Increasing Colorectal Cancer Screening with Stool DNA Tests

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Purpose of Today's Webinar







PRESENT INNOVATIVE APPROACH TO CLOSING THE GAP OF OVERDUE COLOGUARD RESCREENS ILLUSTRATE USE OF A PDSA CYCLE IN A CONTINUOUS QUALITY IMPROVEMENT PROJECT INTRODUCE EXAMPLES OF USEFUL PDSA TOOLS



Empowering our customers to achieve their best health

At North Memorial Health, we're on a mission to change healthcare by treating our customers like family.

31,885

TELEHEALTH VISITS in 2020

DELIVERING THE

most babies

IN MINNESOTA (2019 & 2020)

HELICOPTERS

6,500+

MEMBERS

TEAM

About North Memorial Health



OVERVIEW





Colorectal Cancer Screening (CRCS)

- Test that aims to prevent disease or find it early in those who do not have symptoms
- Is not about a single age
- Key to finding cancer early, when treatment works best

U.S. **Preventive Services Task Force**

Clinician Summary of USPSTF Recommendation Screening for Colorectal Cancer What does the USPSTF recommend? For adults aged 50 to 75 years: A Screen all adults aged 50 to 75 years for colorectal cancer. For adults aged 45 to 49 years: Barada Screen adults aged 45 to 49 years for colorectal cancer. For adults aged 76 to 85 years: C Selectively screen adults aged 76 to 85 years for colorectal cancer, considering the patient's overall health, prior screening history, and patient's preferences.

To whom does this recommendation apply?

Adults 45 years and older who do not have signs or symptoms of colorectal cancer and who are at average risk for colorectal cancer (ie, no prior diagnosis of colorectal cancer, adenomatous polyps, or inflammatory bowel disease; no personal diagnosis or family history of known genetic disorders that predispose them to a high lifetime risk of colorectal cancer [such as Lynch syndrome or familial adenomatous polyposis]).

What's new?

The USPSTF expanded the recommended ages for colorectal cancer screening to 45 to 75 years (previously, it was 50 to 75 years). The USPSTF continues to recommend selectively screening adults aged 76 to 85 years for colorectal cancer.

How to implement this recommendation?

Screen all adults aged 45 to 75 years for colorectal cancer. Several recommended screening tests are available. Clinicians and patients may consider a variety of factors in deciding which test may be best for each person. For example, the tests require different frequencies of screening, location of screening (home or office), methods of screening (stool-based or direct visualization), preprocedure bowel preparation, anesthesia or sedation during the test, and follow-up procedures for abnormal findings.

Recommended screening strategies include:

- High-sensitivity guaiac fecal occult blood test (HSgFOBT) or fecal immunochemical test (FIT) every year
- Stool DNA-FIT every 1 to 3 years
- Computed tomography colonography every 5 years
- · Flexible sigmoidoscopy every 5 years
- · Flexible sigmoidoscopy every 10 years + annual FIT
- Colonoscopy screening every 10 years

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone Clinicians should understand the evidence but individualize decision making to the specific patient or situation.



May 2021



COLORECTAL CANCER SCREENING IN MINNESOTA

2019 REPORT YEAR (2018 DATES OF SERVICE)

Minnesota CRCS Rates @ a Glance



OPPORTUNITIES FOR IMPROVEMENT



of non-English speaking patients in Minnesota

have an up-to-date colorectal cancer screening, compared to 72% of English-speaking patients

years have s rates comp

Patients between 50-54 years of age have significantly lower

have significantly lower rates (59%) of screening compared to patients in age groups 55 years and older in Minnesota



American Indian/Alaskan Native, Asian, Black/African American, Multi-Racial and Native Hawaiian/Other Pacific Islander patients have significantly lower rates of screening compared to ____

White patients in Minnesota

BACKGROUND



Colorectal Cancer Screening Pandemic Trends

• Epic data based on our Internal Reporting built to closely mirror HEDIS specs (is not claims based)







Comparison of screening modalities for Customers who are UTD



Colorectal Cancer Screening (CRCS) Provider Discussion Guide





Existing CRCS Improvement Tactics





PDSA Review



What is PDSA?



