Non-Small Cell Lung Cancer Biomarkers

Introduction

The National Quality Forum (NQF) Measure Incubator®, an innovative effort that facilitates efficient measure development and testing through collaboration and partnership, is soliciting information from measure developers to transform two measure concepts into fully specified and tested measures. This Measure Incubator project is supported by Genentech.

This request for proposal (RFP) describes the measure concepts to be further developed and tested, and requests information on a development and testing plan of these concepts from potential measure developers. **NQF encourages innovative approaches to measure development and testing that promote efficiencies in the processes and associated budget, which do not necessarily have to follow traditional blueprints for measure development and testing. NQF strongly prefers and will prioritize measure developers that tackle both measures but will consider development of one measure.**

In 2019, NQF, also with support from Genentech, convened a strategy session with a multistakeholder Expert Panel to facilitate the development of a suite of measure concepts focused on timely and appropriate biomarker screening and treatment planning for non-small cell lung cancer (NSCLC) that could be translated into performance measures through development and testing. Lung cancer is the second-most common cancer in the United States, making up 13% of all new cancer cases in 2019,[1] and is the leading cause of cancer death.[2] Among individuals with NSCLC, approximately 66% receive a late diagnosis with advanced or metastatic disease.[3] NSCLC outcomes and survival rates may improve with the use of biomarker screening and targeted therapies.[4] However, current patterns in clinical practice do not always align with current biomarker testing and treatment guidelines.

The Expert Panel identified and prioritized four measure concepts, including two 2-part measures, that could become performance measures for NSCLC. These concepts span the continuum of care—from biopsy through treatment—and assess the role of medical oncologists, pathologists, and laboratories in ensuring that patients receive evidence-based diagnosis and care. Participants included individuals with NSCLC, caregivers, clinicians, payers, researchers, data experts, and measure developers. The following two measure concepts were selected for testing and development:

1. **Testing to Inform Treatment (2-part measure):** Part 1) Percentage of patients receiving systemic treatment who received biomarker testing; Part 2) Percentage of patients receiving systemic treatment whose biomarker test results were received <u>before</u> treatment initiation
2. **Turnaround Time:** Percentage of patients with appropriate turnaround time from biopsy to biomarker testing results

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[1] Bronchus Cancer. National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) Program. https://seer.cancer.gov/statfacts/html/lungb.html. Last accessed June 2020.

[2] Cancer.net. Lung Cancer Non-Small Cell: Statistics Website. Cancer.Net. https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics. Published June 25, 2012. Last accessed June 2020.

[3] Ahmadzada T, Kao S, Reid G, et al. An Update on Predictive Biomarkers for Treatment Selection in Non-Small Cell Lung Cancer. J Clin Med. 2018;7(6). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6025105/. Last accessed June 2020.

[4] Lim C, Tsao MS, Le LW, et al. Biomarker testing and time to treatment decision in patients with advanced nonsmall-cell lung cancer. Ann Oncol. 2015;26(7):1415-1421.

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Project Overview

The NQF Measure Incubator seeks to identify an organization with proven experience in developing and testing healthcare performance measures—particularly measures that focus on or incorporate biomarkers, cancer, or lung cancer— to serve as the primary measure developer for the following measure concepts: 1. Testing to Inform Treatment (2-part measure); and 2. Turnaround Time. Tables 1-3 provide early draft specifications for each measure concept recommended by the Expert Panel along with questions for the measure developer to address in development and testing. Each concept requires formal development (i.e., concept refinement and detailed specification) and testing (i.e., feasibility, reliability, and validity testing with risk adjustment/stratification, as appropriate) to produce finalized measures that are evidence-based and determined to be feasible, reliable, and valid.

