Principles for Evaluation of Surveillance After Removal of Colorectal Polyps: Recommendations From the World Endoscopy Organization

C olorectal polyps such as adenomas and serrated polyps are precursors for colorectal cancer (CRC). Therefore, removal of such polyps reduces CRC risk.¹ Patients who had adenomas or serrated polyps removed at colonoscopy are believed to be at increased risk of developing more polyps later in life and eventually CRC.^{2,3} Thus, colonoscopy surveillance after polyp removal is currently recommended.⁴

Case-control and cohort studies have indicated that surveillance after removal of advanced adenomas is associated with CRC incidence reduction,^{5,6} although some modelling studies are reporting only a marginal benefit of surveillance.⁷ No randomized trials have comparing the efficacy of surveillance in reduction of CRC incidence or mortality are available

Owing to increasing colonoscopy screening activity around the world, more and more individuals are diagnosed with polyps and, therefore, surveillance has become one of the most frequent indications for colonoscopy, requiring large amounts of resources and creating capacity problems in many countries.^{8,9} Colonoscopy is an inconvenient. invasive, and expensive procedure with a risk of complications. Thus, surveillance colonoscopy for patients after polyp removal should be targeted at patients who are most likely to benefit, and recommended at the minimum frequency required for decreasing the risk of cancer.^{10–12}

The World Endoscopy Organization (WEO) requested this position

statement to guide decision makers, clinicians, and researchers covering 4 areas of colonoscopy surveillance after polyp removal: (1) general principles and definitions in surveillance after polyp removal, (2) definitions of exposures and outcomes, (3) relevant comparators for surveillance studies, and (4) relevant thresholds to define cancer risk and surveillance efficacy.

Methods

This position statement and its recommendations were developed based on a modified Delphi process.¹¹ For the purpose of the project, the WEO appointed a project steering committee of 4 members of its working group on surveillance after detection of colorectal neoplasia (M.R., M.B., C.H., R.J.).

The WEO invited a multidisciplinary group of 20 experts (Appendix 1) in gastroenterology, gastrointestinal endoscopy, epidemiology, and public health, including the 4 steering committee members, from across the world to participate in an expert panel to discuss the initial questionnaire and to vote in the subsequent successive rounds of the Delphi process. The panelists were chosen based on their expertise in colonoscopy, epidemiology, surveillance practice, and/or research, or participation in surveillance guidelines development, all of them with multiple relevant publications on these topics.

Based on the initial questionnaire and the feedback from the panel, the steering committee developed a series of structured statements for voting in the following 4 areas of colonoscopy surveillance after polyp removal: (1) general surveillance principles, (2) surveillance outcome measures, (3) comparators in surveillance studies, and (4) thresholds for defining benefit of surveillance.

The panel members were asked to indicate their agreement with each statement using a Likert scale with 5 possible answers (strongly disagree, disagree, neither agree nor disagree, agree, or strongly agree). In a free-text field, the panel members were allowed to comment on each statement, if desired.

Two voting rounds were performed. Primary consensus was defined as $\ge 80\%$

of participants agreeing or strongly agreeing to a statement. Statements with no consensus in the first round were either discarded (when consensus was <40%), or modified, merged, or split according to comments and revoted on in a second round. Secondary consensus was defined as $\geq 50\%$ agreeing and <20% disagreeing. Participants received feedback about the anonymized results after each voting round. A flowchart with number of statements at the different rounds can be seen in Supplementary Figure 1. The discussion round and the 2 subsequent voting rounds were performed between January 2018 and December 2018.

Recommendations

The original questionnaire included 42 statements. After 2 rounds of voting, 39 statements achieved primary or secondary consensus ("accepted statements") and are included in this report (Supplementary Figure 1). Supplementary Tables 1, 2, and 3 show all statements and their voting results. Supplementary Table 4 shows the statements that did not reach consensus.

The following outlines the most important statements in the 4 areas (panel recommendations in *Italic*, explaining text in Roman).

