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A Message from the Editor

Public health plays an integral role in immunization coverage throughout the United States. It is this unique public-private partnership of pharmaceutical companies, federal agencies, and health-care providers that has laid the groundwork for successfully introducing vaccines that help eradicate and control vaccine-preventable diseases (VPDs).

In this issue of *Public Health Reports* (*PHR*), the National Vaccine Advisory Committee (NVAC) highlights the Section 317 Immunization Program. Enacted by the Centers for Disease Control and Prevention (CDC) in 1962, the Section 317 Program has played a key role in helping to achieve national immunization goals "by addressing unmet needs and supporting efforts to plan, develop, and maintain an immunization infrastructure that is necessary to ensure high vaccination coverage levels and low incidence of VPDs." According to the NVAC, the Section 317 Program ensures that vaccines are accessible, safe, effective, and used successfully to protect the nation's health.[1]

The Section 317 program is a discretionary federal grant program to all states, six cities, territories, and protectorates that provides vaccines to underinsured children and adolescents not served by the Vaccines for Children (VFC) program as well as to uninsured and underinsured adults, as funding permits.

The Section 317 Operations program remains the primary source of funding for most jurisdictional vaccine program operations. Section 317 Operations funding supports activities that (*1*) direct public vaccine provision; (*2*) oversee provider quality by conducting assessments, training programs, and compliance monitoring; (*3*) develop immunization registries; (*4*) support school- and community-based vaccine service delivery programs; (*5*) create and deliver consumer information; (*6*) conduct VPD surveillance; and (*7*) conduct population needs assessments. The Section 317 Program relies on government funding and has recently received funding from the Prevention and Public Health Fund.

To ensure the continuation of this vital program, the NVAC has made the following recommendations: (*1*) the Section 317 Program should be sustained to ensure high vaccination coverage and low disease burden; (*2*) CDC should provide professional judgment regarding the size and scope of the immunization program; (*3*) the U.S. Department of Health and Human Services should consider CDC's recommendations when formulating the program's budget; and (*4*) federal, state, tribal, and local public health entities should seek efficiency and innovation to achieve Healthy People 2020 targets and ensure high immunization rates.

This issue of *PHR* also includes a supplementary issue on the science and practical applications of sexual health. The articles in this supplement outline a health-focused approached to sexual health, with an emphasis on well-being related to sexuality rather than just the absence of disease. The research, surveillance, program practice, and broad perspectives in this special supplement are intended to influence our understanding and progress on the topic of sexual health.

Topics addressed in the supplement run the gamut from youth sexual health—e.g., socioeconomic disadvantage as it relates to teen childbearing, racial segregation and age at first sexual intercourse, and the Oregon Youth Sexual Health Plan—to preventing sexually transmitted diseases (STDs), human immunodeficiency virus (HIV), and pregnancy. Other articles offer ideas on how to address the stigma surrounding public health efforts, particularly regarding STD and HIV prevention. Finally, former Surgeon General David Satcher provides an interesting historical perspective on national efforts to address sexual health, identifying three key sectors—youth education, the health-care system, and faith-based organizations—that can contribute to improved sexual health throughout the nation.

I would like to extend a special thank you to Janice Huy for her years of service with *PHR*, as she is retiring as acting editor. However, we are fortunate that she will contribute on a part-time basis to advance several special supplements to be released this year.

Mary Beth Bigley, DrPH, MSN, ANP

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Surgeon General's Perspectives

A PLAN TO ADDRESS ALZHEIMER'S DISEASE

VADM Regina M. Benjamin,
Surgeon General

Alzheimer's disease is a significant issue for our nation's public health, affecting as many as 5.1 million Americans and the loved ones who care for them.[1] The challenges of Alzheimer's disease are great and are likely to grow with the aging of our population. The risk of Alzheimer's disease increases with age, and those aged 85 years and older are in the fastest-growing age group in the U.S. for Alzheimer's. If we are to meet the overarching goal of the National Prevention Strategy—to increase the number of Americans who are healthy at every stage of life—then we must make overcoming Alzheimer's disease a priority now.[2]

Millions of American families struggle with the physical, emotional, and financial costs of caring for a loved one with Alzheimer's disease. People with Alzheimer's experience memory loss, personality and behavioral changes, and declines in functional status.[3] The condition significantly damages quality of life, as those who suffer from it may become unable to recognize close family members or perform simple daily tasks such as eating.[4,5] The physical consequences of the disease are compounded by stigma and public misconceptions that contribute to isolation for people with Alzheimer's disease and their families. The majority of people with Alzheimer's disease live in the community, with family members providing most of their care. Caregiving for a loved one with Alzheimer's can exert a major toll on the caregiver's health and well-being. About one-third of individuals who act as caregivers to people with Alzheimer's disease report symptoms of depression,[6,7] and caregivers have worse health outcomes compared with their non-caregiving peers.[8]

The economic impacts of Alzheimer's disease are also significant for families and society. When a person with Alzheimer's disease moves to a nursing home to receive 24-hour care, the financial cost to families is great: an estimated $78,000 per year.[9] Nearly half (48%) of nursing home residents suffer from Alzheimer's.[10] However, people with Alzheimer's disease also have greater acute care needs and are admitted to the hospital two to three times more often than people without the disease who are admitted to the hospital. This disease places a major strain on Medicare and Medicaid, the primary funders of this care.[11]

However, we are making progress. On January 4, 2011, the national significance of Alzheimer's disease was recognized when President Barack Obama signed into law the National Alzheimer's Project Act. The Act requires the Secretary of Health and Human Services to develop a plan to transform the way we approach Alzheimer's disease.[12] A newly formed Advisory Council on Alzheimer's Research, Care, and Services makes recommendations to the Secretary regarding the plan. As the Surgeon General, I am proud to serve on the Advisory Council.

In May 2012, Secretary Kathleen Sebelius released the National Plan to Address Alzheimer's Disease.[11] This document provides a blueprint for significantly reducing the burden of Alzheimer's disease. Specifically, it defines five key goals to transform our nation's fight against Alzheimer's:

1. We seek to prevent and effectively treat Alzheimer's disease by 2025. Currently, no effective pharmacological product or intervention exists to definitively treat, prevent, or cure the disease, and we need more concerted efforts in this area.[11] To aid in this goal, President Obama added $50 million to fund Alzheimer's research in fiscal year 2012, and the President's budget proposes $80 million in fiscal year 2013.
2. We must enhance the quality and efficiency of care for people who have Alzheimer's disease,

including an emphasis on culturally competent patient care provided by specially trained professionals from the point of Alzheimer's diagnosis onward.

3. We must expand support for people with Alzheimer's disease and their families and caregivers. Too often, family members feel unprepared for the challenges of caring for a person with Alzheimer's disease (e.g., addressing sleep disturbances, needs for physical assistance, and behavioral changes).
4. We need heightened public engagement and awareness. Many people can identify the disease and some of its symptoms, but there remains widespread and significant public misperception about diagnoses and clinical management.
5. We need to track progress by improving data. To measure progress against the disease and understand the changing impact of Alzheimer's disease on people who have it, their families, and health and long-term care systems, we need a data infrastructure that supports monitoring and evaluations of our progress in implementing the National Plan.[11]

Since the release of the National Plan, significant steps have been taken to identify research priorities, with new funding going toward research studies. These steps include a genetic analysis aimed at discovering genetic risk factors for Alzheimer's disease, as well as potential protective factors that reduce the risk of disease; initial human trials of new approaches to treat Alzheimer's; and clinical trials of new strategies for preventing Alzheimer's by intervening at early stages in the disease, before symptoms emerge and before irreversible damage has occurred. The national network of Geriatric Education Centers is working to improve and disseminate Alzheimer's-specific interprofessional education and training to health-care providers. The U.S. Department of Health and Human Services launched both an awareness campaign and a website, Alzheimers.gov, which provides current information and resources on Alzheimer's and related dementias to people with Alzheimer's disease and their families.

Alzheimer's disease is a large and complex challenge, but with the ongoing leadership and cooperation from our dedicated team, and our existing and future partners who are working with the Advisory Council, we can achieve our goals. I believe one day we will have a nation free from Alzheimer's disease.

I thank Rohaid Ali, a summer 2012 intern in the Office of the Surgeon General, for his help in producing this column.

Regina M. Benjamin, MD, MBA
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Surgeon General

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Protecting the Public's Health: Critical Functions of the Section 317 Immunization Program—A Report of the National Vaccine Advisory Committee

National Vaccine Advisory Committee

Vaccines are one of our most successful tools for protecting the public's health. It seems simple: a pharmaceutical company develops a new vaccine, the U.S. Food and Drug Administration (FDA) licenses it, health-care providers give it to their patients, and we see disease disappear. But vaccination in the United States is much more complex and only made possible through a robust public-private partnership that begins with the development of the vaccine and continues long after it is used routinely. Along every step of the way, public health—at the national, state, and local levels—plays a fundamental role. The success of the pneumococcal conjugate vaccine (PCV) in preventing suffering, disability, and death is one example that illustrates the essential role of our nation's public health systems and workforce in protecting us from vaccine-preventable diseases (VPDs).

Streptococcus pneumoniae (pneumococcus) is a major cause of invasive disease, including meningitis, pneumonia, and bacteremia. In the absence of a pediatric vaccine, pneumococcus was a significant public health concern, causing approximately 63,000 cases of invasive pneumococcal disease and 6,100 deaths in the U.S. each year.[1] Young children and older adults are especially vulnerable, and many children who develop pneumococcal meningitis have long-term complications such as deafness or seizures.

In 2000, a pediatric heptavalent PCV (PCV7) was licensed for use in the U.S. There are more than 90 strains of pneumococcal bacteria, and PCV7 provided protection against seven of them. Before PCV7 was introduced, these seven strains caused more than 80% of severe pneumococcal infections among children.[2]

Most health-care providers in the U.S. look to public health for guidance in the use of vaccines. After a careful review of the evidence, including data about the burden of disease caused by pneumococcus, the effectiveness and safety of the vaccine, and the feasibility of incorporating it into the immunization program, the Advisory Committee on Immunization Practices (ACIP) made a recommendation for the routine use of PCV7 among children,[2] and the Centers for Disease Control and Prevention (CDC) incorporated it into the immunization schedule, which gives doctors specific recommendations for the use of vaccines across the life span.

Public health helps inform people about the vaccines they need and the risks and benefits of receiving vaccines. Parents consider many factors when deciding to vaccinate their children. Using science-based strategies, public health provided parents with information about the risks of pneumococcal disease and the benefits of the new vaccine. State and local public health experts worked with the health-care providers in their communities to make sure they had the

tools they need to help their patients make informed decisions, from how to hold a child during a vaccination to responding to questions about the need for, and the safety of, the vaccine.

Vaccine supply interruptions are managed by public health to ensure that those most at risk can be protected first. Following the 2000 recommendation, the supply of PCV7 vaccine did not keep up with demand.[3] Because some children are at higher risk of disease and/or its complications than others, public health was called upon to help conserve vaccine and direct it to protect those children at highest risk. CDC issued interim vaccination recommendations to withhold vaccine from healthy children aged 2 years and older, and to defer some doses for healthy children who were younger than 2 years of age.[4] Public health experts and systems at the state and local levels provided strategies for implementing the vaccination guidelines, such as using immunization registries to identify those children who need to be vaccinated and issuing reminders to parents to get them vaccinated.

Public health continued to monitor the supply of PCV7 and, in 2004, when the supply stabilized, public health terminated the interim recommendations so that the vaccine could be used according to the 2000 recommendation.[5]

Public health evaluates our national vaccine programs and policies. Post-licensure evaluation of vaccine performance is necessary to ensure that vaccines have the intended public health impact. In the first five years that PCV7 was used, the incidence of invasive pneumococcal disease in children fell by 94%.[6] In addition to the protection provided to vaccinated children, the work done by our public health systems and experts demonstrated that the vaccine also significantly reduced transmission of pneumococcus to unvaccinated people, including adults. Public health data from Active Bacterial Core surveillance (ABCs) showed a more than 90% decrease in the rate of invasive pneumococcal disease caused by the vaccine serotype disease among people aged 5 years and older, with a dramatic decrease in disease among adults 65 years of age and older.[6] In addition to impressive reductions in disease, economic analyses conducted by CDC showed that every $1 invested in PCV7 resulted in a cost savings of $1.50.[7] This type of information informs our national strategies for preventing invasive pneumococcal disease, including the best investment of health-care resources.

Public health data are critical to the development of new and better vaccines. Over time, public health's pneumococcal surveillance showed that while there were significant reductions in disease caused by the pneumococcus serotypes prevented by PCV7, there were increases in invasive disease caused by non-vaccine serotypes. This finding prompted vaccine manufacturers to develop a new vaccine and, in 2010, the FDA

continued on p. 80

licensed PCV13, which provides protection against six additional serotypes. In particular, PCV13 protects against serotype 19A, which was not covered in PCV7 and which had become the most common pneumococcal serotype. Another important benefit of PCV13 is that *S. pneumoniae* of serotype 19A is often resistant to antibiotics.

Following the recommendation for routine use of PCV13,[8] public health systems and experts at the national, state, and local levels have worked with health-care providers to incorporate this new vaccine into the childhood schedule. This change included guidance for transitioning the use of PCV7 to PCV13, and monitoring vaccine coverage and the incidence of pneumococcal disease caused by the 13 strains in the new vaccine.[9]

A decade after licensure of the first generation of PCV, the story continues. In 2011, PCV13 was licensed for use among adults aged 50 years and older. In June 2012, the ACIP voted to recommend that adults at very high risk due to immunocompromising conditions be vaccinated with PCV13. While PCV13 may prove to be an effective tool for protecting adults from pneumococcal disease, the ACIP is awaiting more data on vaccine efficacy and more information about the indirect protection vaccinating children provides to unvaccinated adults before making a recommendation for routine use of PCV13 in adults.[10] Our public health systems and experts will continue to track the use of PCV13 in the U.S., monitor the vaccine's effectiveness and safety, and gauge its impact on pneumococcal disease among all age groups. This information is essential to inform sound national strategies to prevent pneumococcal disease and guide decisions for investing health-care resources.

Public health infrastructure is fundamental to the provision and execution of public health services at all levels. A strong infrastructure provides the capacity to prepare for and respond to both acute (emergency) and chronic (ongoing) threats to the nation's health. Infrastructure is the foundation for planning, delivering, and evaluating public health.

INTRODUCTION

The achievements of our national immunization program are impressive. Today, we have recommendations for the routine use of vaccines to prevent 17 VPDs. We enjoy record-high immunization coverage rates, most VPDs are at or near record lows, and a majority of diseases are showing a 90% or higher decline in reported cases when compared with the pre-vaccine era.[11] Immunization continues to be one of the most

impactful and cost-effective public health interventions. For each birth cohort vaccinated against 13 diseases in accordance with the routine childhood immunization schedule, $13.6 billion in direct medical costs and 42,000 lives are saved, and 20 million cases of disease are prevented.[7]

The success of our national childhood immunization program rests on a robust public-private partnership. Public health, with unique roles at the national, tribal, state, and local levels, has built the foundation of an immunization system that ensures that our immunization policies and programs promote equitable access to safe and effective vaccines, regardless of whether or not a vaccine is publicly or privately purchased, particularly for the pediatric population.

Purchasing and administering vaccine is only a small piece of the entire enterprise, however, as illustrated by the aforementioned pneumococcal story. A strong immunization system also requires a stable infrastructure from the federal to the local levels that includes a highly trained immunization workforce, disease surveillance experts and systems, scientific support for developing immunization policies, systems for monitoring and assuring vaccine safety, and mechanisms to monitor vaccine coverage rates.

In the past decade, we have also seen several changes that present both new opportunities and challenges to the immunization system. The number of lifesaving vaccines available has increased dramatically, while the cost of vaccines has also risen. The passage of the Affordable Care Act (ACA)[12,13] has the potential to provide unprecedented access to vaccines by increasing the number of people insured and, thus, covered for vaccination, as well as removing copayments for these people, thereby incentivizing administration and receipt of the vaccines. As expanded health coverage is fully realized, greater numbers of children and adults will gain access to vaccines through public and private health insurance. However, as we have learned over the years, insurance coverage alone is not enough to ensure disease control or high vaccination coverage rates. It will be necessary to maintain a strong public health infrastructure to support the U.S. vaccination program. Current vaccine financing strategies, including those offered now by the ACA, do not address the fundamental resource needs to support the immunization infrastructure. With these many changes since the enactment of the Section 317 Immunization Program, the National Vaccine Advisory Committee (NVAC) feels that this is an ideal and indeed critical time to reexamine and strengthen the immunization infrastructure.

THE SECTION 317 IMMUNIZATION PROGRAM

A key resource in support of establishing and maintaining the public health immunization infrastructure is the contribution of the Section 317 Immunization Program.[14] The Section 317 Program, administered by CDC, was enacted in 1962 through the Vaccine Assistance Act, or Section 317 of the Public Health Service Act. During its 50-year history, the Section 317 Program has played a critical role in helping to achieve national immunization goals by addressing unmet needs and supporting efforts to plan, develop, and maintain an immunization infrastructure necessary to ensure high vaccination coverage levels and low incidence of VPDs. A profound strength of the program is its flexibility, allowing it to respond efficiently and effectively to state-specific priorities and unexpected outbreaks of disease. Initially designed to purchase polio, diphtheria, pertussis, tetanus, and smallpox vaccines, with measles vaccines added in 1965, the Section 317 Program has evolved with the introduction of new vaccines and immunization recommendations and the changing health-care landscape to become much more than a vaccine purchase program. However, the Section 317 Program is a discretionary program; therefore, funding is set through the annual appropriations process and is not guaranteed from year to year.

As with all discretionary programs, the President submits the budget request each year to Congress for the following fiscal year, as required by the Budget and Accounting Act of 1921.[15] The President's budget request outlines the administration's intended spending and is developed through an iterative process in which agencies and operating divisions present proposed funding levels for consideration, with the Office of Management and Budget setting a final spending level that is included in the President's budget request. Ultimately, discretionary spending is determined through negotiations between the House and Senate Appropriations Committees and their various subcommittees. They may or may not use the levels requested in the President's annual budget.

The Section 317 Program helps protect all Americans from VPDs by providing the backbone of the U.S. immunization program—regardless of the payer for the vaccine given—by ensuring that vaccines are accessible, safe, effective, and used most successfully to protect the nation's health. The Section 317 Program provides the majority of federal support for national, state, and local immunization systems and the workforce necessary to implement a comprehensive immunization program (Figure 1) through:

- Immunization infrastructure grants: funds awarded to 64 immunization programs (all 50 states, the District of Columbia, five large cities, five U.S. territories, and three Pacific freely associated states) to support immunization workforce and systems at the state and local levels to recruit and educate networks of immunization providers, provide continual quality assurance, promote public awareness of new and expanded vaccine recommendations, manage vaccine shortages, and prepare for and respond to vaccine-preventable outbreaks.
- Vaccine purchase: federally purchased vaccines allocated to the 64 immunization programs to protect non-Vaccines for Children (VFC) Program-eligible populations with routinely recommended vaccines, and to meet urgent needs such as responding to VPD outbreaks. Unlike VFC Program vaccines, for which there are very specific eligibility criteria, Section 317 vaccines can be used to rapidly protect all members of a community when VPD outbreaks occur.
- Extramural program operations: contributes to the systems and workforce that conduct disease surveillance, assess vaccination coverage, perform post-marketing evaluation of vaccine effectiveness and safety, develop and implement immunization information technologies, support centralized vaccine ordering and distribution systems, and create and implement public awareness campaigns and resources, as well as provider education and tools.
- National program operations: provides national public health expertise in VPDs that supports national, state, and local vaccination program efforts, including expertise in epidemiology and surveillance, laboratory methods and science, immunology, immunization policy, health communications science, vaccine management, and program implementation.

During the past decade, appropriations to the Section 317 Program have stagnated at levels that are insufficient to maintain this important work. Most recently, as the annual appropriation to the Section 317 Program has eroded, gaps in support for these important activities have been funded through the Prevention and Public Health Fund (PPHF), which was established through the ACA. The PPHF has proven a valuable resource for strengthening immunization systems and workforce at the national, state, and local levels. However, the instability of this funding source poses risks as it funds a larger proportion of the Section 317 Program (Figure 2).

Figure 1. Section 317 Immunization Program, fiscal year 2012: Section 317 appropriation and Prevention and Public Health Funds ($552 million)

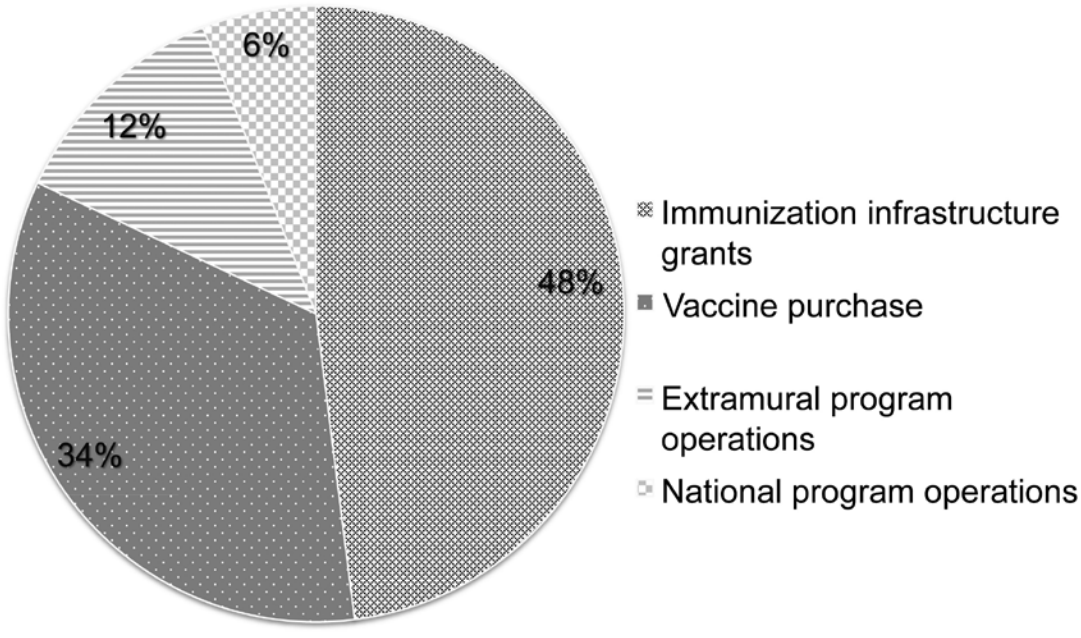
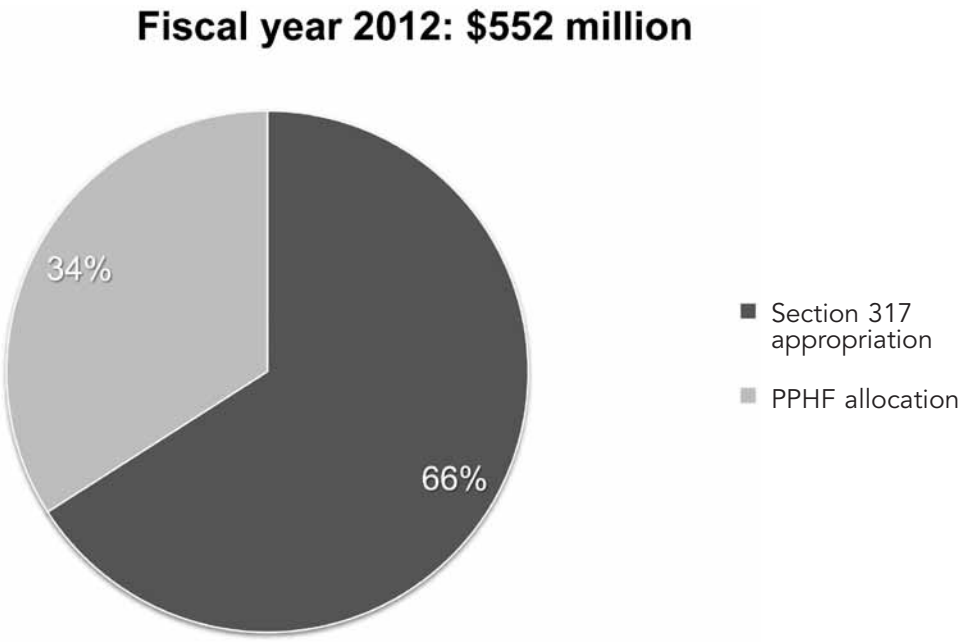


Figure 2. Federal immunization funding: Section 317 Immunization Program appropriation and Prevention and Public Health Funds



PPHF = Prevention and Public Health Fund

THE NATIONAL VACCINE ADVISORY COMMITTEE

The NVAC is a federal advisory committee, established in 1987, that provides vaccine and immunization advice and policy recommendations to the Director of the National Vaccine Program (NVP). The Assistant Secretary for Health (ASH) has been designated by the Secretary of Health and Human Services (HHS) as the Director of the NVP.[14] The NVAC recommends ways to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. Specifically, the NVAC was chartered, through the Public Health Service Act, with four main responsibilities:

- Study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the U.S.
- Recommend research priorities and other measures that should be taken to enhance the safety and efficacy of vaccines.
- Advise the ASH on the implementation of the NVP's responsibilities and the National Vaccine Plan, a coordinated, strategic framework established to achieve the vision of the NVP.
- Identify the most important areas of government and nongovernment cooperation that should be considered in implementing the NVP's responsibilities and the National Vaccine Plan.[16]

In 2011, the NVAC identified the need to describe the nation's public health immunization infrastructure and to explore policy options to assure the stability of that infrastructure through the Section 317 Program in the changing health-care landscape. Increases in Section 317 funding have been positively and significantly associated with increases in vaccination coverage.[17] A Working Group on Immunization Infrastructure was appointed by the chairman of the NVAC to describe critical functions of immunization programs at the national, state, tribal, and local levels, and included representatives from federal agencies, professional organizations, consumer groups, individuals in vaccine research or with manufacturing experience, state and local health departments, and academic centers. This report contains NVAC recommendations based on the Working Group's findings and conclusions. The overall goal of the report is to describe the essential public health functions supported by the Section 317 Program (Figure 3) and to examine and recommend strategies that maintain these functions, while encouraging public health at the national, state, and local levels to adapt

and evolve to meet these new challenges and opportunities toward protecting all Americans from VPDs.

