



# **NPCR Education and Training Series (NETS)**

## **Module 3: Quality Control for Central Registries**

### **Part 1-Section E: Developing an Audit**

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# Developing an Audit



Except as noted, the following session provides a generic approach to developing an audit—either a field audit (reabstracting, casefinding) or an in-house audit (recoding, reliability).

## Developing an Audit

- ◆ Audit team
- ◆ Foundation materials
- ◆ Topic selection
- ◆ Timing
- ◆ Writing the protocol
- ◆ Sampling
- ◆ Conducting the audit
- ◆ Analyzing the data
- ◆ Feedback

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Numerous factors must be considered when an audit is developed. This is not a one-person job; it takes a team of central registry staff to do a good job designing and conducting the audit. There must be documentation of the process from beginning to end, including the reference documents that will be the foundation for coding rules and guidelines or case ascertainment.

There are a variety of ways to select the topic of the audit, and the timing must be carefully planned to avoid overburdening both central registry and facility staff. Sampling is both a science and a skill, and it's more than just picking how many cases to review.

The audit process begins with protocol development and doesn't conclude until the findings have been provided to the audited facilities. All of the aspects of conducting an on-site audit have to be planned carefully.

The job is not finished until the data have been analyzed, summarized, and plans made for follow-through on the findings.

Let us take a look at each of these in more detail.

# Audit Team

- ◆ **Audit manager**
- ◆ **Statistician/sampling expert**
- ◆ **Field staff**
- ◆ **IT staff**
  - **Field staff computer support**
  - **SAS or SPSS programmer**
  - **Audit software developer**
- ◆ **Data analysts**

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The audit team at the central registry consists of a variety of skilled staff, each of whom contributes unique expertise to the audit process. The audit manager is usually the supervisor or coordinator of the quality assurance program and quality control activities at the central registry, although this responsibility may be delegated to an experienced auditor.

A statistician is an important part of the team during the protocol development period and data analysis period. Personal expertise in sampling or access to a sampling expert is important during the facility selection process.

The burden of data collection is on the field staff. They must be involved in audit development so that they understand the purpose of the audit as well as what they are to look for. Furthermore, they must be available to travel during the period of the audit and to complete the reconciliation and any necessary reports once they return to the office.

Information technology (IT) staff are equally important members of the audit team. The principal function of the IT staff regarding the audit is to provide computer support for the field staff, such as making sure laptops are up-to-date, databases are loaded, communications are working, and backup systems are effective. IT staff also must receive and manipulate the databases from the facilities so that the sampled cases can be identified. The IT staff may include statistical software (SAS or SPSS) programmers, or that function may remain with the statisticians. If the audit involves the use of specialized or customized software, the audit software developer must be involved from the outset, so that any particular needs of the auditors or the subject matter can be addressed before the audit actually begins.

Last on this list, but certainly not least, are the data analysts. Depending on the subject matter, number of data fields audited, and so many other factors, analysis of data may be the responsibility of statisticians or other members of the quality control staff. The data need to be calculated, interpreted, and displayed in a meaningful format. The data analysts should be involved in audit planning and review of the audit software so that they can contribute to the study design, rather than be surprised after the field work is complete with data that is not analyzable.

It can take months to plan an audit. In addition to the central registry team, representatives of the constituent facilities should participate in study planning, because they will be able to advise on the availability of records, timing of the audit, and other factors that the central registry staff may not recognize as potential issues.

This list represents just the members of the audit team at the central registry. At the facility, the participants in the audit include the data collectors and administrative staff; such as medical record clerks to pull the source documents. In addition, any hospital staff that may be displaced or inconvenienced by the on-site audit and any physician advisors should be kept informed of the on-site audit.

## Foundation Materials

- ◆ Reporting requirements and policies
- ◆ Case reportability and ascertainment rules
- ◆ Central registry reporting requirements
  - Periodicity
  - Media
- ◆ Confidentiality
  - HIPAA
  - Data security



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The definition of foundation materials is documentation that sets rules and guidelines for the data reviewed during the audit. These documents include the state regulations and laws that mandate reporting of cancer cases, and codes and definitions of the reportable neoplasms. Additional foundation materials consist of central registry rules, standards, guidelines, and documentation that describe the frequency of data submission (periodicity) and how it should be submitted (electronic or paper abstracts).

