A Data Quality Pre-evaluation Framework and Approach to SEER-wide Quality Audit Plan:

Operational results from two pilot studies

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Funded by NCI Contract No. HHSN261200800001E
Building in Quality Learning System into SEER

Quality assurance

- Evaluation via proactive & reactive QAPs
- Identifying root cause of any quality issues
- Systematic assessment of SEER data
- Corrective Action Plans & Implementation
  - Diffusion of knowledge and best practices
  - Inventory of evaluation approaches and strategies
  - QAP portfolio planning

Evaluation via proactive & reactive QAPs
Objectives of the QAP pre-evaluation

- To allow for the systematic estimation of data quality issues:
  - In a timely manner
  - Utilizing minimal resources
  - In sufficient level of detail to support the decision that:
    1. The data are of sufficient quality,
    2. Additional incremental analysis is required, or
    3. The need for a comprehensive QAP
Major aspect of a QAP Framework

**Trigger:**
- Event that cause the creation of a QAP
  - *Proactive trigger:* consistent, planned quality evaluation
  - *Reactive trigger:* dynamic, unplanned events that call for an evaluation of data quality for specific variables or categories of variables
Quality Audit Plans as a function of Triggers & Impact

<table>
<thead>
<tr>
<th>Proactive Triggers</th>
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<tbody>
<tr>
<td>Identify localized issues before visibility increases</td>
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<table>
<thead>
<tr>
<th>Triggers</th>
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<tbody>
<tr>
<td>Proactive Triggers</td>
</tr>
<tr>
<td>Reactive Triggers</td>
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<tr>
<td>Address underlying issues to maintain trust</td>
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Critical importance of hospital and central registrar involvement in the SEER-Quality Audit Plan
QAP Pre-Evaluation Pilot Projects

Overview

• **Objective**: To evaluate the QAP with respect to pre-evaluation
  ○ *What worked? What didn’t? What should be changed?*

• **Test situations**: Selection of two pre-evaluation pilots by the Priorities WG:
  ○ Proactive (pQAP) & Reactive (rQAP)

• Complete the analyses

• Evaluate results:
  ○ Capture lessons learned
  ○ Recommend changes to the QAP and process
QAP Pre-evaluation Process flow chart

1. Establish QAP Team
2. QAP Background Knowledge and Understanding
3. Pre-evaluation General Analysis
   - Milestone A: QAP Orientation Meeting
   - Milestone B: Consultation with QAP Team & Content Experts
4. Pre-evaluation Tailored Analysis
   - Milestone C: Consultation with QAP Team & External Content Experts
5. Preparation of QAP Pre-evaluation Presentation
6. QAP Pre-evaluation Assessment & Decisions

- No Go: Communicate Findings
- Go: Additional pre-evaluation assessment?
  - Yes: To comprehensive QAP Evaluation
  - No: Additional pre-evaluation assessment?
QAP Pre-Evaluation Steps (1 of 2)

1. Establish the team
   - Milestone A: orientation meeting

2. Investigate variable background knowledge & literature
   1. Literature review
   2. Establishment of initial acceptable values & benchmarks

3. General Analysis
   - Milestone B: consultation between the team and content experts
4. Pre-Evaluation Tailored Analysis
   - *Milestone C*: consultation with outside experts (if required)

5. Documentation and Preparation of QAP Pre-evaluation Presentation for leadership

6. Leadership decision:
   - **Stop** QAP: data of sufficient quality
   - **Go** QAP: begin a comprehensive QAP, OR
   - **Minor Anomaly (ies)**: document and trace minor anomalies
rQAP and pQAP presentations
Towards a systematic approach to building in quality

Variable levels of quality, reasonableness, and “sanity checks” across the SEER supply chain

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Pre-evaluation Process Conclusions

• General Knowledge Issues
• Specific Knowledge Issues
• Worksheet changes
• Process changes
QAP Pre-Evaluation Process Findings

• **General knowledge issues:**
  ○ SEER*STAT training is essential for QA evaluators
  ○ Understanding where to find data is important and should be documented
    • e.g., databases, coding instructions, current edit checks
  ○ Understanding the differences between an internal resource and a contractor
QAP Pre-Evaluation Process Findings

- **Specific knowledge issues:**
  - What are the critical contextual factors for the variable(s) of interest?
    - Understanding how the variable is reported compared to how it “behaves” in practice
      - This is important for the use of the data too
  - Need to have experts to draw upon
    - Clinical dimensions
    - History of coding rules, changes, etc.
  - What are the performance benchmarks for a variable w.r.t.:
    - Number of unknowns?
    - Biological plausibility?
    - Number of cases?
    - Other?
QAP Pre-Evaluation Process Findings

- Worksheet
  - Is a checklist is good.. but also need a good process flow
QAP Pre-Evaluation Process Findings

• Process:
  ○ Reporting: considerably more analyses may be completed than is presented at the Leadership meeting
    • Need for data to be sent to Leadership team prior to the meeting
    • Leadership meeting should focus on the key findings and recommendations
  ○ If something is “off”,
    • How to transition from being proactive to a reactive or full QAP?
    • There needs to be a “middle-ground” between a pre-evaluation and a full QAP process
  ○ The process should take considerably less time with practice
  ○ Organizational Memory: A data repository location established for the pre-evaluation analyses and results
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QAP portfolio planning

