Vaccination, Prevention, and Older Adults

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Vaccination, Prevention, and Older Adults
Robert B. Hudson, Editor, Public Policy & Aging Report*

In an underexplored application, this issue of PP&AR brings together the worlds of medicine, human behavior, and public policy. As this collection of articles makes clear, the arena of vaccinations and older adults holds great promise for improving quality of life and cost savings but is plagued with widespread underutilization. Vaccines have proven to be, with some variation, an important preventive intervention whose application is uneven and intermittent across the older adult population. Increasing vaccination rates among elders holds considerable promise, but questions remain about how to increase access and measure vaccine efficacy, as well as how to design, finance, and administer programs most effectively.

The lead article by H. Keipp Talbot and William Schaffner contrasts the shortcomings of the “nonsystem” of vaccination for adults with the highly effective system long in place for children and adolescents. Adult vaccination might not bring the overwhelming results that polio, measles, and rubella vaccines have had among the young, but it can be effective against influenza and pneumonias affecting older people. The authors briefly review financial issues associated with Medicare, as well as delivery issues in which both medical practices and pharmacies are involved. They conclude by calling attention to a major conference that took place in Atlanta in May 2012, which brought together scientific stakeholders in order to move forward a vaccination agenda for elders.

Janet McElhaney systematically reviews how vaccines can meaningfully address many infectious diseases—notably influenza, pneumonias, shingles, and post-herpetic neuralgia. She observes that although vaccine efficacy declines with age (i.e., immune senescence), research generally supports the proposition that these interventions not only are cost effective but also can be cost saving. In addition, she argues that vaccination among older people should be viewed through the lens of compression of morbidity—that is, keeping in mind that primary prevention reduces the risks for morbidity and disability.

Rosa Baier sets forth a three-part approach to improving vaccination rates among older adults, calling for strategies aimed at access, demand, and system change. Based in part on work that she and colleagues have conducted in Rhode Island, she recommends increased access through convenience mechanisms, such as expanded office hours for immunization in clinics, pharmacies, workplaces, and home-based settings. Heightening consumer demand through

Continued on page 30
Vaccination, one of the greatest accomplishments in medicine, provides an opportunity to prevent much of the death and morbidity caused by infection. Although not perfect, the use of vaccines in infants, children, and adolescents in the United States has been very successful. The collaborative public and private delivery of vaccines has virtually eliminated disparities of income, race and ethnicity, and geography in the occurrence of vaccine-preventable diseases in children. Polio, once a feared disease, has been eradicated in the United States using vaccine; Haemophilus influenzae meningitis, measles, rubella, diphtheria, and neonatal tetanus are truly rare occurrences now, with the vast majority of children immunized. Unfortunately, no comparable national program exists to ensure the appropriate immunization of adults. The “nonsystem” of adult immunization in this country differs from the comprehensive pediatric system in numerous critical aspects.

The routine immunization schedule for infants and young children is primarily based on age. Regularly scheduled well-child medical visits coincide with vaccination time-points, and all the recommended vaccines are given to all children with relatively few exceptions. Not so for adults. No routine office visits occur for adult vaccinations. This situation is further complicated by a set of vaccine recommendations for adults that are dependent on an individual’s age, occupation, lifestyle choices, and comorbid conditions. Hence, no universal vaccination recommendation exists other than for annual influenza immunization.

The indications for hepatitis B immunization offer an example of how complicated vaccine recommendations can be. Adults for whom the immunization is recommended include those who have sex with or live with a person who has hepatitis B, those who have sex with more than one partner, men who have sex with men, anyone who seeks care in a sexually transmitted disease clinic, those who use injectable illicit drugs, those on hemodialysis, those with chronic liver disease, individuals under 60 years old with diabetes, and those whose employment involves contact with human blood or the developmentally disabled. Clearly, such baroque recommendations are difficult to remember and challenging to implement. All the more so, because most adults visit their health care providers only for illness-related reasons and so the focus of the encounter is therapeutic rather than preventive, resulting in missed opportunities for immunization. Furthermore, adults often do not have a traditional primary care provider or, if they do, may change providers. In addition, many adults, particularly older adults, receive most of their care from specialists who are unlikely to provide vaccinations. Even well-motivated physicians struggle with verifying whether a new patient has been vaccinated previously because the vaccine registries of most states do not track adult immunizations.

As of 2010, childhood coverage for polio, measles-mumps-rubella, varicella, and three or more doses of hepatitis B vaccines all exceeded 90 percent (Black, Wooten, Yankey, & Kolasa, 2011). Although many factors contribute to this success, among the most compelling are the state mandates that require children to have received certain vaccinations before attending daycare or school. Although permitted exemptions have become a problem in a few states, for the most part parents in the United States comply, producing very high immunization coverage. In contrast, few compulsory immunizations are in place for adults. Exceptions include members of the military and health care workers, who must receive a basic series of vaccinations. Indeed, some health care...
organizations recently have begun to require annual influenza vaccination for employees, resulting in more than 90 percent of employees being vaccinated. Similarly, some states have required that nursing homes vaccinate their residents against influenza and pneumococcal disease. That said, relatively few adults (especially older adults) are subject to immunization mandates.

Vaccine effectiveness is another key contributor to low adult vaccination rates. Childhood vaccines are highly effective, often resulting in the complete elimination of disease from large populations. Vaccinations in adults, however, have had their best success in reducing the morbidity and mortality of infectious diseases. The inability to eliminate disease completely has misled many in the United States, both health care providers and patients, to believe that vaccines targeted for adults are not sufficiently effective. Although pneumococcal polysaccharide vaccine has not been shown convincingly to prevent pneumonia, it has been demonstrated to prevent bacteremia, meningitis, and empyema caused by Streptococcus pneumoniae (Shapiro et al., 1991).

Influenza vaccine has been found to be 60 percent effective in reducing hospitalization in older adults (Talbot et al., 2011). Though perhaps not perfect, influenza vaccination substantially contributes to the prevention of serious disease in older adults. As the older population continues to grow, research will need to continue to produce better vaccines for the aging immune system. Until that time, immunizations will need to use the current vaccines, which do reduce morbidity and mortality. To paraphrase French philosopher Voltaire, waiting for perfection is the greatest enemy of the current good.

Beyond all else, the most formidable challenge to the immunization of older adults is financial. Essentially all adults ages 65 and older participate in Medicare, and one would think that the program provides efficient and comprehensive immunization services. Not so, however. When Medicare first was enacted in 1965, it was designed to cover only diagnostic and therapeutic services. Preventive care was excluded in order to contain the cost of this large new program. Over time, Congress gradually has added certain preventive services; currently, Medicare Part B covers influenza, pneumococcal, and hepatitis B vaccines.

Providers purchase the vaccines and, after their administration, Medicare reimburses the cost at 95 percent of the average wholesale price. This system often enables providers to realize a small profit, which helps cover the expenses associated with vaccine ordering, record keeping, and the like. Providers also receive an administration fee, which varies according to geographic region and whether more than one vaccine was administered during the same visit. Pharmacists and community vaccinators participating in the program have made substantial contributions to providing vaccination services to older adults. Although these provisions seemingly have eliminated the financial barrier to receiving these immunizations, only an estimated 60 percent and 70 percent of adults 65 years of age and older have been vaccinated appropriately with pneumococcal (Williams, Lu, Singleton, Bridges, & Wortley, 2012) and influenza (Setse et al., 2011) vaccines, respectively. Marked racial and ethnic disparities also persist. For example, of adults 65 years of age and older, approximately 64 percent of Caucasians but only 46 percent of African Americans have received pneumococcal vaccine.

Influenza, pneumococcal, and hepatitis B vaccines are not the only vaccines recommended for older adults. After a primary immunization series (usually in childhood), tetanus-diphtheria (Td) vaccine boosters are recommended every 10 years. Medicare, however, does not provide this fundamental vaccination as a covered preventive service. Older adults have to pay for Td vaccine and its administration out of pocket. Ironically, should an older adult sustain an injury and be given a Td booster as part of routine wound care, it would be covered by Medicare because, in that context, the administration of Td would be considered part of therapy for the injury.

If this dysfunctional circumstance were not sufficient, consider two vaccines that in recent years have been recommended for virtually everyone covered by Medicare: zoster (shingles) and tetanus-diphtheria-acellular pertussis (Tdap). The recommendations for both these vaccines were issued after the Medicare prescription drug benefit program (Medicare Part D) had been enacted, and both were assigned to this program. This situation presents several difficulties. First, Medicare beneficiaries who do not elect to participate in Part D must pay for these vaccines themselves. Individuals who elect to participate in Part D must select among a menu of available drug plans. Fortunately, all the plans are expected to cover all commercially available vaccines not covered under Part B. However, some plans have co-pays or deductibles and some may require the patient to pay for the vaccination and then bill the plan to recover the outlay. Both patients and physicians often are uncertain about the benefit structure, making them hesitant to pursue appropriate vaccination.

Furthermore, as a prescription drug benefit, Part D was designed to be implemented by pharmacists; physicians generally do not participate as a network pharmacy, making it difficult for them to administer vaccines.
covered under Part D in their offices. Physicians at some medical centers, including ours at Vanderbilt University School of Medicine, solve this problem by writing a prescription for the vaccine and having the pharmacist administer it. Another method, but one that is not ideal, is that a patient picks up the vaccine and brings it to a doctor’s office for administration (called brown bagging). This practice should be discouraged because the temperature-maintenance requirements of the vaccine cannot be guaranteed, and loss of potency may result. Increasingly, older adults may go directly to pharmacies to receive all the vaccines Medicare covers in both Part B and Part D. Although several legislative attempts have been made to include all recommended vaccines under Part B, none have yet been successful.

