

## **The Affordable Care Act and Patient Navigation: Support for Those in Need**

### **Introduction**

While advances in cancer prevention and treatment have reduced overall cancer mortality in the last few decades, the gains have not been shared equally among all segments of the population.<sup>1</sup> Racial and ethnic minorities and those with low socioeconomic status are still more likely to die from cancer than the general population.<sup>2</sup> Lack of insurance or high out-of-pocket costs despite having insurance are major contributors to the disparity. In addition, minorities and disadvantaged populations can face other obstacles to accessing cancer care including geographic distance, language or cultural barriers, racial bias, and poor provider-patient relationships.<sup>2</sup>

Patient navigation is an intervention to help patients overcome barriers to cancer care through culturally sensitive care coordination and support. Patient navigation includes the following characteristics: 1) it focuses on overcoming individual patient-level barriers to accessing care; 2) aims to reduce delays in accessing care; 3) is provided to individuals for a defined episode of cancer-related care; 4) targets a defined set of health services relevant to that episode (i.e. following up on an abnormal screening test); and 5) has a defined endpoint when provided services are complete.<sup>3</sup>

The first patient navigation program was developed by Dr. Harold Freeman in 1990 to help reduce disparities in breast cancer care among the African American and Latino community of Harlem, New York City by focusing on early detection through free/low-cost breast examinations and timely diagnosis and treatment for suspicious findings.<sup>4</sup> The program was shown to increase the rate of follow up and reduce the waiting time for breast biopsies for positive mammograms, leading to an increase in the diagnosis of breast cancer at an early stage and relatively high 5-year survival rates.

Since 1990, many more patient navigation programs have been implemented and studied through funding provided by private foundations including the American Cancer Society (ACS), the Avon Foundation for Women, and Susan G. Komen for the Cure, as well as through federal, state, and local governments. In 2003, the National Cancer Institute conducted a survey that found more than 200 cancer care programs nationwide included some form of patient navigation.<sup>5</sup> Since then, the ACS added another 137 navigation programs.<sup>6</sup>

While continued research on patient navigation is still needed, studies to date show that patient navigation seems effective in improving cancer screening and outcomes related to cancer diagnosis.<sup>7</sup> There is evidence that navigation improves participation in cancer screening and adherence to the diagnostic care needed following an abnormal result. On the other hand, studies assessing the efficacy of patient navigation on cancer outcomes in the treatment phase have been

inconclusive. There have been no published studies evaluating the effects of patient navigation on cancer survivorship outcomes.

### **Legislative History**

The federal government has supported three major patient navigation initiatives. First, in 2005, the Patient Navigator and Chronic Disease Prevention Act added Section 340a of the Public Health Service Act (PHSA) which authorized demonstration programs to improve health outcomes for patients with cancer and other chronic diseases. As a result, in 2008, the Health Resources and Services Administration (HRSA) awarded \$2.4 million to fund six 2-year demonstration programs using patient navigators to educate individuals about a variety of chronic diseases including cancer, diabetes, cardiovascular disease, and asthma, and to guide them to appropriate screening and treatment as needed. In 2010, HRSA funded ten new patient navigation programs.<sup>8</sup>

Second, in 2005, the National Cancer Institute's Center to Reduce Cancer Health Disparities and the ACS provided \$25 million in funding for the Patient Navigation Research Program (PNRP). PNRP is a clinical trial involving nine sites designed to evaluate the efficacy and cost-effectiveness of patient navigation. The trial focuses on providing access to timely and appropriate care after diagnosis or screening abnormality for breast, cervical, prostate and colorectal cancers with a focus on patients who are racial/ethnic minorities, have low socioeconomic status and are from medically underserved areas.<sup>9</sup>

Third, in 2006, the Centers for Medicare and Medicaid Services funded six 4-year demonstration projects through which navigation services are offered to Medicare or Medicaid beneficiaries with suspected or diagnosed breast, cervical, colorectal, lung or prostate cancers. The demonstrations are funded through the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities in Section 122 of the Medicare, Medicaid, and the State Children's Health Insurance Program Benefits Improvement and Protection Act of 2000.<sup>10</sup> The study utilized a randomized control design to study the impact of navigation on satisfaction, cancer care utilization, and clinical outcomes. Definitive findings of the demonstration's effectiveness will not be available until 2012 due to delays in enrolling participants and starting the actual process of navigation.<sup>11</sup> The results of these and other studies will provide valuable information regarding the efficacy and cost-effectiveness of patient navigation programs.

