



Promoting better healthcare for women

THE SCREENING ADHERENCE FOLLOW-UP (SAFE) PROGRAM:

Patient Navigation/Patient navigation/case management the SAFE Way

***A TOOLKIT FOR EVIDENCE-BASED PATIENT NAVIGATION/PATIENT NAVIGATION/CASE MANAGEMENT
TO IMPROVE ADHERENCE TO ABNORMAL CANCER SCREEN FOLLOW-UP***

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Preface

A SAFe pilot replication and randomized study project was funded by a cooperative agreement awarded in October, 1997 to the Institute for the Advancement of Social Work Research (IASWR) by the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) of the Centers for Disease Control and Prevention (CDC) (www.cdc.gov/cancer/NBCCEDP). A SAFe translational implementation demonstration project in high risk community based clinics selected via project request by the 5 clinics was funded in January 2000 to IASWR by the Cancer Detection Section of the California Department of Health Services in cooperation with CDC aims to advance patient navigation/patient navigation/case management demonstration projects in community clinics serving NBCCEDP program eligible patients.

An estimated 8–11% of U.S. women of screening age are eligible to receive NBCCEDP services. Federal guidelines establish an eligibility baseline to direct services to uninsured and underinsured women at or below 250% of federal poverty level; ages 18–64 for cervical screening; ages 40–64 for breast screening.

To improve women's access to screening for breast and cervical cancers, Congress passed the [Breast and Cervical Cancer Mortality Prevention Act of 1990](#), which guided CDC in creating the NBCCEDP. The NBCCEDP provides screening support in all 50 states, the District of Columbia, 5 U.S. territories, and 12 American Indian/Alaska Native tribes or tribal organizations, and helps low-income, uninsured, and underinsured women gain access to breast and cervical cancer screening and diagnostic services. These services include

- Clinical breast examinations.
- Mammograms.
- Pap tests.
- Diagnostic testing for women whose screening outcome is abnormal.
- Surgical consultation.
- Referrals to treatment.

Since 1991, the NBCCEDP has served more than 3 million women, provided more than 7.2 million screening examinations, and diagnosed 30,963 breast cancers, 1,934 invasive cervical cancers, and 101,624 precursor cervical lesions, of which 43% were high-grade. In October 1998, Congress modified the legislative authority of the NBCCEDP to include patient navigation/patient navigation/case management as a program component in response to the demonstrated need for more intensive individualized intervention for high-risk women with special needs. In late 1999, CDC provided national guidelines for these patient navigation/case management services within NBCCEDP programs. SAFe patient navigation/case management is consistent with the CDC Patient navigation/case management Policy, as it addresses each element of the guidelines.

In fiscal year 2006, the NBCCEDP

- screened 380,719 women for breast cancer using mammography and found 4,013 breast cancers, serving 14.7% of all American women eligible to participate in the NBCCEDP for breast cancer
- screened 367,200 women for cervical cancer using the Pap test and found 5,162 high-grade and invasive cervical lesions, serving 6.7% of all American women eligible to participate in the NBCCEDP for cervical cancer

In 2000, Congress passed the [Breast and Cervical Cancer Prevention and Treatment Act](#), which gives states the option to offer women in the NBCCEDP access to treatment through Medicaid. To date, all 50 states and the District of Columbia have approved this Medicaid option. In 2001, with passage of the Native American Breast and Cervical Cancer Treatment Technical Amendment Act, Congress explained that this option also applies to

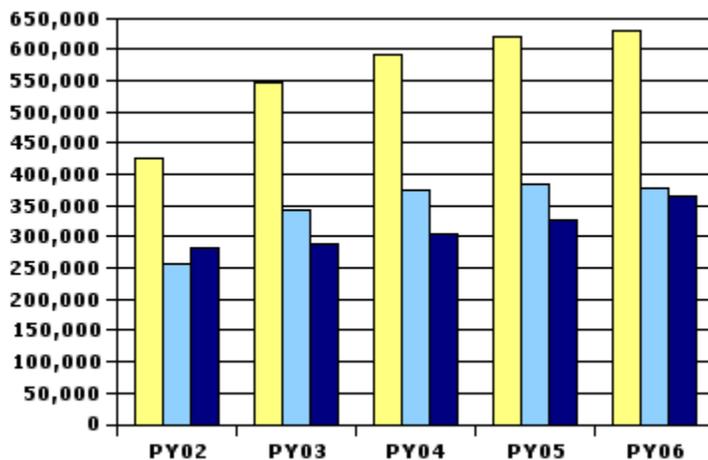
American Indians/Alaska Natives who are eligible for health services provided by the Indian Health Service or by a tribal organization.

