Embedding optical biopsy recommendation in the NICE statements in the UK and possibility to include AI in the NICE

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Disclosure of Conflicts of Interest

I herewith declare the following paid or unpaid consultancies, business interests or sources of honoraria payments for the past three years, and anything else which could potentially be viewed as a conflict of interest:

James East has served on clinical advisory boards for Lumendi, Boston Scientific, and Paion; has served on the clinical advisory board and has share options in Satisfai Health; and reports speaker fees from Falk. He is an Associate Editor for the Journal of Gastroenterology and Hepatology. I was an adviser to NICE for DG28.
Optical diagnosis of small colorectal polyps at routine colonoscopy (Detect InSpect ChAracterise Resect and Discard; DISCARD trial): a prospective cohort study

Ana Ignjatovic, James E East, Noriko Suzuki, Margaret Vance, Thomas Guenther, Brian P Saunders

### Table 3: Difference in diagnosis according to polyp size (only polyps with optical and histological diagnosis included)

<table>
<thead>
<tr>
<th></th>
<th>Polyps ≤ 5 mm N (%)</th>
<th>Polyps 6-9 mm N (%)</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>296</td>
<td>67</td>
<td></td>
</tr>
<tr>
<td>Optical diagnosis made</td>
<td>271 (92%)</td>
<td>52 (78%)</td>
<td>0.002</td>
</tr>
<tr>
<td>Polyps not retrieved</td>
<td>37 (13%)</td>
<td>4 (6%)</td>
<td>0.22</td>
</tr>
<tr>
<td>Histology reported as normal</td>
<td>26 (9%)</td>
<td>0 (0%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Correct optical diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adenomas</td>
<td>144/155 (sensitivity 93%)</td>
<td>42/43 (sensitivity 98%)</td>
<td>0.46</td>
</tr>
<tr>
<td>Hyperplastic polyps</td>
<td>51/58 (specificity 88%)</td>
<td>4/4 (specificity 100%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Accuracy of optical diagnosis</td>
<td>97%</td>
<td>98%</td>
<td>0.21</td>
</tr>
</tbody>
</table>

*Fisher’s exact test.
Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics guidance
Published: 10 May 2017
nice.org.uk/guidance/dg28

https://www.nice.org.uk/guidance/dg28
Arms length government agency
Defines healthcare standards

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

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1st Deep learning papers on CADx 2017
1 Recommendation

1.1 Virtual chromoendoscopy using NBI, FICE or i-scan is recommended to assess polyps of 5 mm or less during colonoscopy, instead of histopathology, to determine whether they are adenomatous or hyperplastic, only if:

- high-definition enabled virtual chromoendoscopy equipment is used
- the endoscopist has been trained to use virtual chromoendoscopy, and accredited to use the technique under a national accreditation scheme
- the endoscopy service includes systems to audit endoscopists and provide ongoing feedback on their performance (see section 6.1) and
- the assessment is made with high confidence.
Virtual chromoendoscopy to assess colorectal polyps during colonoscopy (DG28)

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▶ 高解像度
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▶ 監査とフィードバックのためのシステム
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▶ 高確信度
Who can accredit?
National bodies
Self accredit
Industry

NICE DISCARD “expert” accreditation cycle

Training
Re-accreditation
Accreditation
Audit

1-2 years?
?part web based
Industry online training and certificates

“Killer colon polyps left to save NHS cash”

- Online or on site industry courses with certificate
Community based NBI DISCARD?

Table 7  Hierarchical regression modelling of adenoma detection

<table>
<thead>
<tr>
<th>(1) Unadjusted model</th>
<th>Sensitivity (%)</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>76.1%</td>
<td>(72.8% to 79.1%)</td>
</tr>
<tr>
<td>Specificity</td>
<td>77.5%</td>
<td>(71.0% to 82.8%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sensitivity (%)</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>6.5</td>
</tr>
<tr>
<td>T</td>
<td>60.0</td>
</tr>
<tr>
<td>O</td>
<td>68.0</td>
</tr>
<tr>
<td>B</td>
<td>56.8</td>
</tr>
<tr>
<td>OB</td>
<td>94.9</td>
</tr>
<tr>
<td>TO</td>
<td>96.7</td>
</tr>
<tr>
<td>TB</td>
<td>97.3</td>
</tr>
<tr>
<td>TOB</td>
<td>99.9</td>
</tr>
</tbody>
</table>

(3) Model adjusted by number of polyp characteristics*

<table>
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<tr>
<td>None</td>
<td>6.5</td>
</tr>
<tr>
<td>1 of TOB</td>
<td>62.3</td>
</tr>
<tr>
<td>2 of TOB</td>
<td>96.3</td>
</tr>
<tr>
<td>3 of TOB</td>
<td>99.9</td>
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• Current NICE model – not working: training too hard, long, labour intensive
• 1000s of endoscopists to train already in practice
• Web-based solutions available and “digitally scaleable”
DISCARD and AI

- AI “supported” endoscopist – currently available clinical practice
- Now comes with equipment replacement and stand alone
- Cost savings might justify investment
• No expertise / training required – regulatory difficulties +++
Current AI characterization systems

- Expert level performance
- Confidence level available
- “Plug and play”

NICE polyp classification

Type-1 - 5mm
unaltered footage in real time

Byrne MF et al. Gut 2019;68:94-100
Traditional competence pathway

**RECOMMENDATION**

ESGE suggests endoscopists are competent in optical diagnosis after: (1) meeting the pre-adoption and learning criteria; and (2) meeting competence thresholds by assessing a minimum number of lesions prospectively during real-time endoscopy. Level of agreement 93%.

Dekker E et al. Endoscopy;52:899-923
AI augmented competence pathway

Dekker E et al. Endoscopy; 52:899-923
AI augmented competence pathway

Dekker E et al. Endoscopy;52:899-923
Simple Optical Diagnosis Accuracy (SODA) competence standards for implementation of the optical diagnosis strategy for diminutive colorectal polyps

Attending a validated training course based on a validated classification, including in vivo phase, and reaching the SODA competence standards in at least 60 prospectively collected 1-5 mm lesions during real-time colonoscopies.

**Reaching SODA resect-and-discard standard:** ≥80% sensitivity and 80% specificity for high-confidence endoscopic characterization of 1-5 mm colorectal neoplasia.

**Reaching SODA leave-in-situ standard:** ≥90% sensitivity and 80% specificity for high-confidence endoscopic characterization of 1-5 mm colorectal neoplasia.
Issues to solve for AI NICE

• Can we rapidly accredit endoscopists for:
  • “training lite” or
  • “training +” - with AI during training (current trainees)
  • Black box AI – no training needed (regulatory difficulty)

• Can AI support / automate audit of endoscopist performance?

• If endoscopists can demonstrate performance criteria (with or without AI) do they need “training”
  • Learning through doing?
AI optical biopsy in NICE

Training
Web based learning
National societies accredit sites

Competence
Demonstrate competence thresholds with AI system support

Reaccredit
Re-accreditation built into EPR & Endoscopy reporting tools (+AI)

Solutions need to be digitally scaleable to have rapid widespread impact throughout GI practice

Praveen Suthrum. Scope Forward 2020