Return to Screening Clinical Study

Heidi Nelson, MD, FACS
Brian Brajcich, MD
Hae Soo (Rachel) Joung, MD
Return To Screening Clinical Study

Introduction
IRB Exemption
Principal Investigator
Q&A

FORM A – REDCap Tool
Screening Data
Calculating Monthly Targets
Q&A

Standards Credits
Logistics
Q&A
Why is this topic important?

- Cancer screening has been significantly curtailed
- In person screening events have been discouraged 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
Return To Screening Clinical Study

Association of Cancer Screening Deficit in the United States With the COVID-19 Pandemic

Ronald C. Chen, MD, MPH; Kevin Haynes, PharmD, MSCE; Simo Du, MBBS, MHS; John Barron, PharmD; Aaron J. Katz, PharmD, PhD

Figure 1. Screening Rates per 100 000 Enrollees per Month in 2018, 2019, and 2020

© American College of Surgeons 2021—Content cannot be reproduced or repurposed without written permission of the American College of Surgeons.
Goal: Accelerate Return To Screening

- These are elective; you do not have to participate
- These are intended to use existing guidelines, messaging and toolkits to assist programs in getting patients back to screening
- Can fulfill compliance with CoC Standards 8.3; 7.3; and 9.1
- Can fulfill compliance with NAPBC Standards 6.1; 3.2; 4.1
Return To Screening Clinical Study

CoC Standards

9.1 Clinical Study
7.3 Quality Improvement
8.3 Screening

OR

NAPBC Standards

3.2 Clinical Study
6.1 Quality Improvement
4.1 Screening
Return To Screening Clinical Study

Who can participate?
• Any CoC- or NAPBC- accredited program (or associated screening facility)

How do I get started?
• Read the PDSA and/or Clinical Study materials:
  ✓ Project and Clinical Study Details
• Decide on whether you want to participate in the:
  ✓ Screening Interventions
  ✓ PDSA
  ✓ Clinical Study
• Follow the Instructions and Complete the three FORMS as you do your work
  ✓ For the PDSA – Keep on hand and file with PRQ for future accreditation
  ✓ Submit Forms for the Clinical Study (IRB and REDCap survey are pending)

Where do I turn for FAQs?
✓ FAQ on Return to Screening PDSA/Clinical Research Study
Proposed Interventions for Return to Screening

- **Patient Reminders**
  - Individual patient outreach by healthcare providers
  - Hospital-wide patient outreach

- **Patient Education**
  - One-on-One Education
  - Group Education

- **Small Media**
  - Dissemination of guideline and messaging information to patients across hospital system
  - Dissemination of guideline and messaging information across community sites
  - Social media posts and/or press releases
  - Collaboration with local community group leaders to reach vulnerable populations at risk for screening disparities

- **Provider Awareness & Education**
  - Dissemination of guideline and messaging information to primary care practitioners (defined by institution)
  - Dissemination guideline and messaging information to specialists (defined by institution)

- **Provider Reminder/Recall**
  - Reminders sent to health care providers

- **Provider Assessment/Feedback**
  - Interventions aimed at evaluating provider performance in delivering or offering screening to patients

- **Increase Community Access**
  - Reduce Socioeconomic Barriers
  - Reduce Structural Barriers
  - Reduce Economic Barriers

- **Other interventions**: Evidence-Based Interventions for Cancer Screening from the Community Guide
IRB Approval and Logistics

Study protocol reviewed by a third-party institutional review board (IRB)
• Determined to be exempt from IRB oversight

Why is this the case?
• This study does not involve experimentation on human subjects, but rather dissemination and implementation of institutional best practices
• No individual or identifiable patient data is collected
• Therefore the risk to patients is negligible
What does this mean for my site?
Typically, no additional review is necessary; follow local research practices

Although this study is IRB-exempt, data collection and storage is still safe and secure:
• REDCap is a secure data entry portal
• All data will be maintained on secured ACS servers
• Data access will be limited to the study team
Each site must identify a principal investigator (PI)