Because medical records will be accessed by individuals not directly involved in patient care, confidentiality policies are extremely important. Objections to accessing the records may arise at the facility and can be overcome by citing the central registry's exemption from HIPAA regulations and that quality control activities are part of that exemption. Equally as important are clear guidelines for data security. We have all heard about laptops containing thousands of names and identifiers that have been stolen from cars or hotel rooms. Imagine the potential damage if a registry's master list of cancer patients—with Social Security numbers, birth dates, and even phone numbers—is stolen. Strong data security policies can reduce that risk.

All of these foundation materials lay out what “should be.” The reality will be evidenced by the results of the audit.

## Topic Selection

- ◆ **Targeted audits**
  - Identify extent of specific problems
  - Identify individual data collector training needs
  - Review and improve data quality in problem areas
- ◆ **Random audits**
  - Validate central registry data for research purposes
  - Identify unknown problem areas
  - Identify general data collector training needs
  - Review and improve data quality in unknown areas

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What will be the topic of the audit? This is a major decision that affects many aspects of study design. In fact, the topic may be the first aspect selected. The two big categories of audits are targeted and random. The purposes of these types of audits are different. A targeted audit is usually performed because of an actual or perceived problem with the data. The targeted audit will help determine the extent of the problem. Targeted audits can also identify training needs for individual data collectors. The result of the audit will be database improvement specific to the problem area, but the training or other feedback from the audit may have wider beneficial effects because of the attention paid to the target facility and data collectors.

Random audits are not exactly a fishing expedition. Consider an audit of random data as a spot check or sampling of the data. It is possible that a random audit will identify problem areas that were not previously suspected and that have not been identified through formal data quality monitoring. Another use of random audits is to obtain a clearer perspective of training needs for data collectors in general, not just those with identified problems. A random audit isn't truly random; it still must be planned and executed carefully to be meaningful.

Experience has shown that because of limited resources, most audits performed by central registries are targeted in one way or another.

# Topic Selection

## ◆ Targeted audits

- High risk – high volume
- Major sites – problem sites
- New staff
- New software/conversions
- High volume
- History of problems

## ◆ Random audits

- All facilities
- All primary sites

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Targeted audits have been triggered by something. It could be reviewing submissions by new registrars or checking the reliability of data submitted to the central registry after a software switch or conversion. It could be reviewing one or more facilities with a history of staffing problems or low accuracy rates during acceptance sampling. Even the type of facility (military versus community) or the source of cases (medical records versus pathology or radiation therapy) could be the selected target. Central registry staff who know that particular hospitals have high caseloads and limited staff may target those facilities for a closer look at completeness or accuracy. It could simply be that central registry staff perceive a problem in the data and conduct an audit to confirm or negate the perception.

An important concept in quality assurance methodology is to target areas of high volume or high risk for periodic audits. High-volume areas are those where there are many cases, such as the major cancer sites. Any issues identified and corrected in a high-volume area will improve a large sector of the central registry database. For example, identifying problem patterns in—and better training about—the relationships of the CS Lymph Nodes and Site-Specific Factors fields for breast will result in better quality data for thousands of breast cases. High-risk areas are those prone to error but do not necessarily involve large numbers of cases. For example, hematopoietic diseases are known to be case ascertainment problems, so a casefinding audit targeting bone marrow biopsies or hematology reports could look for cases that escaped abstracting because of imprecise terminology or the data collector's lack of understanding the disease process and its various diagnostic terms. Some issues are both high-volume and high-risk, such as accurate staging of lung cancer or prostate cancer.

Even though the subject matter of the audit may be targeted, the selection of hospitals may still be random. If a problem is perceived in a particular site, an audit of randomly selected facilities can document the validity of the problem. If the issue is with a particular data field or group of fields, such as treatment fields, the audit may be conducted on randomly selected primary sites at each facility.

