Reviews of Evidence Regarding Interventions to Improve Vaccination Coverage in Children, Adolescents, and Adults

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Background:

This paper presents the results of systematic reviews of the effectiveness, applicability, other effects, economic impact, and barriers to use of selected population-based interventions intended to improve vaccination coverage. The related systematic reviews are linked by a common conceptual approach. These reviews form the basis for recommendations by the Task Force on Community Preventive Services (the Task Force) regarding the use of these selected interventions. The Task Force recommendations are presented on pp. 92–96 of this issue.

Medical Subject Headings (MeSH): vaccine-preventable diseases, vaccination coverage, community health services, decision-making, evidence-based medicine, systematic reviews, population-based interventions, practice guidelines, preventive health services, public health practice, task force. (Am J Prev Med 2000;18(1S):97–140) © 2000 American Journal of Preventive Medicine

Introduction

accine-preventable diseases among children, adolescents, and adults represent major continuing causes of morbidity and mortality in the United States. During the latter half of the twentieth century, the success of childhood vaccination programs in the United States has led to a >95 % decline in most vaccine-preventable diseases of childhood. However, >400,000 cases of illness and >30,000 deaths caused by vaccine-preventable diseases still occur each year (CDC unpublished data).

Diphtheria, invasive *Haemophilus influenzae* type b (Hib) disease, measles, poliomyelitis, rubella, tetanus,

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mumps, varicella, and pertussis are typically referred to as vaccine-preventable diseases of childhood. Vaccinations primarily indicated for adults include influenza, pneumococcal, and hepatitis B. However, during the 1990s, the distinction between childhood and adult vaccine-preventable diseases became less clear. Many childhood vaccine-preventable infections, including measles and pertussis, are found increasingly among adults,^{2,3} and hepatitis B vaccinations are now routinely recommended for infants and adolescents. Table 1 outlines universally recommended (i.e., vaccinations recommended for most or all persons in certain age groups) vaccinations for children, adolescents, and older adults.

In children, >50,000 cases of varicella occur each year, making that disease the most common vaccine-preventable disease among children⁴; in adults, influenza, pneumococcal disease, and hepatitis B are all still common vaccine-preventable diseases, with hundreds of thousands of cases occurring each year.⁵ Mortality attributable to vaccine-preventable diseases is still substantial. Each year, approximately 500 persons in the United States die of childhood vaccine-preventable diseases, and >30,000 adults die of influenza, pneumococcal infections, and hepatitis B.¹ Influenza, which accounts for an average of 20,000 deaths/year, is usually the largest killer.⁵

The effectiveness of universally recommended vaccinations in preventing disease for adults, adolescents,

Table 1. Universally recommended vaccinations

Population	Vaccination	Dosage
All young children	Measles, mumps, and rubella	2 doses
, 0	Diphtheria-tetanus toxoid and pertussis vaccine	5 doses
	Poliomyelitis	4 doses
	Haemophilius influenzae type B	3–4 doses
	Hepatitis B	3 doses
	Varicella	1 dose
Previously unvaccinated	Hepatitis B	3 doses total
or partially vaccinated adolescents	Varicella	If no previous history of varicella, 1 dose for children aged <12 years,2 doses for children aged ≥13 years
	Mumps, measles, and rubella	2 doses, total
	Tetanus-diphtheria toxoid	If not vaccinated during previous 5 years, 1 combined booster during ages 11–16 years
All adults	Tetanus-diphtheria toxoid	1 dose administered every 10 years
All adults aged ≥ 65	Influenza Pneumococcal	1 dose administered annually 1 dose

and children is well-established.^{6–14} In addition to protecting individuals from diseases passed from person to person contact, vaccination provides population-based (herd) immunity that prevents circulation of infectious agents. In general, uniformly high coverage levels will maximize protection of individuals and the population.

