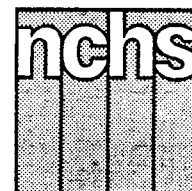


Advance Data



From Vital and Health Statistics of the National Center for Health Statistics

Use of Selected Medical Device Implants in the United States, 1988

by Abigail J. Moss, Division of Health Interview Statistics, National Center for Health Statistics; Stanford Hamburger, D.D.S., M.P.H., Roscoe M. Moore, Jr., D.V.M., M.P.H., Ph.D., and Lana L. Jeng, M.D., M.P.H., Food and Drug Administration; and L. Jean Howie, Division of Health Interview Statistics, National Center for Health Statistics

Introduction

During the past few decades, there have been great increases in the numbers of manmade materials and devices introduced to the medical profession for implantation into humans. The search for replacement of natural body parts began in ancient times. Dental implants are traceable to early Egyptians and to Central and South American cultures (1). The first pacemaker was invented in the 1950's, the first artificial heart valve was implanted by Hufnagel in 1952, and in 1954 Charnley performed the first artificial hip replacement (2).

Despite the many advances made to date in research and development of medical device implants, it remains unclear whether there is or ever will be an implant device suitable for every clinical situation. In addition, the long-term effectiveness and safety of the most widely used implants have yet to be definitively established.

All medical device implants are complex in design, materials, and implementation procedures. The

biocompatibility, durability, and efficacy of medical device implants are a continuing concern of the Food and Drug Administration (FDA), the medical profession, the device manufacturers, and, most importantly, the patients (3-12). Unfortunately, sufficient scientific documentation and literature presently are not available to assess the success of many of these medical device implants. This report presents previously unavailable baseline estimates of medical device implants in an attempt to address some of these concerns.

Included are estimates from the National Center for Health Statistics's National Health Interview Survey (NHIS) of the percent of persons in the United States with one medical device implant or more. Estimates of the total number of artificial joints, fixation devices, intraocular lens implants, pacemakers, artificial heart valves, and ear vent tubes are also presented. The technical notes to this report include definitions of these medical devices.

The report also includes estimates for several details about these devices, such as length of time the current implant has been in use, implant replacement, implant problems, and reason(s) for the original implant. All estimates are shown by the following sociodemographic and health status indicators: age, sex, race, Hispanic origin, family income, poverty status, education, geographic region, place of residence, activity limitation, and respondent-assessed health status.

Background

Under the Federal Food, Drug, and Cosmetic Act, as amended, FDA is responsible for the approval and regulation of new and existing medical devices (13). This act defines a medical device, including any component part, as any article (a) intended for use in the diagnosis of disease or other conditions; (b) intended for use in the cure, mitigation, treatment, and prevention of disease; or (c) intended to affect the structure and/or function of the



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Center for Health Statistics
Manning Feinleib, M.D., Dr. P.H., Director

CDC

human body. Implants are classified as medical devices under this act.

FDA's Center for Devices and Radiological Health (CDRH) currently utilizes several sources of medical device implant data to assess the use, safety, and effectiveness of specific classes of implanted medical devices. Some of the sources used by CDRH to monitor medical device implants provide a count of the number of implant procedures performed in any given year but do not provide any accompanying historical information on the patients who received the implants (14). Other sources provide information that is generated from either mandatory reports of device-related deaths and serious injuries or voluntary and anecdotal reports of device utilization experience (15). Manufacturer data on medical device implants are primarily sales data (16).

These information sources lack denominator data needed for proper clinical evaluations. Furthermore, they have limitations that restrict their use for future epidemiologic studies. Prevalence estimates generated from these combined data are based on mathematical models rather than actual population data; reliance on these sources alone may lead to biased estimates.

In 1988, the National Center for Health Statistics, in collaboration with FDA's CDRH and as part of its ongoing NHIS, collected information to produce the first nationally representative, population-based estimates of the prevalence and utilization experience associated with implanted medical devices. The Medical Device Implant (MDI) Survey had two major objectives: (a) to generate reliable estimates of the total number of medical devices implanted in the U.S. population and (b) to provide specific, detailed information on selected generic classes of devices.

The MDI Survey was designed primarily to provide supportive data for CDRH's postmarketing surveillance programs, regulatory functions, and related public health decisions relative to medical device implants. Other organizations,

agencies, and individuals, however, should also benefit from data generated from the MDI Survey. For example, the medical device industry could use the estimates for marketing, research, and development of new and improved medical device implant products. Other Government agencies, such as the Centers for Disease Control, the National Institutes of Health, the Health Resources and Services Administration, and the Health Care Financing Administration, may also utilize these data for ongoing research, for developing program objectives for health personnel and health service delivery to populations or subgroups of populations, for aiding in activities concerning complications related to special devices, and for developing programs and policies for standards and quality.

Data and methods

NHIS is a continuous, cross-sectional survey representing the household population of the United States. Each year in NHIS basic health and demographic information is collected by face-to-face interviews with a sample of about 122,000 family members in about 47,000 households. These interviews are conducted by personnel employed by the U.S. Bureau of the Census.

In addition to the basic NHIS questionnaire, questions on one or more selected topics are included each year. Through the 1988 MDI Survey questionnaire, information was obtained about five generic types of medical device implants—artificial joints, fixation devices, artificial heart valves, intraocular lens implants, and pacemakers—and a residual class of all other devices. These classes of medical device implants were selected based on two criteria: The specific generic class of device had to be (a) implanted frequently enough for national projections to be made and/or (b) reported to have associated adverse effects that result in significant morbidity or mortality.

The MDI Survey questionnaire contained a common set of questions

for each type of medical device implant: the number, type, and body location of each device reported; the dates of the original and most recent replacement implantation; the frequency of replacement and reasons for the most recent replacement; the length of time in use of the implant; and the types and onset of adverse effects or complications that occurred with each implant, such as healing problems, pain, infection, or mechanical failure. A limited number of other questions unique to each specific implant type were also included. A facsimile of the MDI Survey questionnaire is provided in *Current Estimates from the National Health Interview Survey: United States, 1988* (17).

Persons with a medical device implant were first identified through a series of "screener" questions administered to the NHIS adult household respondent(s). The detailed questions about medical devices asked in response to the screener replies, however, were administered directly to those adult family members with the actual medical device implant. If the person with the medical device was physically or mentally incapable of answering the questions or was temporarily away from home during the interview period, a related family member who was knowledgeable about the person's implant was interviewed. Information about medical devices reported for children was obtained from a knowledgeable adult family member, usually a parent.

The overall response rate, combining the response rates for the household questionnaire and the MDI questionnaire, was about 92 percent. In the survey, 5,592 sample persons reported having one medical device implant or more. A total of about 7,600 devices were reported.

The technical notes to this report contain a brief description of the sample design and data collection procedure employed and the terms used. The definition given for a medical device implant is similar to that used by the International Standards Organization (18). Methods are also provided for deriving

approximate sampling errors for the estimated numbers and percents presented in this report.

Tables 1 and 2 show the number and percent of persons with medical device implants according to the type and total number of implants reported. The number and percent distributions of the medical device implant population are shown by sociodemographic characteristics in table 3. Prevalence estimates by age, sex, and race for several kinds of devices not included elsewhere in this report are given in table 4. Estimates are presented in tables 5–10 of specific types of implants by length of time in use. Table 11 contains percent estimates of implants never replaced by sociodemographic characteristics. In table 12 similar figures are presented for implants with one problem or more reported. Table 13 shows estimates of devices by reason(s) for the original implant.

Estimates of all persons and the medical device implant population are shown in table 14 according to two NHIS health status measures. Table 15 contains population denominators needed to derive various estimated frequencies for the percent estimates presented in this report. The estimates presented in the tables in this report are weighted to produce representative national estimates of the U.S. civilian noninstitutionalized population.

Results

Persons with implants

In 1988, an estimated 11 million Americans (4.6 percent of the civilian noninstitutionalized population of the United States) had at least one medical device implant (tables 1 and 2). Fixation devices were reported with the greatest frequency. About 40 percent of persons with implants reported their use, followed by lens implants (23 percent) and artificial joints (12 percent).

The percent of persons with an implant, as expected, varied by age and type of device reported. For most types of medical devices, older persons

were most likely to have an implant. Of persons 65 years of age and over, about 7 percent had a lens implant, 3.5 percent reported a fixation device, and about 3 percent had an artificial joint. Among those 75 years of age and over, about 1 out of 10 individuals had a lens implant. About 2 percent of children 5 years of age and under used an ear vent tube.

Although the majority of persons with medical device implants reported only one implant, over 30 percent (3.4 million persons) reported multiple implants. Few persons, however (less than 4 percent of the implant population), reported more than two implants. The likelihood of having more than one implant depended somewhat upon the type of implant obtained. For example, over one-half of children with ear vent tubes were reported to have two implants of this type and about 45 percent of persons with a lens implant reported implants in both eyes.

Separate figures are not specifically shown in this report on the proportion of persons in the population with several different kinds of medical device implants. However, estimates from this data base show that about 6 percent of persons with implants reported more than one type of implant.

