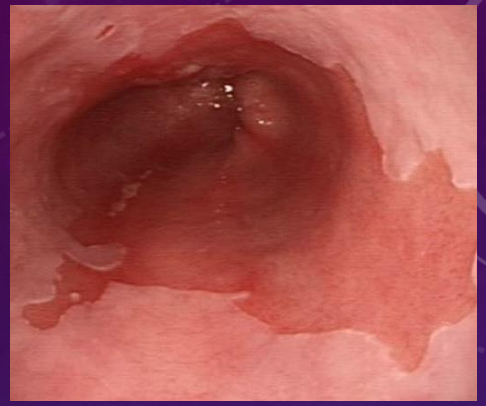


EVALUATING OUTCOMES IN PATIENTS WITH ACID RELATED UPPER GI SYMPTOMS AND IMPLICATIONS FOR THE SET-UP OF A LOCAL CAPSULE SPONGE INVESTIGATIVE PATHWAY

NEIL HAWKES & RHIANNON BOWEN

ENDOSCOPY DEPARTMENT, ROYAL GLAMORGAN HOSPITAL

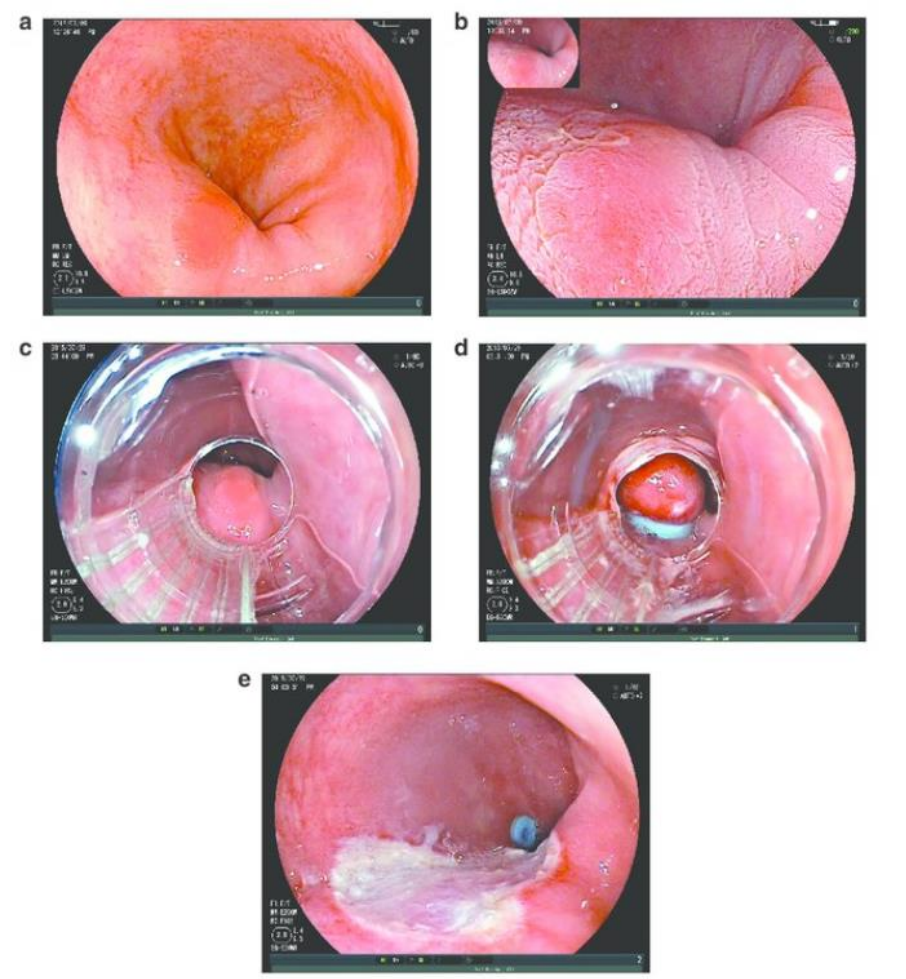
OUTLINE OF PRESENTATION

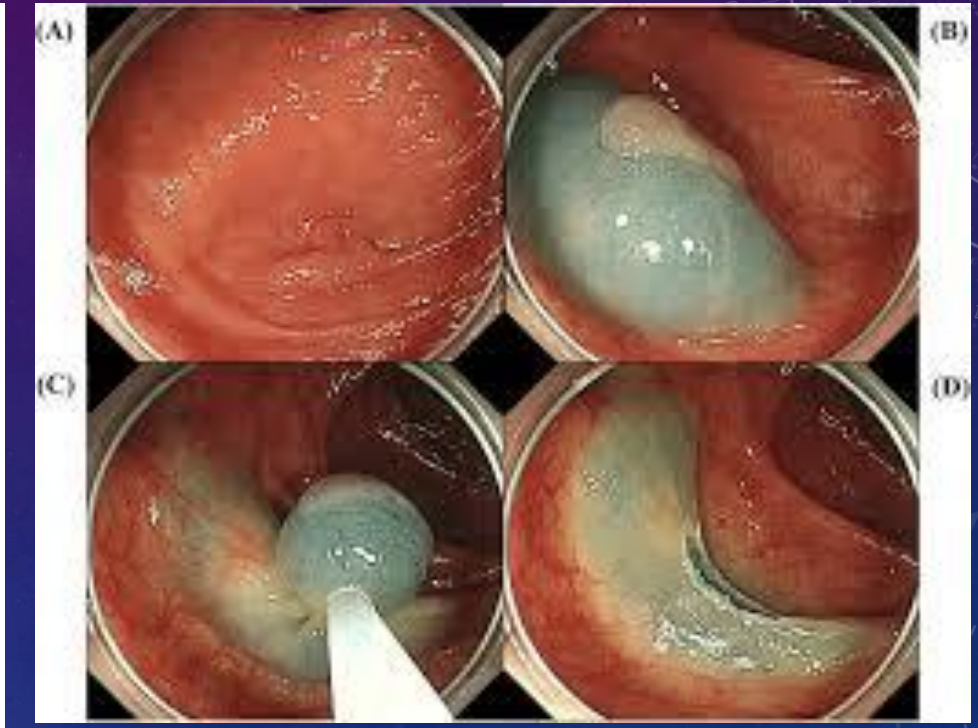
GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Cwm Taf Morgannwg University Health Board

