use case and delineation of use cases. Most commonly colleagues feed back their view that it is important to consider surveillance of Barrett's Oesophagus and detection of Barrett's Oesophagus as separate use cases for the capsule sponge technology. The suggestion from colleagues is that the detection use case would be more suited to an Early-use HealthTech guidance (the guidance type previously known as EVA – Early Value Assessment) and not included in the Technology Appraisal being developed for the surveillance use case. Further concerns from colleagues related to the position first surfaced in the CIB, that already there is a funding mechanism within the NHS payment system for local commissioning, so although guidance is welcomed for this technology, the necessity for TA has been queried.	Thank you for your comment. NICE intends to assess the clinical and cost-effectiveness for both use cases. The committee will be able to make evidence-based recommendations on each use case separately.
	Portsmouth Hospitals University NHS Trust	The topics covered are appropriate. The evaluation it should be appreciated is attempting to answer two distinct questions; 1. Is capsule sponge appropriate as an investigative test for patients with Reflux to *Diagnose* Barrett's and 2. is capsule sponge a suitable tool for the *Surveillance of Barrett's.* There is a clear indication for [2]. The	Thank you for your comment. NICE intends to assess the clinical and cost-effectiveness for both use cases. The committee will be able to make evidence-based

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		1st objective is more controversial but I think reasonable and appropriate to be included in this evaluation.	recommendations on each use case separately.
	University of Oxford	I do not feel it is appropriate to evaluate detection and surveillance in the same consultation. These are very different use cases with different consequences. There is a risk that the use of this device for Barrett's detection becomes 'screening by stealth'. The National Screening Committee have decreed that there is not sufficient evidence for a capsule sponge test screening programme at present, leading to the launch of the BEST4 trial to study mortality outcomes. Implementing the capsule sponge test for detection purposes in the meantime is a risk. We still do not have positive RCT evidence showing mortality benefits of diagnosing and surveilling Barrett's – either with the sponge or endoscopy. Qualitative evidence repeatedly suggests that a Barrett's diagnosis can be life changing for patients. It should only be done if it will ultimately improve their outcomes – and this remains unclear at present. Using the sponge to offer surveillance to patients who have already been diagnosed is a very different question to using it to facilitate detection.	Thank you for your comment. NICE intends to assess the clinical and cost-effectiveness for both use cases. The committee will be able to make evidence-based recommendations on each use case separately.
	NHS Lanarkshire (	I agree that this is an essential evaluation as there are currently no clinical guidelines on this topic (only original research articles).	Thank you for your comment. No action needed.
	University of Cambridge	Timely	Thank you for your comment. No action needed.
	Heartburn Cancer UK	No comment	No action needed.

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	British Oncology Pharmacy Association	Appropriate, also include national community pharmacy representatives in the consultation as detailed further below.	Thank you for your comment. NICE has invited the proposed organisations to register as stakeholders for this assessment.
	East and North Herts NHS Teaching Trust	This is timely and appropriate now there is significant evidence and given the national cancer plan priority for earlier and faster diagnosis in poorly survivable cancers	Thank you for your comment. No action needed.
	Cyted Health Ltd.	The selection of the topic is both timely and appropriate, given the pressures on endoscopy services and growing waiting lists in many parts of the country. The variation in population demographics and availability of appropriate medical education regarding Barrett's Oesophagus and the potential consequences of undetected progression often to late-stage Oesophageal Adenocarcinoma (OAC), leads to a disproportionate burden of disease with poor outcomes falling on disadvantaged communities. Considering how best to reach these communities and removing health inequalities should be of paramount importance. The evaluation of the clinical evidence and the questions being addressed in relation to this are appropriate. We would challenge the premise that a standard Cost Utility health economic approach to calculate an ICER is the most appropriate method to determine the financial impact of capsule sponge on the system for patients, providers and commissioners. Published health economic data from the BOSS study (Deidda et al, Gastroenterology. 2025 Nov;169(6):1244-1252.e7) concluded that	Thank you for your comment. The potential to improve access to care has been included as a consideration for this assessment. NICE and the appraisal committee will consider the potential impact of using the capsule sponge test on endoscopy waiting times. If data are available, the external assessment group (EAG) will include this in the economic evaluation. The proposed methodology will be described in the EAG's protocol and assessment report. A reference to the BOSS trial has been added to the scope.

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		surveillance of Barrett's Oesophagus via endoscopic methods (using study protocols) v endoscopy at need was not cost effective. The BOSS study while flawed in some respects, showed no mortality benefit (all cause and cancer specific) to patients undergoing endoscopic surveillance v endoscopy at need. Capsule sponge may replace endoscopy for surveillance in a significant proportion of patients with low clinical risk according to Tan et al., however the subsequent QALY gain is unlikely to be significant, leading to very high uncertainty in calculated ICERs, since treatment pathways are the same and outcomes are unlikely to change. There is some limited evidence (BEST3) that shows capsule sponge may detect cancer earlier, but due to the low overall incidence of cancer, the numbers are inevitably small. Investigators from the CytoScot study concluded that the test is non-inferior to endoscopy and that evidence of detection of cancer at a more treatable stage is limited. On purely economic grounds, it would seem prudent to discontinue surveillance by either method in patients with low/medium clinical risk, in favour of endoscopy at need. Such a position would likely be unacceptable to patients, and their clinicians, who with a known pre-malignant condition would not receive any monitoring until they become symptomatic. Anxiety levels among these patient groups would be extremely high. Given that some form of monitoring is required, the economic analysis might be better directed at a wider system approach, whereby endoscopy capacity is released to address higher value diagnostic procedures in both upper and lower GI. Such economic outcomes are more likely to be of value to system stakeholders and commissioners considering how best to deploy limited resources.	