# Timing of Audit

- ◆ Time of year
- ◆ Advance preparations
  - Develop protocol
  - Develop sampling plan
  - Notify facilities
  - Freeze database and submit
  - Select cases
  - Make travel plans

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As we have said repeatedly, an audit takes lots of planning. An early consideration must be the time of year that the on-site audit takes place. All things considered, there are only limited periods of time that an audit can take place. Usually the two to three months prior to a data submission are not good because quality control staff will be involved in final database cleanup prior to the submission. Winter months are not good choices if the auditor must drive from one facility to the next after work is completed for the day. April, May, and June are not always good choices because of the large national meetings, including NCRA, NAACCR, and the NPCR directors meeting. Having quality control staff on travel status during preparation of Request For Proposals (RFP) responses or budgets is probably not a good idea either. If the state is relatively small, it may be possible to spread out the audits, for example, doing one per week over a period of weeks or months so as not to disrupt central registry activities too much. On the other hand, if the audit planners and field staff can find one or two weeks in which to complete the audit despite a heavy travel schedule during that period, that may be a better way to get it done. Some courtesies must be given to the facilities themselves, avoiding Joint Commission and Commission on Cancer surveys and the period right before those surveys. Facility staff vacations, maternity leave, and other factors like computer conversions or installations must be considered as well.

Conducting an audit takes tremendous planning and coordination because there are so many people involved. The best way to keep people informed is to develop a protocol and then follow it! We will discuss the contents of the protocol and the sampling plan in a moment. Once the facilities have been selected, it is important to give them as much advance notice as possible. Their arrangements for the on-site audit are almost as time-consuming as the activities of the central registry staff. For example, will the central registry expect that electronic medical records will be printed out, or will the central registry auditor expect to use the hospital's EMR system?

Freezing the database means that the contents of the facility's database as of a specific day are copied into a file and submitted to the central registry. This file becomes the reference database for casefinding or for case selection. Facilities selected for audit can control one more variable for casefinding by freezing their database as of one specific day. Once the central registry has the database, the cases for a reabstracting audit can be selected and the facility can be notified to begin gathering the source documents for those cases. It is a good idea to oversample selected cases so that the registry has some leeway in locating incomplete or missing medical records.

Finally, the field staff can begin to make travel plans. If the audit is to be conducted over a one- or two-week period, the dates the auditor will be at a specific hospital must be confirmed. Driving directions and hotel arrangements can also be worked out. And just as a reminder, the auditor needs to pack any necessary reference materials (ICD-O, casefinding lists, data collection manuals) and learn any data backup or transmission procedures established by the central registry's IT department.

# Audit Protocol

## ◆ Contents

- Introduction
- Purpose
- Description of study
  - ◆ Sample size
  - ◆ Study population
- Audit process
  - ◆ Discrepancy resolution procedures
- Analysis plan
- Feedback plan



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The audit protocol is perhaps the most important document in the audit process, especially if more than one field staff person is doing audits. The protocol assures consistency among participants at the central office level and keeps the audited facilities informed of the process. A thorough audit protocol will contain several sections.

• **Introduction** provides authority to conduct audit and rationale for conducting audit.

• **Purpose** states the reason for the audit (casefinding, quality assessment of data, targeted subject matter). An example is to audit the sites with the highest likelihood of missed cases. Indicate the expected intended outcome of the audit (tabulations, lists, database cleanup—see analysis plan below).

• **Description of study** identifies the type of study (casefinding, reabstracting/recoding, reliability, other). This will give the facility an understanding of what is being looked for. Describe the target population (all cases diagnosed in the first half of the diagnosis year, major cancer sites, breast cancer case with positive nodes with no record of adjuvant therapy). Describe the sample size (all cases, every fifth case from a specific start date, first 30 sequential diagnoses). The study population is also a consideration. It is not efficient to audit files or cases that are too old. A casefinding audit should be done on the most recent complete year. A reabstracting audit should be done on relatively recent cases (within the past 24 months, newer is better) so that the source documents are still available and have not been microfilmed.

