HEALTH CARE UTILIZATION AMONG WOMEN WHO HAVE UNDERGONE BREAST IMPLANT SURGERY

by

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B.A., The University of British Columbia, 1996

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF SCIENCE

in

THE FACULTY OF GRADUATE STUDIES

Department of Health Care and Epidemiology

We accept this thesis as conforming to the required standard

THE UNIVERSITY OF BRITISH COLUMBIA
September 2001

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ABSTRACT

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Background: Women have long used breast implants to enhance their bust-lines or replace what was stolen by cancer or disease. This study, rather than investigating health outcomes, focuses on the issue of health care utilization and tests the hypothesis that receiving breast implants results in increased use of the public health system.

Methods: 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 information (e.g., type of implant, length of implantation) and lifestyle information (e.g., smoking, alcoholic drinks, exercise, marital status, number of children).
**Results:** Statistical analyses 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).

Survey information showed that, despite some limited relationships, neither lifestyle nor implant factors accounted for the increased health care utilization. Length of implantation resulted in decreased hospitalizations, indicating a greater need for short-term hospital care, such as that associated with local breast-implant complications.

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

Thank you to

Hamish Tweed, without whose support I would never have made it.
Penny Ballem for her insights and encouragement.
Kim McGrail, whose patience and advice were unending.
Ann Pederson for all her work and for her friendship.
The women who agreed to participate, despite their misgivings.
And, of course, my parents, who have given me everything.
SECTION 1: INTRODUCTION

For decades, women have used breast implants to enhance their bust-lines or replace what was stolen by cancer or disease. And for almost as long, there has been discussion and acrimonious debate as to whether or not this surgery hurts women more than it helps them. Women 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 predecessor.

In Canada, the issues are muddied even further. An estimated 80% of breast implantation surgeries are performed as cosmetic augmentation. Such surgery is not considered ‘essential’ and is therefore paid for privately. If the public health system does not pay for it, it also does not track it. 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. Much like tobacco, the manufacturers reap the rewards while the public bears the consequences.

To add to the difficulty, breast implant research is beset by challenges, not the least of which being 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.

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 over the financial consequences borne by government and, ultimately, by the public.
a. Purpose

This project strives to answer the question of whether or not women who have undergone breast implant surgery use the public health care system more and/or differently from women who have never had such surgery.

This research was initiated out of the desperate 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 serious issues that make it nearly impossible to come up with conclusive results. This, coupled with the highly politicized nature of the issue, has meant that – deservedly or not – all research has been accused of being biased and flawed by either or both ‘sides’ of the debate.

Although this research is also affected by the same challenges and limitations, it takes a novel approach and therefore sheds some light in new areas. Rather than examining health outcomes directly, this study 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 also provide insights into the publicly borne consequences of a private (and privately funded) surgery. It adds to the body of knowledge about breast implants, empowering women to make informed decisions about implantation. Lastly, it improves understanding of women with breast implants, ultimately improving their health.
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).
- 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

This paper is organized into seven sections. Following this Introduction, Section 2 provides background information about breast implants and some of the health issues associated with them. Section 3 describes the methodology of this project, including details of the study design, study and comparison cohort definitions, and data collection and analysis issues. Section 4 presents some of the challenges and limitations faced not only by this study but by all research examining breast implant related issues. Section 5 presents the results and Section 6 provides some discussion of those results and directions for future research. Final conclusions are presented in Section 7.
SECTION 2: BACKGROUND

a. History

Cosmetic breast enhancement is nothing new. As early as 3000 BCE, Minoan women used early brassieres and corsets to emphasize their breasts. The first true corset was invented in the 13th century and was used, in conjunction with various clothing styles, to raise the breasts to attract men (Sarwer et al. 2000, 844).

The 18th century heralded the age of invasive attempts at breast enlargement, an age which continues today. These surgical efforts were and are intended to provide women with greater self-satisfaction with the appearance of their breasts, or to aid the psychological healing that must accompany a mastectomy (Bondurant et al. 2000, 20).

Cosmetic breast surgery was first recorded in 1887 with the transference of part of a healthy breast transferred on a pedicle to reconstruct the other breast (Bondurant et al. 2000, 21). Other attempts at autologous tissue reconstruction have continued, and today surgery such as the transverse rectus abdominis musculocutaneous (TRAM) flap is highly successful. Approximately one-third of modern breast reconstructions are performed using autologous tissue (Bondurant et al. 2000, 21).

Around the same time as autologous tissue reconstruction became possible, so did the insertion of foreign substances to augment or reconstruct the breast. Beginning in 1889, physicians experimented with the injection of paraffin. Although paraffin seemed successful for a time, later results included fistulas, granulomas, pulmonary emboli and tissue necrosis (Bondurant et al. 2000, 21). Many other fluids were used as experimental injectables for breast augmentation through to the late 1960s. These included poorly defined hydrocarbons called “Organogen” and “Bioplasm”, some forms of petroleum jelly such as Vaseline, body fat from the buttocks and adulterated silicone oil. This silicone oil is believe to have been adulterated with ricinoleic acid, animal and vegetable fatty acids, mineral and vegetable oil, olive oil, croton oil, peanut oil, concentrated vitamin D, snake venom, talc and/or paraffins (Bondurant et al. 2000, 22).
Physicians also experimented with a variety of other oils including beeswax, shellac, glaziers’ putty, epoxy resin and industrial silicone fluids. Substantial amounts of these substances were often injected, as much as two litres for breast augmentation and body contouring in a single patient (Bondurant et al. 2000, 22). Consequences of all these injections included loss of both breasts and death.