Despite the challenges, recognition of the importance of adult vaccination has recently increased. In May 2012, the first National Adult Immunization Summit was held in Atlanta. The 288 attendees represented 150 different organizations, including public health agencies, groups devoted to older adults, vaccine manufacturers, provider organizations, federal agencies, insurance providers, and academicians. Five working groups were established to continue work after the meeting in order to reduce the barriers to adult immunizations. In addition, the Gerontological Society of America and the National Foundation for Infectious Diseases have undertaken campaigns to improve adult immunizations. Together, the summit and these campaigns symbolize a new dedication to the improvement of adult vaccinations, with the goal of reducing morbidity and mortality in older adults.

In addition, renewed research emphasis is being placed on introducing new and improved vaccines for older adults. In 2010, for example, a high-dose influenza vaccine was licensed for adults 65 years of age and older, and a conjugated pneumococcal vaccine was licensed as well. These new vaccines emphasize the opportunity for providing vaccines targeted at the special needs of older adults. The importance of vaccination is highlighted by the number of Americans who die due to preventable infections every year: 44,000 deaths due to pneumococcus (Hinman, Orenstein, & Schuchat, 2011); 630 deaths due to influenza (Thompson et al., 2010); 3,000 deaths due to hepatitis B (Centers for Disease Control and Prevention, 2010); and 26 deaths due to tetanus (Hinman et al., 2011). Immunization provides an opportunity to eliminate these deaths and better protect older adults. Much work remains to be done to ensure that each older adult in the United States receives the immunizations needed to maximize quality of life.

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References

Immunization and Aging: Adding Life to Years

Aging of the population in developed and developing countries and rising rates of chronic diseases or so-called noncommunicable diseases have become global issues. The population in developed countries is beginning to age rapidly due to increases in life expectancy and declining birth rates: From 2010 to 2011 in the United States, the population ages 65 and older grew by 917,000 individuals, and the number of people under age 18 declined by 190,000 (Population Reference Bureau, 2012). Although noncommunicable diseases, including cardiovascular maladies, diabetes, cancers, and chronic respiratory conditions, are the leading causes of death, risk for pneumonia in the context of these comorbidities increases with age (Jackson & Janoff, 2008). The goal of healthy aging is to promote independence and prevent disability that leads to functional decline and frailty.

Immunization and Aging: Adding Life to Years

Infectious illnesses may contribute substantially to the disability that occurs with complications of noncommunicable diseases; in fact, the six leading causes of catastrophic disability (defined as the loss of three or more basic activities of daily living)—including stroke, hip fracture, congestive heart failure, pneumonia, coronary heart disease, and cancer (Ferrucci, Guralnik, Pahor, Corti, & Havlik, 1997)—can all be a complication of influenza illness (Hak et al., 2004; Neupane, Walter, Krueger, Marrie, & Loeb, 2010; Reichert et al., 2004; Thompson et al., 2004). Given that the total annual excess cost of hospital-treated pneumonia was conservatively estimated to cost more than $7 billion in 2010 (Thomas et al., 2012), effective vaccination against influenza, pneumococcus, and other infectious diseases represents a significant opportunity to prevent disability and reduce health care costs.

World Health Organization Consultation on Immunization and Aging

In 2002, the World Health Organization developed a policy framework on active aging to promote interventions that maintain and improve health throughout life. Because noncommunicable diseases contribute to the increased risk of infectious diseases that can cause severe illness, disability, and death as people age, a focus on vaccine-preventable disability would support policies to promote healthy aging and quality of life through immunization. The third of a series of World Health Organization workshops, held in March 2011, brought together 30 scientists from the public and private sectors for an ad hoc consultation on immunization and aging (Thomas-Crusells, McElhaney, & Aguado, in press). The major infectious diseases identified as key contributors to morbidity and mortality in developing countries were those causing acute respiratory illness (including influenza and pneumococcus), digestive tract infections (including Clostridium difficile), and shingles (herpes zoster). Vaccines are available for a limited number of these pathogens in developed countries, but coverage rates remain low in many countries. Workshop participants also recognized that the effectiveness of currently available vaccines is diminished with aging due to a decline in immune function—a phenomenon referred to as immune senescence. The causes of this decline remain poorly understood and so leave a knowledge gap regarding what is needed to develop new and more effective vaccines for the population ages 65-plus.

Other vaccine-preventable diseases, such as herpes zoster and post-herpetic neuralgia, have also been shown to affect functional status and quality of life (Schmader et al., 2007). In addition, reemerging infectious diseases, such as pertussis, and diseases of greater severity in older people—including respiratory syncytial virus, Clostridium difficile, and norovirus—should also be considered targets for vaccine-preventable disability. Vaccines against tuberculosis, malaria, and HIV/AIDS are needed as well, particularly in developing countries.

Vaccine-Preventable Disability

The majority of older individuals will experience usual aging, in which independence is maintained but risk for complicated illness and hospitalization is associated with one or more underlying chronic diseases. In hospitalized older adults, more than 50 percent have at least one comorbidity, and 17.8 percent have three or more comorbidities (Elixhauser, Steiner, Harris, & Coffey, 1998). Given that one in three older people admitted to an
Immunization in Older Adults

Acute-care hospital will experience an increase in disability relative to their pre-morbid state and that most of these individuals will never recover (Covinsky, Eng, Lui, Sands, & Yaffe, 2003), it is critical to focus on primary prevention strategies that prevent hospitalization. From a public health perspective, vaccination should be viewed under the paradigm of compression of morbidity, the reduction of cumulative lifetime morbidity through primary prevention that reduces health risks for morbidity and disability (Fries, 2000). In the primary prevention of disability and frailty in older adults, vaccination has the potential to compress morbidity to the extremes of life and improve quality of life.

Diabetes, as well as cardiovascular and lung diseases, is common in older adults and contributes to the risk for catastrophic disability during acute infections. These common medical conditions and related medications—along with mental and psychosocial health issues, as well as functional dependence—may all interact with the responsiveness of the immune system. The efficacy of currently recommended vaccines (see Figure 1) declines with advancing age and the accumulation of chronic diseases. In order to develop more effective vaccines for the older population, ongoing research is working to close the knowledge gap in how chronic diseases affect immune response in older adults.

Impact of Influenza

Influenza is foremost among all infectious diseases in terms of risk for serious complications and death and is the most vaccine-preventable disease in older adults. Influenza is estimated to cause at least 36,000 deaths annually, and more than 186,000 hospitalizations from respiratory and cardiovascular complications of influenza occur annually in the United States (Thompson et al., 2004; Thompson et al., 2003); A/H3N2 strains of influenza are the leading cause of death due to viral respiratory illness in the population ages 65 and older (Thompson et al., 2003). Influenza has been linked to deaths from pneumonia, heart attacks, and strokes, as well as exacerbations of congestive heart failure and diabetes (Reichert et al., 2004); these complications of influenza are also associated with high risk for catastrophic disability. The impact of influenza on disability rates in older adults and the potential for lost years of active life expectancy is only beginning to be recognized. Thus, recommendations for annual influenza vaccination continue into the older age groups but are particularly important for those ages 65 years and older, regardless of health status.

Influenza Vaccination

Influenza vaccine strains are updated annually to ensure that antibodies to the relevant predicted strains of the influenza A/H3N2 and A/H1N1 subtypes and influenza B are stimulated. Influenza vaccination has been shown to significantly reduce hospitalizations and deaths due to influenza-related pneumonia, heart attacks, strokes, and exacerbations of congestive heart failure (Nichol, 2003; Nichol et al., 2003; Nichol, Nordin, Nelson, Mullolloy, & Hak, 2007). However, in spite of widespread influenza vaccination programs, influenza-related hospital admission rates continue to increase in older adults, particularly in those with underlying chronic diseases.
Impact of Pneumococcal Infections

Streptococcus pneumoniae is the leading cause of community-acquired infections, including bacterial pneumonia, meningitis, and bacteremia, accounting for 5 percent to 58 percent of the 25 per 1000 of annual community-acquired pneumonias in older adults (Janssens & Krause, 2004). Although antibiotics can be used to treat these infections, adverse effects, emergence of drug-resistant strains, and drug costs limit their use to individualized treatment. Delays in the diagnosis of pneumonia due to changes in mental status (O’Keeffe & Lavan, 1997) and the absence of typical symptoms with increasing age (Fedullo & Swinburne, 1985) prolong hospital stays and predict increased disability.

