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ORIGINAL ARTICLE

Generalizability of Epidemiological Findings and Public Health Decisions: An Illustration From the Rochester Epidemiology Project

Jennifer L. St. Sauver, PhD, MPH; Brandon R. Grossardt, MS; Cynthia L. Leibson, PhD; Barbara P. Yawn, MD, MSc; L. Joseph Melton III, MD, MPH; and Walter A. Rocca, MD, MPH

Abstract

Objective: To illustrate the problem of generalizability of epidemiological findings derived from a single population using data from the Rochester Epidemiology Project and from the US Census.

Methods: We compared the characteristics of the Olmsted County, Minnesota, population with the characteristics of populations residing in the state of Minnesota, the Upper Midwest, and the entire United States.

Results: Age, sex, and ethnic characteristics of Olmsted County were similar to those of the state of Minnesota and the Upper Midwest from 1970 to 2000. However, Olmsted County was less ethnically diverse than the entire US population (90.3% vs 75.1% white), more highly educated (91.1% vs 80.4% high school graduates), and wealthier ($51,316 vs $41,994 median household income; 2000 US Census data). Age- and sex-specific mortality rates were similar for Olmsted County, the state of Minnesota, and the entire United States.

Conclusion: We provide an example of analyses and comparisons that may guide the generalization of epidemiological findings from a single population to other populations or to the entire United States.

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Most epidemiological studies in the United States, and in many other countries, are based on limited populations selected for convenience because of favorable historical, financial, or geographic circumstances. Unfortunately, the results from these selected populations can be extrapolated, or generalized, to other populations only through judgment.[1,2] This judgment is guided by similarities of the study population to other populations for demographic variables (eg, age and sex), ethnic variables (eg, inclusion of certain ethnic minorities), socioeconomic variables (eg, occupation and income), or other variables.

All types of epidemiological studies raise concerns about generalizability from the study sample to the target population and from the target population to other populations or to the entire United States. For example, randomized clinical trials are often considered the criterion standard clinical research design, and results from such trials are routinely adopted for clinical care of large populations. However, if the population that participated in the randomized trial differs from the population in which the intervention is applied, the generalizability of the trial results may be limited.[3] Similar problems also plague well-designed cohort studies and even studies using random samples of the US population. These types of studies rely on the voluntary participation of study subjects, and volunteers often differ from the target population. For example, the National Health and Nutrition Examination Survey was limited by low participation rates and by the exclusion of people living in institutions.[4] Even when all people residing in a well-defined population participate in a study, it remains unclear whether the findings can be extrapolated to another population or to the entire United States.

Studies that focus on the Olmsted County, Minnesota, population are less likely to suffer from problems associated with study participation, because they often rely on information collected passively through medical records. The Rochester Epidemiology Project (REP) links together the medical records of virtually the entire Olmsted County population, regardless of demographic or socioeconomic characteristics.[5,6] A small proportion of the population (approximately 4% to 5%) does not allow their medical records to be used for research.[5,6] However, with the exception of this small group of people, all the diseases and risk factors that are documented in medical records in this population can be captured and described.

Although studies that use the REP capture virtually the entire Olmsted County population, it is not always clear whether study results in this population are generalizable to populations outside of this county. For this study, we used data from the US Census to address differences and similarities

From the Division of Epidemiology (J.L.S., C.L.L., B.P.Y., L.J.M., W.A.R.), Division of Biomedical Statistics and Informatics (B.R.G.), Department of Neurology (W.A.R.), Mayo Clinic, Rochester, MN; and Department of Research, Olmsted Medical Center, Rochester, MN (B.P.Y.).

across populations. In particular, we provide details about the demographic, ethnic, and socioeconomic characteristics of Olmsted County, Minnesota, and compare them with characteristics of the state of Minnesota, the Upper Midwest, and the US white and entire US populations. In addition, we compare age- and sex-specific patterns of mortality across these populations. These data provide an example of analyses and comparisons that may guide the generalization of epidemiological findings from a single population to other populations or to the entire United States.

METHODS

Sources of Data and Description of the Olmsted County Population

The REP medical records linkage system was initiated in 1966 to study disease epidemiology and patterns of health care among the residents of Olmsted County.[5,6] For more than 45 years, the REP has supported hundreds of studies of virtually all major diseases and has yielded more than 2000 publications.[7] Details on the history of the REP and on the methods involved in linking medical records across health care providers in Olmsted County have been published elsewhere.[5,6] In this report, we address the generalizability of studies conducted in Olmsted County using the REP. In particular, we used 2 distinct sources of demographic data: (1) data obtained from the US Census and (2) data obtained from local schools. The US Census data were available at the county, state, regional, and national levels, whereas the school data were limited to Olmsted County.