DEVELOPING EVIDENCE-BASED IMMUNIZATION POLICY

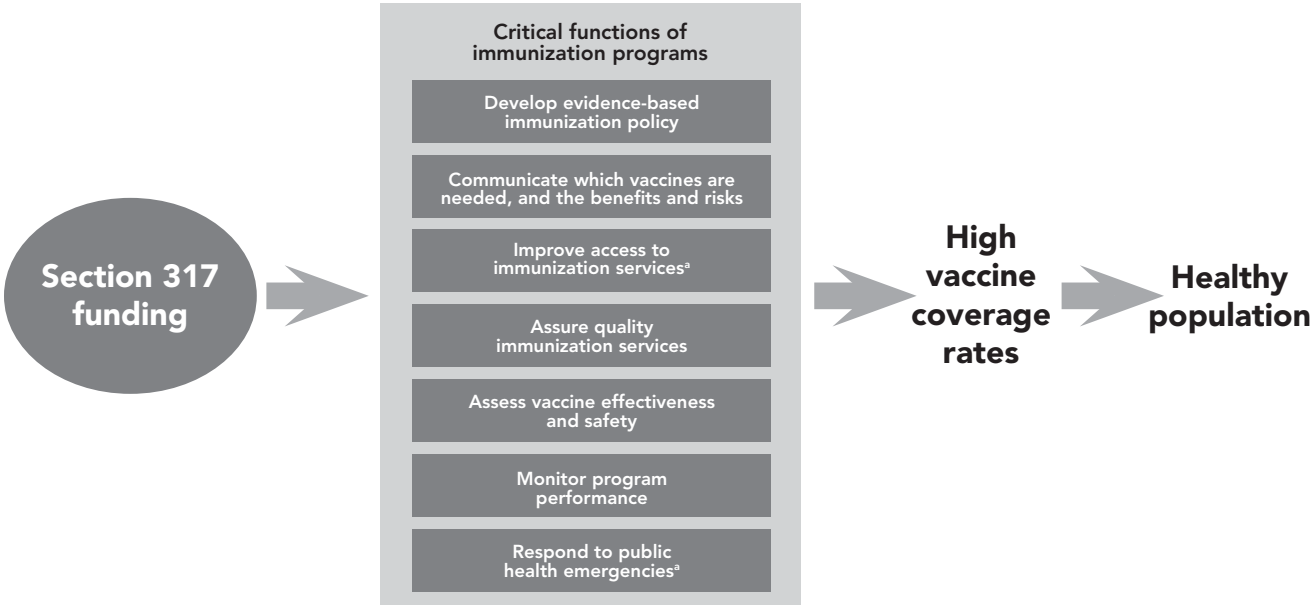
In the U.S., the ACIP advises CDC on national vaccine policy for preventing infectious diseases in the civilian population. Once adopted by CDC, the Committee's recommendations establish the standard of practice for preventing VPDs and, as of September 2010, determine the vaccines that must be covered without cost to vaccine recipients by private health insurance plans.[18]

Comprising 15 voting members with expertise in medicine and public health along with a consumer representative, the Committee holds public meetings three times a year to make its vaccine recommendations. The members consider the approved indications for vaccines, principles of equity and social justice, and the evidence base for use of a given vaccine among the U.S. civilian populations. The immunization systems and expertise that are supported by the Section 317 Program make substantial contributions to the evidence base upon which the ACIP deliberates in making its recommendations. They do so by providing data about the burden of disease that can be prevented, about the safety and efficacy of the vaccine, and by supplying economic analyses (including cost-effectiveness data) in addition to information about other factors, such as how an ACIP recommendation can be implemented by the health-care system in conjunction with other recommended vaccines. The Committee's recommendations provide guidance on the population to be vaccinated; the appropriate route, dose, and frequency of vaccine administration; and information about contraindications and precautions, as well as recognized adverse events. Once the Committee's recommendations are accepted by the CDC Director, they are published in the *Morbidity and Mortality Weekly Report*.

Each year, the individual vaccination recommendations are summarized in immunization schedules for children, adolescents, and adults. The immunization schedule provides a roadmap for health-care providers about all of the vaccines recommended for their patients. To reduce confusion and proliferation of different recommendations, public health collaborates in developing its schedules with the medical associations whose members provide vaccines, including the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Physicians, and the American College of Obstetricians and Gynecologists.

The ACIP continues to review the safety and effectiveness of vaccines even after the vaccines are recommended, and adjustments may be made as more data become available. New data are reviewed in the context of the risks of adverse effects and the benefits provided by the vaccine. For example, when polio was

Figure 3. Role of Section 317 Immunization Program funding in preventing infectious disease



[a]Section 317 funds can be used to purchase vaccine.

more prevalent globally, the U.S. primarily used oral polio vaccine (OPV) to protect Americans from the risk of imported cases because it was perceived to be more effective at reducing the transmission of disease, even though it was associated with a risk of vaccine-associated poliomyelitis of one in 750,000 first doses.[19] As global polio control improved and the risk of polio importations into the U.S. decreased, the risk-benefit of use of OPV was reevaluated. In 2000, the ACIP recommended that OPV be replaced with the inactivated polio vaccine, which has no risk of vaccine-associated paralytic disease.

Immunization policies are also made at the state and local levels, and many states have immunization advisory committees that provide advice. State and local policies can significantly impact the health of their jurisdictions, and public health systems and expertise supported by the Section 317 Program provide important evidence and data to inform those decisions. State and local policies are most often focused on vaccination requirements for day care and school entry, and on vaccinating personnel and patients in health-care settings. Immunization requirements reinforce clinical recommendations for vaccination and are an important tool for improving and maintaining high vaccination coverage. For example, state and local vaccination requirements for school entry have been shown to increase vaccination coverage among elementary schoolchildren, and more recently have been shown to increase coverage for some adolescent vaccinations.[20]

COMMUNICATING VACCINE RECOMMENDATIONS AND THEIR BENEFITS AND RISKS

In the U.S., we enjoy the benefits of vaccination recommendations across the life span, from infancy to old age. Public health plays an important role at the national, tribal, state, and local levels in making the public aware of the vaccines that are recommended for them. Communication specialists apply communication science and best practices to create materials and tools to improve the public's awareness about the vaccines that are available to and recommended for them. The Section 317 Program contributes to this science base and supports efforts to deliver information about the risks of VPDs, the benefits of immunization, and any known side effects of vaccination using various formats, channels, and trusted spokespeople who resonate with the target audience's values and beliefs.

By protecting myself, I am protecting her

Section 317 has contributed to the public health communications research that has found that different groups view the benefits of vaccination differently. Using these findings, materials have been developed that focus on the benefits that a particular group values most. For example, older adults, who are at increased risk of seasonal influenza, value their ability to protect their loved ones more so than protecting themselves from influenza. Based on these findings, public health promotes the influenza vaccination to seniors as the best way to protect themselves and those they love from the flu.

Informed patients make the best decisions for themselves and their families. As with any medical intervention, most patients have questions about vaccines—why they are needed, if they are effective, and if they are safe—and health-care providers are an important and trusted source for answers to these questions. Public health works with medical associations and other partners to develop resources and tools for health-care providers and their patients to inform their decisions about vaccines. The Section 317 Program supports national, state, and local efforts to educate health-care providers through multiple formats and venues about evidence-based strategies and techniques for answering questions about vaccine effectiveness, safety, and the diseases they prevent, as well as advising the public on the vaccines they need for themselves and their children.

IMPROVING ACCESS TO IMMUNIZATION SERVICES

In the U.S., immunization services, especially for children, are provided primarily in the medical home. However, vaccines are also offered in many other settings, such as public health clinics and community health centers, and complementary venues such as pharmacies, retail clinics, and schools. With the expansion of routinely recommended vaccines for adolescents and adults, medical specialties other than pediatrics and family medicine play an increasingly important role in providing access to immunization services.

The Section 317 Program plays an important role in supporting the immunization systems and workforce that recruit and train robust networks of vaccine providers by building strong partnerships at the national, state, tribal, and local levels to ensure that vaccines are accessible, regardless of the individual's insurance coverage. Public health works with associations representing public and private health-care providers, vaccine manufacturers, and health insurance plans to identify strategies to recruit and train networks of vaccine providers so that there is adequate access to VFC Program[21] providers in every community, and

access to in-network providers for those with insurance. It is important to recognize that while the VFC Program provides vaccine at no cost to eligible children and adolescents, the significant achievements of the VFC Program in improving vaccination coverage and eliminating disparities would not be possible without the immunization infrastructure supported by the Section 317 Program.[22] Public health promotes the use of proven strategies to improve vaccination coverage among children, adolescents, and adults through resource materials, trainings, and visits to clinical sites. The Section 317 Program has been an essential resource for developing, evaluating, and promoting evidence-based public health tools,[23] which include:

- AFIX (assessment, feedback, incentives, eXchange), which incorporates four key strategies proven reliable to improve providers' immunization service delivery and raise vaccination coverage levels;
- Standing orders for vaccinations, which stipulate that all people meeting certain eligibility requirements should be vaccinated, thus eliminating the need for individual physician's orders for each patient; and
- Reminder and recall systems that alert health-care providers and patients that the patient is due or overdue for vaccination. Immunization information systems (IISs) and electronic health records (EHRs) can facilitate automation of reminder-recall systems.

ASSURING THE QUALITY OF IMMUNIZATION SERVICES

Quality assurance for vaccine delivery and immunization practice is an important public health function. State and local public health systems and workforces that are supported in part by the Section 317 Program give health-care providers ongoing training and technical assistance to support their vaccination programs. Public health experts visit clinical offices to assure appropriate vaccine storage and handling practices, and to identify opportunities to improve vaccination coverage among their patients. However, the resources required to establish public-private collaborations to fully support and improve practice for immunization across the life span are currently not sufficient and, as a result, efforts in adult immunization have lagged behind those in pediatrics.[24] Thus, while the Section 317 Program is authorized to support adult immunization efforts, historically the funds appropriated have been inadequate to do so.

Vaccines need to be stored in the right equipment at the right temperature to ensure the most protection. The Section 317 Program supports efforts to improve storage and handling practices at the provider office. For example, in California, the Section 317 Program supports the California Department of Public Health's effort to provide training and resources for health-care providers to help them effectively store and manage their vaccine inventory. This maintenance includes easily accessible Web-based materials,[25] such as the EZIZ Online Immunization Skills Curriculum on storing vaccines, monitoring refrigerator temperatures, and monitoring freezer temperatures; and Vaccine Storage and Handling Job Aids for refrigerator and freezer setup, monitoring temperatures, transporting vaccines, and managing vaccine inventory.

State and local public health officials assist providers with response to vaccine administration errors (e.g., what to do when a vaccine is administered subcutaneously instead of intramuscularly) and management of vaccine stocks that have been exposed to temperature conditions outside the recommended range. These important public health functions are also partly funded through the Section 317 Program.

Finally, information technology plays an important role in immunization program management and implementation by improving the quality of immunization data and enhancing accountability and stewardship of public vaccine resources. IISs are now a critical part of immunization programs, ensuring that individuals get the vaccines they need when they need them. The Section 317 Program is a critical resource for assuring that immunization technologies support the integration of quality immunization services into clinical preventive care. The Section 317 Program contributes to the efforts to improve the interoperability of these public health systems with other health-care systems to enhance the completeness, timeliness, and exchange of data across systems. Interoperability of IISs with EHRs will make it easier for health-care providers to report and receive data about their patients' immunization status from state or local IISs, ultimately making the determination of a patient's vaccination needs routine. IISs can also provide vaccine inventory tracking and are now being integrated with the national vaccine ordering and tracking system for vaccines purchased from CDC vaccine contracts, linking information about vaccines administered with vaccine ordering and distribution data. Other efforts to advance improvements in data quality include the addition of two-dimensional barcoding to vaccine packaging, which will allow providers to scan vaccine information into patient records, reducing data input errors and improving data completeness. IISs are computerized systems that:

- Record all shots on all age groups given by all providers in a geopolitical catchment area.
- Have functions and features needed by an immunization program (e.g., vaccine inventory management and adverse event reporting).
- Have interoperability with other health information systems, including EHRs.
- Consolidate vaccine records into a single, electronic source that helps facilitate reminder-recall systems and clinician decision support to avoid missed and unnecessary vaccinations and to reduce wasted vaccine.

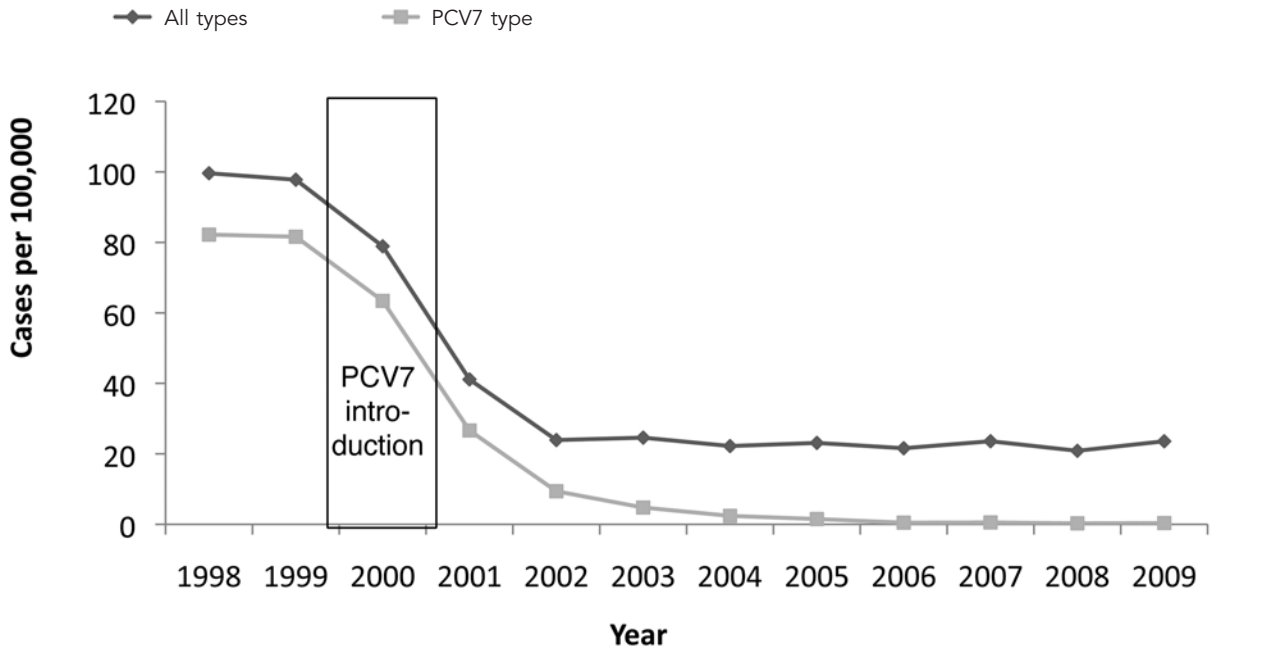
ASSESSING VACCINE EFFECTIVENESS AND SAFETY

Once a vaccine is recommended for routine use, it is essential that systems be in place to monitor the impact of the vaccine on the disease or the vaccine may not provide the level of protection needed to meet disease control objectives. For example, in the 1980s, outbreaks of measles occurred in schools that had high coverage with one dose of measles vaccine. Recognizing that a single dose of measles vaccine was not providing sufficient immunity, the ACIP recommended in 1989 that a second dose of measles vaccine be added to the routine immunization schedule. Unexpected changes in the epidemiology of disease may also follow vaccine introduction, such as following the introduction of PCV7, after which there was an increase in disease caused by non-vaccine serotypes that were resistant to some commonly used antibiotics.

Through its support of extramural and national program operations, the Section 317 Program contributes to the public health systems and expertise that are fundamental to assuring that our national vaccine policies and programs have the intended impact. Public health implements several different approaches to monitor the epidemiology of VPDs. Some diseases are monitored through notifiable disease systems, which collect data at the national and state levels about diseases and conditions for which there is required reporting. For many conditions, laboratory-based diagnosis is essential to confirm the diagnosis, and public health laboratories at the federal and state levels provide essential support for case investigation. Some VPDs are monitored through population-based laboratory reporting systems, such as the ABCs, which provided important data on the impact of PCV7 vaccination of children in the U.S. (Figure 4) and is now providing the first evidence of the impact of the additional serotypes included in the PCV13 vaccine.

Other VPDs that may not be routinely confirmed by

Figure 4. Impact of PCV7 vaccine on invasive pneumococcal disease among children <5 years of age, 1998–2009[a]



[a]Pilishvili T, Lexau C, Farley MM, Hadler J, Harrison LH, Bennett NM, et al. Sustained reductions in invasive pneumococcal disease in the era of conjugate vaccine. J Infect Dis 2010;201:32-41.

PCV = pneumococcal conjugate vaccine

laboratory testing are included in special sentinel surveillance projects. This approach has provided valuable information about the impact of rotavirus vaccines on acute gastroenteritis among young children in the U.S.

Specialized molecular testing provides critical information to help determine the source of disease transmission when epidemiologic linkages cannot be identified. For example, molecular typing data are essential to determine the source of measles and rubella cases in the U.S. and provide documentation of the elimination of endemic measles and rubella. Molecular testing also plays an important role in assessing vaccine safety. For example, genetic sequencing data have documented varicella vaccine strain virus within the cerebrospinal fluid of vaccinated individuals, supporting the hypothesis that varicella vaccine may rarely cause aseptic meningitis as a side effect of vaccination. In contrast, measles vaccine virus has not been isolated from the brain of people with subacute sclerosing panencephalitis, a rare and chronic progressive inflammation of the brain caused by persistent infection of measles virus; indeed, it has been shown with molecular typing that when isolated measles viruses were analyzed, they have always been consistent with wild-type measles instead of measles vaccine virus. Such testing is only available through public health laboratories. There is no private market for such testing; therefore, the capacity must remain in the public sector.

After a vaccine is licensed and used in the U.S., public health employs several approaches to monitor vaccine safety. The Section 317 Program helps support the national expertise in vaccine safety and the systems that identify and evaluate potential vaccine adverse reactions.

The Vaccine Adverse Event Reporting System (VAERS) is a national spontaneous reporting system that is jointly managed by CDC and the FDA. Certain reports are mandatory, but anyone can report any adverse event to VAERS. Although VAERS reports alone rarely can establish causality, and the limitations of the system are significant, the system has helped prompt investigations that ultimately identified serious adverse events. Safety is also assessed by special studies that are organized and funded by CDC, FDA, or the vaccine's manufacturer. Since 1992, the Vaccine Safety Datalink (VSD), a consortium of managed care organizations with access to electronic data files on both immunization and various health outcomes, has provided critical infrastructure for vaccine safety studies in the U.S. In recent years, VSD investigators have developed new methods for more rapid approaches to evaluate safety through ongoing review of accrued data for specified diagnoses during specified intervals following a specified vaccine. This approach, called rapid cycle analysis (RCA), has been used to evaluate the safety of a number of newer vaccines. For example, RCA identified an increased risk of febrile seizures following the combined measles-mumps-rubella-varicella vaccine among children aged 12–23 months compared with the separate administration of measles-mumps-rubella and varicella vaccines in this age group.

Data collected also allow the risks of adverse events following immunization to be reviewed in the context of the benefits provided by the vaccine. Data on adverse events may lead to recommendations for additional information to be provided prior to vaccination, changes in the vaccine recommendation, or even the withdrawal of recommendations for use of a vaccine.

Post-licensure monitoring of vaccine safety

Vaccine safety begins at product development before a vaccine is licensed and continues after licensure to make sure uncommon potential adverse events are identified. If a significant safety event occurs, measures are taken to respond, including suspending the use of and/or withdrawing a product from the market. Such an event occurred in the late 1990s.

