NPCR Education and Training Series (NETS)

Module 3: Quality Control for Central Registries

Part 1-Section B: Principles of Data Quality

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Principles of Data Quality

Quality of Registry Data

Several authors … have noted that insufficient attention has been given to the quality of the information which registries collect.

—Goldberg, Gelfand and Levy
***Epidemiologic Reviews,* 1980**

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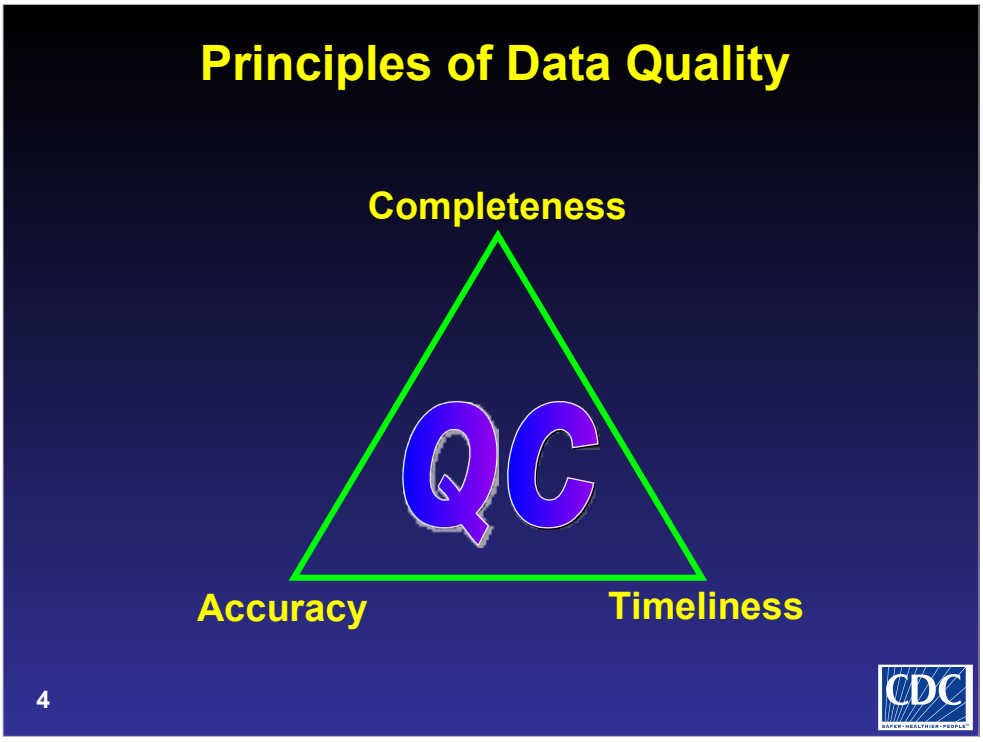
More than 25 years ago, an article was published in the journal *Epidemiologic Reviews* discussing the concepts of disease registries and how to evaluate them. The article defined the function, types, and uses of a disease registry, as well as problems with disease registries. The problems identified were expense of operation, staffing and organization, and quality of data. Even though cancer registries had been around for half a century or more, there had been very little emphasis on the quality of the data on which statistics were based.

The authors went on to recommend various methods to assess the quality of registry data, listing two fundamental concerns: completeness and validity or accuracy. This article is cited on the very first page of the seminal publication *Quality Control for Cancer Registries*, published in 1985 by the National Cancer Institute. The body of *Quality Control for Cancer Registrie*s is less than 25 pages long, but established the foundations for quality control practices in both population-based and facility based registries. The remainder of the 200-page document consists of appendices—articles and examples of various quality control methods for cancer registries—most of which are still appropriate two decades later.

[Article reference: Goldberg, Gelfand and Levy: “Registry Evaluation Methods” 1980, reproduced in *Quality Control for Cancer Registries* (appendix 1)]

[Quality Control for Cancer Registries is no longer in print, but is available as a PDF file from the SEER Program Web site, www.seer.cancer.gov/tools/codingmanuals/historical.html.]



In *Quality Control for Cancer Registries*, Susan Hilsenbeck and her coauthors agree that completeness and accuracy are basic principles of data quality, and they add one more factor: timeliness. The authors go on to mention several management principles without directly citing Deming's 14 points of management. These include creating a culture of quality, building quality in from the beginning, training of data collection personnel, establishing standards, getting everyone involved in error detection, and closing the loop through continuous feedback and analysis.

Early Detection

A maxim in the study of cancer is that early detection *and* early treatment are our best chance for cure. Similarly in tumor registries, a well-thought-out, closed-loop, quality control program, which detects and treats the problem early, is a way for the registry system to maintain a high level of quality.

—Hilsenbeck et al., *Quality Control for Cancer Registries*, 1985

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Hilsenbeck et al. create an analogy between cancer control efforts in public health and quality control efforts in cancer registries. Both attempt to detect and treat problems early.

This part of the session will discuss the three important principles of data quality —completeness, accuracy, and timeliness—including definitions, data standards, and methods to validate.

Completeness

- Definition
  - Assurance that all items that should be included are present and there are no items present that should not be included
- Aspects
  - Case completeness
  - Data completeness

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There really wasn't a good formal definition of completeness in any of the registry references reviewed. Basically, the concept of completeness entails ensuring that everything that should be present is there and that there are no 'extras' included that are outside the scope of the database.

