Return to Cancer Screening PDSA Quality Improvement Project and Clinical Study

Commission on Cancer (CoC), American Cancer Society (ACS) and National Accreditation Program for Breast Centers (NAPBC) Collaboration

An Elective Quality Improvement Project and Clinical Study Open to All CoC/NAPBC Sites

Introduction: We created a Plan/Do/Study/Act (PDSA) quality improvement project and a clinical study.

- These are **elective;** you do not have to participate.
- These are intended to use **existing materials** to accelerate return to screening.
- Completing the PDSA project will fulfill **standard 8.3** (cancer screening event) and NPABC **standard 4.1** (education, prevention, and early detection programs).
- Completing the PDSA project will fulfill **standard 7.3** (quality improvement initiative).and NAPBC **standard 6.1** (quality and outcomes).
- Completing the IRB exempt clinical study (*see below*) you will get local PI status, publication authorship and full credit for **standard 9.1** (Clinical Research Accrual) and NAPBC **standard 3.2** (clinical trial accrual).

Why is this topic important?

This has been a difficult year for cancer care and screening due to the pandemic:

- Cancer screening has been significantly curtailed.
- Hosting of in person screening events has not been encouraged due to safety concerns.
- More cancer deaths will occur if we cannot make up for screening deficits.
- Screening can resume safely in most, if not all, facilities.
- Now is the time to get back to pre-Covid screening rates.

Why are we hosting this **PDSA quality improvement initiative** and clinical study?

- We can **accelerate return to screening** by providing easy to adopt project plans.
- We can **leverage existing guidelines, messaging and interventions**.
- This effort will fulfill compliance with CoC standard 8.3 and NAPBC standard 4.1.
- This effort will fulfill compliance with CoC standard 7.3 and NAPBC standard 6.1.
- This effort will fulfill compliance with CoC standard 9.1 and NAPBC standard 3.2

Who can use this project outline?

- Any CoC- or NAPBC- accredited program and associated screening facility.

How can a program use this project?

- Follow the Plan/Do/Study/Act outline as provided or
- Use the information and interventions to conduct a similar project

How do I get started?

- Decide on whether you want to participate in the PDSA, the Clinical Study or both
- Read and follow the PDSA and/or Clinical Study materials and instructions below
- Complete the three FORMS as you do your work so you can get credit for the standards

When can I get started?

- Now

PDSA INTRODUCTION

PDSA QI Study Title: Post-pandemic Return to Screening Quality Improvement Project

PDSA QI Problem Statement: Cancer screening is an important component of cancer care and is part of CoC standard 8.3 (accredited institutions must hold one event per year to improve cancer screening) and NAPBC standard 4.1. Because of the COVID-19 pandemic, cancer screening has been substantially disrupted due to: 1. closing of screening facilities; 2. Limited staffing of screening facilities and programs; 3. lack of patient awareness that screening is safe when precautions are taken; 4. Backlogs causing scheduling delays; 5. traditional in person screening events curtailed due to safety concerns; and 6. program specific reasons. The American Cancer Society toolkit (https://www.acs4ccc.org/acs-guidance-on-cancer-screening-during-covid-19/) and a list of interventions below, are available to help accelerate return to screening efforts.

PDSA QI Project Aim Statement: The aim of this quality improvement PDSA project is to leverage CoC and NAPBC standards and American Cancer Society toolkit (https://www.acs4ccc.org/acs-guidance-on-cancer-screening-during-covid-19/)and diverse interventions to improve cancer screening rates at CoC-accredited hospitals.

PDSA STEP ONE – PLAN

Step 1a. **Select one or more target screening focus** (breast, colorectal, lung or cervical)

- Each accredited program should select one or more target screening area of greatest importance to their local community: breast, colorectal, lung, or cervical.
- To select the screening area(s) of greatest impact to your community, consider the volume of cancer types in your area and the size of your program. A minimum of one screening intervention is required and intervention details documented on when it was conducted, how it was conducted and what was included in the content.
- The American Cancer Society guidelines; for screening are available at https://www.cancer.org/healthy/find-cancer-early.html.
- The American Cancer Society has developed resources for health care providers on cancer screening during the COVID-19 pandemic available at: https://www.acs4ccc.org/acs-guidance-on-cancer-screening-during-covid-19/
- Effective Messaging for the public on cancer screening during the COVID-19 pandemic. materials for screening are availablehttps://www.acs4ccc.org/acs-guidance-on-cancer-screening-during-covid-19/ from the American Cancer Society.