• **Audit process** describes how the audit will be conducted (on-site, via Internet, mail-in documents) and the steps involved, including how any discrepancies will be resolved after the audit is completed.

• **Analysis plan** describes what type of calculations will be part of the final report. If possible, provide templates of the analysis tables designed by the statistician member of the audit team. This too will give the audited facilities an idea of what the audit is looking for.

• **Feedback plan** provides in the protocol a list or description of the final documents from the audit, for example a list of the “deliverables” from the central registry. These would include an indication of whether the audited facilities will receive a final report or just results for that facility, a summary report or a detailed list of findings, and so forth.

It is a very good idea to allow many people to review the audit protocol before it is sent to the facilities being audited. All members of the central registry audit teams should read the protocol to check that, if followed, the protocol will give the desired result. In addition, it is a good idea to have one or more facilities (who may or may not be on the to-be-audited list) review the document, because there may be issues with access to records in remote storage or on microfiche, or scheduling problems that the central registry may not be aware of.

# Sampling

## ◆ Sample methodology

- Random sample
- Stratified sample
- Probabilities proportional to size (PPS)

## ◆ Stratification versus no stratification

## ◆ Sample selection

- Cost (travel, living expenses)
- Travel between selected facilities

## ◆ Volume

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Concurrent with development of the protocol, the statisticians on the audit team should begin determining the sample selection. This is a science in itself and should not be the responsibility of the Certified Tumor Registrars (CTRs) on the team.

Samples are just that—samples. A different sample from the target population may yield a different result, so the sampling method must be defined carefully. The larger the sample, the lower the probability that the finding will have occurred simply by chance. But a large sample size must be weighed against the amount of time, effort, and fiscal resources required to obtain the large number of cases desired.

Sampling methodologies can be very simple (random sampling) or considerably more complex (stratified, multistage, or probabilities proportional to size). In a random sample, any facility has an equal chance to be selected, regardless of facility size or location. In a stratified sample, the pool of facilities is sorted into groups either by facility size (large, medium, small) or geographic location. Then a random sample is selected from each group. In a state with a large number of facilities, multistage sampling may be appropriate. With this method, first the facilities are sorted into groups, such as geographic locations. A sample number of groups is determined, and then the facilities within the selected groups are sampled randomly.

A different concept called probabilities proportional to size (PPS) is used in some states and federal audits. The basic concept of PPS sampling is that the probability of selecting a hospital is proportional to its volume of cases. For example, a hospital with 1,000 cases has twice the probability of being selected as a hospital with 500 cases. The consequence, of course, is that larger hospitals tend to be audited more frequently than smaller hospitals, but that is where more of the cases are coming from.

Among the important physical factors to consider when selecting the facilities to be audited are the timing of the audit (previously discussed) and the distance between facilities. Take as an example a reabstracting audit for which the auditor will be “on the road” for two back-to-back, five-day periods (10 auditing days in two weeks). In larger states, consideration must be given to selecting facilities that are a reasonable driving distance apart, since the auditor will have to travel to the next location after one facility’s audit has been completed for the day. In addition, decisions must be made regarding the use of public transportation versus state-owned or privately owned vehicles. In smaller states, it may be possible to have a single base of operations for the period, with the auditor traveling from a central location each morning. Mileage and/or fuel charges, hotel expenses, meals, and smaller items such as tolls are all part of the budget planning process and also have an affect on the selection of facilities.

One final consideration is volume, or “bang for the buck.” Small hospitals with fewer than 50 or 100 new cases per year may not be cost-effective to audit. Many times, there is a lower limit set for caseload, and facilities with smaller caseloads than the set limit are excluded from the sample pool. These facilities may, however, be involved in targeted audits if a problem is perceived in quality or casefinding.