In 1998, the first pediatric rotavirus vaccine (RotaShield®, Pfizer, New York, New York) was licensed to protect infants and young children from severe acute gastroenteritis (i.e., vomiting and severe diarrhea) caused by rotaviruses. This vaccine became linked to a condition called intussusception among vaccinated infants, which is a blockage or twisting of the intestines that sometimes requires surgery and can be fatal. Although five cases of intussusception were noted in pre-licensure studies of RotaShield, it was not clear that this incidence was in excess of what would be expected to occur naturally. This information was included in the product labeling when the vaccine was approved, and a code was established to allow specific reporting of this condition to VAERS. By May 21, 1999, 10 cases were identified among infants who had received RotaShield in the U.S.; six of these cases occurred within three to six days following vaccination. In June 1999, CDC initiated a multistate case-control study.[26] By July 7, 1999, 15 cases among recipients of rotavirus vaccine had been reported to VAERS; of these, 12 had developed intussusception within one week of vaccination. Additional data from a manufacturer-sponsored post-licensure study and preliminary data from the CDC case-control study became available in early July 1999. On July 16, 1999, CDC announced a suspension of the use of RotaShield pending completion of ongoing studies.[27] Both the CDC case-control study and a large linked database study were completed by

October 1999 and confirmed an approximately 30-fold increase in risk of intussusception following the first dose of RotaShield. In October 1999, the manufacturer voluntarily withdrew the product from the market and the ACIP withdrew its recommendation for the use of RotaShield in the U.S.[28]

More recently, two new rotavirus vaccines (RotaTeq®, Merck Vaccines, West Point, Pennsylvania, licensed in 2006, and Rotarix®, GlaxoSmithKline, Philadelphia, Pennsylvania, licensed in 2008) have been licensed in the U.S. and are recommended for routine use in infants. Both vaccines were evaluated in large (more than 30,000 vaccinated infants) pre-licensure studies to evaluate the risk of intussusception, and no evidence of increased risk was found. Post-licensure studies in other countries have found about a fivefold increase of risk of intussusception following the first dose in some populations. Ongoing studies of RotaTeq in the VSD in the U.S. have found no evidence of an increase in risk; monitoring of both vaccines continues.

MONITORING PROGRAM PERFORMANCE

The performance of national, state, and local immunization programs is monitored through vaccine coverage assessments toward Healthy People 2020 goals.[29] The public health systems and workforce funded through the Section 317 Program identify gaps in immunization coverage and guide program priorities using multiple approaches.

The National Immunization Survey (NIS), a large, random-digit-dial survey, is conducted at the national level and is used to obtain immunization coverage estimates for children aged 19–35 months. Provider-verified records are obtained and estimates are made both of national and state-specific coverage by vaccine and by several different vaccine series on an annual basis. Since 2006, the NIS has been expanded to collect data on vaccination of adolescents aged 13–17 years (NIS-Teen). NIS-Teen provides coverage estimates by vaccine and by state on an annual basis. Vaccine coverage among adults is monitored at the national level by the National Health Interview Survey (NHIS) and at the state level by the Behavioral Risk Factor Surveillance System (BRFSS). Other systems were developed during the 2009 H1N1 influenza pandemic to collect timely information on coverage. These systems include Internet panel surveys currently used to monitor influenza vaccine coverage among pregnant women and health-care workers, and work is ongoing to identify alternatives to telephone surveys, given their decreasing response rates.

In addition to these national efforts, the Section 317 Program also contributes to efforts at the state and local levels to monitor program performance. This contribution includes efforts to implement IISs that, in addition to quality assurance, can be used to monitor immunization coverage and identify communities with lower vaccine coverage. Through support from the Section 317 Program, states also monitor the impact of state vaccine requirement policies by monitoring vaccine coverage at school entry and exemption rates.

RESPONDING TO PUBLIC HEALTH EMERGENCIES

Immunization programs are regularly involved in responding to public health emergencies. These activities include managing vaccine supply interruptions and shortages and responding to disease outbreaks. The flexibility of the Section 317 Program to support the immunization workforce and systems necessary for responding to such emergencies is an important feature of the program.

Manufacturing vaccines is a complex process, and it is not uncommon for supply interruptions to occur, thereby causing vaccine shortages. When vaccine shortages occur, partners—including vaccine manufacturers, other public health officials, and medical professional societies—work with CDC to manage vaccine orders from both the private and public sectors and to control the distribution of available vaccine to assure equity between the two sectors. If available and projected vaccine supplies are not adequate to provide all recommended doses of the vaccine to the population for whom it is recommended, temporary changes in recommendations may be made to maximize protection while reducing demand to meet supply. During the *Haemophilus influenzae* type b (Hib) vaccine shortage in 2009–2010, the booster dose was temporarily halted except for certain children at increased risk of Hib disease. The Section 317 Program contributes to the communications systems that deliver important information about vaccine supply and encourage compliance with any shortage recommendations. This system includes a CDC Web page with timely and updated information about vaccine shortages.

Public health response to VPD outbreaks is largely conducted at the local and state levels. Some diseases such as polio and measles are no longer endemic in the U.S., so every suspected case requires timely and thorough investigation, including efforts to identify where the infection was acquired and settings in which further transmission may have occurred. Responding to any outbreak is a labor-intensive and costly effort that requires epidemiologists, laboratory support,

and extensive fieldwork. The Section 317 Program contributes to outbreak response by supporting the immunization systems and workforce at the state and local levels that actively search for cases, collect information needed to confirm the diagnosis, identify settings where disease transmission may be occurring, and follow up with all individuals who might have been exposed to implement control. The data from these investigations are essential tools in determining and guiding outbreak control strategies, such as quarantining exposed people, providing antimicrobial or immune globulin prophylaxis, canceling public events, and guiding vaccination efforts. Public health response may also involve mass immunization efforts, such as those done for meningitis, hepatitis A, and pertussis outbreaks in recent years. The Section 317 Program contributes to the workforce and vaccine for such efforts. The flexibility of the Section 317 Program to vaccinate adults is particularly important in outbreak response.

At the national level, the Section 317 Program supports efforts to document and communicate nationally about outbreak response and its impact, provide guidance on outbreak control, and, if invited by state health officials, initiate or enhance field investigations to support state and local public health responses.

The cost of a VPD outbreak: measles

The U.S. recently experienced an increase in measles—a highly contagious disease spread through the air when an infected person coughs or sneezes. Measles is so contagious that if one person is infected, nine out of 10 people with whom they have close contact who are not immune to measles will become infected.[30] Before the measles vaccine was introduced in 1963, there were about three to four million cases of measles in the U.S. alone; essentially every child had the disease by the time they were 15 years of age. About 1,000 people suffered disabilities from the disease, such as deafness or permanent brain damage from encephalitis, and approximately 450 people died each year from measles. By 2000, naturally occurring cases of measles had been eliminated.[31] During 2000–2008, there were approximately 50 measles cases each year that had come from other countries where measles was still endemic,[32] with increasing numbers of importations into the U.S. as a result of increases in measles cases in countries visited by U.S. travelers, including some parts of Europe, Asia, the Pacific, and Africa.[33]

Outbreaks of measles and other VPDs can occur at any time in the U.S. In 2011, 17 measles outbreaks occurred, resulting in 222 cases of measles. Forty-four percent of the outbreak-associated cases were among people who chose not to be vaccinated, and 90% of cases were traced to other countries with lower immunization rates. The 2011 cases marked the highest number of cases in 15 years. The public health investment in staff and resources is significant in responding to these outbreaks. Each case of measles triggers intense public health response to prevent this highly contagious disease from spreading. Section 317 contributes to the public health expertise and workforce, systems, and strategies, such as vaccination, that are necessary to contain measles outbreaks. The following response examples highlight the investment in resources involved in supporting response efforts.

A public health response to measles in Salt Lake County, Utah, from March to April 2011 involved nine measles cases, but required officials to trace thousands of contacts, review immunization records of hospital workers and teachers, give post-exposure prophylaxis to nearly 400 people, and isolate 200 others. The estimated cost of this response was $300,000.

To stop a 14-person measles outbreak that began with one unvaccinated tourist visiting a U.S. hospital emergency room in Arizona in 2008, the Arizona Department of Health had to track down and interview 8,321 people, seven Tucson hospitals had to furlough staff members for a combined 15,120 work-hours, and two hospitals where patients were admitted spent $799,136 to contain the disease.

The 2008 measles outbreak in San Diego, California, exposed 839 people, including 11 unvaccinated children who developed the disease, and resulted in the hospitalization of an infant who was too young to be vaccinated. The total cost of response was $124,517. The net public-sector cost was $10,376 per case, and the average cost to the affected families was approximately $775 per child.

OPPORTUNITIES

In many ways, the potential of vaccines to reach and protect the health of the public has never been greater. We have record-high childhood immunization coverage rates and significant decreases in disease. Since 2000, 11 additional vaccines have been routinely recommended for children, adolescents, or adults along with numerous recommendations for vaccine use in expanded age groups, such as the universal recommendation for seasonal influenza vaccine, to protect Americans from serious and life-threatening diseases. Access to immunization services is expected to improve as health insurance reforms are fully implemented, and improvements in health information technologies have the potential to create efficiencies and improve

health-care quality. Yet, with each of these opportunities come challenges that, if ignored, could undermine our success.

One challenge is a direct byproduct of our success. As we have significantly decreased the rates of most VPDs, the absence of disease has decreased public awareness about the importance of maintaining high vaccination coverage rates. The immunization infrastructure needs to be able to fully support efforts to provide the scientific evidence that underpins national immunization policies, including vaccine safety systems, and the development and dissemination of information about the benefits and potential side effects of vaccines within the context of the risks of the diseases they prevent.

New and expanded vaccine recommendations provide ever-increasing protection from serious and deadly infectious diseases. Along with this protection come increased costs and crowded and complex immunization schedules. There are now new populations recommended for vaccinations and new provider groups to reach and educate. For example, public health is strengthening partnerships with medical specialties, such as obstetricians and gynecologists to improve vaccination of pregnant women, and with complementary health-care venues, such as pharmacies and other retail clinics, to increase capacity and coverage for seasonal flu vaccination. The success of these partnerships in achieving national immunization goals relies on robust public health systems and a highly skilled public health workforce to provide outreach and education, improve collaboration among diverse providers, ensure proper vaccine storage and handling, support the use of effective immunization information technologies, and address disparities. While it has not been the only resource, the Section 317 Program has been and continues to be the core funding for these critical activities, as illustrated in the pertussis response of 2010–2012.

CASE STUDY: THE ROLE OF IMMUNIZATION INFRASTRUCTURE IN RESPONDING TO PERTUSSIS, 2010–2012

Pertussis, also known as whooping cough, is a respiratory infection that causes very prolonged coughing illness in most people, but can lead to pneumonia and fatal respiratory failure in infants. The disease can be cyclical, with peaks every three to five years, and the U.S. experienced a 50-year high in 2012. Most recently, large outbreaks in California and Washington State illustrate public health immunization infrastructure in action.

In 2010, California reported more than 9,000 cases of pertussis, with 10 infant deaths.[34] Experiencing its worst outbreak of whooping cough in decades, Washington State declared an epidemic of pertussis on April 3, 2012. As of early August 2012, Washington State had nearly 3,500[35] reported cases compared with 965 cases reported statewide for all of 2011. As of August 11, 2012, 46 states and the District of Columbia reported increases in disease compared with the same time period in 2011.[36] A number of efforts are under way to control these outbreaks and prevent the spread of disease; these efforts rely upon the following critical immunization program functions, which are illustrated in Figure 5.

Response to public health emergencies

During the past two years, the Section 317 Program[14] has provided critical support for the public health response to the increasing number of pertussis outbreaks. The immunization systems and workforce at the state and local levels have conducted epidemiologic studies, implemented targeted vaccination campaigns, and increased public awareness and provider education activities. At the federal level, CDC has provided scientific expertise in pertussis; science-based communication tools and resources for use nationwide, statewide, and locally; and Section 317-purchased vaccines for targeted campaigns. The ability of the Section 317 Program to respond to public health emergencies makes it a valuable asset in protecting the nation's health.

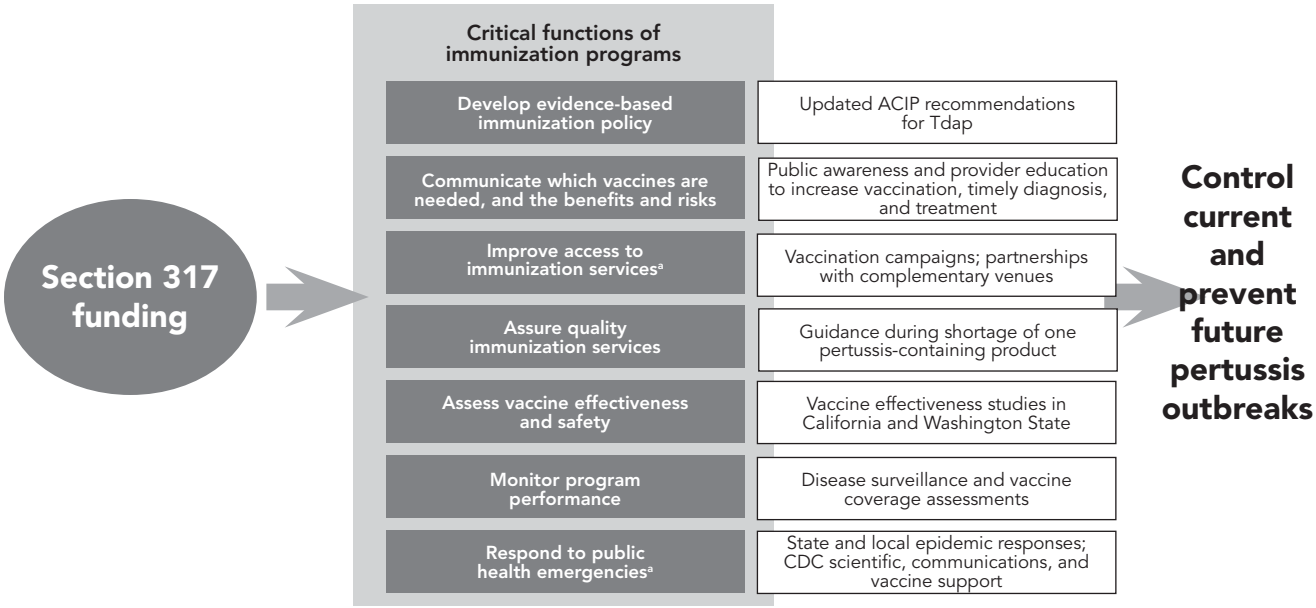
Communicating which vaccines are needed, and the benefits and risks

Messages about the pertussis outbreaks, the risks of serious complications and deaths among infants too young to be vaccinated, and tetanus-diphtheria-pertussis (Tdap) vaccine recommendations for adolescents and adults are delivered using a variety of technologies and venues. CDC made available science-based provider education and public awareness resources, including audio and video, social media, print materials, publications, and multimedia tools. In Washington State, the Department of Health focused its provider education efforts on diagnosing, treating, and preventing pertussis. Its public awareness efforts focused on the signs and symptoms of pertussis and vaccination recommendations, using multiple communication venues (e.g., messages on public transportation).

Improved access to immunization services

An important feature of the Section 317 Program is the flexibility in directing resources to meet priority needs, such as outbreak control, and to support public-private

Figure 5. Role of Section 317 Immunization Program funding in preventing infectious disease: pertussis case study, 2010–2012



[a]Section 317 funds can be used to purchase vaccine

ACIP = Advisory Committee on Immunization Practices

Tdap = tetanus-diphtheria-pertussis vaccine

CDC = Centers for Disease Control and Prevention

efforts to improve access to vaccination across the life span. During the 2010 pertussis epidemic in California, the Department of Public Health offered free Tdap vaccine to birthing hospitals and local health departments to vaccinate mothers and close contacts of newborns. In Washington State, targeted efforts substantially increased Tdap vaccination among adults, with a 140% increase in adult vaccination from March 25 to May 26, 2012, compared with the same time period in 2011, resulting in 82,453 vs. 34,171 doses administered in 2012 vs. 2011, respectively. Washington State was also able to use its Section 317 vaccine funding to allocate an additional 27,000 doses of Tdap vaccine to reach uninsured adults.

Developing an evidence-based immunization policy

Upon review of new data about the incidence of pertussis and the populations affected, the ACIP updated and expanded its recommendations for the use of Tdap vaccines among adolescents and adults to reduce the transmission of pertussis to infants.[37]

Assuring quality of immunization services

Vaccines need to be stored in the right equipment at the right temperature to ensure the most protection. The Section 317 Program supports efforts to help providers store, handle, and use vaccines for the best public health impact. For example, during an anticipated shortage of one pertussis-containing vaccine during the summer of 2012, CDC provided guidance on the use of the available pertussis-containing products to ensure their patients were fully vaccinated.[38]

Assessing vaccine effectiveness and safety

An effective outbreak response controls the outbreak and provides data and information to help prevent future outbreaks, including data and information that can lead to better and more effective vaccines and recommendations. CDC and Washington State are undertaking a number of efforts to evaluate strategies to prevent pertussis, including assessments of the effectiveness of maternal and caregiver vaccination in protecting infants, and the duration of protection provided by the vaccine given to adolescents. This information is valuable in informing and evaluating immunization recommendations.

Monitoring program performance

Vaccination coverage is monitored and reported through the NIS, the BRFSS, and the NHIS. This

information has been used to identify gaps in vaccination coverage to inform targeted pertussis vaccination campaigns and increase public awareness and provider education efforts. It is also contributing to pertussis vaccine effectiveness studies.

CHALLENGES

While expanded coverage provisions of the ACA provide unprecedented access to immunizations, they also have the potential to place greater stresses on the existing immunization infrastructure. Although the health insurance reforms of the ACA, when fully implemented, will improve access to clinical preventive services by improving payment for vaccines and their administration, the essential public health functions that make vaccination possible are not addressed by the ACA.

Some communities may not currently have enough in-network providers to assure access to immunization services across the life span that are now afforded through the health insurance reforms of the ACA. The role of public health in recruiting and training robust networks of in-network vaccine providers will be essential in realizing the potential of the ACA health insurance reforms. However, this training will require public health to forge new and expanded partnerships with employers, health insurance plans, and health-care providers.

The ACA also increases the visibility and role of the ACIP recommendations in determining health-care coverage policies, making it more important than ever that the ACIP has the capacity to make timely and transparent recommendations. The public health systems and workforce that monitor disease, vaccine effectiveness, and safety will become even more essential in the new and evolving health-care landscape to support the work of the ACIP.

Improved health information technologies give us the opportunity to increase vaccination coverage rates as well as promote efficiency and improve quality of care. However, this field is rapidly changing and evolving and spans multiple sectors of the health-care delivery system. It is critical that the public health investments in health information technologies be strategic, coordinated, and standardized to the greatest extent possible to achieve efficiencies and improve quality of care. Expertise has already been developed and is held in the immunization workforce as described previously, but the demands on this knowledge base will grow immensely and must be supported.

Finally, the evolving health-care landscape may call into question the continued relevance of the Section 317 Program to the immunization enterprise. This questioning would be a severe error in judgment. For nearly 50 years, the Section 317 Program has been directed toward filling gaps in the national immunization program through its authorities to provide operations funding to states; to support vaccine-related epidemiology, laboratory, program, and communications efforts; and to purchase vaccines for children, adolescents, and adults. For the past 20 years, the contribution of the Section 317 Program in providing vaccines to underinsured children who are not eligible for VFC Program vaccines has been the most visible aspect of the program, leaving the vital contributions of the Section 317 Program to immunization infrastructure and the workforce largely unknown among decision makers and the public. While the Section 317 Program will continue to be an important resource in providing a vaccine safety net for uninsured Americans[39] and a flexible resource for provision of vaccines when responding to disease outbreaks and urgent needs, it is the Section 317 systems and workforce described in this report that provide the backbone for the U.S. immunization program, regardless of the payer of the vaccine given. Educating decision makers and the public about the need for a strong immunization infrastructure may in fact be one of our greatest challenges and our greatest opportunities. If we fail, we risk the erosion of a sound and trusted immunization system that has contributed to historic improvements in public health. If we succeed, we have the potential to transition and strengthen our immunization infrastructure and performance to realize the full potential of vaccines across the life span for millions of Americans today and well into the future.

CONCLUSIONS AND RECOMMENDATIONS

Conclusion 1

Vaccination is one of our most important public health tools for directly protecting individuals from infectious diseases and indirectly protecting those who cannot be vaccinated, such as those with medical contraindications, those who are too young to be vaccinated, or those with compromised immune systems. This indirect effect, termed "herd or community immunity," is achieved when high vaccination coverage rates stop the transmission of disease from person to person, so that those remaining unvaccinated are protected from exposure to the infectious agent. Achieving high population coverage rates cannot be accomplished with vaccine alone.

The Section 317 Program supports the public health systems and workforce at the local, state, and national

levels that are essential to meeting national immunization goals for children, adolescents, and adults. Much more than a program that can purchase vaccines, the Section 317 Program has inherent flexibility that supports the critical immunization infrastructure to deliver vaccines into the arms of patients. Altogether, Section 317-funded resources are vital to achieving optimal levels of vaccination coverage. Vaccination acts as a firewall in the spread of disease, slowing and preventing the spread of disease to others, particularly to those who are unable to be vaccinated because they are too young, too old, or have compromised immune systems that prevent them from being vaccinated or for other reasons.

However, recent erosion of the Section 317 budget authority for core immunization activities and the use of other funding streams such as the PPHF to fill funding gaps pose a risk to the stability of the immunization workforce and systems at the national, state, and local levels. Although it is a valuable resource for filling public health needs, sources such as PPHF may be unstable or redirected based on other priorities.

Recommendation 1
The NVAC recommends that the Section 317 Program be sustained to assure a strong public health infrastructure necessary to achieve and sustain high vaccination coverage and low disease burden among the U.S. civilian population.

Conclusion 2
During the past years, appropriations for the Section 317 Program have not kept pace with the increasing demand. Estimates of the Section 317 funding necessary to assure a comprehensive immunization program at the state and national levels is a useful tool to fully inform policy and decision makers. Historically, the Section 317 report to Congress has been one important tool for updating the needs of the nation's immunization infrastructure at the local, state, and federal levels.

Recommendation 2a
CDC should present its professional judgment regarding the size and scope of the Section 317 Program necessary to support a comprehensive immunization program. This judgment should include program operations at the federal, state, tribal, and local levels, and vaccine purchase to provide a safety net and timely response to public health emergencies. CDC should present its professional judgment to the NVAC annually at its June meeting for deliberation and discussion.

Recommendation 2b
HHS should consider CDC's professional judgment for the Section 317 Program as an important input to its decision-making during the budget formulation process.

Conclusion 3
The highly decentralized and complex national immunization system is shaped by an increasing number of routinely recommended vaccines, changes in the health-care delivery system, and reductions in federal immunization resources at the national and state levels. The need to sustain high levels of immunization coverage under these circumstances requires adapting immunization programs to operate in ways that meet these new challenges and opportunities.

Recommendation 3
The NVAC recommends that federal, state, tribal, and local public health should seek efficiency and innovation to achieve Healthy People 2020 targets and ensure high immunization levels across all age spans. Examples of such efficiencies include, but are not limited to, improved vaccine ordering, supply management, storage, and handling, such as through the use of vaccine barcodes. Examples of innovation include, but are not limited to, implementation and use of IISs and EHRs; innovative communication strategies; providing vaccines as an in-network provider for the receipt of vaccine in public health clinics; and expanding vaccination sites, such as schools, workplaces, and pharmacies.

The NVAC supports current innovations in operations and encourages continued innovation. The NVAC recommends that HHS through the National Vaccine Program Office hold a public meeting of experts to examine and explore contributions toward efficiency and innovation at state and local health departments.

Some of the contributors are employees of the U.S. Department of Health and Human Services. Although they served as contributors on the basis of their areas of expertise, the views expressed in this article are those of the National Vaccine Advisory Committee. The positions expressed and the recommendations made in this article do not necessarily represent those of the U.S. government or of departmental employees who contributed.