Dow Corning medical-grade silicone was used for a short time, and at first results seemed very good. However, adverse effects became evident among women a few years after injection. These included pain, skin discolouration, edema, ulceration and necrosis, calcification, granulomas, migration of the fluid, infection, cysts, axillary adenopathy, disfigurement and loss of the breast, liver granulomas and dysfunction, acute pneumonitis or adult respiratory distress syndrome, pulmonary embolism, coma and death (Bondurant et al. 2000, 23). Although the FDA has expressly not approved the marketing of liquid silicone for injection for any cosmetic purpose, there are reports of thousands of women who have received such injections in sites other than the breast.

b. Breast Implants

While some were experimenting with injection, others were trying to find appropriate substances to implant into the breast to change its proportions. Substances tried included ivory, glass balls, ground rubber, metal, ox cartilage, Terylene wool, gutta percha, Dicora, Polyethylene chips, polyvinyl alcohol-formaldehyde polymer sponge (Ivalon), Ivalon in a polyethylene sac, polyether foam sponge (Etheron), polyethylene tape (Polystan) or strips wound into a ball, polyester (polyurethane foam sponge) Silastic rubber and Teflon-silicone prosthesis (Bondurant et al. 2000, 21; Sarwer et al. 2000, 844; Silverman et al. 1996, 751). None of these early implants were successful, and many were painful and disfiguring, often leading to illness and even death.

The modern silicone breast implant was first introduced in 1962, developed by Cronin and Gerow. These breast implants soon became very popular, a popularity which has continued to grow. In 1990, the American Society of Plastic and Reconstructive Surgery reported 132,290 breast implantation procedures (Baines et al. 1992, 14). The health concerns of the early 1990s affected these numbers, but only temporarily. By 1998, it was again the second most popular
cosmetic procedure in the United States, and the most popular among young women. Over 132,000 women underwent breast augmentation surgery by an American plastic surgeon in that year, representing a 51% increase from 1996 and an increase of 306% from the 32,607 procedures performed in 1992, the year silicone implants were banned (Sarwer et al. 2000, 844; American Society of Plastic Surgeons Statistics Clearinghouse 1999). Another 69,683 women underwent breast reconstruction surgery, 46% of which (n=32,054) used breast implants and/or tissue expanders (American Society of Plastic Surgeons Statistics Clearinghouse 1999). The true number of women getting breast implants is even higher than this, as many non-surgeon physicians are now performing cosmetic surgery in the United States, and perhaps elsewhere (Sarwer et al. 2000, 844; American Society of Plastic Surgeons Statistics Clearinghouse 1999).

In Canada, thousands of women have chosen breast implant surgery, including an estimated 25,000 or more in British Columbia (Breast Implant Centre 1999, 1). As in all of North America, most (approximately 80%) of these surgeries are for breast augmentation. The other 20% was for reconstruction after cancer or prophylactic mastectomy, or to correct under- or non-developed breasts (Segal 1992, 1; Baines et al. 1992, 12).

Until 1992, plastic surgeons implanted almost exclusively silicone gel-filled breast implants. Concerns grew over a suggested link between breast implants and cancer or autoimmune disease. The American Food and Drug Administration (FDA) received thousands of reports from women with silicone gel-filled breast implants who were experiencing physical symptoms and nonspecific illnesses (Sarwer et al. 2000, 843). In 1992, these concerns came to a head, and then FDA commissioner David Kessler banned the use of silicone implants in the United States, arguing that existing research had demonstrated neither their physical safety nor psychological benefit (Sarwer et al. 2000, 843). Health Canada quickly followed suit by issuing a voluntary moratorium on these implants, asking that distributors of silicone gel-filled implants voluntarily stop the sale of these products. Only saline-filled breast implants are now widely available in both countries, although the safety of these has not been scrutinized either by the US Food and Drug Administration or by Health Canada.

Many studies since have put the cancers concerns to rest. One report reviewed over 100 studies on the medical effects of implants and found that breast implants do not increase a woman’s risk
of breast cancer (Nelson 2000). Health Canada supports this assertion, finding that there is, “no scientific evidence that women with saline-filled, silicone gel-filled or polyurethane foam covered silicone gel breast implants are more susceptible to cancer than other women” (Health Canada 1998, 4). However, there are still some concerns, as many of the studies did not take into account family histories, did not follow women for an adequate period of time, and did not follow women into their post-menopausal years, raising the possibility that we may yet see increased rates of cancer as women with breast implants age (Silverman et al. 1996, 753).