## Audit Notification Letter Checklist

- ◆ Date of audit and estimated time it will take
- ◆ Purpose of the audit
- ◆ Authority to audit (state law) and HIPAA statement
- ◆ List of people performing the audit at the facility
- ◆ Work space requirements and physical accommodations
- ◆ List of sources to be reviewed
- ◆ Post-audit meeting with auditor can be expected
- ◆ Will contact to verify receipt of letter
- ◆ Timeframe of the audit
- ◆ Instructions for data extraction, if necessary
- ◆ List of health records to retrieve (reabstracting)
- ◆ Access to electronic databases, if necessary

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When the protocol has been finalized and the facilities have been selected, the facilities in the audit should be notified as early as possible. This should be done both by e-mail (to more than one person at the facility) and by formal letter. This list of all of the items of information should be included in the notification letter, and the protocol should be included as part of the notification package. Almost as important as the date of visit is the work space requirements and physical accommodations needed for the auditor(s). Too many times an auditor has had to balance the audit laptop on his or her knees because there was not any desk space available due to inadequate advance preparations.

It may be convenient for the recipient to design the notification letter as a check-off list with due dates for data extraction, reminders for notification of other departments (pathology, radiation therapy, and so forth), and responses to other actions indicated in bold. It is also important for the facility to know to whom they should send the response acknowledging receipt of the notification.

On the facility's end, any departments involved in the audit should be notified as early as possible, again a few days in advance of the visit to retrieve any records, and once more the day before the audit. Any questions about the audit process should be directed to the central registry audit team.

One particular issue must be considered well in advance: electronic medical records. If the central registry expects the records to be printed, that will take extra time, and the clerk in charge of the print job may not get all pertinent information if the entire chart(s) are not printed. Or will the auditor expect access to the electronic record while at the facility? That may take special permission from the facility and/or an assignment of a special or limited access password.

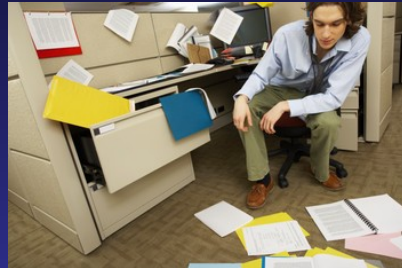
## Conducting the Audit On-site

### ◆ Considerations

- Time available
- Space available
- Access to source documents

### ◆ Wrap-up meeting

### ◆ Reconciliation on-site



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The central registry should stay in touch with the facilities between the notification letter and the actual day of audit, particularly if the facility has missed any deadlines for submitting disease indices or requested databases. The facility should also be able to provide information and advice about where to stay, where to eat, and directions not only to the facility, but also within the facility to the department where the primary point of contact works.

On the day of the audit, the auditor should present him/herself at the office of the point of contact on time and ready to begin work. As a courtesy, the point of contact should accompany the auditor to any of the departments where work is to be done and introduce the auditor to the staff there.

It goes without saying that the auditor has to be flexible on site. If the working-space arrangements are not satisfactory, a request can be made for a different location, but sometimes the space is just not available to be comfortable and efficient at the same time. If the number of records to be reviewed exceeds the time allotted, the auditor may have to stay into the evening to finish things up, or resort to alternative plans (scheduling another audit day or using a smaller sample of cases). At the end of the day, all work should be backed up before leaving the facility.

The auditor should arrange to have some sort of wrap-up meeting at the end of the day to thank the facility for their cooperation and provide some preliminary findings, if possible.

If time and software allow, the reconciliation process can begin on site. For a casefinding audit, the auditor should print a list of “potentially missing” cases so that the facility staff can begin the process of locating further documentation about those cases, such as reviewing a list of unabstracted cases for reasons that the case may not be in the database. For a reabstracting audit, the auditor and the original abstractor can discuss any discrepancies in coding while the source documents are available. Although any resolutions made at this time will not be final, beginning the reconciliation process while everything is still fresh in mind is one way to make the process go more efficiently.

# Analyzing the Data

- ◆ **Predetermined error rates**
- ◆ **Predetermined target thresholds**
- ◆ **Benchmarks**
  - **Where to get benchmarks**
- ◆ **Counting differences**
  - **Major/minor**
  - **Unknown-to-known**
  - **Contextual errors**



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The reconciliation process may take weeks if there are a lot of discrepancies. It is best to state a specific deadline for completion of the reconciliation in the notification letter as well as in the wrap-up meeting. After that deadline, any discrepancies will be counted as true errors.

