

## NCHS PILOT STUDY FOR A NATIONAL CAUSE-OF-DEATH VALIDATION STUDY

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### INTRODUCTION

The National Center for Health Statistics (NCHS) has responsibility for compiling and publishing cause-of-death data for the United States. These data are obtained through a cooperative arrangement with State vital statistics offices. Because of concerns about the quality of these statistics, NCHS is preparing a national study to evaluate cause-of-death data. The objectives of a national study would be to obtain measures of gross and net certification error rates for published cause-of-death statistics, and to identify sources of these errors. Results of the national study would be used to establish programs aimed at improving the quality of the data.

The proposed approach for the national study consists of comparing the original medical certification of death with a newly created certification based on the best available medical information. A pilot study is planned to develop and test the specific methods for the national study.

This paper presents background information on mortality data, the general approach of the national study, and the methodological issues to be addressed in the pilot study.

### BACKGROUND

Cause-of-death statistics for the United States are produced by NCHS from information recorded on approximately two million death certificates in a given year. This information is provided to NCHS by the States, the District of Columbia, and the independent registration area of New York City.

To ensure uniformity in mortality reporting across the United States, a standard certificate of death was first developed in 1900. The standard certificate is periodically revised by NCHS and State vital statistics offices in collaboration with federal agencies, researchers, providers of data, and other groups concerned with vital statistics. The current version (figure 1) was recommended for use in the U.S. beginning January 1, 1978. Work has begun on an evaluation of the current version which may lead to a new revision.

Although some items on death certificates vary from State to State, the medical certification section for each State certificate conforms to that of the standard certificate. This section follows guidelines recommended by the World Health Organization and is designed to facilitate the reporting of the underlying cause of death along with information on the causal sequence of events leading to death. The medical certification section is to be completed in the following fashion (1):

For Part I of the section,

"The direct or immediate cause of death is reported on line (a)...The disease, injury, or complication, if any, which gave rise to

the direct or immediate cause of death is reported on line (b)...The condition, if any, which gave rise to the antecedent condition on line (b) is reported on line (c)...If the decedent had more than three causally related conditions leading to death, lines (d), (e), etc. should be added by the certifier so all conditions related to the immediate cause of death are entered in Part I with only one condition to a line..."

For Part II,

"Any other important disease or condition that was present at the time of death which may have contributed to death but which was not related to the immediate cause of death listed on line a) should be recorded on this line."

State laws require the person who completes the medical certification section of the death certificate to be a physician, medical examiner, or coroner. The medical certifier is required to complete the cause-of-death section of the certificate within a certain number of days of the occurrence of death.

After the information is recorded on the death certificate by the medical certifier, all of the medical conditions and the order in which they are presented are coded by medical coders (2). Traditionally, mortality data have been tabulated by what is called the underlying cause of death, defined by the World Health Organization as: "... (a) the disease or injury which initiated the train of events leading directly to death; or (b) the circumstances of the accident or violence which produced the fatal injury" (3). Information on all conditions reported on the death certificate (nonunderlying as well as underlying causes of death) are referred to as "multiple cause-of-death data." These data, beginning with data year 1968, have recently been made available.

To obtain the underlying cause of death and the multiple causes of death for a particular certificate, the coded medical information is used as input for two NCHS computer programs (4,5). One program, called "ACME" (for Automated Classification of Disease Entities), is designed to select the underlying cause of death. The other program, called "Transax" (for Translation of axis), is designed to produce multiple cause of death statistics. Cause-of-death statistics are then tabulated by various demographic variables and published by NCHS.

Though the use of ACME and Transax provide for rapid, systematic, and consistent selection of both underlying and multiple causes of death, there may be systematic biases introduced by these programs. In the national study and pilot study, possible biases in both underlying and multiple causes-of-death statistics will be examined. Thus, besides determining problems in the certification information on the death certificate, these studies may be able to identify problems resulting from medical coding and processing procedures.

Need for a National Study

Cause-of-death statistics are used by many different types of data users for many different reasons. For example, epidemiologists used cancer mortality maps developed from cause-of-death data to examine the geographic association between asbestos and lung cancer (6). Mortality data are also used to set public health policy. For instance, the identification of areas with high infant mortality rates has led to State and federal programs aimed at reducing infant mortality (7).

