

Inclusion of Women in Nursing Research: 1995–2001

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[Crane, P.](#), [Letvak, S.](#), [Lewallen, L.](#), [Hu, J.](#), [Jones, E.](#) (2004) Inclusion of women in nursing research. *Nursing Research*, 53(4), 237-242.

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Abstract:

Background: Although the inclusion of women in research has been examined in medical publications, little is known about how federal mandates have influenced the inclusion of women in research published in nursing journals.

Objective: This study aimed to examine the inclusion of women in published nursing research from 1995 to 2001, with a focus on the leading causes of mortality.

Method: All the articles in each journal were reviewed, and all the research articles that focused on the top 10 causes of death were sampled to measure the inclusion of women, the characteristics of the women included, the funding source, and the topic.

Results: Of the 1,149 studies reviewed, 139 met the inclusion criteria, and 117 of these studies included women. Only 15 of the studies reported the age of the women in their samples, and 10 of these included women between the ages of 35 and 64 years. The most frequently reported race was White ($n = 21$), followed by African American ($n = 17$), Hispanic ($n = 6$), and Asian ($n = 2$). There were no associations among year of publication ($p = .62$), federal funding ($p = .30$), and inclusion of women. Among the studies including women, heart disease was the most frequent topic ($n = 52$), followed by Alzheimer's disease ($n = 21$), cancer ($n = 14$), respiratory illness ($n = 14$), and diabetes ($n = 8$).

Discussion: Although the majority of the research included women, continuing efforts must be made to include sufficient numbers of women.

Article:

Women's health has received increased attention over the past two decades. Statistics indicate that women have higher mortality rates than men for heart disease, stroke, diabetes, influenza and pneumonia, and nephrotic disorders (U.S. Department of Health and Human Services [DHHS], 2002). Yet, even as late as the 1980s, few studies on these topics included women. This finding initiated a cascade of events, resulting in a law requiring federally funded researchers to include women in their studies unless strong evidence supported exclusion (U.S. Public Health Service, 1985).

Recently, Ramasubbu, Gurm, and Latiker (2001) examined the inclusion of women in studies published in *The New England Journal of Medicine* from 1994 to 1999. These authors reported

that women comprised only approximately 25% of the total sample population (n = 160,801). Similarly, a review by Harris and Douglas (2000) of the inclusion of women in studies funded by the National Heart, Lung, and Blood Institute from 1965 to 1998 showed that except for single-sex studies, there had been no change in the enrollment of women over time, and that women were underrepresented in heart studies. However, little is known about how federal mandates have influenced the inclusion of women in research published in nursing research journals. Therefore, this study examined the inclusion of women in research studies published in nursing journals from 1995 to 2001.

Background

Research focusing on women in the early 1970s and 1980s centered primarily on issues specific to women's biology such as menopause and childbirth. A task force on women's health found little research that included women. This lack of research resulted in a deficit of information on diseases affecting women's health.

After the task force report, the National Institutes of Health (NIH) issued a policy encouraging the inclusion of women in research supported by federal funds. In 1990, the Congressional Women's Caucus advocated for a review of this policy by the NIH to determine whether women were represented adequately in clinical trials. Thus, 4 years after the policy was issued, the General Accounting Office (GAO) reviewed the NIH policy and noted that very little had been done regarding implementation. This finding led ultimately to the legislative action that resulted in the Women's Health Equity Act of 1990 (Prout & Fish, 2001).

The NIH responded to the GAO report by creating the Office for Research on Women's Health to ensure that such research would be an integral part of NIH. In 1993, the policy encouraging the inclusion of women in research became law. The NIH Revitalization Act section on Women and Minorities as Subjects in Clinical Research became law requiring any federally funded study to include women and minorities unless there was convincing evidence why they should not be included (National Institutes of Health [NIH], 1994).

In 2001, the Policy and Guidelines on the Inclusion of Women and Minorities in Clinical Research was amended (NIH, 2001) to define clinical research as any patient-oriented research or research requiring interaction with human subjects. These guidelines were designed to ensure that clinical studies supported by federal funds would collect sufficient information about both sexes from diverse racial or ethnic groups to allow meaningful comparisons.