Vaccination coverage levels among U.S. school children exceeds 98% for vaccination with diphtheriatetanus toxoids and pertussis vaccine (DTP)/pediatric formulation of diphtheria and tetanus toxoids (DT), oral poliovirus vaccine (OPV), measles-containing vaccine, and Hib.¹⁵ Vaccination coverage among U.S. children aged 19-35 months exceeds 90% for 3 or more doses of DTP/DT, 3 or more doses of OPV, 1 or more doses of a measles-containing vaccine, and 3 or more doses of Hib vaccine, 16 but is lower for 4 or more doses of DTP vaccine (81%), 3 or more doses of hepatitis B vaccine (84%), and 1 dose varicella vaccine (26%). In addition, certain populations remain at higher risk for underimmunization. Recent data indicate that coverage levels for children aged 2 years remain significantly lower among urban populations as well as among low-income populations. 16,17

Vaccinations recommended for adults and more recently for adolescents are underused. Recent estimates indicate that $<60\%^{18}$ of adults aged >65 years are vaccinated against influenza and pneumococcal infection. No reliable estimates exist for vaccination coverage levels among adolescents.

Conceptual Approach

An explanation of the methods used to conduct the systematic reviews and arrive at the evidence-based recommendations contained in this paper is found in Appendix A. Tables and figures summarizing effectiveness findings and tables that support our economic analyses are available at the website: http://web.health.gov/communityguide.

An illustration of our logic framework depicts the conceptual approach that we chose during the review process (Figure 1). This figure portrays the relationships between a population, environmental and health system determinants, categories of interventions, and outcomes. By displaying our conceptual approach graphically, we are able to: (1) indicate intervention options for changing relevant outcomes; (2) indicate categories of related interventions; (3) describe the outcomes that the interventions attempt to influence; and (4) indicate the types of interventions that are included in these reviews and those that are not.

We focused on interventions intended to improve routine delivery of universally recommended vaccinations. We chose not to address vaccinations with more targeted indications, e.g., persons with specific medical conditions such as asthma or people who were at higher than usual risk of exposure to vaccine-preventable diseases such as travelers. The major outcomes considered included attendance in health care systems, delivery of vaccinations, and vaccine-preventable disease occurrence.

Three categories of interventions were selected: (1) increasing community demand for vaccination, (2) enhancing access to vaccination services, and (3) provider-based interventions.

The selected interventions within those categories were characterized by: (1) the nature of the activities involved; (2) the manner of delivery of the activities; (3) the type of people targeted, e.g., general population, groups at high risk, or a particular professional group; and (4) the setting in which the intervention was

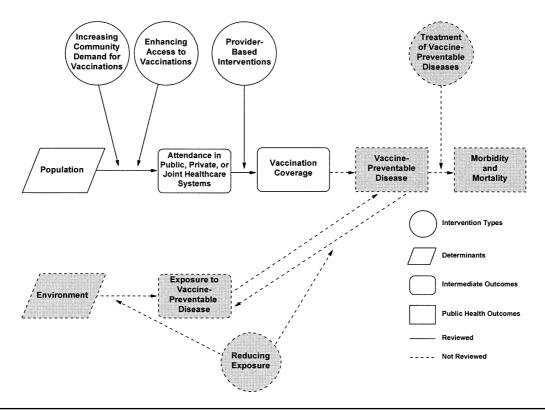


Figure 1. Logic framework depicting the conceptual approach used in these reviews.

applied, e.g., health care setting, nonhealth care setting, or community-wide setting. We reviewed interventions that were either single-component—using only one activity, or multicomponent—using more than one activity together, to achieve desired outcomes. We assessed the effectiveness of multicomponent interventions in improving coverage and changing other outcomes whether or not the relative contribution of individual components could be ascribed. We did not address strategies that reduce exposures to vaccine-preventable diseases, e.g., quarantine or outbreak control, nor did we evaluate the effectiveness of treatment of vaccine-preventable disease to reduce morbidity and mortality.

We grouped similar interventions together on the basis of their similarity and depth of available literature, i.e., the more literature available, the more subcategories that could be evaluated. Sometimes, we found that our classification or nomenclature was different from that used in the original studies being reviewed. When such a discrepancy occurred, we grouped interventions according to our definitions. By the end of the review process, we had reviewed the evidence of effectiveness of 17 interventions that we felt were likely to have a significant impact or were widely practiced. Time and resource constraints prohibited our evaluating other major categories of interventions.