Controversies in Estimates of Influenza Vaccine Effectiveness

Estimates of vaccine efficacy can be established only in randomized, placebo-controlled trials documenting laboratory-confirmed influenza illness. In the case of older adults, the only placebo-controlled trial extant provided an estimate of vaccine efficacy of 50 percent for the prevention of influenza in relatively healthy older adults (Govaert et al., 1994). Such trials are no longer considered ethical in the context of a standard of practice for influenza vaccination in all individuals of 65-plus years, so current estimates of vaccine-mediated protection are based on observational studies of influenza-like illness (i.e., illness not confirmed by laboratory testing) comparing vaccinated and unvaccinated older adults. However, no uniform agreement on vaccine benefit based on subsequent epidemiologic studies exists, and whether vaccination truly benefits older adults continues to be controversial. Methodological differences in selecting the control period for these observational studies, the specificity of the case definition, and the adjustment for functional status and life expectancy have led to estimates ranging from no mortality benefit (Jackson, Jackson, Nelson, Neuzil, & Weiss, 2006; Jackson et al., 2008) to varying degrees of benefit related to the complications of influenza disease (Nichol et al., 2003; Nichol et al., 2007). Given that influenza vaccination remains a cost-saving medical intervention in older adults in spite of the well-recognized decline in vaccine efficacy with aging, clinical protection against illness and hospitalization (mediated by cellular immunity), rather than sterilizing immunity against infection (mediated by antibodies), may be a more realistic target for the future development of vaccines for elders.

Pneumococcoccal Vaccination

The current 23-valent vaccine containing pneumococcal capsular polysaccharide (PPV) is cost-effective in older adults (Sisk et al., 1997); overall effectiveness for preventing pneumococcal bacteremia in older adults is estimated to be approximately 50 percent (Jackson & Janoff, 2008), but the prevention of pneumococcal pneumonia has been more difficult to evaluate. Antibody responses to PPV are similar in healthy young and older adults but opsonophagocytic activity, the major effector mechanism for clearing pneumococcus, appears to decline with aging (Kolibab, Smithson, Rabquer, Khuder, & Westerink, 2005). A significant decline in antibody titers to PPV at six years following vaccination has been observed (Musher et al., 1993), suggesting the need for booster vaccination to maintain protection. However, more recent studies have raised concerns that tolerance to PPV may develop with repeated vaccination (O’Brien, Hochman, & Goldblatt, 2007). Protein-conjugated polysaccharide vaccines have been developed to facilitate T-cell cooperation and a 13-valent formulation has been approved, but licensure awaits the completion of a randomized trial being conducted in the Netherlands.

Impact of Herpes Zoster and Post-Herpetic Neuralgia

Older individuals bear the greatest burden of illness related to herpes zoster or shingles, a reactivation of varicella-zoster virus from a previous chickenpox infection. Each year between 600,000 and 1 million Americans develop zoster, a risk that dramatically increases with age, with an astonishing prevalence of up to 50 percent by age 85 (Hope-Simpson, 1965; Schmader, 2001). Reactivation of varicella-zoster virus causes a painful dermatomal rash called shingles that is often followed by post-herpetic neuralgia, a chronic pain syndrome associated with significant disability in older people. The incidence of post-herpetic neuralgia is almost negligible before age 50, but at least 10 percent of patients 70 years and older, as well as 15 percent of those over age 80, develop post-herpetic neuralgia following an attack of shingles (Bowsher, 1999).
Zoster Vaccination

A randomized trial of a shingles vaccine containing the Oka strain—an attenuated form of wild-type varicella-zoster virus (at 14 times the dose contained in the childhood chickenpox vaccine)—with a total of 38,000 participants showed a 60 percent reduction in burden of illness (based on intensity and duration of the pain), a 50 percent reduction in shingles cases, and a 66 percent reduction in those shingles cases complicated by post-herpetic neuralgia (Oxman et al., 2005). The current recommendations based on cost-effectiveness evaluations is one dose in those ages 60 years and older, even in those who have had shingles.

Tetanus Vaccination

Tetanus is caused by the toxin released by Clostridium tetani infection introduced through a deep puncture wound or laceration of the skin. Tetanus is effectively controlled through vaccination every 10 years and most of the cases occur in under-vaccinated individuals, particularly in older adults (Kretsinger et al., 2006). Due to the reemergence of whooping cough, it is now recommended that acellular pertussis be included in one of the tetanus diptheria booster vaccinations.

Summary

A decline in immune function and increased risk for complicated illness from a variety of infectious diseases is a hallmark of aging. Although the immune response to vaccination declines with aging, a number of available vaccines have been shown to be cost effective and even cost saving in older adults. The prevention of illness and hospitalization leading to disability and functional decline should be the primary focus in the evaluation of vaccine effectiveness. Ongoing research will foster better understanding of how to develop new vaccines against a variety of infectious diseases to add life to years in an aging population.

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Potential Conflicts of Interest

Janet E. McElhaney has received the following (in alphabetical order) in the past five years: Abbot Pharmaceuticals (consultancy and honoraria), CSL (honoraria), GlaxoSmithKline (research funding, consultancy, honoraria, and site PI for clinical trials), Merck (consultancy, honoraria, site PI for a clinical research study and a clinical trial), Novartis (honoraria), Novavax (consultancy), and Sanofi Pasteur (consultancy, honoraria, site PI for clinical trial and Data Safety and Monitoring Board for clinical trial).

References


Immunization in Older Adults


Although immunization remains the most effective protection from infectious disease (Segal-Gidan, 2010) and the Advisory Committee on Immunization Practices recommends several vaccines for older adults (Centers for Disease Control and Prevention [CDC], 2012b), vaccination rates are low (CDC, 2012a)—in fact, they are well below national targets (Stefanacci, 2012; U.S. Department of Health & Human Services [HHS], 2012a). For example, only about 65 percent of adults age 65 years or older received influenza vaccination in 2010 (CDC, 2012a). This percentile falls far short of the Healthy People 2020 goal of 90 percent (HHS), despite the fact that approximately 60 percent of influenza-related hospitalizations and 90 percent of influenza-related deaths occur among patients in this age group (National Council on Aging, n.d.). Similarly, only 60 percent and 10 percent of adults ages 65 years and older in 2010 received the pneumococcal pneumonia or the herpes zoster vaccine, respectively, although both vaccines are indicated for all older adults (CDC, 2012a).

The Healthy People 2020 goals reflect a consensus to work toward improving immunization rates in the United States and provide a helpful framework for regularly assessing national progress (HHS, 2012a). However, public-private collaboration and targeted interventions are necessary to translate the evidence base into practice and achieve these goals. Systematic reviews by multi-stakeholder groups, such as the Task Force on Community Preventive Services, have identified numerous strategies to increase vaccination rates (CDC, 2005; Guide to Community Preventive Services, 2005) and can serve as a guide for health care providers, payers, and other stakeholders seeking interventions. These reviews caution that insufficient evidence exists for the efficacy of many interventions when implemented alone; they indicate that multicomponent interventions are the most effective and suggest that multiple categories of interventions be implemented simultaneously for maximum effect (CDC, 2005; Guide to Community Preventive Services; Task Force on Community Preventive Services).

Specifically, these groups suggest (a) an intervention to enhance access to vaccination plus (b) at least one intervention to increase consumer demand for vaccination and/or (c) at least one systems change or policy-based intervention. For example, an intervention that expands physician office hours to improve access to vaccine might be coupled with one to increase patient awareness about immunizations and another to provide monetary incentives to providers to increase their vaccination rates. See Figure 1 for more examples.

In this paper, I discuss strategies within each of the aforementioned categories, including select interventions from the evidence base and promising strategies based on experience improving adult vaccination in Rhode Island. I also suggest developing strategies to measure interventions and gauge progress over time—for example, by comparing performance against targets, such as the Healthy People 2020 immunization and infectious disease goals (HHS, 2012a). Data can inform a plan-do-study-act
quality-improvement process to identify the root causes of low vaccination rates, and then test and spread successful strategies (Institute for Healthcare Improvement, 2011). This approach enables efficient and effective use of resources by ensuring that interventions are selected to target identified needs and that midcourse corrections can easily be incorporated, thus allowing the flexibility to adapt to real-world challenges and barriers.

**Access**

Strategies to increase patient access to vaccine range from increasing insurance coverage to reducing (or eliminating) out-of-pocket costs and ensuring convenient ways to obtain vaccinations, such as expanded primary care office hours, home visits, workplace clinics, or pharmacy clinics (Guide to Community Preventive Services, 2005; Thomas, Russell, & Lorenzetti, 2010). In 2006, Rhode Island improved vaccine access by becoming the first state to centralize vaccine purchase and distribution. By assuming financial responsibility for the vaccine supply, the state health department stabilized the vaccine market and protected providers from financial risk.

The approach was central to the state’s implementation of a vaccine distribution strategy that targeted at-risk populations, including older adults, and aimed to improve patient access to vaccine in a range of clinical and community settings (American Lung Association, 2010). These settings included primary care—which historically provides 60 percent to 70 percent of all influenza vaccinations and can bill for vaccine administration—as well as pharmacies, schools, and workplaces, where patients have not historically had access to vaccines. In the first year of the program, Rhode Island led the nation in the vaccination of Medicare beneficiaries. The state was also able to ensure sufficient supply in primary care offices, addressing a known barrier that was beginning to reduce access: Practices that had encountered trouble accessing the vaccine due to cost or limited supply had begun to stop providing influenza vaccination.

Centralized distribution reengaged these practices, ensuring their continued participation as an active and engaged segment of the vaccination workforce.