Examining the inclusion of women in federally funded studies yields different results. A study focusing on the inclusion of women among NIH-funded studies in selected medical journals in 1993, 1995, 1997, and 1998 (Vidaver, LaFleur, Tong, Bradshaw, & Marts, 2000) noted that approximately 20% of the NIH-funded research on non-sex-specific topics did not include women, and no significant change in the inclusion of women was noted from 1993 to 1998. Conversely, the NIH Tracking/Inclusion Committee (2000), developed to ensure adherence to the NIH Revitalization Act, reported that federally funded extramural studies, excluding sex-specific studies, enrolled 52% women and 46.6% men in 1997. The National Institutes of Health and the DHHS (2002) reported that such studies enrolled 45.9% women and 53.8% men in 1999, and 45.4% women and 54.2% men in 2000.

Federal support to foster research related to nursing practice and patient care was made available in 1986 with the establishment of the National Center for Nursing Research (NCNR). In 1993, the NCNR was awarded full institute status within the NIH, resulting in the creation of the National Institute of Nursing Research (NINR) (Table 1). The primary focus of the NINR is to improve patient care through nursing research. In 1988, the NCNR hosted a conference of 50 nurse scientists to determine the research priorities for nursing through 1994. Priorities were selected on the basis of the current knowledge, areas nursing can make a significant contribution, and the cost of healthcare problems (National Institute of Nursing Research [NINR], 1996).

Time	Description of Change
1986	NIH establishes policy encouraging the inclusion of women in research supported by federal funds
1986	National Center for Nursing Research (NCNR) established within the NIH
1988	NCNR hosts conference to determine the research priorities for nursing through 1994: (a) low birthweight: mother and infants; (b) HIV infection: prevention and care; (c) long-term care for older adults; (d) symptom management such as pain; (e) nursing informatics to enhance patient care; (f) health promotion for older children and adolescents; and (g) technology dependence across the life span
1990	Women's Health Equity Act
1992	Priorities were expanded also to include: (a) community based nursing models; (b) effectiveness of nursing interventions in HIV/AIDS in women; (c) preventing diabetes, obesity, hypertension, and cognitive impairment; (d) living with chronic illness; (e) families at risk for violence; and (f) biobehavioral factors related to immunocompetence (NINR, n.d.a)
1993	NIH Revitalization Act section, <i>Women and Minorities as Subjects in Clinical Research</i> , becomes law
1994	NIH Guideline stating that women and minorities must be included in clinical research supported by federal funds
2001	<i>Policy and Guidelines on the Inclusion of Women and Minorities in Clinical Research</i> was amended to require collection of sex/race data sufficient to allow comparisons to be made

TABLE 1. Timeline for Federal Policy Changes

Another agency that has influenced the focus of research is the Centers for Disease Control (CDC, 2001), which annually reports the top 10 causes of adult death in the United States. This report has influenced the development of the Healthy People objectives (DHHS, 2000). Over the past decade, the only major changes occurred in 1997, when human immunodeficiency virus (HIV) infection was replaced by nephrotic diseases, and liver disease was replaced by septicemia. The top 10 causes of mortality also include heart disease, cancer, stroke, chronic lower respiratory disease, accidents, diabetes, influenza/pneumonia, and Alzheimer's disease (CDC, 2001).

The report enumerating the top 10 causes of death has had a direct impact on nursing and resource utilization. For example, congestive heart failure, a component of heart disease, has been the leading discharge diagnosis, and therefore one of the most frequent conditions affecting patients under nursing care in the acute care setting. Furthermore, the annual cost for heart disease alone is more than \$200 billion (American Heart Association [AHA], 2001). Research should focus on diseases related to the leading causes of mortality to decrease mortality and healthcare costs.

Including women in research and reporting results by sex are important because recent studies indicate that sex differences exist (Gan et al., 1999; Riedinger, Dracup, Brecht, Padilla, & Sarna, 2001). A report from the Institute of Medicine (2001) supports the importance of exploring sex differences to understand human biology, and thus, to improve health. The amended NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

(NIH, 2001) provide guidelines for analyzing data and reporting findings by sex. In fact, the NIH and the Society for Women's Health Research encourage authors to provide a statement regarding sex-based analysis in all publications (NIH, 2001). Additionally, including the characteristics of women, such as race and age, in published research provides important information for research utilization. The race of women also is important to report because of the varied races in the population (U.S. Census Bureau, 2002), the documented differences in health behaviors according to race (Evangelista, Dracup, & Doering, 2002), and the disparities in health indicators between Whites and racial/ethnic minorities (AHA, 2001; CDC, 2001). The focus of Healthy People 2010 is on reducing health disparities and improving quality and years of life (DHHS, 2000). The inclusion of minority women and the consistent reporting of the sex, race, and age of participants in published studies is needed for the design of interventions to reduce health disparities and meet the goals of Healthy People 2010.

