

## **Benefits and Challenges in Implementation of Artificial Intelligence in Colonoscopy: World Endoscopy Organization Position Statement**

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Study concept and design; acquisition of data; analysis and interpretation of data; drafting of the manuscript; statistical analysis; final approval of the manuscript: YM, JEE, CH, OFA, PS, and DKR

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**Abstract:**

The number of artificial intelligence (AI) tools for colonoscopy on the market is increasing with supporting clinical evidence. Nevertheless, their implementation is not going smoothly for a variety of reasons, including lack of data on clinical benefits and cost-effectiveness, lack of trustworthy guidelines, uncertain indications, and cost for implementation. To address this issue and better guide practitioners, the World Endoscopy Organization (WEO) has provided its perspective about the status of AI in colonoscopy as the position statement.

**WEO position statement:** ***Statement 1.1:** Computer-aided detection (CAdE) for colorectal polyps is likely to improve colonoscopy effectiveness by reducing adenoma miss rates and thus increase adenoma detection; **Statement 1.2:** In the short-term, use of CAdE is likely to increase healthcare costs by detecting more adenomas; **Statement 1.3:** In the long-term, the increased cost by CAdE could be balanced by savings in costs related to cancer treatment (surgery, chemotherapy, palliative care) due to CAdE-related cancer prevention; **Statement 1.4:** Healthcare delivery systems and authorities should evaluate the cost effectiveness of CAdE to support its use in clinical practice; **Statement 2.1:** Computer-aided diagnosis (CAdx) for diminutive polyps ( $\leq 5\text{mm}$ ), when it has sufficient accuracy, is expected to reduce healthcare costs by reducing polypectomies, pathological examinations, or both; **Statement 2.2:** Healthcare delivery systems and authorities should evaluate the cost effectiveness of CAdx to support its use in clinical practice; **Statement 3:** We recommend that a broad range of high-quality cost-effectiveness research should be undertaken to understand whether AI-implementation benefits populations and societies in different healthcare systems.*

## **Background**

Application of artificial intelligence (AI) has gained significant attention as a novel measure to allow standardization in colonoscopy practice. Computer-aided detection (CADe) and computer-aided diagnosis (CADx) are the major use cases for AI technologies, aiming to help endoscopists detect and characterize polyps during colonoscopy (Figure 1). More than 10 high-quality, randomized controlled trials have been published in the past couple of years, and 10 or more CADe and CADx medical devices are now commercially available on the global market<sup>1, 2</sup>.

Nevertheless, these AI medical devices have not been widely implemented in clinical endoscopy practice<sup>2</sup>. The major reasons may include lack of data on clinical benefits and cost-effectiveness, lack of trustworthy guidelines, uncertain indications and training requirements, cost for implementation, and probably lack of reimbursement. Furthermore, lack of good communication between scientific communities and healthcare delivery systems might also hinder the implementation process of these AI tools. Because a variety of issues hinder the implementation process, it becomes difficult for practitioners to understand whether to incorporate these novel tools into routine colonoscopy practice. To better guide practitioners, we developed a position statement project focused on AI in colonoscopy with a clear perspective from the World Endoscopy Organization (WEO). This statement also emphasizes the importance of engaging with healthcare delivery systems and authorities, because these entities usually play important roles in the implementation process of innovative medical devices.

## **Methods**

This position statement is the output of an expert working group of the WEO Colorectal Cancer Screening Committee. The recommendations were developed based on a modified Delphi process<sup>3</sup>. Topics for the review were initially developed by the steering committee members who were gastroenterologists with expertise in AI for colonoscopy (Supplementary material 1). These topics include major clinical benefits and challenges that can either facilitate or hinder clinical implementation of AI in colonoscopy practice.

The steering committee invited a total of 18 panel members (Supplementary material 1). They were selected in consideration of diversity in gender (6 female and 12 male) and geography (4 from North America, 3 from Europe, 1 from Oceania, 8 from Asia, 1 from Latin America, and 1 from Middle East).

All of them were considered to have expertise in gastroenterology and AI according to their publication records.