When choosing any intervention, stakeholders and policymakers should weigh the added benefit of that strategy against unintended consequences, particularly for interventions that target how and where consumers seek health care. For example, if vaccine access increases outside of the physician office, such as at the pharmacy, face-to-face physician office visits may decline. This decline could affect the patient-provider relationship, as well as the delivery of patient education and other preventive services. It would also require capturing vaccination data from disparate providers, which could be difficult in states where vaccine is not centrally distributed (central distribution facilitates keeping track of the number of doses distributed) or in states with a high percentage of national pharmacy chains (pharmacy chains may obtain vaccine through their corporate

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**Figure 1. Menu of intervention strategies targeting older adult vaccination rates, with examples.**

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<td>Out-of-pocket costs</td>
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<td>Performance measurement</td>
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<td>Expanded office hours</td>
<td>Education/activation</td>
<td>QI initiatives</td>
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<td>Centralized vaccine purchase and distribution</td>
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**Figure 2. Quality improvement process to identify the root causes of low vaccination rates, and then test and spread successful strategies.**

The Institute for Healthcare Improvement recommends a quality improvement process to identify the root causes of low vaccination rates, and then test and spread successful strategies (Institute for Healthcare Improvement, 2011). This approach enables efficient and effective use of resources by ensuring that interventions are selected to target identified needs and that midcourse corrections can easily be incorporated, thus allowing the flexibility to adapt to real-world challenges and barriers.
Consumer Demand

Strategies to increase consumer demand range from patient reminders to communitywide educational campaigns (Guide to Community Preventive Services, 2005). Reminders can be either just-in-time triggers, encouraging patients being served in a medical setting to ask their clinicians for vaccination, or individualized prompts delivered via phone or mail (postcards or letters) to patients who are due or overdue for a specific vaccination. Whereas prompts are often specific to a patient’s medical history (risk factors, recommended vaccine schedule, and vaccination history), educational campaigns tend to focus more broadly on raising awareness about vaccinations and their importance, educating target populations about their risk from vaccine-preventable illness and encouraging patients to request vaccinations from their providers. A recent example of such an effort was the 2009 H1N1 influenza vaccination campaign, which targeted children and pregnant women. Campaigns can also address cultural barriers by incorporating social marketing principles, such as identifying opinion leaders from at-risk populations who can help educate their community members about vaccinations.

Prompts and campaigns may be coupled with behavioral economic tactics, such as offering patients monetary or nonmonetary incentives for obtaining a recommended vaccination (HHS, 2012a). Although systematic reviews have determined that interventions targeting consumer demand can increase vaccination rates 5 percent to 12 percent (Guide to Community Preventive Services, 2005), studies have questioned whether these interventions are subject to a ceiling effect—a time when everyone likely to respond has responded and continued intervention will not increase vaccination rates (Ganguly, & Webster, 1995). Incentives may help overcome some such barriers.

Systems Change

Systems change interventions focus on provider-side strategies to improve health care providers’ immunization processes and ensure that opportunities to vaccinate patients due or overdue for vaccines are not missed. A systems approach also can help change the culture of care, including providers’ expectations for taking immunization histories and offering vaccines. Systems change could include modifying patient intake procedures to ensure that immunization histories are always reviewed (called always events), either with each outpatient encounter or at admission to an acute-care or long-term care facility, and that providers discuss needed vaccinations with patients.

Provider recommendations can be powerful and can result in significant increases in vaccination rates. For example, Rhode Island Pregnancy Risk Assessment Monitoring System data demonstrate that pregnant women whose providers recommended that they receive the influenza vaccine were more than 15 times more likely to be vaccinated (62% vs. 4%) than women to whom the vaccine was not recommended or offered (CDC, 2009; Kim, Raymond, Paine, Cain, & Viner-Brown, 2009). Providers can also identify opportunities to recommend due or overdue vaccines by using reminder systems, such as the automated reminder systems included in electronic health records or (until automation is widely available) notations or stickers in patients’ charts or registries. The increasing use of electronic health records may be of particular interest for data-driven quality improvement, as providers gain the ability to audit and assess their aggregate vaccination rates, determining and benchmarking performance over time.

Policy

An effective and widespread policy approach to increase vaccination uptake is by mandate (Task Force on Community Preventive Services, 2005); the most well-known policy may be the requirement to provide immunization records (or documentation of exemptions) when enrolling in schools, colleges, or universities. The requirements that protect older adults, another vulnerable population, are primarily those that target higher-risk patients, such as patients with specific risk factors or those who reside in assisted living or long-term care facilities (Greenberg, 2012). Ensuring up-to-date immunizations is particularly important for long-term care or nursing home residents; these residents are at particularly high risk for infection because of the immunological changes that occur with aging, medical comorbidities, and—relevant to vaccines against contagious infections—communal living (Aspinall et al., 2007; Bender, 2003). Infection is a leading cause of hospitalization in this population (HHS, 2012b), and influenza vaccination has been estimated to reduce hospitalization by 27 percent to 39 percent among nursing home residents (Nichol, Margolis, Wuorenma, & Von Sternberg, 1994). Policies requiring proof of immunization at admission to long-term care therefore have the potential to protect patients and to generate...
Demonstrated and Promising Practices That Improve Older Adult Vaccination Rates

herd immunity that protects fellow residents (Segal-Gidan, 2010).

Requirements that health care workers receive vaccinations against contagious infections also protect older adults, by fostering herd immunity and averting the transmission of infections from providers to patients (Greenberg, 2012). These policies generally target all health care workers who engage in direct patient contact, including clinicians, employees, students, and volunteers. Policies differ at the employer, state, and federal level, but health care worker vaccination requirements commonly include tetanus, diphtheria and pertussis, hepatitis B, measles-mumps-rubella, and varicella (CDC, 2011). However, although the Advisory Committee on Immunization Practices recommends influenza vaccination, its use is more variable, with many employers allowing workers to opt out. Some states, such as New York, are beginning to explore ways to mandate annual influenza vaccination among health care workers or require workers who opt out to wear surgical masks while at work for the duration of the influenza season. Other states, including Rhode Island, have policies that mandate the publication or public reporting of health care workers’ vaccination rates for immunizations such as influenza, with the goal of encouraging providers to benchmark their performance against their peers to drive market competition that encourages improvement.

Most recently, emerging policies have focused on transformational change, payment reform, and local and national surveillance. For example, some patient-centered medical home models include pay-for-performance contracting that encourages physicians to measure and increase vaccination rates for their patients. Many state departments of health, including Rhode Island’s, require providers to submit immunization records to registries, which can help to monitor population health trends and achievement of the Healthy People 2020 goals. Increasingly, these registries are expanding to include the health records of all adults, not just those of children and at-risk populations. The utility of such registries is likely to further improve as electronic health record use increases and providers apply for meaningful-use reimbursement, which includes immunization reporting. Registry information can help stakeholders identify at-risk populations and select suitable interventions, as well as monitor the impact of these interventions over time.

Conclusion

In summary, strategies to improve vaccination rates among older adults include interventions targeting access, consumer demand, provider systems change, and policy. Although immunization remains the most effective protection for older adults who are at particularly high risk for vaccine-preventable diseases, vaccination rates remain low; collaboration and targeted interventions are necessary to improve immunization rates and protect these patients. Systematic reviews have identified strategies and can serve as reference guides. Multicomponent interventions are the most successful; the best choice for those implementing interventions is to implement multiple strategies, and then use a systematic quality-improvement approach to measure effectiveness and spread successful strategies. Also important is evaluating unintended consequences, such as the opportunity cost of shifting influenza vaccination from a face-to-face physician office visit to a pharmacy clinic or other site. Emerging health care initiatives may provide new and promising strategies, such as those that incorporate behavioral economics to encourage patient behavior change (consumer demand) or implement pay for performance that rewards providers for increased rates (systems improvement).

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Demonstrated and Promising Practices That Improve Older Adult Vaccination Rates

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In this report, we highlight one powerful yet under-exploited behavioral intervention that helps people follow through on beneficial intentions without restricting their autonomy. We review two studies showing that planning prompts not only increase healthy behaviors but also are easy and inexpensive to implement.

**The Psychology of Planning Prompts**

People often have trouble engaging in behaviors with benefits that arrive with a delay, such as exercising, scheduling and attending physical exams, and getting vaccinated (Milkman, Rogers, & Bazerman, 2008). Because the cost of exerting immediate effort to achieve such goals is more salient than the anticipated long-term benefits, individuals often procrastinate at the time when action is required (O'Donoghue & Rabin, 1999). Forgetfulness also reduces follow-through on good intentions (Schacter, 1999). People mean to act at some point in the future but then fail to recall that intention at a moment when action is possible.

Creating a plan can reduce the likelihood of both procrastination and forgetfulness. Plans require people to form associations between anticipated future moments (e.g., a given date and time) and specific actions required to attain their goal. As a result, when a given future moment arises, it cues the individual who has made a plan to follow a predetermined course of action, thus reducing the likelihood of forgetting to act. In addition, simply having a plan makes procrastination more difficult because delay then requires breaking a commitment. Finally, planning prompts encourage people to generate solutions to logistical challenges before facing them, a strategy that can remove other impediments to goal attainment.

Past research has demonstrated that prompting people to form a concrete plan about when, where, and how they will fulfill a goal increases goal attainment (Gollwitzer, 1999). In short, by associating a specific future cue with a desired behavior (e.g., “When situation x arises, I will do y”), plan-making helps people overcome several psychological barriers to follow through.

