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# CDC's Surveillance of Surgical Sterilization: Objectives and Methods of Data Collection

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THE POPULARITY OF STERILIZATION among both sexes has increased greatly in the United States in recent years. In 1977, more than a million women of reproductive age had either a tubal sterilization or a hysterectomy (1,2), and almost half a million men had a vasectomy that year, according to the Association for Voluntary Sterilization. Surgical sterilization has become the method of fertility control for almost one-half of all white couples in the United States who have been married for 10 or more years (3).

As with other surgical procedures, sterilization has associated medical risks which vary both with the procedure used and the health status of the patient. To evaluate the general public health effect of surgical sterilization, the Family Planning Evaluation Division (FPED), Centers for Disease Control (CDC), has initiated a program of epidemiologic surveillance of sterilization. The purpose of this paper is to state the objectives of our sterilization surveillance activities and to describe the surveillance methods which we presently use or intend to use to accomplish the objectives.

## Background

As a part of the overall mission to examine the public health impact of legally induced abortion in the United States the FPED, more than a decade ago, began a

program of abortion surveillance (4). The abortion surveillance activities have been important in providing a national perspective on the characteristics of women who have abortions and the associated morbidity and mortality risks (5-10). Similarly, within the past decade as surgery in general and surgical sterilization in particular emerged as public health concerns, the FPED began a program of sterilization surveillance. As with abortion surveillance, these activities will provide a national perspective on the health aspects of surgical sterilization.

Surgery is a relatively new health concern, figuring in the practice of medicine only after anesthesia became widely used early in this century. Until the late 1960s, sterilizations of females were performed primarily on the advice of a physician for medical or obstetrical conditions that would contraindicate future pregnancy or for women who satisfied the obstetrical rule of 120 (age times parity  $\geq 120$ ) (11). These sterilization procedures were usually performed immediately following delivery. Sterilizations of males, most of them involuntary, were first performed on prisoners and mental patients for eugenic reasons because it was believed that criminal tendencies and mental illness were passed on directly to offspring (12).

Today virtually all tubal sterilizations and about one-half of all hysterectomies are performed, not for medical reasons, but at the request of a woman for a permanent method of fertility control (3). Furthermore, sterilization is no longer performed primarily in connection with a delivery (1,2,13,14). The eugenic laws in effect early in this century are no longer acceptable

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to society, and men now seek sterilization voluntarily.

Two important points should be stated before I discuss the objectives and methods of sterilization surveillance. First, most epidemiologic studies of the health aspects of fertility control focus on females. Although temporary methods of contraception, such as oral contraceptive pills and the IUD, are used only by females, and abortion procedures are exclusively for females, sterilization is for males and females alike. On the contrary, among some population groups more husbands than wives have chosen surgical sterilization (3). Studies of health risks associated with sterilizations of males, however, have not revealed a level of morbidity and mortality that is recognized as a significant public health concern (15). Although our surveillance objectives include sterilization of both males and females, the methods of surveillance have concentrated on learning more about sterilization of females because of the recognized risks of morbidity and mortality.

A second point is primarily one of semantics. It is inappropriate to use the terms "sterility" and "sterilization" interchangeably. The program's surveillance activities are concerned with surgical sterilization (tubal sterilization, hysterectomy, and vasectomy, which result in permanent infertility) rather than biological sterility, which can occur in males and females for a number of reasons such as age or disease. We are interested in surgical sterilization, regardless of the purpose for which it is performed. For example, some surgical sterilizations are performed only for medical reasons, some only for contraceptive reasons, and some for both medical and contraceptive reasons. It should be noted that women beyond the reproductive age (15-44 years) can also undergo the same operations that result in sterilization, particularly hysterectomy. Although there are health risks associated with these operations in post-reproductive-age women, the scope of our sterilization surveillance activities is limited to sterilization procedures in reproductive-age women.

