Health Care Utilization Among Women Who Have Undergone Breast Implant Surgery

By Aleina Tweed

Report available in alternate formats
We're Women Too. Identifying Barriers to Gynecologic and Breast Health Care for Women with Disabilities

Women's Health Reports

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Executive Summary

The health consequences of breast implant surgery range from the well-established local complications to the very controversial systemic complications. Complications often lead to additional surgeries. Although most women receive implants through privately-funded health care, when they experience complications they enter the public health care system. This research study tests the hypothesis that receiving breast implants results in increased use of the public health system. Rather than investigating health outcomes, it focuses on the issue of health care utilization.

Data were collected for a study cohort of 147 women who have undergone breast implant surgery and a non-implant comparison group of 583 women matched by birth cohort and geographic region. The data were extracted from the B.C. linked datasets. Outcome variables such as doctor’s visits, specialist visits, number of hospitalizations, level of care in hospital and days of care in hospital were examined over the 11-year period from 1988/89 to 1998/99. Wilcoxon rank sum tests, chi-square tests and odds ratios were performed to analyze these data.

Data were also collected from questionnaires completed by the women in the study group. These questionnaires collected additional implant factors (e.g., type of implant, length of time implant was in place) and lifestyle information (e.g., smoking, alcohol use, exercise, marital status, number of children).

Statistical analyses of the linked datasets showed that women who have or have had breast implants did experience more hospitalizations and did visit doctors and specialists significantly more than women who had not undergone implantation surgery. Women with implants were more likely to be admitted to hospital (OR = 4.26, 95% CI = 2.58, 7.02). They were more likely to be admitted electively (OR = 1.90, 95% CI =
1.50, 2.39) and less likely to be admitted as an urgent case (OR = 0.60, 95% CI = 0.46, 0.78) or emergency case (OR = 0.53, 95% CI = 0.35, 0.79).

The data showed that, despite some limited relationships, neither lifestyle factors (e.g., education level, marital status) nor implant factors (e.g., type of implant, length of time implant was in place) accounted for the increased health care utilization. However, the longer implants had been in place, the fewer hospitalizations women underwent. This indicates a greater need for hospital care in the early years of implantation, care likely associated with local breast-implant complications.

Breast implant surgery does result in increased use of the public health care system. Further investigation is needed to determine the causal mechanism.
Introduction

For decades, women who have undergone breast implant surgery have reported high implant failure rates and general, unidentifiable illness. In 1992, silicone gel-filled implants were subject to government moratoriums in the United States and in Canada, until such time as their safety could be assured. In the years that have followed, researchers have tried to find answers. In the meantime, breast implantation continues to become more and more popular, with saline-filled implants taking the place of their silicone predecessors.

In Canada an estimated 80% of breast implantation surgeries are performed as cosmetic augmentation. Such surgery is not considered “essential” and is therefore paid for privately rather than through public insurance. However, if there are health consequences to this surgery – ranging from the well-established local complications to the very controversial systemic complications – these women enter the public health care system for their care.

Breast implant research is beset by challenges, not the least of which is the lack of a central registry allowing health care professionals or researchers to track women who receive breast implants or to do any follow-up. (A companion paper to this one, Registering the Impact of Breast Implants, discusses the need for such registries (Pederson & Tweed, 2003)). Another challenge is that no retrospective breast implant research study can create an unbiased study sample. It is also difficult for a prospective study to follow women for an adequate period of time.

This project, rather than investigating health outcomes, focuses on this issue of health care utilization. If women who have undergone breast implant surgery use the public health system more than women who have not undergone this surgery, then there is reason not only to be concerned for the health of these
implanted women, but also to be concerned about the financial consequences borne by government and, ultimately, by the public.

A. Purpose

The research study, *Health Care Utilization Among Women Who Have Undergone Breast Implant Surgery*, asks whether or not women who have undergone breast implant surgery use the public health care system more and/or differently than women who have never had such surgery. It was initiated out of the need to answer questions about breast implants for women, for health care practitioners and for policy-makers. Although many researchers have tried to investigate links between breast implants and health outcomes, there are challenges that make it nearly impossible to come up with conclusive results. However, there does seem to be little doubt that at least some women react badly to breast implants (Segal, 1997, p. 1; UK Independent Review Group, 1998, p. 17).

We know that a very high number of women have been affected by breast implant-related complications (Segal, 1997, p. 2; Powell & Leiss, 1997, p. 107). A Mayo Clinic study in the United States, for example, found that 25% of women with breast implants suffered local complications requiring additional surgery within five years (Gabriel et al., 1997, p. 677). With regard to autoimmune disorders, in 1992 the Canadian Independent Advisory Committee on Silicone Gel-Filled Implants stated that, “[s]ome reassurance can be derived from the facts that after three decades of use, there is no evidence of devastatingly harmful effects on the majority of users and that there is an absence of evidence to support a causal association linking [silicone gel-filled implants] to autoimmune disorders. On the other hand, since absence of evidence does not prove anything, more research should be carried out to ascertain the risks associated with implant use” (Baines et al., 1992, p. 6).

Although most of the many studies investigating breast implantation and classic autoimmune and connective tissue diseases have found no association, these studies are limited by inadequate sample size, inadequate follow-up, or poorly defined disease criteria (this is also true of those – fewer in number – that have shown an association) (Silverman et al., 1996, p. 750). Several studies, as well as reviews conducted in the United States and in the United Kingdom, have suggested no greatly increased risk of specific autoimmune or connective

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tissue diseases among women who have undergone breast implant surgery (UK Independent Review Group, 1998, p. 26). However, these studies are generally too small to detect the possibility of a slightly increased risk. The studies have only looked for the symptoms of known autoimmune diseases, instead of the cluster of symptoms experienced by some women with breast implants (Mentor, n.d., p. 9-10). Often these studies are looking and testing for known, defined diseases instead of a possibly new, undefined illness. Because implant removal often results in a reversal of symptoms, a causal link between the implants and these symptoms is suggested (Sarwer et al., 2000, p. 846).

Atypical connective tissue diseases have not been addressed specifically by most studies. Those studies that have attempted to do so were inconclusive due to design flaws (Silverman et al., 1996, p. 750). The conclusion, therefore, is that there is still not enough evidence to discount some causal relationship between breast implants and systemic illness (Baines et al., 1992, p. 32-33).

Health Care Utilization Among Women Who Have Undergone Breast Implant Surgery is beset by some of the same challenges and limitations as other studies. However, it takes a novel approach and therefore sheds some light in new areas. Rather than examining health outcomes directly, it looks at the connection between breast implants and health care use. Although this precludes answering questions about health or illness subsequent to breast implantation or about causation, it does give some indication of potential health trends among women who undergo breast implant surgery, and identifies areas for future research. It also gives Canadian policy-makers information to help them better understand the implications of this procedure and with which they can base future investigation, research and policy decisions.

This research will provide insights into the continuing health of women who undergo breast implant surgery. It will provide insights into the publicly-borne consequences of a private (and privately-funded) surgery. And it adds to the body of knowledge about breast implantation.

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B. Research Objectives

The primary research objective is to examine health care utilization subsequent to breast implantation. This examination will help determine whether or not breast implantation affects women’s use of the public health care system.

As well as providing an answer to the primary research question above, this project:

- comments on the policy implications of this utilization;
- adds to the body of knowledge about breast implants, empowering women to make informed decisions about breast implantation and explantation (removal); and
- seeks to improve women’s health status and ability to access sensitive health care by furthering the knowledge and understanding of breast implant issues with health care practitioners.

C. Report Organization

Following this Introduction, Section III provides background information about some of the health issues associated with breast implants. Section IV describes the methodology of this project, including details of the study design, study and comparison cohort definitions, and data collection and analysis issues. Section V presents some of the challenges and limitations faced not only by this study but also by all research examining breast implant-related issues. Section VI presents the results and Section VII provides some discussion of those results and directions for future research. Conclusions are presented in Section VIII.
Background

A. The Health Outcomes of Breast Implants

In Canada, thousands of women have chosen breast implant surgery, including an estimated 25,000 or more in British Columbia (Breast Implant Centre, Summer 1999, p. 1). As in all of North America, most (approximately 80%) of these surgeries are for breast augmentation. The other 20% are for reconstruction after cancer or prophylactic mastectomy, or to correct under- or non-developed breasts (Segal, 1992, p. 1; Baines et al., 1992, p. 12). Many women who choose breast implantation are very happy with the results of their surgery. They report psychological and emotional benefit from their new body image (Bondurant et al., 2000, p. 28). However, many women report side-effects and feel that their short-term and long-term health have been compromised.

There were 103,343 adverse reaction reports associated with silicone breast implants and 23,454 reports involving saline implants received by the U.S. Food and Drug Administration between January 1, 1985 and September 17, 1996 (Segal, 1997, p. 2; Powell & Leiss, 1997, p. 107). (Because the figures for the reports involving saline implants come from all FDA databases, there may be a few duplicate reports.)

There are three major groups of complications associated with breast implants. These are local complications, systemic complications and psychological complications. Breast implant surgery also carries the same risks associated with any surgical implantation of a medical device.

1. Surgical complications

Any surgery – and breast implantation is no different – involves risks, such as possible complications of general anesthesia, infection, haematoma, hemorrhage, thrombosis, skin necrosis,

A woman who receives breast implant(s) will likely require additional surgery or surgeries related to her implant(s) over her lifetime. These procedures may include treatment of capsular contracture, correction of the implant’s size or position, infection control as the result of other local or systemic complications, or to prevent or treat leakage, rupture or other health problems (Baines et al., 1992, p. 22; Sarwer et al., 2000, p. 847; Bondurant et al., 2000, p. 119).

2. Local complications

Local complications can range from very mild to very severe, and they affect a large percentage of women who undergo breast implant surgery (Gabriel et al., 1997, p. 677). Capsular contracture is one of the most significant complications. Contraction of the wall of scar tissue surrounding the breast implant may cause hardness of the breast, discomfort and even severe pain (Mentor, n.d., p. 8). According to Health Canada, capsular contracture occurs, usually within two years of surgery, in approximately 25% of women who undergo breast implant surgery (Health Protection Branch, 1998, p. 2). Other researchers suggest the percentage is as high as 70%, and some estimate that 100% of women with breast implants will develop capsular contracture to some degree over the life of the implant (Sarwer et al., 2000, p. 847).

Implant deflation and rupture caused by normal deterioration over time, breast trauma or undetected damage or shell weakness in the implant are significant complications; one study found that 70% of removed implants 11 to 15 years old were ruptured or leaking (Sarwer et al., 2000, p. 846). In a U.S. government study, two-thirds of 344 implanted women examined with MRI had ruptured implants (American Broadcast Corporation, 18 May 2000). Deflation, leakage and rupture can result in the filling of the breast implant being spread through the body. The salt-water solution contained within saline-filled implants should be harmless. However, partly because of the semi-porous...
nature of breast implant shells and partly because of faulty valves and difficulties inherent in the sterilization of breast implant materials, it has been suggested that the saline filler does not remain sterile. In one study, most explanted saline-filled breast implants, regardless of their age, had microbial growth in the implant and in the capsule surrounding the implant. If the filler was so contaminated, it would no longer be considered harmless upon deflation or rupture (Blais, 1998, p. 3-4; Mentor, n.d., p. 9).