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Section 317 Immunization Program: Protecting a National Asset

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The article, "Protecting the Public's Health: Critical Functions of the Section 317 Immunization Program—A Report of the National Vaccine Advisory Committee," describes the many critical components of the effective immunization infrastructure that Section 317 funding supports.[1] The federal Section 317 Immunization Program, which disseminates grants to 64 states, cities, and territories, provides core funding for the nation's immunization programs and services.[2] In addition to the purchase of vaccines, Section 317 funding provides resources for the public health capacity that supports outbreak investigation and control, supports providers through education about vaccines and information on storage and handling, and monitors vaccine effectiveness. The Association of State and Territorial Health Officials (ASTHO) agrees with the report's recommendation that the Section 317 Immunization Program should be sustained at adequate funding levels. Our national governmental public health enterprise—comprising federal, state, and local health agencies—must work together to maintain and strengthen the health and economic gains that result from a successful immunization program.

We cannot protect everyone from every disease, and although we have been very successful in protecting the U.S. population from vaccine-preventable diseases (VPDs), we need to remain vigilant and activated. A recent resurgence of pertussis demonstrates that these diseases do not go away and cannot be ignored.[3] In fact, there continues to be room for improvement in the immunity of the public we serve. The network in place to sustain this valuable protection is complex and multifaceted. When someone receives a shot, years of work have enabled the transaction to occur. There has been extensive research to develop the vaccine; years of testing to ensure safety; ongoing monitoring of the vaccine once it is made widely available to the public; and provider training to ensure proper storage, handling, and administration of the vaccine. The successful immunization program in the United States is a model for effective public and private-sector collaborations, and this partnership must be maintained going forward to keep the public protected from these debilitating and costly diseases.

As mentioned in the National Vaccine Advisory Committee (NVAC) report in this issue of *Public Health Reports*, the foundation of this collaboration is a

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strong public health infrastructure at federal, state, and local levels that includes a highly trained immunization workforce, disease surveillance experts and systems, scientific support for developing immunization policies, systems for monitoring and assuring vaccine safety, and mechanisms to monitor vaccine coverage rates.[1] Public health takes the lead role in ensuring that everyone has access to safe and effective vaccines. Immunization infrastructure is a foundational capacity that must be included in the minimum package of public health services provided to every community. A recent Institute of Medicine report, "For the Public's Health: Investing in a Healthier Future," recommends that the nation take steps to ensure that there is adequate funding and capacity for such foundational services that protect and improve the population's health.[4]

Thanks to our nation's public health system and resources made available through the Section 317 Program, childhood immunization coverage rates are high in most parts of the U.S. In 2010, coverage levels of at least 90% were met for five out of seven recommended childhood vaccines.[5] This high coverage rate has resulted in a more than 90% decline in once common VPDs, such as diphtheria, polio, and measles.[6] Although levels of adult vaccination are not as high, new recommendations and initiatives are designed to ensure that more adults are protected from preventable illness. However, we need to transition the Section 317 Program carefully to increase the rates of adult vaccinations. We wish to continue to improve upon our childhood vaccination rates as we take steps to improve adult vaccination. A balanced approach is necessary to make certain the safety net that is the Section 317 Immunization Program remains intact.

In addition to their positive impact on health, vaccines are one of the most cost-effective public health approaches to reducing health-care costs because they prevent disease before it occurs and spreads through our communities. For each birth cohort vaccinated against 13 diseases in accordance with the recommended immunization schedule, society saves $13.6 billion in direct health-care costs, 42,000 lives are saved, and 20 million cases of disease are prevented.[7] However, to realize the savings in lives and costs, we need to continue investments in the nation's immunization program.

ASTHO has followed the trend of shrinking state budgets since 2008, when we initiated a longitudinal study to investigate the impact of budget cuts on state and territorial public health agencies and the people they serve. Since July 2008, 87% of reporting state health agencies have experienced budget cuts, which impact their ability to respond to public health threats, and 31% have experienced cuts that directly impact their immunization programs. The ASTHO Budget Cuts Surveys' findings show that state health agencies continue to experience budget cuts and job losses, resulting in the reduction or elimination of critical public health programs and services.[8]

The effect of such budget cuts has been seen in Washington State, which recently experienced an epidemic of pertussis (also known as whooping cough). Washington State and its local health departments have addressed this epidemic through health-care provider education, public awareness efforts, a substantial increase in providing vaccinations (a 140% increase for adults), and increases in laboratory testing and case investigations.[9] Health departments have struggled to find the staff capacity and resources to provide the increased level of services needed to fully address the cases, the highest number in decades, and maintain all the other day-to-day activities necessary to protect the public's health. *The New York Times* reported that the "response to the epidemic has been hampered by the recession [and] years of sustained budget cuts."[10] Due to the need to limit efforts, there are missed opportunities for collecting rich epidemiologic data that may inform better responses in the future or provide evidence for changed vaccine recommendations. As more states across the country experience increased levels of VPDs, budget constraints may prevent public health from providing appropriate responses to control the surge of cases or address other health emergencies that arise concurrently.

In a time of expanding health insurance coverage, it is important to remember that insurance coverage does not ensure access, and access does not assure quality of care. Successful immunization requires much more behind-the-scenes work than providers purchasing and administering vaccines. There are fundamental activities conducted by public health professionals that are critical to the future of the nation's immunization efforts even if the population is fully insured. Section 317 infrastructure funds are used to ensure that vaccines are accessible, safe, and effective. State and local health agencies conduct activities such as disease surveillance, and offer provider support, quality assurance, communications, outreach, and outbreak response. Furthermore, in some locations, public health agencies are essential community providers, as sufficient private capacity to vaccinate the population does not currently exist. Careful planning and investment must take place either to create a capacity for public health agencies to generate sufficient insurance revenue to support providing immunizations, or to transition direct immunization services to private providers. Measurement

and monitoring of vaccination rates must take place during this time to avoid unintended consequences, such as children being turned away from schools or increased VPDs.

The entire public health enterprise—at the federal, state, and local levels—is involved in the response to outbreaks of VPDs, but much of the on-the-ground burden affects the local and state levels. For example, after an outbreak of measles affiliated with the 2012 Super Bowl, state health officials provided near-daily updates on the number of cases and places visited by those infected to stop the disease's spread.[11] When three cases of meningococcal disease were diagnosed in a small town in Oregon, the state and county health agencies coordinated community vaccinations, immunizing more than 1,000 people.[12] These jurisdictions can be heavily impacted by even a relatively small decrease in funding, especially as public health activities become increasingly integrated.

With lives and health at stake, we cannot afford to slip back on the progress we have made. Continued investment in immunization infrastructure will ensure that gains made by the introduction and continued use of vaccines will not be lost. The Centers for Disease Control and Prevention is providing transition funding in select program areas to a limited number of grantees, in part through the Prevention and Public Health Fund, to build capacity and strengthen the public health immunization infrastructure to be more effective in the changing health-care delivery environment.[13] Funded activities will include enhancing immunization information systems, developing and implementing strategic plans for revenue generation in health department clinics, and supporting adult and school-located vaccination. Although this transition funding will help public health, sufficient and sustained funding is necessary to realize the full benefits that vaccines can provide.

The U.S. vaccine program has had a demonstrated impact on improving the population's health. It is imperative that the infrastructure that supports the nation's immunization program remains intact. The NVAC report in this issue articulates the significant role of public health infrastructure in the U.S. immunization program and the critical need to support Section 317 funding for these programs.

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Area-Level Socioeconomic Disadvantage and Severe Pulmonary Tuberculosis: U.S., 2000–2008

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ABSTRACT

Objectives. Lower socioeconomic status (SES) is associated with increased risk of tuberculosis (TB) and diagnostic delays, but the extent to which this association reflects an underlying gradient in advanced status of pulmonary TB is unknown. We conducted a multilevel retrospective cohort analysis examining the relationship between socioeconomic characteristics and pulmonary TB disease status, as measured via sputum smears and chest radiography results.

Methods. We included 862 incident TB patients reported in King County, Washington, from 2000–2008. We abstracted patient-level measures from charts and surveillance data. We obtained socioeconomic characteristics of TB patients, as well as those of the areas where TB patients lived, from the 2000 U.S. Census. A socioeconomic position (SEP) index was derived to measure SES.

Results. Of those with known results, 814 of 849 patients (96%) displayed abnormal radiography findings. A total of 239 graded patients (39%) had positive smears, 136 (57%) of whom had grades of moderate (3+) or numerous (4+) acid-fast bacilli. In unadjusted analyses, patients living in lower SEP areas did not appear to have higher probabilities of more advanced disease. In multivariate models adjusting for individual demographic and socioeconomic measures, as well as area-based demographic variables, block-group SEP was not significantly associated with more advanced pulmonary disease.

Conclusions. Lower SEP was not significantly associated with greater pulmonary disease severity after controlling for individual age, race, sex, and origin, and block-group race, ethnicity, and origin. These findings suggest that the severity of pulmonary TB at diagnosis is not synonymous with delayed diagnosis.

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Although tuberculosis (TB) incidence continues to decline in the United States, the proportion of advanced pulmonary TB, defined as smear-positive or cavitary disease, has been increasing.[1,2] Advanced clinical presentation may result from delayed diagnosis and treatment and may lead to greater infectivity and likelihood of transmission within a community.[3,4]

Lower socioeconomic status (SES) has been linked to more severe disease status for a variety of diseases including cystic fibrosis,[5] sarcoidosis,[6] subclinical coronary heart disease,[7] cancers,[8,9] and pulmonary fibrosis.[10] While the presence of other comorbidities, poor access to care, substance abuse, low income, education level, and lack of insurance[11–16] constitute risk factors for delays in TB diagnosis, little work has been done to characterize the association between SES and advanced pulmonary TB disease, as more advanced disease is often seen as characteristic of diagnostic delay. Furthermore, much of the work examining diagnostic delay has been examined outside the U.S. Areas in which people live are likely to have differential access to care, including proximity, cost, and presence of public clinics and transportation.[17,18] Disease status is likely to be impacted by such variations in area-level factors and, in particular, by variations in area-level SES across neighborhoods.

Using TB case registry data on incident TB patients combined with chart reviews, we explored the relationship between individual patient demographic and SES attributes, in combination with area-level social characteristics, and two TB severity outcomes at diagnosis—lung cavitation and smear-positive acid-fast bacilli (AFB) in sputum smears. These measures have been linked to impaired pulmonary function, TB treatment failure, or death[19,20] and represent later disease stages.[21,22]

Specifically, this study was designed to assess whether severity of pulmonary TB disease was positively associated with area-based socioeconomic disadvantage within King County, Washington. By examining socioeconomic and demographic characteristics of block groups, our hope was to identify those factors that might play an important role in predicting disease severity at diagnosis. Such findings could provide insight into pathways by which area-level SES independently affects pulmonary disease severity.

METHODS

Study population and setting

A total of 862 incident pulmonary TB patients were reported in King County from January 1, 2000, to December 31, 2008. Criteria for diagnosis of pulmonary TB patients met either Centers for Disease Control and Prevention (CDC) laboratory criteria for a sputum culture positive diagnosis or the clinical case definition, which includes either an abnormal chest radiograph or other signs and symptoms compatible with TB.[23] Individuals had either exclusively pulmonary disease or pulmonary involvement. Due to considerations regarding age of research consent, all models excluded minors (<18 years of age). Included patients represented 380 block groups within King County. A census block group was defined as a cluster of census blocks having the same first digit of their four-digit identifying numbers within a census tract.[24] Block groups have previously been validated as an informative spatial scale at which to report socioeconomic data.[25]

Study design

The analysis used a retrospective cohort design, merging reporting and chart data for TB patients and U.S. block-group-level census data for residents of King County.

Data sources

Measurement of socioeconomic position. A socioeconomic position (SEP) index was constructed combining data on six singular SES measures: percentage of the population who were working class, were unemployed, were living in poverty, had less than a high school education, and owned expensive homes, as well as median household income. To construct the score, we gave each variable a standardized z-score, which was the sum of all block-group values with SEP data (n=1,576), minus the mean sum, divided by the standard deviation, and then summed the individual z-scores. Variables included for each block group were taken from the 2000 U.S. Census Summary Tape File-3 and were consistent with a previously validated composite measure used in the Public Health Disparities Geocoding Project. The Geocoding Project developed this measure based on a factor analysis of 11 individual SES factors using rank values of the Census data.[25] The SEP index was modeled as a four-level categorical variable, using quartiles in the block-group distribution as cutoffs, with the highest quartiles representing the wealthiest block groups.

Measurement of disease severity. We chose two available characteristics of advanced pulmonary TB at diagnosis from 2000–2008: grade of sputum smear and chest radiographic abnormalities. Sputum smears were quantified using fluorochrome stains and categorized using sputum smear grades in an ordinal fashion as negative (no AFB seen), 1+ (rare), 2+ (few), 3+ (moderate),

and 4+ (numerous), depending on AFB load. Smears were also dichotomized as positive or negative. Standard posterior-anterior chest radiographs were categorized ordinally as normal, abnormal non-cavitary, or cavitary in the patient medical chart by the Public Health–Seattle & King County TB Control Program medical director, with patients with normal radiographs serving as the referent category. Radiographs were also separately categorized as to whether there was unilateral or bilateral pulmonary involvement. Both radiography and smear results were obtained from the Tuberculosis Information Management System (TIMS)[26] and supplemented with available data from patient medical charts with quantitative smear grade. Smear grade was obtained for the 76% of patients with complete medical records.

Anthropometric and psychosocial individual measures. The following individual measures from the National Tuberculosis Surveillance System[23] were used: race, sex, age, ethnicity, foreign birth, homelessness, human immunodeficiency virus (HIV) status, and provider type. In addition, an experienced nurse measured height and weight to compute body mass index (BMI). Participants reported on standardized clinic forms whether or not they were in paid employment at diagnosis, as well as their occupation, insurance, smoking status, and alcohol intake history. Patient-level variables were subsequently aggregated by block group.

Other area-level measures. We derived area-based covariates from the U.S. Population Census 2000, SF1 and SF3.[27,28] We modeled the proportion of each block group that was black, Asian, Hispanic, and foreign-born using quartiles of each population in each block group, with the quartile directly below serving as the referent group.

Statistical analysis and modeling

We excluded observations from univariate analyses when the percentage unknown or missing was <2%. We examined unadjusted proportions of individuals in each SEP index quartile and stratified them by both quantitative smear grade and radiography results, with percentages adding up to 100 across SEP index quartiles. We also examined the relationship between TB sputum smear grade and radiology results using Pearson's Chi-square test.

To examine area-level influences in addition to individual attributes as they relate to variation in severity of disease, we used multilevel logistic regression models.[29] These classes of models allowed for analysis of the ordered outcomes and accommodated the hierarchical data structure.

After building multilevel models of significant fixed effects, other parameters were added, allowing for baseline variation in disease severity across block groups. For ordinal models, the forms used were similar, but used an ordered logit model allowing for three responses for radiography outcomes (normal, abnormal non-cavitary, and abnormal cavitary) and five responses for smear grade (negative, 1+, 2+, 3+, and 4+).

For each outcome, we tested four nested models. Model 1 tested area-based socioeconomic quartiles and the association with dependent variables. Model 2 included individual demographic factors (mean-centered age modeled continuously and as a quadratic term, race modeled using dummy variables, sex modeled as a binary term, and foreign birth as a binary term) as covariates. Individual-level SES factors were additionally included (homelessness as a binary term and provider type as a dummy variable) in Model 3. Area-level factors (ethnicity, foreign birth, and race) were added in Model 4 to assess the contextual effects of Asian and black race, Hispanic ethnicity, and foreign birth while controlling for individual confounders and area-level SEP. We used complete case analysis such that the number of patients with missing covariates excluded from each model was the same. We performed multilevel model building and estimation using the Generalized Linear Latent and Mixed Models extension of Stata® version 10.0.[30]

RESULTS

Description of TB patients

Table 1 portrays overall and analysis-specific patient population characteristics. A total of 862 TB patients were included in the initial analysis, with 65% being male and a median age at diagnosis of 44 years. TB patients were primarily Asian (40%), black (24%), or white (26%). More than 70% of the patient population was foreign-born. TB risk factors included homelessness (20%), unemployment prior to diagnosis (36%), HIV infection (9% of known results), and smoking (28% of known results). Patients were included in subsequent analyses if a sputum specimen (n=806) and/or chest radiograph result (n=849) was available. A total of 616 patients were included in a subgroup for quantitative smear-grade analysis, excluding patients for whom smear grades were unknown (n=246). The flow chart shows the patient inclusion process for each severity measure (Figure 1).

Table 1. Characteristics of TB patients reported in King County, Washington: 2000–2008

Characteristic	Population N (percent)[a]	Smear status: Positive N (percent)[a]	Smear status: Negative N (percent)[a]	Chest radiography degree: Normal N (percent)[a]	Chest radiography degree: Abnormal N (percent)[a]	Chest radiography degree: Cavitary N (percent)[a]
Total (*N*)	862	416	390	35	579	235
Sex: male	556 (64.5)	289 (69.5)	237 (60.8)	19 (54.3)	363 (62.7)	168 (71.5)
Age (in years): mean (SD)	44.2 (20.5)	43.4 (19.0)	45.5 (20.3)	39.7 (14.9)	45.8 (21.6)	40.7 (17.8)
Age categories (in years)						
0–4	18 (2.1)	0 (0.0)	3 (0.8)	1 (2.9)	16 (2.8)	1 (0.4)
5–14	14 (1.6)	3 (0.7)	8 (2.1)	0 (0.0)	12 (2.1)	2 (0.9)
15–24	132 (15.3)	76 (18.3)	55 (14.1)	4 (11.4)	78 (13.5)	49 (20.9)
25–44	297 (34.5)	153 (36.8)	137 (35.1)	20 (57.1)	183 (31.6)	90 (38.3)
45–64	236 (27.4)	119 (28.6)	106 (27.2)	9 (25.7)	157 (27.1)	68 (28.9)
≥65	161 (18.7)	65 (15.6)	81 (20.8)	1 (2.9)	133 (23.0)	25 (10.6)
Race						
American Indian	49 (5.7)	31 (7.5)	18 (4.6)	4 (11.4)	36 (6.2)	8 (3.4)
Asian	353 (40.1)	151 (36.3)	175 (44.9)	8 (22.9)	247 (42.7)	95 (40.4)
Black	205 (23.8)	104 (25.0)	94 (24.1)	12 (34.3)	130 (22.5)	59 (25.1)
Native Hawaiian	19 (2.2)	9 (2.2)	9 (2.3)	1 (2.9)	13 (2.3)	5 (2.1)
White	224 (26.0)	115 (27.6)	92 (23.6)	20 (28.6)	148 (25.6)	65 (27.7)
Multiple races	2 (0.2)	1 (0.2)	1 (0.3)	0 (0.0)	2 (0.4)	0 (0.0)
Ethnicity						
Hispanic[b]	96 (11.1)	60 (14.4)	31 (8.0)	6 (17.1)	53 (9.2)	36 (15.3)
Country of origin						
U.S.-born	250 (29.0)	118 (28.4)	102 (26.2)	15 (42.9)	165 (28.5)	63 (26.8)
Foreign-born[c]	610 (70.8)	297 (71.4)	287 (73.6)	20 (57.1)	413 (71.3)	171 (72.8)
Time from U.S. arrival to TB diagnosis (in years)[d]						
0–4	235 (38.5)	110 (37.0)	121 (42.2)	8 (40.0)	165 (39.7)	60 (35.1)
5–9	91 (14.9)	54 (18.2)	36 (12.5)	2 (10.0)	54 (13.1)	35 (20.5)
10–19	135 (22.1)	62 (20.9)	65 (22.7)	3 (15.0)	96 (23.2)	35 (20.5)
≥20	101 (16.6)	53 (17.9)	42 (14.6)	5 (25.0)	66 (16.0)	30 (17.5)
Missing	48 (7.9)	18 (3.1)	23 (8.0)	2 (10.0)	33 (8.0)	11 (6.4)
HIV status						
Negative	634 (73.9)	319 (76.7)	293 (75.1)	23 (65.7)	405 (70.0)	201 (85.5)
Positive	62 (7.2)	34 (8.2)	26 (6.7)	9 (25.7)	44 (7.6)	7 (3.0)
Unknown/missing[e]	162 (18.9)	62 (15.1)	71 (18.2)	3 (8.6)	130 (22.4)	27 (11.5)
Homeless within past year						
No	688 (79.8)	310 (74.5)	327 (83.9)	19 (54.3)	479 (82.7)	182 (77.5)
Yes	169 (19.6)	106 (25.5)	62 (15.9)	15 (45.7)	99 (17.2)	53 (22.6)
Insurance						
No	277 (32.1)	144 (34.4)	198 (33.5)	13 (37.1)	195 (33.7)	65 (27.7)
Yes	144 (16.7)	77 (18.4)	105 (17.7)	2 (5.7)	90 (15.5)	51 (21.7)
Missing	441 (51.2)	198 (47.3)	289 (48.8)	20 (57.1)	294 (50.8)	119 (50.6)
Unemployed within past 24 months						
Yes	314 (36.4)	145 (34.9)	144 (36.9)	15 (42.9)	227 (39.2)	70 (29.8)
No	548 (63.6)	271 (65.1)	246 (63.1)	20 (57.1)	352 (60.8)	165 (70.2)
Injecting drug use within past year						
No	806 (93.5)	384 (92.3)	374 (95.9)	30 (85.7)	547 (94.5)	220 (93.6)
Yes	26 (3.0)	17 (4.1)	8 (2.1)	3 (8.6)	17 (2.9)	6 (2.6)
Missing	30 (3.5)	15 (3.6)	8 (1.0)	2 (5.7)	2 (2.6)	9 (3.8)
Non-injecting drug use within past year						
No	757 (93.5)	353 (84.9)	357 (91.5)	26 (74.3)	524 (90.5)	199 (84.7)
Yes	70 (8.1)	45 (10.8)	23 (5.9)	7 (20.0)	38 (6.6)	24 (10.2)
Missing	35 (4.1)	18 (4.3)	10 (2.6)	2 (5.7)	17 (2.9)	12 (5.1)
Excess alcohol use within past year[f]						
No	704 (81.7)	314 (75.5)	343 (88.0)	25 (71.4)	490 (84.6)	181 (77.0)
Yes	131 (15.2)	87 (20.9)	43 (11.0)	7 (20.0)	79 (13.6)	45 (19.2)
Missing	27 (3.2)	15 (3.6)	4 (1.0)	3 (8.6)	10 (1.7)	9 (3.8)

continued on p. 103

Table 1 (continued). Characteristics of TB patients reported in King County, Washington: 2000–2008

Characteristic	Population N (percent)[a]	Smear status: Positive N (percent)[a]	Smear status: Negative N (percent)[a]	Chest radiography degree: Normal N (percent)[a]	Chest radiography degree: Abnormal N (percent)[a]	Chest radiography degree: Cavitary N (percent)[a]
Smoking history						
No	348 (40.4)	177 (42.2)	273 (46.1)	12 (34.3)	245 (42.3)	86 (36.6)
Yes	135 (15.7)	75 (17.9)	74 (12.5)	5 (14.3)	84 (14.5)	46 (19.6)
Missing	379 (44.0)	167 (39.9)	245 (41.4)	18 (51.4)	250 (43.2)	103 (43.8)
Chest radiographic result						
Normal	35 (4.1)	7 (1.7)	22 (5.6)	NA	NA	NA
Abnormal, non-cavitary	579 (66.0)	211 (50.7)	330 (84.6)	NA	NA	NA
Abnormal, cavitary	235 (27.3)	193 (46.4)	36 (9.2)	NA	NA	NA
Not done	3 (0.4)	1 (0.2)	1 (0.3)	NA	NA	NA
Bilateral lung involvement						
No	288 (33.4)	134 (32.0)	254 (42.9)	16 (45.7)	209 (36.1)	60 (25.5)
Yes	183 (21.2)	114 (27.2)	85 (14.4)	1 (2.9)	108 (18.7)	72 (30.6)
Unknown	391 (45.4)	171 (40.8)	253 (42.7)	18 (51.4)	262 (45.3)	103 (43.8)
Sputum smear result[g]						
Positive	416 (48.2)	NA	NA	7 (20.0)	211 (36.4)	193 (82.1)
Negative	390 (45.2)	NA	NA	22 (62.9)	330 (57.0)	36 (15.3)
Not done	48 (5.6)	NA	NA	4 (11.4)	37 (6.4)	5 (2.1)
Provider type						
Health department	686 (79.6)	338 (81.3)	313 (80.3)	27 (77.1)	454 (78.8)	198 (80.6)
Private provider	65 (7.5)	26 (6.3)	29 (7.4)	2 (5.7)	52 (4.7)	11 (7.7)
Both	101 (11.7)	49 (11.8)	45 (11.5)	6 (17.1)	70 (9.2)	23 (11.7)

[a]Percentages may not total 100 due to rounding and exclusion of unknown when <2%.