- Responsible for leading the project at your site
- Ensures collection of accurate data
- Each site PI will be receive authorship credit on eventual publication of study data
Who can be a PI?
• Cancer liaison physician
• Cancer committee member or chair
• Research coordinator
• Other

This is an IRB-exempt study and the PI will not be involved in consenting patients or conducting human subjects research. Following your local institutional research practices is advised.
The site PI is expected to be engaged in the project

- Organizing the site’s study team
- Ensuring that efforts are made to successfully implement interventions
- Determining how to obtain the necessary data at their institution
- Ensuring that data is accurate and is submitted in a timely fashion
Questions?
Breast: https://redcap.link/breastscreening

Colorectal: https://redcap.link/colonscreening

Lung: https://redcap.link/lungscreening

Cervical: https://redcap.link/cervicalcancerscreening
Form A: Breast Cancer Screening Enrollment and Baseline Data Collection

For clinical research study participation, complete this form and submit no later than May 31st. Fill out separate Form A for each cancer screening target if your facility has more than one target screening focus.

Note: This study is IRB exempt. This study does not require submission of any individual patient information. The only information required is aggregate institutional-level screening rates.

Please refer to this document for detailed instructions

Attachment: Return_to_Screening_PDSA_and_Clinical_Study.pdf (0.37 MB)

Contact Information

Name of Individual Completing this Form
* must provide value

Email of Individual Completing this Form
* must provide value

Phone Number of Individual Completing this Form

Name of Local Study PI (as it should appear on authorship byline for final manuscript)
* must provide value

Email of Local Study PI
* must provide value

Please double check whether you are filling out the correct form (specific to disease site)
### Institution Information

Select the Accreditation Program for which you want Standards Credit (select only one per form)

- CoC
- NAPBC

#### Name of CoC Institution

* must provide value

#### CoC Facility Identification Number (FIN #)

* must provide value

#### State

* must provide value

Select State
## Return To Screening Clinical Study

### Type of CoC Institution
* must provide value

### Breast Cancer Screening Focus and Baseline Data

#### Number of Interventions Selected for June 1 Implementation
* must provide value

#### Check all that apply
* must provide value

<table>
<thead>
<tr>
<th>Academic Comprehensive Cancer Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comprehensive Community Cancer Program</td>
</tr>
<tr>
<td>Freestanding Cancer Center Program</td>
</tr>
<tr>
<td>Hospital Associate Cancer Program</td>
</tr>
<tr>
<td>Integrated Network Cancer Program</td>
</tr>
<tr>
<td>NCI Designated Network</td>
</tr>
<tr>
<td>NCI Designated Comprehensive Cancer Program</td>
</tr>
<tr>
<td>Pediatric Cancer Program</td>
</tr>
<tr>
<td>Veterans Affairs Cancer Program</td>
</tr>
<tr>
<td>Community Cancer Program</td>
</tr>
</tbody>
</table>
### Institution Information

**Select the Accreditation Program for which you want Standards Credit (select only one per form)**

- [ ] CoC
- [x] NAPBC

* must provide value

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Breast Center</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* must provide value</td>
</tr>
<tr>
<td>Breast Center ID #</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* must provide value</td>
</tr>
<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* must provide value</td>
</tr>
</tbody>
</table>

Select State
<table>
<thead>
<tr>
<th>Number of Interventions Selected for June 1 Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>* must provide value</td>
</tr>
</tbody>
</table>

Check all that apply
* must provide value

- Individual patient reminder/outreach by healthcare providers
- Hospital-wide patient reminder/outreach
- One-on-one patient education
- Group patient education
- Dissemination of guideline and messaging information to patients across hospital system
- Dissemination of guideline and messaging information across community sites
- Social media posts and/or press releases
- Collaboration with local community group leaders to reach vulnerable populations at risk for screening disparities
- Dissemination of guideline and messaging information to primary care practitioners (defined by institution)
- Dissemination of guideline and messaging information to specialists (defined by institution)
- Provider Reminder/Recall
- Provider Assessment/Feedback
- Reducing Socioeconomic Barriers
- Reducing Structural Barriers
- Reducing Economic Barriers
- Other Interventions
### Scenario 1: Screening Gap > 10%