- Demand for endoscopy services
- Potential of using Cytosponge within upper GI patient pathways
- Service evaluation to inform selection of patients for Cytosponge testing
- Learning from our findings to implement a local Cytosponge service

ENDOSCOPY - AN EFFECTIVE DIAGNOSTIC AND THERAPEUTIC TOOL

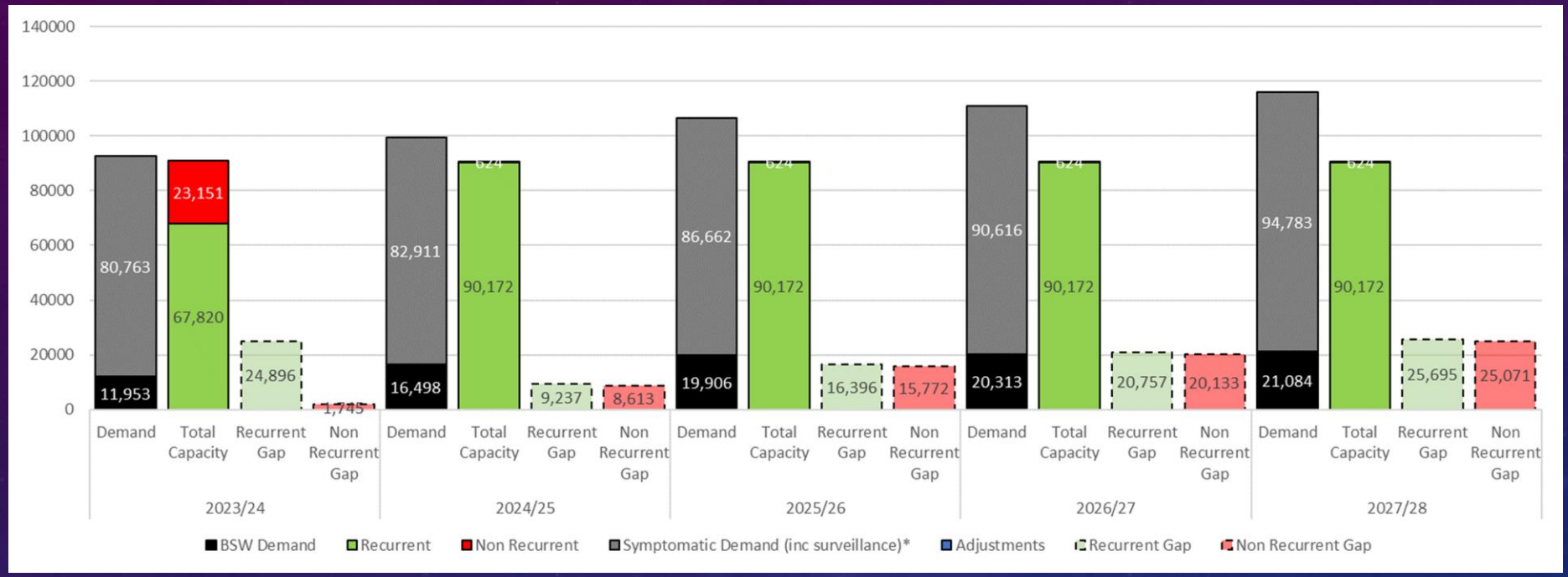
UPPER GI TRACT
Resection of high grade dysplasia in a Barrett's segment