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	Patient representative	fine	Thank you for your comment. No action needed.
	Head and Neck Cancer UK	Content with the proposals	Thank you for your comment. No action needed.
	Independent Cancer Patients' Voice	The evaluation and proposed evaluation route is appropriate from the patient aspect and thoughts.	Thank you for your comment. No action needed.
	Medtronic	No further comments	No action needed.
Wording	NHSE	In the unmet need: the issues regarding detection and surveillance of BO are not stated clearly. In particular, the current referral pathways for patients with GORD and dyspepsia are not followed in clinical practice, hence the large proportion of OGDs undertaken in patients <55 years old. There is also little recognition of GP referral practice or the use of alternative to OGD, eg transnasal endoscopy	Thank you for your comment. The care pathway as described in the scope is based on published, evidence-based national guidance and guidelines. The scope has been updated to include reference to transnasal endoscopy.
	NHSE	It does, subject to necessary updates as per the comment above and the feedback provided via the other consultation comments submitted by NHSE. Suggested alternative wording: "To appraise the clinical and cost effectiveness of capsule sponge tests for surveillance in people with a diagnosis of Barrett's oesophagus".	Thank you for your comment. The detection use case was included in the assessment following feedback from multiple stakeholders that this should be considered and evaluated by NICE.
	Imperial College London	I am happy with the draft remit and scope with only one supportive comment below. The revised Remit is more appropriate as it includes diagnosis	Thank you for your comment. No action needed.

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	Portsmouth Hospitals University NHS Trust	Generally worded very well. A few points: 1. Page 4 line 5. 'Upper GI endoscopy is both invasive and expensive' Compared to what? I think some attempt to quantify what the expense is and the load it puts onto endoscopy services would be valuable. i.e. how many surveillance gastroscopies are performed per annum for Barrett's surveillance with reference to the total number of gastroscopies performed per annum to provide context to the statement. Without this the scale of the problem is unclear 2. Page 7 line 9 'Using a capsule sponge test does not require sedation and can be done in community and primary care settings with lower-grade staff, such as a nurse' I do not like how this is worded. Suggesting a Nurse is a 'lower-grade' staff member comes over to me as a little insulting. Nurse endoscopists provide the vast majority of Barrett's surveillance in the UK. What the authors I think mean is that capsule sponge does not require a trained endoscopist and the learning curve for learning how to administer the device is short. They are correct in going on to describe how it can be administered in primary care.	Thank you for your comment. The referenced statement on page 4 is based on stakeholder feedback received during scoping. NICE sought but could not identify granular data on the proportions of endoscopy procedures done specifically for surveillance of Barrett's oesophagus in the NHS. The referenced statement on page 7 has been updated to ensure inclusive language is maintained.
	NHS Lanarkshire	It would perhaps be clearer if the two populations under evaluation were stated more clearly using bullet points within the draft remit, e.g. "To appraise the clinical and cost effectiveness of capsule sponge tests within their indication for: • Detection of Barrett's oesophagus and oesophageal cancer in people with gastro-oesophageal reflux disease and risk factors • Surveillance in people who have a diagnosis of Barrett's oesophagus"	Thank you for your comment. The remit was updated to clarify that surveillance is done in people with a "known" diagnosis of Barrett's oesophagus. The structure of this paragraph was not changed to maintain consistency with published technology appraisals.

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		Adding the word “known” or “established” before the word diagnosis in the 2nd bullet point may also make this clearer.	
	University of Cambridge	Could the title be changed to: Capsule sponge tests for detection of Barrett’s oesophagus and pre-symptomatic oesophageal cancer and ongoing monitoring of Barrett’s oesophagus A better option could be: Technology Appraisal: Capsule sponge tests for case finding and monitoring of Barrett's oesophagu This is because for symptomatic oesophageal cancer this technology is not relevant- patients need an endoscopy Might be helpful to be explicit that monitoring (or surveillance) is also in scope	Thank you for your comment. The title of this assessment has been amended to clarify that it includes the surveillance use case.
	Heartburn Cancer UK	No comment	No action needed.
	British Oncology Pharmacy Association	Yes	Thank you for your comment. No action needed.
	East and North Herts NHS Teaching Trust	Title should include the use of capsule sponge testing in Barrett’s surveillance For clarity Suggest the remit wording says risk factors for oesophageal cancer	Thank you for your comment. The title of this assessment has been amended to clarify that it includes the surveillance use case.
	Cyted health Ltd.	The wording of the remit reflects the issues of clinical effectiveness, however, please see our comments above regarding Cost Effectiveness v other economic approaches which would better inform stakeholders on resource choices.	Thank you for your comment. The title of this assessment has been amended to clarify that it includes the surveillance use case and that detection is of pre-symptomatic