General Surveillance Principles (for Statements, see Supplementary Table 1)

- a. The primary aim is to reduce CRC incidence.
- b. The secondary goal is to reduce CRC mortality.
- c. CRC mortality reduction by surveillance is achieved firstly by reducing CRC incidence and secondly by detecting early stage CRC at surveillance.

Endoscopic surveillance should aim to reduce CRC incidence by polyp removal rather than mortality by downstaging of diagnosis of invasive cancer. Patients receiving surveillance have already undergone a "clearing"

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colonoscopy; therefore, surveillance should aim to prevent rather than detecting CRC.

- d. Surveillance colonoscopy should only be offered to individuals with a sufficiently high risk to expect a clinically significant benefit from surveillance.
- e. The impact of surveillance on CRC incidence must be balanced against its harms (colonoscopy complications and psychological distress), patient burden, and costs.

Colonoscopy capacity is limited and the number of patients with removed polyps is higher, owing to rapidly increasing CRC screening activity and improvements in technique and technology in detecting polyps during colonoscopy. The benefit of colonoscopy surveillance must be balanced with its harms and burden. The potential benefit should outweigh the potential harm from psychological or physical adverse events at colonoscopy, and the burden that is directly related to the prevalence of each type of polyp at colonoscopy, as well as the frequency at which surveillance is recommended.

Outcome Measures after Polyp Removal and for Evaluation of the Effectiveness of Surveillance (Statements on This Topic Can Be Seen in Supplementary Table 2)

- a. CRC incidence is the preferred outcome measure.
- b. CRC mortality is an acceptable outcome measure.

Once agreed that the primary aim of surveillance is CRC incidence reduction (see above), the presurveillance and postsurveillance estimate of CRC incidence becomes the top-ranking outcome for assessing the baseline risk and the efficacy of surveillance, respectively. Because CRC mortality reduction has been defined as a secondary aim of surveillance, postsurveillance CRC mortality risk is also an acceptable outcome. Both of these outcome measures require long-term follow-up owing to a long time from the initial polyp removal to the outcome.

The choice between CRC incidence and mortality as the primary outcome also entails methodological differences. Despite being agreed upon as the primary goal of surveillance, estimates of CRC incidence reduction are prone to completeness of follow-up, lead time bias, and overdiagnosis bias.¹³ When such bias cannot be properly addressed, CRC mortality represents a more unbiased outcome.¹⁴ If available, the panel recommends reporting of both outcomes.

c. The surrogate measures of "any adenomas," "any serrated polyps," and "any polyps" at surveillance colonoscopy should no longer be used in studies aiming at identifying patients at risk for future CRC or for evaluation of the effectiveness of surveillance, whereas "advanced colorectal polyps" is considered acceptable (although imperfect).

Although widely used, the panel recommends against the use of nonadvanced polyps as a surrogate meapresurveillance sure for or CRC risk. postsurveillance This recommendation is based on the epidemiology of colorectal polyps as compared with invasive CRC; although the panel believes that most CRCs arise from colorectal polyps, the panel recognizes that the vast majority of colorectal polyps do not progress to cancer. Thus, these surrogate measures are not reliable predictors of future CRC risk.

Owing to the inherent limitations in estimating CRC incidence or mortality, the panel recognized the need for possible surrogate measures in surveillance studies. In this regard, the rate of "advanced colorectal polyps"—defined as an advanced adenoma or advanced serrated lesion (Supplementary Table 1)—represents an acceptable surrogate outcome, are considered a target of CRC screening.¹⁵ However, as the transition rate and time of progression from advanced adenomas to cancer is unknown, this surrogate measure is of lower validity compared with CRC incidence and mortality.

d. If the term "advanced colorectal neoplasia" (summating advanced colorectal polyps and CRC) is used as an outcome measure, the panel recommends always also displaying advanced colorectal polyps and CRC separately.

As adopted by most studies, the panel recommends that the use of "advanced colorectal neoplasia" is an acceptable outcome only if the rate of advanced polyps and already invasive lesions are reported separately. These 2 entities entail completely different treatments, risks of harms, and prognoses.

e. Absolute values of CRC risk and absolute estimated risk reductions through surveillance rather than relative effects should be used for scientific studies and for guideline recommendations in polyp surveillance.