In table 3, estimates of persons with specific types of medical device implants are shown by a number of sociodemographic characteristics. About one-half of all persons with ear vent tubes were 5 years of age and under (472,000 children). The risk of having an ear vent tube was 1½ times as great for males (60 percent) as it was for females (40 percent), as shown in figure 1. The vast majority of persons with ear vent tube implants were white (93 percent), had an annual family income of at least \$15,000 (72 percent), and had at least a high school education (90 percent). (For children, the highest educational level for a family member was used.)

As previously mentioned, more persons reported having a fixation device than any other kind of medical device implant (about 4.4 million individuals). Men were somewhat

more at risk of having a fixation device than were women (58 percent compared with 42 percent). This finding probably reflects generally higher rates of injuries found among males. About equal numbers of persons under 45 years of age and persons 45 years and over reported a fixation device.

About 2½ million individuals, almost one-half of whom were 75 years of age and over, had a lens implant. Proportionately more females than males had a lens implant, 12.9 per 1,000 women compared with 8.4 per 1,000 men. The inverse relationship found between lens implants and family income and education is at least partly because of the disproportionate number of elderly persons in the lower income and education categories.

Of the 1.3 million persons with an artificial joint, 62 percent were 65 years of age and over and 58 percent were women. Again, differentials by income and education probably reflect the larger proportion of older individuals, who are at greater risk of having an artificial joint, in the lower income and education groups.

Pacemakers were implanted in an estimated 460,000 persons. Unlike other types of medical device implants, pacemakers were used by about equal numbers of men and women. About 86 percent of those individuals were at least 65 years of age, and 94 percent were white.

In 1988, there were an estimated 253,000 artificial heart valves in use. Although it appears that artificial heart valves were implanted somewhat more frequently in men than in women, the difference between these estimates was not statistically significant. Similarly, the data appear to show that persons living in metropolitan statistical areas (MSA's) were somewhat more likely to have an implant of this type than persons living outside these areas (about 111 per 100,000 persons in MSA's compared with 88 per 100,000 individuals not in MSA's). The difference may reflect greater access to this medical procedure in urbanized areas but also may be due to sampling variation.

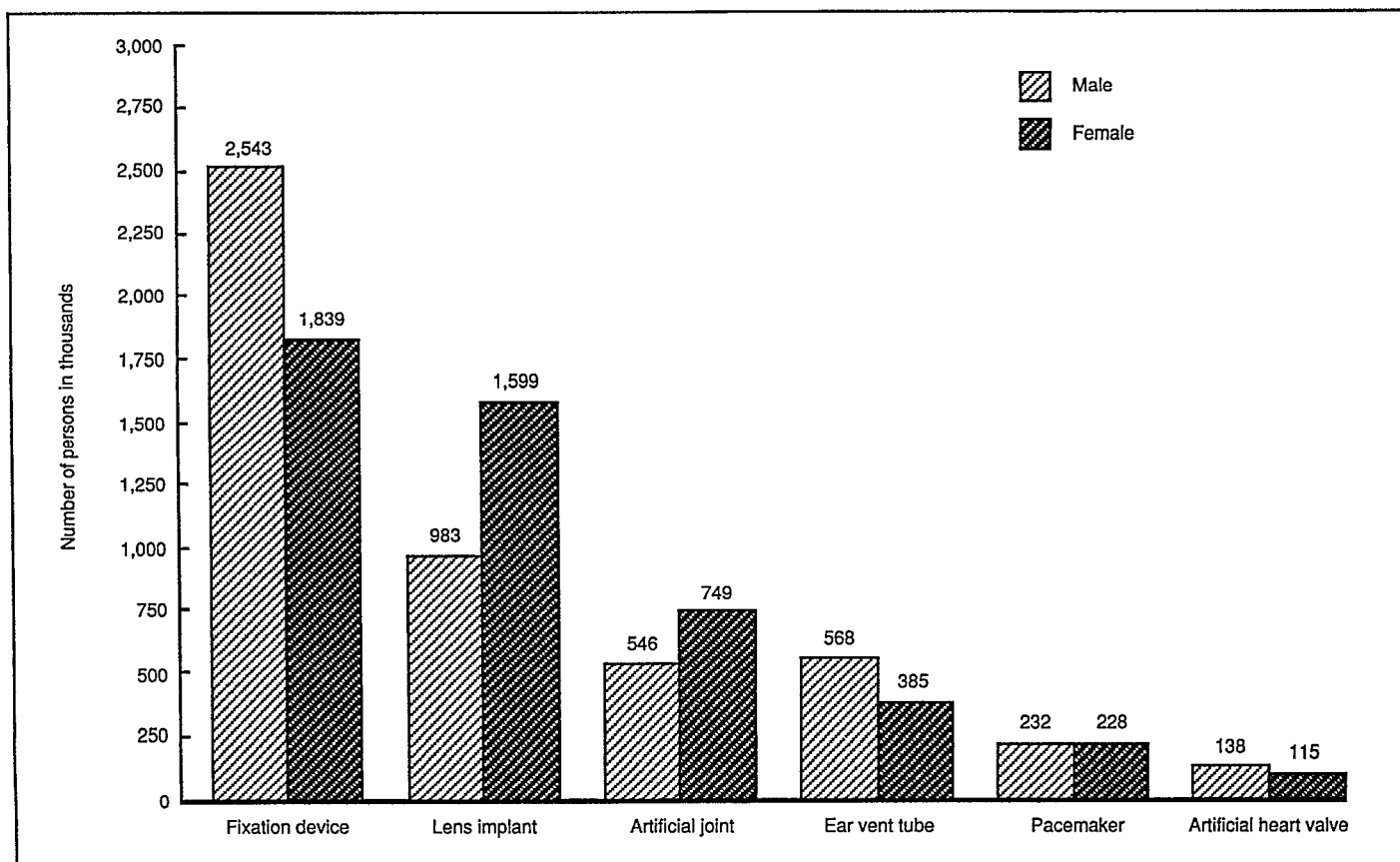


Figure 1. Number of persons with selected medical device implants, by sex: United States, 1988

Prevalence by age, sex, and race

In table 4, number and percent estimates are shown for several additional medical device implants, some by specified body site, that are not included in the other tables of this report. These data are distributed according to age, sex, and race. This table, as well as tables 5–13, differ from tables 2 and 3 in that the estimates are based on the number of implants reported rather than on the number of persons with implants.

About one-half of all reported artificial joints were hip joint replacements (816,000 implants) and another third (521,000) involved the knee. Similarly, over one-half of all fixation devices (about 2.7 million implants) were located in the lower extremities. The distributions of the estimates shown in table 4 according to age, sex, and race closely parallel the patterns found in table 3 for persons with these types of implants.

Women were the primary recipients of silicone implants, with breast implants leading the list of sites reported most frequently. Of the

estimated 620,000 silicone implants, almost 90 percent were breast implants, with about three-fourths of them implanted in women ages 18–44 years. Estimated numbers of silicone breast implants from other sources suggest that the MDI Survey figure may be an underestimate of the actual number of devices of this type.

Dental implants represented less than 2 percent of all medical devices in use in 1988. Based on estimates derived from the MDI Survey questionnaire, a somewhat higher proportion of dental implants was found in males and about 60 percent of dental implants were for persons under 45 years of age.

Length of time in use

Tables 5–10 present estimates that pertain to the interval of time different types of medical devices currently in use have been implanted. About 270,000 of the 1.6 million artificial joints currently in use were obtained within the past year, and about one-half of all artificial joints were implanted 5 years ago or more

(table 5). A somewhat higher proportion of artificial joints in persons 65 years and over were implanted within the past 12 months—19 percent compared with 12 percent of all joints implanted in younger individuals (0.10 level of significance).

Almost two-thirds of all reported fixation devices (62 percent) were implanted at least 5 years prior to the interview (table 6). Among the estimated 193,000 devices of this type reported among children, however, about 30 percent were implanted within the year. With fixation devices, men were somewhat more likely to have had their implant for a minimum of 5 years than were women, 66 percent compared with 57 percent.

The relatively small number of artificial heart valves and pacemakers upon which the estimates in tables 7 and 8 are based limits the type of comparisons that can be made. Of the estimated 279,000 heart valve implants currently in use, over one-half were implanted 5 years ago or more and 90 percent were in use for at least 1 year. Of the estimated 460,000

pacemakers reported, about 75,000 were implanted during the 12-month period preceding the interview.

About one-fifth of all reported intraocular lens implants, an estimated 840,000 devices, were obtained within the past year (table 9). Among white persons, about 22 percent of all lens implants were obtained during the past 12 months. In contrast, about 44 percent of lens implants obtained by black persons were implanted during the same period. This finding may reflect a different usage pattern for intraocular lens implants between these two population groups. Similar distributions, however, were found for most of the other sociodemographic characteristics shown in this table.

Unlike most other medical device implants, ear vent tubes are commonly implanted for temporary conditions and are usually removed once the problem is corrected. Consequently, percent estimates of the length of time this type of device has been in use, shown in table 10, vary considerably from similar figures for the other types of implants described in this report.

About 45 percent of all ear vent tubes, 670,000 devices, were implanted within the past year. Only 9 percent of all such devices were implanted 5 years ago or more, and the vast majority of these were for adult users. Specifically, about one out of three ear vent tubes for persons 18 years of age and over (38.5 percent) were implanted this length of time.