### **Objectives of Sterilization Surveillance**

There are four objectives of our surveillance activities: (a) to determine the incidence of surgical sterilization, (b) to assess sterilization-related mortality, (c) to assess sterilization-related morbidity, and (d) to suggest ways to reduce or prevent mortality and morbidity related to sterilization.

**Objective 1.** The first objective is aimed at determining the magnitude and characteristics of surgical sterilization nationally. More specifically, we would like to be able to estimate the annual number of surgical sterilizations in the United States; characterize the

persons having surgical sterilizations by such variables as age, race, sex, marital status, and place of residence; and describe the surgical event by such variables as type of procedure, place of occurrence, and length of hospital stay.

This first objective presents some interesting problems. Historically, case counts have been kept by the medical and public health community on many diseases and conditions, but the treatment (medication, surgery, and so forth) or therapy used is seldom quantified. For example, although the number of persons with gonorrhea or syphilis might be reported, the number of injections of penicillin given to treat the disease is generally not given attention. Furthermore, since most surgical sterilizations in the United States today are for contraceptive purposes and are performed on healthy persons with no disease or condition, it is even less likely that an account of such surgery is kept. An additional problem is that procedures such as tubal sterilization are performed as an adjunct at the time of abortion or delivery, and in this circumstance the abortion or delivery is most likely to be identified as the prominent event. There is, therefore, no national effort to collect or aggregate case counts of surgical sterilization performed either medically as a "treatment" or nonmedically as a method of fertility control. Just as there is no national systematic count of males or females who are sterilized, no statistics are collected for the purpose of presenting a descriptive national picture of surgical sterilization. Thus, as the subsequent discussion of methods shows, epidemiologists must use a variety of data sets in an attempt to make estimates that achieve the first objective.

**Objective 2.** The second objective is to assess the mortality associated with surgical sterilization. Since there are no documented deaths in the United States associated with nonmedical vasectomy, that is, vasectomy for contraceptive reasons, the data collection is confined to females. Two major problems encountered in assessing sterilization mortality are (a) the difficulties of actually identifying deaths which might be attributed to surgical sterilization and (b) the medical-legal problems encountered in attempting to do an epidemiologic investigation to verify that a death, once identified, is directly or indirectly associated with surgical sterilization.

The first problem, identifying deaths, stems from the fact that, technically, sterilization is not a cause of death. Under the International Classification of Diseases system, surgical sterilization is classified as an operative procedure, and operative procedures cannot be the cause of death. Thus, the death certificate of any per-

son whose death is directly or indirectly related to surgical sterilization would not reflect surgical sterilization as the cause of death. Furthermore, although operative procedures are usually recorded in detail on medical records, they are seldom mentioned on the death certificate.

The second problem centers around medical and legal difficulties arising when a death, alleged to be related to surgical sterilization, is in litigation. This circumstance often makes it impossible to gain access to the records most needed in an epidemiologic investigation, such as the hospital record and autopsy report.

**Objective 3.** The third objective is to assess the morbidity associated with surgical sterilization. Again, as with mortality, the objective is confined to data concerning females since vasectomy is simple and safe, and most of the morbidity that has been noted is short term and minor (15). Surgical sterilization of females involves various risks, depending on factors such as the type and complexity of the procedure, type of anesthesia used, concomitant procedures such as abortion and cesarean section, and the post-operative health condition(s) of the patient. Because of the multiplicity of factors which can affect morbidity and because of the epidemiologic complexities associated with the assessment of short- and long-term post-operative complications, CDC has undertaken a prospective epidemiologic study in cooperation with several medical facilities. The findings in this study will help to assess morbidity associated with surgical sterilization.

**Objective 4.** The fourth objective of surveillance is to identify specific factors that contribute to sterilization morbidity and mortality and to suggest how these factors might be eliminated or modified to reduce or prevent morbidity and mortality.