Other complications include change in shape or volume of the breast; change in breast sensation; calcium deposits; mammographic interference, and breast/chest discomfort or pain and nipple discharge (Segal, 1997, p. 5; Mentor, n.d., p. 7-9; Health Protection Branch, 1998, p. 2-3; Sarwer et al., 2000, p. 847; Baines et al., 1992, p. 19-22; Blais, 1998, p. 5).

3. Systemic complications

Systemic complications appear most frequently several years after breast implantation. These complications tend to present as a cluster of symptoms, including those associated with autoimmune diseases, connective tissue diseases, “human adjuvant disease” and/or fibrositis/fibromyalgia-like disorders. (The classic autoimmune and connective tissue diseases thought to be associated with silicone implants are scleroderma, systemic lupus erythematosus, mixed connective tissue disease, rheumatoid arthritis and Sjogren-Larsson syndrome (Sarwer et al., 2000, p. 846).) Women with breast implants have also reported granulomas and lymph node involvement, chronic flu, respiratory problems and infections (Sarwer et al., 2000, p. 846; Mentor, n.d., p. 9-10; Baines et al., 1992, p. 23-24; Segal, 1997, p. 5). The cluster of symptoms reported by these women often includes those present in more than one such disease. Cancer also remains a concern – albeit a smaller one – associated with breast implants.

The link between breast implants and systemic complications is still not clearly understood. An association has been suggested by anecdotal evidence, case reports and some scientific studies (Brautbar & Campbell, 1995; Baines et al., 1992); however epidemiologic research has not shown a significant increased risk (Baines et al. 1992, p. 29-31; Segal 1997, p. 2).

4. Psychological complications

Unfortunately, studies of the psychological consequences of breast augmentation have been largely anecdotal, consisting primarily of surgeons’ reports of their patients’ satisfaction. These reports suggest that typically 70% or more of patients report satisfaction with their surgical outcome (Sarwer et al., 2000, p. 851). Clearly, such investigations have serious problems. Firstly, how many patients will
admit, face-to-face with their surgeon, that they are not satisfied with the results of their surgery? Secondly, how many surgeons will admit, face-to-face with their colleagues, that their patients are not satisfied (Sarwer et al., 2000, p. 851)?

There are many studies that suggest cosmetic surgery in general leads to immediate post-operative improvements in body image, quality of life, and depressive symptoms. Other studies, however, have found that women who undergo removal of breast implants (explantation) report higher levels of breast anxiety, upper torso dissatisfaction and depression both before and after implant removal, compared to surgical and non-surgical controls (Sarwer et al., 2000, p. 851). These findings suggest that breast implant surgery leads to poorer psychological well-being, rather than better, for many women.

B. Policy Issues in Canada and in British Columbia

In Canada the only breast implants now widely available are saline-filled implants (a silicone bag filled with salt water). These implants, however, have not been reviewed by Health Canada.

The Medical Devices Regulations were introduced in Canada in 1975. These required notification of devices within 10 days of being put on the market, but involved no evaluation. These regulations were amended in 1977 so that evidence of safety and effectiveness was required before marketing. The list of devices covered by this amendment did not, however, include breast implants. In October 1982, a further change to the regulations was implemented, which extended the pre-marketing review to all devices, including breast implants, designed to be implanted in tissues or bodies for more than 30 days, therefore including breast implants (Baines et al., 1992, p. 9).

The 1982 amendment required all implantable devices to go through a pre-market evaluation of safety and effectiveness data in order to obtain a Notice of Compliance and be allowed for sale in Canada (Health Protection Branch, 1998, p. 1). This evaluation included a review of animal and human test results and manufacturing data supplied by the manufacturer, by scientists at Health and Welfare Canada’s Bureau of Radiation and Medical Devices (Regush, 1993, p. 38). However, the review was required only for devices introduced after the date the amendment became effective. Because most saline-filled implants were available for sale before this date, they were exempted from the pre-market review (Health Protection Branch, 1998, p. 1).

Currently, despite the moratorium on silicone gel-filled breast implants, Health Canada has begun allowing their use in
certain circumstances. There are suggestions that their popularity is again growing (Kirkey, 16 June 2001, 16A). Even as these silicone gel-filled implants are being reintroduced, there has still been little evaluation of the effects of the saline-filled implants that are currently widely available. This represents a gap in public policy and should be addressed by Health Canada.
Methods

A. Study Design

This study is a retrospective cohort study. The data used for this project are health care utilization data collected from the British Columbia linked datasets by the Centre for Health Services and Policy Research (CHSPR) at the University of British Columbia (UBC), with permission from the B.C. Ministry of Health. Coded Personal Health Numbers (PHNs) were used to collect the data, which include Medical Services Plan records, Hospitalization records, Mental Health Services records and Long Term Care records.

Data were provided for two groups of women:

- A study group of 147 women (study group) who had undergone breast implant surgery; and

- An anonymous comparison group identified by CHSPR of 583 women matched to the study group by birth cohort and geographic region.

Data from 11 years – 1988/89 to 1998/99 – were used. Although were provided for the preceding three years (1985/86 to 1987/88), they were excluded because of data coding issues that made certain analyses impossible. Also, data from the Long Term Care and Mental Health databases were not used in analyses. The number of cases in those datasets was so small as to render analyses invalid and unreliable, and therefore inappropriate.

B. Study Group

The study group was comprised of women who self-identified as having had breast implant surgery. These women were recruited by means of a letter sent to the women on the mailing list.
list of the B.C. Women’s Breast Implant Centre at Children’s and Women’s Health Centre of B.C. and by way of public service announcements in community newspapers (see Appendix 1).

Women who were interested in participating contacted a dedicated telephone line and were then sent an informed consent letter and form (see Appendix 2). This informed consent document described the project and asked for participation, personal health numbers (PHNs) and permission to use PHNs to access health records. Confidentiality was emphasized given the sensitive and personal nature of this surgery.

Consent forms were returned by 153 women, indicating their willingness to participate. Data from the B.C. linked datasets were collected for 147 of these women. The remaining six were not included for logistical reasons including lack of a personal health number, incorrect personal health number and incorrectly completed informed consent forms.

All 153 women were sent a survey (see Appendix 3) to be completed and returned in the addressed and stamped envelope provided. These questionnaires collected demographic information such as ethnicity, marital status and dependents; implant information such as year of implantation, type of implant and repeat surgeries; and lifestyle information such as smoking, alcohol consumption and exercise. It also asked about the use of alternative health care services and out-of-country health services. Ninety-two women (63%) returned completed questionnaires. (Of the questionnaires that were not returned, 15 women had moved without a forwarding address and two women had passed away.)

C. Comparison Group

The comparison group included women living in British Columbia matched to women in the study group by five-year birth cohorts and geographic region (census tract in most cases, postal code in the very few cases where census tract did not produce adequate matching), in a 4:1 ratio.

These women were selected randomly from the B.C. linked datasets by CHSPR. Women who appeared to have had a breast implant were excluded. These women were identified based on the presence of any of the following hospital procedure codes in Section XV (97):

- 9721: (Unilateral) subcutaneous mastectomy with implantation of prosthesis;
- 9723: Bilateral subcutaneous mastectomy with implantation of prosthesis;
- 9743: Unilateral augmentation mammoplasty by implant or graft;
- 9744: (Bilateral) augmentation
mammoplasty by implant or graft;
- 9793: Revision of implant (prosthesis);
- 9794: Removal of implant;
- 9795: Insertion of breast tissue expander(s);
- 9796: Removal of breast tissue expander(s).

Five women in the comparison group were excluded from analyses because they had died during the course of the study years.

D. Data Preparation

The data were reorganized into master files and were examined for missing or unusual values. Based on this, specific data fields were chosen for inclusion in the analysis.

The key outcome variables were number of doctor’s visits (MSP) and the number of hospitalizations. These were calculated by counting unique dates of service (rather than fee items, for which there may be more than one per visit).

Other outcome variables were examined:

- Specialty code;
- Total hospital days of care;
- Level of care;
- Admission category;
- Patient service code;
- Physician most responsible – service;
- Physiotherapy and occupational therapy; and
- General feelings of health within the study group.

Independent factors included in the statistical analyses are:

- Socio-economic status based on MSP subsidy code. These subsidy codes were entered universally only after September 10, 1993, so only codes after that date contributed to the calculation of socio-economic status. The women were categorized into three socio-economic levels, based on the Statistics Canada Low-Income Cut Offs for the years 1993 to 1999 (see Appendix D). These levels are: (1) annual net income above $19,000; (2) annual net income between $15,000 and $19,000; and (3) annual net income below $15,000. As income changes year to year, the level assigned is based on the most common level over the six years 1993/94 to 1998/99. It should be noted that these levels serve mainly to separate the very poor, the poor and the non-poor, as a “high” annual net income of $19,000 is by no means living in luxury, and there are no data available on income ranges above that level;
- Implant information from
completed questionnaires including type of breast implant and length of implantation; and

- Lifestyle factors from completed questionnaires such as smoking, alcoholic drinks consumed per week, amount of exercise, number of children, highest level of education achieved and marital status.

E. Summary Descriptive Statistics

Statistical analyses were performed to identify any differences or lack thereof in public health care utilization patterns between women who have had breast implants and women who have not. The statistical analyses examined and, where appropriate, controlled for variables such as socio-economic status, lifestyle factors and breast implant information.

All summary descriptive statistics and statistical analyses were done using SPSS Version 10.0.7.

The summary descriptive statistics include frequencies, proportions, means and standard deviations for demographic data, for implant data and for outcome variables.

The statistical tests performed included:

- Wilcoxon rank sum tests to identify significant differences in health care utilization between study and comparison group women for continuous variables;
- Pearson’s chi-square tests to identify significant differences in health care utilization between study and comparison group women for categorical variables;
- Tests for normality of outcome variables; and
- Odds ratios and confidence intervals to examine relative risk.

F. Tests for Normality

Skewness, kurtosis, Kolmogorov-Smirnov tests, histograms and normal probability plots all served to confirm that the outcome variables were not normally distributed.

Attempts at transformations, including natural logarithms, square roots and reciprocals all failed to produce a normally distributed outcome variable. Non-parametric tests were therefore used for analysis.
Challenges and Limitations

There were a number of challenges and limitations that arose during the course of this research. Some are endemic to all breast implant research, while others are specific to this project.

The most significant challenge is sample bias, which is currently unavoidable in most or all breast implant research. Breast implant surgery is most often paid for privately and performed in plastic surgeons’ offices. As a result, individuals who choose this surgery are most often invisible in public health records. Moreover, there is no registry or database that tracks breast implantation at any level, making it impossible to identify those who have chosen this surgery. All retrospective breast implant research therefore relies on those who have undergone this surgery identifying themselves and agreeing to participate in research, rather than having the option of identifying a random study sample.