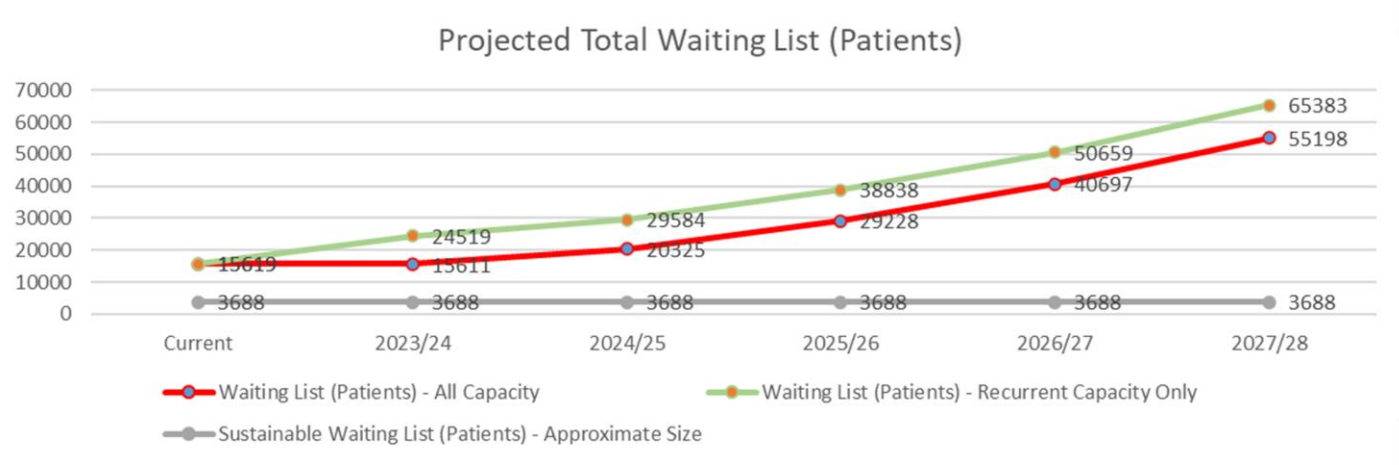


LOWER GI TRACT
Resection of a dysplastic polyp in the colon using Endoscopic Mucosal Resection technique

Demand for endoscopy is increasing



Source: Health Board submitted Endoscopy D&C Models via NEP – October 2023



2027/28 points	D& C "Balance"	Backlog (one time)
Recurrent	25695 points	107688 points
Non-Recurrent	25071 points	90151 points

2027/28 lists	D& C "Balance"	Backlog (one time)
Recurrent	50 lists p/wk	10769 Total Lists
Non-Recurrent	49 lists p/wk	9016 Total Lists