There are two aspects of completeness—

•**Case completeness** for a population-based registry means that all reportable cases within the geographic area of the registry have been identified and included in the registry. The corollary is that there are no extraneous cases in the registry. For example, registry completeness means that all possible casefinding has been performed, and cases treated in surrounding registries have been included. As part of the processing of submitted cases, non-reportable cases have been removed from the database, such as non-CNS borderline tumors. Cases of nonresidents treated in the geographic area must be flagged for exclusion from final incidence reporting, although those cases will be included in the data exchange process. Once the cases are in the database, they must be checked for duplicate records and any duplicate records must be consolidated.

•**Data completeness** means that all of the required fields on an individual abstract are filled in with as much valid information as possible. Valid information means codes that carry specific information, avoiding blanks, default values, and unknown codes. Granted, there will be occasions when the information for a field is truly unknown, but frequent coding of unknowns can be construed as less than complete abstracting on the part of the data collector.

We will discuss methods to evaluate both case completeness and data completeness in a moment.

Importance of Completeness

- Missing data can skew analysis
  - Neither overcount nor undercount
  - Errors of omission
    - Systematic
    - Random

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The importance of both case and data completeness cannot be overstressed. Case completeness for incidence reporting is a function of data completeness. Missing information on a cancer registry abstract can skew the results of any data analysis. The point of monitoring case completeness is to neither overcount nor undercount cases. Overcounting can occur when multiple records on the same patient are inadvertently left in the database, resulting in more cancers of a particular site or type being counted. The results over-emphasize that particular cancer and dilute the accuracy of estimates of other cancers. Good quality control measures to avoid overcounting include the NAACCR algorithm for duplicate testing and systemic data reviews for incompletely consolidated case reports from multiple sources.

Overcounting can also occur when cases are included in the registry that shouldn't be there, for example, if the data collector includes non-reportable cases in the database.

Errors of omission are just as serious. These can take the forms of systematic omissions and sporadic (random) omissions. Systematic omissions can result from failure to identify additional sources of cases, such as physician offices where cancers may be diagnosed and treated but not reported. Systematic omissions can also result from late reporting—cases that don't make it into the central registry database until after the deadline for analysis has passed. Cancer incidence patterns have been modeled by the SEER Program of the National Cancer Institute and show that there is systematic under-reporting of prostate and melanoma cases for several years after all the cases for a given year are supposed to be complete. These two primary sites tend to be diagnosed and initially treated in physician offices that may not be reporting to the central registry. The cases eventually make it into the database when the patient presents at a reporting facility for treatment of recurrence or disease progression, or when the patient's death is reported to the central registry. The NCI delay adjustment model predicts what cancer incidence rates should be for a given year, based on case accrual trends from previous years.

Random omissions can be as simple as a facility registrar accidentally missing a case in the disease index or deciding that the new diagnosis is actually recurrence of a previous cancer.

Rules for Completeness

- NPCR Standards
  - at 12 months 90% complete
  - at 24 months 95% complete
- SEER Requirements
  - at 22 months 98% complete
- NAACCR Criteria – 23 months
  - Gold ≥ 95%
  - Silver ≥ 90%

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Rules for case completeness vary by agency.

NPCR has standards of completeness requirements of 90% of the cases for a diagnosis year at 12 months after the end of the year and 95% completeness by two years from the end of the diagnosis year.

SEER has one data submission at 22 months after the end of the diagnosis year, and case completeness is expected to be 98% or higher.

For NAACCR silver certification, incidence data for a given diagnosis year must be 90% or greater complete based on a NAACCR-prepared worksheet that calculates state-estimated incidence-to-mortality ratios. For gold certification, the estimated completeness based on the worksheet is 95% or higher.

Case Completeness Validation Methods

- "NAACCR method"
  - Incidence/mortality ratios
- Historical case review
  - Observed versus expected
- Death certificate only
- Casefinding audits
- Independent case ascertainment
  - Capture-recapture

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There are a number of methods available to evaluate case completeness in a central registry. As previously mentioned, NAACCR has developed a worksheet that calculates the expected number of new cases a registry would see. More on that in a moment.

Historical case review is often called an observed-to-expected ratio. This method uses the registry's previous reporting experience to determine an expected number of cases.

The death certificate only method monitors the percentage of cases identified only by death certificate.

These three case completeness validation methods are relatively inexpensive to conduct. However, they are limited in several respects because the calculations are based on some assumptions that historic data and historic ratios remain the same.

Most central registries validate central registry cancer database completeness by conducting casefinding audits. These audits are more expensive to conduct, but provide good estimates of completeness for the targeted facilities.

The most expensive and sophisticated type of case completeness validation is independent case ascertainment, which is often called the capture-recapture method. This method uses case estimates from an independent survey of cases or from independent sources. An example of an independent source might be insurance billing records that are not normally used for casefinding. This method requires careful design, sampling methods, and analysis.

SEER and NAACCR have set their own requirements/criteria for completeness.