We compared demographic, ethnic, and socioeconomic characteristics across 5 populations: Olmsted County, the state of Minnesota, the Upper Midwest, US whites (including both Hispanics and non-Hispanics), and the entire United States. The Upper Midwest was defined as the 5-state region including Minnesota, Wisconsin, Iowa, North Dakota, and South Dakota. Each broader geographic region included the smaller regions (eg, the state of Minnesota also included Olmsted County).

Population changes in Olmsted County for specific age groups were obtained by using the following formula: number of individuals at each time point minus the number of individuals in 1970, divided by the number of individuals in 1970 (percent change since 1970). Population pyramids were then used to explore changes in the age and sex structure of the population between 1970 and 2008.[8] Data for 2008 were obtained from publicly available projections.[9]

Comparison of Olmsted County With Other Populations

To determine how the Olmsted County population has compared with the state of Minnesota, the Upper Midwest, US whites, and the entire United States over the years, data were compiled from the 1970, 1980, 1990, and 2000 US censuses.[10-15] Because the data were nonstochastic in nature, statistical testing was not performed and confidence intervals were not provided.[8]

We used school data to describe changes in race and ethnic distributions among children subsequent to the 2000 US Census. Data on the race and ethnicity of children enrolled in the Rochester, MN, school district between 2000 and 2009 were obtained from the Rochester Public Schools (Independent School District No. 535; the city of Rochester is the Olmsted County seat).

Comparison of Mortality Rates

Age- and sex-specific mortality rates for the Olmsted County population were compared with corresponding rates for the state of Minnesota and the entire United States in 2000 (last available US Census data). Mortality curves for Olmsted County were derived from publicly available data from the Minnesota Center for Health Statistics[16] using the smoothing methods described elsewhere.[17] In particular, Olmsted County population counts and number of deaths for the years 1997 through 2003 (7 calendar years centered on the year 2000) were used to ensure more stable estimates for the younger ages. Mortality data for the state of Minnesota were obtained from the Minnesota State Demographic Center,[18] and data for the United States were obtained from the US life tables.[19] Mortality rates were defined as the probability of dying within 1 year of a given reference age (noted as q_x in standard life tables)[8] and were displayed on a logarithmic scale to magnify differences in mortality early in life.

This research was approved by the Mayo Clinic Institutional Review Board and the Olmsted Medical Center Institutional Review Board. The need for informed consent was waived for this study.

RESULTS

Description of the Olmsted County Population

Between 1970 and 2008, the population of Olmsted County increased from 84,104 to 141,360 individuals (a 68.1% overall increase). The percentage increase varied by age and was greatest in the older age groups (a 225.2% increase among persons 80 years of age and older compared with a 12.9% increase in persons 0 to 19 years old; Figure S1, Supplemental Material, available online at http://www.

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mayoclinicproceedings.org). The effect of these changes on the composition of the population is reflected in the changing shape of population pyramids over time (Figure 1). In particular, children composed the largest proportion of the Olmsted County population in 1970; however, that distribution has gradually shifted over time, and the proportion of individuals across the age groups has become similar from birth through age 59 years, tapering to smaller proportions in the oldest ages (stationary population).[20] The proportion of females in the population has varied only slightly, from 52.6% of the population in 1970 to 50.4% in 2008.

Comparisons Across Olmsted County, the State of Minnesota, the Upper Midwest, US Whites, and the Entire United States

Figure 2 includes 3 segments: (1) a map indicating the 4 levels of geographic comparison; (2) 3 population pyramids comparing the age and sex distribution in Olmsted County (red-cross profile) with that in the state of Minnesota, the Upper Midwest, and the entire United States at the 2000 US Census; and (3) bar graphs comparing ethnic and socioeconomic characteristics at the 2000 US Census. At the 2000 US Census, the Olmsted County population of 124,277 persons represented 2.5% of the total Minnesota population (4,919,479 persons) and 0.9% of the Upper Midwest population (14,606,522 persons; Table 1). In turn, the Upper Midwest population of 14,606,522 persons represented 5.2% of the total US population (281,421,906 persons). Historically, the population of Olmsted County has resembled that of the state of Minnesota and the Upper Midwest with respect to age, sex, and ethnicity. The proportion of men and the median age of Olmsted County residents were similar to those of Minnesota and the Upper Midwest from census years 1970 to 2000 (Table 1 and Figure 2). The age and sex distributions of Olmsted County residents also resembled those of the entire US population (Table 1 and Figure 2). In addition, Olmsted County residents were