To reach underserved women, the NBCCEDP supports an array of strategies, including program management, screening and diagnostic services, data management, quality assurance and quality improvement, evaluation, partnerships, professional development, and recruitment. Providers in the program work collaboratively to provide breast and cervical cancer screening, diagnostic evaluation, and treatment referrals (where appropriate). The program's continued success depends in large part on the complementary efforts of a variety of national organizations, as well as on state and community partners.

In 2005, CDC released [The National Breast and Cervical Cancer Early Detection Program: 1991–2002 National Report, \(PDF-1.3MB\)](#) the first summary of the program's progress. The report provides information about the program's framework, history, and future direction, as well as data on breast and cervical cancer screening outcomes for women served through NBCCEDP.

Many deaths from breast and cervical cancers could be avoided if cancer screening rates increased among women at risk. Deaths from these diseases occur disproportionately among women who are uninsured or underinsured. Mammography and Pap tests are underused by women who have no source, or no regular source, of health care; women without health insurance; and women who immigrated to the United States within the past 10 years.¹

Women Screened Through the NBCCEDP, by Program Year
July 2001 to June 2006
National Aggregate



- Women screened (received an NBCCEDP-funded Pap test, mammogram, or clinical breast exam)
- Women who received an NBCCEDP-funded mammogram
- Women who received an NBCCEDP-funded Pap test

Program year (PY) is defined as July 1 through June 30.
For example, 'PY04' represents July 1, 2003 through June 30, 2004.

CDC has invested in developing a system to achieve efficiency in the NBCCEDP and to address the relative stability of funding allocations. The system includes a performance-based approach to making funding decisions. CDC continues to refine this approach, which ensures that funds will be distributed appropriately to programs, based on the programs' ability to comply with program guidelines; provide high-quality care to the largest number of low-income, uninsured women; and maximize available funds.

IASWR is a nonprofit national organization whose mission is to advance social work practice and education and to inform health and social policy through research. Five major national social work organizations: the Association of Baccalaureate Social Work Program Directors, the Council on Social Work Education, the Group for the Advancement of Doctoral Education, the National Association of Deans and Directors of Schools of Social Work, and the National Association of Social Workers founded IASWR. IASWR promotes and facilitates scientific testing and evaluation of health and social service interventions and programs and promotes empirically documented, effective interventions in social work practice. (www.iaswresearch.org).

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Project SAFe Executive Summary

Project SAFe tested a systematic evidence-based patient navigation/case management approach to improve patient cancer screening follow-up adherence. The target population was medically under-served low-income, ethnic minority women with abnormal breast and cervical screens. Controlled clinical trials had demonstrated the efficacy of interactive health education counseling and systems navigation for improving abnormal screening follow-up adherence. The SAFe project adapted these interventions for delivery in different service systems and diverse populations, added mental health screening and assessment, and included more intensive psychosocial counseling for women with special needs. Key study questions concerned: the effectiveness, feasibility and utility of SAFe patient navigation/case management; identification of patient, provider and health systems barriers; and facilitating processes in implementing SAFe in “real world” health care systems. Tested in three separate studies in multiple sites, SAFe patient navigation/case management improved patient adherence significantly over site baseline rates, non-enrollee rates, and control group rates, with adherence rates improving from 6% to 25%. The project developed a SAFe Tool Kit for dissemination to community based clinics.

The Challenge: Why Was Project SAFe Developed?

Significant improvements have been made in providing breast and cervical cancer screening for low-income women. Unfortunately, low-income, minority women who are screened and found to have suspicious or abnormal mammograms are most likely to miss follow-up diagnostic test appointments or to be lost to follow-up, thereby effectively delaying diagnosis and treatment. This is of concern because later stage at diagnosis, morbidity, and mortality remain higher among low-income, minority women. Less than optimal or non-adherence rates to abnormal screening follow-up can be as high as 60% among medically under-served low-income, ethnic minority women.