- Inventory of evaluation approaches and strategies
- Diffusion of knowledge and best practices

National Cancer Institute
Any questions or comments?
Thank you!
QAP Pre-Evaluation: Next Steps

• Conducting two more pre-evaluation pilots
  ○ Proactive and reactive
• Documenting “standard” analyses required
• Executing a full QAP
Bottom-line: SEER Quality Audit Plan

This proactive quality audit plan is integrated into a national cancer registry program to:

- Build in assurances that the data achieve pre-specified levels of quality
- Ensure that the SEER registry maintains its high quality level of data (and support next-generation registry data)
- Utilize the QAP to propose and support benchmarks for quality across the broader cancer surveillance community.
- Involve our cancer surveillance partners in initiatives to assure quality
What is a Quality Audit Plan (QAP)?

• A systematic way of evaluating the quality of existing and potential SEER data

• A standardized framework for verifying and validating such data with respect to:
  ○ Completeness
  ○ Consistency
  ○ Precision / Accuracy
Why a Quality Audit Plan?

• Systematize currently on-going quality activities within SEER
• Develop methods to proactively address the changing data landscape required for cancer surveillance
• Provide a formal method for prioritization of existing and future quality efforts
• Using a standardized method, identify ways to improve data quality and provide better population-based information to users
• Provide more consistent communication to registries and data users with respect to quality efforts within SEER
• Develop a process to know when and how unreleased data could be released
What is in a SEER Quality Audit Plan?

I. Characteristics of the Data Item(s)

II. Scope, Plan & Communication

III. Timeline of the response

IV. Evaluation Plan

V. Identification of Root Causes

VI. Corrective Action Plan / Implementation

Integral within all sections of the Quality Audit Plan

• Standardized/templated approach
• Identification of stakeholder involvement across all phases
• Defined timelines and assigned responsibilities
• Established Communication Plan

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Why a QAP now?

- Much more data available
  - Detailed initial and subsequent therapy
  - Genomic Information
  - Outcomes data beyond survival

- New methods available to collect and evaluate data
  - Natural Language Processing
  - Linkages
  - Patient generated

- Need for refinement in cancer subcategories of reporting to support clinically meaningful use
  - Molecular subtypes of cancer
  - Growth in “–omics” data
Major aspects of a QAP Framework

1. **Trigger:**
   - what will cause the creation of a QAP

2. **Tiers:**
   - the understanding that not all SEER data items are “created equal”
     - **Publicly available data**
       - Tier: site specific factor for cancer with high incidence rate
       - Tier: supporting demographics
     - **Unreleased data**
       - Tier: unreleased or new data (or new methods for collection)
Major aspects of a QAP Framework

1. **Trigger:**
   - what will cause the creation of a QAP

2. **Tiers:**
   - the understanding that not all SEER data items are “created equal”

3. **Level of Impact of Data Quality:**
   - Hospital and Central Registries
   - Research Capabilities
   - Research Findings
   - Long Term Policy and Clinical Practice
### Tiers

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<thead>
<tr>
<th>Tiers</th>
<th>Priority</th>
<th>Frequency of Use</th>
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<tr>
<td>Tier 1</td>
<td>All Cancers</td>
<td>Frequency of Use</td>
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<tr>
<td>Tier 2a &amp; 2b</td>
<td>Unreleased Data</td>
<td>Sub-populations (e.g., site-specific)</td>
</tr>
<tr>
<td>Tier 3</td>
<td>Tier 4 Future Collected Data: “New Product Line”</td>
<td></td>
</tr>
<tr>
<td>Tier 4</td>
<td>Tier 5 Future Collected Data: “Current Product Line”</td>
<td></td>
</tr>
<tr>
<td>Tier 5</td>
<td>To be collected Data</td>
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**Programmatic Priority**

- Core functions
- Supportive functions
- Future Direction
- Obligations

**Future Collected Data:**
- "New Product Line"

**What is done today:** "Current Product Line"
The SEER-wide Quality Audit Plan (QAP) is an innovative approach to systematically evaluate, monitor, and address data quality issues across the entire SEER community.

QAP provides a framework for verifying and validating that data elements are accurate and structured appropriately to support population-based research, clinical research, and statistical reporting.

The QAP will enable the SEER registry system to become a rapid learning organization to meet the current and future demands and assurances.
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How this was developed?
Methods & Efforts to Date

• Stakeholder input
  ○ Internal & External (n=15 interviews)
  ○ Registrars & Researchers

• Quality Audit Plan working group
  ○ Development of Framework (n=8 meetings)
  ○ Specialized Groups
    • Evaluation methodology
    • Prioritization & portfolio management
    • Process & workflow
    • Stakeholders and resources

• Focus Groups (currently underway)
Motivation & Guiding Principles

Develop an innovative & comprehensive framework to systematically **evaluate quality** and establish an approach to **maintain/improve the current level of quality**:

- Utilize standardized methodologies, templates, and processes across the data lifecycle
- Integrate into the ongoing quality program that involves end-to-end registry partners from CTRs to Researchers
- Enable best-practices and lessons learned to be disseminated quickly across SEER
- Establish a benchmark for SEER and other medical registries to compare against and establish goals