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		The title should reflect that the test detects Barrett's Oesophagus and pre-symptomatic Oesophageal Cancer, in GORD patients, and ongoing monitoring of patients with Barrett's Oesophagus. If a patient has red flag symptoms e.g., unplanned weight loss, anaemia and dysphagia they should be referred for an urgent endoscopy not capsule sponge.	oesophageal cancer. The term "early-stage" was used to maintain consistency with other published guidance on capsule sponge tests. The differences in the care pathway for people with red flag symptoms are described in the Diagnosis of Barrett's oesophagus section and are excluded from the population in the decision problem table.
	Patient representative	fine	Thank you for your comment. No action needed.
	Head and Neck Cancer UK	Yes	Thank you for your comment. No action needed.
	Independent Cancer Patients' Voice	The wording of the remit fully reflects all of the issues and cost effectiveness.	Thank you for your comment. No action needed.
	Medtronic	No further comments	No action needed.
Timing Issues	NHSE	There is an urgency for NICE to review the use of cytosponge for surveillance, since some centres have already made plans to move from OGD surveillance to Cytosponge surveillance. HOWEVER, the use of cytosponge to detect BO in patients with GORD (ie opportunistic screening for BO) should wait for the results of the BEST4 study, required by the National Screening Committee to determine if this approach is cost-effective / reduces mortality from OAC	Thank you for your comment. The detection use case was included in the assessment following feedback from multiple stakeholders that this should be considered and evaluated by NICE. This assessment will not consider the use of capsule sponge tests for opportunistic

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			screening in people without risk factors and persistent GORD.
	Portsmouth Hospitals University NHS Trust	Agree this is timely and needs to be done with some urgency	Thank you for your comment. No action needed.
	University of Oxford	This is not urgent.	Thank you for your comment. No action needed.
	NHS Lanarkshire	Timely evaluation of this is key because, as stated, there are currently no clinical guidelines or professional recommendations on this topic: many clinicians have commented on this paucity. In addition, the updated British Society of Gastroenterology guidelines for Barrett's oesophagus surveillance are due to be published imminently. A statement on capsule sponge tests is expected so it would be useful to have formal appraisal from NICE on this topic.	Thank you for your comment. No action needed.
	University of Cambridge	Urgent as updated BSG guidelines being published soon	Thank you for your comment. No action needed.
	Heartburn Cancer UK	This is urgent in our opinion as it could make a significant difference between a curative pathway and a death sentence. The capsule sponge is a quick minimally invasive diagnostic device enabling more people to be triaged and reducing endoscopy waiting list which will ensure that those that need an endoscopy get the procedure in a more timely manner which will also help reduce patient anxiety.	Thank you for your comment. No action needed.
	British Oncology Pharmacy Association	Quite urgent – endoscopy reporting delays very common.	Thank you for your comment. No action needed.

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	East and North Herts NHS Teaching Trust	This evaluation should be prioritised as the technology and expertise are now widely available in the nhs and personnel will become deskilled. National rollout may also reduce heavy pressures on endoscopy services that will facilitate earlier diagnosis of other cancers	Thank you for your comment. No action needed.
	Cyted Health Ltd.	This is an urgent topic, given the growing number of patients waiting up to 1 year for a routine endoscopy	Thank you for your comment. No action needed.
	Patient representative	fine	Thank you for your comment. No action needed.
	Independent Cancer Patients' Voice	As a patient organisation it is considered an urgent evaluation, the alterative is endoscopy that has a higher cost and potential longer waiting time.	Thank you for your comment. No action needed.
	Medtronic	No further comments	No action needed.
Additional comments on the draft remit	Cyted Health Ltd.	None	No action needed.
	Medtronic	No further comments	No action needed.

Comment 2: The draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background	NHSE	The rate of transition from BO to OAC is overstated. (please see attached editorial)	Thank you for your comment. The sentence has been removed to

Section	Consultee/ Commentator	Comments [sic]	Action
information			ensure no factual inaccuracies remain.
	Portsmouth Hospitals University NHS Trust	Good, clear background information provided.	Thank you for your comment. No action needed.
	NHS Lanarkshire	The pathway for low grade dysplasia (LGD) described in the scope implies that patients should immediately go for treatment – the current BSG guidelines advise that antacid medication is maximised and endoscopy is repeated at 6 months. Aside from this comment, the care pathway is correctly described.	Thank you for your comment. The section has been amended to clarify the current care for people with Barrett's oesophagus with low grade dysplasia.
	University of Cambridge	The technology section – table page 4) TFf3 is positive in intestinal metaplasia which can be focal and patchy in Barrett's so just as not all biopsies will be positive for IM in patients having surveillance similarly not all TFf3 will be positive. TFF3 is a diagnostic marker not a Quality Control. The bullet points on how to use the biomarkers in diagnosis and surveillance under the table are correct.	Thank you for your comment. The table has been amended to ensure factual accuracy.
	Heartburn Cancer UK	No comment	No action needed.
	British Oncology Pharmacy Association	With regards to the care pathway (and existing comparators), at present endoscopy is not routinely carried out in primary care settings such as community pharmacies. As such, it appears that this technology is only being evaluated for introduction into the existing pathway, with a nod to "lower-grade staff, such as a [community] nurse". There needs to be clear and detailed evaluation of specific clinical settings where this technology could be implemented, i.e. community pharmacy (carried out by a community pharmacist or trained pharmacy staff member), not just existing pathways.	Thank you for your comment. During scoping, stakeholders notified NICE that the technology can be used in community care, such as community diagnostic centres. NICE was also notified that there is potential to introduce the technology in other community settings, such as community pharmacies, but that this