Step 1b. **Assemble a team of key stakeholders** (**QI Team**):

- Stakeholders will likely include diverse providers who are typically involved with screening, such as family physicians, primary providers and gynecologists for pap smears, radiologists for mammography and CT lung screening, surgeons and gastroenterology for colonoscopies, and others in your program.
- Stakeholders will include providers who are part of outpatient screening facilities affiliated with CoC- and/or NAPBC-accredited institutions.
- Stakeholders will also need to include CoC members: CLPs, CTRs, Administrators, etc, and NAPBC breast program leadership team and breast care team.
- Based on the typical roles and responsibilities of the team members, assign roles and responsibilities for this project.

- Stakeholders should consider all conceivable barriers to screening; which may include concerns about contracting Covid. Widely share available communications that provide reassurance regarding the safety of screening while we are in the pandemic.
- Meet regularly and frequently until the project is moving smoothly forward.

Step 1c. **Follow ACS Guidance on Cancer Screening During COVID-19**

Step 1d. **Draft the Rationale and Problem Statement for your program**.

- Document 3 or 4 reasons screening has been curtailed (use or modify the problem statement provided above).
- Describe what you want to accomplish by answering four fundamental questions:
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- **Question #1**: What are we trying to accomplish?
- **Answer #1**: We are trying to increase screening and close the gap [*fill in blank with screening type, such as colonoscopy, mammography, etc*] that occurred due the pandemic. As possible, we plan to assess and address the backlog from 2020 screening deferrals. For NAPBC sites this would include mammography screening only.

- **Question #2**: How will we know that we have reached our goal? Gather information about pre-pandemic, during pandemic rates of screening and then determine what a reasonable number of additional screenings per month as your goal. The goal should represent at least a 10% increase in screening to achieve compliance.
- **Answer #2**: We will measure clinical screening rates [*fill in blank with screening type, such as colonoscopy, mammography, etc*] before and during the pandemic and follow rates of screening monthly after the implementation of our screening interventions. For NAPBC sites this would include mammography screening only.

- **Question #3**: What change can we make that will result in improvement?
- **Answer #3**: Identify interventions that you believe will reach target populations, providers, and other key stakeholders. In general, you will wish to provide some form of media messaging; some form of education about screening safety during pandemic; identify and address barriers to screening, and select interventions that will be most effective in your community. A full list of interventions and online materials are available below.

- **Question #4**: What is the anticipated timeline for completing the project?
- **Answer #4**: Programs will want to complete this project by the end of 2021. Extensions may be considered.

Step 1e. **Collect data on pre-intervention rates of screening; calculate screening gap and target goal**

- Refer to and complete **Forms A, B, C** (see below)
- Be sure to complete one set of forms for each **target screening focus** selected in Step 1a.
- Document the average **pre-pandemic rates of screening**. To get accreditation credit for the PDSA and/or Clinical Research Study, quantify the average number of screenings/month using data from **September 2019 and January 2020**. These months must be used if you plan to participate in the clinical study.
- Document the average **during-pandemic rates of screening**. To get accreditation credit for the PDSA and/or Clinical Research Study, quantify the average number of screenings/month

using data from **September 2020 and January 2021**. These months must be used if you plan to participate in the clinical study.