"NAACCR Method" for Completeness

- Annual calculation for certification
- Worksheet provided by NAACCR
  - 5-year site- and sex-specific SEER incidence rates for whites
  - 5-year site- and sex-specific mortality rates for whites from NCHS
  - 5-year site- and sex-specific mortality rates for registry

$$(I \div M) \times M_{reg} = I_{reg}$$

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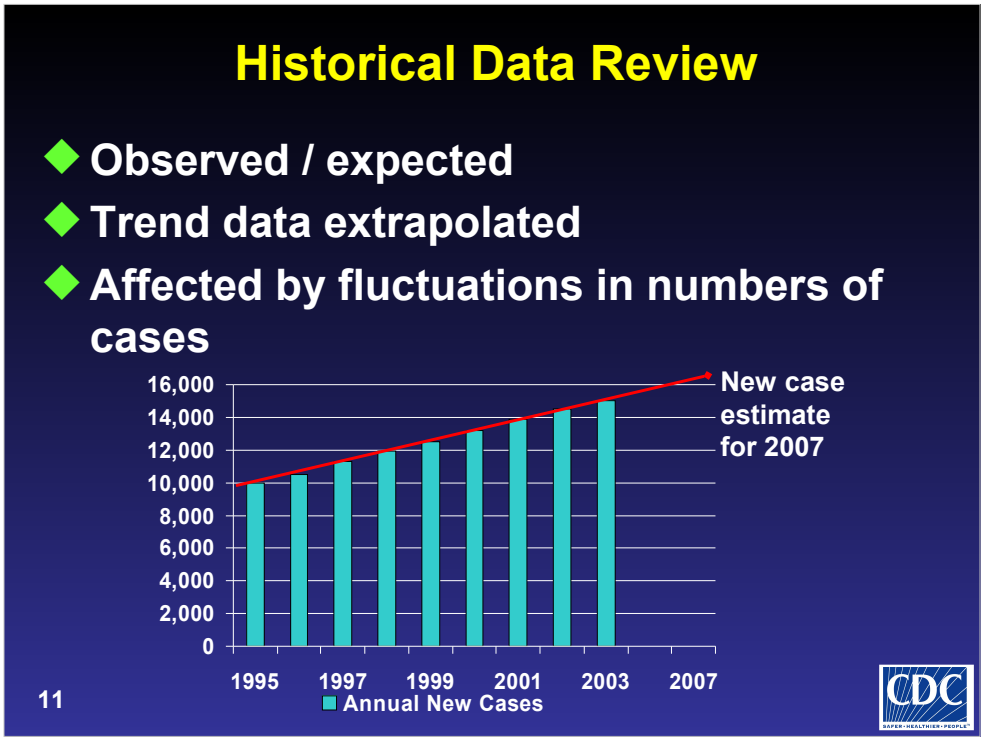
The NAACCR method for evaluating completeness is part of the annual process of submitting data. The NAACCR method uses rate ratios created using 5-year site- and sex-specific SEER incidence data divided by 5-year site- and sex-specific mortality data from the National Center for Health Statistics. The Incidence / Mortality ratio is multiplied by the registry's 5-year site- and sex-specific mortality rates. The product is the registry's expected incidence rate for that site and sex combination. All of the combinations are summed for an estimated total number of cases. The registry's actual or observed incidence rate is then compared to the calculated expected incidence.



Historical data review is a variation of the observed-to-expected numbers of cases. The previous case volumes of the registry are reviewed to determine an annual percent change, or the data are graphically trended. The slope of the trend line is extrapolated to the current year for an estimated number of new cases expected.

While simple and effective, this method can be affected by new developments in early diagnosis and by fluctuations in the total number of cases due to loss of population, military base closings, and even continued trends toward outpatient management of cancer cases.

Death Certificate Only

- Measure of case incompleteness
- Limitations
  - Definition of DCO
  - High mortality rate cancers
  - Accuracy of cause of death
- Standards/Criteria
  - NPCR ≤ 3% at 24 months
  - SEER ≤ 1.5% at 22 months
  - NAACCR Gold: ≤ 3% Silver: ≤ 5%

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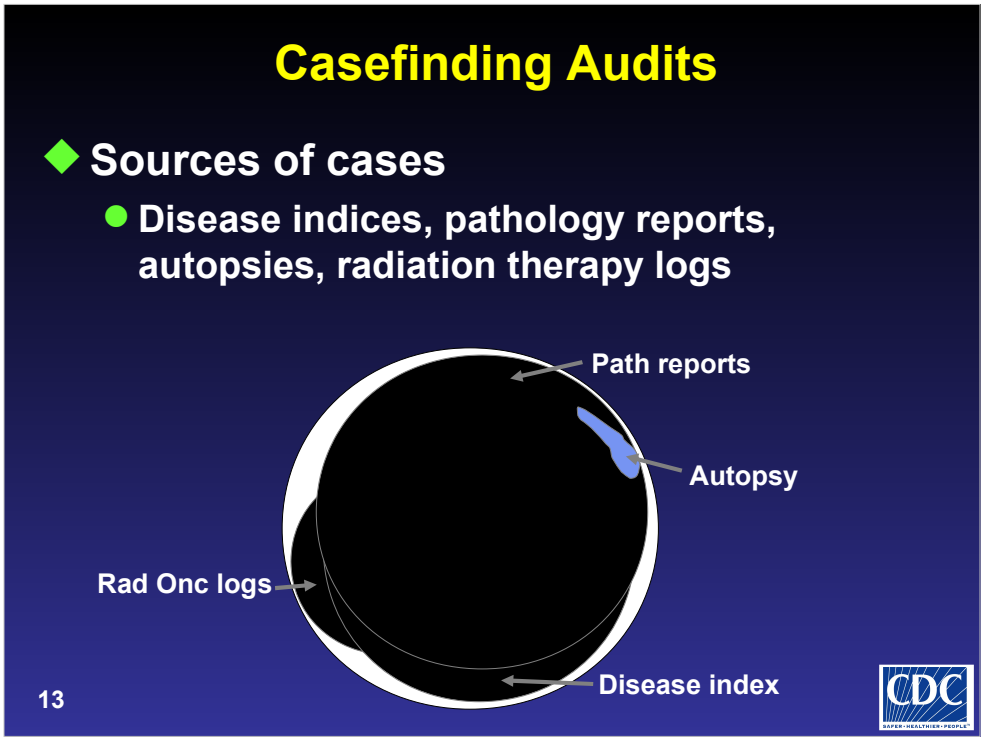
Another calculation, the percentage of death certificate only cases, is a surrogate for actual case completeness estimates. Death certificate only (DCO) cases are those where the only information about the cancer comes from a death certificate. If a case is identified only by death certificate, it means that somewhere along the natural history of the cancer the case was missed in other casefinding procedures. Therefore, this method should be thought of as a measure of registry incompleteness rather than completeness.