Nonrandom errors in mortality data could lead to false conclusions about health and demographic issues. This could result in inappropriate research priorities and a misdirection of funds. As such, an assessment of the quality of mortality data is very important to the many data users.

Studies have already been done which indicate errors in cause-of-death data, but they were limited in either the population studied or in the particular diseases studied (8). The results of these studies do not generalize to current national statistics. Thus, a national study is needed to evaluate the cause-of-death data as published by NCHS.

Objectives and Approach

The primary objectives of the national study would be: 1. to assess the quality of mortality data by measuring the gross and net error rates for published underlying and multiple cause-of-death data; and 2. to determine the sources of these errors so that corrective steps can be taken. In addition, plans for the national study include an assessment of the certainty of diagnosis for the conditions listed on the death certificate. This is being studied because the quality of the medical certification depends to some extent on the quality of the diagnoses for the conditions listed on the certificate.

Briefly, the approach planned for the national study, and that will be used in the pilot study, is to construct a new death certificate based on a medical history of the decedent. This new death certificate will be used as the standard for comparison with the original death certificate.

First, a sample of death certificates will be selected. Medical information for the deceased will be collected from the medical certifier and other sources. All of the medical information will then be combined into a single medical history for the deceased. A panel of experts, the "certification panel", will prepare a new certificate from the medical history. The medical information will also be used to determine a "certainty of diagnosis" classification for each condition reported on the original death certificate. Finally, the original certificate will be compared with the new one and reasons for the discrepancies between the two certificates will be identified.

The pilot study is necessary to resolve several methodological issues for the national study. The pilot study, scheduled for 1985, will also provide information necessary to plan the national study such as estimates of component costs and preliminary analytical measures, which will be used in sample size determination.

In the pilot study, medical history information will be collected by mail for a sample of decedents. Information will be sought from the medical certifier, last hospital (for hospital deaths), and personal physician (if different from the medical certifier). Because information from these sources may not be adequate to compile a medical history or to determine a "certainty of diagnosis" classification, a 20 percent subsample of the sample deaths will be selected. Information will be sought from up to 3 additional medical providers for each death in the subsample.

Target Diseases

For the pilot study, two target conditions have been selected for intensive study: Chronic obstructive pulmonary diseases and allied conditions (COPD) (ICD-9 Nos. 490-496) and Diabetes mellitus (ICD-9 No. 250). As shown in Table 1, COPD was the 5th leading cause of death in 1980 and diabetes was the 7th. These diseases were selected because they are suspected of having certification or diagnostic problems.

In particular, COPD was selected because it presents complex diagnostic problems. There is no diagnostic test that is particularly sensitive or specific to the individual diseases that are collectively called "chronic obstructive pulmonary disease" (9). In addition to a lack of definitive diagnostic tests, physicians are shifting from a more specific diagnosis such as bronchitis, emphysema or asthma to a general diagnosis "obstructive lung disease." This change in certification practice has resulted in changes in the mortality patterns for these diseases (10).

For diabetes, the determination of the certainty of diagnosis is not expected to be difficult. The standard diagnostic procedure is a repeated fasting plasma glucose test, which is both sensitive and specific for diabetes (11). On the other hand, diabetes may present certification problems. It has been speculated that diabetes is underreported on the death certificate from 10 to 50 percent, though these figures are based on small studies not specifically targeted for diabetes (12, 13). There is also known difficulty in determining the underlying cause of death when diabetes coexists with other serious conditions. For example in the Pan American Health Organization study of 1967 it was found that: "Despite the amount of information available to them, the medical referees often found it impossible to select a single cause of death ... the combination of diabetes and arteriosclerotic heart disease was one of the most troublesome" (14).

Sample Design

The sampling frame for the pilot study will be the Current Mortality Sample (CMS). The CMS is a monthly, systematic (10 percent) sample of records received in a one month period in each

State registration office (15). Because the death certificates are ordered in a random fashion, the CMS is an approximate 10 percent simple random sample of deaths from each State and the District of Columbia.

