2022 CoC and NAPBC Assessment of Smoking in Newly Diagnosed Cancer Patients PDSA Quality Improvement Project and Clinical Study: Just ASK Frequently Asked Questions

This information is to help provide additional clarification about this project. Please thoroughly review the PDSA and these FAQs. If you still need clarification, please contact us at ACScancerprograms@facs.org.

General Participation

We have already selected our Quality Improvement projects for 2022. Do we still have to participate? Participation is entirely optional. Programs who choose not to participate may use their own quality improvement studies for 2022 and follow the requirements for meeting all accreditation standards in the usual fashion.

We have already had our first quarter meeting for 2022. Will there still be enough time to complete this project by the end of the year?
Yes, there is enough time to complete this project in 2022. You will not be able to apply this PDSA or clinical study to 2023 standards. We realize that many programs may have selected a quality improvement project for 2022 and may not wish to participate. It is elective.

When do programs need to let CoC/NAPBC know we are participating in the clinical research portion of the project? Programs must indicate intent to participate by completing the baseline REDCap questionnaire by April 15, 2022. Refer to the Project Details for complete details about the timelines and what is required.

What if we decide to participate, then drop out?
In order to get credit for 2022 towards the designated standards, you must complete the entire project, inclusive of your intervention and the three questionnaires.

When should we start the intervention?
Intervention should be started before July 1, 2022, as the mid-year questionnaire data is representative of Jan 1-Jun 30, 2022.

Can we select a specific cancer care or tumor specific site to focus on in this project (e.g., lung, colorectal)? No. It must be focused on newly-diagnosed patients for all cancer sites and tumor types. NOTE: Programs applying for credit towards NAPBC Accreditation Standards may submit data exclusive to breast cancer population. See the NAPBC Specific Questions section below for more details.

We already ask all patients and have a robust tobacco cessation program in our Cancer Center. Should we still participate?
Participation is fully elective. However, it is advisable that you still participate, and include more advanced interventions in your project plan. These can include Advising patients of the importance of tobacco cessation, tobacco cessation counseling, or referral for treatment for tobacco cessation. Please see the 'Resources/Interventions' section of the Project Details for links to tobacco and smoking cessation patient education.

Questionnaire – REDCap

What is the REDCap Questionnaire?
REDCap is a data collection tool that can be accessed online to complete your data. Please find the link on the main project web page. A detailed outline of the questionnaire can be found in Appendix 3 of the Project Details.

Do I have to download software or purchase a subscription?
No. The software is accessed through a link on the project web page and completed online. This secure database is unique to the American College of Surgeons and does not require any downloads or IT interface with your systems. You will not need IT permissions or admin rights to access the program.

How do I use REDCap?
Once you click on the link, you will create your unique password to log back into your questionnaire. *This information will be necessary to complete all three of your questionnaires. You will not get credit if you create a new account for each of the data collection periods.* Once you have completed your account, you will complete the baseline questionnaire. Detailed instructions and tip sheets about accessing the REDCap questionnaire are available on the project web page.

Does more than one person need to complete the questionnaires in REDCap?
No, though it is strongly encouraged that the team discuss the qualitative points in the questionnaire prior to completing. A primary contact is required, and the email associated with this primary contact will be the one used to communicate about the project and access subsequent questionnaires. If this individual leaves or needs to be changed, you will need to contact ACScancerprograms@facs.org to change the primary contact in the REDCap for your program.

There are multiple questionnaires. Are the questions different?
Most of the fields are very similar on all three questionnaires. Please fully review the Project Details (Appendix 3: REDCap Questionnaire) for a more detailed list of the questionnaire fields. There are three different data collection periods; thus, three questionnaires must be completed to obtain full credit. *You will not receive credit towards accreditation if all three questionnaires are not completed.* Be sure you review the date range requirements outlined in the Project Details before completing your questionnaires.

Accreditation Credit for Participation

Can activity on this project extend into 2023?
Yes. However, compliance credit for all standards will only apply to 2022 even if activity and reporting extends into 2023.

Is this project available for programs undergoing initial accreditation?
Yes, we encourage participation by programs working toward their first accreditation as long the application for accreditation has been submitted and an ID number has been issued. This will be a Facility Identification Number (FIN) for CoC, or a Company Identification Number for NAPBC. This Identification Number is a required field in the initial questionnaire.

If a program submits a project for NAPBC credit, can it also be submitted for CoC credit?
No. The project may only be used for CoC credit OR NAPBC credit, but not both. Programs with both CoC and NAPBC accreditations should have a collaborative discussion to determine which route is best for their program. The project will apply to EITHER CoC Standards 7.3, 8.2 and 9.1, OR to NAPBC Standards 3.2, 4.1 and towards one of the studies for 6.1. Participating programs are required to make a selection while completing the initial questionnaire. You may not go back and change your selection once the initial questionnaire is completed.

