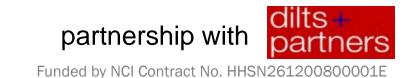


Developing the SEER-wide Quality Audit Plan: Working Groups and Procedures

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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:
 - o Timeliness
 - Availability and Completeness
 - Accuracy (Validity/Precision)

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

Working Groups

Evaluations Working Group

- Develop potential benchmarks
- Categorize SEER variables into audit groupings
- Review, develop, and adopt evaluation approaches

(Statistical Group is integrated into the Evaluations WG)

Statistical Group

- Sampling plan
- Statistical approaches

Prioritization Working Group

- Prioritize Data Quality Studies & Identify reasons for ranking
- Prioritize routine categories & Identify reasons for ranking
- Develop QAP prioritization heuristic

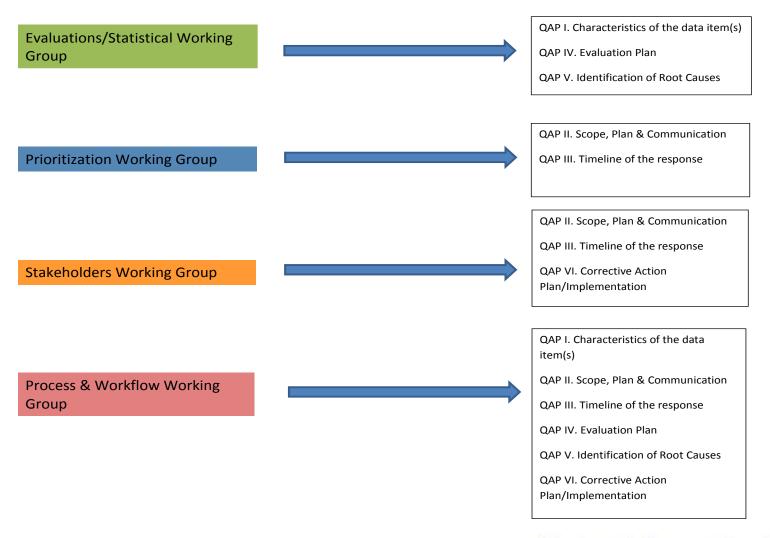
Stakeholders Working Group

 Identify primary responsibilities for leading QAP based on evaluation approaches

Process & Workflow Working Group

- Establish the infrastructure needed to support the QAP
- Manage the QAP

Integration of QAP Framework and Working Groups



QAP I. Characteristics of the data item(s)

- 4 main categories of SEER-collected data items
 - Category 1 Data items abstracted from original source documents (transmitted to NCI following consolidation)
 - Category 2 Data items derived or computed based on category 1 items (transmitted to NCI following consolidation)
 - Category 3 Data items populated with administrative or system-assigned values
 - Category 4 Data items populated by linkages or derivations performed as special projects

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Focusing on Category 1 Data Items

- Several major groups to characterize data items
 - o Patient
 - Tumor (invariant)
 - o Stage
 - o Treatment
 - Prognostic Factors

Focusing on Category 1 Data Items

Further categorization by minor groups

Major Group	Minor Groups
Patient	Demographics, Outcomes
Tumor (invariant)	Geosocial, Tumor Characterization
Stage	NCI Stage, TNM Stage
Treatment	Loco-Regional Rx, Systemic Rx, Other Rx
Prognostic Factors	Site-specific factors, Distinct prognostic factors

Structured Groups for Category 1

Major Group	Minor Group	Description	Examples
Patient	Demographics	Demographics	Race, Hispanic Origin, Sex, DOB, Place of birth
Patient	Outcomes	Vital Status	Date of last contact, Vital status, Cause of death
Tumor (invariant)	Geosocial	Diagnosis date, Address at diagnosis	Address at diagnosis- state, county at diagnosis, Census tract 2010
Tumor (invariant)	Tumor characterization	ICD-0-3	Date of diagnosis, primary site, laterality

Structured Groups for Category 1

Major Group	Minor Group	Description	Examples
Stage	NCI Stage	EOD and Summary stage	EOD items, Summary Stage, Tumor Size
Stage	TNM Stage	AJCC TNM	AJCC items
Treatment	Loco-regional Rx	Surgery and radiation therapy	Surgery dates, radiation therapy dates
Treatment	Systemic Rx	Chemotherapy, immunotherapy	Systemic treatment data items dates and drug categories
Treatment	Other Rx	Treatment sequence	Date of first treatment, reporting source

Structured Groups for Category 1

Major Group	Minor Group	Description	Examples
Prognostic Factors	Site-specific factors	Site-specific factors (include both items required and not required for staging)	CS SSF1-6 (years 2004-2017) CS SSF 7-25 (years 2010-2017)
Prognostic Factors	Distinct prognostic factors	Prognostic and predictive factors 2018+ (include both required and not required for staging)	Distinct prognostic factors 2018+ (currently under development)

What's the next step?