Estimates of the overall length of time ear vent tubes were in use were similar (or within sampling variation) for most of the other sociodemographic groups shown in table 10. Note, however, that about one-half of the ear vent tubes implanted in persons from the South were in use for less than 1 year, a somewhat higher proportion than estimated for the other geographic regions (0.10 level of significance).

Implant replacement

The MDI Survey questionnaire contained a number of items about the replacement experience associated with different types of medical device

implants. For each implant reported, questions were asked to determine whether the device had ever been replaced and, if so, the total number of replacements obtained. Data on the reason(s) for replacement and the length of time implanted before replacement were also collected about the most recent replacement. Reliable estimates cannot, however, be produced for many of these items because of the relatively small number of replacements reported for some types of medical devices.

Overall, of an estimated 15 million medical device implants in use during 1988, about 8.8 percent (1.3 million) were replaced at least one time. Given the diversity of medical device implants and their unique uses, all estimates about replacements presented in this report are shown by type of implant. Specifically, table 11 shows percent estimates of implants that were never replaced by selected sociodemographic variables for the following types of medical device implants: ear vent tubes, fixation devices, artificial joints, artificial heart valves, pacemakers, and lens implants.

These data demonstrate that the vast majority of medical device implants in use have never been replaced—from 69 percent of ear vent tubes to 99 percent of lens implants. Although a greater proportion of ear vent tubes than other types of devices were replaced, these replacements are often the result of a recurrence of a specific health problem. In contrast, replacements involving other types of implants are usually because of some problem with the device itself. Most likely to have had an ear vent tube replacement were non-Hispanic white children 6–17 years of age living in the Northeast and Midwest Regions of the country. (Age and geographic region differences tested at the 0.10 level of significance.)

About 95 percent of all fixation device implants were never replaced or repaired. The risk of replacement or repair for this type of device was inversely related to the person's age, with 93 percent of implants for persons under 45 years of age not replaced, compared with 97 percent

not replaced among persons 65 years of age and over. Although specific estimates of replacement reasons are not provided in this analysis, the most frequently reported reasons for replacement or repair of fixation devices reported by respondents included breakage, loosening, and defects.

Ninety-two percent of artificial joints were never replaced. The Northeast Region had a greater proportion of joint replacements than elsewhere, with 85 percent not requiring replacement versus 94 percent for the other regions of the country (0.10 level of significance).

The likelihood of replacement was somewhat greater for pacemakers than for most of the other types of medical device implants identified in this table. About 16 percent of all pacemakers (72,000 devices) were replaced at least one time. Although not specifically shown in table 11, about 60 percent of them lasted for 5 years or more before they were replaced. Risk of pacemaker replacement was about the same regardless of age, sex, or race.

Problems with implants

The MDI Survey questionnaire also included an extensive set of questions about various kinds of problems sometimes experienced with medical device implants. In addition to questions to identify the kinds of problems encountered with each device, it also contained questions to identify when the problem was first noticed (that is, less than 30 days, 30–90 days, or more than 90 days from the date of implantation).

A different set of problems was used for each type of medical device implant listed on the questionnaire. Even though the problems varied somewhat depending upon the implant, there were similarities in the kinds of problems specified for all devices, such as pain (other than discomfort generally associated with surgery and healing), healing problems, defects or failure, infection, bleeding, or blood clots. One open-ended question about other problems or complications was also included for each type of device.

Because the kinds of problems reported among the respondents varied greatly in severity, the estimates of the percent of implants with one problem or more presented in this report reflect a wide range of experience. Furthermore, as with all information obtained in NHIS, the types of problems reported were only those known and identified by the respondent. These estimates, therefore, may be higher than estimates from other data sources.

Table 12 presents percent estimates of selected types of implants with one problem or more for a number of sociodemographic characteristics. Based on respondent reports from NHIS, it appears that problems occur with a significant number of implants. Depending upon the type of implant, 20–50 percent of all devices resulted in one problem or more. Problems were reported for about one-third of all ear vent tubes, fixation devices, and artificial joints. One out of five artificial heart valves, one out of four pacemakers, and one out of two lens implants also had complications associated with them.

For most types of implants, the most frequently reported problem related to pain. With lens implants, clouding or blurred vision was most often cited. The most common problem for persons with pacemakers was an irregular heartbeat.

A somewhat larger proportion of ear vent tubes (40 percent) caused problems in very young children (under 3 years of age) than among older individuals (0.10 level of significance). With fixation devices, in contrast, proportionately fewer problems were reported for persons in the youngest age group—22 percent under 18 years of age (0.10 level of significance). Among respondents with fixation devices, problems were reported most often by those with the least family income (43 percent) and least completed years of education (38 percent).

Problems were experienced with almost one-half of all artificial joints implanted in persons ages 18–44 years, compared with about one-third of similar implants for other persons.

Artificial joints were also more likely to result in problems among men (37 percent) than women (28 percent). Lens implants were somewhat more likely to cause problems for persons under 65 years of age than for older individuals (0.10 level of significance), but no percent differences in reporting problems were found by sex or race for this type of device.

Reason for original implant

Table 13 contains estimates of the original reason(s) for implantation of five kinds of medical devices: artificial joints, fixation devices, intraocular lens implants, ear vent tubes, and dental implants. The specific reason categories shown in this table appeared on the questionnaire and were used by the interviewers to record the respondent's responses to the question "Why did you need to get the (type of implant) in the first place?" This questionnaire procedure should be considered when assessing the responses. In addition, some device categories such as dental implants show a large proportion of "other" reasons for the original implant. Interviewers appear to have recorded some responses in the "other" reason category when, in fact, the reason may have been one of the specific categories listed on the questionnaire.

According to respondent reports, almost one-half of all artificial joints were implanted because of arthritis. The second leading cause of joint replacements, about one-quarter of all such implants, related to injuries. Injuries also accounted for the majority of fixation devices that were reported. About 70 percent of all fixation devices, 3.4 million implants, resulted from injuries. Injuries were also reported as the cause of about one-fourth of all dental implants.

Almost all lens implants were attributed to the presence of cataracts. Of the estimated 3.8 million lens implants in use during 1988, 94 percent were said to be caused by this condition. Infection was cited as the leading cause of ear vent tube

implants, with 71 percent (about 1 million devices) the result of this reported reason.

Health status of persons with implants

Two NHIS health measures are included in this report to assess the overall health of persons with medical device implants: limitation of activity because of chronic conditions and respondent-assessed health status.

The limitation-of-activity categories are used to classify persons by their ability to perform the major activity most often associated with healthy persons their age and their ability to participate in other activities. Major activities include normal play activities for young children, attending regular school for older children, working and/or keeping house for adults, and performing daily activities associated with independent living for senior citizens. Assessed health status is determined by the respondent's opinion of each family member's overall health as reported when asked the question "Would you say _____'s health is excellent, very good, good, fair, or poor?"

Table 14 shows estimates of all persons and persons with selected types of medical device implants according to the two NHIS health measures described. Data are aggregated according to two broad age groups because measures of overall health and medical device implants are highly correlated with age.

Compared with the general population, persons with implants are more likely to be limited in their ability to perform their major and other activities and to be assessed in fair or poor health. Specifically, about 44 percent of persons with one medical device implant or more were limited, compared with about 14 percent of the U.S. population. When estimates are further compared by age, persons with implants who were under 65 years of age were almost four times as likely to report an activity limitation as other persons of similar age. Among the age group 65 years and over, the implant

population was about 1½ times as likely to be limited, 52 compared with 37 percent. Similar ratios between the estimates for these two population groups were also found for the two separate activity-limitation categories shown in table 14.

The percent of the implant population reporting an activity limitation also differed according to the type of medical device. Of persons under 65 years of age with a medical device implant, proportionately about twice as many persons with an artificial heart valve as persons with a fixation device reported an activity limitation (74 compared with 39 percent). Among older persons with medical device implants, those with lens implants were the least likely to report an activity limitation.

The likelihood of being assessed in fair or poor health was almost three times greater for persons with a medical device implant as it was for the U.S. population. An estimated 10 percent of all persons in the United States were in fair or poor health, compared with about 27 percent of the implant population. Among older persons, differences in the percent of persons in fair or poor health for these two populations were not as great (29 and 37 percent in fair or poor health, respectively). Similarly, whereas about 71 percent of all U.S. persons 65 years of age and over were reported in excellent to good health, 61 to 65 percent of persons with various types of implants specified (except for the pacemaker population) were also assessed in this way.

Accordingly, based on these two health status measures, the relative overall health of persons with implants under the age of 65 years appears to be poorer (when compared with all persons of similar age) than for the older implant population.

Conclusion

Medical device implants are expected to become one of the most

promising areas of medicine in the next decade (19). Although there has been great progress in medical device implant technology, some devices are so new that no baseline data exist to evaluate them, and their effectiveness in future years is unknown. The data collected through the 1988 MDI Survey will serve as a valuable source of information for conducting clinical epidemiologic studies designed to identify risk factors associated with the implantation and replacement of medical devices in humans and for evaluating the long-term safety and effectiveness of these devices.