Table 1. Testing to Inform Treatment for Non-Small Cell Lung Cancer Biomarkers Measure Concept; Part 1 of 2

Measure Concept	Testing to Inform Treatment for Non-Small Cell Lung Cancer
Description	Percentage of patients receiving systemic treatment who received biomarker testing
Numerator	Number of patients with advanced-stage, non-squamous NSCLC patients who received biomarker testing for biomarkers with FDA-approved treatment for NSCLC lung cancer
Denominator	Number of patients with advanced-staged, non-squamous NSCLC who received systemic treatment for NSCLC within the past 12 months
Care Setting	Ambulatory, inpatient
Stratification	Insurance status, ECOG score, tumor histology, diagnosis status, use of a multidisciplinary team/tumor board, comorbidities, age, socioeconomic status, and/or area measures
Level of Measurement	Clinician/practice level
Data Source(s)	Claims (e.g., CPT codes), Electronic Health Records (EHR)
Time Point	Each calendar year
Expert Panel Suggested Questions to Explore for Measure Development	**Definitions:** How should advanced-stage disease be defined? Should the measure include biomarker testing with disease progression and, if so, how would that be incorporated? **Denominator:** Should the denominator be limited to ECOG score ≤ 2? **Exclusions:** Should the measure be limited to patients with two or more medical oncology visits? **Attribution:** How should attribution be assigned? Who should receive/act on these data? **Implementation considerations:** Should this measure be used for internal quality improvement (QI), accountability, or both?

Table 2. Testing to Inform Treatment for Non-Small Cell Lung Cancer Biomarkers Measure Concept; Part 2 of 2

Measure Concept	Testing to Inform Treatment for Non-Small Cell Lung Cancer
Description	Percentage of patients receiving systemic treatment whose biomarker testing results were received before treatment initiation
Numerator	Number of patients with advanced-stage, non-squamous NSCLC patients who received biomarker testing results before beginning systemic treatment
Denominator	Number of patients with advanced-staged, non-squamous NSCLC who received biomarker testing for biomarkers with FDA-approved treatment for NSCLC lung cancer
Care Setting	Ambulatory, inpatient
Stratification	Insurance status, ECOG score, tumor histology, diagnosis status, use of a

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	multidisciplinary team/tumor board, comorbidities, age, socioeconomic status, and/or area measures
Level of Measurement	Clinician/practice, network level
Data Source(s)	Claims (e.g., CPT code), EHR
Time Point	Each calendar year
Expert Panel Suggested Questions to Explore for Measure Development	**Definitions:** How should advanced-stage disease be defined? Should the measure include biomarker testing with disease progression and, if so, how would that be incorporated? **Data Sources:** What other data sources are available to help capture this? **Implementation considerations:** Should this measure be used for internal QI, accountability, or both?

Table 3. Turnaround Time for Non-Small Cell Lung Cancer Biomarkers Testing Measure Concept

Measure Concept	Turnaround Time in Non-Small Cell Lung Cancer Biomarkers Testing
Description	Percentages of patients with appropriate turnaround time from biopsy to biomarker testing results
Numerator	Number of patients with advanced-stage, non-squamous NSCLC whose biomarker results were received within 21 days of the date of biopsy
Denominator	Number of patients with advanced-stage, non-squamous NSCLC whose biopsy(ies) were submitted for biomarker testing within the past 12 months
Care Setting	Ambulatory, inpatient
Stratification	Insurance status, ECOG score, tumor histology, diagnosis status, use of a multidisciplinary team/tumor board, comorbidities, age, socioeconomic status, and/or area measures
Level of Measurement	Laboratory, clinician/practice
Data Source(s)	Laboratory information systems, EHR
Time Point	Each calendar year
Expert Panel Suggested Questions to Explore for Measure Development	**Definitions:** Should the measure include biomarker testing with disease progression and, if so, how would that be incorporated? Should this measure be linked to a measure about pathology reports informing clinical decision-marking? **Numerator:** Is 21 days the right cutoff for turnaround time? **Data Source:** What should be used to determine when the biomarker results were received (e.g., when the test results are available in the medical record)? **Attribution:** How should attribution be assigned and, specifically, who is accountable for managing the 21-day turnaround time? **Implementation Considerations:** Should this measure be used for internal QI, accountability, or both?