Some activities that might improve vaccination coverage were not considered to be interventions for the purposes of these reviews. Activities that provide infor-

mation for public health action (e.g., vaccination registries) provide useful information and might even incorporate or lead to interventions (e.g., client reminder/recall interventions, provider reminder/recall interventions, and assessment and feedback for vaccination providers). However, we considered registries to represent a part of the public health infrastructure rather than being interventions themselves. Similarly, improving vaccines (e.g., developing vaccines that are less likely to cause adverse reactions or increasing numbers of antigens contained in a vaccine, thus reducing the number of injections required) can lead to better vaccination coverage. However, improving vaccines is primarily done for other reasons (e.g., harm reduction or to allow the administration of more antigens than would otherwise be feasible) and is therefore not considered to be an intervention for the purposes of these reviews.

Healthy People 2010 Goals and Objectives for Improving Vaccination Coverage

The interventions reviewed in this paper could be useful for reaching many of the objectives in *Healthy People 2000*¹⁹ and *Healthy People 2010*^a; those objectives are the prevention agenda for the United States. They identify the significant preventable threats to health

^aUS Health and Human Services, Draft for Public Comment, September 1998.

Table 2. 2010 Objectives related to vaccination and vaccinepreventable diseases

22.1	Reduce indigenous cases of vaccine-preventable
22.2	disease Monitor the national impact of influenza vaccinations on influenza-related
	hospitalizations and mortality among high-risk
	populations by annually collecting, analyzing, and reporting data from at least one medical care organization in all nine influenza
	surveillance regions of the country
22.5	Reduce to zero cases per 100,000 hepatitis B
	rates in persons aged <25 (except perinatal infections)
22.17a	Decrease the incidence of invasive
	pneumococcal infections to 49 per 100,000
	persons aged <5 years
22.17b	Decrease the incidence of invasive penicillin-
	reistant pneumococcal infections to 6.2 per
22.21	100,000 population aged ≥65 years Achieve immunization coverage of at least 90%
22.21	among children aged 19–35 months
22.22	Ensure that all 50 states achieve immunization
	coverage of at least 90% among children aged 19–35 months for [selected antigens]
22.23	Maintain immunization coverage at 95% for
	children in licensed day care facilities and
00.04	children in kindergarten through the first grade
22.24	Increase to 90% the rate of [influenza and
	pneumococcal] immunization coverage among adults aged ≥65; 65% for high-risk adults aged
	18–64 years
22.30	Increase to 90% the number of 2-year-old
	children who receive vaccinations as part of
	comprehensive primary care
22.31	(Develomental) increase to XX% the number
	of immunization providers who have
	systematically measured the immunization
00.00	coverage levels in their practice population
22.32	(Developmental) increase to XX% the number
	of children enrolled in a fully functional
	population-based immunization registry (birth through age 5)

XX, percentages not specified

and focus public and private sector efforts for addressing those threats. Many of the proposed Healthy People objectives in Chapter 22, "Immunization and Infectious Diseases," relate to vaccination and vaccine-preventable disease. This paper provides information on tested interventions that could help communities and health care systems reach Healthy People objectives. Healthy People objectives are shown in Table 2.

Information from Other Advisory Groups Information Regarding Use of Vaccines

The *Guide to Clinical Preventive Services* documents the effectiveness of vaccination in preventing disease among individuals and provides general recommendations for clinical practice regarding vaccinations.¹⁴ Recommendations regarding administration of childhood

vaccinations are issued regularly by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Department of Health and Human Services/Centers for Disease Control and Prevention, 11 the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).⁶ Since 1995, the AAP, AAFP, and ACIP have collaborated regarding a harmonized childhood vaccination schedule. 11 Recommendations regarding the administration of adolescent and adult vaccinations are published by ACIP, 12,13 the American College of Physicians,⁹ Infectious Disease Society of America, 9,20 AAFP,6 and the American College of Obstetricians and Gynecologists.8 Vaccination recommendations for adolescents are now coordinated among ACIP, AAP, AAFP, and the American Medical Association.

Information Regarding Improving Vaccination Coverage

Summaries and recommendations regarding interventions to improve vaccination coverage have been developed by the Canadian Community Health Practice Guidelines Working Group, 21,22 ACIP, 23,24 and the National Vaccine Advisory Committee. 25

Interventions: Increasing Community Demand for Vaccinations

Interventions that increase community demand for vaccinations are designed to increase knowledge regarding and demand for vaccination services. Interventions that increase community demand for vaccinations reviewed in this report include client reminder/recall, multicomponent interventions that include education, vaccination requirements for child care, school, and college attendance, community-wide education only, client or family incentives, and client-held medical records.

