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Learning objectives	• Articulate the evidence and rationale supporting the use of coronary computed tomographic arteriogram (CCTA) as a first strategy for the evaluation of stable chest pain. • Evaluate the use of blood eosinophil counts to determine oral glucocorticoid therapy for chronic obstructive pulmonary disease (COPD) exacerbations. • Examine the benefits and related uncertainties of anticancer drugs. • Demonstrate effective medical management practices, including supporting timely primary care follow-up post-hospital discharge to reduce hospital readmission rates, not utilizing repeat endoscopy for non-erosive gastroesophageal reflux disease, and compare the benefits and drawbacks of common cancer screening and stool-based colorectal cancer screening tests.

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Coronary computed tomographic arteriogram as first strategy for the evaluation of stable chest pain

The evaluation and management of stable chest pain has undergone a paradigm change. Stable chest pain can be thought of as the wide range of presentations of suspected coronary artery disease. It excludes unstable angina and the acute coronary syndromes in which urgent management is indicated. Three years ago, we first introduced in the Forum the use of coronary computed tomographic arteriogram (CCTA) with fractional flow reserve (FFR) for the evaluation of stable chest pain. Recall that CCTA was initially unable to differentiate functionally significant stenoses that limited blood flow from those that did not. Software that calculates FFR now allows an accurate estimation of the pressure gradient across a stenotic artery, and therefore can determine functionally significant from non-significant stenoses. FFR only needs to be utilized when visually significant stenoses are observed. The range of studies needing FFR varies between 15%–30%.

Between 2019 and 2023, three large RCTs that compared CCTA/FFR to ischemia testing were published.

- CONSERVE Trial[1] – Over 1,600 patients who had been recommended by their cardiologist to undergo coronary catheterization were randomized to have an initial CCTA/FFR vs. going directly to catheterization. Major adverse cardiovascular events (MACE) were the same in both arms of the trial. However, in the CCTA/FFR patients, there were 78% fewer catheterizations and 45% fewer coronary artery interventions.
- DISCHARGE Trial[2] – Using a similar design to the above trial, over 3,600 patients were randomized to CCTA/FFR vs. coronary catheterization. MACE were non-significantly reduced in the CCTA/FFR patients. Once again in the CCTA/FFR patients, there was a 78% reduction in cardiac catheterization and a 36% reduction in coronary artery interventions
- PRECISE Trial[3] – This trial randomized 1,937 patients to a precision strategy (PS) arm vs. a usual testing (UT) arm. In the PS arm, the lowest risk patients had testing deferred. Those in the higher risk categories received CCTA/FFR. In the UT arm, cardiologists chose their preferred ischemia test and referred for coronary catheterization accordingly. In the PS arm, 20% of patients were classified as minimal risk and had testing deferred. None of these patients had a subsequent MACE. Overall, in the PS arm there was a 75% reduction in catheterizations that did not show obstructive disease compared to the UT arm. Once again, overall MACE was similar in the two arms.

We now have three large well done RCTs showing strikingly similar results. Compared to ischemia testing whether nuclear, stress echo or stress PET, those who have CCTA in lieu of ischemia testing showed a marked reduction in the need for cardiac catheterization, a marked reduction in the “clean cath rate” (those catheterizations that did not show obstructive disease) and similar CV outcomes. Two of the three trials also showed a marked reduction in the need for coronary artery interventions. Based on these accumulated data, in 2021, the American College of Cardiology (ACC/AHA) revised their guidelines on the management of stable chest pain. These guidelines were adapted into our Optimal Care algorithms for the management of stable chest pain, with and without known CAD. These algorithms take into consideration the pretest probability of CAD, and the chart to estimate the pretest probability of CAD is embedded within the algorithm.

Our algorithm for patients with stable chest pain and no known CAD suggests that those patients with a pretest probability of CAD of < 15% should have a coronary artery calcium score with no further testing if the score is zero. The AHA/ACC guideline also states that reassurance with deferral of testing is appropriate for these patients. For those with a pretest probability of > 15%, CCTA will be recommended for most of these patients. In this algorithm, cardiology referral may or may not be indicated based on the result of the CCTA/FFR. Please see the Coronary CT angiography for stable chest pain with no known CAD algorithm for details.

For those patients with stable chest pain and known CAD, if the patient has a known coronary stenosis of > 50% or if they have had a prior coronary intervention, they should be referred to cardiology. If not, they should be treated with guideline directed medical therapy since medical therapy and coronary intervention have equivalent outcomes in stable CAD. If symptoms are not adequately controlled with this approach, a CCTA/FFR should be obtained as the next step with cardiology referral if indicated, based upon the results. Please see the Coronary CT angiography for stable chest pain with known CAD algorithm for details.