**Past Research on Planning Prompts and Flu Shots**

The first study that we review examines the impact of planning prompts on influenza vaccination rates. An estimated 12,047 deaths and 316,588 hospitalizations occurred in the United States due to seasonal influenza and associated complications during the 2000–2001 influenza season (Thompson et al., 2010; Thompson et al., 2004). People ages 65 and over account for nearly 90 percent of all influenza-associated deaths, and people ages 85 and over are at highest risk of influenza-related hospitalizations (Thompson et al., 2010; Thompson et al., 2004). The number of hospitalizations and deaths associated with influenza has increased substantially over the past 3 decades due to the increasing average age of the population (Thompson et al., 2010). The influenza vaccine, which is widely available at low cost, has been shown to reduce flu mortality rates, morbidity rates, and healthcare costs (Gross, Hermogenes, Sacks, Lau, & Levandowski, 1995; Nichol, Margolis, Wuorenma, & Von Sternberg, 1994; Wilde et al., 1999). However, many people who, according to guidelines from the Centers for Disease Control and Prevention, would benefit from receiving an
In this study, all 11,918 employees at four large corporations who were due for a colonoscopy according to standards set by the U.S. Preventive Services Task Force (2008) received a mailed reminder (from Evive Health) that they were due for the procedure. Employees were informed how to schedule an appointment and how much it would cost. All mailings also highlighted the power of using a sticky note as a reminder to follow through on plans. Approximately half of employees were randomly assigned to receive a control mailing, to which a blank, yellow sticky note as a reminder to follow through on plans. The other

The aforementioned research was the first large-scale field study to successfully isolate the efficacy of planning prompts using a confound-free experimental design. The intervention in this study was sent by mail, so there was no social pressure caused by face-to-face or phone interaction. The planning prompts did not contain any extra information about flu vaccination that might encourage behavior uptake. Instead of relying on subject self-reports, the researchers measured outcomes using administrative data without the awareness of participants, removing both self-reporting bias and experimenter-demand effects. Finally, the sample size was large and attrition from the data was negligible, allowing for a precise estimate of the planning prompt effect on flu shot take-up.

Past Research on Planning Prompts and Colonoscopies

The flu shot study demonstrated the effectiveness of planning prompts at encouraging uptake of a fairly easy and innocuous behavior that can be completed with a single action, at most several weeks after the prompt to form a plan. However, many important health behaviors must be executed many weeks or months after a reminder is received, require multiple steps (e.g., scheduling and attending an appointment), and involve discomfort. Thus, the same research team conducted a second field study to examine the efficacy of planning prompts as a means of increasing follow-through on an unpleasant but potentially lifesaving behavior: obtaining a colonoscopy (Milkman, Beshears, Choi, Laibson, & Madrian, 2012).

In this study, all 11,918 employees at four large corporations who were due for a colonoscopy according to standards set by the U.S. Preventive Services Task Force (2008) received a mailed reminder (from Evive Health) that they were due for the procedure. Employees were informed how to schedule an appointment and how much it would cost. All mailings also highlighted the power of using a sticky note as a reminder to follow through on plans. Approximately half of employees were randomly assigned to receive a control mailing, to which a blank, yellow sticky note was affixed on the upper right-hand corner. The other
Planning Prompts as a Means of Increasing Rates of Immunization and Preventive Screening

half of employees were assigned to receive a planning prompt in their mailing. These mailings also contained a yellow sticky note affixed to the upper right-hand corner, but these sticky notes contained a prompt to write down the date of a colonoscopy appointment and the name of the doctor who would perform the colonoscopy.

The outcome of interest was whether an employee received a colonoscopy within approximately 7 months of receiving the reminder mailing. The treatment-reminder mailing significantly increased the percentage of people who obtained colonoscopies during this follow-up period, from 6.2 percent in the control group, which received a reminder without a planning prompt, to 7.2 percent in the planning prompt group. For every 100,000 people who should be screened according to national guidelines, an increase of 1 percentage point in follow-through is associated with an expected 271 life-years saved (Zauber et al., 2008). Demographic groups judged by a panel of survey respondents to be at the highest risk of forgetfulness, such as older adults and those with children, benefited from the planning prompt more than others. This finding is consistent with the hypothesis that planning prompts are effective in part because they reduce forgetfulness.

Colon cancer has the second highest mortality rate among cancers in the United States. If adults ages 50 to 75 sought colorectal screenings at regular intervals as national guidelines have advised, 38 percent of the approximately 50,000 U.S. colon cancer fatalities per year could be prevented (U.S. Preventive Services Task Force, 2008). The aforementioned study demonstrates the potential of planning prompts to improve public health in an important domain that involves far more advance planning and discomfort than receiving an immunization.

Conclusions

We summarize the results presented in two recent academic papers describing large-scale field experiments, both of which show that planning prompts can effectively increase follow-through on important health behaviors. In the context of a simple, relatively painless procedure such as a flu shot, a reminder mailing encouraging employees to write down the date and time when they planned to get vaccinated increased the vaccination rate at free workplace clinics by 13 percent relative to a reminder with no such planning prompt. Similarly, the rate of obtaining a colonoscopy was 16 percent higher among employees prompted to write down when and from whom they would receive an exam than among those in a control group.

Past research has demonstrated that sending reminder letters increases patient immunization rates by an average of 8 percentage points (Briss et al., 2000; Szilagyi et al., 2000). The two studies reviewed here show that compliance rates can be further improved if the reminder mailing includes a prompt to form a specific plan. This intervention requires no additional printing or mailing costs and can easily be implemented. Thus, planning prompts are a potentially cost-effective tool to help people follow through on a wide range of beneficial behaviors that often are delayed or forgotten—such as receiving an immunization, obtaining a health assessment, or refilling a prescription.

Older adults are biologically more prone to forgetfulness (Burns & Zaudig, 2002; Jeong, 2004; O’Brien & Levy, 1992), as well as more likely to believe that they are forgetful due to old age (Commissaris, Ponds, & Jolles, 1998). In addition, older adults often forget to perform actions at a specified time (for a review, see Einstein & McDaniel, 1996), a problem that can be mitigated by generating retrieval cues in advance (Schachter, 1999). Because planning prompts help create retrieval cues, planning prompts could be a particularly valuable technique for helping older adults overcome forgetfulness and engage in beneficial health behaviors.

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Notes

1 This study was conducted prior to February 24, 2010, when the Centers for Disease Control and Prevention (2012) changed its guidelines to recommend that everyone over the age of 6 months receive a yearly flu vaccine.
Planning Prompts as a Means of Increasing Rates of Immunization and Preventive Screening

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The Continuing Challenge of Adult Immunizations: Impact of the Affordable Care Act

Litjen (L.J.) Tan

On June 28, 2012, the U.S. Supreme Court ruled on the constitutionality of the Affordable Care Act (ACA), upholding the law in its entirety with the sole exception that Congress may not revoke a state’s existing Medicaid funding should that state decline to participate in the Medicaid expansion under the act. Now is the prime time to discuss the effect of this ruling, and of the ACA, on removing barriers to adult immunizations. Stakeholders and policymakers should also continue to identify and address remaining barriers to adult immunization in the United States.

Introduction

The benefits of immunization are well established. Pediatric immunization rates are well above 90 percent for the majority of the routinely recommended pediatric vaccines (Roush & Murphy, 2007). The successful pediatric immunization program has been driven in large part by Vaccines for Children, the federal program that provides vaccines for uninsured children (Centers for Disease Control and Prevention [CDC], 2012c). Although provision of free vaccine is important, often overlooked is the substantial contribution that the Vaccines for Children program made toward the initial establishment of the pediatric immunization infrastructure in the country. For example, the public-private collaboration in today’s pediatric program occurred primarily because accountability for the Vaccines for Children program required it. Associated with these high immunization rates are historic low incidence levels of vaccine-preventable disease, such as mumps, measles, and rubella. Additionally, smallpox has been eliminated and, in 2010, no cases of polio, diphtheria, or tetanus were reported (CDC, 2012b). In contrast, the United States has not been successful at vaccinating its adult population (CDC, 2012a).

Currently, the Advisory Committee on Immunization Practices (ACIP) recommends immunizing adults against 14 infectious diseases (ACIP, 2012). As many as 70,000 adults die annually from diseases that can be prevented by existing vaccines, such as those against influenza, pneumococcal disease, and hepatitis B (CDC, 1990; Schaffner, 2008). Hundreds of thousands more are hospitalized. The direct cost of influenza to the health care system alone has been estimated at about $10.4 billion annually (Molinari et al., 2007).

Although immunization is recognized as one of the most effective primary prevention services to improve health and well-being, adult immunization rates remain low and large gaps exist between national adult immunization goals and actual adult immunization rates (CDC, 2012a; Schaffner, 2008). Despite recommended vaccines, adult cases of mumps, tetanus, rubella, varicella, zoster, and hepatitis B remain serious public health concerns (Schaffner). This situation is likely due to the significant gap between national adult immunization goals and actual immunization rates. For example, although Healthy People 2020 sets a goal for influenza immunization of 90 percent for individuals 65 years of age and older, currently only about 68 percent of the target population is vaccinated against flu (CDC, 2012a). This gap appears to have two main causes: (a) health care providers are not consistently offering adult immunizations and (b) the public is not demanding the protection afforded by these vaccines.

Closing the gap requires establishing a national, multifaceted initiative to (a) improve the value of adult vaccines in the eyes of the public, payers, policymakers, and health care professionals; (b) provide convenient access to adult vaccines by improving the adult vaccine infrastructure in the United States; and (c) ensure fair and appropriate payment for the provision of adult vaccines (National Vaccine Advisory Committee, 2012).