[b]People of Hispanic ethnicity may be of any race or multiple races.

[c]Foreign-born includes people born outside the U.S., American Samoa, the Federated States of Micronesia, Guam, the Republic of the Marshall Islands, Midway Island, the Commonwealth of the Northern Mariana Islands, Puerto Rico, the Republic of Palau, the U.S. Virgin Islands, and U.S. minor and outlying Pacific islands.

[d]Among foreign-born patients

[e]Unknown or missing includes indeterminate, refused, not offered, test done but unknown, and unknown.

[f]Excess alcohol use is ≥5 drinks on same occasion on each of ≥5 days in past 30 days.

[g]From the National Tuberculosis Surveillance System; smears not done/unknown account for 56 (6%) of total smear results.

TB = tuberculosis

SD = standard deviation

HIV = human immunodeficiency virus

NA = not available

Block-group characteristics

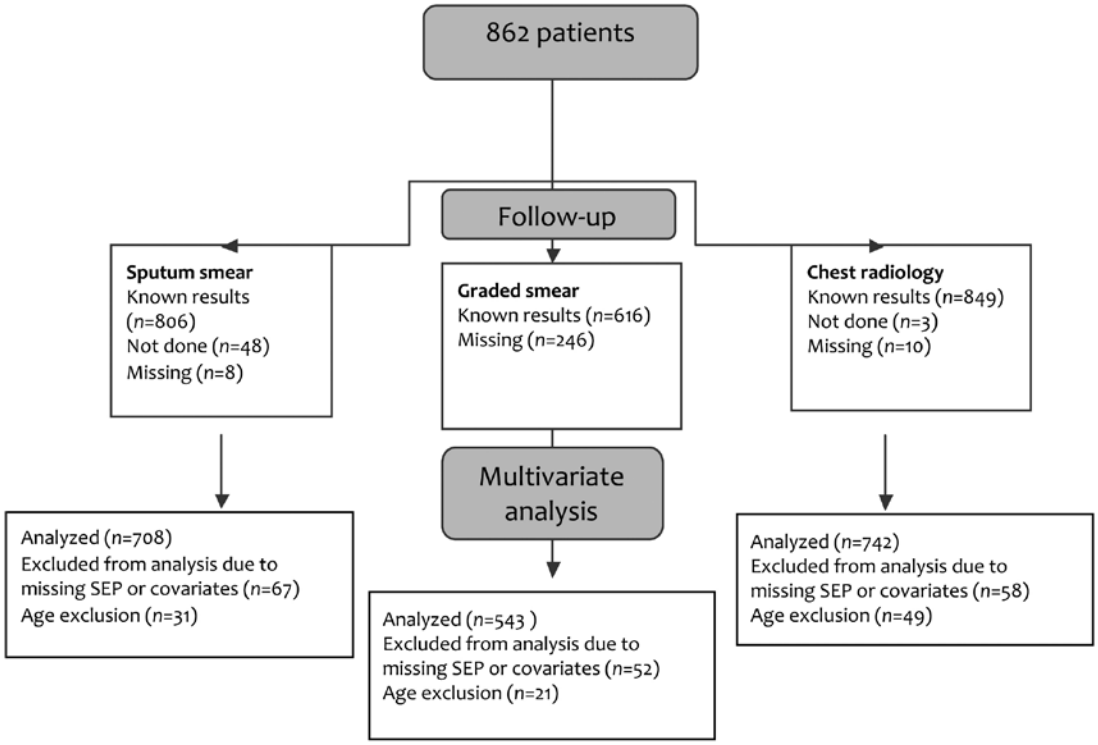
The 380 block groups included in the analysis were more likely to contain individuals reporting black or Asian descent as well as Hispanic ethnicity compared with median values in King County. Additionally, the median proportion of foreign-born individuals in these block groups was more than 1.5 times as high as the King County median (Table 2).

Disease severity findings

Of those with known results, 96% (814/849) of patients displayed abnormal radiography findings, with approximately one-third (33%) exhibiting extensive bilateral lung involvement. For the quantitative smear-grade outcome analysis, 39% (239/616) of graded patients had positive smears, of whom 57% had grades of moderate (3+) or numerous (4+) AFB. Higher grades of smear and cavitary radiographs were positively correlated, where greater proportions of cavitary x-rays were observed with progressively higher smear grade ($p<0.001$). Bilateral lung disease was significantly associated with both higher sputum smear grade ($p<0.001$) and cavitary disease ($p<0.001$) (data not shown).

Eighty-one percent of TB patients resided in block groups in the lowest two SEP index quartiles. In unadjusted analyses, patients living in areas with higher levels of deprivation did not have statistically higher probabilities of severe radiographs or higher smear grade (Figures 2 and 3).

Figure 1. Flow diagram detailing inclusion criteria in an analysis of socioeconomic disadvantage and pulmonary tuberculosis severity: King County, Washington, 2000–2008



SEP = socioeconomic position

Table 2. Characteristics of 380 block groups included in an analysis of socioeconomic disadvantage and pulmonary tuberculosis severity in King County, Washington, based on 2000 U.S. Census data

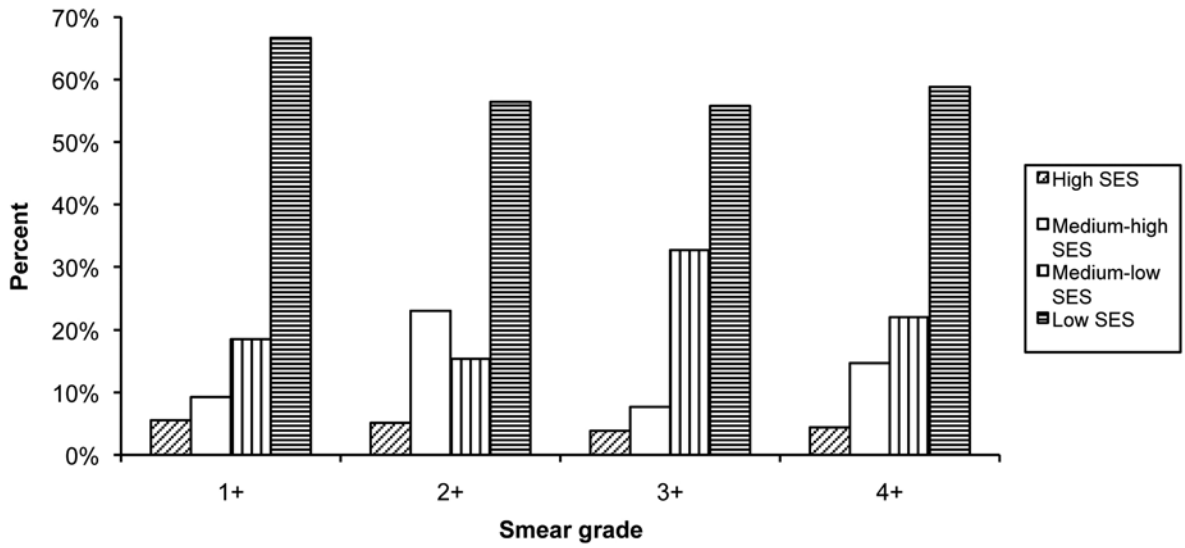
Variable	*Median*	*Mean*	*SD*	*Range*	*King County median*[a]
Demographics					
Population size (*N*)	1,130	1,211	545	246–4,721	1,011
Race					
Non-Hispanic white (percent)	69.1	63.3	22.7	3.1–97.5	79.7
Non-Hispanic Asian (percent)	11.3	14.9	14.0	0.0–73.2	7.1
Non-Hispanic black (percent)	4.7	8.5	10.6	0.0–56.3	1.8
Hispanic ethnicity (percent)	4.9	7.2	7.1	0.0–44.4	3.5
Foreign-born (percent)[b]	17.4	20.2	12.8	0.0–62.4	11.7
Socioeconomics					
<High school education (percent)	8.7	12.2	10.7	0.0–59.7	6.9
Unemployment (percent)	2.9	3.5	3.1	0.0–26.4	2.6
Median household income (in U.S. dollars)	$50,357	$52,741	$21,545	$7,382–$146,129	$56,691
Poverty (percent)	7.5	10.5	10.2	0.0–62.7	5.5
Working class (percent)	56.1	55.5	13.8	14.0–85.4	51.1
Home ownership (percent)	65.1	61.2	27.0	0.0–100.0	73.5
Tuberculosis measures					
Mean patients per block group (per year)	0.1	0.2	0.3	0.1–3.9	0.0
Incidence rate per block group (per 100,000 person-years)	14.4	22.1	29.8	3.5–334.4	0.0

[a]King County median reflects all block groups with socioeconomic status variables available (*n*=1,576).

[b]Excluding U.S. territories and those born abroad to U.S. parents

SD = standard deviation

Figure 2. Proportion of tuberculosis patients in quartiles of block-group SES, by sputum smear grade: King County, Washington, 2000–2008[a]



[a]Excludes smear grades that were not done or unknown, as well as missing SES

SES = socioeconomic status

Multivariate analyses

Chest radiograph model. In unadjusted analyses, the baseline model indicated that individuals living in lower SEP index neighborhoods did not have more severe x-ray presentation, with the odds ratio (OR) of more severe disease not significantly increased in the lowest as compared with the highest quartile (OR=0.95, 95% confidence interval [CI] 0.53, 1.70; p=0.935) (Table 3, Model 1). In addition, in individual-level multivariate models (Table 3, Models 2 and 3), inclusion of demographic and SES covariates did not significantly alter the association between SEP index quartile and disease severity, although foreign birth decreased and white race increased the odds for more severe presentation. Inclusion of individual insurance status and behavioral risk factors (i.e., drug and alcohol use, smoking, and BMI) on smaller available samples did not change the observed association (data not shown). In multivariate analyses restricted to non-HIV-infected individuals, no significant changes were observed in SEP effect estimates on severity.

Comparison of coefficients from Models 3 and 4 did not show substantial change in the SEP-TB association when other area-level influences were added (Table 3, Model 4). There was modest change in the strength of the effect, but direction and magnitude of the associations were consistent across the two models. Of four area-level variables examined at the block-group level in addition to SEP index, none remained statistically significant in the multilevel model (Table 3, Model 4). Area-level variables explained little between-block group variance, such that only 9% of variance in severity was attributable to the block group.

Sputum smear models. As with the radiograph findings, lower SES quartiles were not associated with higher smear grade with any of the models run. In models examining binary positive/negative smear outcomes, a positive smear was not significantly associated with SEP quartile, and this lack of a relationship remained after controlling for demographic, individual SES, and area-based demographic factors. Homelessness was linked to higher odds of positive sputum smears but did not change the observed SEP-smear estimates. The relative contribution of each of the individual-level main effects was similar in both sputum smear models, suggesting that area-level factors did not diminish the effect of individual-level influences. None of the between-block group variance in the probability of having a positive smear result was accounted for by block-group SEP. However, when individual-level age, race, sex, and origin were added in Model 2, the variance increased fivefold, indicating that heterogeneity in disease severity across block groups was partially accounted for by underlying demographic characteristics.

DISCUSSION

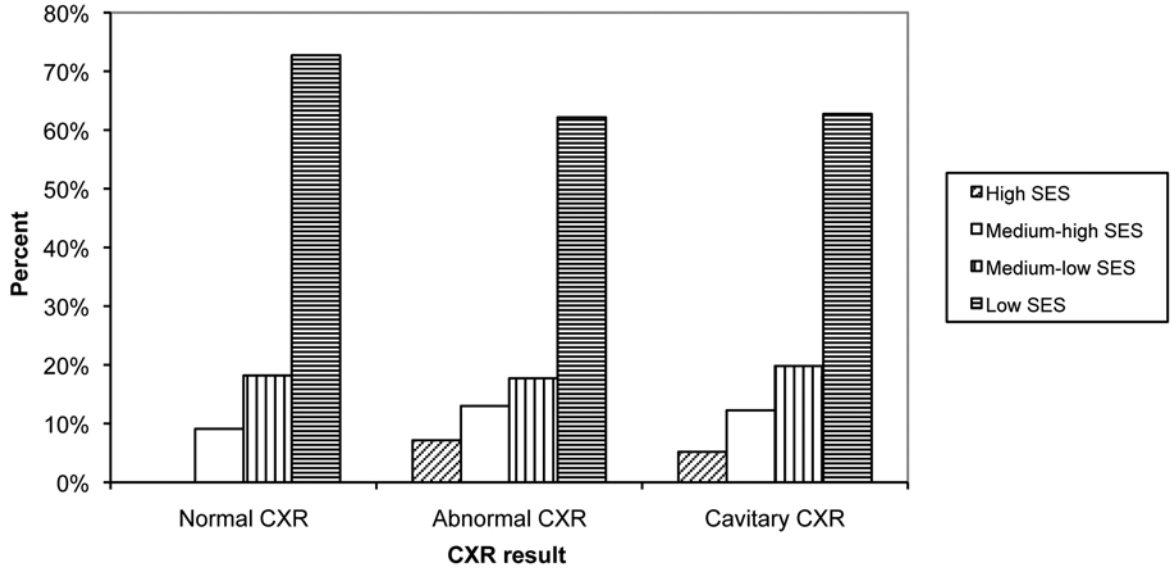
The results of this research, indicating that residing in areas with high levels of poverty is not significantly associated with more severe pulmonary disease at diagnosis, are noteworthy and not consistent with previous studies examining other diseases.[9,31] These findings remained after attempting to control for important individual-level risk factors and area-level measures and were consistent across three measures of severity.

Previous studies of SES and delayed TB diagnoses found that low income and poverty constitute risk factors for delays.[12–14,32] Low education level has previously been described as a risk factor for delays,[15] as have large family size,[33] unemployment,[34] and lack of health insurance.[18] However, no studies have previously documented the direct association between area-based SES and TB disease severity in a multilevel model, perhaps because severity is often seen as representative of diagnostic delays, with longer time to diagnosis thought to lead to increased infectiousness as patients progress to higher bacillary load on sputum smears and cavitary disease.[3,35]

Previous reports have hypothesized that individuals living in poorer SES areas present with later-stage disease because of decreased access to medical care and screening awareness.[10,36] Yet, possible explanatory pathways for these effects are complex. A previous study found that lack of employment and knowledge about where to obtain care were closely associated with clinically significant delay, raising concerns about the equity of access to care among TB patients.[34] More equitable access to care may occur when the need for care or severity of illness predicts utilization better than potential access barriers (e.g., appointment waiting time).[37] If access to care were distributed evenly, we would expect that TB patients with more severe illness would be more likely to promptly seek medical care. But others note that perceived access barriers appeared to explain more of the delay than did illness severity, suggesting that subgroups of the TB population were facing inequitable barriers to care.[34] As such, we might expect that more severe disease would be impacted by area-level access factors influencing delays.

However, while "where you live" may play an important role in disease incidence and transmission, it may be a less important factor in defining the risk of presenting with more severe disease. This finding may be because individual SES factors are often thought to be more closely linked to access or usage of health care, including longer wait times and fewer referrals.[38–40] Effects of individual SES may be more pronounced, such that more comprehensive health insurance, greater health knowledge, and motivation

Figure 3. Proportion of tuberculosis patients in quartiles of block-group SES, by chest radiography result: King County, Washington, 2000–2008[a]



[a]Excludes chest radiographs that were not done or unknown, as well as missing SES

SES = socioeconomic status

CXR = chest radiography

Table 3. Relative odds of being diagnosed with more advanced tuberculosis according to individual and area-level characteristics: King County, Washington, 2000–2008

Variable	*Model 1 OR (95% CI)*	*Model 2 AOR[a] (95% CI)*	*Model 3 AOR[b] (95% CI)*	*Model 4 AOR[c] (95% CI)*
Chest radiography				
Highest SEP	Ref.	Ref.	Ref.	Ref.
Medium-high SEP	0.80 (0.40, 1.59)	0.83 (0.41, 1.67)	0.85 (0.42, 1.71)	0.84 (0.40, 1.73)
Medium-low SEP	1.21 (0.63, 2.30)	1.18 (0.62, 2.25)	1.22 (0.64, 2.34)	1.18 (0.59, 2.36)
Lowest SEP	0.95 (0.53, 1.70)	0.88 (0.49, 1.58)	0.91 (0.50, 1.65)	0.88 (0.43, 1.80)
P-value	0.935	0.680	0.764	0.863
Sputum smear grade				
Highest SEP	Ref.	Ref.	Ref.	Ref.
Medium-high SEP	1.19 (0.69, 2.06)	1.18 (0.68, 2.06)	1.19 (0.68, 2.07)	1.16 (0.66, 2.06)
Medium-low SEP	1.09 (0.62, 1.89)	1.03 (0.59, 1.81)	1.04 (0.59, 1.82)	1.01 (0.54, 1.89)
Lowest SEP	1.06 (0.65, 1.73)	0.99 (0.60, 1.64)	0.95 (0.57, 1.59)	0.93 (0.49, 1.79)
P-value	0.986	0.733	0.611	0.672
Binary sputum smear				
Highest SEP	Ref.	Ref.	Ref.	Ref.
Medium-high SEP	1.45 (0.80, 2.64)	1.42 (0.78, 2.59)	1.49 (0.82, 2.70)	1.48 (0.80, 2.73)
Medium-low SEP	1.44 (0.82, 2.50)	1.40 (0.80, 2.45)	1.41 (0.81, 2.46)	1.33 (0.73, 2.43)
Lowest SEP	1.54 (0.92, 2.63)	1.47 (0.85, 2.53)	1.38 (0.81, 2.37)	1.25 (0.65, 2.43)
P-value	0.246	0.413	0.474	0.880

[a]Model 2 adjusted for age, sex, race, and foreign birth.

[b]Model 3 adjusted for age, sex, race, foreign birth, homelessness, and provider type.

[c]Model 4 adjusted for age, sex, race, foreign birth, homelessness, provider type, area-level race, and ethnicity.

OR = odds ratio

AOR = adjusted odds ratio

SEP = socioeconomic position

Ref. = reference group

to seek care play important roles in predicting severity. Indeed, greater proportions of uninsured and unemployed people were observed in lower SEP quartile block groups in our study, and these variables were significantly associated with more severe radiography results. These data are consistent with observed correlations between unmet medical need and lower income and lack of insurance in King County.[40]

In unadjusted analyses, the association found between more severe disease and various SES surrogates has precedence in the literature. Substance abusers are more likely to have sputum smear-positive TB disease and cavitary disease.[41,42] Homelessness is associated with smear-positive TB disease and cavitary disease,[43] and smoking is associated with cavitary lesions.[44] After two months, sputum smear microscopic examination is more often positive in diabetic patients, but we did not examine diabetes comorbidity in our study population.[45]

The effect of HIV on TB severity is of particular concern. HIV infection may alter the radiographic appearance of pulmonary TB due to altered immunity.[46] HIV infection also promotes rapid progression to active TB disease,[47] though its effect on infectiousness remains disputed.[48] Indeed, our results demonstrated that HIV-infected individuals were more likely to have abnormal non-cavitary disease. However, in multivariate analyses restricted to non-infected individuals, no significant changes were observed in SES effect estimates on severity, likely due to small numbers of HIV-positive people in the analysis.

A recent publication found that increases in proportions of advanced (smear-positive or cavitary disease) pulmonary TB were greatest among groups with lower rates of TB, including white, U.S.-born, employed, HIV non-infected, and non-homeless people.[1] It was hypothesized that greater increases in the proportion of advanced disease among lower-risk groups were due to a lower index of suspicion for TB disease among patients and providers, leading to delays in accessing treatment and diagnosing disease. Our study results demonstrate the importance of examining not only these individual risk factors, but also area-level risk factors for disease.

Strengths and limitations

This study had several strengths, including the careful assessment of block-group boundaries, validation of the

geocode with the county, incorporation of multilevel models, and inclusion of area-based socioeconomic measures to examine SES at both the individual and area level. Because no relationship was observed when either smear grade or presence or absence of a positive smear result was analyzed, lower block-group SEP did not seem more important in distinguishing bacterial load in the lungs any more than it did presence or absence.

This study was also subject to several limitations. One limitation was the scope of area- and individual-level variables studied. There are likely many area-based variables that could have potentially confounded observed associations between area-based SES and disease severity, as well as relevant measures of individual SES that were unavailable to us. The latter precluded our ability to assess relative impact of area and individual SES in the prediction of TB severity. While the geographic availability and accessibility of health-care services, which may result in differential diagnostic delay, were not included, given King County's predominantly urban composition, geography was less likely to have been a strong confounding factor. Additionally, these results may not be generalizable to other regions, given that we adjusted only for certain relevant patient- and area-level demographic factors. And because residence was only measured at TB diagnosis, we also do not know whether residence at previous times could have been relevant to the development of disease. Furthermore, unmeasured variations among block-group risk factor norms (e.g., average alcohol intake) could be residually responsible for community contextual effects, but because controlling for individual-level risk factors did not attenuate the block-group SEP effect on disease severity, it seems unlikely that these factors would have an impact on the neighborhood-level SES-severity association.

CONCLUSIONS

In this study, area-level social resources were not associated with pulmonary TB disease severity at diagnosis. These findings are important because they suggest that factors other than area-level SES may predict severity. At-risk groups should be targeted for TB interventions regardless of area-level SES, with an emphasis on examining those characteristics related to access to and utilization of TB services. This study raises other actionable next steps including understanding what factors are tied in to disease severity, both individually and at the community level, whether the SES-severity association is further modified by other factors such as race, and the potential impact of SES on delays leading to more severe diagnoses.

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Mortality Rates and Age at Death from Sickle Cell Disease: U.S., 1979–2005

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ABSTRACT

Objectives. Improvements in survival for children with sickle cell disease (SCD) during the last 30 years have been well established. Whether similar improvements for adults with the disease have occurred is unknown. We investigated mortality rates for children and adults with SCD.

Methods. We used the National Center for Health Statistics multiple-cause-of-death files to examine age at death and calculate mortality rates from 1979 to 2005. We examined trends in mortality rates using negative binomial regression, and we examined age at death using t-tests and linear regression.