Some research teams have tried to overcome this problem by creating study groups made up of entire populations of women who have received breast implants, drawn from plastic surgeons’ files. Although this is certainly an improvement, it takes a great deal of time, effort and travel, and thus a great deal of money. It also relies on plastic surgeons’ cooperation and, if long-term effects are to be examined, presumes that those surgeons keep their records for a good deal longer than is required by law, as most systemic complaints arise only after seven to ten years of implantation (Breast Implant Centre, 1999).

The inability to create a random study group limits this project as well. It introduces the potential of significant sample bias, as women who are unhappy with their breast implants or who have experienced negative health outcomes are likely to have greater motivation to participate in research. On the other hand,
it is also possible that those who are very pleased with their breast implants are more motivated to participate in research as they want to put to rest the public feelings that they endangered their health or made bad decisions based on vanity.

Either way, this potential for sample bias limits the conclusions that can be drawn from this study. The results cannot with certainty be generalized to the entire population of women with breast implants. However, they are still very useful in that they can identify trends for the study population, and indicate if and where further study is warranted.

Other challenges and limitations of this research include:

- The inability to truly exclude women who have had breast implants from the control group. It is possible that some women in these groups did undergo breast implant surgery, but accessed it privately, making them invisible for these research purposes. However, given the relatively large size of the cohorts in this study and the small estimated percentage of B.C. women who have breast implants, the possible inclusion of some women who have had breast implants will not skew the results.

- The imperfection of any measure of socio-economic status short of asking each participant about income. This was not possible, as women in the control group were not identified at any time. MSP code was therefore used as a proxy for socio-economic status. Although this does not provide specific income-related information, it does serve as an accurate measure to separate the poor from the non-poor.

- The inability, due to time and funding constraints, to test the survey instrument before distribution. This resulted in some problems with the completed questionnaires. The survey instrument was designed to be simple and as short as possible to encourage high return rates. Although these rates were indeed high, the attempt at simplicity hurt the quality of the information provided. Many questions were answered incompletely and/or incorrectly, or lacked clarity and detail. As a result, for example, it was not possible to use the questionnaires to compare pre- and post-implant or explant health care use, nor to compare the effects of different types of implants or different lengths of implantation, except at the most basic level.

- The inappropriateness of making any claims regarding the safety or lack thereof of breast implants,
regardless of results. This project examined only health care services and did not look at health outcomes or causative relationships between breast implants and health. Therefore, although the data indicate that there are associations between breast implants and increased health care utilization, it is not appropriate to expand these claims to include safety issues.

- Those living outside major centres may have limited access to health care services. This should not be a major issue in this study, as most of the women live in major cities, and of those who do not, most live in small cities rather than rural areas. Moreover, study group and comparison group women were matched by geographic region, eliminating the possibility that observed differences were the result of differences in health care accessibility due to place of residence.

- The presence of other implants, silicone or otherwise, could confuse the results. Of the 92 women in the study group who completed questionnaires, only two had implants other than breast implants. This very limited presence will not bias or skew the results.

- Not all health service utilization is recorded in public health care system data. Some women who have had breast implants suggest that they often face such barriers and discrimination in the public health care system that they turn to other types of health care. Over one-half (52.2%) of the women who completed questionnaires reported having accessed at least one type of alternative health care, and many

There are also some possible confounders that were considered:

- The inability, due to the lack of implant information in public health records, to create an “index date” (date of implantation), and thus more accurately assess whether increased health care utilization occurred after implantation. However, the completed surveys from 92 women with breast implants identified the year of initial implantation. Three quarters of these women received their implants before 1990, meaning that they were implanted before (or very soon after) the first year of health care utilization data used in this project (1988/89). Therefore, this gap is not a serious issue that either compromises the validity of this study or precludes drawing conclusions based on the trends seen here.

- Other implants, including those that are not breast implants, could influence the results. Only two women in the study group had implants other than breast implants, so this limitation will not bias or skew the results.

- Health service utilization is not uniformly recorded in public health care system data. While some women may turn to alternative health care due to barriers and discrimination in the public health care system, over half of the women who completed questionnaires reported accessing at least one type of alternative health care.
had used more than one. It is possible – and has been suggested that it is probable – that public health system utilization rates are lower than “true” health services utilization rates because of the use of privately accessed alternative health therapies. This, if true, biases the results of this study towards the null hypothesis, and therefore would only strengthen arguments of associations between breast implants and increased health care usage.
Results

A. Overview

What this research revealed was that there is, indeed, a statistically significant relationship (a p value less than or equal to 0.05, unless otherwise noted) between breast implant surgery and health care utilization. Women who have undergone breast implant surgery show statistically increased use of the public health care system over what we would deem “normal” use (defined as the use by women who have not had breast implant surgery).

Specifically and most importantly, women who have undergone breast implant surgery:

- visited the doctor more often;
- visited more specialists more often; and
- were hospitalized more often.

Poisson regression could be performed to explore further possible relationships between potential confounders or interactions such as lifestyle factors or implant information. Such analyses were not performed in this study, due to the poor quality of such data and the evidence that, in general, such interactions were not significant.

B. Descriptive Statistics: Demographic Descriptions

The study group of women who had undergone breast implant surgery is a fairly homogenous group. According to the completed questionnaires, almost all are Caucasian and speak English at home. They are a well-educated group, with almost all having at least a high school education, and the largest percentage having a post-secondary degree. Most are married.
or in common-law relationships and have at least one child. Table 1 lays out these descriptives.

The women range in age from 29-81 years. The mean age is just over 54 years, and most women fall in the 45-60 year range. As each woman in the study group was matched by age as well as geographic region, the age distributions in the study and comparison groups are the same.

Among those in the study group who completed questionnaires, most (55.4%) live in larger urban centres. The others live in smaller cities outside the Lower Mainland of B.C. (27.2%) or in rural areas (17.4%). This distribution is the same for the control group, given that they were matched by geographic region.

Most of those in both cohorts are in a higher socio-economic level. These levels serve mainly to separate the poor from the non-poor, as they do not provide income information in the annual net income ranges above $19,000. Table 2 provides the socio-economic breakdown for these groups of women.

### Table 1: Demographic information (from questionnaires), Study group (n=92)

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Frequency (%)</th>
<th>Language spoken at home</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasian</td>
<td>90 (97.8%)</td>
<td>English</td>
<td>86 (93.5%)</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (1.1)</td>
<td>Other</td>
<td>1 (1.1)</td>
</tr>
<tr>
<td>Missing*</td>
<td>1 (1.1)</td>
<td>Missing</td>
<td>5 (5.4)</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/common-law</td>
<td>62 (67.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Separated/divorced</td>
<td>15 (16.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>6 (6.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>8 (8.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>1 (1.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Children</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>11 (12.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-2</td>
<td>40 (43.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-4</td>
<td>36 (39.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 or more</td>
<td>5 (5.4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* In the case of information collected from the questionnaires, “missing” means either the question was not completed or it was completed incorrectly and cannot, therefore, be used.
Table 2: Socio-economic level, Study group and Comparison group

<table>
<thead>
<tr>
<th>Socio-Economic Level</th>
<th>Study Group (n=147) Frequency (Valid %)</th>
<th>Comparison group (n=583) Frequency (Valid %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over $19,000</td>
<td>118 (80.3%)</td>
<td>428 (73.4%)</td>
</tr>
<tr>
<td>$15,000 to $19,000</td>
<td>1 (0.7)</td>
<td>9 (1.5)</td>
</tr>
<tr>
<td>Under $15,000</td>
<td>28 (19.0)</td>
<td>69 (11.8)</td>
</tr>
<tr>
<td>Missing**</td>
<td>0 (0.0)</td>
<td>77 (13.2)</td>
</tr>
</tbody>
</table>

** Data from the B.C. linked datasets is coded as “missing” if the data is missing entirely or is coded incorrectly.

C. Descriptive Statistics: Implant Information

The completed surveys provided limited implant information including reasons for implantation, type of implant and length of time since initial implantation.

The reasons that these women chose breast implant surgery vary. All centre on the desire to look “normal” and “feminine.” Consistent with the reports of other studies (Segal, 1992, 1; Baines et al., 1992, 12), most of the women in this study group chose breast implants for augmentation, while a smaller percentage chose breast implants for reconstruction after a mastectomy (see Figure 1).

Of the 92 women who returned questionnaires, almost half (n=40) had their initial breast implant surgery in the 1980s. Twenty-seven percent of the women (n=25) received their implants in the 1970s and 25% (n=23) in the 1990s. Only four women had received their breast implants earlier, in the 1960s. Length of implantation by year is provided in Table 4.

Almost two-thirds (60%) of these women were given silicone gel-filled breast implants as their first set of breast implants. One-quarter (26%) of the women were implanted with saline-filled breast implants, and the rest received bi-lumen, triple-lumen, silicone gel-filled implants with Dacron patches or Même implants. Some of the women (n=4) did not know what kind of breast implant they had. Many of the women (34%) did not know who had manufactured their first set of implants, but of those who did most (75%) had Dow Corning implants. This is not surprising given that Dow Corning was the largest breast implant manufacturer until the 1992 moratorium.

As discussed above, breast implantation is rarely a one-time surgery. Additional surgeries are often required due to complications. Among the 92 questionnaire respondents in this study group, over half (51%) of the respondents reported at least one additional breast implant-related surgery.
subsequent to the initial implantation. Of those, half (49%) had had one additional surgery, 23% had had two, 11% had had three, and 17% had had four or more additional surgeries (see Table 3).

Some of these may have been implant replacement surgeries, while many are not. Three quarters (77%) of the women have not had to replace either of their breast implants. Of the others, two-thirds replaced both their implants, while the remaining third replaced only one. And while half (52%) of these women only had to replace their implant(s) once, 29% replaced their implant(s) twice and 19% replaced their implant(s) three or four times.

For some of these women, the complications were enough to convince them that they no longer wanted breast implants. Thirty-seven of the women...
who returned questionnaires (40%) had had their implants permanently explanted. The rest (n=55), have not.

There was no explicit question on the survey instrument asking about permanent explantation, only asking for a date of permanent explantation if applicable. As with other areas of the questionnaire (discussed in Section V: Challenges and Limitations), there may have been some confusion here, and it is possible that women who have had their implants taken out permanently did not provide a date, in which case they could not be identified as having had permanent explantation.

D. Descriptive Statistics: Outcome Variables

Among those women who returned completed questionnaires, most rated their health as excellent (n=30) or good (n=35) compared to other women their own age. The rest felt that their health was fair (n=12) or poor (n=13).