For the pilot study, the sample size will be approximately 700 deaths. To minimize costs and increase State cooperation, the sample will be limited to three States and six months of the CMS. The States will be chosen to ensure the required sample size. All deaths to infants and all deaths from accidents and violence will be excluded for the pilot study because of special certification problems associated with these groups.

A two stage sample design will be used for the pilot study (Table 2). The first stage sample consists of eligible deaths in the CMS for three States for one-half year; this yields a sample that is equivalent to an approximate 1/20 simple random sample of all eligible deaths in the annual file for three States. The second stage sample will be stratified by underlying cause of death to ensure a sufficient sample for each target disease. The three strata will be COPD as underlying cause, diabetes as underlying cause, and all other eligible underlying causes.

Two hundred deaths will be selected from each of the first two strata and three hundred deaths will be selected from the third strata. The three hundred deaths from the third strata will include approximately 40 deaths with mention of COPD (but not as an underlying cause), 60 deaths with mention of diabetes (but not as an underlying cause), and 200 deaths with no mention of either target condition. The cases with COPD and diabetes mentioned as nonunderlying causes are needed to permit testing of procedures for deaths in which the target conditions are listed, but not as underlying causes of death. The sample of 200 deaths with no mention of either COPD or diabetes will provide estimates of the number of deaths for which the death certificate did not mention but should have mentioned COPD or diabetes.

For the CMS only the underlying cause of death are coded. Because of this, some oversampling in the third stratum will be necessary in order to obtain the approximate 40 and 60 deaths with mention of COPD and diabetes, respectively.

#### Methodological Issues

This pilot study will address several methodological issues that need to be resolved to evaluate the feasibility of conducting a national evaluation study. The major issues are discussed in the following sections.

1. Sampling frame. In the pilot study, the advantage and disadvantage of using the CMS as a sampling frame will be analyzed. The advantage of using the CMS as a sampling frame is that it permits a more timely followback than the annual file of final mortality data. The CMS is available within 3 to 4 months after the month of occurrence for most deaths; the annual file may not be available in NCHS until 18 months or more after the month of occurrence. A timely followback is important in obtaining accurate responses and high response rates.

A disadvantage of using the CMS as a sampling frame is that nonunderlying causes of

death, detailed geographic area, and variables such as place of death are not coded. This limits the possible stratification variables for sample design. The pilot study will examine the gain in timeliness against the loss due to lack of stratification variables in order to determine the effectiveness of using the CMS as a sampling frame for the national study.

2. Data collection procedures. In the pilot study, the effectiveness of a mail survey instead of the more costly personal visit survey will be examined. Of primary importance is the willingness of the sample of medical providers to provide medical history information in a mail survey.

In the recent Cost of Cancer Care Pilot Study (16) conducted by NCHS for the National Cancer Institute, medical providers were contacted using similar mail survey methods and a 94 percent response rate was achieved within the ten week survey period. This high response rate may have been the result of several factors including remuneration for the medical providers, brevity of the questionnaire, and endorsement of the Illinois Cancer Council.

Consequently, in the pilot study remuneration will be considered necessary if the initial response rate is low or if the providers indicate that remuneration is expected. The questionnaires will be kept as brief and simple as possible, and endorsement of influential medical organizations will be sought.

3. Evaluation of collected medical information. The availability of adequate medical information for determining new certifications of death and certainty of diagnosis classifications will be evaluated in the pilot study. Adequate medical information may be a problem for those deaths that occur in places other than medical institutions. Current data indicate that about 35 to 40 percent of deaths in the U.S. occur in places other than medical institutions.

The pilot study will also try to determine the number of medical providers per decedent that should be contacted. Medical information from the certifier, last hospital (if any), and primary physician (if different from certifier) may be sufficient. However, to determine if additional providers are required, up to three additional medical providers (thus, up to a maximum of 6 per decedent) will be contacted for a 20 percent subsample of the sample deaths. Careful records will be kept of how the information from these additional sources effect the medical history summaries, the new certifications of death, and the certainty of diagnosis classifications.