To make informed choices, patients and caregivers need to be able to value the benefits of surveillance colonoscopy after polyp removal in the context of their absolute risk of future disease, that is, CRC. For instance, this would simplify the comparison between the expected benefit of surveillance against the competing cause of general mortality that should marginalize the need of surveillance in patients with severe comorbidities or elderly age.

Comparator Groups and Thresholds (Statements on This Topic Can Be Seen in Supplementary Table 3)

a. Surveillance effectiveness is best assessed using an appropriate comparator group and considering the risk of bias of these comparators.

	Comparator: General population	Comparator: Equivalent cohort of patients not undergoing surveillance
Cohort of patients at increased CRC risk undergoing surveillance	If the surveillance cohort's CRC risk is similar to the general population, surveillance had successfully decreased that increased risk.	If the surveillance cohort's CRC risk is similar to an equivalent nonsurveillance cohort, surveillance had no impact on CRC risk, and is not justified. If the group undergoing surveillance has lower incidence than the equivalent cohort not undergoing surveillance, surveillance should be warranted.
Cohort of patients at increased CRC risk not undergoing surveillance	If the nonsurveillance cohort's CRC risk is similar to the general population, that cohort was not at increased risk of CRC.	_

CRC, colorectal cancer.

- b. When assessing postpolypectomy CRC risk, we consider an age- and gender-matched general population comparator to be the optimal comparator group.
- c. When assessing surveillance effectiveness, we consider a same-risk nonsurveillance comparator to be the optimal comparator group.

The panel established 2 main comparator situations to define the need for surveillance, specially in observational studies. The first is the general population. If there is an equivalent CRC risk between a postpolypectomy cohort with no surveillance and the general population (unscreened), under the basic assumption that if patients are not at increased risk of CRC incidence or screening rather mortality, than surveillance is recommended. The latter is comparison between postpolypectomy patients receiving and not surveillance. If there is an equivalence of CRC risk between 2 cohorts of patients who had polyps removed-one with surveillance and one without surveillance-irrespective of the baseline risk, if surveillance is not reducing the risk, it should not be recommended. In contrast, if the group undergoing surveillance has lower CRC incidence than the equivalent cohort non receiving surveillance, in this case, surveillance should be warranted (Table 1).

It should be noted that although the same-risk cohort that warranted surveillance colonoscopy but did not undergo surveillance serves as a comparator group, it is subject to bias, for example owing to non-attenders potentially being a less health-aware group, thus perhaps making other unhealthy lifestyle choices (eg, smoking). These confounders are likely to exaggerate the necessity for and the benefit of surveillance.

When studying short-term surrogate outcomes (surveillance colonoscopy yield), it is not possible to have a no-surveillance comparator. Useful information can be gained from analyzing the advanced colonic polyp (ACP) yield separately from the CRC yield, and by using a general population comparator (which can be surmised from general population screening colonoscopy datasets).² Appropriate use of these comparators is shown in Table 2.

There may be occasions where other comparator groups are helpful to

Table 2. Surveillance Colonoscopy Tield, Cho and Comparator Grou	Table 2. Surveil	lance Colonosc	opy Yield, CR	C and Corr	parator Gro	ups
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	Low CRC yield (including interval cancers)	High CRC yield (including interval cancers)
Low advanced colorectal polyp	Indicates that the cohort is not at increased risk and therefore the procedure is not warranted	The cohort is at increased risk The current surveillance strategy is ineffective
yield	Remains possible that cohort is at increased risk but the colonoscopy interval is too short	Possibly indicates that CRC has arisen through alternative pathway from adenoma-CRC sequence Possibly indicates that the colonoscopy interval is too long
High advanced	Probably the ideal scenario	Cohort is at risk
colorectal polyp	Cohort probably at risk	Either current surveillance is ineffective, or the quality of the
yield	Interval not too short; does not exclude the possibility that interval could be extended	prior colonoscopy was inadequate Colonoscopy interval is too long

NOTE. The cohort categories do not preclude there being subgroups within each category who do/do not benefit from surveillance.