References

1. Balkin BE. Implant dentistry: Historical overview with current perspectives. *J Dent Ed* 52(12):683-5. 1988.
2. Madison A. Transplanted and artificial body organs. New York: Beaufort Books, Inc. 1981.
3. Freeman R, Gould F. Infection and prostheses. *Clin Mater* 3(4):265-71. 1988.
4. Haggag Y. Late complications of cardiac valve prostheses. *J Clin Eng* 14(1):69-76. 1989.
5. Greenspan A, Kay H, Berger B, et al. Incidence of unwarranted implantation of permanent cardiac pacemakers in a large medical population. *N Engl J Med* 318(3):158-63. 1988.
6. Cooney W, Beckenbaugh R, Linscheid R. Total wrist arthroplasty: Problems with implant failures. *Clin Orthop* (187):121-8. 1984.
7. National Institutes of Health. Intraocular lens implantation consensus development conference. Bethesda, Maryland: Sept 10-11, 1979.
8. National Institutes of Health. Dental implants consensus development conference. Bethesda, Maryland: June 13-15, 1988.
9. Kossovsky N, Snow R. Clinical-pathological analysis of failed central nervous system fluid shunts. *J Biomed Mater Res* 23(A1):73-86. 1989.
10. Finnegan M. The tissue response to internal fixation devices. *Crit Rev Biocompat* 5(1):1-10. 1989.
11. Hanker J, Giammara BL. Biomaterials and biomedical devices. *Science* 242(4880):885-92. 1988.
12. Gristina A. Biomaterial-centered infection: Microbial adhesion versus tissue integration. *Science* 237(4822):1588-95. 1987.
13. Code of Federal Regulations. Federal Food, Drug, and Cosmetic Act. Title 21, part 800. 1981.
14. Health Resources and Services Administration. Inventory of U.S. Health Care Data Bases, 1976-1987. Abstract Nos. 121 and 180. Washington: 1988.
15. Code of Federal Regulations. An overview of the medical device reporting regulation. Title 21, part 803. 1984.
16. Frost & Sullivan, Ltd. Medical prosthetic implants. Monograph 236. 1980.
17. Adams PF, Hardy AM. Current estimates from the National Health Interview Survey: United States, 1988. National Center for Health Statistics. *Vital Health Stat* 10(173). 1989.
18. Bloch B. The International Organization for Standardization technical committee on implants for surgery. *J Med Eng Technol* 8(4):170-6. 1984.
19. Louis Harris and Associates, Inc. The Bristol-Myers Report: Medicine in the next century. Study no 861018:183. New York. 1987.
20. Moss AJ, Parsons VL. Current estimates from the National Health Interview Survey: United States, 1985. National Center for Health Statistics. *Vital Health Stat* 10(160). 1986.
21. Kovar MG, Poe GS. The National Health Interview Survey design, 1973-84, and procedures, 1975-83. National Center for Health Statistics. *Vital Health Stat* 1(18). 1985.
22. Massey JT, Moore TF, Parsons VL, Tadros W. Design and estimation for the National Health Interview Survey, 1985-94. National Center for Health Statistics. *Vital Health Stat* 2(110). 1989.

Table 1. Percent of persons with 1 medical device implant or more, by selected types of implants and age: United States, 1988

<i>Type of implant and age</i>	<i>Percent of persons</i>
All persons with 1 implant or more	4.6
Artificial joint	
All ages	0.5
65 years and over	2.8
Fixation device	
All ages	1.8
65 years and over	3.5
Lens implant	
All ages	1.1
65 years and over	7.3
75 years and over	11.3
Pacemaker	
All ages	0.2
65 years and over	1.4
75 years and over	2.6
Artificial heart valve	
All ages	0.1
65 years and over	0.5
Ear vent tube	
All ages	0.4
Under 3 years	2.0
3–5 years	2.3

¹Includes all types of implants reported, such as artificial joints, fixation devices, artificial heart valves, intraocular lens implants, pacemakers, ear vent tubes, infusion pumps, dental implants, silicone implants, and artificial arteries, ligaments, and veins.

Table 2. Number and percent distribution of persons with 1 medical device implant or more by number of implants person now has of each type, according to selected types of implants: United States, 1988

Number of implants	All persons with 1 implant or more ¹	Type of implant					
		Artificial heart valve	Lens implant	Artificial joint	Fixation device ²	Ear vent tube	Silicone implant
Number of persons in thousands							
Total	11,051	253	2,582	1,294	4,382	953	381
1 implant.	7,659	230	1,399	1,013	3,933	411	144
2 implants	2,982	*22	1,183	251	398	542	235
3 implants or more.	409	*1	—	*30	51	—	*2
Percent distribution							
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1 implant.	69.3	90.9	54.2	78.3	89.8	43.1	37.8
2 implants	27.0	*8.7	45.8	19.4	9.1	56.9	61.7
3 implants or more.	3.7	*0.4	—	*2.3	1.2	—	*0.5

¹Includes all types of implants reported, such as artificial joints, fixation devices, artificial heart valves, intraocular lens implants, pacemakers, ear vent tubes, infusion pumps, dental implants, silicone implants, and artificial arteries, ligaments, and veins.

²Number of fixation device implants refers to the number of body sites containing the devices, such as pins, screws, plates, wires, or rods, that were implanted. It is not the actual number of such devices implanted in a particular body part.

Table 3. Number and percent distribution of persons with selected types of medical device implants by selected sociodemographic characteristics: United States, 1988

Characteristic	Ear vent tube	Fixation device	Artificial joint	Artificial heart valve	Pacemaker	Lens implant	Ear vent tube	Fixation device	Artificial joint	Artificial heart valve	Pacemaker	Lens implant
	Number of persons in thousands						Percent distribution					
All persons ¹	953	4,382	1,294	253	460	2,582	100.0	100.0	100.0	100.0	100.0	100.0
Age												
Under 3 years	222	23.3
3-5 years	250	26.2
6-17 years	328	34.4
18 years and over	152	15.9
Under 18 years	173	3.9
18-44 years	1,932	44.1
45-64 years	1,264	28.8
65 years and over	1,013	23.1
Under 45 years	180	*33	13.9	*13.0
45-64 years	311	88	24.0	34.8
65 years and over	804	132	62.1	52.2
Under 65 years	62	502	13.5	19.4
65-74 years	113	819	24.6	31.7
75 years and over	286	1,261	62.2	48.8
Sex												
Male	568	2,543	546	138	232	983	59.6	58.0	42.2	54.5	50.4	38.1
Female	385	1,839	749	115	228	1,599	40.4	42.0	57.9	45.5	49.6	61.9
Race												
White	890	4,015	1,193	231	431	2,457	93.4	91.6	92.2	91.3	93.7	95.2
Black	48	295	82	*20	*24	102	5.0	6.7	6.3	*7.9	*5.2	4.0
Hispanic origin												
Non-Hispanic	903	4,194	1,256	252	447	2,526	94.8	95.7	97.1	99.6	97.2	97.8
Hispanic	49	187	*39	*2	*13	56	5.1	4.3	*3.0	*0.8	*2.8	2.2
Family income												
Less than \$15,000	167	1,073	452	48	187	975	17.5	24.5	34.9	19.0	40.7	37.8
\$15,000-\$34,999	345	1,664	406	98	121	800	36.2	38.0	31.4	38.7	26.3	31.0
\$35,000 or more	345	1,126	225	57	46	339	36.2	25.7	17.4	22.5	10.0	13.1
Poverty status												
In poverty	132	434	114	*15	51	208	13.9	9.9	8.8	*5.9	11.1	8.1
Not in poverty	784	3,647	1,052	199	327	2,048	82.3	83.2	81.3	78.7	71.1	79.3
Education												
Less than 12 years	96	1,080	504	71	233	1,106	10.1	24.6	38.9	28.1	50.7	42.8
12 years	370	1,733	433	117	141	793	38.8	39.5	33.5	46.2	30.7	30.7
13 years or more	485	1,541	356	61	83	667	50.9	35.2	27.5	24.1	18.0	25.8
Geographic region												
Northeast	128	683	250	47	92	466	13.4	15.6	19.3	18.6	20.0	18.0
Midwest	329	1,193	372	84	128	709	34.5	27.2	28.7	33.2	27.8	27.5
South	353	1,528	443	81	156	918	37.0	34.9	34.2	32.0	33.9	35.6
West	142	977	229	41	84	489	14.9	22.3	17.7	16.2	18.3	18.9
Place of residence												
MSA	694	3,165	909	206	350	1,836	72.8	72.2	70.2	81.4	76.1	71.1
Central city	249	1,225	354	100	159	800	26.1	28.0	27.4	39.5	34.6	31.0
Outside central city	445	1,940	555	106	191	1,036	46.7	44.3	42.9	41.9	41.5	40.1
Not MSA	259	1,217	386	48	110	746	27.2	27.8	29.8	19.0	23.9	28.9

¹Includes all other races, unknown family income, unknown poverty status, and unknown education.

NOTES: Poverty status is determined in the National Health Interview Survey by family size, number of children, and family income using 1987 poverty levels defined by the U.S. Bureau of the Census. MSA is metropolitan statistical area.