Despite widespread relief that breast implants do not seem to significantly increase the risk of cancer, the moratorium continues. Concerns now focus mainly on the possible relationship between breast implants and autoimmune or connective tissue disease.

Today, most women are given saline-filled breast implants. Intuitively, these are safer, as they are filled with a sterile saline solution. However, there are still many concerns. Firstly, the concerns about silicone have not been entirely avoided, as the saline solution is still contained by a silicone bag. Secondly, breast implants — regardless of the material — are still very large foreign bodies implanted very close to major organs for prolonged periods of time. Lastly, there are concerns about the continuing sterility of the saline solution over time. Some studies have found fungal and bacterial growth in and around explanted saline-filled breast implants. One study that examined 69 explanted prostheses found that 66 of the implants showed “grossly visible internal contamination in the form of flocculent suspended material of microbiological origin” (Blais 1998, 1).

c. Health Outcomes of Breast Implants

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, 28). However, there are also many women who experience side effects and feel that breast implants have compromised their short-term and long-term health.

The number of women who have been affected by breast-implant related complications is very high. Between Jan. 1, 1985 and September 17, 1996 the US Food and Drug Administration
received 103,343 adverse reaction reports associated with silicone breast implants and 23,454 reports involving saline implants (Segal 1997, 2; Powell and Leiss 1997, 107).

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 operative risks associated with any surgical intervention to implant a medical device.

i. **Surgical Complications**

There are a number of risks associated with any surgery, and breast implantation is no different. These risks include possible complications of general anesthesia, infection, haematoma, hemorrhage, thrombosis, skin necrosis, delayed wound healing, and additional surgeries (Health Canada 1998, 2; Mentor, 8-9; Bondurant et al. 2000, 114; Sarwer et al. 2000, 847; Baines et al. 1992, 22; Segal 1997, 5).

**Infection:** While most infections appear within the first days to weeks after surgery, they can occur at any time following the implantation. The frequency of infection associated with breast implant surgery is approximately 1% to 3% (Bondurant et al. 2000, 121; Sarwer et al. 2000, 847). These foreign-body related infections are more difficult to treat than infections of normal body tissue, and can result in the need to remove the implant (Health Canada 1998, 2; Mentor, 8).

**Haematoma:** Blood may collect around the implant or around the incision. This may result in swelling, pain and bruising. The frequency of haematoma associated with breast implant surgery is approximately 2% to 3% and most occur within the first month of surgery. The body is able to absorb small haematomas, but large ones must often be drained surgically (Health Canada 1998, 2).

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1 Because these figures come from all FDA databases, there may be a few duplicate reports.
Delayed wound healing: Although it is rare, breast implants sometimes stretch the skin abnormally, preventing the incision from closing and healing properly (Health Canada 1998, 2). This can deprive the skin of blood supply and allow the implant to push out through the skin (Mentor, 9). It usually results in additional surgery.

Additional surgeries: It is likely that a woman who receives breast implant(s) will need additional surgery or surgeries related to her implant(s) over her lifetime. Reasons for re-operation include treatment of capsular contracture, correction of implant size or position, control of infection, as the result of other local or systemic complications, or to prevent or treat implant leakage or rupture or other health problems. (Baines et al. 1992, 22; Sarwer et al. 2000, 847; Bondurant et al. 2000, 119).

ii. Local Complications

Local complications centre on the chest or breast area and can appear anytime from the moment of implantation to many years later. Although their existence was denied for many years, they are now well accepted and well documented.

Local complications can range from very mild to very severe, and they affect a large percentage of women who undergo breast implant surgery. A study conducted by the Mayo Clinic in the United States found that one-quarter (25%) of women who received breast implants required additional surgery within five years due to local complications (Gabriel et al. 1997, 677).

The most significant local complications include capsular contracture, implant deflation and rupture, change in shape or volume of the breast, shifting from the original placement, change in breast sensation, calcium deposits, mammographic interference, breast/chest discomfort or pain and nipple discharge (Segal 1997, 5; Mentor, 7-9; Health Canada 1998, 2-3; Sarwer et al. 2000, 847; Baines et al. 1992, 19-22; Blais 1998, 5).

Capsular contracture: The human body responds to any foreign material by building a fibrous wall between the object and the body. This scar tissue surrounding the breast implant may contract, causing breast hardness, discomfort and even severe pain (Mentor, 8).
Health Canada estimates that 25% of women who undergo breast implant surgery develop capsular contracture, usually within 2 years of surgery (Health Canada 1998, 2). Other researchers place this percentage as high as 70%, and some estimate that 100% of women with breast implants will develop some degree of capsular contracture over the life of the implant (Sarwer et al. 2000, 847).