This categorization illustrates why, for this purpose, combining advanced colonic polyps and CRCs into one category (advanced colorectal neoplasia) is inappropriate. CRC, colorectal cancer.

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address specific questions. Potential comparators include:

- Negative colonoscopy cohort individuals who have undergone a colonoscopy where neither premalignant polyps nor cancer was detected. This cohort is likely to have a risk of CRC that is below that of the general population.
- Low-risk (no surveillance) cohort—individuals who have undergone a colonoscopy where the outcome was that no surveillance was warranted. Again, this cohort is likely to have a risk below that of the general population.
- Local population screening comparator—in a resourceconstrained health care system, there is an opportunity cost of performing colonoscopy with a low yield, because it potentially denies other higher risk patients from undergoing colonoscopy. Therefore, costs and availability of resources may represent additional factors to be considered when setting a surveillance threshold.
 - d. At surveillance colonoscopy, a high advanced colonic polyp and low CRC yield is the optimal combination, because it indicates that the cohort is probably at risk and that the surveillance interval is not too short. However. it does not exclude the possibility that the surveillance interval could be safely extended.

Agreement was reached on the fact that a combination of a high yield of advanced colorectal polyps and low yield of CRC at surveillance supports the need and proper timing of surveillance. Different combinations between advanced colonic polyp and CRC yield can be seen in Table 2.

Thresholds for Surveillance (Statements on This Topic Can Be Seen in Supplementary Tables 3 and 4)

The panel was asked to provide a threshold for an absolute risk of CRC for when surveillance would be worthwhile to recommend. Different alternatives were provided at the questionnaire regarding expected reduction on absolute and relative risk of CRC and advanced polyps (Supplementary Table 4). However, there was not a final agreement and, thus, the steering group decided not to include any statement on threshold for an increased risk to recommend surveillance. The definition of reduction of a high CRC risk cohort to the same risk of the general population as proxy for a favorable efficacy of surveillance did not reach consensus, as some of the experts voiced concerns about this metric as a satisfactory risk reduction (ie, a lower than general population risk should be pursued).

Conclusion

In this WEO recommendations, we have discussed the general principles of surveillance after polyp removal. The panel has defined new and groundbreaking definitions for the evaluation of benefits, harms, and burdens for surveillance, to be used in future studies and guidelines. We recommend CRC incidence as the consensus primary outcome in surveillance studies, with CRC mortality as a secondary outcome. Also, we have defined recommendations for situations that should not be reported routinely as meaningful outcomes for surveillance evaluation in the future.

We have reached a consensus about the most appropriate comparators for surveillance studies, which are the general population and a same risk cohort not receiving postcolonoscopy surveillance, and provided considerations about different scenarios where surveillance can be considered as relevant or irrelevant.

Finally, we have tried to establish relevant thresholds to define baseline cancer risk and surveillance efficacy. However, no agreement was reached for these metrics and more work is needed to establish what we should envision as an adequate reduction in CRC incidence and mortality with surveillance.

The aim of this position statement is that these recommendations may be used in future studies and guidelines about this important topic in colonoscopy activity and CRC prevention.

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Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of *Gastroenterology* at www.gastrojournal.org, and at https://doi.org/10.1053/j.gastro. 2019.12.052.

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Appendix 1

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Supplementary Figure 1. Flow-chart of the Delphi process.

Supplementary Table 1. Consensus Statements on Definitions and General Principles of Surveillance

