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## Backgrounder

# Breast Cancer Risk and Nipple Aspirate Fluid (NAF)

Breast cancer **risk assessment** is the process of evaluating whether a woman has any traits that increase her likelihood of developing the disease. Cellular changes found in *nipple aspirate fluid (NAF)* are one such trait.

Women with abnormal cells in their NAF have a significantly greater risk of eventually getting breast cancer. Working with their physicians, these women can develop risk management strategies that can help protect them against the disease or lead to earlier detection with greater chance for survival.

## Introduction

Approximately 200,000 new cases of breast cancer are diagnosed in the U.S. each year, resulting in 40,000 deaths annually. One in eight women will develop breast cancer in her lifetime. Breast cancer is the leading cause of cancer death in women aged 20-59. (1)

Yet there is no definitive way to determine who will develop the disease. Seventy percent of women who develop breast cancer have no identifiable risk factors other than age, and 89 percent of diagnosed women have no family history. (2, 3)

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Identifying women who are at higher risk is an important tool in improving breast health care -- which can help save lives and reduce costs. Early detection is another key to better outcomes. When cancer is confined to the breast, the five-year survival rate is nearly 100% percent, compared to just 20 percent when the cancer has spread to other areas. (4)

## Screening for Breast Cancer Risk

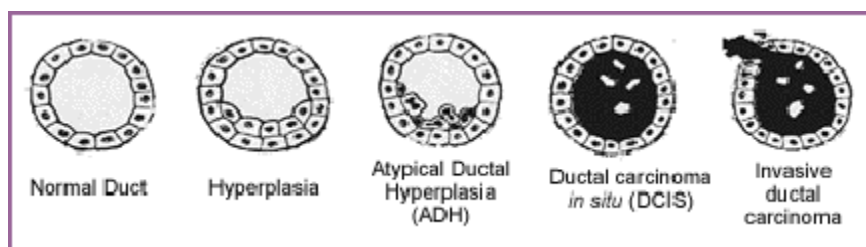
The best current screening to assess a woman's breast health and risk of developing breast cancer is review of family history, personal history, physical breast exam, plus regular mammography for women over 40 or 50. However, clinical experience has shown that the vast majority of women who develop breast cancer have no risk factors that are identifiable with these methods and go unnoticed for years until an abnormality might appear on a mammogram.(2)

In particular, mammography is often not as effective for premenopausal women under 40 or 50, who tend to have dense breasts that make it harder to detect abnormalities. Though young women do not develop breast cancer as often as women over 50, the disease in this population tends to be more advanced and have less favorable outcomes. (5) A recent study found that younger women's tumors tend to have a set of biological and genetic factors that made them more aggressive and more difficult to treat than cancers in older women. (6)

The medical community's focus has traditionally been on detection and treatment. But by the time an abnormality can be identified via mammography, it has been growing for approximately eight years. (7) As a result, more emphasis is now being placed on individualized "risk assessment and prevention." Regardless of their risk assessment status, women should also undergo routine breast exams and mammograms as recommended by their doctors.

### **Nipple Aspirate Fluid (NAF)**

The presence of abnormal cells, or atypia, in nipple aspirate fluid (NAF), which is secreted from the milk ducts where nearly all (95%) of invasive breast cancers begin (8), is a trait proven to increase a woman's chance of developing breast cancer. Multiple studies have concluded that atypia increases a woman's likelihood of developing breast cancer four- to five-fold. (9, 10, 11, 12,)



Cross-section of duct depicting progression of cells from normal to cancerous

The examination of NAF can provide insight into a woman's breast health. Finding atypia years before it might develop into a lesion enables a woman and her doctor to develop the appropriate "care path" for optimal management of her breast health.

Prominent organizations such as National Cancer Institute, American Cancer Society, American Society of Breast Surgeons, and the American College of Obstetrics and Gynecology recognize the use of atypia as a valid measure of breast cancer risk.

In 1958 Dr. George Papanicolaou et al., first demonstrated the ability to find abnormal cells in NAF with the purpose of identifying women at high risk for breast cancer. Dr. Papanicolaou also developed the Pap test for cervical cancer screening, which is considered the most successful cancer screening test ever developed. NAF and the Pap test are both based on the cytological examination of changes in epithelial cells to determine risk for developing cancer.

In the 50 years since the cervical Pap test was developed, cervical cancer deaths have declined more than 80 percent. (14) Only modest progress has been achieved in reducing breast cancer mortality during the same time, due in part to the inability of current screening methods to detect cellular changes at an early stage of development.

Until now, use of NAF has been limited to research studies due to the difficulty of obtaining the fluid from the breast. NAF collection is now simple, inexpensive, noninvasive and easily accomplished in the primary care setting.

Women who do not produce NAF are considered to be at normal risk, not elevated risk of developing breast cancer. Women who produce NAF with normal cells are considered to have about a two-fold risk. Women who have abnormal cells in their NAF are considered to be at high risk (4 to 5 fold). These women and their doctors can then develop the appropriate risk reduction and monitoring strategies in hopes that early intervention will affect survival. Among the strategies available for high-risk patients are: lifestyle modification, enhanced/increased imaging, chemoprevention, and minor surgical intervention (15).

## **Conclusion**

Widespread screening for risk with NAF on an annual basis in premenopausal women could lead to improved detection and reduced mortality from breast cancer, just as the Pap smear led to a drastic reduction in cervical cancer related deaths. Risk assessment tools like NAF are not intended to replace regular screening procedures.

Risk assessment including NAF can help patients and their physicians develop a plan to mitigate any identified risk.

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