**Implant deflation and rupture:** Breast implants last only a limited period of time. Deflation or rupture may be caused by normal wear and deterioration of the implant shell over time, breast trauma, undetected damage at the time of the surgery or a shell weakness due to a flaw introduced during manufacture. It may occur very quickly after implantation or implants may still be intact years after the surgery (Health Canada 1998, 3; Mentor, 7). It is thought that leakage and rupture occurs more frequently in older implants, as the envelopes are known to weaken over time (Baines et al. 1992, 21). In one study, two-thirds of all removed implants – ranging in age from 0 to 17 years old – were ruptured or leaking, including all the implants over 10 years of age. Another study found that 70% of removed implants 11 to 15 years old were ruptured or leaking (Sarwer et al. 2000, 846), and a U.S. government study found that MRI exams on 344 implanted women revealed that two-thirds of the women had ruptured implants (American Broadcast Corporation, 18 May 2000). Of course, it is not appropriate to directly generalize the experience of women requiring explantation to an asymptomatic population with apparently intact implants. More accurate rupture rates can only be estimated using data from a representative sample of all women with implants (Baines et al. 1992, 22), a sample that is currently impossible – or at least very difficult and very costly – to create for a retrospective study.

Deflation, leakage and rupture can result in the breast implant filler being spread through the body. As the results of liquid silicone injections show, this can be dangerous in the case of silicone gel-filled implants. The salt-water solution contained within saline-filled implants should be harmless. However, there have been suggestions that, due in part to the semi-porous nature of breast implant shells and in part to faulty valves and difficulties inherent in the sterilization of breast implant materials, the saline filler does not stay sterile. One study found that most explanted saline-filled breast implants
presented with microbial growth in the implant and in the capsule surrounding the implant, regardless of the age of the implant. If the filler was so contaminated, it would no longer be considered harmless upon deflation or rupture (Blais 1998, 3-4; Mentor, 9).

**Change in shape or volume of the breast:** Implant deflation or rupture and capsular contracture can result in the breast changing shape or volume. Such changes can also result from implant ‘bleed’, which is a slow seeping of implant filler from the implant through the semi-porous implant shell. Implants may also shift from their original position, changing the look of the breast or resulting in the implant being seen at the surface of the breast (Baines et al. 1992, 24).

**Change in sensation:** Sensation in the breast and/or nipple may change after breast implantation surgery (Baines et al. 1992, 24). This change may be temporary or permanent, and may affect sexual response. An estimated 3% to 15% of women report permanently decreased sensation subsequent to breast implant surgery (Health Canada 1998, 2).

**Calcium deposits:** Calcium deposits may appear in some fibrous capsules and cause pain in the breast. These may also interfere with breast cancer screening, as they make it more difficult to interpret mammographic images of the breasts (Health Canada 1998, 2-3; Mentor, 8). The incidence of such calcification may be quite high. One researcher observed this mineralization in 24% of 350 women with breast implants who presented for cancer screening. Another Canadian case series of mammography in 230 women with breast implants found such deposits in 18% (Baines et al. 1992, 23).

**Mammographic interference:** Breast implants are radiopaque, and can therefore interfere with mammographic imaging of the breast, particularly with larger implants inserted subglandularly (Health Canada 1998, 3). The amount of breast tissue obscured by implants during mammography may range from 22% to 83% (Sarwer et al. 2000, 847; Baines et al. 1992, 26, Silverman et al. 1996, 752). There have also been concerns that the pressure exerted on the breast during mammography could result in implant rupture (Mentor, 8).
Breast/chest discomfort or pain: Some women with breast implants report a diffuse burning sensation in their breasts and/or report pain and tenderness around their breasts (Baines et al. 1992, 24).

iii. Systemic Complications

Systemic complications may affect the entire body and most often appear after several years of living with breast implants. They tend to present as a cluster of symptoms. These symptoms include those associated with autoimmune diseases, connective tissue diseases, human adjuvant disease and/or fibroitis/fibromyalgia-like disorders. Granulomas and lymph node involvement, chronic flu, respiratory problems and infections have also been reported among women with breast implants (Sarwer et al. 2000, 846; Mentor, 9-10; Baines et al. 1992, 23-24; Segal 1997, 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.

Autoimmune-like disorders: These are disorders caused by an immune response against the body's own tissues (Medline Plus, 3 October 2001). Signs include joint pain and swelling; skin tightness, redness or swelling; swelling of hands and feet; rash; swollen glands or lymph nodes; unusual, profound fatigue; general aching; greater chance of getting colds, viruses and flu; unusual hair loss; memory and cognitive problems; headaches; muscle weakness and/or burning; nausea or vomiting; and irritable bowel syndrome (Segal 1997, 5; Mentor, 9-10; Baines et al. 1992, 23-24; Sarwer et al. 2000, 846).

Fibroitis/fibromyalgia-like disorders: Symptoms of these disorders include pain, tenderness and stiffness of muscles, tendons and ligaments (Segal 1997, 5).

Connective-tissues diseases: Acquired connective tissue diseases can develop as a result of an abnormal immunological response. Examples of connective-tissue diseases that are most probably the result of an aberration of the immunological reactions that mitigate injury and inflammation of connective tissues are: systemic lupus
erythematous, scleroderma, rheumatoid arthritis, rheumatic fever, polymyositis and dermatomyositis (WebMD, 3 October 2001).