Section	Consultee/ Commentator	Comments [sic]	Action
		Community pharmacies are perfect for introduction of low-risk, non-invasive diagnostic procedures which reduce secondary care financial and capacity burden, help detect malignancies earlier, all whilst being more convenient to the patient's locality (thus improving uptake).	is currently not done. The EAG's clinical evidence review will identify the relevant real-world evidence and will report on the care setting this has been gathered in. The appraisal committee will consider this when it makes its recommendations.
	East and North Herts NHS Teaching Trust	Note that the BSG guidelines on diagnosis and management of Barrett's oesophagus are currently being updated and that European society (ESGE) guidelines were updated in 2023 Note photodynamic therapy for Barrett's dysplasia is no longer used in UK In the Barrett's detection group, safety netting of patients with negative tests may need further definition In the Barretts surveillance group previous ablation/ dysplasia may be considered providing no or only indefinite for dysplasia at most recent endoscopy. Hiatus hernia is not a contraindication unless known to be complicated (eg intrathoracic) or previous fundoplication	Thank you for your comment. The current care section has been updated to clarify that the BSG guidelines are currently being updated. NICE acknowledged that photodynamic therapy may no longer be widely used in the NHS, but has decided to retain reference to this procedure, as the interventional procedures guidance is still available. A subgroup defining people with residual Barrett's oesophagus after ablative therapy has been added to the scope.
	Cyted health Ltd.	This is thorough and seems accurate. Note TFF3 is a diagnostic marker and not a quality control as stated in the table on page 4. The draft needs to reflect that across the country, GPs refer patients with dyspepsia/reflux symptoms direct to scope, and the appropriateness of such referrals is often not reviewed by secondary care prior to patients being seen.	Thank you for your comment. The table has been amended to ensure factual accuracy. The potential to use the capsule sponge test as a triage tool for surveillance has been included in the scope, with reference to proposed

Section	Consultee/ Commentator	Comments [sic]	Action
		A high number of patients are referred to receive routine endoscopy without secondary triage, since secondary care settings lack resources or funding to adequately triage referrals. Additionally, patients with reflux symptoms remain on PPI therapy often longer than the recommended 6 weeks. This can lead to the suppression of symptoms in patients with significant pathology, leading to progression to more serious disease without being picked up. Any discussion of symptomatic GORD patient referral needs to explore these topics to fully consider the role of moving testing closer to the community, and the role of GPs in identifying patients appropriate for capsule sponge v routine endoscopy. There should also be some comment on PEUGIC rates. It is published that patients with known Barrett's Oesophagus often have a higher rate of PEUGIC (> 20%) compared to the national average of (8.5%) (Kamran et al, Gastroenterology. 2025 Nov;169(6):1244-1252.e7). The pressure on endoscopists to move quickly through patient lists, may lead to less strict adherence to the Seattle Protocol. In Scotland, this has led to policy changes and surveillance endoscopies becoming much more thorough. Pan-oesophageal sampling by capsule sponge may reduce this variation in both reflux investigation and surveillance, leading to higher consistency and less missed pathology, since a positive sponge indicates to the endoscopist that there is a 50% likelihood of significant pathology in the symptomatic patient. Urgent endoscopies arising from a positive sponge test lead endoscopists to actively look for pathology rather happening across it.	surveillance strategies described in the literature. The potential for higher consistency or fewer missed pathology cases would be covered by the diagnostic accuracy outcomes.

Section	Consultee/ Commentator	Comments [sic]	Action
		The rate of patients taking up the offer of the procedure in research may differ from the rate in actual clinical practice. This is often a function of the degree of hospital administrative support, and variations in triage practices and education materials shared with patients ahead of clinic.	
	Patient representative	Yes	No action needed.
	Independent Cancer Patients' Voice	The information is accurate and we as a patient organisation are aware of this procedure.	Thank you for your comment. No action needed.
	Medtronic	No further comments	No action needed.
	Durham University	On page 1 of the draft scope reference 7 is quoted as stating that 14,700 diagnoses of oesophageal cancer were recorded in the UK between 2018 and 2020. Please clarify if that is annually or in total over the two years. On page 3 in the paragraph about surveillance; CONSIDER ADDING: The value of current policy of regular endoscopic surveillance of patients with Barrett's oesophagus in the UK, has been called into question in the BOSS study (Barrett's oesophagus Surveillance Study) (refs Old et al 2025 and Deidda et al 2025). This study found that in a population of 3453 patients the surveillance at 2 year intervals was neither effective nor cost effective. This creates a need for alternative and cheaper technologies to identify early cancer in patients with Barrett's Oesophagus 1. Barrett's oesophagus surveillance versus endoscopy at need study (BOSS): a randomized controlled trial	Thank you for your comment. The background information section has been amended to clarify the time period of the quoted data. A reference to the BOSS trial has been added to the scope.

Section	Consultee/ Commentator	Comments [sic]	Action
		O Old, J Jankowski, S Attwood, C Stokes, C Kendall, C Rasdell, ... Gastroenterology 2025 2. Cost-effectiveness of regular surveillance versus endoscopy at need for patients with Barrett's esophagus: economic evaluation alongside the BOSS randomized controlled trial M Deidda, O Old, J Jankowski, S Attwood, C Stokes, C Kendall, C Rasdell, ... Gastroenterology 2025	
Population	NHSE	The two populations need to be considered separately, not only for the indications outlined above, but also because the evidence base for the detection of BO in patients with GORD is very limited. Current pathways are not targeting patients primarily at risk of BO, but for patients with ongoing symptoms of GORD or for patients with dyspepsia. How does detecting BO help the patients symptoms??	Thank you for your comment. The EAG's clinical and economic evidence review, and modelling will distinguish between the different use cases and populations. The appraisal committee's recommendation can also distinguish between the use cases.
	Portsmouth Hospitals University NHS Trust	Suggests could be used for surveillance of patients with low grade dysplasia. This is outside of the remit of this work which is to look at surveillance of patients with Barrett's metaplasia, In the UK patients diagnosed with true LGD will all be offered treatment and ongoing surveillance will be endoscopic. I do not feel this treated subgroup can fit into the remit outlined in the objectives.	Thank you for your comment. The section has been amended to clarify that Barrett's oesophagus with low grade dysplasia is out of scope.
	NHS Lanarkshire	Yes	No action needed.
	Heartburn Cancer UK	With persistent reflux/heartburn symptoms a patient of any age should be considered for the capsule sponge test. We feel that the stipulated 55 years discriminates this younger age group who we as a charity are seeing in increasing numbers.	Thank you for your comment. NICE and other national guidance has prespecified age thresholds because age has been determined as a risk factor. Based on stakeholder feedback, a specific age threshold