Table 4. Number of selected types of medical device implants and percent distribution by age, sex, and race, according to type and location of implant: United States, 1988

Type and location of implant	Number of implants in thousands	Total ¹	Age				Sex		Race	
			Under 18 years	18–44 years	45–64 years	65 years and over	Male	Female	White	Black
			Percent distribution							
All artificial joints ²	1,625	100.0	*0.6	13.0	24.6	61.7	39.9	60.1	92.3	6.2
Hip joint	816	100.0	*0.5	6.5	26.3	66.7	37.5	62.4	93.5	5.5
Knee joint	521	100.0	—	10.9	20.5	68.5	41.8	58.2	88.1	10.0
All fixation devices ^{2,3}	4,890	100.0	3.9	44.3	28.4	23.4	57.2	42.8	91.7	6.6
Head	351	100.0	*4.3	67.8	22.8	*5.4	57.3	42.7	93.2	*4.8
Torso	563	100.0	*5.3	49.6	31.8	13.3	62.7	37.5	92.2	*6.9
Upper extremity	646	100.0	*3.7	55.9	25.4	15.0	70.4	29.7	91.6	*5.6
Lower extremity	2,690	100.0	3.0	39.6	27.9	29.4	52.8	47.2	91.1	7.7
Other site	622	100.0	*6.4	34.4	34.1	25.1	57.9	42.1	93.6	*3.7
All silicone implants ²	620	100.0	*0.5	73.1	23.7	*2.9	8.2	91.8	97.6	*0.8
Breast implant	544	100.0	*0.6	73.0	24.1	*2.6	*2.0	98.0	98.5	—
Shunt or catheter	321	100.0	24.3	24.3	22.1	29.3	50.5	49.2	85.7	*12.5
Dental implant.	275	100.0	*2.2	57.8	27.3	*12.7	56.4	43.6	93.8	*4.0

¹Includes all other races.²Includes all and unknown sites.³Each fixation device represents a single body site, regardless of the number of pins, screws, plates, wires, rods, clips, or nails that were used to hold or fasten it in a fixed position.

Table 5. Number of artificial joints and percent distribution by length of time in use of current joint, according to selected sociodemographic characteristics: United States, 1988

Characteristic	Number of joints in thousands	Total ¹	Length of time in use		
			Less than 1 year	1–4 years	5 years or more
Percent distribution					
All joints ²	1,625	100.0	16.6	34.8	48.6
Age					
Under 45 years	222	100.0	*5.6	31.0	63.5
45–64 years	400	100.0	15.8	40.6	43.3
65 years and over	1,003	100.0	19.3	33.3	47.4
Sex					
Male.	649	100.0	15.6	34.9	49.5
Female	976	100.0	17.3	34.8	48.0
Race					
White	1,500	100.0	16.8	34.7	48.5
Black	100	100.0	*15.0	*40.0	*46.3
Hispanic origin					
Non-Hispanic	1,566	100.0	16.7	34.8	48.5
Hispanic	58	100.0	*12.8	*34.0	*53.2
Family income					
Less than \$15,000	562	100.0	13.5	35.6	50.7
\$15,000–\$34,999	513	100.0	19.1	32.1	48.5
\$35,000 or more	281	100.0	18.5	37.0	44.5
Poverty status					
In poverty	140	100.0	*7.4	34.7	57.9
Not in poverty.	1,320	100.0	17.2	35.2	47.7
Education					
Less than 12 years	645	100.0	19.5	31.2	49.2
12 years	533	100.0	16.0	36.8	47.1
13 years or more.	444	100.0	13.3	37.0	49.8
Geographic region					
Northeast	308	100.0	*11.5	35.1	53.5
Midwest	467	100.0	18.2	32.9	49.0
South	556	100.0	21.1	33.6	45.3
West	293	100.0	*10.9	40.1	48.6
Place of residence					
MSA.	1,150	100.0	14.1	34.1	51.8
Central city	421	100.0	11.9	33.1	54.8
Outside central city	730	100.0	15.2	34.7	50.2
Not MSA	474	100.0	22.8	36.5	40.7

¹Excludes artificial joints with unknown length of time in use.²Includes all other races, unknown family income, unknown poverty status, and unknown education.

NOTES: Poverty status is determined in the National Health Interview Survey by family size, number of children, and family income using 1987 poverty levels defined by the U.S. Bureau of the Census. MSA is metropolitan statistical area.

Table 6. Number of fixation devices and percent distribution by length of time in use of current device, according to selected sociodemographic characteristics: United States, 1988

Characteristic	Number of devices in thousands	Total ¹	Length of time in use		
			Less than 1 year	1–4 years	5 years or more
Percent distribution					
All devices ²	4,890	100.0	12.9	24.9	62.2
Age					
Under 18 years	193	100.0	30.8	43.4	25.3
18–44 years	2,168	100.0	12.6	23.6	63.8
45–64 years	1,388	100.0	10.3	21.8	67.8
65 years and over	1,142	100.0	13.4	27.9	58.7
Sex					
Male.	2,799	100.0	11.3	22.7	66.0
Female	2,092	100.0	15.0	27.8	57.2
Race					
White	4,486	100.0	13.1	25.0	62.0
Black	322	100.0	*10.8	21.2	68.1
Hispanic origin					
Non-Hispanic	4,683	100.0	12.9	25.3	61.8
Hispanic	208	100.0	*13.2	*16.3	70.5
Family income					
Less than \$15,000	1,220	100.0	12.1	25.7	62.3
\$15,000–\$34,999.	1,870	100.0	12.6	23.8	63.5
\$35,000 or more	1,208	100.0	10.8	27.1	62.1
Poverty status					
In poverty	487	100.0	13.6	28.9	57.5
Not in poverty.	4,057	100.0	12.2	24.7	63.0
Education					
Less than 12 years	1,206	100.0	14.7	23.9	61.4
12 years	1,942	100.0	13.6	25.3	61.1
13 years or more.	1,710	100.0	10.9	25.4	63.7
Geographic region					
Northeast	777	100.0	18.3	26.2	55.5
Midwest	1,340	100.0	10.5	27.2	62.3
South	1,680	100.0	13.7	22.1	64.3
West	1,093	100.0	10.8	25.7	63.5
Place of residence					
MSA.	3,534	100.0	13.0	25.3	61.7
Central city	1,387	100.0	12.8	25.9	61.4
Outside central city	2,148	100.0	13.2	24.9	61.9
Not MSA	1,356	100.0	12.7	24.0	63.4

¹Excludes fixation devices with unknown length of time in use.²Includes all other races, unknown family income, unknown poverty status, and unknown education.

NOTES: Number of fixation devices refers to the number of body sites containing the devices, such as pins, screws, plates, wires, or rods, that were implanted. It is not the actual number of such devices implanted in a particular body part. Poverty status is determined in the National Health Interview Survey by family size, number of children, and family income using 1987 poverty levels defined by the U.S. Bureau of the Census. MSA is metropolitan statistical area.

Table 7. Number of artificial heart valves and percent distribution by length of time in use of current valve, according to selected sociodemographic characteristics: United States, 1988

Characteristic	Number of valves in thousands	Total ¹	Length of time in use		
			Less than 1 year	1–4 years	5 years or more
Percent distribution					
All valves ²	279	100.0	*10.3	36.0	53.6
Age					
Under 45 years	41	100.0	*18.9	*54.1	*27.0
45–64 years	99	100.0	*4.0	*39.4	56.6
65 years and over	139	100.0	*12.8	28.0	59.2
Sex					
Male.	146	100.0	*5.9	39.7	55.1
Female	133	100.0	*16.0	*32.8	52.0
Race					
White	249	100.0	*9.1	35.5	55.4
Black	*28	100.0	*25.0	*35.7	*42.9
Hispanic origin					
Non-Hispanic	277	100.0	*10.4	35.8	53.8
Hispanic	*2	100.0	—	*100.0	—
Family income					
Less than \$15,000	55	100.0	*11.8	*33.3	*56.9
\$15,000–\$34,999	102	100.0	*7.0	*37.0	56.0
\$35,000 or more	66	100.0	—	*40.0	*60.0
Poverty status					
In poverty	*21	100.0	*10.5	*26.3	*63.2
Not in poverty.	215	100.0	*5.9	36.9	56.7
Education					
Less than 12 years	86	100.0	*12.2	*35.4	52.4
12 years	123	100.0	*12.0	*29.1	59.8
13 years or more.	67	100.0	*3.4	*50.0	*46.6
Geographic region					
Northeast	49	100.0	*10.6	*25.5	*63.8
Midwest	96	100.0	*6.5	*38.0	55.4
South	87	100.0	*16.0	*42.0	*42.0
West	48	100.0	*9.5	*33.3	*57.1
Place of residence					
MSA.	228	100.0	*10.4	38.2	51.4
Central city	109	100.0	*10.1	*40.4	48.5
Outside central city	119	100.0	*9.7	36.3	54.0
Not MSA.	51	100.0	*12.2	*26.5	*63.3

¹Excludes artificial heart valves with unknown length of time in use.²Includes all other races, unknown family income, unknown poverty status, and unknown education.

NOTES: Poverty status is determined in the National Health Interview Survey by family size, number of children, and family income using 1987 poverty levels defined by the U.S. Bureau of the Census. MSA is metropolitan statistical area.