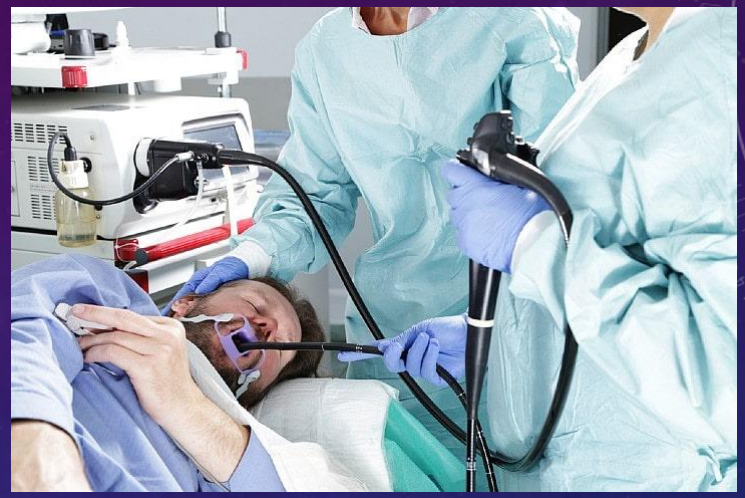
@10 points per list per week

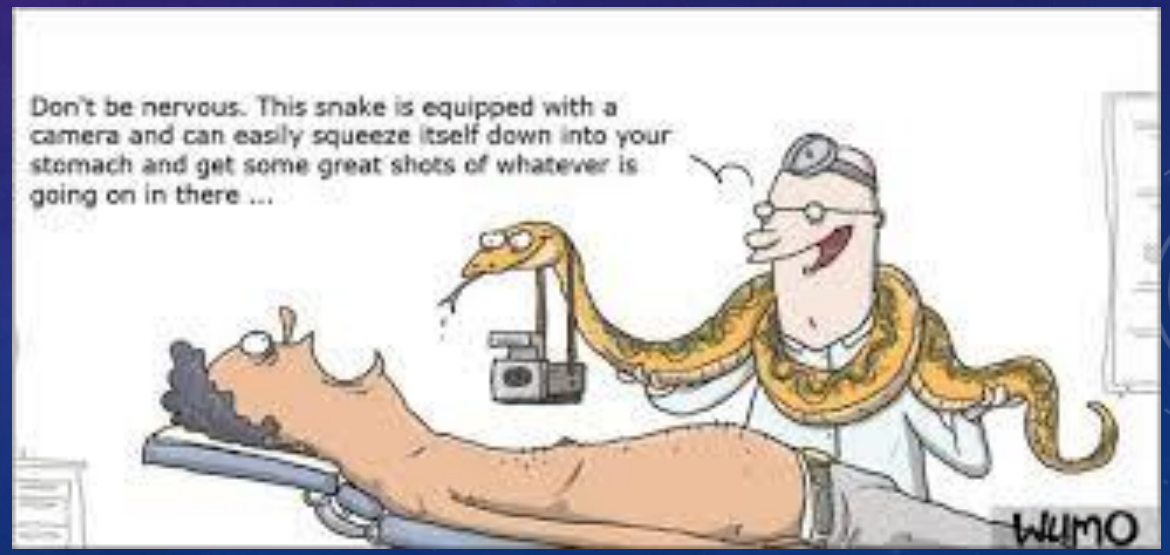
2027/28 rooms	D& C "Balance"	
Recurrent	6.3 rooms	*Backlog is circa 104 lists per week over 2 years*
Non-Recurrent	6.1 rooms	*Backlog is circa 87 lists per week over 2 years*

@8 lists per week

THE PATIENT'S PERSPECTIVE

- Invasive test
- Stories from friends and relatives
- 'Will I be able to breath'
- 'How do I swallow that thing?'
- Fear of doctors
- Fear of hospitals
- Balanced against need to know

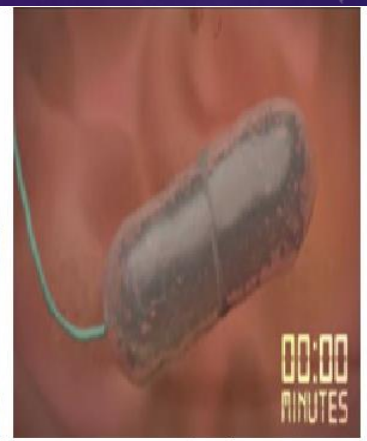




WHAT IS CYTOSPONGE?