Despite these feelings of good health, fully half of these women had been diagnosed with at least one chronic illness. Furthermore, one-third (n=33) felt that they had lost or quit their job or reduced their hours because of health problems, and more than half had problems doing housework or recreational activities due to health problems. The majority reported that the health problems that affected their job or their housework occurred after they got

| Table 3: Implant-related surgeries subsequent to initial implantation, Study group |
|-------------------------------------------------|-----------------|
| Additional surgeries                             | Study group |
| None                                            | (n=92) Frequency (%) |
| One                                             | 23 (25.0) |
| Two                                             | 11 (12.0) |
| Three                                           | 5 (5.4) |
| Four or more                                    | 8 (8.7) |
| Implant Replacement                              |               |
| None                                            | 71 (77.2%) |
| One implant                                     | 7 (7.6) |
| Both implants                                   | 14 (15.2) |
| Number of Replacements (n=21)                    |               |
| One                                             | 11 (52.4%) |
| Two                                             | 6 (28.6) |
| Three or Four                                    | 4 (19.0) |

| Table 4: Length of implantation, Study group (n=92) |
|---------------------------------------------------|-----------------|
| Length of Implantation                            | Frequency (%) |
| 0-5 years                                        | 15 (16.3%) |
| 6-10 years                                       | 16 (17.4) |
| 11-15 years                                      | 20 (21.7) |
| 16-20 years                                      | 19 (20.7) |
| 21-25 years                                      | 12 (13.0) |
| 26-30 years                                      | 6 (6.5) |
| 30-40 years                                      | 4 (4.3) |
their breast implants (88% and 78%, respectively).

The B.C. linked data provides quantitative, rather than qualitative data. These data show that the women in the study group were hospitalized more often and visited doctors in general and specialists specifically significantly (p<0.05, unless otherwise noted) more often than did the women in the comparison group over the eleven-year study period. These women were also much more likely to be hospitalized over this period (Odds Ratio = 4.26, 95% Confidence Interval = 2.58, 7.02). These relationships remained significant when broken down by year, as is illustrated in Table 5. (Hospitalizations were not significant in 2 of the 11 years, presumably aberrations.)

These same analyses were performed comparing only those women in the study group who had self-identified as having chosen breast implant surgery for reasons other than reconstruction after mastectomy for malignant disease to the comparison cohort. The results of these sub-analyses were the same as those comparing the entire study cohort to the comparison cohort.

While 27.5% of the MSP fee items in the study cohort and 30.8% of items in the comparison cohort were for general practitioners (a significant difference, p<0.001), the remainder was for specialists. Table 6 shows the number of items in each specialty among women in both the study group and comparison group. A Pearson chi-square test indicates that the proportions of specialists accessed between the two cohorts is not equal (p<0.001). In other words, having undergone breast implant surgery did appear to affect specialist items both in increased number and in different type.

Despite small apparent differences in the percentages of fee items in each group dedicated to each specialty, these differences were frequently significant. The p-values in Table 6 identify those specialties where the difference between the two cohorts is significant, and in which specialties it is not.

There are also differences in terms of hospital admissions. Women in both the study group and comparison group were most likely to be admitted electively. However, women in the study group were almost twice as likely to be admitted in this category (OR = 1.90, 95% CI = 1.50, 2.39). In other admission categories, however, this trend is reversed. Women in the study group were 40% less likely than those in the comparison group to be admitted in the urgent category (OR = 0.60, 95% CI = 0.46, 0.78) and only half as likely to be admitted as an emergency case (OR = 0.53, 95% CI = 0.35, 0.79). This relationship between cohort and hospital admissions is a significant one (Pearson’s chi-square test p<0.001). Figure 2 illustrates the differences in hospital admissions.
Once admitted to hospital, the services provided to the women in both groups were the same in all but three areas. A Pearson chi-square test showed that the proportions of services accessed in each group are not equal (p<0.001). The difference in services is primarily in general surgery and plastic surgery – areas that we would expect to be associated with local breast implant-related complications. Gastroenterology and urology were other areas where there was a significant difference between cohorts. Table 7 provides the breakdown of services provided for each group.

As with services provided, women in the study group and comparison group had the same types of physicians responsible for their care in hospital. A Pearson’s chi-square analysis rejects a null hypothesis that these physician proportions among the women in the two groups are equal (p<0.001). However, Wilcoxon rank sum tests showed that the only significant differences were for care by plastic surgeons, general surgeons and gastroenterology specialists (see Table 8).

There was no difference between the two groups in terms of their level of care in hospital. As Table 9 shows, women in the two cohorts were most often hospitalized at an acute level of care (55%) or for day surgery (44%). A Pearson chi-square test showed that we could not reject the null hypothesis that the level of care proportions are equal between the two groups (p=0.68) and odds ratios supported the hypothesis that neither group was more likely to be represented in any level of care. The exception is in extended care, where women who have had breast implants...
are more than five times more likely to be. However, the numbers are very small, suggesting that this odds ratio is misleading and should not be considered accurate.

The total number of days spent in hospital is only available for the eight years 1991/92 to 1998/99. Over these years, the mean number of days of care in hospital was 2.2 in the study group and 3.8 in the comparison group, which is not a statistically significant difference. Because hospitalization trends and length of hospital stays have changed dramatically over the last couple of decades, days of care were also analyzed on a yearly basis. The mean number of days of care was still slightly higher among the control group, although again the difference was not significant. (The difference in days of care was significant in 1997/98, presumably an aberration.) Table 10 illustrates these relationships.

Length of stay was also measured by more specific area: Intensive Care Unit (ICU) days, Continuing Care Unit (CCU) days, Rehabilitation Unit days, Discharge Planning Unit (DPU) days, Chronic Behaviour Disorder Unit days and Acute Care days. As with overall length of stay, all observed differences were not statistically significant (see Table 11). Although not significant, the trend was the same as with total days of care with women in the comparison group spending slightly more days in each unit that women in the study group. However, the mean number of days is very small so interpretations must be cautious.

It is interesting to note that while women who had had breast implants were admitted to hospital more often (3.7 visits per woman compared to 2.0 visits per woman, respectively), women who had not had implants seemed to stay longer. This again supports the assertion that local breast implant-related complications are contributing to an increased need for shorter-term hospital care such as plastic or general day surgery.

Some women in both groups received physiotherapy or occupational therapy encounters while in hospital. Women in the study group underwent an average of 0.27 physiotherapy encounters per woman (n=147) compared to 0.21 encounters per woman in the comparison group (n=583). However, women in the study group were overall less likely to be provided with physiotherapy services in hospital (OR = 0.68, 95% CI = 0.47, 0.99). Occupational therapy was utilized even less, with a mean of only 0.068 encounters per woman in the study group and 0.055 encounters per woman in the comparison group. As with physiotherapy encounters, women with breast implants were less likely than those without to need occupational therapy (OR = 0.68, 95% CI = 0.33, 1.39). The differences between the two groups appear small, and indeed, neither difference was statistically significant in a Wilcoxon rank sum test.
<table>
<thead>
<tr>
<th></th>
<th>Study group (n=147) Mean (SD*)</th>
<th>Comparison group (n=583) Mean (SD)</th>
<th>p-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MSP Visits</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1988/89</td>
<td>155.8 (109.56)</td>
<td>95.29 (92.22)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1989/90</td>
<td>11.8 (12.85)</td>
<td>7.81 (9.52)</td>
<td>0.002</td>
</tr>
<tr>
<td>1990/91</td>
<td>10.54 (12.11)</td>
<td>7.44 (9.24)</td>
<td>0.001</td>
</tr>
<tr>
<td>1991/92</td>
<td>11.39 (12.84)</td>
<td>7.90 (10.82)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1992/93</td>
<td>13.52 (14.96)</td>
<td>8.98 (11.83)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1993/94</td>
<td>12.36 (13.15)</td>
<td>7.90 (10.42)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1994/95</td>
<td>16.80 (18.82)</td>
<td>9.06 (12.18)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1995/96</td>
<td>14.39 (12.33)</td>
<td>9.83 (13.98)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1996/97</td>
<td>16.70 (14.11)</td>
<td>9.37 (14.27)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1997/98</td>
<td>16.69 (12.52)</td>
<td>8.94 (11.93)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1998/99</td>
<td>15.48 (10.77)</td>
<td>8.89 (11.48)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Hospitalizations</strong></td>
<td>3.69 (3.57)</td>
<td>2.01 (4.03)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1988/89</td>
<td>0.26 (0.64)</td>
<td>0.15 (0.45)</td>
<td>ns***</td>
</tr>
<tr>
<td>1989/90</td>
<td>0.29 (0.63)</td>
<td>0.17 (0.51)</td>
<td>0.009</td>
</tr>
<tr>
<td>1990/91</td>
<td>0.21 (0.54)</td>
<td>0.19 (0.57)</td>
<td>ns</td>
</tr>
<tr>
<td>1991/92</td>
<td>0.22 (0.51)</td>
<td>0.17 (0.59)</td>
<td>0.041</td>
</tr>
<tr>
<td>1992/93</td>
<td>0.31 (0.73)</td>
<td>0.18 (0.76)</td>
<td>0.005</td>
</tr>
<tr>
<td>1993/94</td>
<td>0.33 (0.74)</td>
<td>0.19 (0.78)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1994/95</td>
<td>0.29 (0.60)</td>
<td>0.23 (0.95)</td>
<td>0.005</td>
</tr>
<tr>
<td>1995/96</td>
<td>0.53 (0.99)</td>
<td>0.21 (0.66)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1996/97</td>
<td>0.46 (0.80)</td>
<td>0.16 (0.63)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1997/98</td>
<td>0.41 (0.97)</td>
<td>0.23 (1.52)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1998/99</td>
<td>0.37 (0.71)</td>
<td>0.16 (0.58)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Specialist Items</strong></td>
<td>224.38 (214.74)</td>
<td>127.88 (143.65)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1988/89</td>
<td>15.67 (22.54)</td>
<td>10.27 (15.59)</td>
<td>0.002</td>
</tr>
<tr>
<td>1989/90</td>
<td>16.52 (24.13)</td>
<td>11.87 (19.27)</td>
<td>0.006</td>
</tr>
<tr>
<td>1990/91</td>
<td>12.02 (17.12)</td>
<td>8.72 (15.50)</td>
<td>0.006</td>
</tr>
<tr>
<td>1991/92</td>
<td>16.88 (22.90)</td>
<td>12.82 (21.45)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1992/93</td>
<td>15.12 (21.98)</td>
<td>9.34 (15.63)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1993/94</td>
<td>28.25 (61.88)</td>
<td>12.68 (23.36)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1994/95</td>
<td>22.93 (30.82)</td>
<td>14.06 (23.66)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1995/96</td>
<td>31.93 (43.20)</td>
<td>15.74 (29.60)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1996/97</td>
<td>27.35 (29.28)</td>
<td>12.83 (21.53)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1997/98</td>
<td>19.99 (20.74)</td>
<td>9.74 (14.28)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1998/99</td>
<td>17.71 (16.43)</td>
<td>9.82 (16.70)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* SD = Standard deviation
** P-values calculated using Wilcoxon rank sum tests.
*** ns = not statistically significant at the p=<0.05 level.
### Table 6: Specialists, Study group and Comparison group (MSP fee items)