Plan, Do, Study, Act (PDSA) is a quality improvement method commonly used for testing change by planning it, trying it, observing results, and acting upon what has been learned



Works best when starting small and fast tests



Prediction based test of change



Designed to run in cycles



Three Fundamental Questions

What are we trying to accomplish? How will we know that change is an improvement? What change can we make that will result in an improvement?



Why Test Changes?

Avoids wasting effort

Provides opportunity learning from "failures" without significant negative impact

Evaluate for any downstream impacts

Reduce implementation resistance from key stakeholders





Root Cause Analysis (RCA)

- Avoid jumping to conclusions
- Avoid addressing only symptoms
- Design and implement lasting solutions that eliminate the "root"

17

PDSA Tool Examples







PDSA Cycle Worksheet

Act 🥽 Plan	Project Name:		Cycle Begin Date:	Cycle End Date:	
L I	Cycle #:	What is pur	pose of cycle? Test Opt-Out		
		Test (Small-Scale) Test (Large-Scale)			
Study	What are we trying to accomplish?	How will we know that change is an improvement?		What change can we make that will result in improvement?	
PLAN:			DO: Carry out the change and collect data		
What is going to happen?			Was the cycle completed as planned? Yes No		
Who will make the change?		Record data and observations:			
Who will receive the change?					
When will the change take place?		What did you observe that was not part of the plan?			
How long will it last?					
Where will the change take place?		STUDY: Analyze and summarize data			
What tasks or tools are needed?		Did the results match your prediction(s)? ☐Yes ☐No Compare the result of your test to your previous performance:			
What types of data will be collected?					
Who will collect data?		What did you learn?			
Prediction:		ACT: Decide to Adopt, Adapt, or Abandon			
		Adopt: Select changes to implement on a larger scale and develop implementation plan			
		Adapt: Improve the change and continue testing plan. Describe what you will change in your next PDSA			
		Abandon: Discard this change idea and try a different one			



PDSA Cycle Tracking Form



Project Name:

Change Tested/Implemented:

CYCLE #:	PLAN	DO	STUDY	ACT
1	Objective of Cycle: Test a Change (Small–Scale) Test a Change (Large-Scale) Implement a Change	Test Begin Date: Test End Date:	What worked well? What could be improved?	Abandon: Discard change idea and try a different one Adapt: Improve the change and continue testing plan Adopt: Develop implementation plan and plan for sustainability
2	Objective of Cycle: Test a Change (Small-Scale) Test a Change (Large-Scale) Implement a Change	Test Begin Date: Test End Date:	What worked well? What could be improved?	Abandon: Discard change idea and try a different one Adapt: Improve the change and continue testing plan Adopt: Develop implementation plan and plan for sustainability
3	Objective of Cycle: Test a Change (Small-Scale) Test a Change (Large-Scale) Implement a Change	Test Begin Date: Test End Date:	What worked well? What could be improved?	Abandon: Discard change idea and try a different one Adapt: Improve the change and continue testing plan Adopt: Develop implementation plan and plan for sustainability
4	Objective of Cycle: Test a Change (Small-Scale) Test a Change (Large-Scale) Implement a Change	Begin Date:	What worked well? What could be improved?	Abandon: Discard change idea and try a different one Adapt: Improve the change and continue testing plan Adopt: Develop implementation plan and plan for sustainability