From the public health perspective it is important that both the medical community and the public at large be aware of the health risk associated with surgical sterilization so that both can make informed decisions about recommending or undergoing sterilization. For example, CDC widely disseminated information through its Morbidity and Mortality Weekly Report (MMWR) on the risk associated with ectopic pregnancy following failed tubal sterilization (16,17). The purpose of these articles was to alert physicians to the fact that signs and symptoms of pregnancy after sterilization should not be disregarded because sterilization failures, although rare, do occur and an ensuing pregnancy has a greater probability of being ectopic with accompanying higher risks of morbidity and mortality.

## Methods of Surveillance

The methods of surveillance are based on the objectives stated previously, namely to determine the magnitude of surgical sterilization in the United States annually and to assess the associated morbidity and mortality risks, including factors that contribute to increased risk.

One of the FPED's first major surveillance activities was exploring data sources that might be useful in estimating the number and characteristics of surgical sterilizations nationally. Three surveys conducted by the National Center for Health Statistics have been explored as possible data sources: the National Hospital Discharge Survey (NHDS), the National Medical Ambulatory Care Survey (NMACS), and the National Survey of Family Growth (NSFG).

The annual NHDS has proved extremely useful in determining the number of women 15 to 44 years of age who received surgical sterilization in non-Federal hospitals for each year beginning with 1970. Currently, the majority of sterilizations of women are performed in hospitals; thus, the NHDS survey design includes the appropriate universe (hospital discharge records). An analysis of the NHDS data has resulted in four descriptive reports for tubal sterilization and hysterectomy for the periods 1970-75 and 1976-78 (tables 1 and 2). The FPED published these reports (1,2,13,14) and disseminated them to a broad spectrum of the health community interested in sterilization. We intend to publish an annual report, combining the data on tubal sterilizations and hysterectomies beginning with the 1979 data.

Tubal procedures are also performed outside of hospitals in surgical clinics and physicians' offices (18,19). We are exploring how to best identify these sites and determine the number of surgical sterilizations performed in them annually. Our initial effort in this regard was a recent survey in collaboration with the American Association of Gynecologic Laparoscopists of more than 300 freestanding ambulatory care facilities to determine the number and characteristics of sterilizations performed in 1980.

The preponderance of vasectomies are performed by private physicians in their offices, according to the Association for Voluntary Sterilization. Thus, to obtain a national estimate of the number and characteristics of men obtaining vasectomies, we explored the use of data from the annual NMACS, which collects information from private physicians' offices. Because of the wording of questions in this survey before 1977, it is not possible to identify specifically sterilizations performed on men. In 1977, however, the survey questionnaire was changed to allow collection of these

Table 1. Tubal sterilizations (in thousands) and rates per 1,000 women 15 to 44 years, by geographic region of the United States, 1970-78

Year	Northeast		North Central		South		West		Total	
	Number	Rate	Number	Rate	Number	Rate	Number	Rate	Number	Rate
1970	47	4.6	50	4.3	76	5.7	28	3.7	201	4.7
1971	69	6.8	75	6.3	90	6.6	34	4.4	269	6.2
1972	89	8.5	89	7.3	128	9.1	44	5.5	350	7.9
1973	115	10.9	130	10.6	140	9.6	50	6.2	435	9.6
1974	117	10.9	148	11.9	169	11.4	51	6.0	484	10.4
1975	124	11.5	168	13.3	193	12.7	66	7.6	550	11.7
1976	138	12.6	171	13.3	215	13.7	70	7.9	592	12.3
1977	143	13.0	200	15.4	270	16.9	89	9.7	702	14.3
1978	131	11.9	179	13.5	265	16.2	78	8.2	653	13.0

SOURCES: References 1, 13.

data. Unfortunately, the current sample size of NMACS is too small to use in estimating precisely the total number of vasectomies performed per year (20).

Recent estimates of the prevalence of surgical sterilization for both males and females are available from the NSFG which is conducted periodically, most recently in 1973 and 1976. Both the 1973 and 1976 NSFG surveys measured surgical sterilization events as they actually occurred and where they occurred, that is, sterilization of females in hospitals or sterilization of males in offices.