Section	Consultee/ Commentator	Comments [sic]	Action
			has been removed from the population definition. If evidence allows, the assessment will include subgroups on people at low or high risk of developing dysplasia or oesophageal adenocarcinoma due to risk factors such as age, sex or family history of oesophageal adenocarcinoma.
	British Oncology Pharmacy Association	Yes	Thank you for your comment. No action needed.
	East and North Herts NHS Teaching Trust	Yes The people with Barretts oesophagus with intestinal metaplasia and any grade dysplasia who are on surveillance	Thank you for your comment. The section has been amended to clarify that capsule sponge tests are considered for the surveillance of Barrett's oesophagus without dysplasia.
	Cyted health Ltd.	The populations seem to be appropriate. Publication of new BSG guidance on who should be referred for routine endoscopy is due for publication in March and may review eligibility. You suggest >55 yrs in the draft. New guidance due out shortly may include different age specific cut offs for men and women referred with GORD. We recommend that you consult BSG for the most appropriate age ranges.	Thank you for your comment. The reference to a specific age threshold has been removed from the population definition. If evidence allows, the assessment will include subgroups on people at low or high risk of developing dysplasia or oesophageal adenocarcinoma due to risk factors such as age, sex or family history of oesophageal adenocarcinoma.

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	Patient representative	Yes	No action needed.
	Head and Neck Cancer UK	Yes	No action needed.
	Independent Cancer Patients' Voice	Yes, but we are seeing many more early onset cancer being diagnosed at late stage so I would consider a population age of 40 rather than 55. Reflux is so often dismissed as not a cancer risk in people under 50 although the symptoms are the same.	Thank you for your comment. The reference to a specific age threshold has been removed from the population definition. If evidence allows, the assessment will include subgroups on people at low or high risk of developing dysplasia or oesophageal adenocarcinoma due to risk factors such as age, sex or family history of oesophageal adenocarcinoma.
	Medtronic	No further comments	No action needed.
	Durham University	Yes	No action needed.
Sub-groups	NHSE	Please see above	No action needed.
	Portsmouth Hospitals University NHS Trust	There is a suggestion of including a high risk sub group with high grade dysplasia. I fundamentally disagree with this. High grade dysplasia invariably progresses to cancer and has to be treated, which will now be an endoscopic treatment. This needs close follow up and capsule sponge is not suitable for follow up in these treated oesophagus. This is clearly and fundamentally outside of the remit here. The numbers of patients in this group are small and their follow	Thank you for your comment. The subgroup has been amended to clarify that it includes people without dysplasia or cancer, but who have risk factors that may increase or decrease the likelihood of

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		up is very different to routine Barrett's surveillance. It is outside of our remit here and remains a research question.	developing high-grade dysplasia or cancer.
	NHS Lanarkshire	These subgroups seem appropriate for consideration based on current literature.	Thank you for your comment. No action needed.
	Heartburn Cancer UK	No comment	No action needed.
	British Oncology Pharmacy Association	I'm not sure I agree that the below subgroup should be considered – due to the listed laboratory return time of 14 days for these capsule sponge tests, being no shorter than an urgent 2 week rule endoscopy request. " • People at a higher risk of high-grade dysplasia or oesophageal adenocarcinoma " Many endoscopy procedures include a H pylori test within the endoscopy, therefore detecting and suggesting H pylori eradication back to the referring clinician (if a H pylori stool antigen test hasn't already been performed). Is there the potential for reduced detection of H pylori if the capsule test becomes more prevalent than endoscopy? Do we need to ask the companies if there is any pipeline development thoughts on adding H pylori detection to their lab analysis??	Thank you for your comment. The subgroup has been amended to clarify that it includes people without dysplasia or cancer, but who have risk factors that may increase or decrease the likelihood of developing high-grade dysplasia or cancer.
	East and North Herts NHS Teaching Trust	Consideration should include benefit in different age groups including younger age groups who have lower risk of Barrett's and cancer but are increasing in incidence of oesophageal cancer in recent years so may evade detection if excluded by age alone Evidence for patients with or without reflux symptoms may need review	Thank you for your comment. The reference to a specific age threshold has been removed from the population definition. If evidence allows, the assessment will include subgroups on people at low or high risk of developing dysplasia or

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			oesophageal adenocarcinoma due to risk factors such as age, sex or family history of oesophageal adenocarcinoma. The use of the technology in people without reflux is out of scope for this assessment.
	Cyted Health Ltd.	The evaluation should consider gender as an appropriate sub population within those listed. Men are 4-5 times more likely to have disease compared to women. Age cut-offs may differ for men and women for investigations of reflux symptoms in patients with GORD.	Thank you for your comment. The reference to a specific age threshold has been removed from the population definition. If evidence allows, the assessment will include subgroups on people at low or high risk of developing dysplasia or oesophageal adenocarcinoma due to risk factors such as age, sex or family history of oesophageal adenocarcinoma.
	Independent Cancer Patients' Voice	This will certainly be a simple and cost effective early diagnosis of a younger population who are struggling with reflux.	Thank you for your comment. The reference to a specific age threshold has been removed from the population definition. If evidence allows, the assessment will include subgroups on people at low or high risk of developing dysplasia or oesophageal adenocarcinoma due to risk factors such as age, sex or family history of oesophageal adenocarcinoma.
	Medtronic	No further comments	No action needed.