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- **Calculate the screening gap** as the difference between average screening rates/month before and during the pandemic.
- **Establish the screening target goal**
    - The screening target goal will be expressed as the number of additional screenings to be achieved each month and indicated on **Form A**
    - The primary (required) study goal is to return to pre-pandemic screening rates.
    - **Each institution is expected to return to pre-pandemic rates of screening.**
    - The secondary study goal is to increase rates of monthly screenings by 10% to help address the backlog of people not screened during the pandemic.
    - **If the screening gap represents less than a 10% increase in screening, the target goal will represent the absolute number of additional screenings per month that represent a 10% increase of screening reported during the pandemic.**
    - **Report the target goal in Form A**
    - **You can use the REDCap tool to calculate your target goal- no need to submit for the PDSA QI Project if you are not participating in the clinical research study.**

PDSA STEP TWO - DO

Step 2a. Review the American Cancer Society toolkit at:https://www.acs4ccc.org/acs-guidance-on-cancer-screening-during-covid-19/

- Is there a particular return to screening approach that could be implemented?
- Can you implement the return to screening interventions?
- Present plan at your CoC Cancer Committee or NAPBC Breast Program Leadership Team and document in minutes.
- Activate the plan no later than June 1, 2021.
- Conduct screening activities with description and implementation dates for each target screening focus.

Step 2b. Consider implementing more than one intervention in sequence or in parallel:

Proposed interventions to improve return to cancer screening:

1. Patient Reminders
    1. Individual patient outreach by healthcare providers
    2. Hospital-wide patient outreach
2. Patient Education
    3. One-on-One Education
    4. Group Education
3. Small Media
    5. Dissemination of guideline and messaging information to patients across hospital system
    6. Dissemination of guideline and messaging information across community sites
    7. Social media posts and/or press releases
    8. Collaboration with local community group leaders to reach vulnerable populations at risk for screening disparities
4. Provider Awareness & Education

9. Dissemination of guideline and messaging information to **primary care practitioners** (defined by institution)
10. Dissemination guideline and messaging information to **specialists** (defined by institution)

5. Provider Reminder/Recall
    11. Reminders sent to health care providers
6. Provider Assessment/Feedback
    12. Interventions aimed at evaluating provider performance in delivering or offering screening to patients
7. Increase Community Access
    13. Reduce Socioeconomic Barriers
    14. Reduce Structural Barriers
    15. Reduce Economic Barriers
8. **Other interventions**: Evidence-Based Interventions for Cancer Screening from the Community Guide

*Information should include details on why return to screening is important, who should return and how to return to screening and some reassurance that it is safe to return to screening.

PDSA STEP THREE - STUDY

Step 3a. Monitor and document for compliance with CoC standards 7.3 and 8.3and NAPBC standard 4.1:

General principles for how to monitor your progress

- Monitor screening activities as you proceed.
- Document as you go to keep track of information for standards compliance or clinical research study participation.
- Modify or intensify efforts according to how much progress has been made in returning to pre-pandemic rates of screening and according to barriers identified.
- The project will be complete when your screening rates have returned to pre-Covid rates and represent at least a 10% increase in screening; Extensions may be considered.

Important instructions for achieving and documenting compliance (all dates are 2021)

1. Complete **Form A** (baseline application) as soon as possible and submit no later than **May 31.**
2. Implement one or more interventions by **June 1st.**
3. Record post-intervention monthly screening rates from **June 1st to November 30.**
4. Complete **Form B** (data collection log) by **December 31st.**
5. Complete **Form C** (intervention log) by **December 31st.**
6. Keep these **completed forms** available in your files to upload into PRQ at the right time when you are preparing for your next accreditation site visit.

PDSA STEP FOUR – ACT

- Reflect on the success of your project.
- Present final results at CoC Cancer Committee and record in the minutes.
- Summarize the details and outcome of the study for future surveys as per standard 7.3, and NAPBC standard 6.1, including using the required Standard 7.3 template.
- Consider using successful interventions in future years to fulfill CoC standard 7.3 and NAPBC 6.1.

- Make sure efforts are ongoing for as long as the pandemic is affecting healthcare delivery.
- Celebrate improvements and lessons learned.
- Communicate accomplishments to internal and external customers (e.g. consider hosting webinars).