PDSA in Action





Identified Gap in Cologuard Rescreen



Fishbone Diagram

CAUSES EFFECT Plan Support Team **Primary Care Provider Patient Barriers** Barriers Barriers 1.Other health priorities 1.Clinic encounter time constraints 1. Staffing constraints 2. COVID workflow challenges 2. Competing organizational priorities 2. Unaware of screening due 3. Time constraints during rooming process Out-of-pocket costs 3. Staffing constraints 4. Lack of access to care 4. Underutilization of system resources 4. Underutilization of system resources 700+ 5. 5. Unclear insurance coverage for dx colonoscopy **CUSTOMERS OVERDUE** COLOGUARD RESCREEN 5. Utilization of telehealth 5. 4. Patients not assigned to a PCP 4. Delay in CRCS Payor Initiatives data 3. Capacity constraints in clinics 3. EHR does not include outside payor initiatives 2. Cologuard data resides outside of internal application 2. Competing organizational priorities 1. No outlined process for Cologuard recall 1.No internal baseline Cologuard rescreen benchmarks Systems/Clinic Data Measurement **Barriers** Barriers NORTH

MEMORIAL HEALTH



Root Cause Analysis (RCA)

- Avoid jumping to conclusions
- Avoid addressing only symptoms
- Design and implement lasting solutions that are capable of eliminating the "root"

Plan RCA Analysis



Missing baseline data/reliance on external application



Competing organizational priorities impacting screening rate





Plan

Problem-Solving

- Exact Sciences on board with opt-out approach for Cologuard Rescreen Pilot
- Worked collectively to mitigate risk



Plan

What is going to happen? Customers overdue for Cologuard rescreen will automatically receive a kit outside of an office visit and without assistance from front-line team members.

Who will make the change? Partnership with QI, Care Access and IT applications

Who will receive the change? Customers who meet inclusion guidelines

When will the change take place? 11/1/2021

How long will it last? 90 days

Where will the change take place? All Primary Care Clinics @ NMH

What tasks or tools are needed? Approval from Operations, IT & Care Access Senior Leaders, accurate identification of customers included, communication blasts, phone line for customers to call in and opt out, workflow for CSRs

What types of data will be collected? Rate of kit completion

Who will collect data? Exact Sciences

Prediction: 80% of customers who are included in Cologuard Opt-Out Outreach will complete kit in 90 days







MEMORIAL HEALTH

Cologuard Rescreen Pilot

What is changing and when?

- On November 1st, 2021 approximately 250 primary care customers will receive automated messaging via Email (preferred), text or voicemail. On November 15th, 2021 batch Cologuard lab orders will be placed for the customers who did not contact <u>NMH</u> to opt out of rescreen.
 - o Sample size relatively low for initial rescreen pilot due to strict eligibility guidelines including:
 - 1. Current Health Maintenance overdue alert for Cologuard
 - 2. Successfully completed a Cologuard test over three (3) years ago and result was negative
 - 3. Attributed PCP identified and provider still active
 - 4. Customer is currently between the ages of 45-75
 - 5. Clinic, telehealth or home visit encounter within the last two (2) years
 - 6. Not a current palliative or hospice care patient
 - 7. No inflammatory bowel disease or colorectal cancer documented within the customer's problem list, medical history or used as an encounter

Why is the change happening?

notifying Primary Care Providers of rescreen

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Delivery of quality adult preventative services such as colorectal cancer screening is essential to improving population health. To effectively close colorectal cancer screening care gaps, leveraging information technology supports is paramount. The USPSTF recommends rescreening every three years for negative sDNA-FIT results. An opportunity exists within Blaze Health to target outreach to customers who have successfully completed Cologuard testing in the past and due for rescreening.

How do I navigate this change?

Review FAQs and email messaging below for your awareness

Frequently Asked Questions:

- When is the customer charged for the Cologuard test? Customer is not charged until the completed kit has been resulted. This means if a kit is sent out to the customer home and is never sent back in, customer will not receive a charge.
- What number is the customer given to call with if they wish to opt out? A unique CSR phone number has been assigned for customers to call to enable tracking responses and provide more accurate data for auditing purposes.
- What will CSR say if a customer does call in? CSR agents have been provided a Tip Sheet and FAQs. If a customer calls in and
 requests to opt out prior to November 15th, the CSR agent will send an in-basket message to ensure customer is removed from bulk
 Cologuard orders.
- Who receives the Cologuard results? The attributed PCP will receive the Cologuard result per the usual process.
- What if the customer has questions related to completion of the Cologuard kit or Insurance Coverage concerns? The automated messaging sent to the customer on November 15th includes an Exact Sciences 24-hour patient representative line 1-844-870-8870 who will be able to assist.