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	Durham University	Currently endoscopic surveillance is limited to patients over 55 years. If a cheaper technology such a Capsule sponge is effective it might be applied to patient at risk, but at an earlier age. Detecting and treating younger patients gives greater opportunity to effect more quality of life years survival than detecting cancer in older populations. Due to a decreased incidence in younger patients a cheaper screening method than endoscopy needs to be tested.	Thank you for your comment. The reference to a specific age threshold has been removed from the population definition. If evidence allows, the assessment will include subgroups on people at low or high risk of developing dysplasia or oesophageal adenocarcinoma due to risk factors such as age, sex or family history of oesophageal adenocarcinoma.
Comparators	NHSE	I think you should also consider Trans-nasal endoscopy for the initial detection of BO. (but it is not an appropriate comparator for the surveillance of BO)	Thank you for your comment. The scope has been updated to include a reference to transnasal endoscopy. Expert feedback has been that it is not widely used in the NHS, and therefore it has not been included as a comparator.
	Portsmouth Hospitals University NHS Trust	Completely correct.	Thank you for your comment. No action needed.
	NHS Lanarkshire	This seems appropriate although it may be useful to add a comment about “following Seattle protocol biopsies” in the context of Barrett’s endoscopy.	Thank you for your comment. The section has been amended to clarify the appropriate sampling protocol.
	Heartburn Cancer UK	Yes in our opinion	Thank you for your comment. No action needed.

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	British Oncology Pharmacy Association	Yes	Thank you for your comment. No action needed.
	East and North Herts NHS Teaching Trust	Yes	Thank you for your comment. No action needed.
	Cyted Health Ltd.	The comparator is appropriate. Given the lengthy waiting times for routine investigation, many patients are waiting up to 1 year (e.g., 52 weeks in Portsmouth) for a routine endoscopy. The long delay effectively means that patients may in practice receive nothing as the real-world comparator. Timing matters and the published impact on the differences in waiting times between the intervention and comparator may have a significant bearing on outcomes.	Thank you for your comment. No action needed.
	Patient representative	Yes	Thank you for your comment. No action needed.
	Independent Cancer Patients' Voice	Yes, all relevant comparators have been listed and are seen as standard treatments.	Thank you for your comment. No action needed.
	Medtronic	No further comments	No action needed.
	Durham University	Yes	Thank you for your comment. No action needed.
Outcomes	NHSE	Yes they are, but there is no consideration given as to the potential impact of using cytosponge to detect BO and the on-going need for confirmation of the diagnosis and measuring the extent of BO by OGD (or TNE)	Thank you for your comment. The outcome "follow-up non-urgent (routine) endoscopies needed" will capture the impact of using capsule

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			sponge tests on follow-up endoscopy procedures.
	Portsmouth Hospitals University NHS Trust	Good outcome measures	Thank you for your comment. No action needed.
	University of Oxford	All cause mortality should also be considered.	Thank you for your comment. Mortality will be included in the economic model, but is not expected to be an outcome identified in the clinical literature review.
	NHS Lanarkshire	This seems appropriate although it may be useful to add a comment about “following Seattle protocol biopsies” in the context of Barrett’s endoscopy.	Thank you for your comment. The section has been amended to clarify the appropriate sampling protocol.
	University of Cambridge	For dysplasia/cancer the p53 and atypia should be considered together as they are not intended to be evaluated separately. The clinical risk factors for moderate risk should also be evaluated. Moderate + High risk should catch all dysplasia and cancer in an ideal world. Procedure uptake will be different when offered for research versus in a clinical setting	Thank you for your comment. The outcome has been amended to ensure accuracy with regards to the interpretation of biomarkers.
	Heartburn Cancer UK	The comments that we have responded to under population cover this section.	Thank you for your comment. No action needed.
	British Oncology Pharmacy Association	I would add “procedure delayed due to concurrent medication issue” e.g. patient not temporarily discontinuing/being advised to temporarily	Thank you for your comment. The outcome “procedure uptake” has already been included in the

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		discontinue anticoagulant medication ahead of procedure, leading to capsule test procedure being cancelled/delayed. I would include this as a separate outcome measure of its own, separate to simply including in amongst “adverse events” as this issue undoubtedly leads to many investigation delays and is often not captured in data. Possibly an outcome within use of resources, breaking down where the laboratory results are sent back to – e.g. secondary care, general practice, community hubs, community pharmacy, etc. If eventually rolling out in community pharmacy, a barrier is often pharmacists not having access to clinical repositories to see and act on results. This is a potential barrier to implementation of this service more broadly across boundaries, and may be useful to include as a thought from the outset. Further to this, clarification would be needed on the clinical responsibility of follow-up, as the majority of community pharmacy-based diagnostics lead to transfer of clinical responsibility at the point of testing/referral.	scope to capture the extent of uptake of capsule sponge tests subject to evidence availability. This assessment will not investigate the use of capsule sponge tests without a GP referral. Therefore, self-referral or proactive screening in settings such as community pharmacies will not be included.
	East and North Herts NHS Teaching Trust	Reduction in all endoscopy waiting times as technology may free up endoscopy time that may impact colonoscopy and other endoscopic procedures as well potentially freeing up endoscopist, nursing and endoscopy suite capacity-this should be considered in cost evaluation Patient preference for capsule sponge or endoscopy should be considered in the barretts surveillance group (the case finding group may not have had a previous endoscopy for comparison)	Thank you for your comment. NICE and the appraisal committee will consider the potential impact of using the capsule sponge test on endoscopy waiting times. If data are available, the external assessment group (EAG) will include this in the economic evaluation. The proposed methodology will be described in the