### **The Affordable Care Act**

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, was signed into law.<sup>12</sup> The intent of the law, known as the Affordable Care Act (ACA), was to help close the gap in coverage for the uninsured by building on the current system of private and public insurance vehicles, while also promoting value and quality of care through a number of pilot programs and payment changes.

Implementation of the ACA is underway and will continue through 2014 when most of the major reforms go into effect.

It is estimated that the ACA will expand coverage to 32 million nonelderly Americans by 2016 and to 34 million by 2021.<sup>13</sup> By 2021, 95% of legal nonelderly residents will have insurance coverage compared with a projected 82% without the ACA. About half of the coverage expansion would be achieved through an expansion of Medicaid and the Children's Health Insurance Program which would enroll an estimated 16 million more individuals by 2019.<sup>13</sup>

The ACA will also create new state-run entities called Health Benefit Exchanges, which will act as marketplaces for the purchase of health insurance. Individuals with incomes below 400% of the federal poverty level will be eligible for premium subsidies through the exchanges in the form of tax credits to purchase insurance. There will be limits on out-of-pocket costs that are indexed to income level. The Congressional Budget Office estimates approximately 24 million people will purchase their own coverage through new state insurance exchanges by 2019.

Beginning in 2014, the law will prohibit insurance plans from denying coverage to individuals due to a preexisting health condition and from charging higher premiums to those with health conditions. Premiums can vary based only on age (limited to 3:1 ratio), premium rating area, family composition, and tobacco use (limited to 1.5:1 ratio).

In addition, the ACA improves access to care by increasing funding for community health centers by \$11 billion over five years. All health centers are located in medically underserved communities and half of the patients who receive care in community health centers are people of color.<sup>14</sup> This investment will significantly expand health center capacity for patients who are racial/ethnic minorities or medically underserved, the same populations targeted through patient navigation programs.

### **The Affordable Care Act and Patient Navigation**

The only specific reference to patient navigation in the ACA is in Section 3510 which reauthorizes Section 340a of the PHSA, the Patient Navigator and Chronic Disease Prevention grants, referenced above. The program would have sunset in 2010, but through the ACA was reauthorized for five more years through 2015 with the additional requirement that to receive a grant the entity must ensure the navigators meet minimum core proficiencies tailored to the specific intervention, as defined by the entity. Authorization levels beyond fiscal year 2010 were not specified in the law.

Despite the fact that patient navigation is only explicitly mentioned in one section of the ACA, the principles of patient navigation can be found throughout the Act. The goals of patient navigation—to focus on racial/ethnic minorities and medically underserved populations, promote a more patient-centric health care service delivery model, integrate a fragmented health care system for the benefit of patients, and eliminate barriers to timely and appropriate care—are

well-aligned with the intent of the ACA. These objectives are addressed in the law within quality improvement provisions, fostering of new delivery and payment models such as the patient-centered medical home, establishment of the Patient Centered Outcomes Research Institute, and emphasis on reducing racial/ethnic health disparities. Nevertheless, patient navigation has received little attention during the drafting or implementation of health reform to date.

### *National Quality Strategy*

The ACA called for the establishment of a national strategy to improve the delivery of health care services, patient health outcomes, and population health. In developing this strategy, the Secretary of HHS was directed to lay out priorities that have the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of health care for all populations, including vulnerable populations; address the health care provided to patients with high-cost chronic diseases; and reduce health disparities.

Through a participatory process involving a range of stakeholders, the Secretary developed a National Quality Strategy with three broad aims: 1) improve the overall quality of care by making care more patient-centered, reliable, accessible, and safe; 2) improve the health of the US population by supporting proven interventions to address behavioral, social, and environmental determinants of health; and 3) reduce the cost of quality health care. To reach these aims, the strategy will focus on several priorities including ensuring that each person and family is engaged as partners in their care, promoting effective communication and coordination of care, and promoting the most effective prevention and treatment practices for the leading causes of mortality.

In addition, a set of ten basic principles were also described which will guide how health care services should be provided. At least four of these principles are aligned with the goals of patient navigation including person-centeredness and family engagement; taking into consideration varying patient needs; eliminating disparities in care; and improving coordination among providers. In March 2011, a report to Congress on the National Strategy for Quality Improvement in Health Care was submitted.<sup>15</sup> This report elaborated on each of the listed priorities and provided examples of federal initiatives that promoted each priority. For instance, improving care coordination through health information technology and the First Lady's "Let's Move" campaign were included as examples. The quality report did not include any discussion or reference to patient navigation.

