Recommendation from the Danish Health Technology Council concerning

Use of artificial intelligence as clinical decision-support in colonoscopy for the diagnosis of neoplastic disease

Recommendation from the Danish Health Technology Council:
The Danish Health Technology Council recommends that computer-aided detection (CADe) should not be implemented as a decision-support tool to aid in the diagnosis of neoplastic disease.

About this recommendation:
The reason behind the recommendation is that computer-aided colonoscopy can pose a risk to patient safety due to an increased number of unnecessary tissue samples and can lead to unnecessary additional work for the hospital and overtreatment of patients. This is due to the national clinical guidelines concerning colonoscopy requiring all polyps identified should be removed. This is problematic considering that modern colonoscopy equipment is increasingly allowing clinicians to identify even minor changes in the intestine, and therefore the risk of complications due to an increased number of unnecessary tissue samples may exceed the possible benefits.

Therefore, the Danish Health Technology Council calls for an update of the national clinical guidelines in this area, and notes that the guidelines may pose a barrier to exploiting the benefits of future computer-aided technology.

The Danish Health Technology Council is aware of the rapid rate of advances in computer-aided technology and artificial intelligence and has therefore limited the period of validity of this recommendation.

Validity period: This recommendation is valid from 1 February 2023 until Q1 2025. Any update to this recommendation should preferably cover both CADe and CADx (computer-aided characterisation), if the literature supports this.

About the technology	In recent years, several manufacturers of colonoscopes have begun promoting the use of AI-assisted colonoscopies, including the use of CADe. CADe systems in colonoscopy provide real-time information about changes in the intestine and help clinicians to detect neoplastic disease. These technologies act as add-ons to existing endoscopy columns.
Patient population	This recommendation pertains to adults undergoing colonoscopy to diagnose neoplastic disease.
Scope	Colonoscopy examinations are performed at gastrointestinal surgery outpatient clinics and gastrointestinal departments at hospitals.
Implementation	No remarks because the technology is not recommended.
Tendering procedures and price formation	No proposal for national procurement.
Other considerations	The expert committee notes that CADe systems without a built-in characterisation function (CADx) may no longer be marketed in the future as a result of technological developments.

About the analysis

This recommendation from the Danish Health Technology Council is based on the expert committee's analysis report regarding the use of artificial intelligence (AI) as clinical decision-support in colonoscopy for the diagnosis of neoplastic disease answering the following question:

Should computer-aided detection (CADe) be used in the diagnosis of neoplastic disease?

Clinical effectiveness and safety

The analysis of clinical effectiveness and safety is based on two RCT studies. The results indicate that there is a clinically relevant difference for 'Proportion of patients with at least one histologically confirmed adenoma' (ADR) when comparing CADe-assisted colonoscopy with standard colonoscopy. Furthermore, there is a statistically significant difference for 'Proportion of patients with detected adenoma ≤ 5 mm' and 'Proportion of patients with detected adenoma of 6-9 mm', which indicates that CADe-assisted colonoscopy aids in the detection of more adenomas <10 mm. However, the expert committee notes that there is *no* clinically relevant difference for these outcome measures. Furthermore, there is no statistically significant difference for the 'Proportion of patients with detected adenoma ≥ 1 cm' and the 'Proportion of patients with at least one sessile serrated lesion (SSL)', which, in the expert committee's assessment, would have been of particular clinical relevance. There is no data to inform whether the findings have any positive effects for the patient group in the form of improved overall survival rate and improved quality of life. Nor is there data to inform any negative outcomes for the patient group in the form of complications. However, the expert committee expects that CADe-assisted colonoscopy will have only a minor effect on the incidence of complications. Furthermore, the expert committee has assessed that the data does not give rise to concern with regard to overtreatment due to the 'Proportion of patients with no adenoma or SSL within any excised lesions who had undergone at least one excision with histopathological examination'. The GRADE-assessment of the quality of evidence suggests moderate to low confidence in the generalisability of the results for the individual outcome measures.

The overall assessment of the expert committee is that CADe-assisted colonoscopy is equivalent to standard colonoscopy. This is because there is only a clinically relevant difference for ADR. The expert committee notes that the increase in ADR is probably attributable to an increased detection of adenomas <10 mm, which are likely to be low-risk findings.

Patient perspective	The analysis of the patient perspective is based on seven studies on patient preferences, opinions, and experiences regarding clinical AI, as no scientific literature aimed specifically at the patient perspective on CADe-assisted colonoscopy was identified in the systematic literature search. Three themes were identified across the seven studies in the analysis: 1) attitudes and acceptance, 2) benefits and apprehensions, and 3) patient-clinician-AI relationship. The analysis indicates that patient-related factors such as previous knowledge of AI, disease, and experience with the healthcare system influence people's attitude towards and acceptance of clinical AI. The same applies for a number of non-patient-related factors such as level of information and area of application of clinical AI. The benefits of clinical AI identified by patients relate to improved precision and more efficient health services, whereas apprehensions are attributed to lack of transparency and increased risk of misdiagnosis. Furthermore, patients express concerns about the influence of AI on their relationship with clinicians and they express a preference for and confidence in clinicians over AI. It was also evident that clinical AI is more accepted if used as a tool to assist clinicians rather than being a replacement. Although the results are not directly transferable to CADe-assisted colonoscopy, the expert committee notes that the results can help draw attention to certain areas when considering the application of AI-assisted decision-support in colonoscopy. The assessment of the quality of evidence indicates a risk of bias. Based on the analysis of the patient perspective, the expert committee concludes that there are no patient concerns that speak in favour of implementing either the intervention or the comparator. This is attributed to the lack of evidence regarding patients' attitudes towards CADe-assisted colonoscopy, and the uncertainty of the transferability of the results.