With the enactment of the Women and Minorities as Subjects in Clinical Research law in 1993, projected increases in the inclusion of women should occur in proposals funded after this date. Considering the time delays from proposal submission, funding, and study completion to subsequent dissemination, the earliest changes in the literature were expected in 1998. Examination of nursing research published 3 years before 1998 would allow for comparisons over time.

Therefore, the purpose of this study was to examine the inclusion of women in published nursing research from 1995 to 2001 focusing on the leading causes of mortality. The following research questions were asked: Did the NIH Revitalization Act influence the inclusion of women in published research articles that focused on the top 10 causes of death from 1995 to 2001? What were the characteristics of women included in nursing research from 1995 to 2001? and What variables were associated with the inclusion of women in these studies?

Methods

Sample

Research articles from five leading nursing research journals were sampled from 1995 to 2001. Using Swanson, McCloskey, and Bodensteiner's (1991) list of journals publishing the greatest majority of nursing research, four journals were selected: Nursing Research, Research in Nursing and Health, Western Journal of Nursing Research, and Applied Nursing Research. An additional journal, the Journal of Nursing Scholarship, was added because this journal also has published research and is considered one of the top nursing research publications.

The inclusion criteria required reports of original research published between 1995 and 2001 from the five designated journals, research with either the topic of study or subject selection related to one of the top 10 causes of death, studies that used human subjects, subjects who were adults 18 years of age or older, and studies conducted in the United States. Studies of caregivers for individuals with one of the diseases related to the top 10 causes of death also were included. All studies on reproductive issues or sex-specific cancers and instrumentation studies were excluded.

Procedure and Data Analysis

The researchers used Cooper's (1982) guidelines for conducting integrative research reviews. A standardized form was developed to collect data from the journals. Using this standardized form, each investigator reviewed all the articles in one issue of one journal among the five selected research journals. After this review, the team met to check interrater reliability. The standardized form then was revised and piloted. The revised form yielded a 100% agreement and was used for all subsequent data collection. All research articles published from 1995 to 2001 in the five journals were reviewed using this form. The research team met regularly to discuss issues related to data collection. All issues were discussed until consensus was reached.

The following variables were measured: inclusion of women, characteristics of women (age and race), funding source, and topic. The inclusion of women was recorded as the absolute number or percentage of women in the sample reported in the text of the article. The characteristics of women were recorded as the age and race of women reported in the text of the article. Funding was defined as notation of support either within the text of the article or in the author acknowledgment notes. Studies reporting funding by the Veteran's Administration were coded to denote federal funding. Studies reporting more than one funding source were coded to denote a combination of funding. The topic was coded as one of the top 10 causes of death. If the sample included subjects with more than one disease among the top 10 causes of death, the study was coded for the highest ranked cause of death. For example, if a study had subjects with acute renal failure and myocardial infarction, the study was coded to denote heart disease, the number one cause of death (CDC, 2001).

All data were coded by the investigators, then entered and analyzed using the Statistical Program for Social Sciences (SPSS) version 11.0. To check validity, 10% of the articles in each journal were randomly selected and reviewed to ensure that the number of women in each study matched the number in the original article, and that the data entered were identical to the data on the form.

Results

Sample

Of the 1,149 studies reviewed, 139 met the inclusion criteria (Table 2). Nursing Research had the most articles ($n = 41$) addressing the top 10 causes of death, followed by Research in Nursing and Health ($n = 39$), Applied Nursing Research ($n = 31$), Western Journal of Nursing Research ($n = 17$), and Journal of Nursing Scholarship ($n = 11$). The largest number of the studies meeting the inclusion criteria (43%) focused on heart disease.