Please see FORMS A, B and C page 7 for the PDSA Quality Improvement Project

Complete these forms if you are only participating in the PDSA QI Project

Completing these forms will provide you with credit for CoC standard 7.3 and 8.3 OR NAPBC standard 4.1 and 6.1

Please SKIP to PAGE 13 for the REDCap FORMS for the Clinical Study

Complete these forms if you are participating in the PDSA QI Project AND the Clinical Study

Completing these forms will provide you with credit for CoC standards 7.3, 8.3 and 9.1 OR NAPBC standards 4.1, 6.1 and 3.2

Return to Screening PDSA QI Form A – Enrollment and Baseline Data Collection

*Instructions: Complete this form right away; no later than May 31, 2021. IF your program only plans to participate in the **PDSA Quality Improvement Project then you only need to** complete this form and keep it in your files for future PRQ submission and review at your next accreditation site visit.*

Completing these forms will provide you with credit for CoC standards 7.3 and 8.3 OR NAPBC standards 4.1 and 6.1

Local study PI name*:	
Contact Information:	*Email:* *Phone number:*
Name of Institution and FIN#* Or Name of Breast Center and ID	
Type of CoC Institution:	
Focus of Screening Effort: (submit one form per site)	☐ *Colorectal* ☐ *Breast* ☐ *Lung* ☐ *Cervical*
Number of Interventions selected for June 1 implementation	_____*#*
Pre-Pandemic Rates of Screening	*Average monthly pre-pandemic rate (September + January rates/2):*
Pandemic Rates of Screening	*Average monthly pandemic rate (September + January rates/2):*
Select Screening Target Goal (see instructions -PDSA Step 1e.)	_____ *represents the number of additional monthly screenings to be achieved by November 30, 2021.*
Data Source for screening rates	

Return to Screening Study Form B – Post-Intervention Monthly Data Collection

Instructions: ***Monthly data collection should start in April 1, 2021 and continue through November 30, 2021****. Complete this form no later than December 31, 2021. IF your program only plans to participate in the* ***PDSA Quality Improvement Project then you only need to*** *complete this form and keep it in your files for future PRQ submission and review at your next accreditation site visit.*

Completing these forms will provide you with credit for CoC standards 7.3 and 8.3 OR NAPBC standards 4.1 and 6.1

Local study PI name*: **Name of Institution and FIN#*or** **Name of Breast Center and ID#:**	
Contact Information:	*Email:* *Phone number:*
Disease site (check one per form):	◯ Breast ◯ Cervical ◯ Colorectal ◯ Lung
Intervention start date:	

Post-Intervention Monthly Screening Rates (for one disease site)
April:
May:
June:
July:
August:
September:
October:
November:

Return to Screening Study Form C – Intervention Log

*Instructions: Select all interventions implemented and provide the date when the intervention was started. Fill in this log as you conduct your efforts and complete the form no later than December 31, 2021. IF your program only plans to participate in the **PDSA Quality Improvement Project then you only need to** complete this form and keep it in your files for future PRQ submission and review at your next accreditation site visit.*

Completing these forms will provide you with credit for CoC standards 7.3 and 8.3 OR NAPBC standards 4.1 and 6.1

Local study PI name **Name of Institution and FIN # or** **Name of Breast Center and ID#**	
Contact Information	*Email:* *Phone number:*
Increase Community Demand	
PATIENT REMINDERS	
1. **Patient outreach by healthcare providers to eligible and at-risk patients*** (e.g., phone calls, EMR portal, email, text messages, letters)	◯Yes ◯No *Start date:* _____
2. **Facility/Institution-level outreach*** (e.g., automated notifications to eligible patients within health system)	◯Yes ◯No *Start date:* _____
PATIENT EDUCATION	
3. **One-on-One Education** (delivers information to individuals about indications for, benefits of, and ways to obtain cancer screening)	◯Yes ◯No *Start date:* _____
4. **Group Education** (Group education is usually conducted by health professionals or by trained lay people who use presentations or other teaching aids in a lecture or interactive format to a variety of groups)	◯Yes ◯No *Start date:* _____
SMALL MEDIA	
5. **Dissemination of guideline and messaging information to patients across the hospital system** (e.g., banners/posters pamphlets, hospital website)	◯Yes ◯No *Start date:* _____
6. **Dissemination of guideline and messaging information across community sites** (e.g., vaccination sites, grocery stores, pharmacies, etc)	◯Yes ◯No *Start date:* _____
7. **Institutional social media posts and/or press releases** (e.g., Twitter and Facebook. See Example Social Media Posts and Press Release Template)	◯Yes ◯No *Start date:* _____
8. **Collaboration with local TV/radio/new channels** to communicate the importance of cancer screening and the safety of screening despite the COVID-19 pandemic	◯Yes ◯No *Start date:* _____
Increase Provider Delivery	