Dc

Communication tool for

pilot

Study

Do

Communication tool for customers included in pilot

Automated Phone message or text (Customer does not have email on file)

From North Memorial Health: Hello, our records indicate that you may be eligible for Colorectal Cancer rescreening with Cologuard. We recommend screening three years after a negative Cologuard result. For your convenience, we will send you a rescreen kit unless you opt out. Please call for more information or to opt out.

Automated Email Message

MORTH CLINIC

Dear (Patient's Name),

Our records indicate that you're eligible for Colorectal Cancer Rescreening with Cologuard. The U.S. Preventive Services Task Force (USPSTF) recommends screening again three years after a negative Cologuard result. For your convenience, a Cologuard rescreening order will be placed for you. If you want to opt out of the rescreen or have completed colorectal cancer screening such as a colonoscopy since your last Cologuard, please call to speak with an agent who can assist with opting out.

How it Works:

- Contact Exact Sciences at 1-844-870-8870 with questions related to insurance coverage or completion of the Cologuard kit.
- A kit will be shipped to you with instructions and a prepaid, preaddressed UPS return label.
- · You collect your own stool sample in the privacy of your own home.
- Call Exact Sciences at 1-844-870-8870 to schedule a pick-up of your completed kit right from your home
- You will receive your Cologuard test results via MyChart notification or a letter will be mailed to your home
 address if you have not signed up for MyChart.
- Your provider will also receive your results and advise on any follow-up steps. The test result will be positive, negative or no result obtained.

What does a positive result mean?

- The test detected abnormal DNA and/or blood that could be caused by precancerous polyp or cancer in the colon. The test can detect 92% of colon cancers and 42% of large adenomatous polyps (the precursor to cancer).
- The test can also have a positive result that is incorrect (false positive). This means the test result is
 positive, but no colon cancer or precancerous polyps were present.
- The test has a 13% false positive rate, which means about 1 in 8 positive tests will incorrectly identify colon cancer or polyps.
- Your provider will recommend a follow-up diagnostic colonoscopy for all positive results (please note: a diagnostic colonoscopy may incur an insurance copay or deductible based on your healthcare coverage).

What does a negative result mean?

- The test did not detect abnormal DNA and/or blood in the sample.
- The test can also have also an 8% false negative rate, which means that 1 in 12 negative tests will
 incorrectly miss colon cancer or a precancerous polyp.

What does no result obtained mean?

- · The test was not able to provide a result
- If this happens, your provider will advise if further steps are required. For example, you may be asked to
 provide another stool sample.

Thank you for taking the steps to protect your health.



Study

Do

Do

CSR Process Flow for Cologuard Rescreen Pilot





Do

Was the cycle completed as planned? There was an approximate one-week delay in customers receiving their kits due to initial omission of a diagnosis code for the Batch orders. Cycle ended up being extended from 90 days to 180 days to get a full picture of data completion rates.

Record Data & Observations: Four customers opted out; one customer called to report current rectal bleeding; 206 out of 250 eligible customers received kits. 138 customers completed a kit @ 60 days. 144 customers completed a kit @ 90 days. 159 customers successfully completed a kit @180 days.

What did you observe that was not part of the plan? Batch orders had to be entered by each clinic location for individual providers to receive results; impact of real-time tools for outreach; customers receiving results prior to provider addressing







Study

Analyze and summarize Data: Our test with outreach intervention of auto sending kit to home showed 77% completion rate by May 2022. While we did not reach our prediction of 80% kit return rate in 90 days, we are confident this outreach approach is effective at closing the gap of Cologuard rescreen and did result an improvement.