When the reconciliation is complete, the central registry audit team can begin the analysis of findings, first by individual facility, and then in aggregate. The design of the audit will affect how the data are analyzed. For example, the audit team may have made a decision to compare all facilities against a standard, such as a threshold for completeness or accuracy. This might be considered a “pass-fail” type of standard—if the facility exceeds the threshold, it passes, regardless of how “perfect” it is. If the threshold is not met, the facility fails, regardless of how many errors were made. Another option might be considered a grading system with ranges for error rates on a scale of one to five stars, A-B-C-D-F, or poor-satisfactory-excellent. In this option, the ranges would be predetermined as part of the study design. Either way, the central registry must decide what the acceptable quality level should be in advance of the audit itself.

Benchmarks vary according to the type of audit. For casefinding, the benchmark is usually the established standard for case completeness set by the federal agency. The SEER standard for case completeness is 98% completeness at the time of the first data submission, which is 22 months after the end of the diagnosis year. Thus in an audited facility that reported 1,200 new cases for a year, the missed-case rate should be no more than 2% or 24 cases. The NPCR case completeness standard is based on the cutoff date for the audit. If the cutoff data is at 12 months, the individual facility database must be 90% complete. For that same example hospital, the missed-case rate can be no more than 10% or 120 missed cases. For a cutoff at 24 months, the missed case rate can be no more than 5% or 60 missed cases. Keep in mind that the standard for facilities may be higher than the overall standard for the central registry, because that also includes cases from pathology labs, nursing homes, and death certificate only cases.

In addition to federal agency standards, benchmarks can be obtained from published reports developed by other central registries and the Commission on Cancer’s National Cancer Data Base, as well as by reviewing journal articles and documents issued by NAACCR.

For a reabstracting study, there should be an overall error rate. In addition, the central registry may decide to subcategorize differences (which after reconciliation can be described as errors) into major/minor, and unknown-to-known. In addition, there may be contextual errors; for example, if the primary site is incorrect, all of the staging and treatment codes will be incorrect. A decision will have to be made whether that will count as a single error or the total number of incorrect data fields.

# Major/Minor Differences

## ◆ Major

- Affects incidence counts
- Affects research
- Examples: diagnosis year, primary site, sex

## ◆ Minor

- Does not affect incidence counts
- Examples: quadrant of breast, type of resection

## ◆ Unknown-to-known

- Valid data found but initially coded as unknown

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As noted elsewhere in this module, the definition of an error is relative to how the data will be used. Demographic information, particularly county/state of residence, age, sex, and race are critical measures for incidence reporting and the calculation of incidence rates, in addition to primary site and tumor behavior. If these data fields can be visualized an incidence table by primary site, any shift from one cell to another or into/out of the table itself is an important error. If the incidence table is only invasive tumors, incorrect designation of the behavior is an error. Shifting a case from lung to prostate because the case was incorrectly abstracted as a lung primary is a major difference.

Other differences may be considered major in the context of research. If the research involves differences in treatment by stage, any shift of stage or type of treatment for a case would be considered a major difference. If the central registry uses major and minor differences as part of its analysis, it should define clearly the context in which they are included.

In most circumstances, a minor difference does not affect incidence counts. Even in research, the subcategory site codes of most primaries are analyzed together, such as the different lobes of the lung or the areas of the bladder. It may not matter whether a surgical procedure was an excisional biopsy or complete removal of the organ.

A difference in Collaborative Staging Extension field codes could be major or minor, depending on the derived stage that results from the codes. For example, in lung, code 10 and code 30 both map to summary stage localized, so that would probably be a minor difference. But there would be a major difference between code 10 (localized) and code 45 (regional by direct extension) in a research study based on stage at diagnosis.

One other audit difference is worth noting: unknown-to-known. This occurs when the original abstractor codes a data field as unknown and the auditor finds enough information to code a specific value. Unknown-to-known differences are signals that the abstractor needs additional training in how to interpret information in the medical record.