Table 8. Number of pacemakers and percent distribution by length of time in use of current pacemaker, according to selected sociodemographic characteristics: United States, 1988

Characteristic	Number of pacemakers in thousands	Total ¹	Length of time in use		
			Less than 1 year	1–4 years	5 years or more
Percent distribution					
All pacemakers ²	460	100.0	16.3	45.9	38.0
Age					
Under 65 years	62	100.0	*14.5	*41.9	*41.9
65–74 years	113	100.0	*20.2	49.5	*30.3
75 years and over	286	100.0	14.9	44.9	39.9
Sex					
Male.	232	100.0	18.7	48.9	32.4
Female	228	100.0	*13.5	42.8	43.7
Race					
White	431	100.0	15.6	46.2	38.5
Black	*24	100.0	*34.8	*34.8	*30.4
Hispanic origin					
Non-Hispanic	447	100.0	16.9	45.0	38.3
Hispanic	*13	100.0	—	*71.2	*28.8
Family income					
Less than \$15,000	187	100.0	*18.0	47.5	34.4
\$15,000–\$34,999	121	100.0	*12.7	42.4	44.1
\$35,000 or more	46	100.0	*17.4	*47.8	*34.8
Poverty status					
In poverty	51	100.0	*29.4	*62.7	*7.8
Not in poverty.	327	100.0	13.2	43.8	42.9
Education					
Less than 12 years	233	100.0	*11.4	44.3	43.9
12 years	141	100.0	*20.4	46.7	33.6
13 years or more.	83	100.0	*22.8	*48.1	*30.4
Geographic region					
Northeast	92	100.0	*10.3	*46.0	*43.7
Midwest	128	100.0	*21.4	43.7	34.9
South	156	100.0	*16.3	47.1	36.6
West	84	100.0	*14.8	*46.9	*38.3
Place of residence					
MSA.	350	100.0	14.0	47.4	38.3
Central city	159	100.0	*13.8	48.4	37.7
Outside central city	191	100.0	*14.2	46.4	39.3
Not MSA	110	100.0	*22.9	40.0	*36.2

¹Excludes pacemakers with unknown length of time in use.²Includes all other races, unknown family income, unknown poverty status, and unknown education.

NOTES: Poverty status is determined in the National Health Interview Survey by family size, number of children, and family income using 1987 poverty levels defined by the U.S. Bureau of the Census. MSA is metropolitan statistical area.

Table 9. Number of Intraocular lens implants and percent distribution by length of time in use of current implant, according to selected sociodemographic characteristics: United States, 1988

Characteristic	Number of lens implants in thousands	Total ¹	Length of time in use		
			Less than 1 year	1–4 years	5 years or more
Percent distribution					
All lens Implants ²	3,765	100.0	22.3	54.8	22.9
Age					
Under 65 years	703	100.0	25.6	54.2	20.0
65–74 years	1,193	100.0	24.4	50.1	25.5
75 years and over	1,869	100.0	19.6	58.0	22.3
Sex					
Male.	1,415	100.0	21.6	53.8	24.6
Female	2,349	100.0	22.7	55.5	21.8
Race					
White	3,599	100.0	21.6	55.1	23.3
Black	131	100.0	44.0	42.4	*12.8
Hispanic origin					
Non-Hispanic	3,675	100.0	22.4	54.9	22.7
Hispanic	90	100.0	*18.5	51.9	*29.6
Family income					
Less than \$15,000	1,432	100.0	20.0	56.6	23.4
\$15,000–\$34,999	1,157	100.0	24.7	53.2	22.1
\$35,000 or more	486	100.0	22.9	57.0	20.0
Poverty status					
In poverty	302	100.0	20.2	54.6	25.5
Not in poverty.	2,987	100.0	22.6	55.2	22.2
Education					
Less than 12 years	1,621	100.0	21.4	55.9	22.8
12 years	1,164	100.0	21.1	53.1	25.8
13 years or more.	957	100.0	24.6	55.6	19.8
Geographic region					
Northeast	646	100.0	22.4	57.9	19.5
Midwest	1,049	100.0	22.5	51.2	26.3
South	1,334	100.0	24.4	54.8	20.8
West	736	100.0	18.0	57.2	24.6
Place of residence					
MSA.	2,687	100.0	21.8	56.4	21.8
Central city	1,185	100.0	21.1	55.1	23.8
Outside central city	1,501	100.0	22.3	57.4	20.3
Not MSA	1,078	100.0	23.5	51.0	25.5

¹Excludes lens implants with unknown length of time in use.²Includes all other races, unknown family income, unknown poverty status, and unknown education.

NOTES: Poverty status is determined in the National Health Interview Survey by family size, number of children, and family income using 1987 poverty levels defined by the U.S. Bureau of the Census. MSA is metropolitan statistical area.

Table 10. Number of ear vent tubes and percent distribution by length of time in use of current implant, according to selected sociodemographic characteristics: United States, 1988

Characteristic	Number of ear vent tubes in thousands	Total ¹	Length of time in use		
			Less than 1 year	1–4 years	5 years or more
Percent distribution					
All ear vent tubes ²	1,494	100.0	44.9	46.0	9.0
Age					
Under 3 years.	385	100.0	65.9	33.8	—
3–5 years	404	100.0	45.6	54.4	—
6–17 years.	517	100.0	35.6	53.1	11.4
18 years and over	188	100.0	28.0	33.0	38.5
Sex					
Male.	896	100.0	47.0	45.2	7.8
Female	599	100.0	42.0	47.3	10.9
Race					
White	1,400	100.0	45.0	46.7	8.3
Black	69	100.0	*47.5	*34.4	*18.0
Hispanic origin					
Non-Hispanic	1,413	100.0	45.2	46.3	8.5
Hispanic	82	100.0	*40.0	*41.3	*17.5
Family income					
Less than \$15,000	267	100.0	44.2	42.1	*13.6
\$15,000–\$34,999.	528	100.0	44.2	46.1	9.8
\$35,000 or more	556	100.0	45.3	50.6	*4.3
Poverty status					
In poverty	211	100.0	41.3	41.8	*17.3
Not in poverty.	1,231	100.0	45.5	46.9	7.5
Education					
Less than 12 years	151	100.0	35.2	50.0	*14.8
12 years	566	100.0	44.3	45.3	10.6
13 years or more.	775	100.0	47.2	45.8	6.9
Geographic region					
Northeast	196	100.0	34.1	56.1	*9.8
Midwest	505	100.0	44.7	43.5	11.8
South	568	100.0	51.4	42.8	*6.0
West	226	100.0	37.9	51.7	*10.3
Place of residence					
MSA.	1,087	100.0	44.0	47.0	8.9
Central city	387	100.0	45.8	43.0	*11.2
Outside central city	700	100.0	42.9	49.4	7.7
Not MSA	408	100.0	47.3	43.5	*9.5

¹Excludes ear vent tube implants with unknown length of time in use.²Includes all other races, unknown family income, unknown poverty status, and unknown education.

NOTES: Poverty status is determined in the National Health Interview Survey by family size, number of children, and family income using 1987 poverty levels defined by the U.S. Bureau of the Census. MSA is metropolitan statistical area.

Table 11. Percent of selected types of medical device implants never replaced, by selected sociodemographic characteristics: United States, 1988

Characteristic	Ear vent tube	Fixation device	Artificial joint	Artificial heart valve	Pacemaker	Lens implant
Percent of implants never replaced						
All Implants ¹	68.7	94.6	92.2	95.3	84.3	99.1
Age						
Under 3 years	90.6
3-5 years	67.7
6-17 years	54.7
18 years and over	64.7
Under 18 years	90.6	*100.0
18-44 years	93.3	93.1
45-64 years	94.9	90.9
65 years and over	97.2	92.5
Under 45 years	*92.7
45-64 years	94.9
65 years and over	96.4
Under 65 years	87.1	99.1
65-74 years	83.2	99.3
75 years and over	83.9	98.8
Sex						
Male	66.2	93.7	90.6	97.9	84.5	98.7
Female	72.6	95.7	93.3	92.5	84.6	99.3
Race						
White	67.3	94.6	92.8	95.1	84.7	99.2
Black	87.7	95.6	84.7	*96.4	*83.3	95.9
Hispanic origin						
Non-Hispanic	67.3	94.5	92.3	95.3	84.3	99.0
Hispanic	92.4	95.9	88.5	*100.0	*92.3	100.0
Family income						
Less than \$15,000	65.3	94.9	91.0	94.3	80.2	98.5
\$15,000-\$34,999	72.0	93.6	93.5	97.1	87.6	99.8
\$35,000 or more	67.6	96.0	92.3	98.5	89.1	99.0
Poverty status						
In poverty	67.3	93.9	91.4	*89.5	*76.5	98.6
Not in poverty	68.7	94.8	92.1	95.8	84.1	99.1
Education						
Less than 12 years	74.5	95.3	91.9	96.5	85.4	99.0
12 years	67.6	95.2	92.6	94.3	89.4	99.0
13 years or more	68.3	93.4	92.3	96.9	73.5	99.3
Geographic region						
Northeast	60.0	94.1	85.4	91.5	76.1	99.2
Midwest	64.3	94.7	95.2	92.7	86.7	98.4
South	73.6	94.1	93.9	96.6	87.2	99.6
West	73.5	95.6	91.1	100.0	84.5	98.6
Place of residence						
MSA	68.4	94.4	91.8	95.6	84.0	98.9
Central city	73.6	95.2	90.3	93.5	82.4	99.0
Outside central city	65.4	93.9	92.5	97.5	85.3	98.9
Not MSA	69.5	95.0	93.2	94.1	86.4	99.4

¹Includes all other races, unknown family income, unknown poverty status, and unknown education.