Compare the result of your test to your previous performance: Our average completion rate at NMH from 1/1/21 to 6/1/22 is 59% for customers completing Cologuard for the first time. Rescreen average completion rate without outreach intervention from 1/30/18 to 12/31/22 was 81

Lessons Learned: Need for customized internal reporting; set more realistic goals; have more data points during cycle including clear baselines; need provider guidelines on response expectations for positive results



Act 🔙 Plan

Study

Decide to adopt, adapt or abandon: All parties agree to **adapt** this change.



Cycle #2: Customers with MyChart as preferred method of communication

Cycle #3: Customers seen in clinic > 2 years ago but still active

Cycle #4: Implement as annual outreach activity





PDSA Cycle Worksheet

Act 🥽 Plan	Project Name: Cologuard Opt-Out Rescreen			Cycle Begin Date: 11/1/21	Cycle End Date: 5/1/21
	Cycle #: 1	What is purpose of cycle? Test Opt-Out Test (Small-Scale) Test (Large-Scale)			
Study	What are we trying to accomplish? Decrease number of customers overdue for Cologuard rescreen		e know that change is an nt? <i>Data collected on kit completion</i>	What change can we make that wi Automatically send out Cologuard kits rescreen	
PLAN: What is going to happen? Customers overdue for Cologuard rescreen will automatically receive a kit in the mail once they have been identified as overdue for Cologuard rescreen and meet inclusion criteria		DO: Carry out the change and collect data Was the cycle completed as planned? Yes No			
Who will make the change? Partnership with QI, Care Access and IT applications			<u>Record data and observations:</u> Four customers opted out; only 206 out of 250 eligible customers received kits due to outdated or inaccurate emails or phone numbers on file; January 2022 completion rate was 67%; March completion rate was 72%, completion rate by May 2022 77%		
Who will receive the change? Custor	mers who meet inclusion guidelines		What did you observe that was not part of the plan? Batch orders had to be entered by each clinic		
When will the change take place? 1	1/1/2021		location for individual providers to receive results; impact of real-time tools for outreach; customers		
How long will it last? 90 days			receiving results directly prior to provider addressing <u>STUDY:</u> Analyze and summarize data		
Where will the change take place? All NMH Primary Care Clinics			Did the results match your prediction(s)? Yes No Compare the result of your test to your previous performance: Our average completion rate at NMH from		
What tasks or tools are needed? Approval from Operations, IT & Care Access Senior Leadership,			1/1/21 to 6/1/22 is 59% for customers completing Cologuard for the first time. With our rescreen average completion rate from 1/30/18 to 12/31/22 is 81%, our pilot completion rate of 77% is lower.		
Accurate identification of customers included, communication blasts, phone line for customers to call in and opt out, workflow for CSRs			What did you learn? Need for customized internal reporting; set more realistic goals; have more data points during cycle including clear baselines; need provider guidelines on response expectations for		
What types of data will be collected? Rate of Kit Completion					
Who will collect data? Exact Sciences		positive results <u>ACT:</u> Decide to Adopt, Adapt, or Abandon			
		Adopt: Select changes to implement on a larger scale and develop implementation plan			
Prediction: 80% of customers included in Cologuard Opt-Out Outreach will complete kit in 90		t in 90	Adapt: Improve the change and continue testing plan. Describe what you will change in your next PDSA		
days and close the gap of custom	ers overdue for this test		Abandon: Discard this change idea and try a different one		
			!		