	Consensus (%)
Definitions	
Advanced adenoma: An adenoma with any of the following features: \geq 10 mm in size, tubulovillous or villous histology, or high-grade dysplasia.	90
Advanced serrated polyp: A serrated polyp of either \geq 10 mm in size or containing dysplasia.	86
Advanced colorectal polyps: Comprising both advanced adenomas and advanced serrated polyps.	86
Advanced colorectal neoplasia: This term comprises both advanced colorectal polyps and invasive CRCs.	90
Principles	
The primary aim of postpolypectomy surveillance is to reduce CRC incidence in patients found to have prior colonic polyps, once polyp clearance has been achieved.	90
The secondary aim of CRC surveillance is to reduce CRC mortality. This is achieved both by reducing CRC incidence and through the identification of CRC at an earlier stage when CRC treatment carries a better prognosis.	81
Surveillance should only be offered to individuals who remain at higher risk of developing CRC, beyond the reduction seen by baseline polyp clearance, as compared with the general population.	80
The impact of surveillance in terms of CRC risk reduction should be balanced with the risks of harm (e.g., colonoscopy complications or psychological distress), the patient burden and the costs.	95
In a financially or endoscopy resource-constrained system, surveillance should also be considered in the context of other nonsurveillance cohorts of patients with higher positive predictive value for CRC/advanced polyps who may benefit more from the same resource (opportunity cost).	95
The findings at surveillance comprise both de novo pathology and pathology missed or incompletely excised at the prior colonoscopy. Higher quality colonoscopy will decrease the latter proportion.	95
Ideally, surveillance effectiveness should be measured after an appropriate period of postsurveillance follow-up.	90
Long-term (postsurveillance) follow-up of \geq 5 years, preferably 10 years, is recommended.	85

CRC, colorectal cancer.

Supplementary Table 2. Consensus Statements on Outcomes for Surveillance Studies

	Consensus (%)
Outcomes	
For surrogate (short-term) outcome measures such as ACP yield on surveillance colonoscopy, the comparator general population risk can be ascertained by using data from populations undergoing primary screening colonoscopy.	76 (19 disagree)
Outcome measures should be reported in terms of absolute risk (as opposed to relative risk) wherever possible.	90
The findings of "any adenomas," "any serrated polyps," or "any polyps" on a surveillance colonoscopy are not acceptable outcome measures for the identification of patient cohorts at increased risk of CRC beyond baseline clearance colonoscopy.	90
The finding of advanced colorectal polyps on a surveillance colonoscopy is an acceptable, though imperfect, surrogate outcome measure for the identification of patient cohorts at increased risk of CRC beyond baseline clearance colonoscopy.	90
The finding of CRC on a surveillance colonoscopy is an acceptable outcome measure for the identification of patient cohorts at increased risk of CRC beyond baseline clearance colonoscopy. Interval-type postcolonoscopy CRCs should be included.	85
The finding of advanced colorectal neoplasia (summating ACP and CRC) on a surveillance colonoscopy is an acceptable surrogate outcome measure for the identification of patient cohorts at increased risk of CRC beyond baseline clearance colonoscopy. However, it is preferable to analyze ACP prevalence and CRC prevalence (including interval-type PCCRCs) separately.	85
Long-term (postsurveillance) CRC incidence is the preferred outcome measure for the identification of patient cohorts at increased risk of CRC beyond baseline clearance colonoscopy.	85
Long-term (postsurveillance) CRC mortality rate is an acceptable outcome measure for the identification of patient cohorts at increased risk of CRC beyond baseline clearance colonoscopy	90
All-cause mortality rate is not an acceptable outcome measure for the identification of patient cohorts at increased risk of CPC beyond baseline clearance colonoccopy.	90
The findings of "any adenomas," "any serrated polyps," or "any polyps" on a surveillance colonoscopy are not acceptable outcome measures for the assessment of whether a surveillance strategy has been effective in mitigating this increased CRC risk.	95
The finding of advanced colorectal polyps on a surveillance colonoscopy is an acceptable, although imperfect, surrogate outcome measure for the assessment of whether a surveillance strategy has been effective in mitigating this increased CRC risk.	90
The finding of CRC on a surveillance colonoscopy is an acceptable, though imperfect, outcome measure for the assessment of whether a surveillance strategy has been effective in mitigating this increased CRC risk. Interval-type postcolonoscopy CRCs should be included	72 (19disagree)
The finding of advanced colorectal neoplasia on surveillance is not an acceptable outcome measure for the assessment of whether a surveillance strategy has been effective in mitigating this increased CRC risk, as it inappropriately combines 2 discrete patient cohorts, those with advanced adenomas and those with CRC.	90
Long-term (postsurveillance) CRC incidence is a preferred outcome measure for the assessment of whether a surveillance strategy has been effective in mitigating this increased CRC risk.	100
Long-term (postsurveillance) CRC mortality rate is a preferred outcome measure for the assessment of whether a surveillance strategy has been effective in mitigating this increased CRC risk.	85
All-cause mortality rate is an unrealistic outcome measure for the assessment of whether a surveillance strategy has been effective in mitigating this increased CRC risk. However, assessing all-cause mortality might be worthwhile to ensure that surveillance does not cause overall patient harm.	90