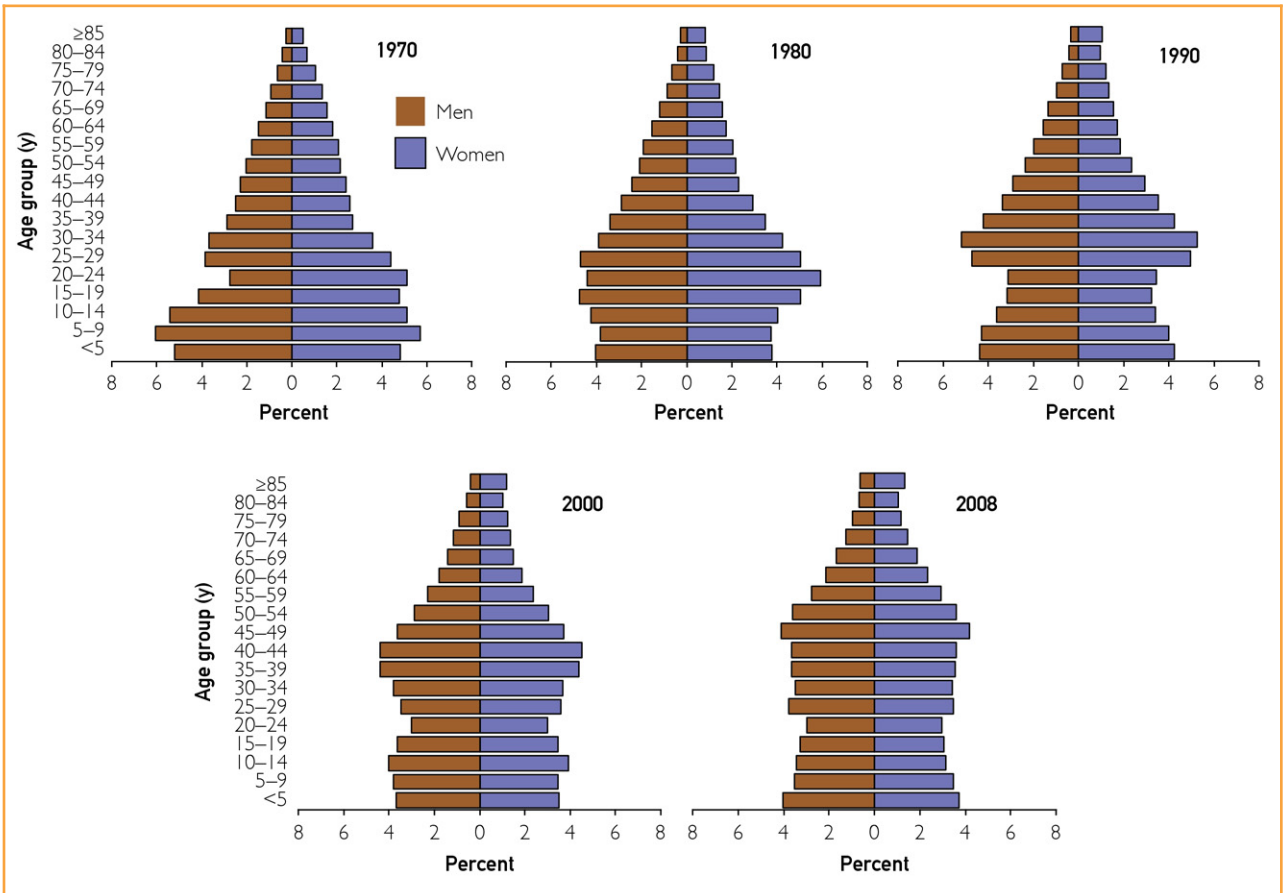

FIGURE 1. Population pyramids for Olmsted County, Minnesota, from 1970 to 2008. This figure is based on publicly available US Census data.