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Study group (n=45,815) Frequency (%)</th>
<th>Comparison group (n=108,173) Frequency (%)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthesiologist</td>
<td>1096 (3.3%)</td>
<td>1665 (2.2%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Casualty Officer</td>
<td>78 (0.2)</td>
<td>209 (0.3)</td>
<td>0.017</td>
</tr>
<tr>
<td>Chiropractor**</td>
<td><strong>4849 (14.7)</strong></td>
<td>12110 (16.2%)</td>
<td><strong>&lt;0.001</strong></td>
</tr>
<tr>
<td>Dental Surgeon</td>
<td>0 (0.0)</td>
<td>9 (&lt;0.1)</td>
<td>ns***</td>
</tr>
<tr>
<td>Dermatologist</td>
<td>318 (1.0)</td>
<td>911 (1.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>General Surgeon</td>
<td>541 (1.6)</td>
<td>1063 (1.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Internal Medicine Specialist</td>
<td>1480 (4.5)</td>
<td>3631 (4.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Massage Therapist</strong></td>
<td><strong>2855 (8.6)</strong></td>
<td>4954 (6.6)</td>
<td><strong>&lt;0.001</strong></td>
</tr>
<tr>
<td>Medical Microbiologist</td>
<td>486 (1.5)</td>
<td>843 (1.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Naturopath</td>
<td>470 (1.4)</td>
<td>725 (1.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Neurologist</td>
<td>193 (0.6)</td>
<td>339 (0.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Neuropsychiatrist</td>
<td>0 (0.0)</td>
<td>3 (&lt;0.1)</td>
<td>ns</td>
</tr>
<tr>
<td>Neurosurgeon</td>
<td>17 (0.1)</td>
<td>63 (0.1)</td>
<td>ns</td>
</tr>
<tr>
<td>Nuclear Medicine Specialist</td>
<td>208 (0.6)</td>
<td>323 (0.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Obstetrician/Gynaecologist</td>
<td>612 (1.9)</td>
<td>1185 (1.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ophthalmologist</td>
<td>550 (1.7)</td>
<td>1593 (2.1)</td>
<td>0.001</td>
</tr>
<tr>
<td>Optometrist</td>
<td>508 (1.5)</td>
<td>1458 (2.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Oral Surgeon</td>
<td>6 (&lt;0.1)</td>
<td>51 (0.1)</td>
<td>ns</td>
</tr>
<tr>
<td>Orthodontist</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>n/a****</td>
</tr>
<tr>
<td>Orthopaedic Specialist</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>n/a</td>
</tr>
<tr>
<td>Orthopaedic Surgeon</td>
<td>144 (0.4)</td>
<td>505 (0.7)</td>
<td>ns</td>
</tr>
<tr>
<td>Osteopath</td>
<td>0 (0.0)</td>
<td>28 (&lt;0.1)</td>
<td>ns</td>
</tr>
<tr>
<td>Otolaryngologist</td>
<td>287 (0.9)</td>
<td>492 (0.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Paediatric Cardiologist</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>n/a</td>
</tr>
<tr>
<td>Paediatrician</td>
<td>62 (0.2)</td>
<td>86 (0.1)</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Pathologist</strong></td>
<td><strong>8406 (25.4)</strong></td>
<td>21636 (29.0)</td>
<td><strong>&lt;0.001</strong></td>
</tr>
<tr>
<td>Physical Medicine Specialist</td>
<td>34 (0.1)</td>
<td>127 (0.2)</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Physiotherapist</strong></td>
<td><strong>6125 (18.5)</strong></td>
<td>13365 (17.9)</td>
<td><strong>&lt;0.001</strong></td>
</tr>
<tr>
<td>Plastic Surgeon</td>
<td>728 (2.2)</td>
<td>298 (0.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Podiatrist</td>
<td>339 (1.0)</td>
<td>1259 (1.7)</td>
<td>ns</td>
</tr>
<tr>
<td>Psychiatrist</td>
<td>720 (2.2)</td>
<td>1116 (1.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Public Health Specialist</td>
<td>0 (0.0)</td>
<td>4 (&lt;0.1)</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Radiologist</strong></td>
<td><strong>1696 (5.1)</strong></td>
<td>4129 (5.5)</td>
<td><strong>&lt;0.001</strong></td>
</tr>
<tr>
<td>Special Nurse</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>n/a</td>
</tr>
<tr>
<td>Thoracic &amp; Cardiovascular Specialist</td>
<td>24 (0.1)</td>
<td>136 (0.2)</td>
<td>ns</td>
</tr>
<tr>
<td>Urologist</td>
<td>152 (0.5)</td>
<td>236 (0.3)</td>
<td>0.002</td>
</tr>
<tr>
<td>Missing</td>
<td>57 (0.1)</td>
<td>97 (0.1)</td>
<td></td>
</tr>
</tbody>
</table>

*P-values calculated using Wilcoxon rank sum tests for each individual specialty.
**The five most common specialists are the same in both cohorts, and are highlighted.
***ns = not statistically significant at the p=<0.05 level.
****n/a = not applicable, as there are no values in either cohort.
### Table 7: Service provided in hospital, Study group and Comparison group

<table>
<thead>
<tr>
<th>Service</th>
<th>Study group (n=542) Frequency (%)</th>
<th>Comparison group (n=1189) Frequency (%)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alternate Level of Care</td>
<td>0 (0.0%)</td>
<td>1 (0.1%)</td>
<td>ns**</td>
</tr>
<tr>
<td>Cardiology</td>
<td>5 (0.9)</td>
<td>41 (3.4)</td>
<td>ns</td>
</tr>
<tr>
<td>Cardiovascular Surgery</td>
<td>1 (0.2)</td>
<td>16 (1.3)</td>
<td>ns</td>
</tr>
<tr>
<td>Family Practice</td>
<td>0 (0.0)</td>
<td>1 (0.1)</td>
<td>ns</td>
</tr>
<tr>
<td>Gastroenterology***</td>
<td>36 (6.6)</td>
<td>79 (6.6)</td>
<td>0.001</td>
</tr>
<tr>
<td>General Medicine</td>
<td>58 (10.7)</td>
<td>190 (16.0)</td>
<td>ns</td>
</tr>
<tr>
<td>General Surgery</td>
<td>141 (26.0)</td>
<td>243 (20.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gynaecology</td>
<td>58 (10.7)</td>
<td>156 (13.1)</td>
<td>ns</td>
</tr>
<tr>
<td>Haematology</td>
<td>0 (0.0)</td>
<td>2 (0.2)</td>
<td>ns</td>
</tr>
<tr>
<td>Nephrology</td>
<td>5 (0.9)</td>
<td>5 (0.4)</td>
<td>ns</td>
</tr>
<tr>
<td>Neurology</td>
<td>2 (0.4)</td>
<td>6 (0.5)</td>
<td>ns</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>2 (0.4)</td>
<td>10 (0.8)</td>
<td>ns</td>
</tr>
<tr>
<td>Obstetrics Aborted</td>
<td>10 (1.8)</td>
<td>13 (1.1)</td>
<td>ns</td>
</tr>
<tr>
<td>Obstetrics Antepartum</td>
<td>2 (0.4)</td>
<td>13 (1.1)</td>
<td>ns</td>
</tr>
<tr>
<td>Obstetrics Delivered</td>
<td>26 (4.8)</td>
<td>83 (7.0)</td>
<td>ns</td>
</tr>
<tr>
<td>Obstetrics Postpartum</td>
<td>0 (0.0)</td>
<td>2 (0.2)</td>
<td>ns</td>
</tr>
<tr>
<td>Oncology</td>
<td>2 (0.4)</td>
<td>6 (0.5)</td>
<td>ns</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>6 (1.1)</td>
<td>49 (4.1)</td>
<td>ns</td>
</tr>
<tr>
<td>Oral Surgery</td>
<td>0 (0.0)</td>
<td>5 (0.4)</td>
<td>ns</td>
</tr>
<tr>
<td>Orthopaedic Surgery</td>
<td>17 (3.1)</td>
<td>70 (5.9)</td>
<td>ns</td>
</tr>
<tr>
<td>Otolaryngology</td>
<td>7 (1.3)</td>
<td>22 (1.9)</td>
<td>ns</td>
</tr>
<tr>
<td>Palliative Care</td>
<td>0 (0.0)</td>
<td>11 (0.9)</td>
<td>ns</td>
</tr>
<tr>
<td>Plastic Surgery</td>
<td>115 (21.2)</td>
<td>25 (2.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>8 (1.5)</td>
<td>22 (1.9)</td>
<td>ns</td>
</tr>
<tr>
<td>Rehab in Acute Care Hospital</td>
<td>3 (0.6)</td>
<td>5 (0.4)</td>
<td>ns</td>
</tr>
<tr>
<td>Respirology</td>
<td>1 (0.2)</td>
<td>22 (1.9)</td>
<td>ns</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>0 (0.0)</td>
<td>1 (0.1)</td>
<td>ns</td>
</tr>
<tr>
<td>Thoracic Surgery</td>
<td>1 (0.2)</td>
<td>3 (0.3)</td>
<td>ns</td>
</tr>
<tr>
<td>Urology</td>
<td>32 (5.9)</td>
<td>65 (5.5)</td>
<td>0.003</td>
</tr>
<tr>
<td>Missing</td>
<td>4 (0.7)</td>
<td>22 (1.9)</td>
<td></td>
</tr>
</tbody>
</table>

*P-values calculated using Wilcoxon rank sum tests for each individual service.