There are a number of limitations to using death certificate only rates as an indicator of case completeness. Among them, cancer deaths reported during a given year are most likely from diagnoses made in previous years, unless a particular cancer has a very high mortality rate in the first year, like carcinoma of the pancreas or glioblastoma multiforme of the brain. There is also a concern about the accuracy of coding the cause of death, which is not the responsibility of the registry but rather the responsibility of a medical practitioner and nosologists and the state office of vital statistics. A third issue that relates directly to central registries is the definition of a death certificate only case. During the death clearance process, cases identified on death certificates are followed back to other sources indicated on the death certificate. If further information is found, the DCO classification may be changed to a hospital case or physician only case, thereby reducing the number of death certificate only cases. However, the case had been missed by other sources and should reasonably be classified as a DCO. The definition of what comprises a death certificate only case is being discussed through the appropriate NAACCR committee.

Note that standards vary for the percentage of allowable death certificate only cases. SEER's are the most stringent; NAACCR's silver level certification is the most tolerant.



One of the principal methods of validating central registry cancer database completeness is conducting a casefinding audit. For targeted facilities, this involves reviewing the most likely sources of cases, such as pathology reports, autopsies, radiation therapy logs, and the disease indices in the health information department. Each of these sources will yield different types of cases potentially missed. The Venn diagram illustrates that casefinding sources may overlap for many cases, but there are still some patients who are seen in only one area of the hospital.

Casefinding audits, though time-consuming and relatively expensive to perform, are a practical way for a central registry to assess completeness from the same source documents originally reviewed by the data reporter.

Casefinding Audits

- Considerations
  - Size of facility
  - Available sources
  - Paper vs. electronic records
  - Complete audit vs. sampling
  - High-risk or high-volume cases

$$\frac{\text{\# Missed cases}}{\text{Total cases identified}} \times 100 = \text{Percentage missed}$$

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When a casefinding audit is developed, several factors must be considered. First of all, the size and location of the facility are factors. If the casefinding audit is performed on-site, time must be allowed for travel to the location. If the facility is small and has limited casefinding sources (for example, no radiation therapy department), multiple case sources can be assessed for the entire year in the course of a single day. On the other hand, if the facility is large, it might take several days to review all sources for an entire year. The amount of time it takes to review pathology reports, for example, may depend on whether the pathology reports are stored electronically or in hard copy, and whether hard copy documents are bound in volumes or loose in files. Even if the reports are stored electronically, speed of access to the documents is a factor. Also, if reports are stored electronically, it might be possible to access the files remotely and avoid the need to travel to the facility, or a copy of the file might be sent to the central registry to be worked on in the central office.

If it is not feasible to review all of the facility's sources, it would be better to sample the sources rather than not perform an audit. There are a variety of ways to sample cases. The central registry may opt for auditing only certain types of cases. High-volume cases are the ones most commonly seen—breast, colon, lung, prostate, and other frequent sites. An audit of these sites would yield data on the number of missed cases that were called recurrences and the number of cases that might have been missed simply because there were so many of that type of case to abstract. An audit of high-risk cases would search for less common sites, missed diagnoses, and other types of cases. Alternatively, the audit could look for all types of missed cases but sample a limited number of months during the year. For example, the auditor could review pathology reports from randomly sampled months, say February, June, August, and November, request radiation therapy records from four other months, and review the diagnosis index from yet other months. This type of sampling would indicate whether there were casefinding issues in a particular department. Regardless of the method of sampling, it is necessary to keep track of the number of cases that were identified as already being in the registry database to have a denominator for the proportion of missed cases.

When potentially missed cases are identified, there should be a follow-back process with the facility data collector to find out why the case was missed. Sometimes it is because the data collector thought that the case was a recurrence. Sometimes it is because the patient had a history of cancer and to the facility the case should not be abstracted. And sometimes, the case was simply missed. When all the potentially missed cases have been reconciled with the facility database, the missed case rate can be calculated by dividing the number of missed cases by the total number of cases identified and found in the registry. That calculation produces a decimal fraction which when multiplied by 100 produces a percent missed case rate.

There will be more about designing a casefinding audit later in this module.

Data Completeness

- Core data items
- Missing information
  - 9s Unknown vs. not applicable
  - Blank
  - Default
- Completeness is relative
  - Demographics
  - Staging
  - Treatment

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In addition to assuring that the central registry has gathered all the reportable cases in residents of its geographic area, the registry must assure that the data for the individual cases are usable. This means checking for missing data in each abstract.