**Human adjuvant disease:** This term has been widely used to describe constitutional and rheumatic symptoms in patients exposed to silicone or paraffin. However, it has been discredited as lacking precise and reproducible criteria (Silverman et al. 1996, 748).

**Granulomas and lymph node involvement:** Silicone particles (released from the silicone breast implant envelope), silicone droplets from silicone gel and oil, and silica filler all elicit a fibrotic inflammatory response. All can migrate to the lymph nodes, possibly contributing to the formation of granulomas. These granulomas are a focal chronic inflammatory response to tissue injury evoked by a poorly soluble substance. However, they cannot be taken in and of themselves as evidence of an immune or autoimmune response (Baines et al. 1992, 23).

**Cancer:** There were many concerns about possible links between breast implants and cancer, particularly breast cancer and particularly among women who had received polyurethane foam-covered breast implants. Several studies to date have indicated that there is no increased risk of breast cancer in women with implants. However, many of the women who received implants did so when they were young, and are not yet in the age group that is more prone to breast cancer. It remains to be seen whether they will eventually have a higher incidence of breast cancer than women without implants (Segal 1997, 3).

The classic autoimmune and connective tissue diseases thought to be associated with silicone implants include scleroderma, systemic lupus erythematosus, mixed connective tissue disease, rheumatoid arthritis and Sjogren's syndrome (Sarwer et al. 2000, 846).

It is not known what percent of women with breast implants experience these complications, or even whether breast implants cause these problems at all. The link between breast implants and systemic complications is still not clearly understood. Anecdotal evidence, case reports and some scientific studies suggest an association (Brautbar and Campbell 1995; Baines et al. 1992)
while epidemiologic research has failed to show a significant increased risk (Baines et al. 1992, 29-31; Segal 1997, 2).

Although many studies have found no association, most of these have limitations such as inadequate sample size, inadequate follow-up, or poorly defined disease criteria (the same is true of those – fewer in number – that have shown an association) (Silverman et al. 1996, 750). Several studies, as well as reviews conducted in the United States and in the United Kingdom, have concluded that there is no greatly increased risk of specific autoimmune or connective tissue diseases among women who have undergone breast implant surgery (UK Independent Review Group 1998, 26; McKinney 2000, 1). However, these studies are, in general, too small to detect whether there might be a slightly increased risk of any one of these rare diseases. Also, they have looked only for the symptoms of known autoimmune diseases, rather than for the cluster of symptoms that some women with breast implants experience (Mentor, 9-10). Lastly, they are often looking – and therefore testing – for known, defined diseases, rather than for a possibly new and as yet undefined illness. The fact that implant removal frequently produces an immediate reversal of symptoms does suggest a causal link between the implants and these symptoms (Sarwer et al. 2000, 846).

More recent studies have tried to address these shortcomings. Once again, however, all these studies face the difficulties discussed in Section 4: Challenges and Limitations. Most importantly, no retrospective breast implant research study can create an unbiased study sample, and it is difficult for a prospective study to follow women for an adequate period of time.

Taken together, the studies performed to date suggest no substantial increase in risk for well-defined connective tissue diseases as a result of breast implantation. However, most studies have not specifically addressed atypical connective tissue diseases, and the few studies that have attempted to do so have had design flaws that rendered them inconclusive (Silverman et al. 1996, 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, 32-33).

Based on the experiences of many women with breast implants, there seems to be little doubt that at least some women react badly to breast implants (Segal 1997, 1; UK Independent Review
However, there are no clear answers regarding the nature of the causal relationship, how many women are affected or how to predict who will experience these health problems. In 1992, the Canadian Independent Advisory Committee on Silicone Gel-Filled Implants stated that while, “some 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, 6).

iv. Psychological Complications

Psychological complications can also be significant for women who have or have had breast implants, particularly for those who experience health problems after implantation. For some women, they are quite simply let down and depressed if their breast implants do not change their life in the ways they had hoped for. For many others, depression is the result of the extreme difficulty they face in dealing with a health system that does not have answers, does not understand and is often dismissive or accusatory. These women feel like they are fighting a war, not only for survival and good health, but also for recognition, affirmation and respect (Breast Implant Centre 1999).

Unfortunately, studies of the psychological consequences of breast augmentation have been largely anecdotal. They consist primarily of surgeons’ reports of their patients’ satisfaction. These reports suggest that typically 70% or more of patients report satisfaction with their surgical outcome. However, there are serious problems with such investigations. Firstly, how many patients will admit, face to face with their surgeons, 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, 851)?

Those studies that have attempted to assess changes in psychological status after augmentation surgery have found that, in the absence of physical complications, women experienced psychological benefits from the surgery, including improved body image and self-esteem (Sarwer
et al. 2000, 851). Once again, however, these investigations used interviews rather than quantitative measures. Two studies did use psychometric measures postoperatively, and produced mixed results. One found a decrease in symptoms of depression compared to preoperative status, while the other reported increased symptoms of depression in 30% of patients in the period following the surgery. Neither of these studies used control or comparison groups, however, and so both caution against drawing firm conclusions (Sarwer et al. 2000, 851).