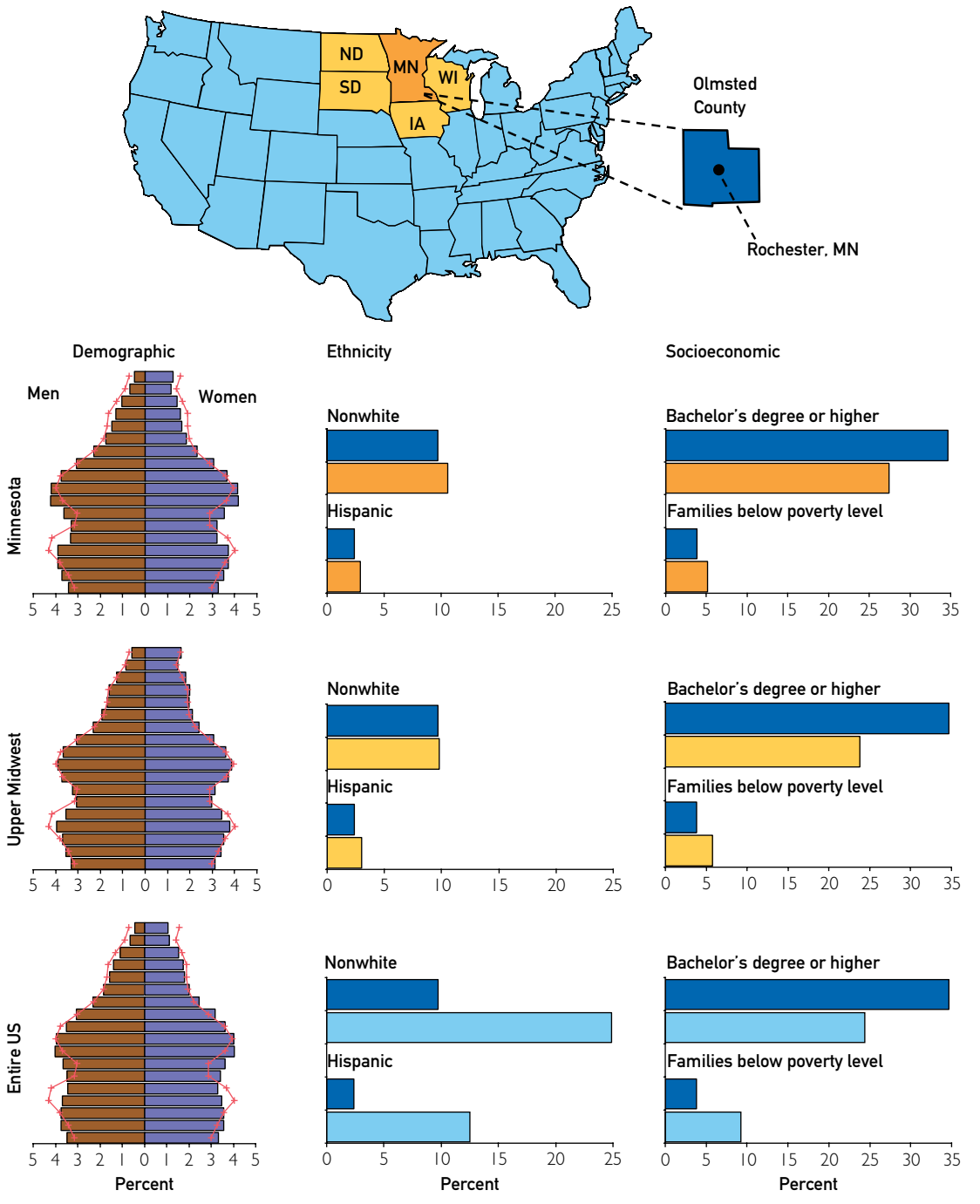

FIGURE 2. Top, a geographic map of the 4 regions that were compared in this study: Olmsted County, the state of Minnesota, the Upper Midwest, and the entire US. At the 2000 US Census, the Olmsted County population of 124,277 persons represented 2.5% of the total Minnesota population (4,919,479 persons) and 0.9% of the Upper Midwest population (14,606,522 persons). In turn, the Upper Midwest population of 14,606,522 persons represented 5.2% of the total US population (281,421,906 persons).
Bottom, 3 population pyramids comparing Olmsted County (red-cross profile) with the population of Minnesota, the Upper Midwest, and the entire United States. For the pyramids, we used 5-year age groups (see also Figure 1). The bar graphs compare the 4 study populations for ethnicity and socioeconomic indicators (bars are color-coded as per the top geographic map). This figure is based on publicly available US Census data.