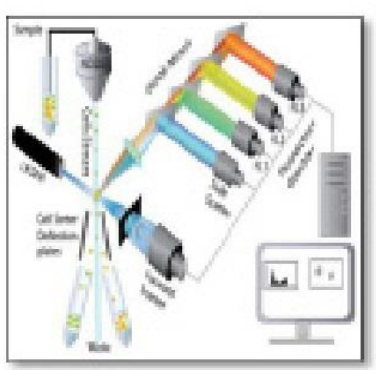
- ‘Brillo pad on a string’
- Nurse-led outpatient service
- Perform in any clinic room
- Quick and minimally invasive
- Minor discomfort reported
- Most patients tolerate well
- 1:1000 risk of sponge detachment

Pill swallowed by patient

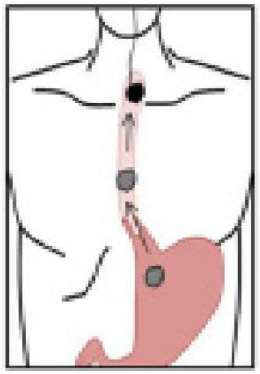


Cytosponge in the GIT

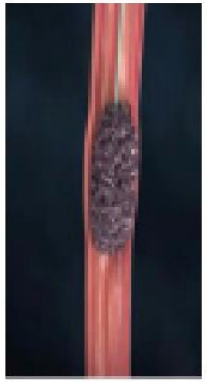
Gelatin shell dissolves

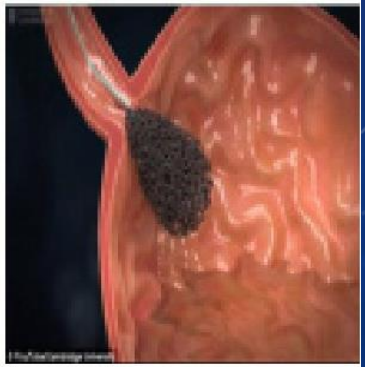


Analysis of cells collected



Cytosponge pulled back





after 5mins

WHY MIGHT CYTOSPONGE BE USEFUL?

- There is a direct relation between reflux and adenocarcinoma of the oesophagus[1]
- Barrett's oesophagus, a premalignant transformation of the oesophageal mucosa, links the causal pathway from reflux to cancer
- Cytosponge gains cytological samples from the GO junction and oesophagus - when combined with TFF3 immunochemistry has high sensitivity and specificity for detecting Barrett's oesophagus[2]
- Cytosponge provides a cost-effective alternative to endoscopy[2]
- A retrospective, multi-centre, cross-sectional study has demonstrated cytosponge atypia, p53 overexpression, and clinical risk factors (age, sex, and segment length) can be effectively used to prioritise patients for endoscopy[3]
- Validation studies using Cytosponge in clinical practice point to the potential for substantial reduction (>70%) in endoscopy procedures compared with current surveillance pathways[4-6]

1. Lagergren et al. Gut 2004;53:1064–1065. 2. Paterson et al. Histopathology 2017, 70, 203–210. 3. Pilonis et al. Lancet Oncol 2022; 23: 270–78 4. Cancer research UK, early diagnosis hub 2023. 5. IQVIA NHSE Cytosponge Final Report 2023. 6. Scottish Health Technologies Group Assessment – Cytosponge. Nov 2023.

KEY QUESTIONS FOR OUR SERVICE EVALUATION

1. Which patients in CTMUHB should we select for evaluation with Cytosponge?
2. What are the safety considerations within our population?
3. How many patients would a new Cytosponge pathway be applicable to?