4. Certainty of diagnosis. Two methods will be tested for determining the certainty of diagnosis for the conditions listed on the death certificate. The first method is a disease-specific method and will be tested for deaths with COPD or diabetes listed as causes of death. For this method medical providers will be asked about the results of specific diagnostic tests they may have performed in arriving at the diagnosis of COPD or diabetes. For each of these conditions, a certainty of diagnosis algorithm will have been developed which will allow for computer-automated assignment of a certainty of diagnosis to each case based on the disease-

specific diagnostic information that is collected.

The second method is a more general approach. Here, the same general set of questions is asked about the kinds of diagnostic tests which were performed for each of the conditions listed on the death certificate. If the general approach is found to be valid in the pilot study, it could simplify both data collection and analysis for determining the certainty of diagnosis in the national study.

5. Medical history summary. Information obtained from medical providers will include the medical conditions present at the time of death and the circumstances surrounding the death. This information will then be combined into a single description of the medical events leading to death. The feasibility of summarizing data from different medical sources, especially when conflicting information is collected, will be evaluated in the pilot study. The pilot study will also evaluate whether the medical history summary form is adequate in determining the sequence of events leading to death for the new medical certifications.

6. Certification panel. The medical history summary will then be reviewed by a certification panel who will construct new certifications of death. The certification panel will consist of clinicians, pathologists, and nosologists trained in the proper procedures for filling out the death certificate.

In the pilot study two certification panels of three members each will be used to prepare new certificates. The sample of 700 certificates will be allocated to the two panels so that measures can be obtained of both between and within panel variation in the completion of new certificates. Results will be used to determine the allocation of sample certificates to panels for the national study.

7. Evaluation of death certificate. Reasons for discrepancies between the original and new certifications of death will be analyzed in the pilot study. Some of the discrepancies may be due to the certifier's lack of medical information about the deceased. The certifier may not be the patient's attending physician, in which case, he/she may not have immediate access to the decedent's medical history. Or, because of legal requirements or other reasons, the medical certifier may not be able to collect information on autopsies or diagnostic tests before completing the medical certification of death.

Discrepancies could also result from the improper recording of medical information onto the death certificate. The NCHS has found many examples of certification errors such as:

- entering more than one disease or condition to a line in part I of the death certificate;
- recording an inverted order with the underlying cause recorded first and the immediate cause of death last; and
- specifying one condition as due to another condition which sequence is medically unlikely.

These types of certification problems may be due to the medical certifier having had either little training in certification practices or his having

misunderstood instructions for certifying the causes of death.

Other discrepancies could result from a lack of specificity for the cause-of-death statement. For example, cancer may be reported on the death certificate without reference to a specific organ site even though the specific site may be available from the medical records.

Many of these discrepancies can be alleviated by implementing programs to improve the quality of the data. Other discrepancies can not be so alleviated. For example, some discrepancies may be due to differences in medical opinion for diagnoses or for which condition initiated the sequence of events leading to death.

## SUMMARY

A national evaluation of the quality of cause-of-death data would be extremely valuable to the many users of mortality statistics. In designing such a national evaluation study, there are many methodological issues which need to be resolved concerning the sampling frame, the methods of data collection, the assignment of certainty of diagnosis, and the construction of a new death certificate. These methodological issues will be addressed in the pilot study. In addition, should sources of certification problems be identified in the pilot study, then these problems can be addressed even before the national study takes place.

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Figure 1  
**Standard certificate of death**