Results. We identified 16,654 sickle cell-related deaths. Mean age at death was significantly different for males (33.4 years, 95% confidence interval [CI] 33.0, 33.7) than for females (36.9 years, 95% CI 36.5, 37.4). In a regression model controlling for gender, the mean age at death increased by 0.36 years for each year of the study. The median age at death in 2005 was 42 years for females and 38 years for males. The overall mortality rate increased 0.7% ($p<0.001$) each year during the time period studied. The adult (>19 years of age) mortality rate increased by 1% ($p<0.001$) each year during the time period studied. The pediatric mortality rate decreased by 3% ($p<0.001$) each year during the time period studied.

Conclusions. These data confirm prior findings of a significant decrease in mortality for children with SCD. The mortality rate for adults appears to have increased during the same time period. It seems unlikely that this increase is due merely to an influx of younger patients surviving to adulthood and may reflect a lack of access to high-quality care for adults with SCD.

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Sickle cell disease (SCD) is a common genetic disorder with potentially devastating consequences for those afflicted. It affects approximately 90,000–100,000 Americans, the majority of whom are African American.[1,2] In the last 50 years, survival has improved dramatically for people with SCD in the United States. Their average life expectancy in the 1970s was <20 years of age. By the early 1990s, the Cooperative Study of Sickle Cell Disease estimated a median life expectancy of those with sickle cell anemia, the most severe form of the disease, of 42 years of age for males and 48 years of age for females.[3] This dramatic improvement has been attributed to several interventions in early childhood, including widespread newborn screening programs, the use of penicillin prophylaxis, and the use of pneumococcal vaccination.[4] Several studies have demonstrated decreasing mortality rates over time for children with SCD.[4,5] Mortality rates in adults have not been reported recently.

In the last 15 years, hydroxyurea has become available for the treatment of SCD. This medication has demonstrated efficacy to reduce morbidity and mortality in SCD;[6,7] therefore, there is an expectation that a reduction in mortality rates should occur with its widespread use. However, recent studies suggest that hydroxyurea is being underused[8] and that the expected benefits of this therapy are not being realized at the population level.

The purpose of this study was to use a large population-based dataset to describe age at death and possible contributors to death in individuals with SCD. In addition, we investigated mortality rates for adults with SCD during the last 26 years, and determined whether mortality rates for this population have changed in the era of hydroxyurea use.

METHODS

We extracted age at death, underlying cause of death (COD), and contributing CODs for people in the U.S. with SCD from 1979 through 2005 from the National Center for Health Statistics multiple-cause-of-death (MCOD) databases.[9] The MCOD files contain data from all death certificates filed in the U.S. Each certificate in the dataset includes the age at death, underlying COD, and a list of up to 20 conditions thought to contribute to the underlying COD. We identified deaths in people with SCD during the time period under study using International Classification of Diseases Ninth Revision (ICD-9)[10] codes (282.41, 282.42, 282.60–64, 282.68, and 282.69) and ICD 10th Revision (ICD-10)[11] codes (D570–D578) found in either the underlying COD or anywhere within the list of up to 20 diagnoses that contributed to the COD. We excluded records with the codes for sickle cell trait (282.5, D573) from analyses.

Analyses were not stratified by sickle genotype due to concerns regarding the accuracy of the coding. We restricted our analysis of the potential contributors to the underlying COD to illnesses known to be associated with mortality in SCD. These conditions included acute chest syndrome, renal disease, pulmonary hypertension, stroke, and infection.[3,12] In addition, we investigated whether overdose of prescribed narcotics was also a significant contributor to COD.[13] When evaluating the COD, the analysis reported in this study was restricted to those conditions identified in the MCOD files as the underlying COD. We conducted sensitivity analyses that suggested that the relative prevalence we observed for the different underlying CODs would not change had we expanded our scope to include the contributory CODs as well as the underlying COD. Therefore, we restricted our analyses to the underlying COD for the sake of simplicity and ease of interpretation.

We used logistic regression analyses to assess potential changes in the likelihood of the different specific conditions under study appearing as the underlying COD over time. To assess changes in mean age at death over time, we used multiple linear regression, t-tests, Mann Whitney, and F tests to determine the bivariate and multivariate relationships between age at death and gender, year of death, and underlying COD. We considered $p<0.05$ values to be significant. We examined the distribution of age at death, as well as the distribution of the residuals from regression analyses of age at death, using the Shapiro-Wilk test, which demonstrated significant non-normality. Robust and resistant regression methods were used as needed to account for slight departures from the assumptions of linear regression analysis and the presence of outliers. As these analyses led to the same conclusions as the ordinary linear regression, the results of the ordinary linear regressions are reported for ease of interpretation.

We examined trends in SCD mortality rates over time (1979–2005) using negative binomial regression. Mortality rates were calculated overall and stratified by pediatric/adult status (age ≤19 years = pediatric, age >19 years = adult). The African American population (overall and by pediatric/adult status) served as our denominator, and all rates are presented as deaths per 100,000 African Americans. We obtained our denominators for each year from the intercensal population estimates made available through the U.S. Census.[14,15]

Following the overall analysis, and to assess potential nonlinear trends in the mortality rates over time, we

conducted analyses using linear spline terms. Visual inspection of graphical analyses suggested a nonlinear change in the trend in mortality rates during the early 1990s. To examine this trend, we used negative binomial regression models placing linear spline terms at different periods throughout the early 1990s. The best fitting model was selected using Akaike's Information Criterion.[15]

Finally, we conducted a subanalysis examining trends in mortality rates for the period 1992–2005 to assess potential changes in the SCD mortality rate restricted to the era of hydroxyurea use. We placed a linear spline term at the year 1998 to compare trends in mortality rates for the seven years before/up to Food and Drug Administration (FDA) approval of hydroxyurea (1992–1998) with trends in mortality rates for the seven years after FDA approval of hydroxyurea (1999–2005). We used Stata® version 10.0[16] to perform all statistical analyses.

RESULTS

We identified 16,654 sickle cell-related deaths during the period of study, 1979–2005. Table 1 shows the demographic characteristics by the most prevalent underlying CODs. The age range was 0–107 years. The female who was reported as being 107 had ICD-9 codes for SCD (unspecified) and coronary artery disease. The median age at death during the entire time period was significantly lower for males (33 years, interquartile range [IQR] = 20) than for females (37 years, IQR=23) ($p<0.001$ for both). The median age at death in 2005 (our most recent year of study) was 42 years (IQR=23) for females and 38 years (IQR=18) for males (data not shown).

Sixty-five percent of the death certificates listed SCD as the underlying COD. The top five most common diagnoses (not including SCD) that were listed as the underlying COD were infectious disease (6%), non-ischemic heart disease (4%), ischemic heart disease (3%), stroke (3%), and liver disease (2%). The odds of the COD being infection or stroke decreased by 2% and 1%, respectively, each year during the time period studied. In a regression model of age at death over time and controlling for gender, we found that the mean age at death increased by 0.36 years for each year of study. Table 2 shows how the known sickle cell comorbidities were associated with age at death. People with infection listed as the underlying COD were 5.17 years younger, on average, than people for whom infection was not listed as the underlying COD. Conversely, people with an underlying COD of stroke, pulmonary hypertension, or renal disease were older, on average, than those without those conditions listed as the underlying COD.

Based on U.S. Census data estimates, the African American population grew in size from 26,072,963 to 39,067,463 during the time period studied. The

Table 1. Demographic characteristics of people with sickle cell disease who died from the top 14 underlying causes of death: U.S., 1979–2005[a]

Underlying cause of death	*Total* N *(percent)*	*Female* N *(percent)*	*Mean age (SD)*	*Median age (IQR)*
Sickle cell disease	7,722 (46)	3,646 (47)	31.4 (16.5)	31 (19)
SS without crisis	2,738 (16)	1,392 (51)	37.0 (15.3)	38 (21)
Infection	982 (6)	478 (49)	29.7 (19.0)	30 (28)
Non-ischemic heart disease	699 (4)	334 (48)	41.2 (17.3)	40 (21)
Ischemic heart disease	497 (3)	246 (50)	54.0 (16.5)	53 (21)
SS with crisis	467 (3)	216 (46)	37.2 (14.4)	36 (19)
Stroke	410 (3)	223 (54)	38.6 (17.5)	37 (22)
Liver disease	390 (2)	148 (38)	40.6 (14.1)	41 (20)
Accidental	385 (2)	137 (36)	33.2 (13.7)	32 (15)
Lung disease not PHTN	305 (2)	140 (46)	33.5 (18.7)	33 (24)
Renal disease	301 (2)	143 (48)	44.6 (16.4)	44 (22)
PHTN	282 (2)	169 (60)	39.4 (12.0)	38 (15)
Solid tumor	255 (2)	137 (54)	52.5 (17.5)	53 (23)
Pulmonary embolism	189 (1)	99 (52)	35.3 (12.9)	32 (16)

[a]The table represents 93.8% of all deaths during this time period. All other diagnoses were present in <1% of deaths.

SD = standard deviation

IQR = interquartile range

SS = homozygous S

PHTN = pulmonary hypertension

Table 2. Linear regression model for correlates of age at death for people with sickle cell disease: U.S., 1979–2005

Correlate	*β*
Year	0.36[a]
Male	–3.30[a]
Infection	–5.17[a]
Stroke	3.49[a]
Pulmonary hypertension	2.42[b]
Renal	9.57[a]

[a]$p<0.001$

[b]$p<0.05$

overall sickle cell mortality rate calculated from this Census data increased by 0.7% ($p<0.001$) each year during the time period studied. This rate represents an 18.2% increase in mortality rate during the 26 years studied. A graph of the smoothed mortality rates for adults and children over time are shown in the Figure. The adult (>19 years of age) mortality rate increased by 1% ($p<0.001$) each year during the time period studied. The pediatric mortality rate decreased by 3% ($p<0.001$) each year during the time period studied. In examining the graph of mortality rate, there appears to be a change in the adult mortality rate sometime in the early 1990s. This apparent nonlinearity was assessed using a spline term at 1994. We found that prior to 1994, the mortality rate increased by 2.6% ($p<0.001$) each year; however, from 1994 on, the mortality rate decreased by 0.9% each year ($p=0.007$). The adult mortality rate in 2005—2.5 per 100,000 African American population—never returned to the baseline value seen in 1979—2.2 per 100,000 African American population. The apparent decreasing trend does seem sensitive to the presence of the year 2005 data point, however, as removal of this data point from the analysis negates the statistical significance seen in this trend.

In examining the potential impact of the use of hydroxyurea on mortality rates, we compared rates using spline terms for the seven years before and up to the FDA approval of hydroxyurea (1992–1998) with the seven years of data we had after the approval of hydroxyurea (1999–2005). We found that there was no significant change in mortality rates between these two time periods (incidence rate ratio [IRR] = 1.00, 95% CI 0.99, 1.02 for 1992–1998 vs. IRR=0.99, 95% CI 0.96, 1.01 for 1999–2005).

DISCUSSION

Our data suggest that, unlike in children, the mortality rate for adults with SCD in the U.S. increased during the time period studied, with little impact at the population level seen from the introduction of hydroxyurea. Several prior publications have demonstrated an improved survival rate for children with SCD. Quinn et al.[5] examined deaths in the Dallas Newborn Cohort and demonstrated that the overall incidence rate for deaths per 100 patients decreased from 0.67 in children from the 1983–1990 era to 0.15 in the 2000–2007 era. Yanni et al.[4] compared mortality rates for children using the MCOD files, as we did in this study. They compared mortality rates for children during the period 1983–1986 with rates during the period 1999–2002. They demonstrated that the relative rate of mortality dropped 68% for children 0–3 years of age, 39% for children 4–9 years of age, and 24% for children 10–14 years of age between the two time periods. Our data are consistent with those findings and demonstrate a decrease in mortality rate for children from the late 1970s through 2005. Along with the finding of a decrease in childhood mortality, we found a decrease over time in the odds of infection being listed as the underlying COD. This finding is consistent with, and would seem to support, the widely held view that interventions such as penicillin prophylaxis and vaccination provided to people with SCD in early childhood have played an important role in decreasing childhood mortality and preventing life-threatening infections.

While comprehensive care for children with SCD has been linked to improved survival, the lack of comprehensive care for adults with SCD[17] may explain the overall increased mortality rate for this population seen during the entire study period. During this same time period, the age-adjusted death rates for the entire African American population steadily decreased from 1,314.8 per 100,000 population in 1980 to 1,016.5 per 100,000 population in 2005.[18] While we found an overall increased mortality rate for adults with SCD comparing the end of our period of study with the beginning, it is interesting to note that the trend in adult SCD mortality rate did appear to start decreasing in 1994. It is difficult to identify any intervention in the early 1990s for adults that might easily explain this trend. In addition, the mortality rate for adults with SCD never returned to the baseline value seen in 1979. And if we take out the final year of data, the significance of the downward trend in adult mortality is no longer seen. It is likely too early to tell whether the apparent decrease seen is real or an artifact of an outlying late data point. Unlike the interventions for children, only one intervention has been expected to influence outcomes for adults with SCD and that is the use of hydroxyurea. Although there have not been any

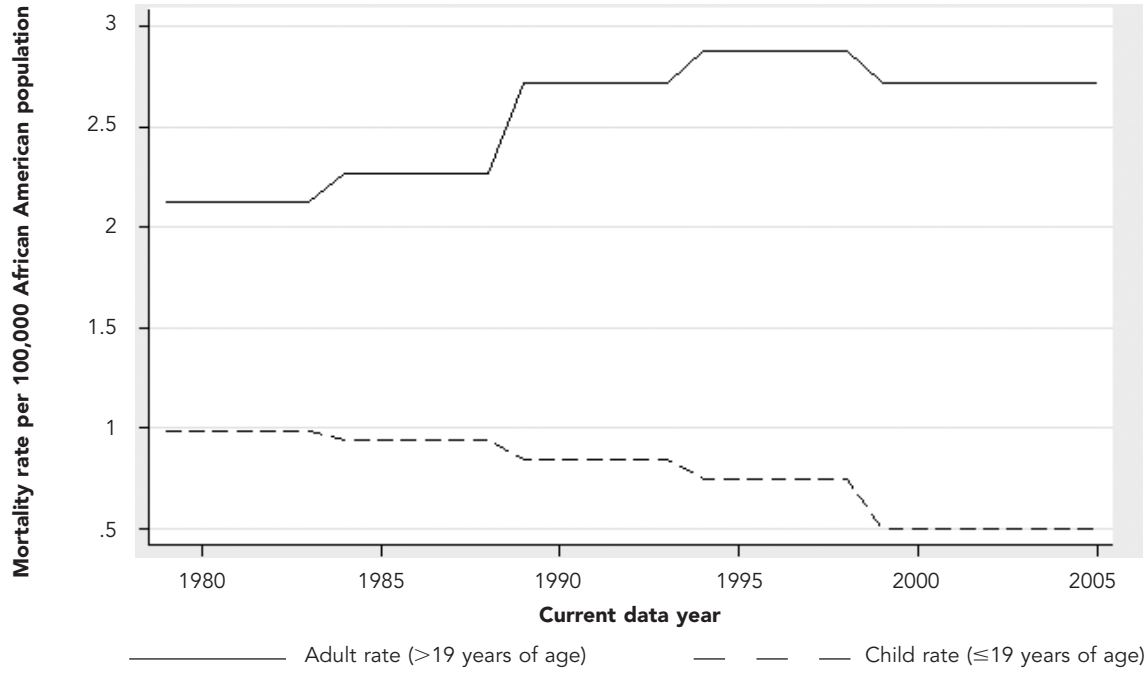
randomized studies showing the effect of hydroxyurea on survival, there are observational studies suggesting that the use of hydroxyurea may decrease mortality.[7,19] Nevertheless, we found no change in mortality rates during the period before and after hydroxyurea was approved by the FDA. This finding may reflect poor use of this drug by this population or it may be that it is too early to see the effect using death certificate data.

A number of factors might be contributing to the overall increase in mortality rates for adults with SCD that we observed in this study. One hypothesis is that the increase in adult mortality rate is due in part to an increase in the number of children with SCD who are living to adulthood. While this is certainly a distinct possibility, it must be noted that the interventions that are thought to have improved childhood mortality, such as newborn screening and penicillin prophylaxis, all occur early in life. Given this fact, one would predict that interventions implemented in the early 1980s reducing pediatric mortality would result in a significant increase in the adult sickle cell population 20 years later. Yet, the trend seen in the Figure demonstrates an increase in mortality rate starting in the mid-1980s.

Another hypothesis is that changes in our overall approach to inpatient SCD care may have had an unintended detrimental effect on SCD mortality rates. The average length of hospital stays for SCD has been decreasing over time while the rate of hospital admissions has been increasing.[20] Shorter hospital stays, however, may be associated with increased hospital visits for SCD, especially increased hospital readmissions. It is clear that hospital readmissions represent a significant number of the total hospital admissions for this patient population.[21] Ballas and Lusardi[22] have shown that patients with SCD who were readmitted within one week of discharge had a significantly higher mortality rate than other patients admitted with SCD. Houston-Yu et al.[23] have shown that individuals with SCD who have the highest rates of hospitalization also have higher mortality rates. Increasing hospitalizations and readmissions, therefore, may explain some of the increase in mortality rates for adults that we have observed in this study.

The fact that the median age at death for people with SCD appears to be unchanged from that reported by Platt et al. in the early 1990s is of additional concern. Especially troubling is the fact that the median age at death reported in this study is for people with all genotypes of SCD, as we did not analyze the death certificates by separate genotypes. In their 1994 publication of the Cooperative Study of Sickle Cell Disease cohort, Platt and colleagues showed that for individuals with hemoglobin SC genotype, the median age at death was 60 years of age for males and 68 years of age for females, and it was those with the most severe form of SCD, homozygous SS genotype, that had a median age at death in their fifth decade of life.[3] It may be that greater survival with SCD may introduce

Figure. Mortality rates for adults and children with sickle cell disease: U.S., 1979–2005



an inherent bias in these data. That is, if the sickle cell population lives longer, it may become less likely for a death certificate to include SCD as a COD. Were this to happen relatively frequently, our analyses would miss that percentage of patients who had SCD but were thought to die from causes unrelated to this underlying disease. This consequence may be especially true for individuals with the less severe forms of SCD, such as SC or S-Beta thalassemia. However, if greater survival with SCD truly introduced the biases we hypothesize in this study, the implication for our findings is that we would underestimate the overall mortality rate for people with SCD.

Limitations

This study was subject to several limitations. One limitation was that death certificates lack details and in 11% of cases, the only diagnosis on the certificate was SCD, thereby limiting the interpretation of the true immediate COD. In addition, the validity of our administrative mortality data depends upon the accuracy of the physician diagnosis and the use of appropriate coding of CODs. In calculating mortality rates, we used denominators based on the estimated number of all African Americans and not specific numbers of individuals with SCD, as these numbers were not available. There were also limitations in the intercensal population estimates provided by the U.S. Census that we used to estimate the African American population. Although errors in these estimates are less likely to occur when looking at data for larger populations (state or county level), more discrepancies have been noted when the data are stratified by race.[24] Finally, as these data only contained age at death, we were unable to comment on life expectancy. We could only make comments on changes in the ages at death for those who died. As we did not have information about people who were alive during the time period under study, we could not comment on changes in life expectancy for the sickle cell population as a whole over time.

CONCLUSIONS

As has been described in a number of prior studies, we demonstrated a decrease in mortality rate for children with SCD during a 26-year period. What has not been shown previously, however, is that mortality rates for adults with SCD increased overall during the same time period. Although the mortality rate for adults appears to be decreasing in the tail end of the time period under study, the overall mortality rates for adults remain above the baseline rates of 1979. While it is impossible to know why there has not been a clear decrease in mortality rates for adults with SCD, we do know that there are interventions, including the provision of comprehensive care,[25,26] which are not universally available for adults and may decrease hospitalization rates, thereby impacting mortality rates. Additional longitudinal studies of patients are required to have better estimates of mortality rates and life expectancy for this population.

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As the authors used a publicly available deidentified database, they were not required to obtain Institutional Review Board approval.

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Missed Connections: HIV-Infected People Never in Care

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ABSTRACT

Objective. Clinical interventions that lengthen life after HIV infection and significantly reduce transmission could have greater impact if more HIV-diagnosed people received HIV care. We tested a surveillance-based approach to investigating reasons for delayed entry to care.

Methods. Health department staff in three states and two cities contacted eligible adults diagnosed with HIV four to 24 months previously who had no reported CD4+ lymphocyte (CD4) or viral load (VL) tests. The staff conducted interviews, performed CD4 and VL testing, and provided referrals to HIV medical care. Reported CD4 and VL tests were prospectively monitored to determine if respondents had entered care after the interview.

Results. Surveillance-based follow-up uncovered problems with reporting CD4 and VL tests, resulting in surveillance improvements. However, reporting problems led to misspent effort locating people who were already in care. Follow-up proved difficult because contact information in surveillance case records was often outdated or incorrect. Of those reached, 37% were in care and 29% refused participation. Information from 132 people interviewed generated ideas for service improvements, such as emphasizing the benefits of early initiation of HIV care, providing coverage eligibility information soon after diagnosis, and leveraging other medical appointments to provide assistance with linkage to HIV care.

Conclusions. Surveillance-based follow-up of HIV-diagnosed individuals not linked to care provided information to improve both surveillance and linkage services, but was inefficient because of difficulties identifying, locating, and recruiting eligible people. Inefficiencies attributable to missing, incomplete, or inaccurate surveillance records are likely to diminish as data quality is improved through ongoing use.

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Clinical interventions that are capable of improving the quality and length of life after human immunodeficiency virus (HIV) infection and significantly reducing transmission[1–16] have limited population-level impact because many HIV-diagnosed people cannot or do not access HIV medical care. Marks et al. estimated that 72% of people newly diagnosed with HIV in the United States had received medical care for their HIV infection within four months of diagnosis.[17] Studies have shown that many of those not entering care soon after diagnosis continue to delay care entry;[18–20] evidence suggests that antiretroviral therapy may not restore health as fully when initiated late.[21–24]

As the capacity of HIV surveillance to monitor care use has increased, some health departments have begun to use HIV surveillance as both a source of feedback to public health workers and health-care providers on rates of linkage to and retention in care and a bridge among health departments, patients, and medical care providers to facilitate case management.[25,26] We summarize findings from the Never in Care Pilot Project, which tested the use of case surveillance data to prompt investigation of the system-level barriers and human factors affecting entry to care.

METHODS

In 2005, the Centers for Disease Control and Prevention (CDC) funded Indiana, New Jersey, New York City, Philadelphia (Pennsylvania), and Washington State to conduct the Never in Care Pilot. State laws in these jurisdictions mandated reporting of either all CD4+ lymphocyte (CD4) or all viral load (VL) values. Health departments sampled people diagnosed from December 2006 to December 2009 and reported to the enhanced HIV/Acquired Immunodeficiency Syndrome Reporting Systems (eHARS) in these project areas. Eligible adults were diagnosed ≥90 days previously and had no reported CD4 or VL tests, with the exception of tests in the same month and year as the HIV diagnosis, unless followed by additional CD4 or VL tests. (A test during this period may have been ordered along with confirmatory testing and before referral to care.[27]) The investigators have described the sampling methods in greater detail in a previously published report.[28]

Staff investigated the eligibility of sampled people by searching CD4 and VL reports for any evidence of care entry after selection and checking diagnosis dates against available records. Routine matching of surveillance data with vital statistics data, and ongoing interstate efforts to de-duplicate reported HIV cases,[29] identified deaths and migration out of the project area, respectively, among sampled people. Those not excluded as ineligible as a result of these efforts were contacted by mail, phone, and home visit—in that order, if possible—depending on the availability of contact information. Contact information was obtained from the surveillance record when available, from diagnostic service providers, or by other means available to the health departments for case investigation, if necessary. Contact attempts continued until six months from the initial contact, after which the case was closed and the person was considered unable to be located.