**ns = not statistically significant at the p=<0.01 level.

***The five most common specialists are almost the same in both cohorts, with the only difference being plastic surgery and obstetrics delivered. All those falling in the top five of either cohort are highlighted.
## Table 8: Physician most responsible (service) in hospital, Study group and Comparison group

<table>
<thead>
<tr>
<th>Service</th>
<th>Study group (n=542) Frequency (%)</th>
<th>Comparison group (n=1189) Frequency (%)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthesiologist</td>
<td>0 (0.0%)</td>
<td>5 (0.4%)</td>
<td>ns**</td>
</tr>
<tr>
<td>Cardiologist</td>
<td>3 (0.6%)</td>
<td>23 (1.9%)</td>
<td>ns</td>
</tr>
<tr>
<td>Cardiovascular Surgeon</td>
<td>0 (0.0%)</td>
<td>5 (0.4%)</td>
<td>ns</td>
</tr>
<tr>
<td>Critical Care Specialist</td>
<td>2 (0.4%)</td>
<td>3 (0.3%)</td>
<td>ns</td>
</tr>
<tr>
<td>Dentist</td>
<td>0 (0.0%)</td>
<td>1 (0.1%)</td>
<td>ns</td>
</tr>
<tr>
<td>Diagnostic Radiologist</td>
<td>1 (0.2%)</td>
<td>35 (2.9%)</td>
<td>ns</td>
</tr>
<tr>
<td>Endocrinologist and Metabolism</td>
<td>0 (0.0%)</td>
<td>3 (0.3%)</td>
<td>ns</td>
</tr>
<tr>
<td>Specialist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family Practitioner</td>
<td>58 (10.7)</td>
<td>187 (15.7)</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Gastroenterologist</strong>*</td>
<td>32 (5.9%)</td>
<td>65 (5.5%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>General Practitioner</td>
<td>0 (0.0%)</td>
<td>3 (0.3%)</td>
<td>ns</td>
</tr>
<tr>
<td><strong>General Surgeon</strong>*</td>
<td>89 (16.4%)</td>
<td>155 (13.0%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Geriatrician</td>
<td>3 (0.6%)</td>
<td>0 (0.0%)</td>
<td>ns</td>
</tr>
<tr>
<td>Haematologist</td>
<td>0 (0.0%)</td>
<td>4 (0.3%)</td>
<td>ns</td>
</tr>
<tr>
<td>Infec. Disease Specialist</td>
<td>0 (0.0%)</td>
<td>1 (0.1%)</td>
<td>ns</td>
</tr>
<tr>
<td>Internist</td>
<td>9 (1.7%)</td>
<td>31 (2.6%)</td>
<td>ns</td>
</tr>
<tr>
<td>Nephrologist</td>
<td>0 (0.0%)</td>
<td>2 (0.2%)</td>
<td>ns</td>
</tr>
<tr>
<td>Neurologist</td>
<td>2 (0.4%)</td>
<td>5 (0.4%)</td>
<td>ns</td>
</tr>
<tr>
<td>Neurosurgeon</td>
<td>3 (0.6%)</td>
<td>7 (0.6%)</td>
<td>ns</td>
</tr>
<tr>
<td>Obstetrician/Gynaecologist</td>
<td>56 (10.3%)</td>
<td>152 (12.8%)</td>
<td>ns</td>
</tr>
<tr>
<td>Oncologist</td>
<td>0 (0.0%)</td>
<td>2 (0.2%)</td>
<td>ns</td>
</tr>
<tr>
<td>Ophthalmologist</td>
<td>8 (1.5%)</td>
<td>49 (4.1%)</td>
<td>ns</td>
</tr>
<tr>
<td>Oral Surgeon</td>
<td>1 (0.2%)</td>
<td>2 (0.2%)</td>
<td>ns</td>
</tr>
<tr>
<td>Orthopaedic Surgeon</td>
<td>17 (3.1%)</td>
<td>61 (5.1%)</td>
<td>ns</td>
</tr>
<tr>
<td>Otolaryngologist</td>
<td>8 (1.5%)</td>
<td>14 (1.2%)</td>
<td>ns</td>
</tr>
<tr>
<td>Physiatrist</td>
<td>0 (0.0%)</td>
<td>3 (0.3%)</td>
<td>ns</td>
</tr>
<tr>
<td>Plastic Surgeon</td>
<td>119 (22.0%)</td>
<td>38 (3.2%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Podiatrist</td>
<td>1 (0.2%)</td>
<td>0 (0.0%)</td>
<td>ns</td>
</tr>
<tr>
<td>Psychiatrist</td>
<td>2 (0.4%)</td>
<td>18 (1.5%)</td>
<td>ns</td>
</tr>
<tr>
<td>Radiation Oncologist</td>
<td>0 (0.0%)</td>
<td>1 (0.1%)</td>
<td>ns</td>
</tr>
<tr>
<td>Respirologist</td>
<td>9(1.7%)</td>
<td>26 (2.2%)</td>
<td>ns</td>
</tr>
<tr>
<td>Rheumatologist</td>
<td>0 (0.0%)</td>
<td>2 (0.2%)</td>
<td>ns</td>
</tr>
<tr>
<td>Thoracic Surgeon</td>
<td>1 (0.2%)</td>
<td>5 (0.4%)</td>
<td>ns</td>
</tr>
<tr>
<td>Urologist</td>
<td>34 (6.3%)</td>
<td>51 (4.3%)</td>
<td>ns</td>
</tr>
<tr>
<td>Vascular Surgeon</td>
<td>1 (0.2%)</td>
<td>4 (0.3%)</td>
<td>ns</td>
</tr>
<tr>
<td>Missing</td>
<td>83 (15.3%)</td>
<td>226 (19.0%)</td>
<td></td>
</tr>
</tbody>
</table>

*P-values calculated using Wilcoxon rank sum tests for each individual physician service area.
**ns = not statistically significant at the p=<0.01 level.
***Physician areas where the observed relationship is statistically significant (p=<0.01) are highlighted.
### Table 9: Level of care during hospital visits, Study group and Comparison group

<table>
<thead>
<tr>
<th>Level of Care</th>
<th>Study group (n=542) Frequency (%)</th>
<th>Comparison group (n=1189) Frequency (%)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td>297 (54.9%)</td>
<td>649 (54.6%)</td>
<td>1.01 (0.82, 1.24)</td>
</tr>
<tr>
<td>Day Surgery</td>
<td>240 (44.3)</td>
<td>527 (44.3)</td>
<td>1.00 (0.814, 1.23)</td>
</tr>
<tr>
<td>Extended Care</td>
<td>5 (0.9)</td>
<td>2 (0.2)</td>
<td>5.53 (1.07, 28.57)</td>
</tr>
<tr>
<td>DPU**/GEAR</td>
<td>0 (0.0)</td>
<td>5 (0.4)</td>
<td>n/a***</td>
</tr>
<tr>
<td>Rehabilitation</td>
<td>0 (0.0)</td>
<td>4 (0.3)</td>
<td>n/a</td>
</tr>
<tr>
<td>LTC Holding</td>
<td>0 (0.0)</td>
<td>2 (0.2)</td>
<td>n/a</td>
</tr>
</tbody>
</table>

*OR = Odds Ratio
**DPU = Discharge Planning Unit
***Odds Ratios could not be calculated for three of the levels of care because there were no values in these levels in the study group.

### Table 10: Length of stay in hospital, Study group versus Comparison group 1991/92 to 1998/99

<table>
<thead>
<tr>
<th>Total Hospital Days of Care</th>
<th>Study group (n=147)</th>
<th>Comparison group (n=583)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of visits</td>
<td>Mean (SD**)</td>
<td>No. of visits</td>
</tr>
<tr>
<td>All years</td>
<td>431</td>
<td>2.2 (4.03)</td>
<td>890</td>
</tr>
<tr>
<td>1991/92</td>
<td>34</td>
<td>1.9 (3.1)</td>
<td>104</td>
</tr>
<tr>
<td>1992/93</td>
<td>45</td>
<td>1.8 (2.7)</td>
<td>104</td>
</tr>
<tr>
<td>1993/94</td>
<td>50</td>
<td>1.5 (2.1)</td>
<td>108</td>
</tr>
<tr>
<td>1994/95</td>
<td>42</td>
<td>2.1 (2.9)</td>
<td>133</td>
</tr>
<tr>
<td>1995/96</td>
<td>78</td>
<td>3.0 (4.8)</td>
<td>122</td>
</tr>
<tr>
<td>1996/97</td>
<td>67</td>
<td>2.0 (4.5)</td>
<td>95</td>
</tr>
<tr>
<td>1997/98</td>
<td>61</td>
<td>2.7 (5.3)</td>
<td>134</td>
</tr>
<tr>
<td>1998/99</td>
<td>55</td>
<td>1.9 (4.1)</td>
<td>93</td>
</tr>
</tbody>
</table>

* P-values calculated using Wilcoxon rank sum tests.
** SD = Standard Deviation
*** ns = not statistically significant at the p<=0.05 level.
### E. Other Variables and Confounders

Age and geographic region were two potential confounders that were controlled for during sample selection. Most other lifestyle and implant factors did not affect the number of MSP visits, specialist fee items or hospitalizations among the women with breast implants who returned completed questionnaires.

- There was no association between any of these outcome variables and marital status, highest education level achieved, number of alcoholic drinks per week or exercise.

- Number of children resulted in a marginally significant decrease in hospitalizations among those with no children compared to those with one and two children or three and four children. This relationship was not observed in comparing those with five or more children to those with no children, or in other combinations of these groups.

- Ethnicity and language could be confounders. However, this project’s study sample is a very homogeneous group. The vast majority (98%) of those who completed questionnaires consider themselves Caucasian and speak English at home. It was therefore not possible to examine differences due to these factors.

- At first, it appeared that saline-filled breast implants were associated with significantly higher numbers of

---

#### Table 11: Hospital days in specific units, Study group versus Comparison group

<table>
<thead>
<tr>
<th>Unit</th>
<th>Study group (n=542)</th>
<th>Comparison group (n=178)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Days (SD)</td>
<td>Days (SD)</td>
<td></td>
</tr>
<tr>
<td>ICU</td>
<td>0.004 (0.061)</td>
<td>0.043 (0.551)</td>
<td>ns</td>
</tr>
<tr>
<td>CCU</td>
<td>0.007 (0.086)</td>
<td>0.050 (0.515)</td>
<td>ns</td>
</tr>
<tr>
<td>Rehabilitation</td>
<td>0.094 (1.332)</td>
<td>0.130 (2.063)</td>
<td>ns</td>
</tr>
<tr>
<td>DPU</td>
<td>0.000 (0.000)</td>
<td>0.062 (1.27)</td>
<td>ns</td>
</tr>
<tr>
<td>Chronic Behaviour Disorder</td>
<td>0.000 (0.000)</td>
<td>0.000 (0.000)</td>
<td>n/a</td>
</tr>
<tr>
<td>Acute Care</td>
<td>2.197 (4.025)</td>
<td>3.553 (9.131)</td>
<td>ns</td>
</tr>
</tbody>
</table>

*SD = Standard Deviation

*ns = not statistically significant at the p=<0.05 level
hospitalizations than silicone gel-filled implants (mean of 4.50 compared to 3.07; p=0.006). However, this was a result of the greatly increased percentage of saline-filled breast implants that had been implanted for five years or less (the time when many local complications are first experienced). Among the rest, there was no significant difference between those with saline-filled implants and those with silicone gel-filled breast implants for any of the outcome variables.

There were observed associations in certain areas:

- Having ever smoked was strongly associated with a significant increase in all outcome areas among women in the study group. Those who had ever smoked at all (n=50) experienced an average of 4.12 hospital visits, compared to 2.81 visits among those who have never smoked (n=42; p=0.048). They also visited the doctor more on average over the study period (160.20 visits compared to 126.02; p=0.006) and averaged more specialist fee items (251.48 compared to 235.60; p=0.009). Neither amount smoked nor number of years as a smoker further affected utilization rates.

- Increased socio-economic status was associated with a decrease in overall MSP visits and in specialist fee items (p=0.001 and p=0.002, respectively). This association was only true among the study group.

- Length of implantation did not significantly affect either total Medical Services Plan visits or specialist items. However, there was a significant decrease in hospitalizations among those who had their implants for more than 10 years compared to those who had received their implants five years ago or less.

- Dow Corning breast implants were associated with more hospitalizations than were Mentor Corporation breast implants. Dow Corning manufactured most silicone gel-filled breast implants while Mentor manufactured most saline-filled implants. However, as discussed above, type of implant does not account for this difference in manufacturer results.