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TABLE 1. Demographic, Ethnic, and Socioeconomic Characteristics of Olmsted County, MN, the State of Minnesota, the Upper Midwest, the US White Population, and the Entire US Population in 1970 and 2000

Year, characteristics	Olmsted County, Minnesota	Minnesota	Upper Midwest[a]	US white	US total
1970 total population	84,104	3,804,971	12,330,346	177,748,975	203,211,926
Demographic characteristics					
Age ≥18 y (%)	62.3	63.7	64.2	66.8	65.7
Age ≥65 y (%)	8.6	10.7	11.1	10.3	9.9
Median age (y)	25.5	26.8	27.3	28.9	28.1
Men (%)	47.4	49.0	49.0	48.8	48.7
Ethnic characteristics					
White (%)	99.1	98.2	97.4	–	87.5
Black or African American (%)	0.3	0.9	1.6	–	11.1
American Indian/Alaska Native (%)	<0.1	0.6	0.7	–	0.4
Asian/Native Hawaiian/Pacific Islander (%)	0.4	0.2	0.1	–	0.7
Other race (%)	0.1	0.1	0.1	–	0.3
Two or more races (%)	–	–	–	–	–
Hispanic or Latino (%)	0.5	0.6	0.7	–	3.8
Socioeconomic characteristics					
High school or higher (%)	70.2	57.6	56.2	54.5	52.3
Bachelor's degree or higher (%)	18.0	11.1	9.9	11.3	10.7
Median household income ($)	10,972	9931	9535	9961	9590
Families below poverty level (%)	5.4	8.2	8.7	8.6	10.7
Individuals below poverty level (%)	8.2	10.7	11.3	10.9	13.7
2000 total population	124,277	4,919,479	14,606,522	211,460,626	281,421,906
Demographic characteristics					
Age ≥18 y (%)	73.0	73.8	74.3	76.5	74.3
Age ≥65 y (%)	10.8	12.1	13.3	14.4	12.4
Median age (y)	35.0	35.4	35.9	37.7	35.3
Men (%)	49.1	49.5	49.4	49.1	49.1
Ethnic characteristics					
White (%)	90.3	89.4	90.2	–	75.1
Black or African American (%)	2.7	3.5	3.7	–	12.3
American Indian/Alaska Native (%)	0.3	1.1	1.4	–	0.9
Asian/Native Hawaiian/Pacific Islander (%)	4.3	2.9	1.9	–	3.7
Other race (%)	0.9	1.3	1.3	–	5.5
Two or more races (%)	1.5	1.7	1.4	–	2.4
Hispanic or Latino (%)	2.4	2.9	3.0	–	12.5
Socioeconomic characteristics					
High school or higher (%)	91.1	87.9	86.2	83.6	80.4
Bachelor's degree or higher (%)	34.7	27.4	23.8	26.1	24.4
Median household income ($)	51,316	47,111	43,200	43,916	41,994
Families below poverty level (%)	3.8	5.1	5.8	7.8	9.2
Individuals below poverty level (%)	6.4	7.9	8.9	9.5	12.4

[a]The Upper Midwest included Minnesota, Wisconsin, Iowa, North Dakota, and South Dakota.

ethnically similar to residents of Minnesota and of the Upper Midwest; all 3 populations have been predominantly white, and they have differed from the entire United States (Table 1 and Figure 2). In 1970, the Olmsted County population was 99.1% white, shifting gradually to 90.3% white in 2000. In contrast, the US population was 87.5% white in 1970 and 75.1% white in 2000. These differences reflect relatively lower numbers of black and Hispanic residents in Olmsted County (Table 1 and Figure 2).

Even though the Olmsted County population as a whole is less ethnically diverse than the US population, the children residing in Olmsted County are becoming increasingly diverse. Between 2000 and 2009, the proportion of children from an ethnic minority background enrolled in the Rochester public school district (the largest school district in Olmsted County) grew from 18.7% to 29.3%. The black population increased from 7.0% in 2000 to 11.8% in 2009, and the Hispanic population increased from 2.9% in 2000 to 7.3% in 2009 (Table 2).

Olmsted County residents are more highly educated compared with residents of Minnesota, the Upper Midwest, and the total United States (Table 1). In 1970, 70.2% of Olmsted County residents were high school graduates compared with 57.6% of Minnesota, 56.2% of Upper Midwest, and 52.3% of US residents. The gap has narrowed over the years, and 91.1% of Olmsted County residents were high school graduates in 2000 compared with 87.9% of Minnesota, 86.2% of Upper Midwest, and 80.4% of US residents. In 2000, 34.7% of Olmsted County residents had a bachelor's degree or higher compared with 27.4% of Minnesota, 23.8% of Upper Midwest, and 24.4% of US residents. Higher educational attainment has also corresponded with higher median household incomes and lower poverty levels among Olmsted County residents (Table 1 and Figure 2). The socioeconomic characteristics of the Olmsted County population more closely resembled the US white population than the total US population; however, Olmsted County has consistently had a higher educational level, higher median income, and lower poverty level than even the US white population (Table 1).