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			EAG's protocol and assessment report.
	Cyted Health Ltd.	These seem appropriate.	Thank you for your comment. No action needed.
	Patient representative	Yes	Thank you for your comment. No action needed.
	Independent Cancer Patients' Voice	The outcomes listed are appropriate, and will be acceptable to and welcomed by patients, this this a early diagnostic tool to enable further in-depth procedures if anything is found.	Thank you for your comment. No action needed.
	Medtronic	No further comments	No action needed.
	Durham University	Yes	Thank you for your comment. No action needed.
Equality	Portsmouth Hospitals University NHS Trust	I do not see any issues here. I think the authors have done a good job at clearly stating the highest risk groups here and I think all reasonable measures have been taken to consider inclusion. The only suggestion I would make here is that there could be more emphasis on examining impact across socio-economic groups. There are clear differences in health care seeking behaviour between the least and most deprived sectors of society and sadly this is reflected in cancer mortality data. Would be very interesting to see if capsule sponge could increase compliance in Barrett's surveillance in the post deprived groups and would be worth considering in the technology appraisal.	Thank you for your comment. The potential impact of socioeconomic deprivation has been noted in the equality impact assessment for scoping. The scope has been updated to include socioeconomic status as a risk factor. If evidence allows, the assessment will include subgroups on people at low or high risk of developing dysplasia or oesophageal adenocarcinoma due to risk factors such as socioeconomic status.
	NHS Lanarkshire	No further comments	No action needed.

Section	Consultee/ Commentator	Comments [sic]	Action
	Heartburn Cancer UK	We have commented on what we feel is the discrimination of the younger population ie below 55 with the right symptoms which are not necessarily alarm symptoms.	Thank you for your comment. The reference to a specific age threshold has been removed from the population definition. If evidence allows, the assessment will include subgroups on people at low or high risk of developing dysplasia or oesophageal adenocarcinoma due to risk factors such as age, sex or family history of oesophageal adenocarcinoma.
	British Oncology Pharmacy Association	Consideration of suitability of this technology to roll out in community settings closer to patient's homes is required, per NHS 10-year plan of making more care available closer to home.	Thank you for your comment. The scope has been amended to clarify that providing care closer to the home is among the priorities of the 10 Year Health Plan for England.
	East and North Herts NHS Teaching Trust	The technology which may be delivered in any low tech setting including residential facilities, prisons , pharmacies etc may potentially improve access as able to deliver in communities outside secondary care to include diverse populations that traditionally may be exclude and these could be considered as a subgroup	Thank you for your comment. The scope specifies that capsule sponge tests can be used in the community care setting. No action needed.
	Cyted Health Ltd.	We have already mentioned the need to consider 'place' for delivery of the intervention, particularly in disadvantaged segments of the population. Patients who present to their GP are more likely to be affluent, female and relatively young, while incidence of serious disease is predominantly in older men who often don't present to their GP.	Thank you for your comment. The scope has been amended to clarify that socioeconomic deprivation may impact access to healthcare and rates of health literacy.

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		Oesophageal cancer may disproportionately affect less affluent patients and those from populations who have less access to medical education. The draft should include some narrative on these topics.	
	Patient representative	fine	Thank you for your comment. No action needed.
	Head and Neck Cancer UK	No changes required	Thank you for your comment. No action needed.
	Independent Cancer Patients' Voice	Although the risk of Barrett's and possible cancer is most common in older people, men and white, as a patient support network we are seeing more younger patients and women being diagnosed, women especially seem to diagnosed with squamous cell cancer in the Oesophagus rather than the common adenocarcinoma at the junction for older men. The UK has a large Asian community and we know that they are also predominantly diagnosed with squamous cell cancer.	Thank you for your comment. The reference to a specific age threshold has been removed from the population definition. If evidence allows, the assessment will include subgroups on people at low or high risk of developing dysplasia or oesophageal adenocarcinoma due to risk factors such as age, sex or family history of oesophageal adenocarcinoma.
	Medtronic	No further comments	No action needed.
	Durham University	The application of this study in different populations is adequately considered	Thank you for your comment. No action needed.
Other consider ations	NHSE	The evaluation should also consider how BO surveillance can be improved by concentrating skills and resources in centres of excellence	Thank you for your comment. Providing recommendations on service organisation is outside the remit of this assessment. NICE will engage with NHS England and other stakeholders regarding the