Overall, the role of potential confounders seemed to be interesting, but minimal. Those variables that did affect utilization rates did so in very specific ways and often only in very specific relationships. They were rarely overarching, affecting all areas, all years, or all women.
Discussion

A. Overview

This study sheds new and interesting light on a question that seems to have no easy answers. Although the results may be subject to sample bias, they do indicate that breast implantation is related to increased use in key areas of the British Columbia public health care system.

Women in this study who had undergone breast implant surgery visited significantly more doctors and more specialists than their counterparts who had not received these implants. They were more than four times as likely to be hospitalized (OR = 4.26, 95% CI = 2.58, 7.02), and the number of hospitalizations they experienced over the study period was significantly higher than was experienced by women in the control group.

There were other differences in health care utilization patterns. Women who had received breast implants accessed slightly different specialists and hospital services than did women who did not. They were more likely to be admitted to hospital electively (OR = 1.90, 95% CI = 1.50, 2.39) but less likely to be admitted urgently (OR = 0.60, 95% CI = 0.46, 0.78) or in an emergency (OR = 0.53, 95% CI = 0.35, 0.79). The study group women seemed to spend slightly less time in hospital than did those in the comparison group, a relationship that was stable, although not statistically significant, over the years.

There are also similarities in health care utilization patterns. The main difference in services provided in hospital was in the greatly increased need for plastic and general surgery services and for gastroenterology services. Other hospital services and hospital physicians were distributed in very much the same way between the two groups. Likewise, there was no difference in the proportions of women from the cohorts in the different
Women in this study who had undergone breast implant surgery were more than four times as likely to be hospitalized than the women who had not received these devices.

hospital levels of care, nor was hospital length-of-stay significant.

Type of implant did not significantly affect utilization rates, indicating that women who have received saline implants are no less likely than women who have received silicone gel-filled implants to experience this increased need for public health care services. Similarly, other implant factors and lifestyle factors did not appear to be significant confounders. (Smoking was a factor that increased health care utilization, and future research could investigate this possible confounder within both study and comparison cohorts.)

B. External Validity

The study results must be interpreted with caution, and in full light of the challenges and limitations encountered.

In terms of generalizability, the study group is made up almost entirely of Caucasian women who speak English as their primary language, which means that although the results can perhaps be generalized to other women in this group, the results may not be applicable to women of other ethnic groups.

There is also the issue of sample bias that comes from relying on a self-identified study group. This could significantly skew the results and reduce generalizability to the general population of women with breast implants. As the entire population of women with implants cannot be observed, the extent to which this bias is or is not present cannot be evaluated.

The potential for such bias may be less significant than it could have been. As the questionnaires show, most of the women participating in this study did not consider themselves to be in poor health. Quite the contrary, they felt that their health is good or excellent compared to other women their age (although half reported being diagnosed with a chronic illness and one-quarter felt that health problems subsequent to breast implantation had caused them to lose or quit a job). The results also indicate increased need only in very specific areas; areas that are related to well-documented breast implant-related complications. These factors indicate that the study group is not significantly biased either towards sick or healthy women.

That being said, a self-identified study
sample is often subject to some sample bias, especially in an area as charged as this one is. That being the case, generalizations and conclusions about causality must be cautious and limited.

C. Internal Validity

Past studies have reported that women with breast implants have different characteristics (e.g., more alcoholic drinks, more sex partners, and dying hair more often) than do non-implanted women (Cook et al., 1997). These factors are potential confounders that could not be considered in this study, given the anonymity of the comparison cohort. This research was able to examine some lifestyle, demographic and implant factors among the women in the study group, and found that these factors did not, in general, markedly affect health care use. Differences in these areas between the study and comparison groups, therefore, would not be responsible for the observed results.

D. Health Trends

Are increased visits among women who have received breast implants indications of poorer health or just of more questions or concerns about their health? Or are they related to specific health concerns?

The increased utilization observed in this research is not simply a matter of perceived need, as could be the case if only ambulatory visits (MSP data) were inflated. In an increasingly strict health care climate that discourages hospitalizations for all but those in most serious need, women with breast implants are using more of these services more often. And, given the specific areas involved, this increased use is a direct consequence of their privately-funded surgery.

In an increasingly strict health care climate that discourages hospitalizations for all but those in most serious need, women with breast implants are using more of these services more often. And, given the specific areas involved, this increased use is a direct consequence of their privately-funded surgery.
This study is probably too small to pick up differences in health care utilization due to systemic illness, given the rarity of classic autoimmune or connective-tissue disorders, and given that this type of illness probably affects only a subset of women with breast implants (although there was an observed association between breast implants and use of gastroenterology services—a relationship that was stable across several analyses and should therefore be explored further). The results support this, indicating increased utilization in areas and time frames that would be associated with local rather than systemic complications. The high rate of such problems is well known, and thus we cannot minimize the large—and growing—number of women who will rely on the public health care system to a greater extent following breast implant surgery.

E. Future Research Directions

This study opens many avenues for future research. Further study in this area of health care utilization would serve to expand on the results observed here and could delve deeper into specific health consequences. Additional examination with larger study samples and, once a breast implant registry is established, random study samples are highly recommended.

This research does not answer the question of causality. It does not tell us why breast implantation results in increased public health system use, only that it does. Assumptions can be made based on breast implant knowledge and literature, but additional study is needed to further examine and explain the reasons for this increased use—to better understand it and therefore address it.

Certain variables also bear closer examination. For example, hospital length of stay results proved to be very interesting. Days of care in hospital were shorter (though not significantly) among the women with breast implants. This trend is likely related to the types of services they are accessing in hospital, and thus could be an indication of the specific health care problems that are contributing to increased need for services.
Conclusion

The results from this study indicate that undergoing breast implant surgery does affect health care system utilization. It is associated with increased doctor’s visits and increased hospitalizations.

Breast implant surgery is not deemed medically necessary and is performed – and paid for – privately in the vast majority of cases. However, it appears to directly contribute to an increased need for public health care services among the women receiving these devices. If, as the literature suggests, serious local complication rates are at least 25% (Gabriel et al., 1997, p. 677) – and more likely are 50% or higher (Sarwer et al., 2000, p. 847) – there are many thousands of women in British Columbia who are using greater health care resources as a result of this surgery.

This study makes no claim to be able to ascertain or predict health outcomes subsequent to breast implantation. However, it does tell us with confidence that women who have undergone this surgery use the publicly funded health care system more than women of the same age and region who have not.

This study points the way towards more research in order to more definitively and completely investigate the health care utilization patterns of women with breast implants and to better understand the causal relationship between breast implants and health care use. This research and that to follow will help guide women in their decision-making and governments in their policy-making.
References and Bibliography


Rubin, R. (2000, March 1). Saline implants studied for safety: FDA finally injects data into decision to get them. USA Today, 01D.


Appendix 1: Public Service Announcement

Are you interested in helping us learn more about breast implants? We are looking for volunteers for a research project on the use of the health care system by women who have or have ever had breast implants. Your confidentiality will be guaranteed. If you have ever had breast implant surgery and are interested in taking part in this research project, please contact Aleina Spigelman at the Centre of Excellence for Women’s Health at Children’s and Women’s Health Centre of B.C. at (604) 875-2280.
Appendix 2: Informed Consent Letter and Form

Consent Form
Health Care Utilization for Women Who Have Undergone Breast Implant Surgery

Dear friend,

This letter outlines a research project in which we hope you will agree to participate. Below we describe the project and explain why your participation will be of great value to this study. We explain the process that will be used to ensure that your identity and the information you provide is kept strictly confidential. Please read the project outline carefully. Two copies of a consent form are attached to this letter. If you are willing to be part of this study, please complete one copy and return it to us in the envelope provided. The second copy is for you to keep for your own records. If you have any questions or concerns please feel free to contact the project coordinator, Aleina Spigelman at (604) 837-4800. Thank you for your time and interest.

Project Overview

A team of health care consumers and medical researchers are studying how women who have undergone breast implantation surgery use health care services as compared to women who have never had such surgery.

We want to know if there are differences in the rates of health care service use between women in these two groups. We want to know how women use both the publicly-funded health care system (e.g., family physicians, hospitals, specialists) and other forms of health care (e.g., counselors, herbalists, massage therapists) that are paid for privately. We are also interested in women’s use of “alternative” or “complementary”
therapies.

From this study, we hope to better understand some of the consequences of breast implantation surgery and the health care needs of women who have undergone such surgery. This in turn may help researchers identify, prevent and find better treatments for side effects of this surgery.

Description

We will compare two groups of women. The study group will be made up of women who have undergone breast implant surgery and who are willing to participate in this project. The control group will be made up of women who have never had such surgery.

We are asking that women who have had breast implant surgery give us their permission to use their Personal Health Numbers (PHNs) to access health care usage data available in the B.C. Linked Health Database. This Database links information about consumer activity and health care provider services in the MSP, Hospitalization, Continuing Care, Deaths and Births and Pharmacare databases.

Once we have your permission, we will submit your PHN to a database manager at the Ministry of Health in Victoria, B.C. This person will scramble your PHN to ensure confidentiality and then will forward the number (with others) to the Centre for Health Services and Policy Research (CHSPR) at the University of British Columbia.

Once the Centre for Health Services and Policy Research receives the scrambled PHNs, it will in turn obtain permission from the Ministry of Health to extract the data from the B.C. Linked Health Database. Our research team will have access to these data for a limited period of time for analysis.

The study group will also be sent a questionnaire that will take approximately 20 to 30 minutes to complete. This questionnaire will ask questions about you, your lifestyle and your implants. It is intended to provide a more complete picture of health care usage. It will also help us to determine if there are any differences dependant on age, location, ethnicity, socio-economic status, type of breast implant, and so on. No identifying information will be asked, and the results of the questionnaires will be kept strictly confidential.

Confidentiality

If you agree to participate in this study, you will not be identified personally in the analysis or reported findings. We will ensure confidentiality through several methods:

♦ Names, addresses and Personal Health Numbers (PHNs) will be separated from all other information. Only the research
team leader will ever see the identifying information. She will assign file numbers, and any information (including the utilization data and questionnaires) contained in the file will always be kept separate from names and addresses.

♦ All information (names, addresses, PHNs, utilization data, questionnaire responses, etc.) will be kept locked in filing cabinets and computer files will be secured by password.

♦ The B.C. Ministry of Health will receive only PHNs and file numbers, with no other identifying information. When the Ministry receives this list, it will use a computer program to scramble the PHNs so that they cannot be used to trace the identity of the person. Only then will the Centre of Health Services and Policy Research (CHSPR) have access to the numbers. The Ministry does not keep either list (of scrambled or unscrambled PHNs).

♦ The questionnaires will be identified by file number only – never by name.

Permission

We hope that you will agree to be part of this important study. In order to understand the impact of breast implant surgery on women’s health, we need to know how it affects women’s use of health care services, both traditional and “alternative.” We hope we have your support and cooperation.