Comparison of Mortality Rates

The pattern of mortality rates by age and sex was remarkably similar for Olmsted County, the state of Minnesota, and the entire United States in 2000 (Figure 3). For all 3 regions, a relatively higher infant mortality was followed by a minimum in mortality in the first decade of life and by a marked increase around adolescence; mortality around age 20 years was higher in men than women in all 3 populations. Between the ages of 20 years and 60 years, the residents of Olmsted County and overall Minnesota had a somewhat lower mortality compared with the entire United States, but the 3 curves were similar past the age of 60 years, when mortality was highest (Figure 3).

DISCUSSION

Extrapolations of findings from studies conducted in selected populations must be judged on a study-by-study basis.[1,2] These extrapolations should take into account the specific demographic, ethnic, or socioeconomic characteristics of the populations being compared, as well as the likely association of these characteristics with the specific disease of interest.[1,2] In this article, we compared the demo-

TABLE 2. Ethnic Characteristics of Children Enrolled in Public Schools in the City of Rochester, MN, from 2000 through 2009

	Total children enrolled	American Indian		Asian		Black		Hispanic		White		Total nonwhite	
Year	N	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
2000	16,087	48	(0.3)	1369	(8.5)	1123	(7.0)	472	(2.9)	13,075	(81.3)	3012	(18.7)
2001	16,123	60	(0.4)	1359	(8.4)	1374	(8.5)	555	(3.4)	12,775	(79.2)	3348	(20.8)
2002	16,387	64	(0.4)	1390	(8.5)	1477	(9.0)	623	(3.8)	12,833	(78.3)	3554	(21.7)
2003	16,447	60	(0.4)	1377	(8.4)	1611	(9.8)	750	(4.6)	12,649	(76.9)	3798	(23.1)
2004	16,310	59	(0.4)	1412	(8.7)	1679	(10.3)	806	(4.9)	12,354	(75.7)	3956	(24.3)
2005	16,109	72	(0.4)	1399	(8.7)	1640	(10.2)	907	(5.6)	12,091	(75.1)	4018	(24.9)
2006	16,381	71	(0.4)	1438	(8.8)	1812	(11.1)	1022	(6.2)	12,038	(73.5)	4343	(26.5)
2007	16,330	67	(0.4)	1511	(9.3)	1820	(11.1)	1072	(6.6)	11,860	(72.6)	4470	(27.4)
2008	16,352	68	(0.4)	1567	(9.6)	1875	(11.5)	1125	(6.9)	11,717	(71.7)	4635	(28.3)
2009	16,385	57	(0.3)	1629	(9.9)	1927	(11.8)	1190	(7.3)	11,582	(70.7)	4803	(29.3)

Data from the Rochester Public Schools (Independent School District No. 535).

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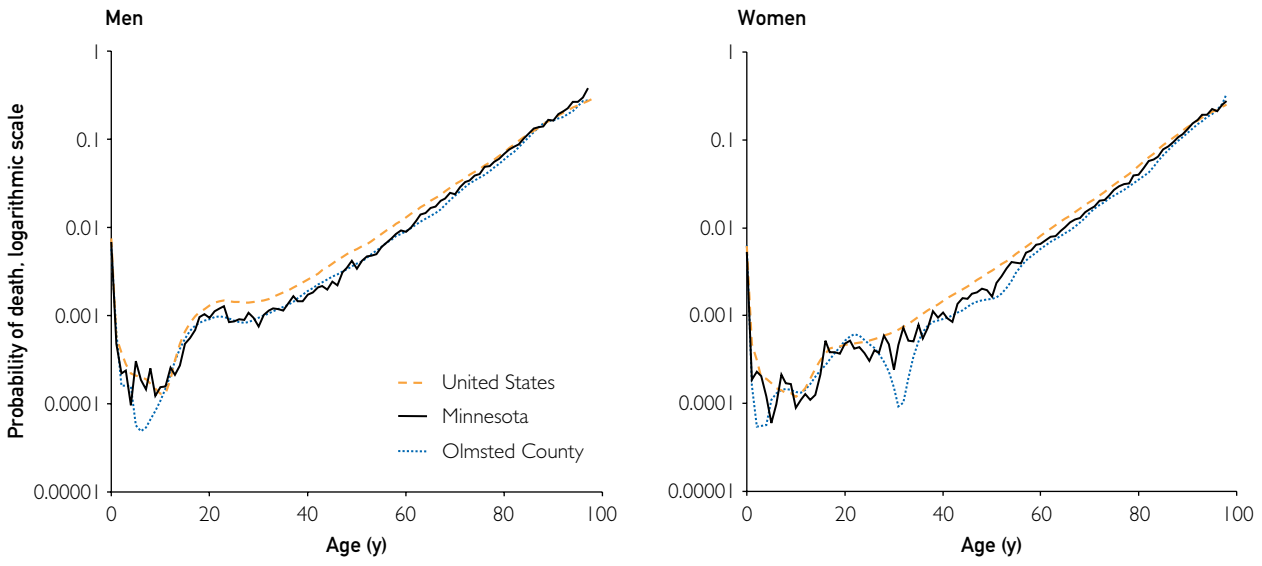