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			implementation of capsule sponge tests in the NHS.
	Portsmouth Hospitals University NHS Trust	I think this is a broad enough remit and would not extend it any further. One of the issues that needs to be considered in the case finding component of the work (i.e. investigation of reflux) is cost effectiveness. It is possible many clinicians referring for investigation of reflux are also expecting the stomach and 1st part of duodenum to be examined to exclude pathology. Risk that patients will therefore end up undergoing capsule sponge followed by a gastroscopy anyway. Numbers need to be evaluated where this may occur and how this effects the overall economic benefits. What the likely miss rate from missed gastric and duodenal pathology, particularly cancer, needs to be reviewed for this group.	Thank you for your comment. The outcome "follow-up non-urgent (routine) endoscopies needed" has been included to assess whether evidence exists regarding the extent of use of any non-urgent, follow-up endoscopy following a capsule sponge test. Those cases will also be included in the EAG's economic model when investigating the cost-effectiveness of the technology.
	NHS Lanarkshire	No further comments	No action needed.
	Patient representative	Under Patient Preferences perhaps consider that some patients find endoscopies very unpleasant and will avoid them if possible. Such patients with long-term GORD and a high potential for developing Barrett's Oesophagus/high grade dysplasia could benefit from the much less intimidating and invasive Cytosponge test.	Thank you for your comment. The section has been amended to clarify that some people may altogether avoid an upper GI endoscopy procedure.
	British Oncology Pharmacy Association	If this was being rolled out in community pharmacies or community hubs in future, how will the laboratory results be returned and to whom? Will community pharmacist prescribers be expected to act on and issue PPIs, etc, or will this then generate referrals into General Practice, for them to act on a test they haven't requested? Re Training: is the technology being evaluated to decide whether it is restricted for specific health professional usage, or can be administered by suitably trained individuals (i.e. assistant roles under	Thank you for your comment. Providing recommendations about service organisation is beyond the scope of this assessment. NICE will engage with NHS England and other stakeholders to explore the need to provide support regarding the implementation of capsule sponge tests in the NHS.

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		supervision), to improve targeted usage of this technology in community settings?	
	East and North Herts NHS Teaching Trust	Please note Anticoagulants/ antithrombotics do not need to be stopped prior to capsule sponge in contrast to endoscopy- this is an increasingly large group of patient and a potential advantage that should be considered	Thank you for your comment. The reference to contraindications based on use of anticoagulants and antithrombotics is based on information supplied by the companies.
	Cyted Health Ltd.	None	No action needed.
	Patient representative	None	No action needed.
	Independent Cancer Patients' Voice	I have already mention the increase of early onset cancers.	Thank you for your comment. No action needed.
	Medtronic	No further comments	No action needed.
Questions for consultation	NHSE	The Title should be limited to the use of Cytosponge for the management of BO surveillance	Thank you for your comment. The detection use case was included in the assessment following feedback from multiple stakeholders that this should be considered and evaluated by NICE.
	Cyted Health Ltd.	None	No action needed.
	Medtronic	No further comments	No action needed.
Additional	NHSE	Please see the attached editorial. We shouldn't be looking for BO in the first instance if we are not confident that surveillance helps	Thank you for your comment. The detection use case was included in

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comments on the draft scope		patients and is affordable. The rate of progression from BO to OAC has been overestimated previously	the assessment following feedback from multiple stakeholders that this should be considered and evaluated by NICE. A reference to the BOSS trial has been included for information.
	Gauis Richard Longcroft – Wheatcroft	Overall the draft scope is very good.	Thank you for your comment. No action needed.
	University of Cambridge	The revised scope is better	Thank you for your comment. No action needed.
	Heartburn Cancer UK	Widely available use of capsule sponge device across the population irrespective of age but with persistent GORD would make significant difference to curative outcomes	Thank you for your comment. No action needed.
	West Suffolk NHS Foundation Trust	Thank you. This document accurately reflects the discussion we had at the scoping meeting last year.	Thank you for your comment. No action needed.
	British Oncology Pharmacy Association	EndoSign mention a contraindication for “people on anti-thrombotic drugs which cannot be temporarily discontinued before and after the procedure”. I think significant clarification is needed on what they mean by this, and how this advice would work practically in real world patients. Many elderly patients are on anticoagulation, and endoscopy pathways often have consistent guidance for patients who are advised to temporarily suspend their anticoagulant medication for example 24 hours before and after the procedure. I think that robust advice is needed here, to prevent large numbers of patients presenting for their capsule test to then be turned away and potentially returned back into the endoscopy pathway experiencing further delays, creating inefficiencies in the system rather than streamlining it.	Thank you for your comment. Providing recommendations about service organisation is beyond the scope of this assessment.

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	Cyted health Ltd.	None	No action needed.
	Patient representative	I am happy with the document. In particular,I am happy about the target population characteristics including the age. I think appropriate at this stage to consider the most at risk.	Thank you for your comment. The subgroups section has been amended to specify a subgroup based on differing risk of developing pathology.
	Medtronic	Medtronic would like to address the comment: *"There is no publicly available information on the number of sites in England that use Cytosponge and whether the company provides any training to healthcare professionals administering the technology."* • Over the last 24 months 6 sites have used Cytosponge • 58 sites have been trained to use the Cytosponge device over the last 5 years • All NHS Pilot sites used Cytosponge throughout the pilot A pan UK train the trainer programme delivered by Medtronic clinical education team was set-up at the time of the pilot, at a site level. Each of these sites (>50) were visited by nurse trainers. All training is now managed by our team of Clinical Education Managers. Medtronic have a training pathway for Cytosponge users across the UK.	Thank you for your comment. The section of the scope has been amended to include this information.

The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope

British Society of Gastrointestinal and Abdominal Radiology (BSGAR)
Wales Cancer Network NHS Wales
Guts UK Charity
Joint response from Cardiff and Vale University Health Board, National Endoscopy Programme for Wales and NHS Wales Cancer Recovery Programme