Client Reminder/Recall

Background. Reminders and recalls allow clients to know when vaccinations are due or overdue, as well as when to contact their vaccination provider to determine if vaccinations are needed. Reminders or recalls can be mailed or communicated by telephone; an autodialer can be used to expedite telephone reminders. Client reminders can be either specific (i.e, certain vaccinations are due on a specific date) or general.

Review of evidence: effectiveness. Our search identified 60 studies regarding the effectiveness of client reminder/recall interventions. ^{26–85} Nine additional papers provided more information regarding an already included study. ^{86–94} A total of 18 studies had limited execution ^{26,27,34,51,54,56,60,62,69,70,75,81,85} or least suitable designs ^{35,44,53,58,73} and were therefore not included in

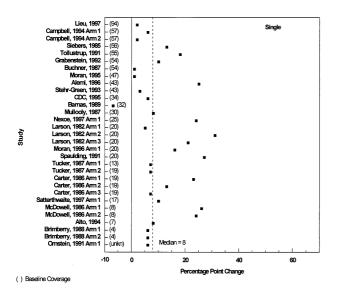


Figure 2. Percentage point change in vaccination coverage attributable to single component client reminder/recall interventions from studies that qualified for inclusion in this review.

the review. Details of the 42 qualifying studies are provided in Figures 2 and 3, Appendix B, and at the website: http://web.health.gov/communityguide.

The qualifying studies reported on 34 intervention arms that evaluated reminders or recalls used alone and 25 intervention arms evaluating multicomponent interventions that included reminders or recalls. Multicomponent interventions also included expanded access, ^{31–33,36,37,57,63,66,72,84} provider reminders, ^{36,38,42,43,52,72,74} clinic-based education, ^{28,29,31,33,36,42} provider education, ^{30–33,36,63} reducing out-of-pocket costs, ^{28,30,32,66,71,76}

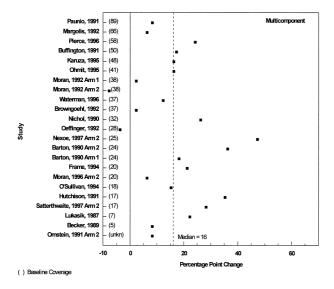


Figure 3. Percentage point change in vaccination coverage attributable to multiple component interventions including client reminder/recall from studies that qualified for inclusion in this review.

provider assessment and feedback, ^{36,42,47} client incentives, ^{33,66,84} community-wide education, ^{30,32,38} standing orders, ^{63,72} the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) program interventions, ³² home visits, ³³ and client-held medical records. ²⁸

Two qualifying studies 78,84 provided data that could not be expressed as a percentage point change in coverage. The remaining studies provided data regarding 31 single-component and 23 multicomponent intervention arms. Overall, these studies documented a median percentage point change of 12% (range, -8%-47%). Studies that evaluated client reminder/recallonly interventions documented a median percentage point change of 8% (range, -7%-31%). Studies that evaluated client reminder/recall as part of a multicomponent intervention documented a median percentage point change of 16% (range, -8%-47%).

Most qualifying studies evaluated reminders, although some evaluated both reminders and recalls³⁹ or recalls only. ^{61,82} Studies evaluated both telephone ^{39,40,45,52,64,80} and mailed ^{29,40,41,45–50,55,57,61,64–68,71,76–78,82–84} reminders. Mailed reminders included both letters and postcards. Two studies ^{45,64} directly compared mailed reminders with telephone reminders and did not find a difference regarding effectiveness between them. Six studies evaluated intensity of reminders (e.g., general to more specific, generic to personalized, and signed by physician as well as greater versus lesser numbers of reminders), ^{49,50,59,66,83,84} and five of the six studies found greater increases in coverage with more-intensive reminders. No studies were found evaluating reminders delivered by computers (e.g., by e-mail).