FIGURE 3. Age- and sex-specific mortality rates for Olmsted County, the state of Minnesota, and the entire United States in 2000 displayed using a logarithmic scale. Mortality rates were computed as the probability of dying within 1 year of a given reference age (q_x in standard life tables notation). This figure is based on published data from the National Center for Health Statistics (United States), the Minnesota State Demographic Center (Minnesota), and the Minnesota Center for Health Statistics (Olmsted County).

graphic and socioeconomic characteristics and the mortality rates in the Olmsted County population with those in the rest of the United States. These data provide a framework for investigators attempting to determine whether the results of a study in this population may be generalizable to other populations.

The age, sex, and ethnic characteristics of Olmsted County residents were similar to those of the state of Minnesota and the Upper Midwest. In addition, mortality rates of Olmsted County residents were similar to those of Minnesota and the entire United States. However, Olmsted County residents have been less ethnically diverse and have had a higher socioeconomic status than the overall US population. Therefore, Olmsted County is not completely representative of the entire United States, and judgment is necessary when generalizing study results from this community to other populations, especially for diseases or conditions that have strong ethnic or socioeconomic determinants.[21,22]

However, we emphasize that no single community in the United States is completely representative of the entire United States, neither rural counties of Nebraska or Oregon nor metropolitan areas such as New York or Los Angeles.[1,2] Therefore, with the exception of national surveys specifically designed to represent the entire US population via stratified random sampling across multiple geographic areas, no specific geographic unit can claim any superior level of representativeness. For example, the Framingham Heart Study has provided fundamental evidence in cardiovascular epidemiology, yet Framingham is a small Italian-American community selected for its proximity to Boston.[23,24] The original Framingham cohort consisted of 5127 white participants between 30 and 59 years of age.[25] Despite these characteristics, Framingham has contributed essential information to the epidemiology of cardiovascular disease.

Other well-known community cohorts, such as those in Tecumseh, MI,[26] and Muscatine, IA,[27] have provided important data on medical conditions ranging from childhood risk factors for heart disease to rotavirus transmission to breast cancer.[28-33] However, these populations were chosen for their proximity to the University of Michigan and the University of Iowa, respectively, not because they were thought to be representative of the entire US population.

Lack of representativeness is also a limitation of studies from specific health care systems, such as Kaiser Permanente[34] (California and Oregon) or the Group Health Cooperative[35] of Puget Sound (Washington State and Idaho). These plans provide passive access to diagnoses and procedures for thousands of patients[36-38]; however, the samples do not provide complete coverage of a geographically defined population, may overrepresent persons who are employed, and may exclude care given in the

community but outside the health plan.[39,40] In addition, members of the plan often change insurers over time.[37,41-44] Finally, because participants in these health maintenance organizations are employed, they may be systematically healthier than the general population (or less healthy, depending on occupation).

Generalizations from Olmsted County Epidemiological Studies

Results from studies in Olmsted County have generally been consistent with national data, where available. For example, the annual incidence of hip fractures for persons aged 50 years and older was 386 per 100,000 in Olmsted County from 1999 to 2001[45] compared with 391 per 100,000 in US whites in 2001.[46] Likewise, the decrease in heart disease mortality among Olmsted County residents parallels the trends seen nationally between 1979 and 1994.[47] Incidence rates of breast cancer and multiple myeloma and changes in mortality rates of prostate cancer in Olmsted County are also similar to those observed in other US populations.[48-50] The mortality data presented here also showed similar patterns by age and sex compared with the state of Minnesota and the entire United States.