Inadequate follow-up occurs when low-income women encounter health system, health provider, and personal barriers to optimal diagnostic follow-up. Low-income women are more likely to be uninsured or underinsured, to lack a regular source of medical care, and to receive fragmented screening, diagnostic resolution, and treatment services. Health systems serving these women may lack adequate patient tracking and record-keeping mechanisms, flexible appointment scheduling resources, and staffing resources. A breakdown in provider-patient communication due to time constraints and language and health literacy barriers may result in women never being adequately informed about their abnormal test or what specific follow-up is being recommended and why.

The health action a woman takes after being told that her screening test indicates a need for further testing or treatment will also be strongly influenced by: 1) her understanding of the meaning (and urgency) of the abnormal result; 2) what she believes is her risk of actually having cancer (including whether she has symptoms she believes are serious); 3) whether she believes that what is being recommended will make a difference (e.g., her perceptions about cancer prevention and survival); and 4) what problems, barriers, and costs she will face in following medical recommendations, such as perceived discomfort or embarrassment of follow-up procedures and difficulty in navigating fragmented systems of care and obtaining supportive resources. Women may be torn between wanting to know and being afraid to find out whether they have cancer. Women may take no action to learn the results of an initial screen or may place low priority on timely follow-up. Women’s personal assessment of their cancer risk as well as their choice of health behavior may also be strongly influenced by culturally determined beliefs, psychological distress (e.g., depressed women have been shown to be diagnosed at a later stage and to be less adherent to diagnostic follow-up), competing health and psychosocial problems in their daily lives³¹ and out-of-pocket costs, including time away from work.

Patient navigation/case management approaches are increasingly being used to promote patient adherence to recommended treatment and to monitor patient appointment keeping. Controlled clinical trials of patient navigation/case management interventions find that interactive counseling, education, monitoring and reminders, and resource navigation (in-person or telephonic) are effective in improving patient care management over usual care for a range of health conditions. **Controlled clinical trials have also shown that interactive health education counseling and systems navigation interventions significantly improve breast and cervical screening and abnormal screen follow-up adherence, particularly among low-income medically**

underserved populations. (See Table 1: Examples of Clinical Trials.) Several of these studies find that low-income and ethnic minority patients are most likely to need and to benefit from more intensive counseling plus systems navigation resources. **In general, the evidence provides convincing support for providing a combination of services at different levels of intensity and cost (e.g., written educational materials and appointment reminders, brief telephone reminders, and interactive counseling). Conducting an assessment of individual women’s risk for nonadherence and implementing methods to match educational counseling and service intensity to individual patient need is likely to be effective and cost sensitive.**

Despite the very promising results of these studies, critical translational implementation and dissemination questions remain.

- Are these interventions effective across culturally diverse patient populations and diverse health care systems?
- What organizational resources and cost barriers affect providing these interventions in real world and sometimes under-resourced primary care and community clinic systems.
- What key intervention elements facilitate adherence and the efficient implementation of patient navigation/case management?
- Are there efficient and effective ways to match service type and intensity with individual women’s needs?
- Which intervention elements can be standardized to facilitate their delivery and provider staff training?
- Which intervention elements are adaptable for diverse patient populations and health systems and which are optional?
- What is the cost of patient navigation/case management services?

Project SAFe was developed and supported under a CDC initiative aimed at addressing these unanswered questions within diverse health systems that provide abnormal screen follow-up for ethnically diverse and medically disadvantaged populations. A series of SAFe studies aimed to:

- Evaluate a multifaceted patient navigation/case management intervention that combined interactive assessment and individually tailored counseling and systems navigation to improve abnormal screen follow-up among low-income, ethnic minority women.
- Evaluate the feasibility of mental health screening, assessment, and referral within breast and cervical screening and diagnostic programs.
- Evaluate the effectiveness of SAFe among diverse populations and in diverse health care systems.
- Identify patient, provider, and health systems barriers and facilitating processes to implementing the SAFe patient navigation/case management model in “real world” health care systems.
- Identify cultural competency elements in SAFe patient navigation/case management.
- Develop case manager training materials, implement training of staff in different health care systems, and evaluate training outcomes.
- Examine the cost of SAFe intervention.

What is SAFe?