PDSA Cycle Tracking Form



Project Name: Cologuard Opt-Out Rescreen

Change Tested/Implemented: Auto kit shipment to customers who were overdue for Cologuard Rescreen

CYCLE #:	PLAN	DO	STUDY	ACT
1	Objective of Cycle: Test a Change (Small–Scale) Test a Change (Large-Scale) Implement a Change	Test Begin Date: 11/1/2021 Test End Date: 5/1/2022	What worked well? Customer completion of kits, few opt-outs What could be improved? Use MyChart messaging, reduce cycle length, goal setting, tracking data, customer identification, order entry	Abandon: Discard change idea and try a different one Adapt: Improve the change and continue testing plan Adopt: Develop implementation plan and plan for sustainability
2	Objective of Cycle: Test a Change (Small-Scale) Test a Change (Large-Scale) Implement a Change	Test Begin Date: 7/15/2022 Test End Date:	What worked well? What could be improved?	Abandon: Discard change idea and try a different one Adapt: Improve the change and continue testing plan Adopt: Develop implementation plan and plan for sustainability
3	Objective of Cycle: Test a Change (Small-Scale) Test a Change (Large-Scale) Implement a Change	Test Begin Date: Test End Date:	What worked well? What could be improved?	Abandon: Discard change idea and try a different one Adapt: Improve the change and continue testing plan Adopt: Develop implementation plan and plan for sustainability
4	Objective of Cycle: Test a Change (Small-Scale) Test a Change (Large-Scale) Implement a Change	Begin Date:	What worked well? What could be improved?	Abandon: Discard change idea and try a different one Adapt: Improve the change and continue testing plan Adopt: Develop implementation plan and plan for sustainability





In Minnesota, more than 96% of Cologuard® patients have no out-of-pocket cost for screening.*

Minnesota •

×

Most insured patients pay \$0*

Cologuard is covered by Medicare/Medicare Advantage and most major insurers.

Currently, 93% of Minnesota Cologuard patients aged 45-49 have no out-of-pocket cost for screening.*

In Minnesota, Exact Sciences Laboratories is innetwork** for most Commercial Insurers including:



†Not a comprehensive list of in-network insurers available.

^Exceptions for coverage may apply; only an insurer can confirm how Cologuard would be covered.

¶Colorectal Cancer screening policy updated to reflect the 2021 USPSTF recommendations for screening average-risk patients beginning at age 45 (Grade B). Exceptions for coverage may apply; only an insurer can confirm how Cologuard would be covered.

*Exact Sciences estimate based on historical patient billing as of November 30, 2021. Rate of coverage varies by state and region. Exceptions for coverage may apply; only your patients' insurers can confirm how Cologuard would be covered.

Cologuard Insurance Coverage

COLOGUARD® IS COVERED BY MINNESOTA MEDICAID



For members 50-75 years old, who are asymptomatic, at average risk of developing colorectal cancer (CRC), and are eligible for screening.

Complete insurance information should be provided with each order.

Eligible patients who are actively enrolled in any State Medicaid program can access Cologuard.*

No payment will be expected from the patient unless the plan requires a co-pay.

Visit cologuardhcp.com/medicald

Indications and Important Risk Information

Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by diagnostic colonoscopy. Cologuard is indicated to screen adults of either sex, 45 years or older, who are at typical average risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

Cologuard is not for high-risk individuals, including patients with a personal history of colorectal cancer and adenomas; have had a positive result from another colorectal cancer screening method within the last 6 months; have been diagnosed with a condition associated with high risk for colorectal cancer such as IBD, chronic ulcerative colitis, Crohn's disease; or have a family history of colorectal cancer, or certain hereditary syndromes.

Positive Cologuard results should be referred to diagnostic colonoscopy. A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Following a negative result, patients should continue participating in a screening program at an interval and with a method appropriate for the individual patient.

False positives and false negatives do occur. In a clinical study, 13% of patients without colorectal cancer or advanced adenomas received a positive result (false positive) and 8% of patients with cancer received a negative result (false negative). The clinical validation study was conducted in patients 50 years of age and older. Cologuard performance in patients ages 45 to 49 years was estimated by sub-group analysis of near-age groups.

Cologuard performance when used for repeat testing has not been evaluated or established. Rx only.

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Cologuard Insurance Coverage

What questions do you have?