Many studies suggest that cosmetic surgery in general leads to improvements in body image, quality of life, and depressive symptoms immediately postoperatively. However, other studies have also found that women who undergo breast implant removal (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, 851). This suggests that for many women, breast implant surgery leads to poorer psychological well-being, rather than better.

**d. 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 1975. These required notification of devices within 10 days of being put on the market, but involved no evaluation. In 1977, these regulations were amended so that evidence of safety and effectiveness was required before marketing. Breast implants, however, were not on the list of devices covered by this amendment. In October 1982, a further change to the regulations was implemented. This amendment extended the pre-marketing review to all devices designed to be implanted in tissues or bodies for more than 30 days, therefore including breast implants (Baines et al. 1992, 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 Canada 1998, 1). This pre-market evaluation includes a review by scientists at
Health and Welfare Canada’s Bureau of Radiation and Medical Devices of animal and human test results and manufacturing data supplied by the manufacturer (Regush 1993, 38). However, it applied only to devices introduced after the date the amendment became effective. Most saline-filled implants were available for sale before this date and were therefore ‘grandfathered’, or exempted, from the pre-market review (Health Canada 1998, 1).

Currently, although the moratorium on silicone gel-filled breast implants remains in place, Health Canada has begun allowing their use in certain circumstances, and there are suggestions that their popularity is again growing (National Post, 16 June 2001, 16(A)). While these gel-filled implants are being re-introduced, there has still been little thorough, independent evaluation into 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.
SECTION 3: 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;
- 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 – 1998/99 to 1998/99 – were used. Although data 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 of the BC Women’s Breast Implant Centre at Children’s and Women’s Health Centre of BC and by way of public service announcements in community newspapers (see Appendix A).
Women who were interested in participating contacted a dedicated telephone line and were then sent an informed consent letter and form (see Appendix B). 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 stressed given the sensitive and personal nature of this surgery.

One hundred and fifty-three women returned consent forms 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 logistic 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 C) and 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, drinking 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.

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 BC 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

2 Of the questionnaires that were not returned, 15 women had moved without a forwarding address and two women had passed away.
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 also excluded from analyses because they had died during the course of the study years. Given that the women who were part of the self-identified study group were all, by definition, alive, the same needed to be true of the comparison cohort.

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 is no data available on income ranges above that level.

- Implant information from completed questionnaires including type of breast implant and length of implantation.

- Lifestyle factors from completed questionnaires such as smoking, alcoholic drinks 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 include:

- 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.
SECTION 4: 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, those 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 god 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 be generalized to the entire population of women with breast implants
with certainty. However, they are still very useful in that they can still 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 indicates that there are associations between breast
implants and increased health care utilization, it is not appropriate to expand these claims to include safety issues.

- 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.

There are also some possible confounders that were considered:

- Those living outside major centers 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 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.
SECTION 5: RESULTS

a. Overview

What this research revealed was that there is, indeed, a statistically significant relationship 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 have 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.

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References to "statistically significant" mean a p value less than or equal to 0.05, unless otherwise noted.
The women range in age from 29 years to 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 centers. The others live in smaller cities outside the Lower Mainland (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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Marital Status</th>
<th>Frequency (%)</th>
<th>Education Level</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married/common-law</td>
<td>62 (67.4%)</td>
<td>Less than high school</td>
<td>3 (3.3%)</td>
</tr>
<tr>
<td>Separated/divorced</td>
<td>15 (16.3)</td>
<td>High school</td>
<td>21 (22.8)</td>
</tr>
<tr>
<td>Single</td>
<td>6 (6.5)</td>
<td>Some post-secondary</td>
<td>31 (33.7)</td>
</tr>
<tr>
<td>Widowed</td>
<td>8 (8.7)</td>
<td>Post-secondary degree</td>
<td>35 (38.0)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (1.1)</td>
<td>Missing</td>
<td>2 (2.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Children</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>11 (12.0%)</td>
</tr>
<tr>
<td>1-2</td>
<td>40 (43.5)</td>
</tr>
<tr>
<td>3-4</td>
<td>36 (39.1)</td>
</tr>
<tr>
<td>5 or more</td>
<td>5 (5.4)</td>
</tr>
</tbody>
</table>

Table 2: Socio-economic level, Study group and Comparison group

<table>
<thead>
<tr>
<th>Socio-Economic Level</th>
<th>Study Group (n=147)</th>
<th>Comparison group (n=583)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency (Valid %)</td>
<td>Frequency (Valid %)</td>
</tr>
<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>

* 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.

b 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).

Figure 1: Reasons for Choosing Breast Implantation, Study group (n=92)\(^\text{4}\)

\(^{4}\)The category “Augmentation for non-development of one breast/both breasts” was meant to refer to a condition called micromastia where usually one breast, but sometimes both breasts, does not develop at all. This is different from feelings of having small breasts. However, this distinction may not have been clear in the survey instrument,
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 Meme 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%) 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 obviously enough to convince them that they no longer wanted breast implants. Thirty-seven of the women who returned

and it is possible that some women checked this category when, in reality, it would have been more appropriate for them to have checked 'cosmetic augmentation.'
questionnaires (40%) had had their implants permanently explanted. The rest (n=55), have not\(^5\).