Roles and Responsibilities

NQF Measure Incubator® (Facilitator)

The NQF Measure Incubator brings together the necessary resources—such as measure developers, clinicians, patients, data sources, and funding—to spur development of needed measures. In its role as project facilitator, the Measure Incubator will facilitate measure development and testing by others. The Measure Incubator will conduct activities such as coordinate monthly calls with the measure developer(s) and data partner(s) to facilitate the work and provide suggestions and opportunities for efficiencies based on other Measure Incubator projects. However, the Measure Incubator will not enter into contractual agreements with any other partners the measure developer might work with,

particularly data vendors and test sites. NQF does not develop measures and will not be involved in day-to-day measure development and testing activities

Genentech (Funder)

This Measure Incubator project is supported by Genentech. In its role as project funder, Genentech will not directly engage with the measure developer, data partner(s), and/or potential test sites. Genentech will not specify or influence the outcome or processes of measure development and testing, in accordance with NQF Measure Incubator® COI principles.

Measure Developer

The measure developer will lead development and testing of these concepts (including stratification and risk adjustment, where appropriate) using a process that is cost-effective and efficient; novel development and testing approaches are encouraged. The developer is not required to submit the incubated measure(s) to NQF for endorsement review. If the developer elects to pursue endorsement, the incubated measures are conferred no advantage in the endorsement process in terms of endorsement or fast track review.

Scope of Work

The measure developer will be responsible for the following tasks:

- Task 1: Solicit expert input to refine measure specification and development.
  Note: NQF is able to facilitate introductions between the measure developer and the Expert Panelists from the NQF-convened strategy session, as requested, and NQF will facilitate identification of additional experts, as needed. The developer is encouraged to propose novel ways to integrate expert input into the process outside of the typical Technical Expert Panel process.

- Task 2: Collate and synthesize scientific evidence to support measure intent and specifications, along with performance gaps.
  Note: The measure developer can build upon the environmental scan and strategy session summary produced by NQF.

- Task 3: Identify and secure an appropriate data partner(s) and/or test site(s).
  Note: The measure developer will be responsible for identifying and securing the appropriate data source(s) and test beds. The measure developer should identify how the data partner(s) can be utilized throughout the development and specification process. The measure developer will enter into agreements with the data vendor and test site organizations.

- Task 4: Create measure specifications, along with stratification and/or risk adjustment approach(es), as appropriate, and determine feasibility of initial set of data elements.
  Note: Measure specifications should contain sufficient details to support testing and implementation.

- Task 5: Refine measure specifications and stratification approach(es), based on expert input, initial data analyses, and broad multistakeholder input (e.g., public commenting, and engaging patients and caregivers).

- Task 6: Develop and execute a detailed measure testing plan, with timeline and quality assurance protocols, to demonstrate the feasibility, reliability, and validity for each measure (including stratification and/or risk adjustment). Describe coordination of development and testing of both measures, if proposing to develop and test both measures.

- Task 7: Provide monthly project status updates, including work completed, in progress and upcoming, potential risks or delays, problems experienced, mitigation strategies, and proposed solution(s).
- Task 8: Summarize measure development and testing results, including final measure specifications and risk stratification/risk adjustment methodology, in a final report for each measure.

Deliverables

The measure developer will be responsible for producing the following deliverables throughout the project's lifecycle:

- Task 2: Summary of scientific evidence to support measure intent and specifications, along with performance gaps
- Task 3: Identify and secure appropriate data partner(s) and/or test site(s)
- Task 4: Initial measure specifications and feasibility assessments for collection of broad multistakeholder input
- Task 5: Refined measure specifications, if multistakeholder input and initial data analyses generates refinements to the initial measure specifications
- Task 6: Detailed measure testing plan with timeline and quality assurance protocols
- Task 7: Written monthly project status updates
- Task 8: Two fully specified and tested measures on testing to inform treatment and turnaround time
- Task 8: Complete final report for each measure with measure specifications, stratification methodology, detailed feasibility, reliability, and validity testing results, and recommendations for implementation and further refinement

Estimated Measure Development Timeline

The measure developer should create a timeline outlining the estimated time by task for measure development and testing.