As a baseline, the registry must have a defined list of data items that will be checked for completeness. The Commission on Cancer's *FORDS* manual has hundreds of data fields, many of which are not needed or used in central registries. By defining a core data set, the registry indicates what they are looking for on a cancer abstract. The comprehensiveness of that data set must be carefully considered.

Missing data can be represented in several ways. A well-structured data field will have some code representing *unknown*, *not documented in record*, or *cannot be assessed*. Often this is the default, meaning that if the abstractor hits the [ENTER] key, the value will be inserted by the computer software. In most software systems, use of [blank] is discouraged, as it cannot be distinguished from a skipped field. Even when the field is filled with 9s, it may not be possible to distinguish 9s-as-default from situations where the information is truly unknown. There is also a difference between 9s used for unknown values and 9s used to indicate that a particular field is not applicable. For this reason, more sophisticated code structures also include another code, usually represented as 8s, to indicate "not applicable" for that site.

Completeness of the cancer abstract is relative, meaning that missing data are important when it becomes a factor in data analysis. For example, demographic data are critical to incidence reporting, so every effort should be made to abstract sex, race, and residence data. If a researcher is trying to find case distribution patterns by race, specific coding of the race fields is very important. On the other hand, if staging doesn't depend on tumor size, then a code of 999 not stated in the tumor size field is not going to affect analysis of data. Treatment information for cases treated outside the facility is notoriously difficult to collect and is known to be incomplete, but when treatment patterns are analyzed, missing data on adjuvant systemic therapy can skew the results.

Data completeness should be the goal in any registry, because we never know how the data will be used and analyzed.

Monitoring Data Completeness

- Computer edit checks
- Visual editing
- Frequency of using unknown codes
- Reabstracting studies

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Data completeness can be monitored in several ways. The easiest is by reviewing computer edit checks. Basic computer edits can check whether a field has been left blank, but cannot distinguish meaningful valid codes from valid codes such as 9s that contain no useful data. More sophisticated edit checks can look for unknown values and monitor their frequency of use. We will be discussing edit checks as a quality control tool later in this module.

Visual editing—the process of reviewing coded data fields against supporting text fields—will also monitor the use of unknowns. Even fields coded as unknown should be backed up by supporting text. Central registry visual editors should look for patterns in missing data.

There will always be situations where some data field is unknown; therefore, a reasonable rate of unknown codes that is stable over time is to be expected. When that rate fluctuates, however, quality control staff should investigate the causes. An increase in unknown codes could imply incomplete coding on the part of the abstractor or a change in procedures at the facility where something is no longer mentioned in the record. A decrease in unknown codes could imply that the registrar may be making unsupported assumptions about the facts of the case. In either situation, the central registry should make an attempt to discover the reason for the change and provide some training if indicated.

Reabstracting and reliability studies will help differentiate between lack of thoroughness on the part of the abstractor and truly missing information. These too will be discussed later in this session.

Visual Review

- Percentage of cases to be visually reviewed
  - Tracking data accuracy rate
  - Clean edits with no consolidation
  - Proven data quality
- List of variables to review
  - State-specific
- Consistency among editors

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Time and resource constraints have moved most central registries away from 100% visual review. Tracking data accuracy for your facility registrars allows you to determine the abstractors with consistent data quality and also identifies training needs for those without good accuracy rates. After you identify quality abstractors, you can then safely move abstracts with no edit errors and no other admissions (consolidation) through to your permanent database. Another consideration might be to allow quality abstractors who meet a threshold to pass along to the permanent database. An example of this is California Cancer Registry. If an abstractor meets the goal of 99% accuracy on his or her data submissions, their data is not visually reviewed.

You must identify which variables will be reviewed and monitored. This list should include demographic information, primary site, histology, grade, behavior, stage, and treatment information that will be in your NPCR data submission. State central registries might wish to collect more than the NPCR required data set and can visually review those items as well. They should be included in the list so that the staff review the same items.

It is important for quality control staff to review cases consistently and uniformly. Central registries should provide quality control staff time to discuss coding issues regularly for uniformity. Exercises can be used to determine consistency or actual cases that are being reviewed might be discussed. Questions should be thoroughly researched and training issues can be identified through this process.

Accuracy

- Definition
  - Degree of conformity of a measure to a standard or true value; a true representation of the facts about something
- Other names
  - Reliability, consistency, validity, reproducibility, concordance
- Importance

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The next big category of data quality is accuracy.

Accuracy can be defined as how close a representation (in other words, a code or abstracted statement) is to the true value (the facts in the medical record). For example, if the pathology report says that the invasive tumor size is 1.2 cm, the coded value 012 in the CS Tumor Size field is considered accurate. A coded value of 999 (unknown; not stated) or 992 (stated as less than 2 cm) would not be accurate, because it is not the most concise code.

Accuracy has been variously referred to as reliability, consistency, validity, reproducibility, and concordance. Most of these terms refer to whether two or more people looking at the same piece of information in the medical record will arrive at the same code.

The importance of data accuracy cannot be overstated. Without assurance that the data are accurate, researchers will not use the data, and all the efforts of data collectors, quality control staff, and other registry professionals will be for nothing. The analogy of a cancer registry to an astronomical black hole will continue to be valid.

Once a coded data item has been separated from the source document, little can be done to verify the accuracy of the code, other than to compare to a text field on the abstract. Thus to verify the accuracy of abstracted information, the best way is to compare it to the source document.