In their 1983 article on epidemiological surveys, Anderson and Mantel[1] quote the REP as an example of how medical research is preferentially conducted in certain populations because of favorable historical, financial, or geographic circumstances. They also mention that a long tradition of conducting studies in a single population creates an accumulation of data that may allow investigators to build a new study at little additional cost. Data collected as outcomes for one study may provide exposure data for another study or may be used as comparison data for yet another study. This study-to-study synergistic amplification may facilitate new projects and reduce costs.[1]

The Issue of Ethnic Diversity

Limited ethnic diversity has been viewed as a weakness of some Olmsted County studies. Olmsted County was almost 90% white at the 2000 US Census, but there has been an influx of populations from around the world in the last decade. This change is most noticeable in the younger age groups so that almost 30% of Rochester schoolchildren were nonwhite in 2009. The largest minority group among children enrolled in the Rochester school district during 2009 was black, reflecting the continuing growth of the Somali immigrant population.[51] These shifts in ethnicity among younger Olmsted County residents are important for future studies and will be reflected in the 2010 US Census. However, Olmsted County residents, particularly in the older age groups, are still predominantly white and, overall, are more highly educated than the rest of the US population. These characteristics may make it more difficult to study diseases that are strongly influenced by ethnicity, because the Olmsted County population may not have a large enough sample size to study rare conditions in these populations.

On the other hand, we agree with several authors that race defined by skin color or by continent of origin is not a useful variable for epidemiological studies.[21,22,52] The marked genetic heterogeneity shown within racial groups such as "blacks," "whites," or "Hispanics" explains why these labels have been abandoned in social sciences such as anthropology and should be abandoned in medicine.[52,53] Culturally-based concepts of ethnicity that reflect language of origin, religion, diet, education, income, and lifestyle are likely better markers of risk and prognostic factors than the broad concept of race, as defined by skin color or continent of origin.

Limited minority representation has been recognized in many US studies, and studies which focus specifically on underrepresented minorities may be important. However, even these types of studies are likely to encounter problems of generalizability. For example, the Jackson Heart Study was designed to study cardiovascular disease risk factors in a large African American population residing in Jackson, MS. Difficulties in recruitment led to an overrepresentation of women and older adults in the study sample.[54] In addition, it is unclear whether the participants in this study as a whole are broadly representative of the larger US African American population.

If ethnic or socioeconomic characteristics are important for specific disease etiologies or outcomes, care must be taken when attempting to generalize results of Olmsted County studies. In such cases, conducting subanalyses restricted to persons with specific socioeconomic or demographic characteristics is desirable. For example, if socioeconomic status plays an important role in the onset and progression of a particular disease, investigators should repeat their overall analyses in subgroups with differing socioeconomic characteristics. These types of analyses are possible in Olmsted County, because virtually all of the health care in the entire population is captured, regardless of race/ethnicity, insurance status, or socioeconomic status.[5,6] Subgroup analyses in populations with different ethnic or socioeconomic characteristics may therefore provide important information about how these characteristics influence disease onset and outcomes. Some research has been conducted in the Olmsted County population to develop new surrogate mea-

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sures of socioeconomic status to be used for stratification or for adjustment in statistical analyses.[55,56]

CONCLUSION

Extrapolations and generalizations from studies in any single selected population must be judged on a study-by-study basis and should consider specific demographic or socioeconomic variables relevant to the study question. We provide an example of analyses and comparisons that may guide the generalization of epidemiological findings from a single population to other populations or to the entire United States. Epidemiological findings from any single population are best used when compared with findings from other populations in the United States or worldwide to investigate geographic similarities or differences in disease patterns. Data derived from several populations selected because of favorable historical, financial, or geographic circumstances, or because they were judged to represent the ethnic or socioeconomic characteristics of a larger reference population, may be the only data available. In the absence of more general data, findings from these single populations can be used to guide our decisions in clinical practice or in public health.

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SUPPLEMENTAL ONLINE MATERIAL

Supplemental material can be found online at http://www.mayoclinicproceedings.org.

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Correspondence: Address to Walter A. Rocca, MD, MPH, Division of Epidemiology, Mayo Clinic, 200 First St SW, Rochester, MN (rocca@mayo.edu).

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