May participation be used to satisfy deficiency resolution?
Yes, participation in this project and completing requirements may be counted toward a deficiency resolution for the standards participation will be given credit for. For example, if you have a deficiency in CoC Standard 7.3, participation may be applied towards resolving that deficiency. It may not be applied to an unrelated standard. It may be applied only to deficiencies in the standards listed in the Project Details.

Why are we only asking about combustible tobacco use (smoking)?
The scope of the project has been narrowed to include the population for which we have the most research and literature on the impact to cancer mortality, even for cessation after diagnosis. While capturing smokeless tobacco use (such as chew or vaping) or marijuana use is important, it is not included in the data set for this study as controlled variables. Refer to the Project Details Appendix 3: REDCap Questionnaire for an outline of the data required in the questionnaires.

Data Collection

Does the PDSA require us to capture information about the patients and will each patient need to sign a participation agreement?
No. Patients will not sign a participation agreement for the PDSA or sign a consent**.** We are not gathering any patient data. Refer to the Project Details Appendix 3: REDCap Questionnaire for an outline of the data required in the questionnaires.

Do programs have to enter data on individual patients?
No, just aggregated data is required. No patient information is collected in the questionnaires.

What patients are included in the data set?
The initial questionnaire requires the analytic case load total for the most recent complete calendar year. If 2021 analytic total is not available, 2020 total may be used. In addition, each questionnaire asks for new patient volume, number of newly diagnosed patients ASKed about current smoking, and identification of how many of those patients were identified as currently smoking.

Our program sees both newly diagnosed patients and those who were diagnosed and/or previously treated elsewhere. Do we need to separate out these populations?
"Newly Diagnosed Cancer Patients" is defined to include those diagnosed elsewhere and being seen by your program for initial treatment. This is consistent with the STORE v22 definition for newly diagnosed cancer patients. Ideally, you would be able to utilize your tumor registry to help identify patients who are classified as "newly diagnosed cancer patients". Refer to the Project Details Appendix 3: REDCap Questionnaire for an outline of the information required in the questionnaires.

Our EHR does not include this information. How can we capture this data?
Most EHRs have embedded fields included that ask about tobacco use. You may need to check with your IT administrators to activate, or 'turn on', these fields. Alternatively, data may be captured through template documentation in the record, or even with simple questionnaire forms used during the first visit. Consider your current workflows and resources, and what is most feasible for your program. Please visit the 'Resources & Interventions' section of the Project Details for links that may be useful for your program.

Our program uses multiple EHRs,and does not have 2021 data abstracted yet. How are we to find/report the data in the Data Reporting Metrics section, where it requires total newly diagnosed patients and number of patients ASKed about smoking use?
In the final section of the questionnaire, total number of newly diagnosed patients in 2021 is a required field. This is NOT necessarily analytic case load. This is data which should be pulled from volume reports, such as a practice administrator might use for seeing how many new patients were seen in a year. The data collection period for the baseline questionnaire is for calendar year 2021. This data is NOT likely to be available from your Registry. In programs where you may see many patients who are not newly diagnosed, but have been treated elsewhere and are new to you, it is acceptable to include these patients in your data.

The project committee recognizes this is a shift from how many programs review and report their information. For that reason, there is also the option to answer '0' if the value is not able to be extracted from the EHR.

Some programs are choosing to use a sub-set of their total population which is representative of the majority of their patients. For example, collecting new patient volume from medical oncology, or for the top 3 disease sites, allows programs to narrow the scope of the query for this information, without overwhelming their IT resources. However, the interventions and data provided should cover as many of your patients as possible.

Remember that credit is applied for *participation*. Use this opportunity to evaluate how your program uses current resources to ask about and document smoking use after patients are diagnosed. Specific limitations about your data set, or details about how you approached this unique project, can be summarized in the 'Comments' section at the end of the questionnaire.

Documentation Questions

What do we need to submit to let the CoC/NAPBC know we are participating? Where is it submitted?
Programs must complete the initial questionnaire and put aggregated baseline data within the REDCap by April 15, 2022. Refer to the Project Details for complete details about the timelines and what is required.

Do we need to notify CoC/NAPBC now if we are going to do the PDSA project for CoC Standards 7.3, 8.2, and 9.1 or NAPBC Standards 3.2, 4.1, and 6.1?
This information will be completed during the initial questionnaire. Because subsequent questionnaires are linked back to the Primary Contact login, this information may not be changed after completing the initial questionnaire.

What documentation do we need to keep for our Pre-Review Questionnaire (PRQ)?
Each of the three questionnaires must be completed by the specified deadlines. Once completed, a PDF can be downloaded which contains your unique responses. Keep this document to include in the Pre-Review Questionnaire (PRQ) at the time you prepare for your next site visit. Additionally, discussion must be included in the minutes from your Cancer Committee or Breast Program Leadership Committee (BPLC) meetings. The applicable Clinical Research template must also be completed.