Information on sterilizations for the NSFG was obtained by personal interview of a sample of female respondents who were married, previously married, or single with children of their own in the household. There is a potential for an underestimate of surgical sterilization surveys because of a respondent's reluctance to discuss her sterilization and her lack of information about her spouse or partner's sterilization or her reluctance to discuss it. Further, all single women ages 15-44 with no children in the household are excluded from the survey population.

Another major surveillance activity has been to devise a method to identify deaths that might be somehow related to surgical sterilization and, once identified, to acquire enough information about each death to ascertain if that event was directly or indirectly associated with a sterilization procedure. Our surveillance of sterilization mortality has, as previously mentioned, been directed to females.

A primary surveillance effort has been to explore the use of death certificates to identify deaths associated with sterilizations in a retrospective study and a prospective study. In the prospective study we asked the nosologists in two State vital statistics units to set aside for a 6-month period each death certificate of a female 15-44 years regardless of the cause of death. They were then to review in detail these certificates for any mention of surgery that might have produced surgical sterilization. The results of this prospective study made it clear that either sterilization mortality is too low to detect with the small number of certificates reviewed, or the death certificates do not usually include an indication of surgical sterilization.

Table 2. Hysterectomies (in thousands) and rates per 1,000 women 15 to 44 years, by geographic region of the United States, 1970-78

Year	Northeast		North Central		South		West		Total	
	Number	Rate	Number	Rate	Number	Rate	Number	Rate	Number	Rate
1970	63	6.2	83	7.1	109	8.2	52	6.9	306	7.2
1971	69	6.7	88	7.4	116	8.5	59	7.7	332	7.6
1972	65	6.3	94	7.8	162	11.5	70	8.8	391	8.8
1973	71	6.7	105	8.5	163	11.2	75	9.2	413	9.1
1974	60	5.7	114	9.1	164	11.1	77	9.2	415	9.0
1975	61	5.6	114	9.1	178	11.7	77	8.9	430	9.1
1976	55	5.0	108	8.4	174	11.1	67	7.6	403	8.4
1977	57	5.2	113	8.6	188	11.8	84	9.2	442	9.0
1978	49	4.4	110	8.3	179	11.0	66	6.9	404	8.1

SOURCES: References 2, 14.

At the same time a retrospective study was done with the cooperation of two other State vital statistics units to see if reviewing selected categories of deaths would identify those associated with surgical sterilization. For this study, a list of all nonviolent deaths (excluded were homicides, automobile, and other accidental deaths) and noncancer deaths was produced. It contained all data on the certificates of females 15-44 years old who died in the study year. The lists from each State were reviewed by an epidemiologist who paid special attention to cause of death. The certificates for selected deaths that might have resulted from a surgical procedure were pulled and reviewed. Again, we found that either the mortality attributable to surgical sterilization is too low to detect in our limited study, or surgical sterilization is not recorded on the certificate. Thus we concluded from the two studies that identification of sterilization-associated deaths directly from an ongoing surveillance system that relies on retrospective or prospective review of death certificates was not feasible.

Other surveillance activities related to identification of sterilization-associated deaths have depended on hospital records. Three studies have been or are currently being done—one uses national sample data from the NHDS; another uses data from hospitals associated with the Commission on Professional and Hospital Activities (CPHA); and a third uses hospital-care data from one State that has 100 percent reporting of hospital discharges to a State health department data system.

While the NHDS has proved extremely useful for obtaining an estimate of the number of women surgically sterilized per year, a study we conducted using NHDS data showed that this information could not be used for a national estimate of sterilization mortality or for the identification of sterilization-associated deaths specifically. Again, the sample size was too small to make reliable national estimates of the number of sterilization deaths, and confidentiality restrictions placed on the use of the data prohibit disclosure to CDC of identifying information which is necessary to confirm the data.