PROVIDER AWARENESS & EDUCATION	
9. **Dissemination of guideline and messaging information to <u>primary care practitioners</u>** (defined by institution)	◯Yes ◯No *Start date:* _____
10. **Dissemination guideline and messaging information to <u>specialists</u>** (defined by institution)	◯Yes ◯No *Start date:* _____ *List all providers involved:*
PROVIDER REMINDER/RECALL	
11. Reminders sent to health care providers that it is time for a client's cancer screening test or that the patient is overdue for screening	◯Yes ◯No *Start date:* _____
PROVIDER ASSESSMENT & FEEDBACK	
12. Interventions aimed at evaluating provider performance in delivering or offering screening to patients	◯Yes ◯No *Start date:* _____
Increase Community Access	
13. **Reduce Socioeconomic Barriers** (ex. Collaboration with local community group leaders to reach vulnerable populations at risk for screening disparities)	◯Yes ◯No *Start date:* _____
14. **Reduce Structural Barriers** (ex. Modifying hours of service)	◯Yes ◯No *Start date:* _____
15. **Reduce economic barriers** (ex. Reduce out-of-pocket costs)	◯Yes ◯No *Start date:* _____
OTHER	
16. **Other** – Please describe other interventions performed by your institution.	◯Yes ◯No *Start date:* _____ *Description:*

Return to Screening Clinical Research Study (CoC Standard 9.1 and NAPBC Standard 3.2) –

CoC-accredited hospitals and NAPBC-accredited centers participating in the **Post-pandemic Return to Screening Quality Improvement Project MAY ALSO** choose to become contributors to a clinical research study. The goals of the study are: (1) to estimate the decline in cancer screening due to the pandemic; (2) to test the hypothesis that the rate of return to pre-pandemic baselines screening rates will be determined by the number interventions implemented.

This clinical research study is entirely **elective**.
Benefits of participating in this clinical research study include:

- Lead participant will be granted the status of local principal investigator (PI)
- Lead participant will be granted authorship on scientific publication of the study findings
- **Full credit for CoC standard 9.1 or NAPBC standard 3.2** (even though programs will be granted full credit for CoC 9.1 or NAPBC 3.2, they are also being asked to report clinical research accruals that occurred in 2021 as part of their future program accreditation review).

The roles and responsibilities of the local principal investigator:

- Organizing and leading the study team.
- Ensuring that interventions are successfully implemented.
- Determining how to obtain the necessary data at their institution.
- Ensuring that data is accurate and is submitted in a timely fashion.

A local PI is required for a program to participate in the clinical research study.
Only one local PI can be listed in the REDCap tool.
A Network program can list the same local PI in more than one REDCap.

IRB: This study has been reviewed by a third-party institutional review board (IRB), which has determined that it is exempt from IRB oversight. Although this study is exempt from IRB oversight, usual institutional research practices still apply. See the IRB exemption approval letter (**Supplement 1**) and IRB-reviewed study protocol (**Supplement 2**) at the end of this document.

As a participant in the clinical research study, you agree to do the following in 2021:

- ✓ Complete and submit **Form A** (baseline application) in RECAP no later than **May 31.**
- ✓ Implement one or more interventions by **June 1.**
- ✓ Record post-intervention monthly screening rates from **June 1st to November 30.**
- ✓ Complete and submit data collection log (**Form B**) by **December 31st.**
- ✓ Complete and submit the intervention log (**Form C**) by **December 31.**

<u>Proposed interventions to improve return to cancer screening</u>:

Patient Reminders

1. Individual patient outreach by healthcare providers
2. Hospital-wide patient outreach

Patient Education

3. One-on-One Education
4. Group Education

Small Media

5. Dissemination of guideline and messaging information to patients across hospital system
6. Dissemination of guideline and messaging information across community sites
7. Social media posts and/or press releases
8. Collaboration with local community group leaders to reach vulnerable populations at risk for screening disparities

Provider Awareness & Education

9. Dissemination of guideline and messaging information to **primary care practitioners** (defined by institution)
10. Dissemination guideline and messaging information to **specialists** (defined by institution)

Provider Reminder/Recall

11. Reminders sent to health care providers

Provider Assessment/Feedback

12. Interventions aimed at evaluating provider performance in delivering or offering screening to patients

Increase Community Access

13. Reduce Socioeconomic Barriers
14. Reduce Structural Barriers
15. Reduce Economic Barriers

Other interventions:

16. Evidence-Based Interventions for Cancer Screening from the Community Guide

*Information should include details on why return to screening is important, who should return and how to return to screening and some reassurance that it is safe to return to screening.