Review of evidence: applicability. The same body of evidence used to assess effectiveness was used to assess the applicability of these interventions to different settings, populations, and vaccinations. Studies have included adults^{30,36,37,41–43,45–47,49,52,55,57,59,63–68,71,72,74,76,77,83} and children. ^{29,31–33,38–40,48,61,78,80,82,84} Adolescents have been studied in mother-infant pairs²⁸ but have not been studied regarding their own vaccinations. Studies have included white, 31,55,84 black, 28,29,39,41,43,48,74 and Hispanic^{29,31,32,40} persons, urban, 28,36,39,41,45,48,49,57,67 suburban, 41,45,46 and rural 45,46,50,52 populations, and both poor^{28,31–33,39,40,43,46,48,52,65,74} and nonpoor^{31,46,55,61} persons. Studies have been done in a range of settings including academic clinical settings, ^{28,29,40,43,45,48,59,64,66,77} public health settings, ^{31,80,82,83} managed care, ^{33,61,63,68} private practice, ^{36,46,47,52} pharmacies, ⁵⁵ and communitywide settings. 30,38,50,78 Studies are available to assess the effectiveness of these interventions to improve vaccination delivery of measles, mumps, and rubella (MMR), 32,33,38-40,61 DTP, ^{29,31–33,39,40,48,80,82} OPV, ^{29,31–33,39,40} Hib, ^{33,39,40} influenza, 30,36,37,41-43,45-47,49,50,55,57,59,63-68,71,72,76,79,83 pneumococcal, 43,77 and adult formulation of diphtheria and tetanus toxoids (Td).43,52,64 No studies were found

evaluating client reminder/recall to encourage adolescent vaccinations or to improve delivery of hepatitis B vaccinations.

Review of evidence: other positive or negative effects. No other positive or negative effects of client reminder/recall interventions were sought in this review.

Review of evidence: economic. Our search identified 11 economic evaluations of client reminder/recall interventions. 27,46,52,61,65,71,93,95-98 One additional paper provided more information regarding an already included study.⁶⁴ Details of the studies are provided in Appendix C and at the website: http/web.health.gov/ communityguide. A total of 9 studies provided 12 cost-effectiveness ratios for single-component reminder/recall interventions and 3 cost-effectiveness ratios for multicomponent interventions that include reminder/recall. Adjusted cost-effectiveness ratios for singlecomponent interventions based on those studies ranged from \$3 per additional vaccination to \$46 per additional vaccination (median, \$9). Adjusted costeffectiveness ratios for multicomponent interventions were \$4 per additional vaccination for a combination of client and provider reminders⁵²; \$51 per additional vaccination for a combination of reminders and a lottery-type incentive⁶⁵; and \$43 per additional vaccination for a combination of mailed reminders and free vaccinations.⁷¹

Adjusted average costs based on 2 available studies varied from \$0.65 to \$5.75 per child. The lower cost is an underestimate because the cost of the in-kind contribution of volunteer time was not included. The upper cost might be an overestimate because it includes costs of clinical time to provide vaccinations.

Barriers to intervention implementation. Barriers to implementing reminder/recall interventions might include lack of information infrastructure and administrative burden on providers or systems.

Conclusion. According to the *Guide*'s rules of evidence, strong scientific evidence exists that client reminder/ recall is effective in improving vaccination coverage.

Multicomponent Interventions That Include Education

Definition. Multicomponent interventions that include education provide knowledge to target populations and sometimes, to vaccination providers, and use at least one other activity to improve vaccination coverage.

Background. Multicomponent interventions that include education address health concerns and barriers to vaccination in an integrated way. Multicomponent interventions that include education are based on the premise that prerequisites to health include the physical, social, and political environment in which health

risks occur. These interventions make community members aware of vaccination services available to them, the utility and relevance of these services, and information that will help to take advantage of these services. These interventions also incorporate a variety of associated strategies to improve vaccination.

Review of evidence: effectiveness. Our search identified 34 studies regarding the effectiveness of multicomponent interventions that include education. 26-38,99-120 Three additional papers provided more information regarding an already included study. 86,87,89 Seventeen studies had limited execution and were therefore not included in the review. ^{26,27,34,99–105,109,110,112,113,115,116,119} Details of the 17 qualifying studies are provided at the website: http://web.health.gov/communityguide. All qualifying studies evaluated interventions that included community or client education. The interventions also included client reminders, 28-33,35,36,38 provider education, 30-33,36,108 expanded hours or access in clinical settings, 31-33,36,107,111 provider reminders, 28,36-38,106,114 reducing out-of-pocket costs, 28,30,32,108 client-held vaccination records, 28,117 WIC interventions, 32 medical and psychosocial assessments,107 nutrition services,107 and home visits. 33 Fifteen studies 28-33,35-38,106-108,117,118 that reported measures of vaccination coverage found percentage point changes in vaccination coverages ranging from -4% to 29% (median, 16%) in follow-up times of as much as 5 years. Positive effects were found both in clinical and community settings (median, 16%, range, -4%–25% versus median, 12%, range, 5%– 29%, respectively). Available data do not allow attribution of the portion of the overall effect of the interventions to individual components but suggest that combined interventions increase vaccination coverages.