(PHYSICIAN, MEDICAL EXAMINER OR CORONER)  
**U.S. STANDARD**  
**CERTIFICATE OF DEATH**

Form Approved  
OMB No. 68R 1901

LOCAL FILE NUMBER		STATE FILE NUMBER	
DECEDENT-NAME FIRST MIDDLE LAST		SEX	DATE OF DEATH (Mo., Day, Yr.)
<b>1 Name of decedent</b>			
1a RACE (e.g. White, Black, American Indian, etc.) (Specify)	1b AGE - Last Birthday (Yr.)	1c UNDER 1 YEAR MDS. DAYS	1d UNDER 1 DAY HOURS MINS.
2a CITY, TOWN OR LOCATION OF DEATH	2b HOSPITAL OR OTHER INSTITUTION - Name (if not in either give street and number)	2c DATE OF BIRTH (Mo., Day, Yr.)	2d COUNTY OF DEATH
7a STATE OF BIRTH (if not in U.S. name country)		7b MARRIED, NEVER MARRIED, WIDOWED, DIVORCED, SEPARATED	
8 SOCIAL SECURITY NUMBER		11 SURVIVING SPOUSE (if wife give maiden name)	
13 RESIDENCE - STATE COUNTY		14a USUAL OCCUPATION (Give kind of work done during most of working life, even if retired)	
15a FATHER - NAME FIRST MIDDLE LAST		14b KIND OF BUSINESS OR INDUSTRY	
16 MOTHER - MAIDEN NAME FIRST MIDDLE LAST		15a INSIDE CITY LIMITS (Specify Year of Year)	
17a Informant - Name (if spouse or friend)		17b MAILING ADDRESS STREET OR R.F.D. NO. CITY OR TOWN STATE ZIP	
18a BURIAL, CREMATION, REMOVAL, OTHER (Specify)		18b CEMETERY OR CREMATORY NAME	
19a FUNERAL SERVICE LICENSEE Or Person Acting As Such (Signature)		19b NAME OF FACILITY	
20a		19c ADDRESS OF FACILITY	
20b		20c	
21a To the best of my knowledge, death occurred at the time, date and place and due to the cause(s) stated (Signature and Title)		21b DATE SIGNED (Mo., Day, Yr.)	
21c HOUR OF DEATH		21d M	
21e NAME OF ATTENDING PHYSICIAN IF OTHER THAN CERTIFIER (if spouse or friend)		21f	
22a On the basis of examination and/or investigation, in my opinion death occurred at the time, date and place and due to the cause(s) stated (Signature and Title)		22b DATE SIGNED (Mo., Day, Yr.)	
22c HOUR OF DEATH		22d M	
22e PRONOUNCED DEAD (Mo., Day, Yr.)		22f	
22g		22h AT	
22i		22j M	
23 Certifier (physician, medical examiner, or coroner)			
24a REGISTRAR		24b DATE RECEIVED BY REGISTRAR (Mo., Day, Yr.)	
25 IMMEDIATE CAUSE (ENTER ONLY ONE CAUSE PER LINE FOR (a), (b), AND (c))			
<b>25a Immediate cause of death</b>			
25b DUE TO, OR AS A CONSEQUENCE OF			
<b>25c Due to, or as a consequence of:</b>			
25d DUE TO, OR AS A CONSEQUENCE OF			
<b>25e Due to, or as a consequence of:</b>			
25f OTHER SIGNIFICANT CONDITIONS (Conditions contributing to death but not related to cause given in PART II a)			
<b>25g Other significant conditions</b>			
26a ALL SURVIVE HUMAN UNDER 18 (Remaining Incest)		26b DATE OF INJURY (Mo., Day, Yr.)	
26c HOUR OF INJURY		26d M	
26e PLACE OF INJURY (At home, farm, street, factory, other building, etc.) (Specify)		26f	
26g		26h	
26i		26j	
26k		26l	
26m		26n	
26o		26p	
26q		26r	
26s		26t	
26u		26v	
26w		26x	
26y		26z	
26aa		26ab	
26ac		26ad	
26ae		26af	
26ag		26ah	
26ai		26aj	
26ak		26al	
26am		26an	
26ao		26ap	
26aq		26ar	
26as		26at	
26au		26av	
26aw		26ax	
26ay		26az	
26ba		26bb	
26bc		26bd	
26be		26bf	
26bg		26bh	
26bi		26bj	
26bk		26bl	
26bm		26bn	
26bo		26bp	
26bq		26br	
26bs		26bt	
26bu		26bv	
26bw		26bx	
26by		26bz	
26ca		26cb	
26cc		26cd	
26ce		26cf	
26cg		26ch	
26ci		26cj	
26ck		26cl	
26cm		26cn	
26co		26cp	
26cq		26cr	
26cs		26ct	
26cu		26cv	
26cw		26cx	
26cy		26cz	
26ca		26cb	
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26ce		26cf	
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26ci		26cj	
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26cm		26cn	
26co		26cp	
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26cs		26ct	
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26ca		26cb	
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26ce		26cf	
26cg		26ch	
26ci		26cj	
26ck		26cl	
26cm		26cn	
26co		26cp	
26cq		26cr	
26cs		26ct	
26cu		26cv	
26cw		26cx	
26cy		26cz	
26ca		26cb	
26cc		26cd	
26ce		26cf	
26cg		26ch	
26ci		26cj	
26ck		26cl	
26cm		26cn	
26co		26cp	
26cq		26cr	
26cs		26ct	
26cu		26cv	
26cw		26cx	
26cy		26cz	
26ca		26cb	
26cc		26cd	
26ce		26cf	
26cg		26ch	
26ci		26cj	
26ck		26cl	
26cm		26cn	
26co		26cp	
26cq		26cr	
26cs		26ct	
26cu		26cv	
26cw		26cx	
26cy		26cz	
26ca		26cb	
26cc		26cd	
26ce		26cf	
26cg		26ch	
26ci		26cj	
26ck		26cl	
26cm		26cn	
26co		26cp	
26cq		26cr	
26cs		26ct	
26cu		26cv	
26cw		26cx	
26cy		26cz	
26ca		26cb	
26cc		26cd	
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26co		26cp	
26cq		26cr	
26cs		26ct	
26cu		26cv	
26cw		26cx	
26cy		26cz	
26ca		26cb	
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26ce		26cf	
26cg		26ch	
26ci		26cj	
26ck		26cl	
26cm		26cn	
26co		26cp	
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26cu		26cv	
26cw		26cx	
26cy		26cz	
26ca		26cb	
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26cq		26cr	
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26cu		26cv	
26cw		26cx	
26cy		26cz	
26ca		26cb	
26cc		26cd	
26ce		26cf	
26cg		26ch	
26ci		26cj	
26ck		26cl	
26cm		26cn	
26co		26cp	
26cq		26cr	
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26cu		26cv	
26cw		26cx	
26cy		26cz	
26ca		26cb	
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26ca		26cb	
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26ce		26cf	
26cg		26ch	
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26ck		26cl	
26cm		26cn	
26co		26cp	
26cq		26cr	
26cs		26ct	
26cu		26cv	
26cw		26cx	
26cy</			