The current clean cath rate across Optum Health is ~60%, not significantly different than the national average. With widespread adoption of the new AHA/ACC guideline embedded in our Optimal Care algorithms, we should be able to reduce the rate of unnecessary catheterizations dramatically. In fact, our Optum Health data has shown that as our CCTA utilization increases, our clean cath rate decreases. Lower catheterization rates also equate to lower coronary intervention rates. A recent study by the Lown Institute[4] suggested that 22% of stents were unnecessary with a cost to Medicare of $2.44 billion over three years.

There are several barriers to widespread adoption of the CCTA first strategy:

- While all of our markets have access to the appropriate CT scanners through owned or contracted imaging centers, many care delivery organizations (CDOs) have not yet formalized the referral network for CCTA and/or executed a contract for FFR which is needed for these readings.
- Many cardiologists are unwilling to forgo the revenue associated with ischemia testing and therefore don't prioritize the use of CCTA first.
- This does require a bit more work from the primary care physician (PCP). A referral to cardiology requires only a click or two. Scheduling a CCTA requires checking to see if the eGFR is > 30 ml/min and prescribing a beta blocker to be used pretest,as the HR needs to be in the 60 bpm range for optimal imaging. The beta blocker regimen is simple:
  - If the patient heart rate (HR) is > 70 bpm, prescribe short-acting metoprolol tartrate 100 mg one hour prior to the CCTA.
  - If the patient HR is between 60-70 bpm, prescribe short-acting metoprolol tartrate 50 mg one hour prior to the CCTA.
- CCTA can't be used for patients with atrial fibrillation if they have heart rates much over 60 bpm, a severe contrast allergy or BMI > 40.

We are addressing all of the above. Our newly formed Cardiology Forum, made up of our employed cardiology thought leaders, has created a CCTA sub-committee to strategize on the mitigation of all of the above barriers. Given the compelling evidence of improved patient outcomes, reduced harms of invasive coronary interventions, and reduced cost of care, the use of the CCTA first strategy is one of the chief priorities for the Optimal Care model.

Use of blood eosinophil counts to determine glucocorticoid therapy for COPD exacerbations

Multiple studies have demonstrated that the blood eosinophil count (BEC) should be used to guide inhaled corticosteroid therapy (ICS) in COPD, as reflected in the updated GOLD guideline.[5] This is because it is now well-established that ICS therapy increases the risk for bacterial pneumonia from secondary immunodeficiency due to steroids. In those individuals with an elevated BEC, the improvement in COPD exacerbation rate with ICS use is greater than the risk of pneumonia and therefore ICS use is indicated. Our Optimal Care COPD algorithm therefore recommends ICS use in patients with a BEC >300 cells/ul or for those patients with >100 cells/ul if there are repeated exacerbations.

Similar studies have not been done to evaluate whether the BEC should inform the use of oral glucocorticoids for COPD exacerbations. Although the risks of short-term treatment are low, about 30% of seniors have type 2 DM complicating the use of oral glucocorticoids. A recent study in the British Medical Journal examined the use of BEC informed use compared to the standard of care in COPD exacerbation, using a double blind, placebo-controlled approach.[6] Patients with COPD and at least one exacerbation in the past year were recruited from 14 PCP practices in the U.K. Participants were randomly assigned (1:1) to blood eosinophil-directed treatment (to receive oral prednisolone 30 mg once daily if eosinophil count was high [≥ 2%] or placebo if eosinophil count was low). Prednisolone was used in all of the standard care patients. Treatment was prescribed for 14 days, and all patients also received antibiotics. The primary outcome was the rate of treatment failure, defined as any need for re-treatment with antibiotics or steroids, hospitalization for any cause, or death, assessed at 30 days after exacerbation.

There were just over 70 patients in each treatment group. There were 14 (19%) treatment failures at 30 days post-exacerbation in the BET group and 23 (32%) in the ST group, resulting in a large non-significant estimated effect between BET and ST (RR 0·60 [95% CI 0·33–1·04]; p=0·070) in reducing treatment failures after a COPD exacerbation. Frequency of adverse events was similar between the study groups and hospital admission for COPD exacerbation (2/102 [2%] in BET group and 1/101 [1%] in the ST group) were the two most common adverse events in both groups. No deaths occurred in the study.

Two previous studies looking at BEC to guide glucocorticoid therapy in COPD exacerbations found similar results.[7,8] Given the consistency in these studies, withholding glucocorticoid therapy in COPD exacerbations when the BEC is low seems reasonable, particularly in a patient with type 2 DM who would experience hyperglycemia related to treatment.