Based on the initial topics proposed by the steering committee and the feedback from the panel members in a teleconference, structured statements were developed in March 2022. These statements consisted of three different categories: 1. CAdE, 2. CAdx, 3. Promotion of research. The panel members were asked to indicate their perspectives with each statement by using a Likert scale with 5 possible answers (strongly agree, agree, neutral, disagree, strongly disagree). They were also asked to make comments in a free-text box per each statement. Consensus was confirmed when 80% or more chose either “strongly agree” or “agree”. Statements that did not reach the consensus threshold during the voting processes were either removed or modified in accordance with discussion after each voting process. The voting processes were done anonymously. There were three voting rounds in total between April and September 2022. The final version of the developed statements have been reviewed and approved by the WEO leadership on the 10th of November in 2022. The statements were also endorsed by the Japan Gastroenterological Endoscopy Society on the 28th of November in 2022.

## **Recommendations**

There were three statements which were evaluated in the first-round voting (Supplementary material 2). After the first-round voting and subsequent discussion with the panel members, the steering committee decided to split these statements into seven distinct and detailed statements. This revision was done because the committee considered that the first draft statements were too comprehensive and included different types of information within each of the statements. The developed seven statements, then, were assessed in the second-round voting (Supplementary material 3). After this round, the steering committee further split one statement into two and modified wording of several statements in accordance with the discussion with the panel members. Thereafter, a total of eight statements were assessed in the third-round voting in which 15 out of the 18 panel members participated (Supplementary material 4). Finally, seven statements out of the eight reached consensus level and were included in the final version as follows.

### **1. Computer-aided detection (CAdE)**

**Statement 1.1:** *CADe for colorectal polyps is likely to improve colonoscopy effectiveness by reducing adenoma miss rates and thus increase adenoma detection. (100% agreement)*

**Statement 1.2:** *In the short-term, use of CADe is likely to increase healthcare costs by detecting more adenomas. (80% agreement)*

**Statement 1.3:** *In the long-term, the increased cost by CADe could be balanced by savings in costs related to cancer treatment (surgery, chemotherapy, palliative care) due to CADe-related cancer prevention. (80% agreement)*

**Statement 1.4:** *Healthcare delivery systems and authorities should evaluate the cost effectiveness of CADe to support its use in clinical practice. (100% agreement)*

Missing neoplastic lesions is one of the biggest challenges in colonoscopy, which is considered a major cause of post-colonoscopy colorectal cancer. A recent meta-analysis suggested 26% of adenomas are missed during colonoscopy<sup>4</sup>. While some of the missed adenomas were overlooked due to the limited exposure of mucosal surface<sup>5</sup>, an image-based retrospective study suggested 14% of adenomas were not recognized by endoscopists even though they were visualized<sup>6</sup>. CADe has been developed to support endoscopists by indicating the location of possible polyps on the monitor (Figure 1). This may help reduce missed adenoma<sup>7, 8</sup> and thus increase detection rate of adenomas (ADR). Indeed, a recent meta-analysis of six RCTs including 4,354 patients demonstrated a relative increase of ADR of 44% with CADe<sup>9</sup>. In this regard, CADe offers promise to reduce unwanted operator-dependent variability in colonoscopy performance and thus maximize colonoscopy effectiveness<sup>10</sup>. However, we should also take account of the fact that CADe cannot pick up any adenomas that are not visualized. Addition of mucosal exposure devices may contribute to further detection of adenomas<sup>11</sup>.

While clinical effectiveness is widely considered to be the most important factor for medical innovation, health economic evaluation is another critical area to be considered for implementation in clinical practice. Most healthcare systems undertake health technology assessments to inform decisions regarding the adoption and reimbursement of new innovations, with increasing emphasis placed on cost-effectiveness given the trend to use scarce resources more efficiently within constrained budgets. A recent microsimulation study suggested that the use of CADe can increase healthcare cost in the short-term by increasing the number of detected polyps, polypectomies, and histopathological examinations, in addition



to the cost of CAdE<sup>12</sup> (Figure 2). Furthermore, another simulation study suggested the number of intensive surveillance colonoscopies (e.g., 3-year follow-up) may increase by 35% in the US<sup>13</sup> which is another burden that needs to be addressed.