Accuracy Standards/Criteria

	NPCR		NAACCR	
Unknown	Standard	*USCS* Criteria for Publication	Gold Certification/Publication	Silver Certification/Publication
Age	≤2%	≤3%	≤2%	≤3%
Sex	≤2%	≤3%	≤2%	≤3%
Race	≤3%	≤5%	≤3%	≤5%
County	≤2%	NA	≤2%	≤3%

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These current accuracy standards shown are critical to incidence reporting. For the demographic items listed, the NAACCR criteria for gold certification are the same as the NPCR standard. The current criteria for inclusion in *United States Cancer Statistics* are the same as NAACCR's silver criteria with the exception of county codes. The *USCS* and the silver criteria are slightly more lenient, but still quite stringent because of the importance of these fields to age-specific, sex-specific, and race calculations.

Note: SEER does not allow any missing demographic information in its public use file. Any cases with missing information are censored when received.

Monitoring Accuracy

- Computer edit checks
- Error detection programs
- Visual review
  - Consistency checks

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The accuracy of data fields can be monitored in many ways. Here again, computer edit checks are the inexpensive MINIMUM level of quality control. Edit checks should be performed at the facility before abstracts are submitted, but if they are not, edit checks must be run before a batch of submitted cases is added to the central registry database. Edit checks can look for blanks or missing data. Edit checks can also look for codes that are outside the acceptable range for a data field as well as consistency between fields, such as the primary site coded as cervix and sex coded as male. We will talk about edit checks again in another part of this module.

Comparing the codes to the source document is another type of consistency check. In this instance, either the original abstractor or an independent reviewer or auditor obtains the source documents and compares the coded abstract to the original reports. Ideally, the abstractor will visually review the case while the source documents are still readily available. A good method of developing concordance or reproducibility is to have another registrar review the source documents and code the case. This way, another pair of eyes may see something different in the source documents than what is represented in the codes. Any discrepancies can be discussed and resolved as part of the ongoing education process.

Monitoring Accuracy

- Audits
  - Reabstracting
    - Standardize interpretation
    - Estimate concurrence
    - Look for trends
  - Recoding
    - Compares text to codes
    - Verifies rules for assigning codes
  - Reliability/test case studies
    - Measure concordance
    - Target further education

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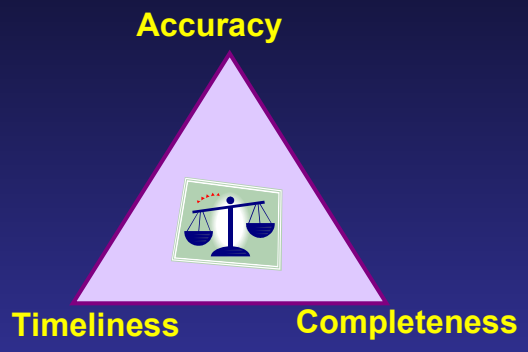
More formalized audits can be conducted in the same way. An outside auditor will request source documents to review against abstracts that have been submitted to the central registry. Those cases will be *reabstracted* blindly (with no knowledge of the previous codes) and then the auditor's codes will be compared to the original codes. Again, any discrepancies should be resolved before results are calculated. The intents of a reabstracting audit are to standardize interpretation and abstracting of the medical record among data collectors, to estimate concurrence rates between the original data collector and the auditor, and to look for trends or patterns in incorrect data that would lead to further training. For example, consistent disagreement between the data collector and the auditor about the coding of surgery fields may indicate that additional instructions or training are necessary in how those fields should be coded.

A *recoding* audit will compare the text documentation on the abstract with the coded values, verifying that rules and guidelines for assigning codes are understood and correctly applied by the abstractors. A recoding audit will demonstrate lack of documentation for some fields and perhaps incorrect interpretation of source information in other fields. If the latter is true, additional training may be warranted.

Reabstracting and recoding audits work with real abstracts from the central registry database. Reliability audits measure the concurrence or concordance when the participants in the study all abstract the same cases. Although reliability audits take time away from the registrar's normal work load, they are an immensely successful learning tool. The Collaborative Staging Reliability Study conducted in November 2005 had wide-ranging effects. First, it showed that registrars are willing to take the time to find out whether they are doing things the same way as other registrars. Second, it showed that there were some issues in Collaborative Staging documentation that have since been addressed in updates to the manual. Third, the reliability study demonstrated that there were several areas in the abstracting process for which further education was needed, for example in understanding the anatomy of the primary organ and the relationships of adjacent organs and structures. These educational issues have been addressed in a series of recorded presentations available for review on the Commission on Cancer/AJCC online education center.

Timeliness

- Definition
  - Making things happen on schedule
- A constant struggle in registries



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Timeliness is a critical aspect of registry operations. The data flow must keep moving. There is always work to be done, but at some point it is necessary to move to the next step. Making things happen on schedule is a vital part of keeping a registry functioning.

Timeliness is a quality assurance characteristic that treads the fine line between the need for current readily available information and the reality that it takes time to do a good job of abstracting and quality control. Submitting data too early may necessitate omission of important data on treatment occurring after the submission deadline. On the other hand, late data reduces the usefulness of registry reports.

As the graphic shows, there is constant tension among the three principal characteristics of good quality. Researchers want data as current as possible, but quality control staff need time to ensure that everything is complete and accurate. Data lose their value if they are too old. The hard part is trying to balance all three, but it can be done.