Cause of Death	Frequency	Percentage
Heart disease	60	43.2
Cancer	17	12.2
Stroke	4	2.9
Chronic lower respiratory	14	10.1
Accidents	4	2.9
Diabetes	10	7.2
Pneumonia/influenza	0	0
Alzheimer's	24	17.3
Nephritis/nephrotic	6	4.3
Septicemia	0	0

TABLE 2. Top 10 Causes of Death (N = 139)

Inclusion of Women and Characteristics

The findings show that 117 of the studies included women, and that 22 of the studies either excluded women or did not report the sex of the participants. The number of women in the samples ranged from 1 to 1,945 (mean, 97 ± 220 ; median, 40). A scatter plot demonstrated five outliers, and after removal of these studies, the range was 1 to 310 (mean, 60 ± 63). Only 15 studies reported the age of the women in their samples, and 10 of these included women between the ages of 35 and 64 years. In the 29 studies that reported race, White was the race most frequently reported ($n = 21$), followed by African American ($n = 17$), Hispanic ($n = 6$), and Asian ($n = 2$).

In each year of publication, the majority of studies included women (Figure 1). From 1995 to 1997, there was no change in the proportion of studies including women. In 1998 and 1999, there was a decrease, but 2000 and 2001 showed an increase. To test for an association between the inclusion of women and the years of publication, the years of publication were collapsed into two categories: 1995–1998 and 1999–2001. No such association was found ($[\chi]^2 = 0.252$; $df = 1$; $p = .616$).

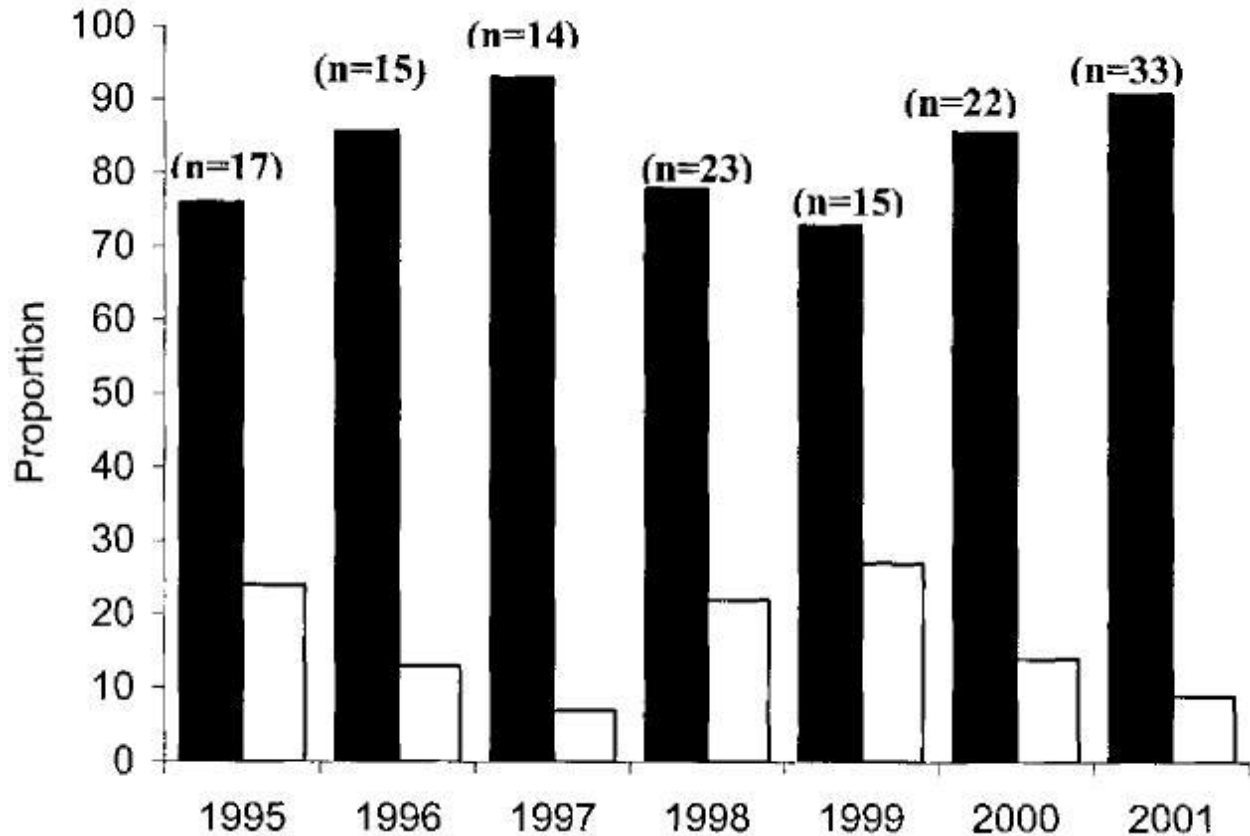


FIGURE 1. The proportion of women in studies meeting the inclusion criteria (n = 139). [black small square] = Women; [white square] = No women.