On the contrary, CAdE-driven increases in ADR may contribute to reduction of colorectal cancer in the long-term which may lead to cost reduction. The same microsimulation study suggested the use of CAdE could contribute to an absolute 5% and 3% reduction of colorectal cancer incidence and death, respectively, when compared to standard colonoscopy-based screening in the U.S. This reduction of colorectal cancer could result in savings of overall healthcare costs by roughly 290 million US dollars annually in the US<sup>12</sup> (Figure 2). In this regard, healthcare delivery systems and authorities should evaluate the cost effectiveness of CAdE to support its use in clinical practice.

However, there may be two major hurdles that hinder translation of this data into the real-world healthcare arena. First, analyses are limited in terms of methodologies and geographical diversity. For now, cost-effectiveness was evaluated in only one study considering the U.S. healthcare system. Secondly, there are always significant uncertainties in the microsimulation modelling due to many assumptions. Large-scale observational studies and/or randomized controlled trials with long-term follow-up will be required to understand if the use of CAdE truly contributes to health economy and patient care<sup>1</sup>.

## **2. Computer-aided diagnosis (CADx)**

***Statement 2.1:*** CADx for diminutive polyps ( $\leq 5\text{mm}$ ), when it has sufficient accuracy, is expected to reduce healthcare costs by reducing polypectomies, pathological examinations, or both. (93.3% agreement)

***Statement 2.2:*** Healthcare delivery systems and authorities should evaluate the cost effectiveness of CADx to support its use in clinical practice. (92.9% agreement)

Polyp characterization, or optical diagnosis, is a method to predict histopathology of a polyp based on its appearance. This can be used as an alternative to actual histopathological assessment when it is predicted with high confidence<sup>14</sup>. The concept of optical diagnosis has been gaining significant attention because it can help select appropriate treatment measures in accordance with the predicted histopathology (e.g., no treatment for a hyperplastic polyp, endoscopic treatment for an adenoma, and surgery for a cancer),

without a need to take pre-treatment biopsy. This will reduce costs and patients' burden as long as prediction provides sufficient accuracy<sup>14, 15</sup>. However, the lack of endoscopists' competence and motivation in polyp characterization has hindered implementation of optical diagnosis in clinical practice<sup>16, 17</sup>. A large-scale clinical trial conducted in community-based hospitals in the UK showed that the sensitivity and specificity to identify adenomas were limited to 83% and 74%, respectively<sup>16</sup>. Furthermore, a nation-wide questionnaire survey in the US revealed that only 40% of US endoscopists are willing to perform optical diagnosis<sup>17</sup>.

Use of CADx is expected to play a significant role to overcome these challenges because it can reduce the operator-dependent uncertainties in optical diagnosis and assure prediction accuracy. The main arena where CADx contributes to real-world colonoscopy for now is differentiation between neoplasia and non-neoplasia although several pre-clinical, advanced CADx are being investigated<sup>18</sup>. Several large-scale prospective studies have demonstrated the great value of using CADx to correctly differentiate diminutive polyps with over 90% negative predictive value and over 80% sensitivities/specificities for identification of adenomas<sup>19, 20</sup>, which exceeded the threshold required for optical diagnosis in the US<sup>14</sup> and Europe<sup>15</sup>.

This indicates that introduction of CADx-driven optical diagnosis can lead to significant reduction of polypectomy and pathology-related cost in colonoscopy<sup>21</sup>. A post-hoc analysis of a large-scale prospective study showed the use of CADx could lead to 11% reduction of average colonoscopy cost with at most 85.2 million US dollars saving in the US<sup>21</sup>. In this regard, healthcare delivery systems and authorities should evaluate the cost effectiveness of CADx to support its use in clinical practice. Furthermore, the importance of CADx is further emphasized with the broader use of CAdE that may increase detection of small polyps, many of which indeed are hyperplastic polyps<sup>9</sup>. CADx may play an important role to minimize the number of polypectomies which CAdE increases (Figure 2).