Organisational implications

The analysis of organisational implications is based on an interview study, which is supported by the scientific literature. A thematic analysis identified five themes. It appears from the data that CADe technology is simple to implement in an everyday clinical setting, as it is a plug-and-play solution that only needs to be turned on to help clinicians identify changes in the lining of the intestine, which limits the need for training. However, the expert committee notes that education is central to any national dissemination, including communication about clinical needs, possibilities, and limitations to ensure the technology is being used as intended. The expectation is that the technology will assist less experienced endoscopy practitioners, particularly in detecting diminutive polyps. There is a general concern about whether the use of the technology may result in deskilling if these endoscopy practitioners solely rely on the technology and do not use their professional skills in the clinical assessment of the intestine lining. The expert committee supports that CADe-assisted colonoscopy can increase ADR, regardless of the level of experience, but like the interviewees, the expert committee remains uncertain about the clinical relevance. For this reason, there is a concern about whether the use of the technology will result in overtreatment. Furthermore, the interviewees find that CADe-assisted colonoscopy is associated with a large number of false positive findings. The analysis also shows that the use of the technology may result in more resections and histological examinations. However, this is not expected to influence the overall course of treatment, including the number of follow-up examinations. There is broad agreement that, with CADx, the technology could hold potential, and this is also the belief of the expert committee. The expert committee notes that the analysis is based on a limited evidence base and there is a risk of bias.

The overall assessment of the expert committee is that there are organisational implications speaking both for and against the use of CADe-assisted colonoscopy. The expert committee assesses that it is possible to establish uniform national implementation of the technology, but that increased ADR is unlikely to be commensurate with the investment, as the committee assesses CADe will primarily assist in detection of low-risk adenomas.

Health economics

In order to examine the health economic perspective, a cost-effectiveness analysis (CEA) and budget impact analysis (BIA) was performed. The result of the CEA indicates that CADe-assisted colonoscopy can increase ADR by 14.85% compared to standard colonoscopy, associated with an additional cost of [redacted] per colonoscopy. This results in an incremental cost-effectiveness ratio (ICER) of [redacted] per 1% increase in ADR when using CADe-assisted colonoscopy compared to standard colonoscopy. The expert committee notes that the increase in ADR most likely is attributted to an increased detection of low-risk adenomas. Whether CADe-assisted colonoscopy is a cost-effective alternative to standard colonoscopy depends on the willingness to pay to increase ADR. The expert committee notes that ADR has not been used as a surrogate measure for patient-related outcomes, such as incidence of intestinal cancer and mortality, as the current evidence base does not support the application of this correlation. Furthermore, the expert committee notes that the CEA has been performed exclusively for index colonoscopies in the national screening programme for colon and rectal cancer, as the current evidence base does not support the examination of cost-effectiveness across indications of colonoscopies.

Based on the BIA, it is estimated that the use of CADe-assisted colonoscopy will have a total budget impact of approx. [redacted], during a five-year period. The budget impact includes purchases of the CADe-technology as an add-on to existing colonoscopy columns. The expert committee notice that the budgetary implications of implementing CADe-assisted colonoscopy should be considered in relation to the results of the CEA. The expert committee notes that the calculation of the expected number of CADe-technologies-technologies to be purchased in a national implementation is uncertain.

The overall assessment of the expert committee concludes that there are no health economic implications for or against the application of CADe-assisted colonoscopy. This is attributed to the lack of evidence available to support a health economic evaluation of CADe-assisted colonoscopy across indications and the use of patient-related outcome measures. Because no scientific literature solely constitute the primary evidence base for the health economic perspective, no formal quality assessment has been made of the supporting evidence.

About the recommendation from the Danish Health Technology Council

The Danish Health Technology Council's recommendation is intended as an aid for regions when deciding on the use of a given health technology. The recommendation is based on the expert committee's analysis report. Depending on the health technology under examination, this report includes a review of one or more of the following perspectives: 1) clinical effectiveness and safety, 2) patient perspective, 3) organisational implications and 4) health economics.

This recommendation is based on the Danish Health Technology Council's analysis report regarding the use of artificial intelligence as clinical decision-support in colonoscopy for the diagnosis of neoplastic disease, which was prepared collaboratively by the expert committee and the secretariat. The analysis report was prepared with outset in the Danish Health Technology Council's process guide and methodological guidelines. The expert committee's terms of reference are available on the Danish Health Technology Council's website.

Information about this document		
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