Any of several reasons could explain the fact that multicomponent interventions that include education seemed effective in improving vaccination coverages, whereas some components (e.g., community-wide education [section 4], clinic-based education [section 5], and expanded clinic hours or access [section 9]) by themselves demonstrate less-convincing evidence of effectiveness. Possibly, this reflects the following:

- more studies of multicomponent interventions;
- greater intensity (and thus greater effectiveness) of multicomponent interventions;
- synergy between components of multicomponent interventions (i.e., the whole is more effective than the sum of the parts); or
- education only might not cause large increases in acceptance of vaccinations, but could facilitate implementation of other components.

Review of evidence: applicability. The same body of evidence used to assess effectiveness was used to assess the applicability of these interventions to different settings, populations, and vaccinations. Studies have

adults^{30,36,37,106,108,114,117,118} and included children. 28,29,31-33,35,38,107 Adolescents have been studied in mother-infant pairs^{28,107} but have not been studied regarding their own vaccinations. Studies have been performed in populations including white, 31,117,108,118 black, ^{28,29} and Hispanic ^{29,31,32,107,117} persons and in populations including poor^{28,31–33,114} poor^{31,107} persons. Studies in clinical settings come academic primarily from clinical organizations^{28,29,106,107,114,117,118} but have also been done in private physician's offices, 36 public health clinics, 31 and managed care.³³ Studies are available that demonstrate improvements in vaccination delivery of influenza, ³⁰, 36, 37, 108, 117, 118 pneumococcal, ¹⁰⁶, 117, 118 Td, ¹¹⁴, 117 DTP and OPV, ²⁹, ³¹ – ³³ MMR, ³², ³³, ³⁸, ¹¹¹ and Hib. ³³ No studies were found evaluating multicomponent educational strategies to encourage adolescent vaccinations or to improve delivery of hepatitis B vaccinations.

Review of evidence: other positive or negative effects. Several qualifying studies that assessed nonvaccination outcomes (e.g., improved delivery of other preventive or clinical care)^{28,107,114,117} found improvements in some nonvaccination outcomes. Other positive or negative effects of multicomponent educational interventions are discussed under the individual components.

Review of evidence: ecomonic. Our search identified two economic evaluations of multicomponent interventions that include education. 109,120 Details of the studies are provided at the website: http//web.health.gov/ communityguide. No studies of cost-effectiveness were available. One study evaluated the costs of an intervention that included assembling a community task force, undertaking a media campaign, and implementing a school-based program that assessed students' immunization status and delivered vaccinations. 109 The adjusted estimate of average program costs based on that study is \$23 per child vaccinated. Another study estimated the costs of an intervention that included expanded access to vaccination services, multiple education and health promotion activities, and possibly, provider assessment and feedback. 120 The adjusted estimate of average program costs based on that study is \$7.65 per vaccination delivered. Children in the first study could have received more than one vaccination, so the estimates might be more similar than they appear.

Barriers to intervention implementation. Potential barriers to implementing multicomponent educational strategies could include difficulties in coordinating strategies between varying programs and administrative systems.

Conclusion. According to the *Guide*'s rules of evidence, strong scientific evidence exists that multicomponent interventions that include education are effective in improving vaccination coverage. However, the contri-

bution of individual components to the overall effectiveness of these interventions cannot be attributed.

Vaccination Requirements for Child Care, School, and College Attendance

Definition. Child care, school, and college requirements are laws or policies requiring vaccinations or other documentation of immunity as a condition of attendance.

Background. Enactment and enforcement of state immunization laws during the 1970s–1980s led to >95% of school–aged children now being appropriately vaccinated with recommended doses of vaccine. Immunization requirements for child care and college attendance and their enforcement are more recent and vary greatly among states.