# Reconciliation

- ◆ Unmatched cases verified
  - Diagnosis Year
  - Residence at diagnosis
- ◆ Data Discrepancies
  - Review Central database
  - Correct errors
- ◆ Summary/Recommendations
  - Training

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Reconciliation is the process of checking the database for cases flagged as **unmatched** or “potentially” missed or with data discrepancies. Reconciliation is a review process for both unmatched cases and data discrepancies. In the review of the CCR files, this may be due to the sample that you were comparing against—for example, looking at 2006 diagnosis year, and the case is in the CCR database for an earlier year—and the contact you were reviewing was a subsequent admission, or recurrence. Another reason for what appeared as a missed case, is one that is truly an out of state resident.

In the reabstracting portion of an audit, there are often data discrepancies (or differences) found. In the reconciliation phase, the CCR should review what other source documentation may have been available to explain the differences that were noted; for example, there is a difference in the date of diagnosis; the facility may have made a phone call to the neighboring hospital and obtained this information without documentation in the text fields to substantiate the difference. Corrections should then be made to the appropriate database (CCR or hospital).

At the end of the audit of the facility there should be a written summary of the findings and recommendations for corrective actions. Sometimes this is just a reminder of coding rules and resources, and other times, it will lead to further training.

## Feedback After Audit

- ◆ Report to individual facilities
- ◆ Overall audit report
  - Distribution of final report
- ◆ Action plan
  - Revision of documentation
  - Training
    - ◆ Group
    - ◆ One-on-one

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The last step in an audit is feeding the results back to the audited facilities, and creating an aggregate report. This is more than just common courtesy for those who were involved in the audit. This is closing the loop on data quality assurance. Unless the facility and the central registry are notified of the findings, they will not be able to take the appropriate actions to correct the errors and develop strategies for education or process improvement that hopefully result in a lower error rate during the next audit. And eventually, there WILL be another audit to monitor whether the corrections were effective.

For a casefinding audit, the report to an individual facility should include, at a minimum, the total number of cases reviewed and “found” already in the database, as well as the total number of cases that were not found in the database. It would be helpful to summarize the “missing” cases by category, such as nonresident but reportable, recurrence, not a reportable diagnosis, and truly missed. Breakouts by source document would also be helpful, so that an excess missed rate in one or more departments can be used as a tool for improving casefinding in those areas. Reports to the individual facilities can be in boilerplate format, inserting facility-specific data in a generic report.

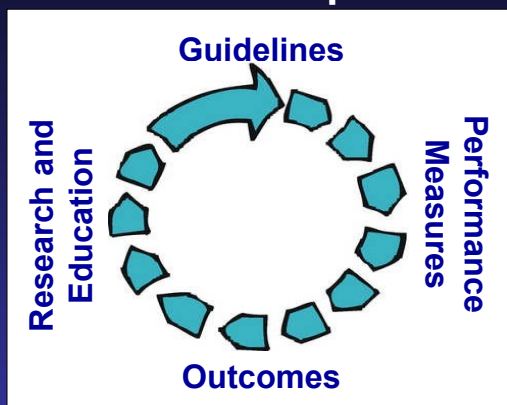
The overall audit report will be combined numbers from all the audited facilities. The statisticians on the audit team will have to determine whether the results should be weighted. For example, does a missed case from a small hospital (1 in 100) have the same importance as a missed case in a large facility (1 in 1,200)? Similarly, breakouts by source document will help identify areas where additional casefinding training for all facilities may be needed.

Another question to be addressed is the distribution of the final report. Should it be published on the central registry’s Web site? Who besides the quality assurance team should see it? Certainly researchers using the data should be informed of any findings of concern, such as patterns of missing data or the accuracy of staging and treatment codes. Beyond internal dissemination of the report at the central registry, decisions should be made about submitting the report to the legislature, central registry advisory board, or others with vested interests in the quality of registry data.