NOTES: Percents exclude implants with unknown number of times replaced. Poverty status is determined in the National Health Interview Survey by family size, number of children, and family income using 1987 poverty levels defined by the U.S. Bureau of the Census. MSA is metropolitan statistical area.

Table 12. Percent of selected types of medical device implants with 1 problem or more, by selected sociodemographic characteristics: United States, 1988

Characteristic	Type of implant ¹				
	Ear vent tube	Fixation device	Artificial joint	Lens implant	Pacemaker
	Percent of implants with 1 problem or more				
All implants ²	31.4	33.2	31.6	49.3	26.9
Age					
Under 3 years	40.2
3-5 years	29.6
6-17 years	25.9
18 years and over	32.6
Under 18 years	22.3	*33.3
18-44 years	36.1	46.6
45-64 years	33.7	32.4
65 years and over	29.1	28.2
Under 65 years	56.0	*20.7
65-74 years	46.1	*24.3
75 years and over	48.8	29.7
Sex					
Male	31.9	32.9	37.4	48.8	21.6
Female	30.5	33.7	27.7	49.7	32.5
Race					
White	31.2	32.9	30.6	49.4	26.4
Black	*43.1	34.9	*40.8	48.1	*19.0
Hispanic origin					
Non-Hispanic	31.6	33.2	31.6	49.3	27.3
Hispanic	*28.0	33.7	*32.7	*52.8	*15.4
Family income					
Less than \$15,000	33.6	42.7	32.9	51.1	30.3
\$15,000-\$34,999	31.7	31.6	26.1	45.3	*21.9
\$35,000 or more	28.7	27.1	36.8	50.6	*28.2
Poverty status					
In poverty	34.1	47.6	43.9	51.7	*22.0
Not in poverty	30.0	31.8	30.2	48.3	27.4
Education					
Less than 12 years	38.9	37.9	31.0	54.3	25.7
12 years	27.4	32.3	32.4	44.5	33.1
13 years or more	32.8	31.3	31.7	46.6	*21.1
Geographic region					
Northeast	29.5	32.1	29.1	52.4	*25.3
Midwest	35.1	33.1	28.3	45.5	*24.8
South	28.6	34.5	35.5	46.6	*27.1
West	32.1	32.3	32.4	57.1	*30.0
Place of residence					
MSA	29.5	32.8	30.4	48.4	28.0
Central city	27.9	34.6	31.4	47.7	27.0
Outside central city	30.1	31.7	29.9	49.0	29.1
Not MSA	36.6	34.3	34.5	51.5	*24.0

¹Detailed estimates for artificial heart valves are not shown because data are statistically unreliable as a result of small cell size. The percent of all artificial heart valve implants with 1 problem or more is 19.5.

²Excludes implants with unknown problems experienced. Includes all other races, unknown family income, unknown poverty status, and unknown education.

NOTES: Poverty status is determined in the National Health Interview Survey by family size, number of children, and family income using 1987 poverty levels defined by the U.S. Bureau of the Census. MSA is metropolitan statistical area.

Table 13. Number and percent distribution of selected types of medical device implants by reason for original implant: United States, 1988

<i>Type of implant and reason for original implant</i>	<i>Number of implants in thousands</i>	<i>Percent distribution of implants</i>
Artificial joint		
Total implants ¹	1,625	100.0
Arthritis ²	778	47.9
Osteoarthritis	246	15.1
Rheumatoid arthritis	190	11.7
Injury	460	28.3
Pain	135	8.3
Other	373	23.0
Fixation device		
Total implants ¹	4,890	100.0
Injury	3,362	68.8
Deformity	275	5.6
Cancer	*39	*0.8
Infection	*21	*0.4
Other	1,140	23.3
Intraocular lens implant		
Total implants ¹	3,765	100.0
Cataract	3,552	94.3
Injury	*26	*0.7
Other	166	4.4
Ear vent tube		
Total implants ¹	1,494	100.0
Infection	1,057	70.7
Injury	*4	*0.3
Other	474	31.7
Dental implant		
Total implants ¹	275	100.0
Injury	67	24.4
Infection	*15	*5.5
Other	194	70.5

¹Includes unknown reason.²Includes all arthritis, specified and unspecified.

NOTE: Percents may total more than 100.0 because some devices are implanted for multiple reasons.

Table 14. Total number of persons and number of persons with 1 medical device implant or more, and percent distribution by activity limitation and respondent-assessed health status, according to type of implant and age: United States, 1988

Age, activity limitation, and respondent-assessed health status	All persons	Persons with 1 implant or more ¹	Type of implant				
			Fixation device	Lens implant	Artificial joint	Pacemaker	Artificial heart valve
Number in thousands							
All ages	240,890	11,051	4,382	2,582	1,294	460	253
Under 65 years	212,207	6,617	3,369	502	490	62	121
65 years and over	28,683	4,434	1,013	2,080	804	398	132
Percent distribution							
All ages							
Activity limitation:							
All persons	100.0	100.0	100.0	100.0	100.0	100.0	100.0
No limitation	86.3	56.4	56.5	56.3	39.6	38.0	34.0
Limitation	13.7	43.6	43.4	43.7	60.5	62.0	66.0
Major activity	9.4	30.2	31.7	25.6	42.0	40.0	47.8
Other activities	4.3	13.3	11.7	18.1	18.5	21.7	18.2
Respondent-assessed health status:							
All persons ²	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Excellent to good	90.0	72.8	77.0	66.5	63.0	49.2	59.7
Fair or poor	10.0	27.2	23.0	33.6	37.0	50.8	40.3
Under 65 years							
Activity limitation:							
All persons	100.0	100.0	100.0	100.0	100.0	100.0	100.0
No limitation	89.4	61.8	61.2	58.6	38.8	*35.5	*25.6
Limitation	10.6	38.2	38.8	41.2	61.4	*64.5	74.4
Major activity	7.7	29.2	29.0	33.5	49.4	*50.0	61.2
Other activities	2.9	9.0	9.8	*7.8	12.0	*14.5	*13.2
Respondent-assessed health status:							
All persons ²	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Excellent to good	92.7	79.6	81.0	73.5	66.2	*51.6	58.7
Fair or poor	7.3	20.4	19.0	26.7	34.0	*48.4	41.3
65 years and over							
Activity limitation:							
All persons	100.0	100.0	100.0	100.0	100.0	100.0	100.0
No limitation	63.0	48.4	41.1	55.8	40.0	38.4	40.9
Limitation	37.0	51.6	58.9	44.2	60.0	61.6	59.1
Major activity	22.6	31.9	40.7	23.6	37.6	38.7	35.6
Other activities	14.4	19.7	18.3	20.6	22.4	22.9	*23.5
Respondent-assessed health status:							
All persons ²	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Excellent to good	70.6	62.7	63.7	64.8	61.2	48.9	61.4
Fair or poor	29.4	37.3	36.3	35.2	38.9	51.1	39.4

¹Includes all types of implants reported, such as artificial joints, fixation devices, artificial heart valves, intraocular lens implants, pacemakers, ear vent tubes, infusion pumps, dental implants, silicone implants, and artificial arteries, ligaments, and veins.²Excludes persons with unknown respondent-assessed health status.

**Table 15. Number of persons by selected sociodemographic characteristics:
United States, 1988**

<i>Characteristic</i>	<i>Number of persons in thousands</i>
Total ¹	240,890
Age	
Under 18 years	63,569
Under 3 years	11,122
3-5 years	10,826
6-17 years	41,621
18-44 years	103,066
45-64 years	45,573
65 years and over	28,683
65-74 years	17,565
75 years and over	11,118
18 years and over	177,320
Under 45 years	166,635
Under 65 years	212,207
Sex	
Male	116,657
Female	124,232
Race	
White	203,256
Black	29,382
Hispanic origin	
Non-Hispanic	221,386
Hispanic	19,504
Family income	
Less than \$15,000	47,514
\$15,000-\$34,999	82,664
\$35,000 or more	74,869
Poverty status	
In poverty	26,017
Not in poverty	195,466
Education²	
Less than 12 years	39,502
12 years	68,301
13 years or more	67,872
Geographic region	
Northeast	49,271
Midwest	59,543
South	82,278
West	49,797
Place of residence	
MSA	186,222
Central city	74,860
Outside central city	111,362
Not MSA	54,668

¹Includes all other races, unknown family income, unknown poverty status, and unknown education.²Persons 18 years and over.

NOTES: Poverty status is determined in the National Health Interview Survey by family size, number of children, and family income using 1987 poverty levels defined by the U.S. Bureau of the Census. MSA is metropolitan statistical area.