ACP, advancer colorectal polyp; CRC, colorectal cancer; PCCRC, postcolonoscopy colorectal cancer.

Supplementary Table 3. Consensus Statements for Comparators and Thresholds in Surveillance Studies

	Consensus (%)
Comparators	
Surveillance effectiveness is best assessed with an appropriate comparator group.	95
The risk of bias in both the active and comparator groups (eg, from contamination by colonoscopy) should be considered.	85
When assessing postpolypectomy CRC risk, we consider an age- and gender-matched general population comparator to be the optimal comparator group. In this context, general population should reflect the background population risk, irrespective of screening status.	81
When assessing surveillance effectiveness, we consider a same-risk nonsurveillance comparator to be the optimal comparator group.	90
If long-term CRC incidence/mortality in a postpolypectomy cohort not undergoing surveillance is the same as that of the general population, then surveillance is not justified (as this indicates that the cohort is not at increased risk).	81
If long-term CRC incidence/mortality in a postpolypectomy cohort not undergoing surveillance is the same as that of the same-risk cohort undergoing surveillance, then surveillance is not justified (because this indicates that surveillance is having no impact).	90
At surveillance colonoscopy, a high ACP and low CRC yield is the optimal combination, as it indicates that the cohort is probably at risk and that the surveillance interval is not too short. However, it does not exclude the possibility that the surveillance interval could be safely extended.	90
At surveillance colonoscopy, if yields of both ACP and CRC are low, this may indicate that the cohort is not at increased risk (hence did not require that surveillance) or that the surveillance interval is too short.	86
At surveillance colonoscopy, if the yields of both ACP and CRC are high, this confirms that the cohort is at risk, but that the current surveillance strategy has been ineffective at mitigating the risk. This pattern may indicate that the surveillance interval is too long, or that the quality of the prior colonoscopy was inadequate.	95
At surveillance colonoscopy, a low ACP but high CRC yield confirms that the cohort is at risk, but that the current surveillance strategy has been ineffective at mitigating that risk. This pattern may indicate that CRC has arisen through an alternative pathway from the polyp-carcinoma sequence, and that alternative strategies should be sought.	86
The threshold for any increase in risk in the surveillance cohort should be clinically relevant, not just statistically significant.	95

ACP, advanced colorectal polyp; CRC, colorectal cancer.

Supplementary Table 4. Statements Without Consensus

The finding of multiple adenomas on surveillance may be an acceptable outcome measure for the identification of patient cohorts at increased risk of CRC beyond baseline clearance colonoscopy.

If long-term CRC incidence/mortality in a postpolypectomy cohort undergoing surveillance is the same as that of the general population, then (assuming this cohort of patients was indeed at increased CRC risk), this indicates that surveillance has been effective in suppressing the excess CRC risk.

What level of 10-year CRC risk would you consider high enough to warrant surveillance?

- Same as FIT screening positive
- 3%
- 2%

• 1%

When assessing surveillance effectiveness, what reduction in this level would you consider CLINICALLY significant?

• Reduction to no higher than 2 times the general population risk

• Reduction to no higher than 1.5 times the general population risk.

What would you consider the appropriate threshold for advanced adenoma yield found on surveillance, below which surveillance is unnecessary?

- · Same as FIT screening positive
- 20%
- 15%
- 10%

Given that adenoma surveillance aims to prevent CRC, above what threshold for CRC yield found on surveillance, would you consider surveillance to have been ineffective?

- 2 times general population risk
- 1.5 times general population risk.