**Table 3: Implant-related surgeries subsequent to initial implantation, Study group**

<table>
<thead>
<tr>
<th>Additional surgeries</th>
<th>Study group (n=92)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency (%)</td>
</tr>
<tr>
<td>None</td>
<td>45 (48.9%)</td>
</tr>
<tr>
<td>One</td>
<td>23 (25.0)</td>
</tr>
<tr>
<td>Two</td>
<td>11 (12.0)</td>
</tr>
<tr>
<td>Three</td>
<td>5 (5.4)</td>
</tr>
<tr>
<td>Four or more</td>
<td>8 (8.7)</td>
</tr>
</tbody>
</table>

**Implant Replacement**

<table>
<thead>
<tr>
<th></th>
<th>Study group (n=92)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency (%)</td>
</tr>
<tr>
<td>None</td>
<td>71 (77.2%)</td>
</tr>
<tr>
<td>One implant</td>
<td>7 (7.6)</td>
</tr>
<tr>
<td>Both implants</td>
<td>14 (15.2)</td>
</tr>
</tbody>
</table>

**Number of Replacements (n=21)**

<table>
<thead>
<tr>
<th></th>
<th>Study group (n=92)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency (%)</td>
</tr>
<tr>
<td>One</td>
<td>11 (52.4%)</td>
</tr>
<tr>
<td>Two</td>
<td>6 (28.6)</td>
</tr>
<tr>
<td>Three or Four</td>
<td>4 (19.0)</td>
</tr>
</tbody>
</table>

**Table 4: Length of implantation, Study group (n=92)**

<table>
<thead>
<tr>
<th>Length of Implantation</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5 years</td>
<td>15 (16.3%)</td>
</tr>
<tr>
<td>6-10 years</td>
<td>16 (17.4)</td>
</tr>
<tr>
<td>11-15 years</td>
<td>20 (21.7)</td>
</tr>
<tr>
<td>16-20 years</td>
<td>19 (20.7)</td>
</tr>
<tr>
<td>21-25 years</td>
<td>12 (13.0)</td>
</tr>
<tr>
<td>26-30 years</td>
<td>6 (6.5)</td>
</tr>
<tr>
<td>30-40 years</td>
<td>4 (4.3)</td>
</tr>
</tbody>
</table>

\(^5\) 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 4: 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 their breast implants (88% and 78%, respectively).

The BC 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 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 (OR\(^7\) = 4.26, 95% CI\(^8\) = 2.58, 7.02). These relationships remained significant when broken down by year\(^9\), as is illustrated in Table 5.

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

---

6 "Significant" or "statistically significant" means a p-value equal to or less than 0.05, unless otherwise noted.
7 OR = Odds Ratio
8 CI = Confidence Interval
9 Hospitalizations were not significant in two of the 11 years, presumably aberrations.
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.

**Figure 2: Hospital admissions, Study group versus Comparison group**

![Figure 2](image)
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. Gastro-enterology 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 gastro-enterology 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 over 5 times more likely to be. However, the numbers are very small, and so I believe 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 has 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. 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.

\^ The difference in days of care was significant in 1997/98, presumably an aberration.
Table 5: Doctor visits, hospitalizations and specialist items, Study group versus Comparison group.

<table>
<thead>
<tr>
<th></th>
<th>Study group (n=147)</th>
<th>Comparison group (n=583)</th>
<th>p-value(^{12})</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>16.67 (12.53)</td>
<td>9.32 (11.95)</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(^{11})</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>

\(^{11}\) SD = Standard deviation  
\(^{12}\) P-values calculated using Wilcoxon rank sum tests.  
\(^{13}\) 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)</th>
<th>Comparison group (n=108,173)</th>
<th>p-value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency (%)</td>
<td>Frequency (%)</td>
<td></td>
</tr>
<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&lt;sup&gt;b&lt;/sup&gt;</td>
<td>4849 (14.7%)</td>
<td>12110 (16.2%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Dental Surgeon</td>
<td>0 (0.0)</td>
<td>9 (&lt;0.1)</td>
<td>ns&lt;sup&gt;c&lt;/sup&gt;</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>2855 (8.6)</td>
<td>4954 (6.6)</td>
<td>&lt;0.001</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&lt;sup&gt;d&lt;/sup&gt;</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>8406 (25.4%)</td>
<td>21636 (29.0%)</td>
<td>&lt;0.001</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>6125 (18.5%)</td>
<td>13365 (17.9%)</td>
<td>&lt;0.001</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>1696 (5.1)</td>
<td>4129 (5.5)</td>
<td>&lt;0.001</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>

<sup>a</sup> P-values calculated using Wilcoxon rank sum tests for each individual specialty.

<sup>b</sup> The five most common specialists are the same in both cohorts, and are highlighted.