Interviewers screened potential respondents to confirm eligibility when contact was made. Those determined to be ineligible and who had not yet entered care received referrals to medical services. All those who remained were invited to participate in the interview and fingerstick blood draw. Consenting participants had whole blood collected (250 microliters [μL]) using the Microtainer® tube microcollection device (Becton, Dickinson and Co., Franklin Lakes, New Jersey). The CD4 count in whole blood was measured by immunophenotyping with the FACSCalibur™ flow cytometer (BD Biosciences, San Jose, California) using the BD Multitest™ CD3/CD8/CD45/CD4 kit (BD Biosciences). HIV plasma VL was measured when a sufficient blood volume was collected using the COBAS® AMPLICOR HIV-1 Monitor Test, v1.5 (Roche Molecular Systems Inc., Pleasanton, California).

Incoming reports of surveillance of CD4 and VL tests were prospectively monitored via eHARS through August 31, 2010, to determine if respondents had entered care after they were interviewed. A CD4 or VL test reported to surveillance after the interview was treated in this analysis as the first CD4 count or first VL measurement for (*1*) people from whom blood was not collected at the interview and (*2*) those whose blood collected at the interview could not be tested because of insufficient volume or clotting.

Participants were offered an incentive for their participation. All people contacted were encouraged to seek HIV medical care and given information about the benefits of care (a brochure produced by CDC) as well as referrals (i.e., contact information for medical care and other service providers in their area).

Variables

The following information was collected from consenting adults through a 30-minute structured interview: demographic characteristics, barriers to and facilitators of HIV medical care, and general health. We used reported income and number of dependents to determine the percentage of respondents who fell below 300% of the federal poverty level (FPL), a common eligibility criterion for publicly funded care, according

to standardized methods.[30] We grouped individual reasons for not entering care into the following categories: financial/insurance, knowledge/information (e.g., believing that there is no need for care if one feels good), psychological (e.g., not wanting to think about HIV status), service organization (e.g., inconvenient clinic location or hours), and other (too sick to initiate care, fully occupied with other responsibilities such as child care, homeless, or no transportation).

Analyses

We analyzed data using SAS® version 9.2.[31] We examined frequencies and percentages of responses through univariate and bivariate analyses with Chi-square tests to assess differences in proportions.

RESULTS

In the five project areas combined, 19,516 adults were diagnosed with HIV infection from December 2006 to December 2009 and reported to eHARS by February 28, 2010. Of these 19,516 adults, 11,156 (57%) had CD4 or VL evidence of care entry and 8,360 (43%) had no evidence of care entry through the month they were eligible for selection. Of the latter, 4,885 were sampled. Of those sampled, 219 were excluded as ineligible after record review because of a diagnosis date that was outside of the eligible date range, leaving 4,666 adults eligible for field investigation. Of those considered eligible for investigation, 2,299 (49%) adults were determined to be ineligible before contact was made. The Figure summarizes the results of the field investigation. Of 132 people interviewed, 105 (80%) provided a blood specimen, a CD4 count was available for 96 respondents (73%), and a VL was available for 90 respondents (68%) (data not shown).

We found significant differences in characteristics between people who were interviewed and those who were not interviewed (i.e., not contacted or refused the interview), as well as between people who were interviewed and people who had evidence of care entry. As shown in Table 1, information available in eHARS indicated that the majority of respondents were non-Hispanic black (63%), male (75%), younger than 30 years of age (46%), born in the U.S. (82%), and interviewed in Indiana (51%).

Table 2 presents additional characteristics of the respondents. At the time of the interview, 46% were >6 months from their HIV diagnosis. The majority of respondents (60%) had ≤high school education, and most (95%) had incomes of <300% FPL. Blood collected at interview was tested for CD4 for 69 respondents and for VL for 61 respondents; first CD4 and/or VL was available from subsequent monitoring of reports to surveillance for an additional 27 respondents (CD4) and an additional 16 respondents (VL). Of 96 respondents for whom CD4 count was available either through the Never in Care Pilot or a later report to surveillance, 47% had counts of <350 cells/cubic millimeter (mm^3) and 20% had counts of <200 cells/mm^3; 44% of the 77 people with VL results had a VL of >100,000 copies/milliliter (mL).

Table 3 describes respondents' health and relationship with the health-care system. Twenty-six percent said they felt depressed all or most of the time in the past four weeks, 15% had never received health care for any reason, 71% either had no health insurance or had a gap in health insurance in the past three months, and 38% had a medical care visit after their HIV diagnosis that was not HIV-related and did not lead to care entry.

As shown in Table 4, the five most frequently reported reasons for not entering care were lack of money or health insurance (57%), not wanting to think about being HIV-positive (55%), feeling good/healthy (55%), feeling depressed (45%), and not wanting to disclose HIV-positive status (43%). Of those who cited lack of money or health insurance as a reason for not entering care, 97% met a common eligibility threshold for public HIV care (income <300% FPL) (data not shown). For most respondents, barriers to care were multidimensional—only 14% reported barriers in only a single category.

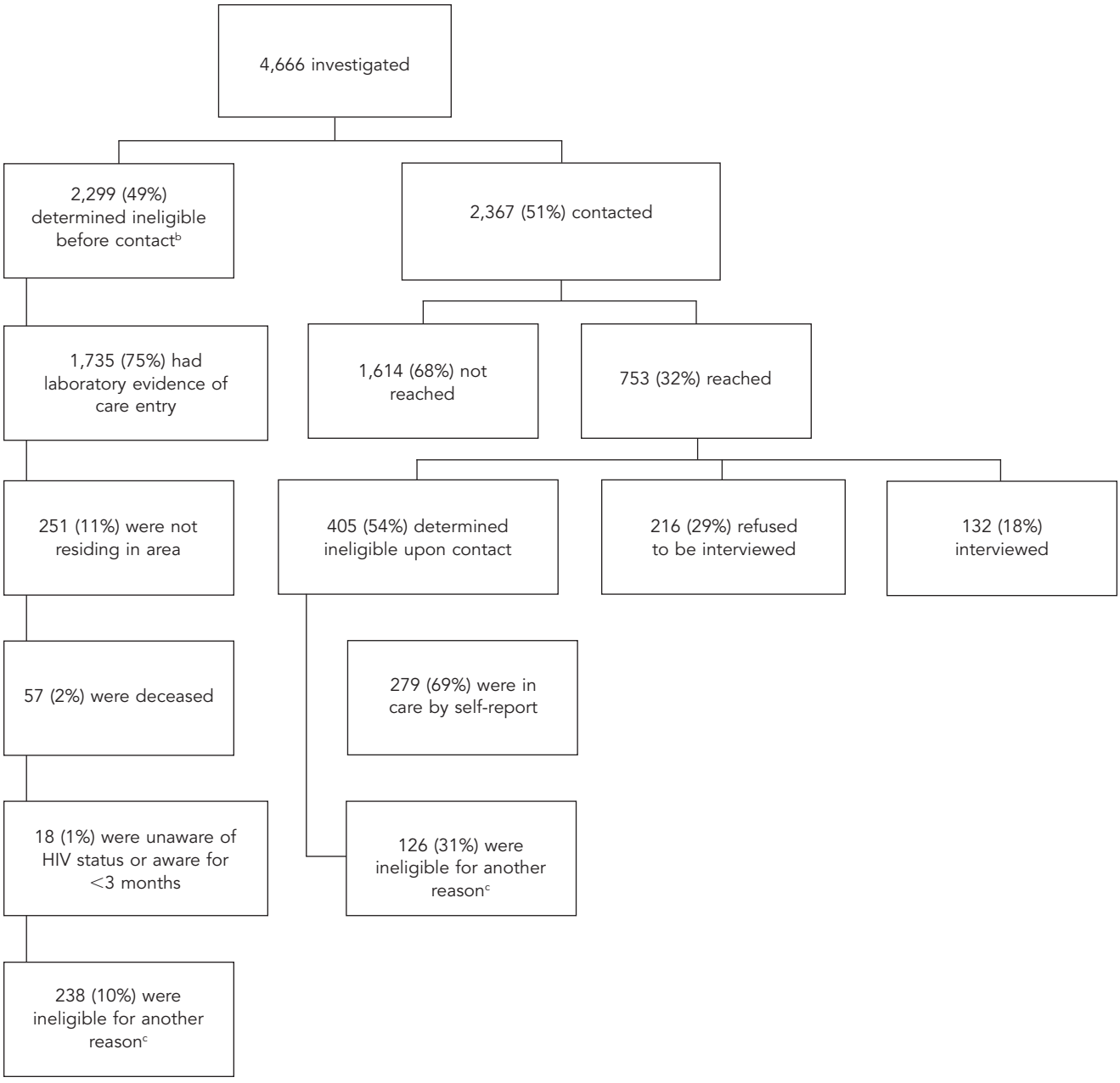
Reported CD4 and VL tests were monitored for a median of 17 months (range 1–29 months). Overall, 43 participants (33%) entered care during this period (as evidenced by a CD4 or VL test after the interview). Of those who had a CD4 or VL test after the interview, the median time from interview to first reported CD4 or VL test was 97 days. Of 102 (77%) respondents who reported being fairly to very likely to enter HIV care within the next three months, only 17 (17%) actually did. Among factors respondents said would make care entry more likely, the top two were having sufficient money or health insurance to enter care (33%) and feeling sick (31%).

DISCUSSION

The Never in Care Pilot tested a concept for enhanced surveillance to investigate reasons for delayed initiation of HIV medical care. HIV case surveillance records triggered follow-up and voluntary interviews that provided useful leads for improving linkage to care. However, the tested approach was challenging to implement.

Finding and recruiting those who had been

Figure. Outcomes of case investigation and recruitment of HIV-infected people with no evidence of care entry in five project areas:[a] Never in Care Pilot Project, 2009–2010



[a]The five project areas were Indiana, New Jersey, New York City, Philadelphia (Pennsylvania), and Washington State.

[b]Of 4,666 people with no evidence of care entry at the time of selection from the sampling frame, 2,299 people were determined to be ineligible before contact was made: 1,735 people were ineligible because they had laboratory evidence of care entry. Among these, 1,393 had a CD4 or viral load test performed before they were selected, but not reported until after their selection, and 342 had a CD4 or viral load performed after their selection.

[c]Other reasons for ineligibility included being diagnosed before the eligibility period, not being able to speak English or Spanish, being younger than 18 years of age, or having a CD4 or viral load date before the HIV diagnosis date.

HIV = human immunodeficiency virus

Table 1. Comparison of sampled HIV-infected people[a] who were interviewed with sampled people who were not interviewed and sampled people who were ineligible to be interviewed: five project areas,[b] Never in Care Pilot Project, 2009–2010

Characteristic	*Sampled people interviewed[c] (n=132) Percent*	*Sampled people not interviewed[d] (n=1,830) Percent*	*People ineligible because of evidence of care entry[e] (n=11,156) Percent*	*Comparison of people interviewed vs. not interviewed P-value*	*Comparison of people interviewed vs. people ineligible for interview because of evidence of care entry P-value*
Age at diagnosis (in years) (missing = 4)				0.01	<0.0001
18–29	46	34	28		
30–39	24	25	27		
40–49	23	26	26		
≥50	7	15	19		
Race/ethnicity (missing = 7)				0.60	0.002
Hispanic	12	17	19		
American Indian/ Alaska Native	0	0.2	0.4		
Asian/Pacific Islander	0	1	3		
Non-Hispanic black	63	59	46		
Non-Hispanic white	20	17	25		
Multirace	4	5	6		
Unknown	1	1	0.2		
Sex				0.90	0.80
Male	75	76	74		
Country of birth				0.007	NA
U.S.	82	72	NA		
Risk category				0.003	0.006
MSM	42	31	41		
MSM + IDU	5	2	5		
IDU	4	9	4		
Heterosexual	33	44	42		
Undetermined	17	13	8		
Time since diagnosis at selection				<0.006	NA
≤6 months from diagnosis	84	73	NA		
Project area				<0.0001	<0.0001
Indiana	51	6	5		
New Jersey	9	22	10		
New York City	21	36	64		
Philadelphia	11	31	10		
Washington State	8	5	11		

[a]Sampled people were diagnosed with HIV between December 2006 and December 2009 and had no evidence of care entry (includes those with only one CD4 or VL test in the same month as their HIV diagnosis).

[b]The five project areas were Indiana, New Jersey, New York City, Philadelphia (Pennsylvania), and Washington State.

[c]For sampled people interviewed, never in care status was confirmed by self-report.

[d]Sampled people not interviewed included 216 people who declined to participate when contacted and 1,614 people not reached through contact attempts (neither group was confirmed to be never in care).

[e]People ineligible because of evidence of care entry included people with >1 CD4 or VL tests unless they had only one test in the same month as their HIV diagnosis.

HIV = human immunodeficiency virus

NA = not available

MSM = men who have sex with men

IDU = injection drug user

CD4 = CD4+ lymphocyte

VL = viral load

diagnosed four to 24 months previously was difficult. The degree of difficulty encountered was consistent with some other, similar efforts.[32–34] Unless these challenges can be overcome, the surveillance-based follow-up approach may not be cost-effective. Perhaps both contact and response rates might be increased by preparing those who test HIV-positive to expect follow-up contacts that allow them, if they are willing, to share their experiences for the improvement of services and service access, and also to receive referrals to medical care and other services. Strong emphasis on the benefits of early and ongoing HIV care, even for those who feel healthy, might provide a context for follow-up efforts that would more successfully engage those who have delayed starting care.

Starting the follow-up closer to the time of diagnosis proved more successful than subsequent attempts during the pilot. One reason for the low contact rates among those diagnosed less recently was that contact information obtained at diagnosis was frequently incorrect. A report from San Francisco documented follow-up contact and interviews with 76% of 160 newly diagnosed people.[26] Contact and response rates varied across project areas participating in the Never in Care Pilot, with the highest rates in Indiana, but none as high as reported by San Francisco. Identifying critical factors leading to high contact and response rates in areas having greater success might allow for improved outcomes elsewhere if the conditions underlying success can be replicated.

Despite the challenges, the Never in Care Pilot demonstrated that interviewing those who have not yet linked to care can complement a practice that is gaining momentum: the use of reported CD4 and VL test results as proxy indicators to estimate how many HIV-diagnosed individuals have initiated HIV care.[25] Interviewing those without CD4 or VL evidence of care entry can help to validate these proxy indicators that are increasingly being used to monitor progress toward national linkage-to-care objectives. Such interviews may also provide a more useful description of who is not linked to care and why—information that has implications for improving support for HIV-diagnosed individuals to begin and continue with HIV medical care.

Those who delay entry to care continue to represent a substantial proportion of people recently diagnosed with HIV.[17] The delay is lengthy for many of these people.[35] There is an ongoing need to understand the reasons for delayed care entry to provide for the service needs of this group. The Never in Care Pilot identified lack of money or insurance as the most commonly reported barrier to care. Almost all (97%) of those who said they had not entered care because they lacked money or insurance appeared to be financially eligible for publicly funded care, according to reported income and number of dependents. The fact that those who appeared to qualify for public services perceived lack of money or insurance to be a barrier to care entry suggests that they may not be aware of their eligibility. What is known about why eligible HIV-diagnosed people do not use HIV medical services is evolving.[33,36]

Table 2. Characteristics of HIV-infected people with no evidence of care entry[a] interviewed in five health project areas (*n*=132):[b] Never in Care Pilot Project, 2009–2010

Characteristic	*Percent*
Time since diagnosis at interview (in months)	
4–6	46
7–12	42
>12	11
Sexual orientation (missing = 1)	
Homosexual, gay, or lesbian	40
Heterosexual or straight	45
Bisexual	14
Possible exposure to HIV[c] (missing = 2)	
Injected drugs	8
Sex with a person who injected drugs (missing = 5)	14
Sex with a man (males, missing = 2)	61
Sex with a man who had sex with men (females, missing = 3)	14
Sex with a person known to be HIV-positive (missing = 17)	28
Education (missing = 2)	
<High school	28
High school	32
Some college, associate's degree, or technical degree	33
≥Bachelor's degree	5
Employment status (missing = 2)	
Unemployed	52
Working occasionally	11
Employed full-time	9
Employed part-time	26
Income <300% FPL[d] (missing = 15)	95
Homeless in past three months[e]	18
In jail, detention, or prison in past three months (missing = 1)	9
Never disclosed HIV status (missing = 2)	35
Know someone with or who has died from HIV/AIDS (missing = 3)	77
CD4 count (cells/mm^3) (missing = 36)	
<200	20
200–349	27
350–500	17
>500	36

continued on p. 123

Table 2 (continued). Characteristics of HIV-infected people with no evidence of care entry[a] interviewed in five health project areas (*n*=132):[b] Never in Care Pilot Project, 2009–2010

Characteristic	*Percent*
Viral load (copies/mL) (missing = 55)	
<10,000	44
10,000–100,000	12
>100,000	44

[a]Diagnosed between December 2006 and December 2009

[b]The five project areas were Indiana, New Jersey, New York City, Philadelphia (Pennsylvania), and Washington State.

[c]Reported behavior prior to diagnosis (respondents could choose more than one category).

[d]Reported income and number of dependents were used to determine the percentage of poverty level for each respondent according to standardized methods. Department of Health and Human Services (US). Annual update of the HHS poverty guidelines. Fed Reg 2009;74:4199-201. Also available from: URL: http://aspe.hhs.gov/poverty/09fedreg.shtml [cited 2012 Aug 30].

[e]McKinney-Vento definition of homelessness: living on the street, staying in a shelter, living in a single-room-occupancy hotel, temporarily staying with friends or family, or living in a car. A person is categorized as homeless if that person lacks a fixed, regular, adequate nighttime residence or has a steady nighttime residence that is (*1*) a supervised publicly or privately operated shelter designed to provide temporary living acccommodations, (*2*) an institution that provides a temporary residence for people who are intended to be institutionalized, or (*3*) a public or private place not designed for or ordinarily used as a regular sleeping accommodation for human beings (e.g., in an automobile or under a bridge). Taken from: Stewart B. McKinney Homeless Assistance Act, 42 U.S.C. §11301, et seq. (1987).

HIV = human immunodeficiency virus

FPL = federal poverty level

AIDS = acquired immunodeficiency syndrome

CD4 = CD4+ lymphocyte

mm^3 = cubic millimeter

mL = milliliter

Table 3. Health and interaction with the health-care system reported by HIV-infected people with no evidence of care entry[a] interviewed in five health project areas (*n*=132):[b] Never in Care Pilot Project, 2009–2010

Reported health	*Percent*
Perception of general health (missing = 1)	
Excellent	16
Very good	27
Good	36
Fair	18
Poor	3
Felt depressed in past four weeks (missing = 2)	
All of the time	15
Most of the time	11
Some of the time	27
A little of the time	22
None of the time	24
Never received health care for any reason (missing = 1)	15
No insurance during past three months (missing = 1)	61
Gap in insurance sometime during past three months	10
Number of urgent care visits during past three months	
0	83
1	8
2–3	7
≥4	2
Had no regular place for medical care	56
Had a non-HIV-related medical care visit after HIV diagnosis that did not lead to initiation of HIV care	38
Had a CD4/VL reported after the interview[c]	33

[a]Diagnosed between December 2006 and December 2009

[b]The five project areas were Indiana, New Jersey, New York City, Philadelphia (Pennsylvania), and Washington State.

[c]Reports of CD4 and VL tests received by the HIV surveillance units in participating project areas were monitored for a median of 17 months (range: 1–29 months); median time from interview to first reported CD4 or VL test was 97 days.

HIV = human immunodeficiency virus

CD4 = CD4+ lymphocyte

VL = viral load

Our findings suggest that providing information about public benefits to eligible people may address one possible underlying reason.

To date, with two exceptions,[33,37] studies of barriers to HIV care entry have been retrospective.[38–44] Never in Care Pilot interviews with people who had not yet entered care at the time of the interview show that barriers to care are multidimensional, and indicate that poverty and mental health problems may be contributing factors, underscoring the importance of supportive services to help with starting and staying in care.

Fragmentation of the health-care system and separate funding streams for prevention and care present challenges to achieving the seamless system advocated in the National HIV/AIDS Strategy to immediately link people to continuous and coordinated quality care when they learn they are infected with HIV.[45,46] The Never in Care Pilot identified health-care system missed opportunities and disconnects worthy of further investigation as potential leverage points for improving early linkage-to-care rates. A previously published article about the pilot described missed opportunities for linkage to care at HIV diagnosis.[47] Findings presented in this article indicate that non-HIV-related care visits could also provide an opportunity to facilitate

Table 4. Barriers and facilitators to HIV care reported by HIV-infected people[a] with no evidence of care entry interviewed in five health project areas (*n*=132):[b] Never in Care Pilot Project, 2009–2010

Barriers and facilitators to HIV care	*Percent*
Barriers to HIV care entry[c]	
Lack of money or health insurance	57
Felt good (healthy)	55
Avoidance of HIV status	55
Depressed	45
Disclosure issues	43
Denial of HIV status	30
Medicines are harmful or unpleasant	26
No cure	20
Lack of transportation	19
Couldn't get an appointment	17
Distrust health-care workers	16
Other responsibilities	14
Substance use	11
Clinic hours are inconvenient	8
HIV doesn't cause AIDS	6
Didn't know where to go	5
Other[d]	<5
Likelihood of starting HIV care in next three months (missing = 2)	
Very likely	45
Fairly likely	32
Fairly unlikely	5
Very unlikely	12
Don't know	5
Reported facilitators to HIV care entry[e] (missing = 2)	
Felt sick	33
Sufficient money or health insurance	31
Disclosure issues addressed	10
Cure discovered	7
HIV medicines that are not harmful or unpleasant	7
Other[f]	<5

[a]Diagnosed between December 2006 and December 2009

[b]The five project areas were Indiana, New Jersey, New York City, Philadelphia (Pennsylvania), and Washington State.

[c]Percentages add to more than 100% because respondents could select more than one reason.

[d]Unstable housing, religious reasons, felt sick, and language barriers were each reported by <5% of respondents as reasons for not entering care.

[e]Respondents were asked, "What, if anything, would make you more likely to start HIV medical care within the next three months?" Sixty respondents who had previously answered that they were very likely to start HIV medical care in the next three months were not asked this question.

[f]The following were reported by <5% of respondents as facilitators to HIV care entry: having other responsibilities covered, stable housing, stable mental health, substance use recovery, cure for HIV/AIDS available, if medicines weren't harmful or unpleasant, trustworthy health-care workers, transportation available, convenient clinic hours, convenient clinic location, available appointments, no language barrier, or nothing would facilitate care entry.

HIV = human immunodeficiency virus

AIDS = acquired immunodeficiency syndrome

entry to HIV care. Almost 40% of the study population received health care after HIV diagnosis, not including urgent care visits; however, they did not start HIV care. An innovative project, the Louisiana Public Health Information Exchange, demonstrates how surveillance data can be used to leverage non-HIV-related care visits in settings with electronic health records.[48] Yet, the majority of those we interviewed did not have any medical care visits, which suggests that waiting for such a visit to occur to start HIV care may lead to later-than-optimal HIV care entry, and that approaches such as surveillance-based follow-up may also be needed.