If you are willing to be part of this study, please complete one copy of the attached consent form and return it to us in the envelope provided. Please keep the other copy for your own records.

Please note that if you agree to be part of the study, you can withdraw that permission at any time. You have the right to refuse to participate and to withdraw your participation without any negative consequences to you. Refusing to participate or withdrawing from the study will not in any way jeopardize any future treatment or medical care you need.

If at any time you have any concerns about your rights or treatment as participants in this project, you may contact Dr. Richard Spratley, Director of the UBC Office of Research Services and Administration at (604) 822-8598.

Risks and Advantages

There are no immediate benefits that this project will provide to you. However, there are also no risks and there may be long-term benefits. This project may provide important information that will benefit all breast implant consumers in the long run.
Thank you for your time in reading this letter. We believe this project is an important step in the search for more information about breast implants and their effects on women.

If you have any questions or concerns about this project, please feel free to contact the project coordinator, Aleina Spigelman at (604) 837-4800.
**Consent Form**

I, (full name) ________________________________________________, give my permission to the researcher identified above to use my Personal Health Number to access my health care utilization data. I understand that the researcher guarantees my confidentiality and that the methods outlined in the above letter will be followed to achieve this guarantee. Only the research leader (Ms. Aleina Spigelman) will have access to the key that links my questionnaire and utilization data with my identifying information.

The data collected will be used to examine the health care utilization of women who have undergone breast implant surgery and will be compared to the health care utilization of a group of women who have never had such surgery.

I understand that a questionnaire will be sent to me to ask about other health care utilization.

_____________________________ _______________________________  
Participant Signature                   Witness Signature

_____________________________ _______________________________  
Participant Name (please print)        Witness name (please print)

_____________________________ _______________________________  
Date (day/month/year)                  Date (day/month/year)

Address: ___________________________________________________________
(Apartment) (Street)

_____________________________ _______________________________  
(City) (Province)

_____________________________ _______________________________  
(Postal Code) (Country)

Phone number: (_________) _________-____________

Personal Health Number: _________   _________   _________

☐ I have received a copy of this consent form
Appendix 3: Health Practices Questionnaire

Health Care Utilization for Women Who Have Undergone Breast Implant Surgery

Health Practices Questionnaire

Name: _________________________________________

Address: _________________________________________

________________________________________

________________________________________

________________________________________

Personal Health Number: _________________________
Health Care Utilization for Women Who Have Undergone Breast Implant Surgery

Health Practices Questionnaire

Demographics: Please tell us a bit about yourself.

1. Date of Birth (day/month/year): _______/_______/_________

2. Where do you live?
   □ Major city (E.g., Lower Mainland, Victoria)
   □ Small city outside of Lower Mainland
   □ Rural area

3. Ethnicity (please check one):
   □ Caucasian
   □ Asian
   □ Indo-Canadian
   □ First Nations
   □ African-Canadian
   □ Other (please specify) _______________________________________

4. What language do you speak at home? (Please check one)
   □ English
   □ French
   □ Cantonese
   □ Mandarin
   □ Other (please specify) _______________________________________

5. What is your marital status? (Please check one)
   □ Married/Common-law
   □ Separated/Divorced
   □ Single
   □ Widowed

6. What is the highest education level you have completed? (Please check one)
   □ Less than high school
   □ High School
   □ Some post-secondary
   □ Post-secondary degree
7. Do you have any children?
   ☐ No, none
   ☐ Yes, 1-2
   ☐ Yes, 3-4
   ☐ Yes, 5 or more

Implants: Please give us some information about your breast implants.

8. Why did you get breast implants?
   ☐ Cosmetic augmentation
   ☐ Reconstruction after mastectomy for malignant disease (e.g., cancer)
   ☐ Reconstruction after other mastectomy (e.g., breast cysts, prophylactic)
   ☐ Augmentation for non-development of one breast/both breasts
   ☐ Other (please specify) ________________________________________

9. How many breast-implant-related surgeries have you had after your initial breast implantation surgery?
   ☐ None
   ☐ One
   ☐ Two
   ☐ Three
   ☐ Four or more (If more, how many? __________)

10. Have you ever had to replace one or both of your breast implants?
    ☐ No
    ☐ Yes, one
    ☐ Yes, both

    a. If yes, how many times have they been replaced?
       ☐ One
       ☐ Two
       ☐ Three
       ☐ Four or more (If more, how many? __________)
11. Have you ever had a silicone implant of any kind other than breast implants (e.g., hip replacement, chin implants, etc.)?  
☐ No  
☐ Yes  

If yes, what type of implant(s)? __________________________________

For the next questions, please provide information for each set of breast implants you have had (if you have had more than four sets of implants, please use a separate sheet of paper).

<table>
<thead>
<tr>
<th>Set #1</th>
<th>Set #2</th>
<th>Set #3</th>
<th>Set #4</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. In what year did you get your breast implants?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. If your breast implants have been permanently removed, in what year were they removed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. What type are/were your breast implants? (Please see reference guide below for appropriate number)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Who manufactured your implants? (Please see reference guide below for appropriate number)</td>
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</tr>
</tbody>
</table>

**Type of Breast Implant**
1. Silicone gel-filled  
2. Saline filled  
3. Bi/Double/Triple lumen  
4. Meme (coated with Polyurethane foam)  
5. Dacron patch  
6. Other (please specify)  
7. Don’t know

**Breast Implant Manufacturers**
1. Dow Corning  
2. Mentor  
3. McGhan  
4. Other (please specify)  
5. Don’t know
Health: Please tell us a bit about your health.

16. Compared to other women your age, how would you describe your health at this time?
   □ Excellent
   □ Good
   □ Fair
   □ Poor

17. Have you been diagnosed with a chronic illness? (If more than one, please use separate paper)
   □ No
   □ Yes (please specify) ________________________________

   a. If yes, in what year was this illness diagnosed? _________

18. Have you ever lost your job or had to quit your job or reduce your hours because of health problems?
   □ No, neither
   □ Yes, lost my job
   □ Yes, reduced my hours
   □ Yes, quit my job

   a. If yes, was this before or after you got breast implants?
      □ Before
      □ After
      □ Don’t know

19. Have health problems interfered with your ability to do housework or recreational activities?
   □ No, never
   □ Yes, occasionally
   □ Yes, often

   a. If yes, was this before or after you got breast implants?
      □ Before
      □ After
      □ Don’t know
Health Behaviour: Please tell us a bit about activities that might affect your health.

20. Do you exercise regularly?
   □ No
   □ Yes
   a. If yes, how many times per week?
      □ One or two times
      □ Three or more times

21. Have you ever smoked?
   □ No
   □ Yes If yes, when did you start (year)? __________

22. Do you still smoke?
   □ No If no, when did you stop (year)? __________
   □ Yes

23. If you have ever smoked, how much do/did you smoke per day?
   □ Less than ½ pack per day
   □ ½ to 1 pack per day
   □ More than 1 pack per day

24. Approximately how many alcoholic drinks do you have per week? (One drink is one bottle of beer, one five-ounce glass of wine or one-and-a-half ounces of hard alcohol.)
   □ None
   □ 1 to 2
   □ 3 to 5
   □ 6 to 10
   □ 11 or more
Health Services: Please tell us about private health services you use.

25. Have you ever sought alternative health care services, that is, services not paid for by your medical services plan (e.g., acupuncture, homeopathy, etc.)?
   □ No
   □ Yes

   a. If yes, what alternative health care services have you used?
      ________________________________________________________________
      ________________________________________________________________
      ________________________________________________________________

26. Have you ever accessed health care services outside of Canada?
   □ No
   □ Yes

   a. If yes, in what country(ies)? ______________________________________
   b. If yes, in what year(s)? ________________________________
   c. If yes, what service(s) did you access?
      ________________________________________________________________
      ________________________________________________________________
      ________________________________________________________________

Thank you very much for your time and effort. If you have any further comments related to your health care usage or your breast implants, please feel free to add any comments to the end of this survey, or attach additional pieces of paper. If you have any questions, please contact Aleina Spigelman at (604) 837-4800 or by email at aleinas@hotmail.com.
Appendix 4: B.C. MSP Subsidy Codes and Statistics Canada Low-Income Cut-Offs

The Low-Income Cut-Offs (LICOs) are published by Statistics Canada. Families living below these income levels are considered to be living in “straitened circumstances.” The LICOs are more popularly known as Canada’s poverty lines. They measure relative rather than absolute poverty.

Although Statistics Canada avoids referring to the LICO as the “poverty line”, researchers have long used the LICO to identify the population living “in poverty” and to measure changes in this population over time.

<table>
<thead>
<tr>
<th>Low-Income Cut Off: Family Size 1 (1992 Base)</th>
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<tbody>
<tr>
<td>Population of Community of Residence</td>
</tr>
<tr>
<td>Year</td>
</tr>
<tr>
<td>------</td>
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<tr>
<td>1999</td>
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<td>1993</td>
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From: Canadian Council on Social Development, www.ccsd.ca
The British Columbia Medical Services Plan provides MSP subsidy assistance to individuals whose net income from the previous year falls below certain levels, less deductions for family size, age and disability.

<table>
<thead>
<tr>
<th>Net Income</th>
<th>Subsidy</th>
<th>Subsidy Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0,000.00 - $11,000.00</td>
<td>100%</td>
<td>A</td>
</tr>
<tr>
<td>$11,000.01 - $13,000.00</td>
<td>80%</td>
<td>E</td>
</tr>
<tr>
<td>$13,000.01 - $15,000.00</td>
<td>60%</td>
<td>B</td>
</tr>
<tr>
<td>$15,000.01 - $17,000.00</td>
<td>40%</td>
<td>F</td>
</tr>
<tr>
<td>$17,000.01 - $19,000.00</td>
<td>20%</td>
<td>G</td>
</tr>
<tr>
<td>$19,000.01 +</td>
<td>0%</td>
<td>D</td>
</tr>
<tr>
<td>Temporary Premium Assistance*</td>
<td>100%</td>
<td>C</td>
</tr>
<tr>
<td>Paid by Social Services</td>
<td>100%</td>
<td>H</td>
</tr>
</tbody>
</table>

*Temporary premium assistance is offered to individuals due to unexpected hardship who do not qualify for the maximum level of assistance based on the previous year’s income.
Advisory Committee

Aleina Tweed (née Spigelman)  
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Dr. Penny Ballem  
Haematologist, Vice President Services, Specialized Women’s Health and Reproductive Health, BC Women’s Hospital and Health Centre

Dr. Milton Baker  
Private Practice, Internal Medicine & Rheumatology
Les femmes qui ont subi une intervention chirurgicale destinée à l'implantation d'une prothèse mammaire utilisent-elles le système de soins de santé public plus souvent ou différemment en comparaison des femmes qui n'ont jamais subi une telle chirurgie? La présente étude offre un aperçu de la santé des femmes qui ont subi une intervention chirurgicale destinée à l'implantation d'une prothèse mammaire et des conséquences inhérentes à une chirurgie privée (relevant d'un financement privé) sur le secteur public.