Table 1

## Leading causes of death in 1980

	<i>Underlying cause</i>		<i>Multiple cause</i>	
	<i>Number of deaths</i>	<i>Percent</i>	<i>Number of deaths</i>	<i>Percent</i>
<b>All causes</b>	<b>1,989,841</b>	<b>100.0</b>	<b>1,989,841</b>	<b>100.0</b>
1. Heart disease	761,085	38.2	1,099,864	55.3
2. Cancer	416,509	20.9	472,272	23.7
3. Stroke	170,225	8.6	283,009	14.2
4. Accidents	105,718	5.3	163,640	8.2
* 5. COPD	56,050	2.8	131,456	6.6
6. Flu and pneumonia	54,619	2.7	164,634	8.3
* 7. Diabetes mellitus	34,851	1.8	135,931	6.8
8. Cirrhosis of liver	30,583	1.5	45,511	2.3
9. Atherosclerosis	29,449	1.5	158,471	8.0
10. Suicide	26,869	1.4	27,004	1.4

\*Target diseases for pilot study

Table 2

## Sample size for pilot study, three states

(6 months)

<i>Source</i>	<i>Target cause of death</i>		<i>Other underlying causes of death</i>		
	<i>COPD</i>	<i>Diabetes</i>	<i>w/Diabetes</i>	<i>w/COPD</i>	<i>Remainder</i>
<b>Annual file</b>	<b>6,000</b>	<b>4,000</b>	<b>12,000</b>	<b>8,000</b>	<b>177,000</b>
<b>CMS (10%)</b>	<b>600</b>	<b>400</b>	<b>1,200</b>	<b>800</b>	<b>18,000</b>
<b>Sample n<sub>i</sub></b>	<b>200</b>	<b>200</b>	<b>60</b>	<b>40</b>	<b>200</b>

**Note:** Residual excludes all deaths from infant causes and from external causes