- Prioritization
 - Depending on the categorization of the SEER data items, the next step is to decide the priority of each item to be evaluated
 - Very high
 - High
 - Moderate
 - Low

Input and Framework For Prioritizing QAPs

The goal is to capture the prioritization thought process across all dimensions

M. Assessment of the Magnitude

M.1 Magnitude of the Error

to be completed after preliminary evaluation of the observed trigger

M.2 Burden/Magnitude of the Impacted

Population

Incidence, Survival, Mortality

U. Utilization of the impacted variables

U.1 Use/importance of research Relevance related to newly published research findings

U.2 Use/importance of clinical decisions
Implications on treatment & assessment guidelines/policies

U.3 Use/importance to SEER Funding decisions, future expansion of SEER,

C. Characteristics of the the Trigger (Integrated into the Quality Audit Plan Worksheet)

C.1 Criticality & interaction on other variables: (tumor size, HPV)

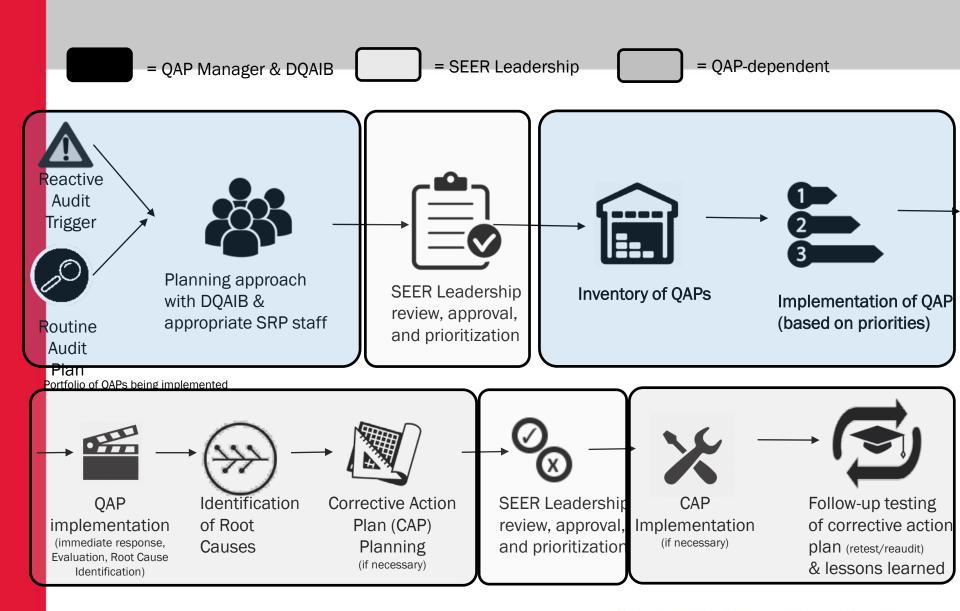
C.2 Feasibility to address the trigger Resource intensity, timeliness, how easy is it to fix?

C.3 Visibility by the community / press Entity bringing the issue to attention (e.g. influential advocacy group)

C.4 Duration of the variable release Length of time the variable(s) have been in public release

C.5 Are any of the variables undergoing changes and/or impacted by any transition?)

C.6 Are the data currently released?



Guiding Principles of the QAP workflow

- Quality manager to coordinate across a multidisciplinary team of subject matter experts
 - Need for tight integration and coordination in order to reduce variation and set expectations early on
- Every audit should have at least one member from DQAIB involved in planning stages
- Implementation of QAPs will be assigned based on scope, skill, and expertise
- Every audit needs input from all branches to provide a diverse set of perspectives on interpretation of quality

Guiding Principles of the QAP workflow

- Communication is key to the success of the QAP
 - Across the branches
 - With participants/stakeholders
- Every QAP has assigned roles/responsibilities & timelines
- The results of all QAP will be tested and lessonslearned will be applied to future QAPs (i.e. SEER will be a learning organization)

Building in Quality Learning System into SEER

Quality assurance

Evaluation via proactive & reactive QAPs

QAP Portfolio[®] Planning

Inventory of evaluation approaches and strategies



Identifying root cause of any quality issues

Corrective Action Plans & Implementation

Systematic assessment of SEER data

Diffusion of knowledge and best practices

National Cancer Institute

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 SEER registry maintains its high quality 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