On the other hand, there have been several challenges that hinder clinical implementation of CADx. First, the additional value of using CADx to optical diagnosis is uncertain<sup>22, 23</sup>. Two large-scale prospective studies showed use of CADx did not increase the sensitivity to identify adenomas when compared with standard optical diagnosis<sup>22, 23</sup>. However, the introduction of CADx obviously increased the proportion of high confidence diagnosis (74% to 93%)<sup>23</sup> and motivation to adopt optical biopsy (40 to 57%<sup>17</sup>) which will lead to increased use of optical diagnosis. Secondly, the benefits of CADx may be limited to non-experienced endoscopists<sup>22</sup>. Thirdly, there is a relative lack of both number and variety of

health economic studies. For now, we have a couple of simulation results in the U.S., the U.K., Norway, and Japan based on the leave-in-situ strategy for rectosigmoid polyps<sup>14</sup>, while there is no other data supporting the broader use of CADx from an economic point of view, including the lack of data focused on resect-and-discard strategies for a whole colon<sup>14</sup>. Fourth, clinical implementation of CADx, compared to CAdE, faces resistance among practitioners related to perceived medical-legal risk that is particularly associated with the resect-and-discard strategy. Practices and policies that reduce risk, such as systematic photo documentation or videorecording of endoscopic features that support diagnoses and clinical management decisions, combined with financial incentives to physicians who utilize CADx, may be essential to effective spread of CADx in clinical practice.

### **3. Promotion of research**

***Statement 3:** We recommend that a broad range of high-quality cost-effectiveness research should be undertaken to understand whether AI-implementation benefits populations and societies in different healthcare systems. (100% agreement)*

In contrast to the rapid pace of development and translation for AI based technologies in healthcare, cost effectiveness research has dramatically lagged behind the speed of technological innovation. A recent systematic review identified only 20 health economic studies focused on AI medicine<sup>24</sup>. To date, only two cost-effectiveness studies for AI in colonoscopy have been published, relating to CADx<sup>21</sup> and CAdE<sup>12</sup> respectively. Considering the potential global applications for AI in colonoscopy, it is critical that future research addresses cost-effectiveness in different healthcare systems internationally. This is simply because there are huge variations in healthcare delivery systems, socioeconomic status, and policies of reimbursement (e.g., incentivizing outcomes instead of volume, utilizing advance market commitments and time-limited reimbursements<sup>25</sup>).

In addition, more robust health economic evaluation will depend upon long term clinical outcome data, such as the impact on colorectal cancer incidence, as opposed to simulation-based modelling which is limited by assumptions. Furthermore, more complex economic evaluation will also be required given the fact that endoscopists are likely to use multiple AI tools in the future practice. This may include simultaneous

use of both CADe and CADx as part of multi-algorithm endoscopic “full workflow solutions” for lower GI procedures.

### **Discussion:**

We have reached a consensus about the importance of addressing both clinical benefits and cost-effectiveness in relation to the implementation of both CADe and CADx in colonoscopy. However, implementation of a new innovative medical device in clinical practice is a huge challenge because there are multiple factors that affect this process, including regulatory approval, indications, clinical benefits, requirement of training, cost-effectiveness, cost for implementation, reimbursement, physicians’ sentiment, and legal and ethical challenges. In this regard, some of the optimistic results in the recent clinical studies in the AI colonoscopy field are just part of the process.

Many consider financial support from health insurance bodies such as reimbursement to be the strongest driving force in implementation. In fact, this is well illustrated by the use of AI in mammography. The US Food and Drug Administration approved CADe for mammography in 1998, and Medicare and Medicaid have reimbursed its use since 2002. As a result, AI detection tools are used for more than 80% of the screening mammograms in the US<sup>26</sup>. However, introduction of reimbursement is not straightforward. Recently, experts in health economy cautioned that per-use reimbursement may result in the overuse of AI, and thus careful design of payment for AI is essential for improving patient outcomes while maximizing cost-effectiveness and equity<sup>25</sup>.

Given that multidisciplinary issues potentially hinder smooth implementation, we strongly encourage healthcare delivery systems and authorities to consider multiple factors including the clinical benefits, cost effectiveness, or other formal health technology assessment of AI tools to support use in clinical practice.

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**Figure legends:**

Figure 1: Left, computer aided detection (CAdE) for colorectal polyps (EndoBRAIN, Olympus Corp, Tokyo); Right, computer-aided diagnosis (CAdx) for colorectal polyps (GI GENIUS CAdx, Medtronic Corp. Dublin)

Figure 2: Possible cost increase and reduction introduced by artificial intelligence in colonoscopy. AI, artificial intelligence; ADR, adenoma detection rate

**Supplementary Material:**

Supplementary material 1: Steering committee and panel members

Supplementary material 2: Results of the first voting

Supplementary material 3: Results of the second voting

Supplementary material 4: Results of the third voting