For questions about the clinical research study, please contact Heidi Nelson (hnelson@facs.org), Rachel Hae-Soo Joung (Research fellow, haesoo.joung@northwestern.edu) and/or Brian Brajcich (Research fellow, bbrajcich@facs.org). Questions regarding REDCap forms should be directed to Jessica Dangles (jdangles@facs.org).

Return to Screening Clinical Research Study REDCap Form A – Enrollment and Baseline Data Collection

*Instructions: **For clinical research study participation**, complete this form and submit in REDCap no later than **May 31st**. The REDCap forms can be your record of completing the PDSA Quality Improvement Project and you can save as PDF. You can save it and then submit it to the PRQ for your next site visit.*

***Fill out a separate form for each cancer screening target if** your facility has more than target screening focus:*

***Breast**: https://REDCap.link/breastscreening*
***Colorectal**: https://redcap.link/colonscreening*
***Lung**: https://redcap.link/lungscreening*
***Cervical**: https://redcap.link/cervicalcancerscreening*

Completing these forms will provide you with credit for CoC standards 7.3, 8.3 and 9.1 OR NAPBC standards 4.1, 6.1 and 3.2

*as it should appear on authorship byline for final manuscript

Local study PI name*:	
Contact Information:	*Email:* *Phone number:*
Name of Institution and FIN#* Or Name of Breast Center and ID	
Type of CoC Institution:	
Focus of Screening Effort: (submit one form per site)	☐ *Colorectal* ☐ *Breast* ☐ *Lung* ☐ *Cervical*
Number of Interventions selected for June 1 implementation	_____*#*
Pre-Pandemic Rates of Screening	*Average monthly pre-pandemic rate (September + January rates/2):*
Pandemic Rates of Screening	*Average monthly pandemic rate (September + January rates/2):*
Select Screening Target Goal (see instructions -PDSA Step 1e.)	_____ *represents the number of additional monthly screenings to be achieved by November 30, 2021.*
Data Source for screening rates	

Return to Screening Study Form B – Post-Intervention Monthly Data Collection

Instructions: ***For clinical research study participation****, complete this form and submit in REDCap by* ***December 31st, 2021 .*** *Monthly data collection should start in April 1, 2021 and continue through* ***November 30, 2021****. These forms will be sent to programs who completed FORM A. Links to these forms will be sent to your email in early June.*

Completing these forms will provide you with credit for CoC standards 7.3, 8.3 and 9.1 OR NAPBC standards 4.1, 6.1 and 3.2

*as it should appear on authorship byline for manuscript

Local study PI name*: **Name of Institution and FIN#*or** **Name of Breast Center and ID#:**	
Contact Information:	*Email:* *Phone number:*
Disease site (check one per form):	☐ Breast ☐ Cervical ☐ Colorectal ☐ Lung
Intervention start date:	

Post-Intervention Monthly Screening Rates (for one disease site)
April:
May:
June:
July:
August:
September:
October:
November:

Return to Screening Study Form C – Intervention Log

*Instructions: **For clinical research study participation**, complete this form and submit in REDCap by **December 31st, 2021 . We recommend that you keep a running log of interventions** starting in June and continuing through **November 30, 2021**. These forms will be sent to programs who completed FORM A. Links to these forms will be sent to your email in early June.*

Completing these forms will provide you with credit for CoC standards 7.3, 8.3 and 9.1 OR NAPBC standards 4.1, 6.1 and 3.2