AIMS

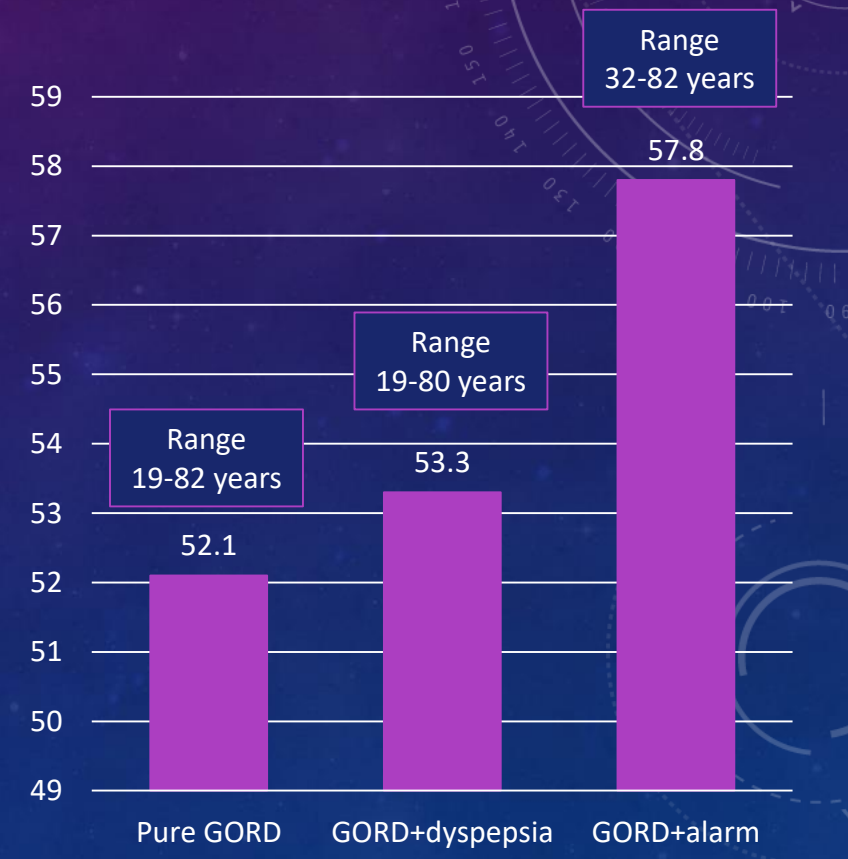
- Determine the frequency and demographics of patients with GORD (reflux) symptoms associated with one of three distinctive symptom patterns;
  I. ‘Pure’ acid reflux symptoms (heartburn)
  II. Acid reflux combined with dyspeptic symptoms (e.g. abdominal pain, bloating)
  III. Reflux with dysphagia or alarm symptoms (e.g. weight loss, anaemia)
- Assess the proportion of significant endoscopic and histological findings in each group.

METHODS

- EMS endoscopic database used to find all patients attending for upper GI endoscopy from 1 January to 31 March 2024 (Royal Glamorgan and Prince Charles Hospital)
- Documented referral symptoms used to categorise patients into one of three groups: 1) pure GORD, 2) GORD with dyspepsia, 3) GORD with dysphagia or alarm symptoms
- Endoscopic, histological and relevant radiological investigations were reviewed to evaluate whether there were significant investigative findings
- Significant pathology was defined as - presence of cancer, dysplasia, peptic ulceration, GORD grade C or D, peptic stricture or oesophageal ulceration
- Presence or absence of a Barrett's segment was also noted
- Differences in the proportion of significant findings between groups were assessed using Chi-Squared test, with significance value set at $p<0.05$.

RESULTS – DEMOGRAPHICS

- 1499 patients attended for upper GI endoscopy during the study period
- 67 (4.5%) had pure GORD
- 73 (4.9%) had GORD plus dyspepsia
- 44 (2.9%) GORD plus dysphagia or alarm symptoms
- Male:Female ratios: pure GORD 23M:44F; GORD plus dyspepsia 32M:41F; GORD plus alarm 22M:22F
- The dysphagia/alarm symptom group had a higher mean age at the time of endoscopy 57.8 years compared to the other groups (pure GORD 52.1 and GORD plus dyspepsia 53.3 years).