Federal Funding

Funding was reported in 107 publications (77%). Of these studies, the majority (n = 90, 84%) included women. Funding sources for these 90 studies were federal (57%), association (15%), intramural (12%), combined (9%), and foundation (7%) sources. There was no association between the inclusion of women and federal funding ($[\chi^2 = 1.065; df = 1; p = .302]$).

Topic

Of the top 10 causes of death, the most frequently studied was heart disease, and most of the studies (87%) included women. In addition, 88% of the studies investigating Alzheimer's disease and 83% of the studies published on cancer included women. Among the published studies on the top 10 causes of death, in all but one category, accidents, more of the studies than not included women. Among the studies including women, heart disease was the most frequent topic (n = 52), followed by Alzheimer's disease (n = 21), cancer (n = 14), respiratory illness (n = 14), and diabetes (n = 8). No studies meeting the inclusion criteria were found on septicemia or pneumonia/influenza.

Discussion

In this study, most of the research (87%) that focused on the leading causes of mortality published in nursing journals from 1995 to 2001 included women as subjects. These results on the inclusion of women are similar to those found in selected medical journals (Vidaver et al.,

2000). Although the current study noted an increase in the numbers of studies including women from 1995 to 2001, the NIH Tracking/Inclusion Committee (2000) did not. This difference may be related to the delay in time from manuscript submission to publication and to the fact that the latter report included only federally funded studies.

The 117 studies that included women did not adequately report demographic data. Only 15 studies reported the age of women participants, and the majority of these studies included women younger than 64 years (62% of the population). This is alarming because many disease processes are associated with increasing age, and 12% of the U.S. population is 65 years of age or older (U.S. Census Bureau, 2000). When age of the participants by sex is not reported, the reader cannot discern whether participants of various ages are adequately represented, and thus has difficulty applying the findings to various groups of women. Therefore, when appropriate, analysis by sex and age by sex should be reported.

Only 25% of the studies including women reported race. However, some diseases disproportionately affect minority women. For example, cardiovascular disease is more prevalent among African American women (40%) than among White women (24%) (AHA, 2001). Although the Hispanic population currently is the largest minority group in the United States (U.S. Census Bureau, 2002), only 5% of the studies including women reported Hispanic women participants. These results may have been attributable to the small number of older Hispanic women (U.S. Census Bureau, 2000) or to language barriers.

None of the study variables were significantly associated with the inclusion of women. Because of the NIH Revitalization Act, it was expected that federal funding would be associated with the inclusion of women. Yet, fewer than half of the studies reviewed had received federal funding. This lack of association between the study variables and the inclusion of women also may have been attributable to the inclusion of only research on topics related to the top 10 causes of death. The National Institute of Nursing Research places emphasis on issues of health promotion, management of illness, recovery from illness, and quality of life, including end-of-life care. These broad foci do not directly match the leading causes of mortality. However, because the patients in the care of most nurses have conditions that reflect leading causes of mortality, it was assumed that the majority of research articles would address topics associated with the top 10 causes of death. Future studies examining the inclusion of women in nursing research may use other publication inclusion criteria such as the most common reasons for hospitalization or the most frequent diagnoses by diagnostic related groupings.

This study had several limitations. By excluding sex-specific cancers, many studies including women were excluded from this review. Furthermore, because research topics were related to the top 10 causes of death, many research articles important to nursing were excluded. Thus, the results cannot be generalized to all published research. Page restrictions or editorial restrictions also may have influenced the reporting of sex, age, and race. Additionally, underrepresentation of research topics may have resulted from limitation of the search to five research publications.

Given the growing evidence of sex-based differences, the inclusion of women in research is essential to the description, explanation, and prescription of interventions and services tailored to women. Although most of the research articles reviewed included women, continuing efforts

to include sufficient numbers of women are needed. Continued diligence in examining the inclusion of women in nursing research is needed.

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