Two recent literature reviews found evidence of the potential for patient navigation to improve outcomes related to the screening and diagnosis of cancer.<sup>3,7</sup> The reviews noted that multiple studies provided evidence of the efficacy of patient navigation in increasing rates of cancer screening, but that there were methodological limitations in several of these studies. The most

recent review concludes that additional studies are needed to evaluate the impact of patient navigation in improving cancer outcomes beyond the detection and diagnosis phase of care.

Beyond cancer outcomes, patient perspectives are also important, especially given the current emphasis on patient-centered care. Patients report that navigators are effective because they provide emotional support, information and assistance with problem-solving.<sup>16</sup> Additional assessment of patient navigation with validated patient-reported outcome metrics would be valuable.

One of the challenges in evaluating patient navigation programs is in comparing results across various studies, given that many programs are specifically and culturally tailored to meet the needs of their target population. As illustrated by the CMS Cancer Prevention and Treatment Demonstrations, conducting randomized controlled trials of patient navigation programs is not straightforward. Study sites faced difficulty in enrolling patients and in training and supervising navigators. It can be problematic to include a control arm of non-navigated patients due to ethical concerns about withholding resources to needy patients.

A major barrier to serious consideration of patient navigation as a policy solution is the lack of data on cost-effectiveness. Fortunately, the multi-center PNRP study will begin to answer the question of cost-effectiveness of patient navigation.

Patient navigation has largely been described and implemented for cancer care, but there is no reason navigation cannot be deployed more broadly in the prevention or management of other chronic diseases. In particular, the ACA places a strong emphasis on prevention of chronic disease by removing financial barriers to accessing preventive care and providing incentives for healthy behaviors.

### ***Innovative Models of Care***

The ACA established the Center for Medicare and Medicaid Innovation to test innovative delivery and payment models and empowers the HHS Secretary to expand demonstrations if the program reduces costs and improves or maintains quality of care. New models of paying for care, such as Accountable Care Organizations (ACO) and bundled payments, are designed to promote care coordination in a fragmented system where providers receiving fee-for-service reimbursement have little incentive to coordinate care.

To ensure quality of care, ACOs would be asked to report on over 60 measures including patient/caregiver care experiences, care coordination, patient safety, preventive health, and at-risk populations/frail elderly health. Based on previous studies, patient navigation might be a useful tool for ACOs to improve patient/caregiver experiences, improve patient safety, and increase utilization of preventive care, such as recommended cancer screening tests.

While removing barriers to preventive care is helpful, studies show that covering cancer screening services is not enough to ensure patients receive recommended screening and care. Patients often have to be informed about their need for cancer screening and receive a recommendation from a health care provider to seek preventive care. It is estimated that a physician with a typical patient load would need to spend 7.4 additional hours per workday on preventive care alone in order to comply with current recommendations.<sup>17</sup> Patient navigators might be one possible solution for how to deliver effective screening care as studies indicate the intervention is most effective in improving cancer screening.

## **Conclusion**

Passage of the ACA certainly did not obviate the need for patient navigation services. The ACA leaves much of the current health system intact, but helps to fill in gaps to improve access to care and coverage. Even after full implementation of health reform, there will continue to be significant fragmentations in the system, making interventions to coordinate and deliver care that are patient-centric important. In some cases, there might even be more fragmentation of care as some individuals will have more insurance options after reform, which could lead them to different providers. Individuals could also cycle between Medicaid coverage and the exchanges due to income fluctuations. Quality of care and efficiency could suffer unless interventions or new models of care can promote coordination among multiple providers.

As patient navigation continues to grow, the use of defined standards for navigators and common metrics in evaluation studies will be essential so that results can be compared across projects.<sup>18</sup> Current demonstration programs indicate interest at the federal level in exploring patient navigation, but long-term sustainability of these programs, particularly in an increasingly constrained budget environment, is uncertain. Patient navigation is currently not a billable service. Well-designed studies would need to demonstrate both efficacy and cost-effectiveness to make the argument for securing reimbursement for navigation. Fortunately for patient navigation, many principles in the ACA seem aligned with those of navigation. As a result of health reform, there may be opportunities to apply patient navigation in new contexts in an effort to improve the quality and efficiency of care delivered.

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