NHS England Capsule Sponge Programme – BSG Webinar

Frequently Asked Questions

V 3.0 – 18 March 2024

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1.0	Initial draft	Kris Foerster	-	-
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Introduction

These Frequently Asked Questions (FAQs) were developed following the British Society of Gastroenterology (BSG) NHS England (NHSE) webinar hosted on 17 January 2024. You can watch a recording here.

These FAQs are in response to specific questions that were asked at the webinar and will not be updated. The questions and answers should be treated with caution if using beyond 31 March 2024 (the end date of the NHS England national pilot).

Section 1: Clinical

1. **What is the patient cohort and what do you mean by routine reflux?**
   NHS England explored the implementation of capsule sponge in three settings (patient cohorts):
   a) Diagnosis of Barrett's Oesophagus
   b) Surveillance of Barrett's Oesophagus
   c) Two-week wait referral pathway (prioritising patients for cancer)

   A comprehensive assessment and consultation process was completed to assess the evidence and impact of these use cases. A decision was made to set-up a pilot for patients on a routine referral to secondary care with reflux symptoms to prioritise patients most at risk of developing cancer by identifying patients with Barrett's Oesophagus.

   NHS England set up an Oversight Group who developed clinical guidance for the pilot. The patient cohort was defined as '*patient referred with reflux symptoms with no alarm symptoms by general practitioners to secondary care on an upper GI endoscopy pathway.*'

   The inclusion criteria is patients with symptoms of reflux including heartburn, regurgitation, and waterbrash.

   The exclusion criteria outlined a number of absolute contraindications and specifically included alarm symptoms such as dysphagia, dyspepsia and weight loss, and dyspepsia and anaemia.

   The clinical guidance has not been published nationally as it is only intended to support the national pilot programme. Local providers will need to develop their own clinical guidance from 1 April 2024.

2. **Were there any complications, risks, or adverse events, including missed cancers?**
   There were no adverse events reported during the evaluation period of the NHS England pilot (March 2021 – March 2022), however two adverse events were reported during the NHS England pilot period (March 2021 – March 2024). Over 8,500 procedures were completed between March 2021 and March 2024.

The adverse events were managed in accordance with the NHS England risk escalation policy and local NHS trust policy, with oversight from the NHS England National Clinical Director for Cancer and the NHS England Cytosponge Oversight Group.

The two events were:

a) Sponge detachments: on 5 June 2023, a safety recall was issued by Medtronic due to reported sponge detachments. Sponge detachments are not life-threatening and there was no significant harm to any patients. The safety recall threshold was not reached; however a recall was taken as a precautionary approach. Medtronic completed an investigation of the detachments and process improvements were made. The devices were reissued in October 2023 and no further reports have been made.

b) Missed cancer: on 4 September 2023, a missed cancer incident was reported by an NHS Trust. The missed cancer was due to an incorrect pathology report due to a moderately difficult diagnosis, conducted by Cyted. Cyted completed an audit of similar cases with no other adverse findings and implemented new reporting procedures. No further reports have been made.

3. **How are patients with negative results being managed? What are the safety-netting procedures and is there any indication of re-referral rates for patients?**
The safety-netting procedures vary by NHS trust. These procedures range from a six-month follow-up for all patients who received a negative capsule sponge result to patient discharge letters informing patients of symptoms that require further investigation and information on when to present back to a GP.

Although a long-term follow-up has not be completed, the evaluation demonstrated that patients who received a negative capsule sponge result and were referred for an onward endoscopy did not receive a Barrett's Oesophagus diagnosis. The majority of these patients did not have any diagnosis, and for those with a diagnosis, the majority had hiatus hernia or inflammation.

Long-term follow-up (up to three years in some sites) is being reviewed and will be reported by individual sites.

4. **What is the most appropriate setting for the capsule sponge test (e.g., primary care, secondary care)?**
There is not enough real-world evidence to assess the most appropriate setting for the capsule sponge test in the NHS.

The evidence from the NHS England pilot demonstrates a case for use in secondary care and NHS England is funding a pilot in primary care, which is expected to conclude in late 2024.

5. **If capsule sponge is used in primary care, how is access to urgent OGD managed?**
   An urgent OGD is extremely rare. Local procedures will need to be agreed to ensure access to an urgent OGD is managed within the required timeframes. For example, patients who require retrieval of a device will need an endoscopy within four to six hours via emergency endoscopy in secondary care.

6. **Is any histopathology upskilling required?**
   The pathology is currently procured through Cyted, who use specially trained pathologists to read the samples. Some training would be required to support new pathologists to read, report and process on specific biomarkers.

7. **Is there any evidence that the natural history of oesophageal cancer can be altered with capsule sponge?**
   The NHS England pilot was not designed to assess this.

   The BEST4 randomised control trial, which started earlier this year, will explore this.

8. **How long is each capsule sponge appointment?**
   On average, a typical capsule sponge appointment is 15-20 minutes.

9. **How is capsule sponge explained to patients? Are patients informed that capsule sponge is different to OGD and is it likely to influence their choice and satisfaction?**
   Patients received information on the capsule sponge procedure from a nurse and a patient information leaflet.

   The nurses used a telephone triage script to offer patients the test which explained the procedure including how the test is performed (pill on a string, dissolves in stomach, nurse removes the sponge by pulling the string and the sponge collects cells from the lining of the oesophagus). The patients could accept or decline the offer.

   Patients were also provided with a patient information leaflet before their appointment (via email) or before their test (at clinic). The patient information leaflet provided details on the capsule sponge test and why a patient might need one, how to prepare for a test, what to expect during the test, what happens after the test, the risks of the tests, and the alternatives to the test.