<table>
<thead>
<tr>
<th>Pre-Pandemic Rate of Breast Cancer Screening</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>* must provide value</td>
<td>Average monthly pre-pandemic rate (September '19 + January '20 rates/2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pandemic Rate of Breast Cancer Screening</th>
<th>50</th>
</tr>
</thead>
<tbody>
<tr>
<td>* must provide value</td>
<td>Average monthly pandemic rate (September '20 + January '21 rates/2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pandemic Screening Gap</th>
<th>50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Gap calculated for you as: Pre-Pandemic minus Pandemic Screening Rates</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10% Increase in Screening</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>10% Increase calculated for you as: 10% over the Pandemic Screening Rate</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-Intervention Monthly Breast Cancer Screening Target</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target calculated for you as: Screening Gap or 10% increase (if gap is less than 10%)</td>
<td></td>
</tr>
</tbody>
</table>
# Scenario 2: Screening Gap < 10%

<table>
<thead>
<tr>
<th>Pre-Pandemic Rate of Breast Cancer Screening</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average monthly pre-pandemic rate (September '19 + January '20 rates/2)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pandemic Rate of Breast Cancer Screening</th>
<th>99</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average monthly pandemic rate (September '20 + January '21 rates/2)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pandemic Screening Gap</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Gap calculated for you as: Pre-Pandemic minus Pandemic Screening Rates</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10% Increase in Screening</th>
<th>9.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>10% increase calculated for you as: 10% over the Pandemic Screening Rate</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-Intervention Monthly Breast Cancer Screening Target</th>
<th>108.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target calculated for you as: Screening Gap or 10% Increase (if gap is less than 10%)</td>
<td></td>
</tr>
</tbody>
</table>
Scenario 3: Pandemic Rate > Pre-Pandemic

<table>
<thead>
<tr>
<th>Pre-Pandemic Rate of Breast Cancer Screening</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td>Average monthly pre-pandemic rate (September '19 + January '20 rates/2)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pandemic Rate of Breast Cancer Screening</th>
<th>200</th>
</tr>
</thead>
<tbody>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
<tr>
<td>Average monthly pandemic rate (September '20 + January '21 rates/2)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pandemic Screening Gap</th>
<th>-100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Gap calculated for you as: Pre-Pandemic minus Pandemic Screening Rates</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10% Increase in Screening</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>10% Increase calculated for you as: 10% over the Pandemic Screening Rate</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-Intervention Monthly Breast Cancer Screening Target</th>
<th>220.000000000000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target calculated for you as: Screening Gap or 10% Increase (if gap is less than 10%)</td>
<td></td>
</tr>
</tbody>
</table>
## Scenario 4: Pandemic Rate = Pre-Pandemic

<table>
<thead>
<tr>
<th>Pre-Pandemic Rate of Breast Cancer Screening</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
</tbody>
</table>

**Average monthly pre-pandemic rate (September ’19 + January ’20 rates/2)**

<table>
<thead>
<tr>
<th>Pandemic Rate of Breast Cancer Screening</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>* must provide value</td>
<td></td>
</tr>
</tbody>
</table>

**Average monthly pandemic rate (September ’20 + January ’21 rates/2)**

<table>
<thead>
<tr>
<th>Pandemic Screening Gap</th>
<th>0</th>
</tr>
</thead>
</table>

**Screening Gap calculated for you as: Pre-Pandemic minus Pandemic Screening Rates**

<table>
<thead>
<tr>
<th>10% Increase in Screening</th>
<th>10</th>
</tr>
</thead>
</table>

**10% increase calculated for you as: 10% over the Pandemic Screening Rate**

<table>
<thead>
<tr>
<th>Post-Intervention Monthly Breast Cancer Screening Target</th>
<th>110.0000000000000</th>
</tr>
</thead>
</table>

**Target calculated for you as: Screening Gap or 10% Increase (if gap is less than 10%)**
Return To Screening Clinical Study

Source of Information for Breast Cancer Screening Rate

Breast Cancer Screening Test (select all that apply)

* must provide value

- Review/Search of Clinical Records
- Review/Search of Administrative Records
- Review/Search of Individual Case Volume Records
- Other

Other
Return To Screening Clinical Study

Breast Cancer Screening Test (select all that apply)

* must provide value

- [ ] Screening Mammograms
- [ ] Screening MRIs (for high-risk women)
- [x] Other

If other, please describe
Your survey responses were saved!