SAFe’s **systematic evidence-based patient navigation/case management** approach to improve patient cancer screening follow-up adherence combines two effective interventions to reduce patient non-adherence to follow-up: interactive telephone assessment and counseling and systems navigation. Interactive telephone educational counseling, using trained patient navigators/case managers, has been proven effective in randomized clinical studies of women at high risk for non-follow-up after an abnormal cancer screen and in improving mammography adherence. Patient and Systems navigation was developed under the leadership of Dr. Harold Freeman at Harlem Hospital to assist patients in navigating the hospital and human services systems to achieve optimal follow-up for cancer detection and treatment. SAFe adapted each of these interventions for delivery in

different service systems and included mental health screening, assessment, and more intensive psychosocial counseling for women with special needs.

The SAFe patient navigation/case management service model provides patient-centered assessment and educational counseling, centralized interpersonal patient tracking, reminders, and follow-up assistance, and links to community resource programs. Individualized assessment of known barriers to follow-up determines the type of follow-up service plan – i.e., telephone reminders and interpersonal counseling. Interpersonal health education, counseling, skill enhancement in patient-doctor communication, and information about and assistance with the use of community based resources aim to empower women to act in their own best health interests. The goal is to improve diagnostic, treatment, and repeat screening adherence by enhancing women’s health care utilization knowledge and coping skills. Links to community resources aim to facilitate women’s access to services and effective clinic use of and communication with community based programs. Centering patient follow-up tracking, reminders, and counseling services under the responsibility of a designated clinic staff case manager aims to achieve systematic coordination of abnormal screen follow-up services and monitoring of patient adherence. To address the special needs and barriers to follow-up experienced by a minority of women (i.e., women diagnosed with cancer, women with depression or high anxiety and psychosocial stress), brief counseling and mental health referral is provided by an onsite or community based master’s degreed social worker in collaboration with the case manager. The SAFe model closely parallels the CDC patient navigation/case management guidelines. A baseline clinical decision-making algorithm is used to distinguish the women that require more intensive follow-up interventions from those who do not, and to assign a level of service consistent with individually assessed barriers.

What Was Learned?

Evidence that SAFe is Effective in Improving Follow-up Adherence

- Tested in three separate studies in multiple real world service systems with diverse patient groups (multi-site pilot (n=753), randomized (n=409), and implementation (n=398) (see Table 2), SAFe patient navigation/case management **improved patient adherence significantly** over site baseline rates, non-enrollee rates, and control group rates, with rates of adherence improving from 6% to 25%.
- In most cases, receiving SAFe patient navigation/case management resulted in **significantly more timely adherence** over women receiving usual care as represented by site baseline, women never enrolled in the SAFe program, and randomized control group timeliness rates, with timeliness rates improving from 10% to 21%.
- In the SAFe randomized control trial, women receiving SAFe patient navigation/case management achieved equal or higher rates of both adherence and timely adherence across all classification categories for both mammography and PAP when compared to women in the control group. SAFe patient navigation/case management achieved the largest gains in both adherence and timely adherence for women with less severe initial screening classifications (ACR 3; LGSL).
- Adherence rates of women receiving SAFe patient navigation/case management were similar across ethnic groups.
- Improved adherence outcomes were achieved across urban and rural community based screening clinics, urban diagnostic and treatment medical centers, and geographic regions.
- Mental health screening identified 8-10% of women with depressive or anxiety disorders. These women and others with special needs achieved good adherence and were referred to community-based services.
- Rescreening rates were higher among women receiving SAFe services than non-enrolled women.

- Patient satisfaction with SAFe was high.

Evidence of Barriers to the Implementation of SAFe

- Significant percentages of women in all three studies ultimately could not be located. Random sampling of adherence rates for these women showed dramatically lower adherence rates.
- Difficulty in identifying women eligible for SAFe services in some systems. Depending on medical or nursing staff referral to the case manager failed to identify all women with an abnormal screen.
- Clinic system lack of a centralized patient tracking method resulted in failure to identify all women with an abnormal and required additional patient navigation/case management time in tracking women.
- Existing processes for informing women of their abnormal result did not routinely provide adequate or motivating information that led to prompt adherence. In some cases these processes were untimely and incomplete.
- Clinical time and staffing constraints resulted in delayed appointments for many women.
- Problematic transfer of patient information and communication between screening and diagnostic programs resulted in delayed follow-up and increased time of SAFe case manager.
- When the case manager is not viewed as a member of the clinic team, communication and other barriers impair efficiency and effectiveness.