Communication of anticancer drug benefits and related uncertainties to patients and clinicians

Research around the accuracy of communication of anticancer drug benefits and toxicities to patients is limited. When patients are receiving cancer drug treatment they need high quality information, including information about the benefits and risks of the drugs that are being offered. This information can support ethical principles of patient autonomy, facilitate shared decision making, and help to ensure that treatment is sensitive to, and meets the needs and priorities of, individuals. Patients with advanced, non-curable cancer can face particularly difficult decisions as they must often weigh a small, or even unknown increase in survival time against the toxicity and expense of treatment. In the U.K. and European Union, it is mandatory for all approved medicines to be accompanied by written information for patients and healthcare professionals that has been approved. This is not the case in the U.S., although the U.S. Food & Drug Administration (FDA) is considering implementing this approach.

A recent study examined the quality of this information in 29 cancer drugs newly approved between 2017 and 2019 for 32 indications.[9] Only 28% of the indications showed benefits on patient-relevant outcomes of survival or quality of life at the time of approval. The remaining 72% of indications lacked evidence that the drug extended survival or improved quality of life. As in the U.S., these drugs were approved on the basis of a surrogate endpoint such as progression-free survival or tumor response. For a quarter of indications, the degree of uncertainty was such that regulatory agency was unable to reach a consensus on whether the benefits of the drug had been shown to outweigh the risks, although they were approved for use.

In the drug leaflet information given to the patients, none of the drugs provided any information on anticipated clinical benefit, overall survival or improvements in quality of life. They also provided no information on how the drug was studied or what outcomes endpoints were used in the approval trials. Recent research suggests that in the absence of explicit information about the strength of the evidence around recommended treatments and interventions, people assume the evidence is of high quality.[10] Patients need to be educated that the surrogate endpoints such as progression-free survival and tumor response do not reliably predict either improved patient survival or improved quality of life. Regulated information sources for anticancer drugs in Europe fail to address the information needs of patients and patient education around new drugs is not currently addressed by the FDA. Until there is effective FDA regulation on this issue, we need to challenge our oncology colleagues to educate our patients about how these drugs will impact the outcomes that matter to them – will I live longer, or will I feel better?

Timely PCP follow-up reduces hospital readmission

Unplanned readmission following hospital discharge is a costly and often preventable outcome. Yet another study highlights the highly significant quality and cost benefits of patients being seen in their PCP office following hospital discharge. In a recent cohort study that included over 345,000 Medicare beneficiaries who were hospitalized with an emergency general surgery (EGS) condition, likelihood of readmission within 30 days was substantially lower in the 45.4% of subjects who had a follow-up PCP visit than those who did not.[11] The median time to a follow up PCP visit was 12 days post discharge. Overall, the adjusted odds ratio (AOR) of readmission was 67% lower in this group who had PCP follow-up (AOR, 0.33; 95% CI, 0.31-0.36). More specifically, those who were treated operatively had 79% reduced odds of readmission (AOR, 0.21; 95% CI, 0.18-0.25) and those treated non-operatively had 64% reduced odds of readmission (AOR, 0.36; 95% CI, 0.34-0.39). The two groups were propensity-matched to minimize risk of bias. Even when adjusting for those who saw their surgeon in follow-up after hospitalization, the benefit of PCP follow-up remained robust (AOR, 0.42; 95% CI, 0.38-0.46). These findings comport with previous studies that show a clear patient benefit of PCP follow-up after hospital discharge,[12,13] reinforcing the importance of care coordination, PCP follow-up, and appropriate hand-off between care teams.

Non-erosive gastroesophageal reflux disease does not require repeat endoscopy to monitor for cancer

A recent large cohort study demonstrated that patients with non-erosive gastroesophageal reflux disease (GERD) are at "average" risk of esophageal cancer and therefore do not need follow-on screening endoscopy.[14] Non-erosive GERD is the most common type. The study included 285,811 patients, median age of 59, 58.7% women, with non-erosive GERD with over 2 million person-years of follow-up. The incidence of esophageal cancer in this group was 11 per 100,000 person-years, which is similar to that of the general population (standardized incidence ratio 1.04 [95% CI, 0.91-1.18]). This is in contrast to a similar cohort (n=200,745) with endoscopically-confirmed erosive esophagitis, who had an incidence rate of esophageal cancer of 31 per 100,000 person-years (standardized incidence ratio of 2.36 [95% CI, 2.17-2.57]). Study participants were from Scandinavian countries (Denmark, Finland, Sweden) from 1987–2019 so findings may not be generalizable to all populations, but they do suggest that for those patients with endoscopically-confirmed non-erosive GERD and no change in signs or symptoms, no additional screening for esophageal cancer is indicated.

Longevity benefits of common cancer screening tests may be smaller than anticipated

Screening programs for common cancers are major public health initiatives in the U.S. and are integral to primary care and preventive healthcare. When detected early, many forms of cancer (CA) are more likely to be amenable to curative treatment and at lower cost and patient discomfort. Successful screening programs for common cancers, when applied to the correct populations of patients, use cost-effective tests with appropriate sensitivity and specificity for conditions that are important to identify and treat before symptoms or signs develop.