<sup>c</sup> ns = not statistically significant at the p = <0.05 level.

<sup>d</sup> 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)</th>
<th>Comparison group (n=1189)</th>
<th>p-value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency (5)</td>
<td>Frequency (%)</td>
<td></td>
</tr>
<tr>
<td>Alternate Level of Care</td>
<td>0 (0.0%)</td>
<td>1 (0.1%)</td>
<td>ns&lt;sup&gt;b&lt;/sup&gt;</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>Gastro-Enterology</td>
<td>0 (0.0)</td>
<td>1 (0.1)</td>
<td>ns</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>
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<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>
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<td>Psychiatry</td>
<td>8 (1.5)</td>
<td>22 (1.9)</td>
<td>ns</td>
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<td>Rehab in Acute Care</td>
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<td></td>
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<td>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>

<sup>a</sup> P-values calculated using Wilcoxon rank sum tests for each individual service.

<sup>b</sup> ns = not statistically significant at the p=<=0.01 level.
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 b</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 Specialist</td>
<td>0 (0.0)</td>
<td>3 (0.3)</td>
<td>ns</td>
</tr>
<tr>
<td>Family Practitioner</td>
<td>58 (10.7)</td>
<td>187 (15.7)</td>
<td>ns</td>
</tr>
<tr>
<td>Gastro-enterologist</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><strong>89 (16.4)</strong></td>
<td><strong>155 (13.0)</strong></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>Psychiatrist</td>
<td>0 (0.0)</td>
<td>3 (0.3)</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Plastic Surgeon</strong></td>
<td><strong>119 (22.0)</strong></td>
<td><strong>38 (3.2)</strong></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><strong>Missing</strong></td>
<td><strong>83 (15.3)</strong></td>
<td><strong>226 (19.0)</strong></td>
<td></td>
</tr>
</tbody>
</table>

* 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.

a P-values calculated using Wilcoxon rank sum tests for each individual physician service area.

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

c 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>OR(^{15}) Study/Comparison (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<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(^{16})/GEAR</td>
<td>0 (0.0)</td>
<td>5 (0.4)</td>
<td>n/a(^{17})</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>

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(^{18})</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of visits</td>
<td>Mean (SD(^{19}))</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>

\(^{15}\) OR = Odds Ratio  
\(^{16}\) DPU = Discharge Planning Unit  
\(^{17}\) 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.  
\(^{18}\) P-values calculated using Wilcoxon rank sum tests.  
\(^{19}\) SD = Standard Deviation  
\(^{20}\) ns = not statistically significant at the p=<0.05 level.
Table 11: Hospital days in specific units, Study group versus Comparison group

<table>
<thead>
<tr>
<th>Unit</th>
<th>Study group (n=542) Days (SD&lt;sup&gt;21&lt;/sup&gt;)</th>
<th>Comparison group (n=1189) Days (SD)</th>
<th>p-value&lt;sup&gt;22&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<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</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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>

<sup>21</sup> SD = Standard Deviation

<sup>22</sup> 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 5 or more children to those with no children, nor 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 speaks 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 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 that which 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 (\( r=50 \))
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 MS Plan 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 over-arching, affecting all areas, all years, or all women.
SECTION 6: DISCUSSION

a. Overview

This study sheds new and interesting light on an issue 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 gastro-enterology 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 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.23

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 study women participating in this study did not consider themselves to be in poor health. Quite the contrary, they feel 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 health women.

23 Smoking was a factor that increased health care utilization, and future research could investigate this possible confounder within both study and comparison cohorts.
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. Rather, 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 gastro-enterology services, a
relationship that was stable across several analyses and should therefore be explored farther). 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 is 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.
SECTION 7: 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% – and more likely are 50% or higher – 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.

There are many issues in research such as this. Women are struggling to find answers to their health concerns, while lawyers are seeking justice (or at least a piece of the pie) and health care professionals are trying to figure out how best to serve and treat their patients. In Canada, governments must also be considering their role. Although so far the federal and provincial governments have shied away from developing any specific breast-implant related policy, this study indicates that such policy should indeed be on the table.

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.
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APPENDIX A: 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 BC at (604) 875-2280.
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 BC 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, BC. 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 BC 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 dependent 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 BC 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 if affects women’s use of health care services, both traditional and ‘alternative.’ We hope we have your support and cooperation.
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
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

a. 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>
<td></td>
<td></td>
<td></td>
</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 D: BC 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>Year</th>
<th>Population of Community of Residence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>500,000 +</td>
</tr>
<tr>
<td>1999</td>
<td>$17,886</td>
</tr>
<tr>
<td>1998</td>
<td>$17,571</td>
</tr>
<tr>
<td>1997</td>
<td>$17,409</td>
</tr>
<tr>
<td>1996</td>
<td>$17,132</td>
</tr>
<tr>
<td>1995</td>
<td>$16,874</td>
</tr>
<tr>
<td>1994</td>
<td>$16,511</td>
</tr>
<tr>
<td>1993</td>
<td>$16,482</td>
</tr>
</tbody>
</table>

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.