The potential value of surveillance-based follow-up is its promise for identifying where and why problems, such as gaps between testing and care, are occurring area-wide.[25] If implemented as a routine part of public health practice, enhanced surveillance involving interviews with people who have not linked to HIV care could catalyze necessary changes in supportive services. As changes are implemented, their impact could be measured by area-wide linkage-to-care rates estimated from case surveillance data. Repeated assessments of what is preventing linkage to care among those who delay care entry, along with information on the extent to which services have changed to meet needs, could provide iterative cycles of feedback that are critical for incremental improvements in linkage to care.

Our findings point to conditions that would increase the efficiency of surveillance-based follow-up. In the Never in Care Pilot, delayed reporting of CD4 and VL tests resulted in misspent effort, leading to the investigation of 405 cases in which a person selected for participation was actually already in care. An expected reduction in reporting delays as health departments complete the transition to electronic reporting of CD4 and VL tests will likely sharpen the focus of future follow-up efforts. In addition to reporting delays, reporting completeness and other data quality issues may affect how well the presence or absence of reported CD4 or VL tests reflects care entry or non-entry. We found that inconsistent reporting of CD4 and VL tests by a laboratory led to selection of people who were already in care; for some people, initial CD4 and VL tests were ordered before referral to care rather than at the first HIV care visit. Identifying these problems strengthened surveillance data or improved understanding of the data, paving the way for more successful follow-up efforts in the future. Finally, if surveillance data are to be useful for follow-up and facilitating linkage to care, the completeness and accuracy of contact information in the case record must also be improved.

Limitations

This study was subject to several limitations. For one, the Never in Care Pilot was a first attempt at using HIV case surveillance data as a trigger for follow-up interviews about barriers to care in the five participating project areas. We did not assess the continuing benefit to surveillance of investigating the absence of reported CD4 and VL testing in people diagnosed with HIV, nor the potential benefit to linkage-to-care rates of repeated cycles of addressing barriers identified. Additionally, respondents may not be representative of all HIV-diagnosed people who have yet to be linked to HIV medical care. Also, people who did not speak English or Spanish were excluded from participation; their barriers to care may be different from those described in this article. Lastly, the five project areas' unequal success with obtaining interviews was likely the result of multiple factors; the project was not designed to identify the relative contribution of different factors in determining response rates.

CONCLUSIONS

The enhanced surveillance concept tested by the Never in Care Pilot was inefficient because many HIV-diagnosed people who delayed care entry could not be found or refused to be interviewed, and because incompleteness, inconsistency, and delays in reporting CD4 and VL tests led to follow-up of a large number of people who were already receiving HIV medical care. However, using surveillance data to identify people for interviews about barriers to care yielded useful information for improving surveillance, and the interviews provided feedback for improving linkage services. Incremental improvements in surveillance, some underway and some resulting from the pilot, raise expectations of greater efficiency of this approach in the future. The responsibility of public health to facilitate access to life-saving treatment among those inadequately served by the health-care system—and to control the spread of HIV—necessitates enhanced surveillance approaches that identify reasons for delayed care entry and suggest possible solutions.

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Law and the Public's Health

One of the most important legal issues arising in public health policy is the source of legal power to address issues affecting the public's health. This issue of *Law and the Public's Health* examines the question of gubernatorial executive power, an increasingly important source of power in the case of laws that protect and advance public health.

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USING GUBERNATORIAL EXECUTIVE ORDERS TO ADVANCE PUBLIC HEALTH

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The law is a critical tool to address public health concerns. One important constraint on the government's ability to use law as a public health tool, however, is the separation of powers created by the U.S. Constitution and echoed in state constitutions. Within this framework, the legislative branch creates policies and allocates funding, the executive branch enforces laws and establishes precise rules, and the judicial branch interprets laws and resolves disputes, creating a system of checks, balances, and oversight for each branch.[1]

The gubernatorial executive order (GEO) is an increasingly visible legal tool within the public health arsenal that may blur some of the traditional lines created through the separation-of-powers framework. At the federal level, executive orders are rooted in the President's constitutionally granted "executive power."[2] GEOs are also significant sources of law in every state.[3] However, the meaning of "executive order" and the basis of a governor's executive order authority varies by state. Historically, governors have issued informal orders through directives or letters, but issuing formal GEOs is a more contemporary phenomenon. As gubernatorial orders have been formalized, interest in them has grown.[4] Yet, little has been written describing how GEOs can be used as a public health tool, as well as the advantages and disadvantages of such an approach.

SOURCES OF GUBERNATORIAL EXECUTIVE ORDER AUTHORITY

Federal or state laws may permit the issuance of a GEO. The power to issue a GEO may arise from a federal law that requires action at the state level.[4] For example, recently governors have issued GEOs in response to the federal Patient Protection and Affordable Care Act's mandate requiring states either to create and operate a state health insurance Exchange or permit the federal government to carry out the Exchange.[5] New York Governor Andrew Cuomo used a GEO to create a state health insurance Exchange[6] after a bill to establish an Exchange failed in the state legislature.[7]

Various state laws and cases also authorize governors to issue executive orders, and some states authorize GEOs using more than one legal mechanism. According to a survey conducted by the Council of State Governments, among the 50 states, 26 have explicit GEO authority in their state constitutions and 37 authorize GEOs through legislation. Governors' authority to issue GEOs is also recognized in the case law of seven states. Furthermore, in 18 states the governor's general responsibility to execute the state's laws includes the ability to issue GEOs.[3] Through these varied legal mechanisms, governors issued more than 3,400 executive orders from 2004 to 2005.[8]

Many GEOs are not specifically relevant to public health. For example, during 2004 and 2005, 33% of all GEOs consisted of appointments, 6% ordered flying of flags at half-mast, 3% ordered pardons, and 1% established state holidays.[8] Other types of GEOs directly affect the public's health.

USING GEOs TO IMPROVE PUBLIC HEALTH

Governors use GEOs to address various state concerns without directly involving the legislative or judicial branches. In the public health context, GEO uses include tackling public health emergencies, establishing new programs and entities, directing or reorganizing agencies, increasing the profile of an issue, and controlling state operations.

Addressing public health emergencies

GEOs related to disaster-relief activities represented 11% of all GEOs issued during 2004 and 2005.[8] Disaster-relief activities involve emergency preparedness and response efforts that can directly affect the public's health. The Deepwater Horizon Oil Spill off the Gulf Coast provides a powerful example.

In April 2010, an offshore drilling unit leased to BP exploded, creating the largest offshore oil spill in U.S. history.[9] The immediate health concerns for response workers and people residing near the spill included respiratory problems, skin irritation, headaches, dizziness, eye irritation, and nausea. Exposed workers also reported injuries, faintness, and fatigue, as well as musculoskeletal and psychosocial symptoms.[10] After proclaiming and extending a state of emergency,[11,12] Louisiana Governor Bobby Jindal issued a GEO in June 2010 that permitted out-of-state emergency medical technicians to practice in Louisiana as long as they were licensed and in good standing in another state. The GEO suspended any legal requirements that would prohibit their practice.[13] In issuing this GEO, Governor Jindal relied on a Louisiana statute authorizing the governor to suspend any state statutes or regulations "if strict compliance with the provision . . . would in any way prevent, hinder, or delay necessary action in coping with the emergency."[14] Through this GEO, Governor Jindal increased the availability of medical care for the surge of disaster victims when there were not enough local providers to address medical needs.

Establishing new public health programs and entities

Governors can use executive orders to establish new programs to address pressing public health concerns.[8] By issuing Executive Order 72 in 2005, New Jersey's Acting Governor Richard Codey created a new program[15] addressing the abuse of anabolic steroids, which have been linked to increased risks of cancer, cardiovascular disease, and mental health issues, as well as harmful effects on the immune, hormonal, and metabolic systems.[16] Executive Order 72 requires the state department of education to work with the interscholastic athletic association to randomly test athletes for steroid use and incorporate steroid education into school curricula. It also requires the department of health to randomly test dietary supplements for steroid contamination. Finally, the GEO mandated the development of an anti-steroid advertising campaign, the creation of public service announcements to be displayed at school games, and the establishment of a Steroid Awareness Week.[15]

Asserting that chronic disease is "the biggest threat to the health of Pennsylvania's residents," in 2007 Governor Edward Rendell used a GEO to create the Governor's Chronic Care Management, Reimbursement, and Cost Reduction Commission. The Commission is required to create a statewide chronic care information system, implement and evaluate disease management programs, work with insurance companies, and otherwise support the use of chronic care disease management.[17] While this GEO and the Commission were scheduled to expire in 2010, the Pennsylvania House of Representatives attempted to save the Commission by unanimously voting to establish it through legislation, although the bill did not emerge from the Pennsylvania Senate.[18]

Directing public health agencies

Governors can issue executive orders that require public health agencies to take specific actions. Pursuant to this power, in December 2010, New York Governor David Paterson issued a GEO addressing hydraulic fracturing[19] (also known as "fracking") in the extraction of natural gas from New York's Marcellus Shale deposit. Some forms of fracking have been controversial due to concerns about the possibility of contaminated drinking water,[20] respiratory diseases, and chronic conditions such as endocrine dysfunction.[21]

Governor Paterson's GEO requires the New York Department of Environmental Conservation (DEC) to (*1*) review public comments on a draft environmental impact statement analyzing the effects of hydrofracking, publish a revised statement, and hold hearings on the revision; and (*2*) identify conditions that should be incorporated into hydrofracking permits "to protect public health and the environment."[19]

Governor Paterson issued this GEO after vetoing legislation that would have imposed a moratorium on hyrofracking. This GEO nonetheless delayed the DEC's ability to issue hydrofracking drilling permits.[22] As this example demonstrates, when a GEO is substituted for legislation, it can help the governor retain control over a policy decision.

Reorganizing public health agencies

Of all GEOs, fewer than 3% reorganize state administrative agencies.[8] However, this reorganization remains a potentially potent use of GEOs. For example, in an attempt to improve public health, Governor Pat Quinn of Illinois used a GEO in April 2010 to transfer the Diabetes Prevention and Control Program (which includes diabetes-related grants administration, the state diabetes commission, and the "diabetes, asthma, and pulmonary disorder educational prevention functions") from the state's Department of Human Services to its Department of Public Health (DPH).

In conducting this transfer, Governor Quinn cited his authority under the state constitution to "reassign functions among or reorganize executive agencies which are directly responsible to him" and his authority under state statutory law to transfer an agency in whole or in part.[23] After this GEO was issued, statutory language related to the program was altered to reflect the transfer.[24] In this case, an administrative change originally established by a GEO—which is subject to expiration, may change with subsequent administrations, or may be legislatively overturned—became permanent through a statute.

The transfer of a program, such as the reorganization of an agency, allows the governor to improve public health with a GEO by optimally assigning programs to agencies with the most expertise and infrastructure to implement them. Governor Quinn specifically cites the expertise of DPH to award grants, develop programs, and provide education to justify this transfer.[23] At the same time, in states where transferring authority using a GEO is permitted, relocating or reorganizing an agency creates an opportunity for a governor to make changes that may reduce the agency's ability to address a health concern. The governor, for example, could use a GEO to transfer oversight of a program from a public health department to a department less versed in public health.

Increasing the profile of a public health issue

A governor may also rely on a GEO to raise the prominence of a public health issue, particularly through the creation of a task force or board. Task forces and boards allow the governor to set priorities, elevate the salience of an issue, and provide a venue for expert input.[8]

For example, Virginia Governor Tim Kaine established the Governor's Commission on Climate Change in December 2007 to develop a state climate change action plan. In establishing the Commission, he acknowledged that the state had taken certain steps to address climate change but that "additional tools and resources" were necessary. Governor Kaine charged the Commission with inventorying gas emissions, evaluating their consequences (including impacts on health), and identifying policy options.[25] The Commission released a report in December 2008 finding that climate change would be likely to adversely affect the health of Virginians, with a particular impact on children, the elderly, and other vulnerable populations.[26] These findings contributed to enactment of state legislation related to climate change and renewable energy, including legislation authorizing local governments to create green roof incentives, requiring investor-owned utilities to obtain 15% of their distributed energy from renewable sources, and creating incentives for the use of advanced biofuels.[27] Through this GEO, Governor Kaine helped to establish a knowledge base and focus the political agenda on climate change, which led to state legislative action.

Controlling state operations

While overseeing the management of their state, governors face many administrative decisions that can affect public health. As the head of the executive branch and state administration, the governor has certain powers to direct the action of the state as a market participant and to take public health into account.

In 2009, Governor Paterson used this power to prohibit state agencies from purchasing bottled water to "promote sound environmental practices," encourage use of New York's tap water, conserve energy, reduce emissions of greenhouse gases, and save taxpayer dollars.[28] Colorado followed suit when, in 2010, Governor Bill Ritter, Jr., used a GEO to prohibit state agencies from purchasing bottled water unless "water supply is unavailable, bottled water is needed to protect safety and health, and for use in emergencies."[29]

The power to control state operations also allows governors to issue executive orders related to state employment and facilities. Governor Kaine used this power in 2006 to issue a GEO that, with few exceptions, prohibits "smoking in offices occupied by executive branch agencies and institutions, including institutions of higher education," buildings operated by the executive branch, and state vehicles "to improve the health of employees and minimize health risks in the workplace."[30] In so doing, Governor Kaine relied on powers derived from both the Virginia Constitution and relevant state laws.[31,32] Until Virginia enacted legislation addressing environmental smoke in state and local government buildings in 2009,[33] this GEO protected state employees and visitors in state buildings and vehicles from secondhand smoke exposure.

DISCUSSION AND POLICY IMPLICATIONS

GEOs advance public health by establishing and implementing state policies. GEOs may be especially important public health tools when legislation, regulation, or litigation is not immediately available or sufficient. To effectively advocate for a GEO that could advance the public's health, public health professionals must appreciate its advantages and disadvantages.

A GEO's primary advantage is to allow for swift formulation and implementation of public health policy. With fewer decision makers to convince, advocating for a GEO may be less cumbersome than advocating for

legislation. The speed with which GEOs can be issued may be particularly useful to tackle a pressing public health problem that demands immediate attention. The inherent flexibility and adaptability of GEOs also allow for rapid responses to changing circumstances. Additionally, GEOs provide opportunities to test innovative public health programs that, if successful, could be incorporated into state law through legislation.

Despite these benefits, GEOs present certain disadvantages. Most notably, each state places its own limitations on the scope of GEOs, which could potentially limit their public health utility. Furthermore, a governor's successor may override any GEO with a superseding GEO or by failing to renew an expiring one. The state legislature may enact a bill overriding a GEO or the courts may rule that a GEO exceeds the governor's authority and is therefore invalid.

In deciding whether to advocate for a GEO rather than an alternative legal tool, it is important to recognize that GEOs are not appropriate for addressing public health issues in every state. However, particularly during legislative gridlock or inaction by a state agency, a GEO may be a useful instrument for change. The GEO may be especially helpful as an incremental step in advancing a public health policy that may otherwise face stagnation. Such an action could set the stage for more comprehensive or permanent change.

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NCHS Dataline

The National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention has released preliminary birth and death statistics for 2011. The 2011 preliminary mortality report documents a record low age-adjusted death rate and indicates that life expectancy and infant mortality were unchanged from 2010. According to the birth report, teen childbearing reached a record low, as did the general fertility rate for the United States. A new NCHS report describing the current contraceptive patterns in the U.S. shows that the pill and female sterilization are the most popular methods of contraception. And another new report examines the frequency of human immunodeficiency virus (HIV) testing.

2011 PRELIMINARY DEATH DATA RELEASED

A new report by NCHS, "Deaths: Preliminary Data for 2011,"[1] documents a record low age-adjusted death rate of 740.6 deaths per 100,000 population in 2011, down from 747.0 deaths per 100,000 population in 2010. From 2010 to 2011, the age-adjusted death rates decreased significantly for five of the 15 leading causes of death: diseases of the heart; malignant neoplasms; cerebrovascular diseases; Alzheimer's disease; and nephritis, nephrotic syndrome, and nephrosis. The age-adjusted death rate increased for six leading causes of death: chronic lower respiratory diseases, diabetes mellitus, influenza and pneumonia, chronic liver disease and cirrhosis, Parkinson's disease, and pneumonitis due to solids and liquids. From 2010 to 2011, the age-adjusted death rate decreased by 1.4% for males and 0.5% for females and was down in each of the racial/ethnic groups. The death rate declined by 1.0% for white males, 3.3% for black males, and 4.8% for Hispanic males. The death rate declined by 1.6% for black women and 2.5% for Hispanic women. The drop of 0.2% for white females was not significant.

The preliminary number of deaths in the U.S. for 2011 was 2,513,171. The crude death rate of 806.6 per 100,000 population in 2011 was 0.9% higher than the rate of 799.5 per 100,000 population in 2010. Statistically significant decreases in mortality from 2010 to 2011 were registered for those younger than one year of age and across age groups for those aged 65 years and older. Mortality for those aged 1–4, 5–14, 15–24, 35–44, 45–54, and 55–64 years did not change significantly from 2010 to 2011, but the mortality rate increased for those aged 25–34 years. The preliminary estimate of life expectancy at birth for the total population for 2011 was 78.7 years, which was the same as in 2010. Life expectancy for males in 2011 was 76.3 years of age; for females, it was 81.1 years of age.

The preliminary infant mortality rate for 2011 was 6.05 infant deaths per 1,000 live births, which did not differ significantly from the final 2010 rate. The infant mortality rate has either remained the same or declined each year since 1958. The neonatal (i.e., infants aged <28 days) mortality rate was 4.04 per 1,000 live births in 2011, which was not significantly different from 2010. The postneonatal (i.e., infants aged 28 days to 11 months) mortality rate decreased by 4.3%, from 2.10 deaths per 1,000 live births in 2010 to 2.01 deaths per 1,000 live births in 2011. The three leading causes of infant mortality in 2011 were congenital malformation, disorders related to short gestation and low birthweight, and sudden infant death syndrome.

The report presents preliminary U.S. data on deaths, death rates, life expectancy, leading causes of death, and infant mortality for 2011 by selected characteristics, such as age, sex, race, and Hispanic origin. Data in this report are based on death records filed in state vital statistics offices and reported to NCHS through the National Vital Statistics System, comprising more than 98% of the demographic and medical files for all deaths in the U.S. in 2011. Comparisons are made with 2010 final data.

BIRTH STATISTICS FOR 2011 PUBLISHED

According to a new report, "Births: Preliminary Data for 2011,"[2] the preliminary number of U.S. births for 2011 was 3,953,593, which was 1% fewer births than in 2010. The general fertility rate (63.2 per 1,000 women aged 15–44 years) declined to the lowest rate ever reported for the U.S. The number of births declined for most racial/ethnic and Hispanic-origin groups in 2011. The birth rate for teenagers aged 15–19 years fell 8% in 2011 to 31.3 births per 1,000 population—another record low—with rates declining for younger and older teenagers and for all racial/ethnic and Hispanic-origin groups. The birth rate for women aged 20–24 years also declined to a historic low of 85.3 births per 1,000 population. The birth rate for women in their early thirties was unchanged in 2011 but rose for women aged 35–39 and 40–44 years.

The birth rate for women in their late forties was unchanged in 2011. The birth rate, the number of

births, and the percentage of births to unmarried women each declined for the third consecutive year. The birth rate was 46.1 per 1,000 unmarried women aged 15–44 years, and the percentage of births to unmarried women was 40.7%. The cesarean delivery rate of 32.8% was unchanged from 2010. The preterm birth rate in 2011 fell for the fifth straight year to 11.7%, with declines reported for each of the largest racial/ethnic and Hispanic-origin groups. The 2011 low birthweight rate was 8.1%, down slightly from 8.2% in 2010.

The report presents preliminary data on births and birth rates based on approximately 100% of the 2011 birth certificates filed in state vital statistics offices and reported to NCHS through the National Vital Statistics System. This report includes data on births by age, live-birth order, race/ethnicity, and Hispanic origin of mother. Data on marital status, cesarean delivery, preterm births, and low birthweight are also presented. Comparisons are made with final 2010 data.

CURRENT PATTERNS OF CONTRACEPTION

Findings from the National Survey of Family Growth (NSFG) for 2006–2010, which are published in "Current Contraceptive Use in the United States, 2006–2010, and Changes in Patterns of Use Since 1995,"[3] show that 62% of women of reproductive age are currently using contraception. The NSFG is based on personal interviews with a national sample of women and men aged 15–44 years.

The survey reports that of women using a contraceptive method during the month of the interview, the most common methods used were the pill (28% or 10.6 million women) and female sterilization (27% or 10.2 million women). Use of intrauterine devices as a current method has increased since 1995 (from 0.8% in 1995 to 5.6% during 2006–2010). Fewer women reported that their partners were using condoms as their current, most effective contraceptive method. Of women at risk of an unintended pregnancy, 11% reported not currently using a method of contraception.

Use of contraception and the effectiveness of the method used to prevent pregnancy are major factors affecting national pregnancy and birth rates and the ability of women to plan their pregnancies. The report presents national estimates of contraceptive use among women of childbearing age (15–44 years) during 2006–2010. Selected comparisons are made with 1995 data to describe changes in contraceptive use and method choice over time. The report is based primarily on the sample of 12,279 women interviewed during 2006–2010; some tables are supplemented with the sample of 10,847 women interviewed in 1995.

HIV TESTING

"HIV Testing in the U.S. Household Population Aged 15–44: Data from the National Survey of Family Growth, 2006–2010"[4] presents nationally representative estimates and trends for HIV testing among the U.S. household population aged 15–44 years. The report includes data on lifetime experience with HIV testing and HIV testing in the past year, including testing conducted as part of prenatal care.

Among U.S. women aged 15–44 years, the percentage ever tested for HIV outside of blood donation increased significantly from 35% in 1995 to 55% in 2002 to 59% in 2006–2010. Among men aged 15–44 years, the percentage ever tested outside of blood donation fell from 47% in 2002 to 42% in 2006–2010. During 2006–2010, the proportions ever tested for HIV outside of blood donation were similar for Hispanic and non-Hispanic white women (about 60% tested) and for Hispanic and non-Hispanic white men (roughly 40% tested). However, a higher percentage of non-Hispanic black women (75%) and non-Hispanic black men (61%) had ever been tested for HIV outside of blood donation. Based on 2006–2010 data, 21% of women were tested for HIV within the 12 months prior to interview compared with 13% of men.

Data for this report came from the 2006–2010 NSFG, which consists of 22,682 interviews with men and women aged 15–44 years conducted from June 2006 through June 2010. The overall response rate for the 2006–2010 NSFG was 77%: 78% for women and 75% for men. The NSFG collects data on factors related to childbearing and reproductive health.

NCHS Dataline was prepared by Sandra S. Smith, MPH, Communications Consultant at the National Center for Health Statistics.

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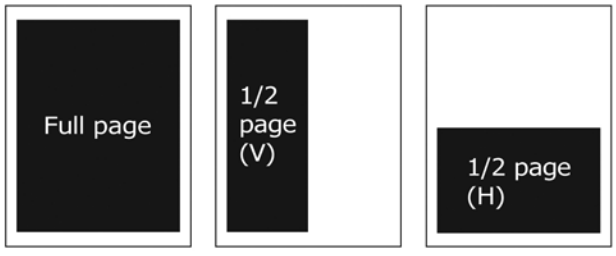

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