A recent meta-analysis of randomized clinical trials examined the impact on longevity of six different CA screening tests: mammography, prostate-specific antigen testing, colonoscopy, flexible sigmoidoscopy, fecal occult blood testing (FOBT), and computed tomography (CT for lung CA screening).[15] 2,111,958 patients were included across all screening tests, with a median follow-up ranging from 10–15 years. Sigmoidoscopy was the only test to demonstrate significant lifetime gain (110 days; 95% CI, 0-274 days). All other tests did not demonstrate significant lifetime gains, with the 95% confidence interval crossing zero days, as shown in the table below. Of note, on average, follow-up did not extend past 15 years for any test.

Table: Lifetime gains for each of six screening tests for common cancers

Test	Lifetime gain (number of days; 95% confidence interval)
Flexible sigmoidoscopy for colorectal CA	110 days; 0–274 days
Colonoscopy for colorectal CA	37 days; -146 to 146 days
FOBT every year or every other year for colorectal CA	0 days; -70.7 to 70.7
Mammography for breast CA	0 days; -190 to 237 days
Prostate specific antigen for prostate CA	37 days; -37 to 73
CT for lung CA	107 days; -286 to 430 days

The current study analyzes a large group and does not address potential individual benefits of early CA detection through screening. Nor do these results address the potential individual harms of CA screening that include direct harms from the test itself (such as perforation during colonoscopy) or indirect harms such as false positive tests with additional testing and patient anxiety. There is little doubt that evidence-based cancer screening programs as promoted by various national bodies such as the USPSTF provide important public health benefits, outside of an estimation of lifetime days gained. Both patients and physicians overestimate the benefits and underestimate the harms of cancer screening. The current study does reinforce the benefits of screening wisely by using the most cost-effective screening modalities and schedules, and adhering to established guidelines and not broadening screening beyond those populations identified.

Expansion of arsenal of stool-based colorectal cancer screening tests

Colorectal cancer (CRC) remains one of the leading causes of death in the U.S., and screening of asymptomatic adults remains one of the most effective ways to identify early disease more amenable to curative treatment. There are many studies reporting on the effectiveness of various screening modalities.

Two recent reports signal additional progress and options for CRC screening. The CRC-PREVENT study is a Phase 3 clinical trial comparing the test performance of a multitarget stool RNA (mt-sRNA) screening test with the fecal immunochemical test (FIT).[16] The BLUE-C trial compared test performance of a multitarget stool DNA (mt-sDNA) screening test with FIT[17] (this test can be thought of as the next generation of the Exact Science Cologuard test). Both trials used screening colonoscopy as the gold standard with which to compare. The mt-sRNA and mt-sDNA both had sensitivities that significantly outperformed the FIT for CRC and for advanced precancerous lesions (APL), although specificity was worse (see Table). Given trade-offs in test performance, frequency, costs, risks, and convenience, clinicians should engage their patients in a shared decision-making conversation to determine which is the most appropriate method for them.

Table: Sensitivity and specificity for CRC and for APL for three stool-based CRC screening tests

	CRC sensitivity	APL sensitivity	Specificity for "no lesions"
mt-sDNA	93.9% (95% CI, 87.1–97.7)	43.4% (95% CI, 41.3–45.6); sensitivity for APL with high-grade dysplasia was 74.6% (95% CI, 65.6–82.3)	93.4% (95% CI, 92.8–93.9)
FIT performance in mt-sDNA study	67.3 (95% CI, 57.1–76.5)	23.3 (95% CI, 21.5–25.2)	96.0% (95% CI, 95.5–96.6)
mt-sRNA	94.4% (95% CI, 81–99)	45.9% (95% CI, 42–50)	87.9% (95% CI, 87–89)
FIT performance in mt-sRNA study	77.8% (95% CI, 61–90)	28.9% (95% CI, 25–33)	95.7% (95% CI, 95–96)

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Dr. Kenneth Cohen is an experienced physician leader, practicing internist and researcher who has attained national recognition for health care quality improvement. He was one of the founding physicians of New West Physicians, which is the largest primary care group practice in Colorado and now part of Optum Care. He served as Chief Medical Officer from 1995–2020. He now serves as the Executive Director of Translational Research for Optum Care and co-leads the Optum Center for Research and Innovation. Dr. Cohen has received awards of recognition and distinction for teaching, including the Lutheran Medical Center Physician of the Year award in 2011. Under his stewardship New West Physicians was awarded the AMGA Acclaim award in 2015 and the CDC Million Hearts Hypertension Champion Award in 2017. He is a Clinical Associate Professor of Medicine and Pharmacy at the University of Colorado School of Medicine and School of Pharmacy. He is a Fellow of the American College of Physicians and a member of the Phi Beta Kappa and Alpha Omega Alpha honor societies.

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