Finally, the overall report needs an action plan. The action plan is based on interpretation of the analysis and the overall experiences of the auditors. For a reabstracting audit, did the final analysis indicate that only certain fields (or groups of fields like the staging section) were problem areas? If so, the action plan should describe training efforts, either for all data collectors in the state or for individual data collectors. For a casefinding audit, was one source of documents particularly problematic? If so, the action plan might describe efforts to reeducate that department by sending copies of the state laws and other documents mandating reporting. Did the audit reveal that there were areas in the central registry’s documentation that were not clear? If so, the action plan should describe the areas of the coding manual or the reportable list and reporting requirements that should be clarified. Did the audit indicate that the protocol was not clear enough to the participants? If so, revise the protocol now while it is still fresh in mind, so that the improvements will not be forgotten the next time a similar audit is done in the future.

## Determinates of Quality

- ◆ Scientific Method
- ◆ Plan-Do-Check-Act
- ◆ Plan-Act-Evaluate-Improve



Adapted from Dryden M and Brogan K, Quality Control. Chapter 20 in *Central Cancer Registries: Design, Management and Use*, 2nd edition, 2007



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At the beginning of this session, we talked about the scientific method: observation, hypothesis, prediction, testing and reporting. The Deming quality cycle updated that to Plan, Do, Check, Act and the concept of closing the loop. Then we moved to different terms to describe parts of the cycle: Plan, Act, Evaluate, Improve. Now let us take one more look at the cycle as it relates to the total effort of data quality assurance.

The quality assurance cycle begins with guidelines. Performance measures evaluate those guidelines and produce outcomes. The outcomes generate research to understand why that outcome happened and education or revised guidelines to improve the desired outcome. In fact, EVERYTHING feeds back into the loop to make improvements. Then the cycle starts again to measure the effect of the new guidelines.

# Closing the Loop

## ◆ Techniques

- Follow-back
- Feedback
- Discussion
- Training and retraining
- Correction/updating of records
- Override flags
- Re-auditing and reviewing

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- Various techniques can be used to close the loop on data quality and keep the quality improvement cycle evolving.
- The findings of individual audits (discrepancies, errors, inconsistencies) should be followed back to the source documents and original abstractors for verification.
- Results of audits should be fed back to the audit participants. This step is absolutely crucial to maintaining a good working relationship with the people who provide the data to the central registry.
- Discussions of audit findings can lead to further quality improvement projects.
- Results of audits can lead to development of training and retraining efforts directed at improving the quality of future data.
- It goes without saying that any errors identified as part of an audit must be corrected and the central registry database must be updated.
- Errors or discrepancies identified as a result of tight edit checks should be reviewed and override flags can be added to the case record in the central registry.
- Ultimately, after interventions such as training, clarification of guidelines, improvement of coding instructions, and other efforts to ameliorate the processes of casefinding and data quality, audit topics should be revisited and reviewed. A re-audit of data submitted after the interventions will indicate whether the efforts to improve the data have been successful.
- Quality assurance is a never-ending process.

## Resources

1. Dryden M and Brogan K. Quality Control. Chapter 20 in Menck H, et al. *Central Cancer Registries: Design, Management and Use, second edition*. Kendall Hunt Publishing Co., 2007.
2. Hilsenbeck SG, et al. *Quality Control for Cancer Registries*. National Cancer Institute, U.S. Department of Health and Human Services, 1985.
3. Hilsenbeck SG. Quality Control. Chapter 7 in: Menck H, et al. *Central Cancer Registries: Design, Management and Use*. Harwood Academic Publishers, 1994.
4. Ross F. Quality Control of Cancer Registry Data. Chapter 21 in Menck H, et al. *Cancer Registry Management: Principles and Practice, second edition*. Kendall Hunt Publishing Co., 2004.



## Resources

1. NAACCR *Standards for Cancer Registries Volume III: Standards for Completeness, Quality, Analysis, and Management of Data*, October 2004.
2. NPCR Educational Materials for Cancer Registrars
  - Volume 3: Data Editing and EDITS: Procedures for Central Registries
  - Volume 4: Coding and Visual Editing: Procedures for Central Registries
  - Volume 6: Audits: Casefinding and Reabstracting: Procedures for Central Registries
7. Unpublished materials provided by National Program of Cancer Registries



**All done**

The findings and conclusions in this presentation are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

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