Estimated Measure Development Budget

The measure developer should provide an estimated budget outlining the costs by task with justification.

Minimum Qualifications of Key Personnel

Staff identified to be a part of the project team should include one or more methodologists, project managers, statisticians, data analysts, quality improvement experts, and subject matter experts in oncology and biomarker testing. Measure developers may contract with outside individuals or organizations to ensure that the project team has the necessary expertise to support this project. The key personnel should be able to demonstrate the following qualifications:

- Established track record for successful evidence-based measure development, including cancer-specific measures, screening and testing measures, eCQMs, composites, paired measures and/or outcome measures
- Substantial experience with all aspects of design and execution for measure development and testing, including scientific evidence review, measure specification and testing (for feasibility, reliability, and validity), data analysis, risk adjustment (including clinical and social risk factors), and report writing

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- Depth and breadth of relevant expertise, such as clinical practice, measurement methodology, health services research and/or epidemiology, clinical informatics, professional and technical claims coding, statistics, quality improvement, electronic health record (EHR) data systems and workflows, other healthcare data sources (including claims and registries), quantitative and qualitative data analysis, programming, and technical writing
- Strong project management skills, including the ability to manage accelerated and overlapping timelines
- Familiarity with rigorous methods, such as those outlined in NQF guidance for measure developers

  Note: In accordance with [NQF Measure Incubator® COI principles](), incubated measures are conferred no advantage in the NQF endorsement process, nor is pursuit of NQF endorsement a requirement for incubated measures.

RFP Requirements

The measure developer should include the following information in the response:

- **High-level work plan outlining measure development and testing activities** including feasibility, reliability, and validity testing and risk stratification (or risk adjustment) methodology, as appropriate

  Note: The work plan should address the methods, processes, procedures, and protocols necessary for effective and efficient completion of all measure development and testing activities and associated deliverables. There should be sufficient description that Measure Incubator staff can evaluate the appropriateness and adequacy of the proposed testing methods.

- **Project timeline with key milestones and dates**

  Note: At a minimum, the proposed project timeline should include each task, with key milestones and dates.

- **Summary-level budget**

  Note: At a minimum, the proposed budget should include estimated hours and fees for each task.

- **Staffing and management roles and responsibilities** (including contracted resources) for each task. Please provide resumes or curriculum vitae for key personnel, which demonstrate specific experience with measure development and validation (including cancer-specific measures, screening and testing measures, eCQMs, composites, paired measures and/or outcome measures)

- **Measure development and project management capabilities** (including examples of previous measure development and references), specifying which capabilities are in-house and which capabilities would be outsourced

Responses to the RFP should be <u>no more than 10 pages</u> in length, excluding resumes and references.

Evaluation of the Responses

Responses will be evaluated based on the following criteria:

- <u>Overall Suitability</u>: Proposed development and testing approach(es) must meet the scope and needs outlined above and be presented in a clear and organized manner.
- <u>Value and Cost</u>: Respondents will be evaluated on the timeline and cost of their approach(es) based on the work to be performed in accordance with the scope of this project.

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- Past Experience/Qualifications: Respondents will be evaluated based on their experience as it pertains to the scope of this project. Respondents must provide descriptions and documentation of assigned key personnel's technical expertise and experience.
- Novelty and Efficiency: Proposed development and testing approach(es) will be evaluated for their novelty and ability to provide efficient and cost-effective measure development and testing.

Submission Instructions

Responses should be submitted via email to incubator@qualityforum.org by 5:00pm Eastern on August 14, 2020.

Please direct any questions regarding the RFP to incubator@qualityforum.org.