Local study PI name **Name of Institution and FIN # or** **Name of Breast Center and ID#**	
Contact Information	*Email:* *Phone number:*
Increase Community Demand	
PATIENT REMINDERS	
1. Patient outreach by healthcare providers to eligible and at-risk patients* (e.g., phone calls, EMR portal, email, text messages, letters)	□ Yes □ No *Start date:* _____
2. Facility/Institution-level outreach* (e.g., automated notifications to eligible patients within health system)	□ Yes □ No *Start date:* _____
PATIENT EDUCATION	
3.One-on-One Education (delivers information to individuals about indications for, benefits of, and ways to obtain cancer screening)	□ Yes □ No *Start date:* _____
4. Group Education (Group education is usually conducted by health professionals or by trained lay people who use presentations or other teaching aids in a lecture or interactive format to a variety of groups)	□ Yes □ No *Start date:* _____
SMALL MEDIA	
5.Dissemination of guideline and messaging information to patients across the hospital system (e.g., banners/posters pamphlets, hospital website)	□ Yes □ No *Start date:* _____
6.Dissemination of guideline and messaging information across community sites (e.g., vaccination sites, grocery stores, pharmacies, etc)	□ Yes □ No *Start date:* _____
7.Institutional social media posts and/or press releases (e.g., Twitter and Facebook. See Example Social Media Posts and Press Release Template)	□ Yes □ No *Start date:* _____
8.Collaboration with local TV/radio/new channels to communicate the importance of cancer screening and the safety of screening despite the COVID-19 pandemic	□ Yes □ No *Start date:* _____
Increase Provider Delivery	
PROVIDER AWARENESS & EDUCATION	

9.Dissemination of guideline and messaging information to <u>primary care practitioners</u> (defined by institution)	□ Yes □ No *Start date:* _____
10.Dissemination guideline and messaging information to <u>specialists</u> (defined by institution)	□ Yes □ No *Start date:* _____ *List all providers involved:*
PROVIDER REMINDER/RECALL	
11.Reminders sent to health care providers that it is time for a client's cancer screening test or that the patient is overdue for screening	□ Yes □ No *Start date:* _____
PROVIDER ASSESSMENT & FEEDBACK	
12.Interventions aimed at evaluating provider performance in delivering or offering screening to patients	□ Yes □ No *Start date:* _____
Increase Community Access	
13.Reduce Socioeconomic Barriers (ex. Collaboration with local community group leaders to reach vulnerable populations at risk for screening disparities)	□ Yes □ No *Start date:* _____
14. Reduce Structural Barriers (ex. Modifying hours of service)	□ Yes □ No *Start date:* _____
15.Reduce economic barriers (ex. Reduce out-of-pocket costs)	□ Yes □ No *Start date:* _____
OTHER	
16.Other – Please describe other interventions performed by your institution.	□ Yes □ No *Start date:* _____ *Description:*

Supplement 1. IRB Exemption Approval Letter

ADVARRA

6100 Merriweather Dr., Suite 600
Columbia, MD 21044
410 884 2900

EXEMPT DETERMINATION

DATE:	30 Apr 2021
TO:	Heidi Nelson, MD
PROJECT:	American College of Surgeons; Commission on Cancer, Return to Cancer Screening: Clinical Study of a PDSA Quality Improvement Project (Pro00053714)

DOCUMENTATION REVIEWED:

Protocol Version:	• Protocol (Not Dated)
Recruitment Material:	• Internet, Hospital Recruitment Material (Not Dated)

Using the Department of Health and Human Services regulations found at 45 CFR 46.104(d)(4), the IRB determined that your research project is exempt from IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this exemption with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.
2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.104(d)(4), you will resubmit revised materials for IRB review.
3. It is the responsibility of each investigator to ensure that the project meets the ethical standards of the institution. Specifically, the selection of subject is equitable, there are adequate provisions to maintain the confidentiality of any identifiable data collected, and when there are interactions with research subjects, they will be informed that the activity involves research, a description of the procedures, participation is voluntary, and the contact information for the researcher.

The IRB will evaluate the new information and make a determination at that time regarding the research project's status.

This project is not subject to requirements for continuing review.