Technical notes

Source and description of data

This report contains data from the 1988 National Health Interview Survey (NHIS). NHIS is a continuing cross-sectional nationwide survey of the civilian noninstitutionalized population. Each week a probability sample of households in the United States is interviewed by personnel of the U.S. Bureau of the Census. Interviewers obtain information about the health and other characteristics of each household member included in the NHIS sample.

NHIS consists of two parts: (a) a basic health questionnaire that remains the same each year and is completed for every household member and (b) special topics questionnaires that vary from year to year, some of which may be completed only for selected persons in each family. In 1988, the special topics included medical device implants, alcohol, occupational health, child health, and acquired immunodeficiency syndrome (AIDS) knowledge and attitudes. These data sets can be linked to provide additional sources for analysis.

The total interviewed sample for 1988 for the basic health questionnaire consisted of 47,485 households containing 122,310 individuals. The total response rate for the basic questionnaire was 95 percent, or 5-percent nonresponse. Although all households in the NHIS sample were eligible to receive the Medical Device Implant (MDI) Survey questionnaire, an additional 3 percent of interviewed households did not complete the MDI Survey questionnaire.

The MDI Survey family-style questions were administered to the NHIS household respondent, and, in most cases, the person with the medical device responded to the detailed questions about each reported implant. The family-style questions on medical device implants were used to identify whether any family members had any of the following implants: artificial joints; surgically inserted pins, screws, nails, wires, rods, or plates;

artificial heart valves; intraocular lenses; silicone implants; pacemakers; ear vent tubes; infusion pumps; brain or spinal column shunts; any other type of surgically inserted shunt or catheter; or any other kind of surgically inserted medical device, such as artificial arteries and veins, ligaments, and dental implants.

For each device reported, additional information was obtained, including (but not limited to) date of implantation, reason for implant, status as an original or replacement implant, number of replacements, and any problems or complications experienced with the current implant, such as infection or pain.

The MDI Survey questionnaire underwent a number of major modifications during its development. One of the changes was based on findings from the pretest of the proposed 1988 NHIS questionnaire, conducted in Seattle, Washington, in June 1987. Pretest results showed that a disproportionately large number of fixation devices were being reported for the family-style question about "other" types of medical devices. Although a specific set of questions had not been planned for this type of medical device, following the pretest a separate section for fixation devices was developed.

These and subsequent changes affected the date that the MDI Survey questionnaire was implemented by NHIS. Only the initial MDI Survey family-style questions were finalized in time for their use at the beginning of calendar year 1988. As a result, detailed information about specific medical devices reported in NHIS in January and February was subsequently obtained by followup telephone interview. The complete MDI Survey questionnaire was implemented in March 1988 and remained a part of NHIS throughout the year.

Sampling errors

Because estimates shown in this report are based on a sample of the population rather than on the entire population, they are subject to

sampling error. When an estimate or the numerator or denominator of a percent is small, the sampling error may be relatively high. In addition, the complex sample design of NHIS has the effect of making the sampling errors larger than they would be had a simple random sample of equal size been used.

Approximate standard errors of the estimated percents in table 1 of this report may be calculated by using the formula

$$SE(p) = p \sqrt{0.0000307 + 3,640/x}$$

where p is the estimated percent and $x = py/100$ with y = the population denominator.

Approximate standard errors of the estimated numbers (x) in tables 2, 3, 14, and 15 (except for age, sex, and race for all persons when the standard error is assumed to be 0.0) may be calculated using the formula

$$SE(x) = \sqrt{0.0000307(x)^2 + 3,640(x)}$$

Approximate standard errors of the estimated percents in tables 2, 3, and 14 may be calculated using the formula

$$SE(p) = \sqrt{\frac{3,640(p)(100-p)}{y}}$$

where p is the estimated percent and y is the population denominator.

Approximate standard errors of the estimated numbers (X) in tables 4-10 and 13 may be calculated by using the formula

$$SE(X) = X \sqrt{0.0000307 + \frac{3,640}{x}}$$

where X is the number of implants and x is the number of persons with the specific type of implant, as found in table 3 (not the actual number of implants, as shown in these tables). For example, it is estimated that 1,625,000 artificial joints have been implanted (table 5). Using this formula, the standard error for the estimated number is

$$1,625,000 \sqrt{0.0000307 + \frac{3,640}{1,294,000}} = 87,000$$

(NOTE: The number of implants may be used as the population denominator (x) for those few types of implants for which the estimated number of persons with a device is not provided in this report—for example, dental implants.)

Approximate standard errors of the estimated percents (P) of implants in tables 4–13 may be calculated by using the formula

$$SE(P) = \sqrt{\frac{3,640(P)(100-P)}{y}}$$

where P is the estimated percent and y is the population denominator, which in this case is the total number of persons with that particular type of implant (as found in table 3). For example, it is estimated that 48.6 percent of all artificial joints have been implanted for 5 years or more (table 5). Using this formula, the standard error for the estimated percent is

$$\sqrt{\frac{3,640(48.6)(100-48.6)}{1,294,000}} = 2.65$$

(NOTE: The number of implants may be used as the population denominator (y) for those few types of implants for which the estimated number of persons with a device is not provided in this report—for example, dental implants.)

If x_1 and x_2 are two estimates, then the approximate standard error of the difference ($x_1 - x_2$) can be computed as follows:

$$\sqrt{SE(x_1)^2 + SE(x_2)^2 - 2r SE(x_1) SE(x_2)}$$

where $SE(x_1)$ and $SE(x_2)$ are computed using the appropriate formulas previously presented in this section and r is the correlation coefficient between x_1 and x_2 . Assuming $r = 0.0$ will result in an accurate standard error if the two

estimates are actually uncorrelated and will result in an overestimate of the standard error if the correlation is positive or an underestimate if the correlation is negative.

In this report, unless otherwise noted, a difference was considered statistically significant at the 5-percent level if the difference ($x_1 - x_2$) was at least twice as large as its standard error.

Definitions of terms

Medical device implant—Defined for the MDI Survey questionnaire as a device that is surgically implanted in the body by a physician or other health care provider to replace a body part or function and cannot be removed by the recipient. Excluded were removable limb prostheses; silicone injections; organ transplants, such as corneal transplants; natural bone, artery, and vein transplants; intrauterine devices (IUD's); and regular dentures, bridges, fillings, sealants, and other forms of dental work.

Artificial joint—A mechanical substitute for a diseased or painful joint in the body.

Fixation device—A medical device that is surgically placed in the body to hold or fasten a body part in a fixed position, such as screws, pins, nails, plates, clips, or wires.

Intraocular lens implant—An artificial lens that is surgically implanted in the eye.

Pacemaker—A medical device that is implanted in the body to regulate heart rhythm.

Artificial heart valve—A substitute valve that controls the flow of blood through the heart and/or aorta.

Ear vent tube—A tube that is placed in the ear drum (tympanic membrane) to create a passageway between the middle and outer ear.

Silicone implant—An implant of material used to enhance form or function of selected body sites; for example, breast or chin enlargements. Silicone injections are not included.

Catheter or shunt—A flexible tube implanted in the body for the introduction or withdrawal of fluids.

Dental implant—An artificial device or material used to promote bone regeneration around the teeth and jaws or to support a dental prosthesis. Root canals, sealants, fillings, crowns, and bridges are not considered dental implants.

Other types of medical devices—Include artificial blood vessels (manmade tubes or ducts used to carry blood in the body), artificial ligaments (substitutes used to connect bones and strengthen joints), artificial urinary sphincters (substitutes that aid the control of urine flow), and infusion pumps (mechanical pumps, fully or partially implanted, that introduce chemotherapeutic fluids into the body).

Related documentation

More detailed discussion of the sample design, estimating procedures, procedures for estimating standard errors, nonsampling errors, and definitions of other sociodemographic terms used in this report have been published in *Vital and Health Statistics*, Series 10, nos. 160 and 173; Series 1, no. 18; and Series 2, no. 110 (20, 17, 21, and 22, respectively).

A public use data file based on the 1988 MDI Survey questionnaire was released in April 1990.

Information regarding the purchase of the public use tape may be obtained by writing the Division of Health Interview Statistics, National Center for Health Statistics, 6525 Belcrest Road, Hyattsville, Maryland 20782.

Symbols

- - - Data not available
 - . . . Category not applicable
 - Quantity zero
 - 0.0 Quantity more than zero but less than 0.05
 - Z Quantity more than zero but less than 500 where numbers are rounded to thousands
 - * Figure does not meet standard of reliability or precision
 - # Figure suppressed to comply with confidentiality requirements
-

Suggested citation

Moss AJ, Hamburger S, Moore RM, et al. Use of selected medical device implants in the United States, 1988. Advance data from vital and health statistics; no 191. Hyattsville, Maryland: National Center for Health Statistics. 1990.

Copyright information

This report may be reprinted without further permission.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Center for Health Statistics
6525 Belcrest Road
Hyattsville, Maryland 20782

BULK RATE POSTAGE & FEES PAID PHS/NCHS PERMIT No. G-281
--

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, \$300

To receive this publication regularly, contact the National Center for Health Statistics by calling 301-436-8500

DHHS Publication No. (PHS) 91-1250