Rules for Timeliness

- NPCR
  - at 12 months 90% complete
  - at 24 months 95% complete
- SEER
  - at 22 months 98% complete
- Commission on Cancer
  - complete abstract within 6 months of diagnosis or first contact
- NAACCR
  - Gold ≥ 95%
  - Silver ≥ 90%

  } within 23 months

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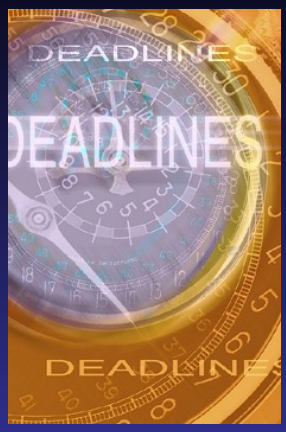
Timeliness standards go hand-in-hand with completion standards. There has to be a cut-off date for data submission. NPCR requires data submission at 12 months after the end of the diagnosis year and again 12 months after that, or 24 months after the end of the diagnosis year. The cut-off time for the publication of the *United States Cancer Statistics* is 25 months for NPCR and 22 months for SEER. SEER requires data submission 22 months after the end of the diagnosis year. The Commission on Cancer, not previously discussed, requires that cancer abstracts be completed within 6 months of diagnosis or the patient's first contact with the facility.

For NAACCR, the cut-off is the time of data submission for the publication *Cancer Incidence in North America*, 23 months after the end of the diagnosis year.

Monitoring Timeliness

- Deadlines
- Process monitoring
- Casefinding audits
- Tracking accruals



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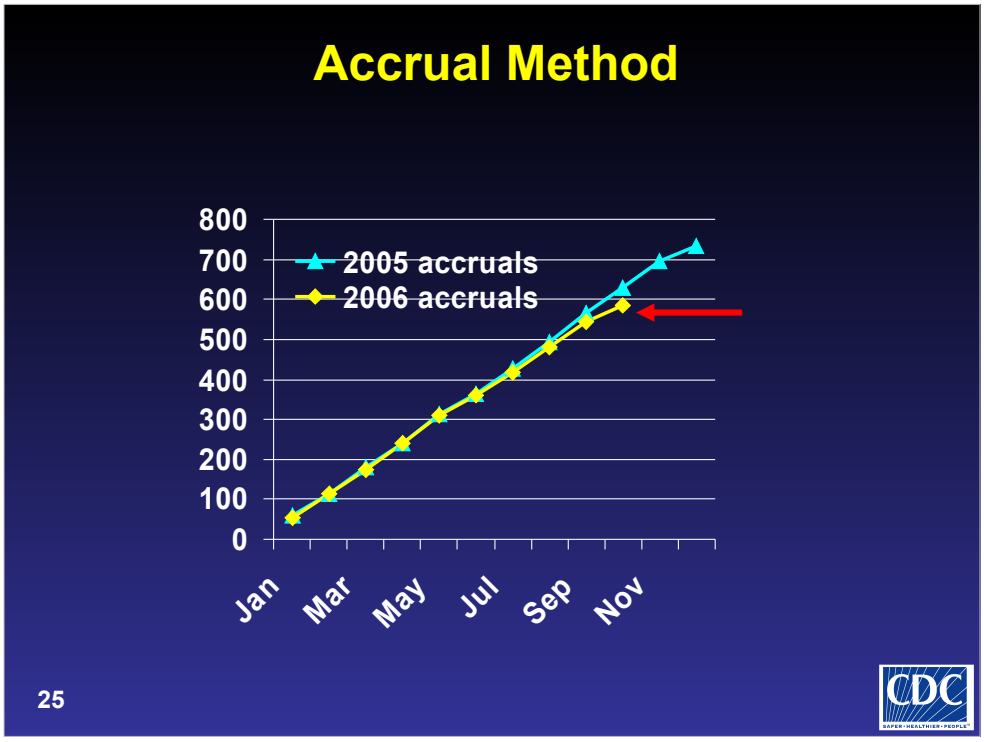
One of the first criteria for monitoring timeliness is having well-published deadlines for various processes. The standards for timeliness and data submission previously described are examples. Internally, the registry should monitor the amount of time a case spends in various central registry operations. For example, if the processing of data is continuous, the registry may have a standard saying that a case may spend no longer in visual review than five business days and no longer in case consolidation than five business days. Cases must be date-stamped at various points in the work flow to monitor internal deadlines.

Cancer registry abstracts have several dates stamped by the computer software, including Date Case Completed and Date Case Report Exported to the central registry. These dates can be compared to the date of admission or the date of diagnosis to see whether there is a delay in case reporting from the facility to the central registry. The software can flag cases that are outside the tolerance limits set by the central registry, such as four months or six months after diagnosis. In accounting, this is called monitoring of aging. The central registry can contact the facility if a significant number of cases are “older” than the desired thresholds. The same type of process monitoring can occur in a central registry where management reports can keep track of how many unprocessed abstracts are in a holding pattern in various areas of registry operations.

Part of the reason for these deadlines is to keep work flow at both the facility and the central registry moving along at a fairly even rate throughout the year. Variability in work flow can cause staffing issues and backlogs in other areas of registry operations.

In the central registry, casefinding audits can detect cases that have been submitted after the cut-off date when a case is identified that is not in the database provided to the auditor. If during reconciliation that case is found in the central registry database, it is an indication of a problem in timeliness.