You have chosen to stop the survey for now and return at a later time to complete it. To return to this survey, you will need both the survey link and your return code. See the instructions below.

1.) Return Code
   A return code is *required* in order to continue the survey where you left off. Please write down the value listed below.

   Return Code 99MDW3FT

   * The return code will NOT be included in the email below.

2.) Survey link for returning
   You may bookmark this page to return to the survey, OR you can have the survey link emailed to you by providing your email address below. For security purposes, the return code will NOT be included in the email. If you do not receive the email soon afterward, please check your Junk Email folder.

   Enter email address  Send Survey Link

   * Your email address will not be stored

Or if you wish, you may continue with this survey again now.

Continue Survey Now
Form A: Breast Cancer Screening Enrollment and Baseline Data Collection

For clinical research study participation, please select one cancer screening target if your facility has the ability to complete this assessment.

Note: This study is IRB exempt. This study uses the only patient information required is aggregate institutional, therefore all information is de-identified.

Please refer to this document for further information.

Attachment: Return to Screening Study Form

Contact Information

© American College of Surgeons 2021—Content cannot be reproduced or repurposed without written permission of the American College of Surgeons.

Returning? Begin where you left off.

If you have already completed part of the survey, you may continue where you left off. All you need is the return code given to you previously. Click the link below to begin entering your return code and continue the survey.

Continue the survey
Form A: Breast Cancer Screening Enrollment and Baseline Data Collection

To continue the survey, please enter the RETURN CODE that was auto-generated for you when you left the survey. Please note that the return code is *not* case sensitive.

Submit your Return Code
### eTable 3. Screening rates per 100,000 enrollees by month

<table>
<thead>
<tr>
<th></th>
<th>January</th>
<th>February</th>
<th>March</th>
<th>April</th>
<th>May</th>
<th>June</th>
<th>July</th>
<th>Jan-July</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Breast</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td>4,142</td>
<td>3,760</td>
<td>4,024</td>
<td>4,287</td>
<td>4,170</td>
<td>4,050</td>
<td>4,500</td>
<td>4,133</td>
</tr>
<tr>
<td>2020</td>
<td>4,127</td>
<td>3,680</td>
<td>2,343</td>
<td>394</td>
<td>1,975</td>
<td>3,936</td>
<td>4,329</td>
<td>2,971</td>
</tr>
<tr>
<td>% change</td>
<td>-0.3%</td>
<td>-2.1%</td>
<td>-41.8%</td>
<td>-90.8%</td>
<td>-52.6%</td>
<td>-2.8%</td>
<td>-3.8%</td>
<td>-28.1%</td>
</tr>
<tr>
<td><strong>Colorectal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td>1,962</td>
<td>1,821</td>
<td>1,950</td>
<td>2,073</td>
<td>2,013</td>
<td>19,302</td>
<td>2,048</td>
<td>2,262</td>
</tr>
<tr>
<td>2020</td>
<td>2,050</td>
<td>1,875</td>
<td>1,300</td>
<td>430</td>
<td>852</td>
<td>1,631</td>
<td>1,781</td>
<td>1,417</td>
</tr>
<tr>
<td>% change</td>
<td>4.5%</td>
<td>2.9%</td>
<td>-33.3%</td>
<td>-79.3%</td>
<td>-57.7%</td>
<td>-15.4%</td>
<td>-13.1%</td>
<td>-37.3%</td>
</tr>
</tbody>
</table>
Figure 1. Screening Rates per 100,000 Enrollees per Month in 2018, 2019, and 2020

**A** Breast cancer screening among female enrollees

**B** Colorectal cancer screening among enrollees
Return To Screening Clinical Study

CoC Standards

9.1 Clinical Study
7.3 Quality Improvement
8.3 Screening

NAPBC Standards

3.2 Clinical Study
6.1 Quality Improvement
4.1 Screening

OR