Mean age and age range of patients in the 3 groups

RESULTS – ENDOSCOPIC AND HISTOLOGICAL FINDINGS

- A higher proportion of significant pathology was found in the GORD plus dysphagia or alarm group ($p<0.00001$)
- Malignant disease was only identified in this group.
- No significant different in significant pathology between the pure GORD and GORD plus dyspepsia groups.
- Rates of significant findings very low in patients under 50 years without dysphagia or alarm symptoms
- GORD plus dyspepsia group were more likely to have gastroduodenal pathology
- 4/67 (6%) of patients in the pure GORD group had endoscopically and histologically confirmed Barrett's segments, compared to 0/73 (0%) of patients in the GORD-dyspepsia group ($p<0.01$)

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	Pure GORD	GORD+ dyspepsia	GORD+alarm
Barrett's	4**	0	0
Advanced GORD	3	0	4
Adenoma	1	1	0
Gastric ulcer	0	0	1
Coeliac disease	0	0	1
GIST	0	0	1
ACA	0	0	1
Oesophageal candidiasis	0	0	2
% significant findings	**5.9%**	**1.4%**	**22.7%****

WHAT HAS BEEN LEARNT?

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Which patients in CTMUHB should we select for evaluation with Cytosponge?

- Patients with 'pure' GORD (reflux) symptoms and surveillance of patients with known Barrett's
- We did not detect any Barrett's in patients with GORD plus dyspepsia symptom profile

What are the safety considerations within our population?

- True dysphagia and/or alarm symptoms are risk factors for cancer – refer for early endoscopy

How many patients would a new Cytosponge pathway be applicable to?

- Approximately 6000 patients have upper GI endoscopy per year across RGH and PCH
- Rates of 'pure GORD' using incidence rate of 4.6% of those presenting = 276 patients
- If all 'pure GORD' patients were offered Cytosponge as a screening test (assuming only 30% of screened patients would go on to need an endoscopy) would save 193 UGI endoscopies per year
- We know from other evaluation studies an additional 250 patients per year have known Barrett's segments that need surveillance – using Cytosponge could save a further 175 endoscopies per year

IMPLEMENTATION: NEXT STEPS

- Data from this service evaluation informed successful bid for SBRI Healthcare funding to support pilot Cytosponge (Endosign™, Cyted Ltd) evaluation
- Cytosponge testing in 50 patients with pure GORD and 50 patients with known Barrett's segments will commence in January 2025 (across CTMUHB and Cardiff & Vale UHB)
- Allows feasibility testing of the new service, patient feedback and evaluation data for scale-up across CTMUHB of new technology

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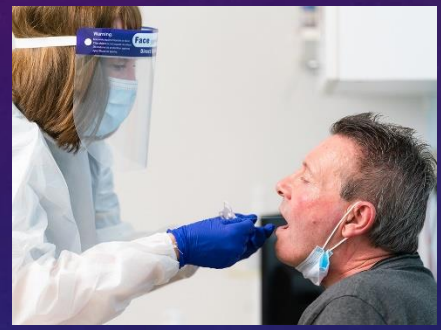


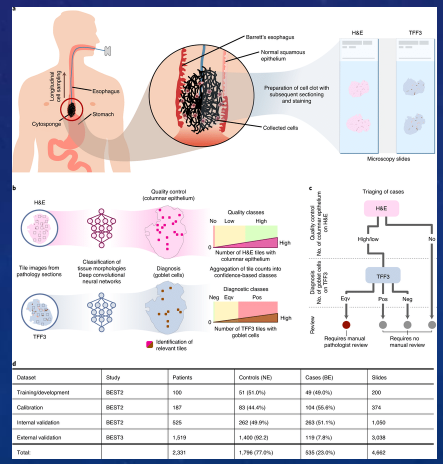
STAFF RECRUITMENT

STAFF TRAINING

LONG TERM FUNDING

ADMIN & BOOKING

CLINIC SPACE



Dataset	Study	Patients	Controls (NE)	Cases (BE)	Slides
Training/development	BEST2	100	51 (51.0%)	49 (49.0%)	200
Calibration	BEST2	187	83 (44.4%)	104 (55.6%)	374
Internal validation	BEST2	525	262 (49.9%)	263 (51.1%)	1,050
External validation	BEST3	1,519	1,400 (92.2)	119 (7.8%)	3,038
Total		2,331	1,796 (77.0%)	535 (23.0%)	4,662

TEST VALIDATION

RESULT ONTO WCP

LINKS TO ENDOSCOPY

THANK YOU FOR LISTENING

For further enquiries: Neil.D.Hawkes@wales.nhs.uk

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