Another method can be either manual or computer-generated. The accrual method is based on the data submission history of the facility.



An adequately staffed facility registry will abstract and submit cases to the central registry at a fairly even rate during a year, allowing for holidays, vacations, and other time not spent abstracting. The facility and the central registry will have a general idea of how many cases to expect during a given month by reviewing how many cases were submitted during the same month in the past one to three years. As cases are accrued, the cumulative number can be tracked or graphed and compared to what is actually coming in this year. If the numbers of submitted cases fall below a pre-determined threshold, the central registry should investigate possible causes for the slowdown. It could be anything from computer transmission problems, to an extended vacation or maternity leave, to a change in facility patient load, to an unfilled vacancy in the registry. The point is that the accrual method can identify an area of concern before it becomes a major problem in timeliness.

Constancy

- Definition
  - Reliability over time
- Difficult to assess
- Reasons for lack of constancy
  - Changes in coding rules
  - Learning curve
  - Improved education of abstractor
- Methods
  - Reliability study

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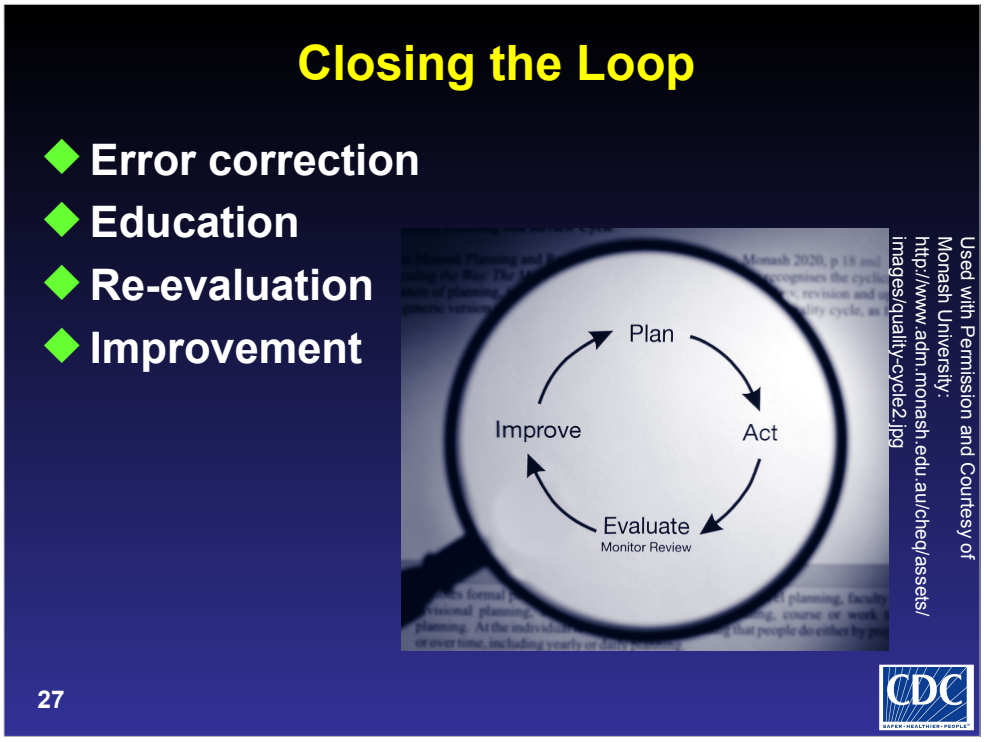
The authors of the quality control chapter in *Central Cancer Registries: Design, Management and Use* added a fourth characteristic of good quality data to timeliness, completeness, and accuracy. Constancy is the reliability of coding over time. When registries were young, this was not as much of an issue as it is now. But as standard references change, and as more education is available to data collectors, things will change.

Constancy is difficult to assess and monitor because it is subject to human bias. As noted, rules can change over time. A data collector faced with a new set of rules, such as implementation of Collaborative Staging (CS) or the multiple primary and histology coding rules, has a learning curve to overcome. The same case abstracted after a year of experience with a new coding structure will not look the same as when it was originally abstracted. Furthermore, continuing education improves a registrar's understanding and that will improve coding. (In this case, the lack of constancy is a good thing.)

Constancy can be monitored with reliability studies both among central registry staff and data collectors. In particular, reliability studies are effective when new concepts are introduced. The previously mentioned Collaborative Staging Reliability Study is a case in point, because it showed that there were areas of the CS manual rules and guidelines that were open to interpretation. Educational opportunities have been developed in response to the results of that study, and if the "Loop" were closed in the near future with a follow-up CS reliability study, it is to be hoped that participants will do better because of the improved documentation and targeted education.



At the beginning of this session, we talked about the Deming cycle of Plan-Do-Check-Act and the concept of closing the loop. At this point, we might consider different terms to describe parts of the cycle. A quality assurance program for a central registry involves not only a plan and monitoring of quality (acting); the outcomes of any monitoring must be evaluated and applied to improve the data further.

In other words, knowing that errors exist is not enough. The errors must be corrected in the database, and steps must be taken to educate those responsible for the errors. This is not a punitive step; this is a positive step toward improvement. Periodically, there must be a re-evaluation of the quality status and adjustment of the structures and processes as needed to keep the improvement on track. That's what *continuous quality improvement* is all about.

(Go to Part 1C of Module 3).

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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