It is important to recognize that although the rest of this article will focus on the issue the impact of the ACA on financing adult vaccination, the failure of adult immunization in the United States must be addressed by establishing a comprehensive national adult immunization program. Such a program would likely require the establishment of public-private partnerships to facilitate effective immunization behaviors and must provide solutions that simultaneously offset the problems of demand, access, and financing. These solutions would require a culture shift by policymakers, health care providers, and the patients they serve—a shift that is unlikely to occur without several years of sustained effort. By expanding on existing collaborations and developing new ones, immunization partners could work to address all three aspects of the aforementioned solution.
Adequate Payment for Adult Vaccines

Payment for administration of adult vaccines remains one of the most visible barriers to a successful program in adult immunizations (Hurley et al., 2008; Johnson, Nichol, & Lipczynski, 2008; Szilagyi et al., 2005; Tan & Dickinson, 2010). This barrier also presents the strongest level of frustration for health care providers (Freed, Cowan, & Clark, 2009; Tan & Dickinson). Many providers state that payment for administering vaccines is often inadequate: Either the reimbursement for the cost of the vaccine is insufficient to cover what was paid, or the payment for administering the vaccine (the administration fee) does not cover the actual costs. Unlike in pediatric immunizations, no federal financing mechanism exists for procuring vaccines for uninsured adults. The adult vaccine financing system does not provide any incentive for new immunizers (particularly physicians) to enter the field. Although many providers want to immunize adults, the uncertainty of adult vaccine financing represents a strong financial disincentive to doing so. In particular, any success in increasing awareness of—and demand for—adult immunization will be meaningless if providers choose not to vaccinate for financial reasons (Freed, Clark, Cowan, & Coleman, 2011).

Insurance Coverage Before the ACA

Prior to the introduction of the ACA, a significant component of insurance coverage was based on a voluntary, employer-sponsored system (Stewart, Richardson, Cox, Hayes, & Rosenbaum, 2010). This system resulted in large gaps of coverage for many individuals. The lack of coverage was particularly pronounced for those in lower income brackets, for young adults just entering the workforce, and for those employed within small businesses. Affordability of insurance varied widely, in part due to the fact that the employer decision to subsidize insurance premiums was entirely voluntary and no assistance was offered to lower-wage employees to improve affordability of their share for insurance coverage. Additionally, an individual health care insurance market for unemployed or self-employed people was almost completely lacking. Any options that existed were unaffordable and no federal subsidies existed to help make these plans affordable for individual insurance purchasers. Individuals with any preexisting condition found their access to insurance either prohibitively expensive or nonexistent.

In addition to the health care insurance available in the private sector, the federal government provided insurance options to targeted populations. Indeed, the largest insurance payer in the United States is Medicare, which provides coverage for those 65 years of age and older and for certain disabled populations (Centers for Medicare & Medicaid Services, 2012b). However, Medicare preventive services were limited to certain tests and screenings, and to immunizations. Medicaid is a means-tested program jointly funded by the federal and state governments for individuals and families within low income brackets. For many eligibility groups, income is calculated in relation to a percentage of the federal poverty level (FPL) (Centers for Medicare & Medicaid Services, 2012a). Although the federal government sets minimum guidelines for Medicaid eligibility, states can choose to expand coverage beyond the minimum threshold. In all states, the Children’s Health Insurance Program (CHIP) provides additional health coverage to nearly 8 million children in families with incomes too high to qualify for Medicaid who cannot afford private coverage. Medicaid minimum guidelines did not emphasize prevention and thus had no required immunization coverage for adults; children were provided required immunizations through CHIP.

As a result of this fragmented system, about 50 million people were without health care coverage. In addition, an annual turnover rate (i.e., people switching insurance payers) of 33 percent created an unstable insurance market (Stewart et al., 2010).

The ACA

The intent of the ACA was to ensure near-universal, stable, and affordable health care insurance by leveraging and enhancing the existing private-public health insurance markets (Stewart et al., 2010; U.S. Department of Health & Human Services [HHS], 2012). Costs were to be contained by leveraged spending reductions in health care coupled with targeted tax increases, as well as fundamental changes in the way health care would be delivered. Of note, the ACA acknowledges the importance of prevention in reducing costs and attempts to integrate prevention efforts into health care and into the community. Finally, the ACA also strives to promote efficiency across payers in order to reduce costs and improve quality of care. However, the ACA does not set out to improve the adequacy of payment to providers of health care. It can be argued, however, that improving payment will indirectly improve access to care.

It is important to understand that the ACA sets out an intent through legislation that is then enforced through regulation by federal agencies. Thus, it is essential that said regulations properly capture the essence of the ACA. Indeed, much debate has arisen over the regulations to enforce the ACA and the attempt to clarify the intent of these regulations to Congress.

ACA Requirements Beginning January 1, 2014

Under the ACA, individual health care insurance coverage will be required of most Americans (Stewart et
al., 2010). Those who decline to purchase health care insurance will be assessed a tax of the greater of $695 per person ($2,085 per family) or 2.5 percent of the household income. Some exceptions are allowed, including those with financial hardships or religious objections, as well as individuals for whom the lowest cost health plan available to them exceeds 8 percent of their income. Advance refundable tax credits and cost sharing assistance up to 400 percent of the FPL will be available for individuals and families.

Although employers are not mandated to provide health care insurance to all their employees, there are penalties for not doing so. For example, employers with 50 or more employees that do not offer coverage and have at least one employee who receives a premium credit through a state exchange plan will be assessed a tax of $2,000 per employee. A similar assessment will be made on employers with more than 50 employees that do offer coverage but have at least one employee who receives a premium credit through a state exchange plan. Employers who offer coverage must provide their employees the option of enrolling in a state exchange plan, with a subsidy to those employees with incomes below 400 percent of the FPL whose share of the premium is greater than 8 percent of their income. Large employers (more than 200 full-time employees) that offer coverage must automatically enroll employees who do not sign up for employer coverage or do not opt out of coverage into their lowest-cost premium plan.

**ACA Requirements That Began Before January 1, 2014**

Many ACA requirements are already in effect, having been implemented over various dates leading up to January 1, 2014 (Stewart et al., 2010; White House, 2012). For example, all adult children up to the age of 26 years can now be covered as dependents on a parent’s health plan. In the case of children who are younger than 18 years of age, preexisting condition exclusions to coverage are no longer allowed; beginning in 2014, this benefit will be extended to all people regardless of age. The provision of all U.S. Preventive Services Task Force category A or B recommended preventive services is required at no cost sharing. Of note, all ACIP-recommended vaccines must be provided per the ACA at no cost sharing. With this provision, more than 190 million privately insured individuals now have access to all ACIP-recommended vaccines. Pre-2014 provisions also specify that insurers must cover new ACIP recommendations within a year of adoption by the Centers for Disease Control and Prevention. The ACA does not require a health plan to provide coverage for immunizations that are given by an out-of-network provider. However, if the plan does cover such out-of-network immunizations, it can do so at out-of-network cost-sharing standards.

**Self-insured group health benefit plans (Employee Retirement Income Security Act plans).** The Employee Retirement Income Security Act of 1974 (ERISA) is a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry to provide protection for individuals in these plans. Self-insured plans are regulated by this act and thus are commonly called ERISA plans. Although these plans will continue to operate outside of the insured market, the ACA extends many of its standards for preventive coverage to these plans. In particular, effective September 2010, ERISA plans are required to cover all ACIP-recommended vaccines at no cost sharing (Stewart et al., 2010).

**Grandfathered plans.** Private health insurance plans in the individual and group health insurance markets established prior to the implementation of the ACA (March 23, 2010) are grandfathered into the ACA (HHS, 2011; Stewart et al., 2010). In the case of grandfathered plans, the preventive services (including immunization services) guaranteed by the ACA are not in play until grandfathered status is lost. With grandfathered plans, routine changes are allowed without loss of grandfathered status. Thus, plans can make cost adjustments that are consistent with medical inflation, add new benefits, make modest adjustments to existing benefits, voluntarily adopt new patient protections established under the ACA, or make changes to comply with state or federal requirements—all without losing grandfathered status. However, if plans (a) reduce or eliminate existing coverage, (b) increase deductibles or co-payments by more than the rate of medical inflation plus 15 percent, (c) require patients to switch to another grandfathered plan with fewer benefits or higher cost sharing, or (d) are acquired by or merge with another plan to avoid compliance with the ACA, then grandfathered status is lost.

It is estimated that by 2013, about 55 percent of large-employer plans and approximately 33 percent of small employer plans will retain grandfathered status (HHS, 2011). In 2014, small businesses and individuals that purchase insurance on their own will gain access to the state exchanges, which should offer individuals and workers in small businesses a greater choice of plans at more affordable rates. These reduced premiums do not take into account the tax credits available to small businesses and middle-class families to help make insurance affordable, which therefore reduces the likelihood that workers at small businesses will remain in grandfathered health plans. In
Effect of the ACA on Medicaid and CHIP

Prior to the June 28, 2012, Supreme Court ruling in National Federation of Independent Business v. Sebelius, the ACA required, effective 2014, that all states expand Medicaid to cover nonelderly individuals with incomes up to 133 percent of the FPL. The federal government would provide 100 percent funding for the incremental cost of providing coverage for all the newly eligible individuals from 2014 through 2016. Beginning in 2017, the funding level would decline gradually, to 90 percent by 2020. Thus, a considerable number of previously uninsured individuals will now be newly eligible for Medicaid coverage, including coverage for the provision of preventive services, such as immunizations. Indeed, the ACA incentivizes states to cover ACIP-recommended vaccines and administration costs with no cost sharing by providing to those states that do so, beginning in 2013, a 1 percent increase in federal matching funds. The Congressional Budget Office (2012) has estimated that with this Medicaid expansion, by 2019, an estimated 16 million uninsured, low-income Americans who would otherwise have remained uninsured will have coverage. From January 1, 2014, through December 31, 2015, expansion states that do not have any newly eligible Medicaid beneficiaries, because they already cover individuals up to 133 percent FPL or higher, will receive a temporary 2.2 percentage point increase in their Medicaid federal matching funding for the coverage provided to all populations.