We are now conducting a study with the cooperation of CPHA and Professional Activities Study (PAS) hospitals in which we hope to determine if ongoing surveillance of sterilization mortality is feasible, based on routinely collected hospital discharge abstracts reported to the Commission. In this study, we received permission for a CDC epidemiologist to review medical records from all hospitals that had had a death possibly associated with sterilization within the 2-year

period 1977-78, as determined from the CPHA data file. This review should verify the occurrence of a sterilization-associated death and provide descriptive epidemiologic information. The shortcoming of this surveillance effort, even if the study shows that CPHA data can be useful, is that the hospitals belonging to CPHA do not necessarily represent a national cross section; thus statistical inference nationally would not be possible.

In the third study, still in progress, of the completeness of sterilization mortality reported in a State during 1 year, we chose a large State which has both 100 percent reporting of hospital discharges from all hospitals and an ongoing thorough review of maternal deaths that should identify sterilization deaths of postpartum women, even after discharge from the hospital.

CDC, in cooperation with State health departments, is conducting an indepth study of maternal deaths based on review of death certificates, autopsy reports, and other medical records for 1974-78. When the study is completed, we hope to have an epidemiologic perspective of maternal mortality nationally. Although this study has a different purpose, we should also gain a better view of mortality related to sterilizations performed in connection with abortions and deliveries for the 5-year period.

Currently, one of the most valuable sources of information on sterilization-associated deaths is the informal reporting of deaths to CDC by physicians and other interested persons in the health community. More than half of the deaths identified for epidemiologic investigation since 1978 have been reported informally. To make our interest in sterilization mortality more widely known, we have asked several national groups and organizations and State health departments for assistance. FPED staff have made presentations to the National Association of State and Territorial Maternal and Child Health Directors, the Association for Voluntary Sterilization, the American Association of Gynecologic Laparoscopists, and other groups and asked their members to notify CDC of any suspected sterilization-associated deaths. Also, the first tubal sterilization surveillance report (13) was mailed to all members of the American Association of Gynecologic Laparoscopists, the Association for Voluntary Sterilization, and Fellows of the American College of Obstetricians and Gynecologists with a letter requesting members of these organizations to notify CDC of any sterilization-associated deaths since 1978 that might have come to their attention.

Additionally, in 1979 the FPED sent a letter to each State Director of Maternal and Child Health enlisting cooperation in surveillance. We asked for

specific suggestions on how to best identify deaths associated with sterilization procedures, especially those in the postpartum period, since the investigation of postpartum deaths comes under the direct purview of directors of maternal and child health.

We recognized at the outset that the assessment of morbidity resulting from surgical sterilization would require a thorough epidemiologic study to deal with the problems of defining a case, definition and classification of complications, standardization of clinical information, and of obtaining followup data.

Our first morbidity study, conducted with the cooperation of three hospitals, was primarily a retrospective review of medical records to determine who had had surgical sterilization procedures and to abstract relevant clinical data. The results of this study led us to conclude that a retrospective record review was not sufficient for a precise epidemiologic analysis of complications because of (a) difficulties in determining who actually had had surgical sterilization, (b) difficulties in locating necessary medical records within the hospital, (c) missing or inadequate information from medical records, (d) lack of comparability of the clinical data among the participating institutions, and (e) problems of locating women to obtain followup information.

Drawing on our experience with the retrospective study, we designed a prospective study with a 2-year followup to collect two sets of detailed clinical and epidemiologic data—one on women having tubal sterilization procedures and another on women having hysterectomies. We are in our second year of data collection. The study, although it is not designed to allow statistical inference of complication rates to a larger population of reproductive-age women, will be the largest data set specifically designed to identify both short- and long-term complications in a group of women who undergo surgical sterilization. Furthermore, the study will help to determine factors that contribute to sterilization morbidity.

## Conclusions

CDC recognizes the need for establishing a clear epidemiologic perspective of surgical sterilizations in the United States. We have begun, on several fronts, to establish ongoing surveillance of the magnitude of surgical sterilizations and of the morbidity and mortality associated with these procedures. We are examining various surveillance methods to determine which would be the most useful in the long term, and we continue to seek assistance from public health and medical groups that can provide insight on how to best improve our surveillance methods.

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