Supplement 2. IRB-Approved Study Protocol

ACTIVITY TITLE:

Return to Cancer Screening: Clinical Study of a PDSA Quality Improvement Project

PRINCIPAL INVESTIGATOR:

Heidi Nelson, MD FACS
American College of Surgeons
312-202-5146
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PURPOSE:

The aim of this study is to evaluate the success of a Return to Cancer Screening quality improvement project designed to improve breast, colorectal, lung, and cervical cancer screening rates at Commission on Cancer (CoC)- and National Accreditation Program for Breast Centers (NAPBC)-accredited hospitals.

BACKGROUND:

Cancer screening permits early detection of malignant and premalignant lesions, allowing for treatment of disease at an earlier stage and intervention to prevent progression of premalignant lesions to cancer. This has contributed substantially to reductions in cancer mortality observed over the past several decades. The COVID-19 pandemic has resulted in significant decreases in cancer screening, however, which unless addressed will result in delays in diagnosis and significant increases in cancer mortality.

Typically, the CoC requires hospitals to engage in an annual screening event to encourage cancer screening in their local community. However, due to the COVID-19 pandemic, traditional cancer screening events have not been feasible. Therefore, the CoC, in collaboration with the NAPBC and American Cancer Society (ACS), has initiated a national quality improvement project to assist hospitals in resuming cancer screening in a safe and effective manner. This quality improvement project is based on a Plan-Do-Study-Act (PDSA) framework and allows CoC- and NAPBC-accredited hospitals to select one or more alternative approaches to traditional screening events. A comprehensive list of evidence-based screening awareness approaches is provided for hospitals to select from. This research study aims to utilize data generated by the quality improvement project to evaluate its effectiveness at increasing screening rates for breast, colorectal, lung, and cervical cancers.

METHODS:

Participants:

Eligible study participants include CoC- and NAPBC-accredited hospitals who have elected to participate in the Return to Screening quality improvement project. These hospitals are given the option to enroll in this research study.

Approaches:

As part of the quality improvement project, hospitals have been provided with a collection of evidence-based awareness, education and communication approaches to help improve rates of cancer screening. These approaches are designed to help with patient education and outreach, assist with reminding patients about the need to schedule recommended exams, provide guidance regarding media outreach, and aid clinician awareness and education regarding the importance and safety of cancer screening. Participating programs may also employ screening awareness approaches that they have previously used. A full summary of the screening awareness approaches can be found on the American Cancer Society Comprehensive Cancer Control website (https://www.acs4ccc.org/acs-guidance-on-cancer-screening-during-covid-19/).

Outcomes:

The outcomes to be assessed include the number of screening exams performed for breast cancer (e.g., mammograms), colorectal cancer (e.g., screening colonoscopy), lung cancer (e.g., screening computed tomography scans), and cervical cancer (e.g., Papanicolaou tests) at each hospital. The number of screening exams performed will be collected from three time periods: before the COVID-19 pandemic (September 2019 and January 2020), during the COVID-19 pandemic (September 2020 and January 2021), and after dissemination of the interventions (June 2021-November 2021).

Data Collection:

Data and/or Specimen Collection and Analysis

Data collected for this study will include the number of various cancer screening procedures (mammography, colonoscopy, computed tomography scans, and Papanicolaou tests) performed at various points in time. The data collected for this study will only include aggregate hospital procedure volume data. Individual patient data will not be collected, and no protected health information (PHI) will be collected.

Data and/or Specimen Collection Method

Hospital data will be collected through a REDCap secure portal maintained by the American College of Surgeons. Data will be entered by a representative each participating institution. Study data will be accessible only by study personnel. Data will be stored on secure HIPAA-compliant servers.

Identifiability of Data or Specimens

Data will be identifiable to an individual institution, but no patient-identifiable data will be collected.

INFORMED CONSENT:

This study only involves the collection of data generated by a quality improvement project and does not involve experimentation on human subjects. Additionally, no individual patient data will be collected. Therefore, informed consent is not applicable. Hospital participation in the quality improvement project, utilization of any disseminated interventions, and participation in this research study is purely elective.

RISKS AND BENEFITS:

This study only involves the collection of data generated by a quality improvement project and does not involve experimentation on human subjects. Additionally, no individual patient data will be collected. Therefore, the risk to individual patients is negligible.