Should a state not participate in the Medicaid expansion, it would lose its existing Medicaid funding, thereby providing an incentive to states to participate. However, the Supreme Court ruled in National Federation of Independent Business v. Sebelius (2012) that should a state not participate in the Medicaid expansion called for by the ACA, it cannot lose its existing federal funding. Thus, all states, both expansion and nonexpansion, will receive their regular federal matching funds for assistance provided to parents who were eligible for Medicaid on March 23, 2010. Currently, there is a lot of uncertainty about which states will choose to participate in the Medicaid expansion. As of July 2012, 10 states and the District of Columbia are participating in the expansion; 5 states have indicated that they will not (Advisory Board Company, 2012). The remaining states have not yet expressed an intent. Depending on how states decide, as many as 9 million people could remain uninsured, with no access to such important preventive services as immunizations (Congressional Budget Office, 2012).

The ACA also provides an increase in Medicaid payments to primary care physicians for preventive services (including immunizations) to 100 percent of Medicare payment rates and would fund this increase at 100 percent for the first 2 years (2013 and 2014). Of note, this increases immunization administration fees paid by Medicaid to the higher levels paid by Medicare for two years and provides an opportunity to demonstrate the importance of adequate payment for vaccine administration on coverage.

Effect of the ACA on Medicare

Prior to the ACA, Medicare has been covering ACIP-recommended vaccinations either as a Part B or Part D benefit. Immunizations provided through either benefit had cost-sharing standards. With the ACA, effective 2011, Medicare beneficiaries will receive a cost-free personalized prevention plan that will also incorporate ACIP-recommended vaccines (Stewart et al., 2010). This change offers providers an opportunity to engage their Medicare patients in a conversation about necessary immunizations and to provide them—or, minimally, to refer patients to another provider. Additionally, for influenza, pneumococcal, and hepatitis B vaccines (all provided as a Part B benefit), cost sharing has been eliminated. For other vaccines that are covered under Medicare Part D, some cost-sharing standards will remain. However, as part of the ACA, eligible Medicare beneficiaries in 2010 received a one-time, tax-free $250 rebate.

As required by the ACA, the Government Accountability Office (2011) studied the effect of Medicare Part D coverage of immunizations on beneficiary access and utilization of vaccines. Released in December 2011, this report indicated that many barriers existed to beneficiaries receiving vaccines under Medicare Part D (Government Accountability Office; Hurley et al., 2010). The report also highlighted multiple reasons why immunization rates for Part D vaccines may be lower than...
those in Part B. However, it is unclear what action Congress will take to follow up on this Government Accountability Office report.

**Conclusions**

As a result of the ACA, any person in a nongrandfathered, private insurance plan will have access to all ACIP-recommended vaccines with no cost sharing. Additionally, Medicare and Medicaid beneficiaries will see certain improvements to the cost-sharing standards for ACIP-recommended vaccines; for example, influenza, pneumococcal, and hepatitis B vaccines will have cost sharing eliminated for those on Medicare. The number of people eligible for Medicaid benefits will increase significantly—an increase that will ultimately depend on the final number of states that choose to participate in the Medicaid expansion the ACA allows.

Challenges will remain, however, despite the many benefits of the ACA. A significant number of U.S. adults will remain uninsured. Therefore, public-health safety nets will still be necessary to provide access to vaccinations for these uninsured. Until the establishment of a national adult immunization program that provides vaccines for uninsured adults, this burden of adult vaccine-preventable disease will remain one of the more important issues facing public health. Additionally, the increased number of newly eligible insured people will stress the ability of the immunization infrastructure to deliver the recommended vaccines. In particular, many of the newly eligible will be those in lower income brackets and residents of medically underserved communities.

An additional challenge is raised by the fact that although immunizations will be covered at no cost to the patient, the adequacy of the payment to providers of the immunizations remains uncertain. If providers continue to perceive that payment for administering vaccines to adults remains insufficient to cover their costs, the ability to improve adult immunizations will be severely diminished. In particular, within Medicare, much concern remains about the barriers to receiving vaccinations as a Part D benefit. Providers are concerned about the coverage gap in Part D (the so-called donut hole) and about the lack of information regarding whether beneficiaries under Part D will have their vaccine covered, and at what level of coverage (Hurley et al., 2010).

Finally, the ACA has many other implications, not related to payment, that will have an impact on immunization efforts. In particular, with a substantial increase in the number of people covered by health insurance, the role of the community in supporting access to preventive services, such as immunization, will increase. Indeed, the ACA grants authority for community prevention efforts and provides for plans to improve policy, environmental, programmatic, and infrastructure changes to promote healthy living and reduce disparities. Because community prevention and public health organization, financing, and operations will continue to evolve with the changing health care environment, it is imperative that immunization advocates ensure that programmatic efforts for adult immunization are included in these community and public health transformation programs.

It is also important that immunization advocates continue to develop and promote innovations that will leverage the benefits of the ACA to improve access to, and payment for, adult vaccines. The Centers for Disease Control and Prevention’s billables project, whereby the public health department bills private insurance for a vaccine given to an insured person in a public health clinic, is a good example of such innovation.

Above all, it is essential that adult immunizations be integrated into the rubric of ongoing prevention efforts. With near-universal coverage at no cost sharing for ACIP-recommended adult vaccines, patients (and their employers) need to be told to capitalize on their immunization benefits, and many providers should be educated that providing adult vaccines is no longer the financially losing proposition that they have previously perceived it to be. Clearly, national leadership can take a role here to integrate the multiple partners (in both the public and the private sector) to implement a cohesive strategy for accomplishing this goal.

Making adult immunizations a standard of care will require the development of a preventive care infrastructure within which the vaccines can be provided. It is this author’s opinion that the time is ripe to promote the development of such an adult preventive care infrastructure, perhaps by starting with the establishment of an annual adult wellness visit. This annual visit could be analogous to Medicare’s annual wellness visit, whereby a minimum of 30 to 45 minutes is set aside and covered by insurance for the discussion of prevention, preventive services, and the assessment and provision of recommended vaccines.

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**References**


Influenza vaccination is the primary means of preventing the aforementioned issues, although the mortality benefits for the older population have been called into question. In this paper, we will summarize the main vaccine efficacy and effectiveness data in elders, as well as the associated implications for vaccine policy and research in older adults.

Vaccine Efficacy in Elders—Randomized Controlled Trials

Data from randomized controlled trials with elders are scarce. The largest study enrolled more than 1,800 individuals during one influenza season and showed a vaccine efficacy of 50% for preventing serologically confirmed influenza (Govaert et al., 1994). Nursing home residents were not included in the study. Moreover, serologically confirmed influenza as a study outcome has been criticized as overestimating vaccination efficacy, because not all vaccinated individuals can mount a fourfold increase in antibody titers after infection (Petrie, Ohmit, Johnson, Cross, & Monto, 2011). Given these limitations, this study was not included in a recent meta-analysis (Osterholm, Kelley, Sommer, & Belongia, 2012) that considered only outcomes diagnosed by viral culture or molecular methods. The meta-analysis concluded that evidence for use of trivalent inactivated vaccines in individuals older than 60 years of age is lacking (Osterholm et al.).

Performing randomized controlled studies of influenza is difficult. Laboratory-confirmed influenza is a low-incidence event, and circulating flu strains vary each year. Multiple flu seasons and large sample sizes are required for an accurate estimate of vaccine efficacy. Since the Centers for Disease Control and Prevention recommended the flu vaccine for all elders in the mid-1990s, placebo-controlled trials are no longer considered ethical. Therefore, the question of vaccine effectiveness in elders relies primarily on interpretation of data from observational studies.

Vaccine Effectiveness in Elders—Observational Trials

Numerous observational studies have reported significant mortality reductions associated with influenza vaccination among community-dwelling elders. A meta-analysis of 20 case-control and cohort studies found vaccine effectiveness for preventing all-cause mortality, pneumonia and influenza mortality, hospitalizations due to pneumonia and influenza, and influenza-like illness to be 50%, 47%, 33%, and 37%, respectively (Vu, Farish, Jenkins, & Kelly, 2002).

Among nursing home residents, a meta-analysis of observational studies found reductions of 23% for influenza-like illness, 45% for hospitalizations due to pneumonia and influenza, 42% for pneumonia and influenza mortality, and 60% for all-cause mortality in seasons with high influenza viral circulation and good match vaccines (Jefferson et al., 2005).

The strong health benefit associated with influenza vaccination of the older population has been somewhat controversial recently. A frequently cited ecological analysis reported that the average influenza-attributable mortality each season does not exceed 5% to 10% of all winter deaths, and is thus incompatible with the larger mortality benefits reported by observational studies (Simonsen et al., 2005). In light of the limitations associated with ecological analyses (i.e., lack of individual-level data, inability to control for confounders or account for heterogeneity of exposure within different...
population groups), the discrepancy between results from aggregated population-level data and individual-level data in clinical trials can be considerable (Nichol, 2009). Thus, although data from ecological studies are helpful in generating hypotheses, they should be interpreted with caution due to inherent biases.