   The evaluation assessed patient experience through patient surveys (n=352 respondents) and patient interviews (n=28) and found that:
   - 99% of patients understood the explanation of the capsule sponge test.
   - 98% of patients were satisfied with the explanation given by the person carrying out the capsule sponge test.
   - 86% of patients understood what would happen after the capsule sponge test.
   - 95% of patients understood why a capsule sponge test was offered.

- 90% of patients felt they had enough time to discuss the capsule sponge test with a healthcare professional.
- 92% of patients were offered a patient information leaflet.
- 92% of patients found the leaflet useful to read.
- 83% of patients did not have any questions about the test after reading it.
- 38% of patients were told they would be removed from the endoscopy waiting list once agreeing to a capsule sponge test. 22% did not remember.

A number of reasons for the positive levels of patient satisfaction included:

- Capsule sponge is less invasive than endoscopy.
- Patients were reassured by the results because it scrapes cells rather than visually assessing.
- Timeliness and speed of attaining their appointment and receiving a result, and the duration of the procedure itself.

Section 2: Evaluation

1. **Where can I access the published report?**
   The report is available by contacting england.cancerpolicy@nhs.net or on the BSG website.

2. **How many years follow-up has been completed? How many patients are re-referred and does this impact the cost-effectiveness?**
   The evaluation collected data from patients who participated in the pilot between March 2021 and March 2022. A minimum of three-month follow-up data was collected for all patients, although this is longer for patients who were seen at the start of the pilot (i.e., a patient who completed a test in March 2021 would have follow-up data for up to 15 months, compared to a patient who completed a test in March 2022 who would have follow-up data for three months). However, this is limited to patients who would have re-presented to the same NHS trust as long-term follow-up data linkage did not form part of this evaluation.

   NHS England is currently undertaking a project to link data which would enable long-term follow-up for all patients. This work is not yet complete and a commission to analyse the long-term data has been made.

3. **When will the Barrett's surveillance evaluation be published and will any long-term follow-up be conducted?**
   A combined analysis for DELTA and NHS England surveillance cohort is ongoing and is expected to complete the data collection and analysis by the autumn 2024.

Section 3: Commissioning

1. **Will there be national guidance (e.g., NICE, BSG) published to support with local commissioning (after the pilot has concluded)?**
   The British Society of Gastroenterology (BSG) are working with the Joint Advisory Group on GI Endoscopy (JAG) and NHS Scotland to develop guidance. There is currently no timeline for when the guidance will be developed and published.

   The evaluation report has been shared with the NICE guidelines team and they are investigating whether there is a possibility to amend any guidance.

2. **What is the estimated average savings per trust?**
   The average savings per trust will vary based on local services and was not analysed as part of the national evaluation. The national evaluation determined a £421 per-patient cost saving. The key drivers of this figure are the cost of an endoscopy compared with the cost of a capsule sponge device and pathology. Trusts can use the data and analysis in the evaluation report to inform their own cost-savings.

3. **How should capsule sponge be commissioned following the NHS England pilot?**
   Capsule sponge services will be commissioned locally from 1 April 2024. There will be no national targeted funding.

   Trusts should engage with their regional Cancer Alliance to explore local commissioning arrangements. Cancer Alliances can:
   a) Support writing business cases
   b) Provide funding to support continuation of services
   c) Explore other funding options

   The support provided by Cancer Alliances will vary based on local needs and priorities. A list of Cancer Alliances and contact details can be found here. Cancer Alliances also have access to implementation resources via NHS Futures (please note this is a closed group and access to resources will need to be obtained via a Cancer Alliance).

4. **Where can I find more information about using the capsule sponge in Community Diagnostic Hubs?**
   There are many ways to obtain more information about Community Diagnostic Hubs:
   - Contact england.cdcprogramme@nhs.net
   - Engage with your Regional Endoscopy Lead
   - Engage with your Regional Diagnostic Team
   - Engage with your Cancer Alliance

Section 4: Other

1. **Is the capsule sponge procedure recorded in trust endoscopy systems? Does the pathology report reach the trust ERP?**
   This will vary by trust depending on reporting systems.

2. **Can capsule sponge be recorded in secondary care?**
   There are two ways to record capsule sponge in healthcare systems:
   a) OPCS-4.10 code: G21.6 – Cytology of oesophagus using ingestible sponge
   b) SNOMED code: 1202027002 |Collection of esophageal cells via swallowable cell collection sponge in capsule (procedure)|

3. **Is the capsule sponge biodegradable or recyclable? What is the cost of waste disposal?**
   The EndoSign device (sponge and thread) is clinical waste and is disposed of accordingly. The EndoSign applicator is recyclable and NHS partners can either use local recycling facilities or a Cyted collection scheme (expected in Q2 2024). For more information, please contact hello@cyted.ai.

   The Cytosponge device (sponge and thread) is considered clinical waste and is disposed of accordingly (it is not biodegradable). The box and IFU are biodegradable. For more information, please contact rs.csukiecustomercare@medtronic.com.

4. **How does this pilot and evaluation align with the service in Scotland?**
   A capsule sponge programme has been instituted across Scotland since September 2020 in the secondary care setting, with the same indications of symptomatic reflux and screening of known Barrett's oesophagus. Complications, risks, and adverse events are in line with the England pilot data. The Scotland programme sought to gain as much learning as possible through an internal evaluation, and the results will be published as follow-up time for patients increases. (Siobhan Chien, et al for CytoSCOT group. National adoption of an esophageal cell collection device for Barrett's esophagus surveillance: impact on delay to investigation and pathological findings, Diseases of the Esophagus, 2024)