Evidence Supporting Key Intervention Element

- Designating the patient navigator/case manager as a member of the clinic care team facilitates implementing SAFe.
- Integrating patient navigation/case management services with the process for informing women of results facilitates the patient navigation/case management service, improves time efficiency, and provides the opportunity to assess and counsel women on their understanding of the screen results, the subsequent diagnostic or treatment follow-up, and barrier reduction.
- Computerized appointment and results tracking improves follow-up and reduces patient navigation/case management service time.
- Routine interactive assessment of patient adherence barriers enables education and systems navigation counseling to be tailored for individual women. This is consistent with findings from other studies that tailoring educational and counseling messages is likely to be more effective.
- Standardized scripted assessment and counseling and service tracking methods facilitate patient navigation/case management staff training, service quality monitoring, and ongoing evaluation of service costs, and barriers encountered.
- Assessment can be used to assign different levels of service follow-up. In SAFe, the case manager used a clinical decision-making algorithm to determine women's assigned level of service intensity. The algorithm was based on assessment of patient barriers. The finding that there were no differences in adherence rates across service levels supported the effectiveness of this method.
- SAFe patient navigators/case managers maintained linkage with community based resources that facilitated systems navigation.
- Brief counseling and referral to appropriate community based services were provided for a significant minority of women (15%-24%) who were assessed as having special needs – being diagnosed with cancer or depressive or anxiety disorder or experiencing significant current psychosocial stress. These women achieved rates of adherence similar to that of women without these needs.
- SAFe case managers reported that the scripted assessment and counseling responses facilitated their work and that empowerment strategies were most frequently undertaken.
- Initial case manager training must be augmented over time by specific supervisory support within clinic programs or by linking with other case managers through a telephone network.

Evidence of Adaptations and Optional Intervention Elements in Different Health Care Systems

- Having a script in English facilitated translation into Spanish and was helpful in adapting elements for the Chinese-speaking patients. Thus, having scripted tools was helpful in adapting materials for different cultural groups and facilitated responses that were sensitive to health literacy issues.
- Counseling services for women with special needs were provided through different organizational arrangements within the different health systems in which SAFe was studied. It is possible to distinguish the cost of these services from general patient navigation/case management direct costs.

Evidence of the Cost of SAFe

Cost breakdown found that the case manager cost was \$11/month for mammogram patients and \$15/month for cervical patients, based on one year of service. Assuming an average of social work contacts ranging from 3-5 per patient, direct costs can be estimated using local hourly rates, which average \$35/hour. These figures include the cost of extensive outreach efforts - an average of 6 phone attempts to yield one enrolled woman - when calls to the many women who were never reached were factored in. The annual cost represents direct activities (time spent in interaction with a woman or collaterals) and indirect activities (appointment tracking and paperwork) of the navigator and MSW, as well as supervisory and consultation time (to the navigator/case manager) for the MSW.

KEY PATIENT NAVIGATION/CASE MANAGEMENT INTERVENTION ELEMENTS

The following outlines the critical patient navigation/case management components that are based on existing clinical trial evidence. Programs planning to implement a quality patient navigation/case management program in their clinics should consider planning for each of these elements.

ORGANIZATIONAL REQUIREMENTS FOR PROVIDING SYSTEMATIC PATIENT NAVIGATION/CASE MANAGEMENT

Implementing effective patient navigation/case management requires organizational planning and preparation. Key elements include:

- **Assessment of Clinic Population Characteristics and Need**
 - Is there a need to improve the follow-up adherence of women in your program?
 - What are the socio-cultural characteristics of the women you serve - are they of predominantly low-income, of culturally diverse backgrounds, with limited health literacy?
 - Would your clinic population benefit from being linked to community-based resources?
 - Are there deficiencies in the current process of informing patients of abnormal results? Is the notification process centralized and systematic?
 - Could your current processes for patient tracking and appointment reminders be improved? Is this process centralized and systematic?
 - Could your clinic communication processes about patient follow-up among medical providers, with other provider systems, and with community programs be improved?
 - Is your program making optimal use of existing state and local community program resources?

KEY INTERVENTION ELEMENTS

In designing a patient navigation/case management program, individual programs should design their intervention model to meet specific needs of its patient population and to enhance its organizational service strategies. While individual adaptations are recommended, key elements are supported by existing evidence from SAFe and other clinical trials reviewed above.

- Empower a designated individual and group of individuals to assume leadership for implementing SAFe patient navigation/case management.
- Designate a patient navigator/case manager.