Observational studies of vaccine effectiveness have also been heavily criticized for selection bias. For example, studies in which individuals with healthier lifestyles are more likely to be vaccinated (healthy-user bias) tend to overestimate vaccine effectiveness (Hak, Hoes, Nordin, & Nichol, 2006). Jackson, Jackson, Nelson, Neuzil, and Weiss (2006) have argued that flu vaccine observational studies in the United States are more likely to suffer from this bias, with unmeasured confounders leading to artificially increased mortality benefits. They propose that functional status is one such unmeasured confounder, with unvaccinated individuals having significantly lower functional status in their studies (Jackson, Nelson, et al., 2006).

A study among elderly patients in enrolled in a health-management organization (Kaiser Permanente) also found that the sickest patients with the highest odds of dying had the lowest vaccination rates. After controlling for this generally unmeasured bias, the authors found an all-cause mortality reduction of only 4.6% over nine laboratory-confirmed flu seasons (Fireman et al., 2009). In light of these findings, Jackson, Jackson, and colleagues (2006) have argued that unvaccinated patients who are sicker at baseline are more likely to die during influenza season due to non-flu-related reasons, biasing the mortality benefits of the flu vaccine away from the null.

Jackson, Nelson, and colleagues (2006) further illustrate the example of unmeasured confounders as a source of bias in an 8-year cohort study, where mortality reductions were observed both during the influenza season (expected), as well as during the pre-influenza period (unexpected, because the authors considered the pre-influenza season as a control period with no influenza circulation). Exploring selection bias in who is vaccinated, Wong, Campitelli, Stukel, and Kwong (2012) compared the results of standard regression with those of an instrumental variable analysis, a method designed to control for unmeasured residual confounders. With standard regression, they found a 33% vaccine-associated mortality reduction during influenza season and a 15% mortality reduction after flu season. With instrumental variable analysis, however, they found a statistically nonsignificant mortality reduction of 6% during the flu season, and no mortality reduction during the post-influenza season (Wong et al.).

On the other hand, observational studies from countries where the flu vaccine is primarily offered to severely ill individuals (confounding by indication) are more likely to underestimate vaccine effectiveness (Hak, Verheil, Grobbee, Nichol, & Hoes, 2002). This seems to be the case in a study from the Netherlands, where vaccinated patients had significantly lower functional status than their unvaccinated counterparts. The authors argued that the functional status variable was already highly correlated with other confounders routinely collected, and did not change the association between vaccine exposure and all-cause mortality significantly (Groenwold, Hoes, Nichol, & Hak, 2008).

Complexities of Vaccine Research in Elders

The limitations and sometimes conflicting results associated with observational trials are a function of the particularities of influenza as a disease that make vaccine research enormously challenging in the older population. First, defining an influenza-related outcome that accurately reflects the burden of influenza in elders has proven extremely challenging. Many studies settled on nonspecific definitions, such as influenza-like illness or all-cause mortality, although the high rates of false positives associated with these outcome measures bias vaccine estimates toward the null (Orenstein et al., 2007). To illustrate, the overall vaccine effectiveness for preventing clinical influenza in a meta-analysis of 30 randomized and quasi-randomized controlled trials among healthy adults was 23% (Villari, Manzoli, & Boccia, 2004). Reanalysis of these data by varying outcome specificity yielded vaccine effectiveness values ranging from 54% to 11%, with the most and least specific outcome definitions, respectively (Beyer, 2006). More accurate laboratory methods, such as viral culture or molecular diagnostics, are not readily available in clinical practice. Most clinical laboratories still use rapid-flu diagnostic kits, which have limited specificity and have been shown to underestimate vaccine effectiveness (Ferdinands & Shay, 2012).

Moreover, laboratory confirmation of influenza in elderly patients seen in an outpatient or urgent-care setting is rarely obtained, because the diagnosis is primarily made on clinical grounds and treated empirically. Influenza-triggered exacerbations of underlying respiratory and cardiovascular illnesses that may present in the post-influenza season among elderly patients are often under-recognized in clinical practice (Nichol, 2009). Other influenza-related outcomes, such as decline in functional status, have been under-investigated in vaccine effectiveness studies. Therefore, population-based studies using large databases from
clinical health care settings have yet to provide an accurate estimate of disease burden in elders. Second, studies of vaccine effectiveness are dependent on the annual variations in influenza severity and the virulence of the circulating strains in that year. In seasons with low influenza activity, detecting a significant difference between vaccinated and unvaccinated individuals against a high background of other respiratory illnesses presenting as influenza-like illness is extremely difficult (Beyer, 2006). Similarly, vaccine efficacy is affected by the degree of antigenic match between the vaccine strains used and the seasonally circulating influenza strains. For example, the vaccine effectiveness in preventing winter deaths among elderly individuals varied from 61% in a well-matched season to 35% in a poorly matched season (Nordin et al., 2001). Because circulating influenza strains can vary considerably with time and region in a given flu season, so does the degree of antigenic match and the corresponding amount of protection conferred by the vaccine. To date, few studies have attempted to account for this significant variability when assessing vaccine effectiveness.

Third, despite general agreement that older, frail individuals have impaired vaccine responses compared with younger individuals on account of immune senescence (Nichol, 2009), the correlates of immune protection remain poorly understood. Most studies document lower post-vaccine antibody titers for elderly patients (Goodwin, Viboud, & Simonsen, 2006), although T-cell mediated immunity may be at least equally important (McElhaney et al., 2006). Standardized essays for measuring T-cell immunity have yet to be validated.

Implications for Vaccine Research and Policy

In light of the complexities surrounding the assessment of influenza infection in elderly people and their increased vulnerability to disease, designing and implementing a sound preventive policy for this population is imperative. It is evident that further high-quality research is needed before the protective impact of influenza vaccination in older adults can be reliably determined.

As understanding of immune senescence increases, developing more immunogenic vaccines for this population should also be a priority. To this end, the data on adjuvanted vaccines that stimulate higher antibody titers and improved cellular responses are encouraging (Podda, 2001). Increasing the vaccine antigenic dose is another strategy worth investigating. The Fluzone High-Dose produced by Sanofi Pasteur and FDA approved in the United States has been found to have a favorable immunogenicity and safety profile (Centers for Disease Control and Prevention, 2010), although further research is needed to decrease dose-related adverse reactions at the injection site for high-dose vaccines (Keitel et al., 2006).

Current evidence suggests that universal vaccination of children offers a protective benefit for older adults (Reichert et al., 2001). Randomized-controlled studies also suggest that vaccinating health care personnel is associated with reduced work absenteeism and decreased mortality in nursing home residents (Thomas, Jefferson, & Lasserson, 2006).

In conclusion, accurately measuring the protective effects of influenza vaccine in elders deserves further study, with increased attention devoted to improving the quality of observational studies in this field. Assessing the indirect protection to the elderly population conferred by vaccination of children and younger adults, as well as developing more immunogenic vaccines for older adults, should also represent high priority research areas.

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public education, reminder programs, and now social media constitutes the second avenue Baier highlights. Finally, systemic changes—ranging from such modest reforms as better patient intake procedures to major ones of a transformational nature—also could increase utilization. Baier strongly recommends that elements of each of these three strategies be used in combination to maximize efficacy.

Complementing Baier’s approach is that of Hengchen Dai and colleagues, who explore the role that planning might play in raising immunization rates. Borrowing from the work of behavioral scientists, they focus on the seemingly mundane but critical reasons why (older) people often put off or forget to take the fairly straightforward steps needed to maintain their health. The authors’ interesting formulation regarding why people often delay taking these steps is that “the cost of exerting immediate effort to achieve such goals is more salient than the anticipated long-term benefits,” thus resulting in procrastination. The authors go on to review two major controlled planning studies—one involving flu shots and the other colonoscopies—in which control and experimental groups that received instructions of increasingly specific steps to be taken led to modestly higher follow-through on the part of the more directed participants.

L.J. Tan places vaccination initiatives into the context of the recently enacted Affordable Care Act (ACA). He reviews the pre-ACA vaccine-relevant environment, which suffered eligibility gaps and widespread disincentives to potential providers of vaccinations. He highlights the ACA’s emphasis on prevention, in particular that Medicare’s ongoing vaccination coverage of 14 infectious diseases will be extended to currently grandfathered private plans when the ACA phases out that status over the next few years. Despite the ACA’s promise, Tan does worry about a residual pressure on public health structures from those who remain uninsured and from the persistent issue of payment adequacy to immunization providers.

The issue concludes with Aurora Pop-Vicas, Stefan Gravenstein, and Vincent Mor’s assessment of research needs that would move forward an agenda of universal vaccination for elders. They speak most notably to the challenges that researchers face. Defining the desired influenza-related outcomes, accounting for the annual variations in influenza severity and virulence, and dealing with the confounding presence of other respiratory illnesses—all in the face of the aforementioned immune suppression among older adults—are barriers to arriving at more definitive research findings. The varying results from randomized controlled trials and observational studies underscore these difficulties. The authors highlight a range of needed steps, including more accurately measuring the protective effects of vaccines, improving the quality of observational studies, and developing more immunogenic vaccines targeted toward the particular needs of elders.
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