NAPBC Specific Questions

Our program sees breast cancer patients across all of our cancer care areas. Do we have to separate out just the breast patients in order to get credit, or may we use our total data if needed?
Data reported for NAPBC credit is ideally representative of only your breast cancer population. However, if you are applying for NAPBC credit, but are not able to segregate your newly diagnosed breast cancer patient visits from the total in your data reporting in this situation, you may use the total for all newly diagnosed cancer patient visits. It is important that your data be reported in a consistent manner for all three questionnaires.

If a NAPBC program does the Just ASK project and a physician specialty-specific quality improvement program, does it satisfy Standard 6.1 for 2021?
No. Programs are required to complete two quality studies for Standard 6.1, one of which must be a center-specific study. Participation in the Smoking Cessation Just ASK project does **not** count towards that center-specific study. You will need to do a center-specific Quality Improvement study to fully satisfy the requirement for NAPBC Standard 6.1.

Can Just ASK and a specialty-specific quality improvement program (e.g. QOPI, TOPS) be used to meet Standard 6.1?
No. Participation in the Smoking Cessation Just ASK project does **not** count towards that center-specific study. You will need to a do a center-specific Quality Improvement study in addition to Just ASK to fully satisfy the requirement for NAPBC Standard 6.1.

Can a program fully comply with Standard 6.1 by doing the Just ASK project?
No. A center-specific study must be completed in addition to the Just ASK project.

Does participation in the tobacco PDSA count for full credit for NAPBC Standard 4.1?
Yes, for 2022. Additional events are encouraged, but not required.

CoC Specific Questions

By completing the Just ASK project can programs get credit for CoC Standards 7.3, 8.2, and 9.1 for the same work? We know that usually this is not the case, and you can only get credit in one standard area for a project.
We are giving credit for multiple standards for participation in this project. Programs will get credit for CoC standards 7.3, 8.2, and 9.1 if they complete all required elements of the project. Refer to the Project Details for complete details about requirements and deadlines for completion.

Does an "event" have to occur to get credit for CoC Standard 8.2 as stated in the standard definitions and requirements? The intervention listed is not event related.
An event does not have to take place to get credit. We expect programs to use the intervention listed as an alternative to events. It does not need to be a traditional event. All three REDCap questionnaires must be completed in order to receive credit.

Can this project also count for Standard 8.1: Addressing Barriers to Care?
No. This project does not apply to CoC standard 8.1.

If we complete the REDCap questionnaires in the Just ASK project, do we also need to complete the Standard 7.3 Quality Improvement Initiative or Standard 8.2: Cancer Prevention Event templates?
No. You will need to download the PDF of your questionnaire responses. These will need to be uploaded to demonstrate your 2022 compliance in your Pre-Review Questionnaire (PRQ) during the year of your next site visit. It is recommended that you also keep any additional documentation related to your selected intervention(s) and data tracking methods. *For the Standard 9.1, you will still need to complete the Clinical Research Template.*

For network (INCP/NCIN) programs, is this project done at the network parent level? Or must it be done at each of the children?
For Network Accreditations (INCP/NCIN) to receive credit, BOTH of the following criteria must be met:

- All network children within the network each submit their own questionnaire series; **AND**
- at least 20% of the network analytic case load must be impacted by the intervention implemented.

This requires that network organizations must coordinate with each other to ensure that at least 20% of the total network population is impacted by the intervention implemented. When completing the questionnaire, both the parent and child FIN are required.

Research Study Questions

For the clinical study portion of the PDSA, do we need to identify a local study Principal Investigator (PI)? Does the designated PI need to be someone with experience having served as a study PI before?
Your program will be responsible for selecting someone to serve as the Primary Contact for this project. Ideally, this individual is comfortable with the data and validation points, so we can be confident the data being reported is accurate. This person should be familiar with tobacco cessation practices, be able to verify the data source, and verify the accuracy of tobacco use and assessment rates that are being submitted at multiple time points. Ideally, this individual should be an active member of the Cancer Committee or Breast Program Leadership Committee. NOTE: The questionnaire requires a primary and secondary contact, in the event that a primary contact leaves or is no longer available.

How is the patient enrollment being captured for credit towards CoC Standard 9.1 or NAPBC Standard 3.2?
Participation does not capture patient-specific enrollment in this study. Participation is specific to PROGRAM participation. For that reason, there is not a patient enrollment percent, nor a consent requirement. Full credit is being applied to participating programs for CoC Standard 9.1 or NAPBC Standard 3.2 for 2022. NOTE: Programs are expected to track and report unique clinical research patient enrollments in the PRQ and related templates for 2022. Programs that have patient enrollment below the standard requirement will NOT receive a deficiency for 2022 IF THEY ALSO complete all required elements of this project. Refer to the Project Details for complete details about the timelines and what is required.

Do I need local IRB approval to participate and get credit for CoC Standard 9.1 or NAPBC Standard 3.2?
The American College of Surgeons has provided an IRB exemption form, as aggregated program data is all that is submitted. There is no patient information submitted and patients do not need to sign a consent. This is not a clinical trial requiring patient participation. However, depending on your specific institutional policies, you may need approval from your local IRB. It is recommended that you check your local IRB policies.