Review of evidence: effectiveness. Our search identified 10 studies regarding the effectiveness of vaccination requirements for child care, school, or college attendance. 121-130 An additional paper provided more information regarding an already included study. 131 One study had limited execution and was not included in the review. 130 Details of the 9 included studies are provided at the website: http://web.health.gov/communityguide. Six of the available studies found reductions in disease rates. 121,123,125,127–129 Three nationwide cross-sectional or before/after studies found that states with immunization requirements for school-age children had lower incidence of measles 125,129 mumps. 128 Additionally, officials in areas with low incidence of measles were more likely to enforce school laws by excluding noncompliant children from attendance. 125 A cross-sectional study from New Jersey found that children covered by a law requiring mumps vaccination were much less likely to have mumps during an outbreak than other children. 123 A time-series study from New York found that requiring Hib vaccinations for attendance in child care (without any enforcement) resulted in declines in Hib incidence among child care attendees that exceeded declines for New York as a whole. 127 A retrospective cohort study found that state laws requiring prematriculation measles vaccinations resulted in lower risk for measles outbreaks after controlling for other variables. 121

The three studies that looked at vaccination coverage as an outcome found a median percentage point change of 15% (range, 5%–35%). A before/after study in Ontario, Canada, 122 found that immunization requirements for all school attendees aged 5 to 17 years produced coverage differences ranging from 3% to 9% by antigen (equally weighted average = 5%) from a relatively high baseline coverage of 87%. A time-series study 126 over a 7-year period (1979–1986) following enactment of school laws in California in 1977 and enforcement in 1986 documented that vaccination

coverage among children aged 5 to 6 years increased approximately 15% from a baseline coverage of approximately 75%. A cross-sectional study¹²³ in New Jersey found that children aged <7 years required by a school law to be vaccinated against mumps were more likely to have "documented immunity" (either vaccination or physician documented history of disease) than children not covered by the law (96% versus 61%, respectively). A time-series study¹²⁴ that evaluated the effect of a school law for rubella regarding immunity to rubella found an initial improvement in immunity that was not sustained several years later.

Review of evidence: applicability. The same body of evidence used to assess effectiveness was used to assess the applicability of these interventions to different settings, populations, and vaccinations. The majority of the available studies evaluated school laws, ^{122,123–126,128,129} but other studies also evaluated vaccination requirements for child care ¹²⁷ and college attendance. ¹²¹ Generally, available studies did not describe the study populations in detail. However, many of these studies included all 50 states. ^{125,128,129} Other studies used representative samples of U.S. 2- and 4-year colleges ¹²¹; statewide data from New York ¹²⁷ or California ¹²⁶; or provincial data from Ontario, Canada. ¹²² The evidence of effectiveness should apply to most children and young adults in the United States.

Studies are available that assess the effectiveness of these interventions in improving delivery of MMR or other measles-containing vaccinations^{122,126} and in reducing occurrence of measles^{125,129} and mumps^{123,128}; in improving coverage with DT or DTP and OPV^{122,126}; and in reducing incidence of Hib.¹²⁷ No studies were found evaluating the effectiveness of these interventions in improving delivery of hepatitis B vaccinations.

Review of evidence: other positive or negative effects. No other positive or negative effects of vaccination requirements for child care, school, or college attendance were sought in this review.

Review of evidence: ecomonic. No economic evaluations of vaccination requirements for child care, school, and college attendance were identified.

Barriers to intervention implementation. Potential barriers to implementation of vaccination requirements for child care, school, and college attendance include administrative burden, difficulty coordinating various programs, and difficulty passing legislation.

Conclusion. According to the *Guide*'s rules of evidence, sufficient scientific evidence exists that vaccination requirements for child care, school, and college attendance are effective in improving vaccination coverage and immunity and/or in reducing rates of disease.

Community-wide Education Only

Definition. Community-wide education-only interventions provide information to most or all of a target population in a geographic area. These interventions can also provide information to vaccination providers. Interventions that have additional features (e.g., reminders), are used in combination with other interventions (e.g., multicomponent interventions that include education), or are limited to site-specific efforts in a particular setting (e.g., schools or child care centers) are reviewed elsewhere in this paper.

Background. Community-wide education is intended to improve the availability of information regarding vaccinations and increase knowledge, thereby changing behavior. Educational messages can be delivered by various methods (e.g., mail, radio, newspapers, television, and posters). Community-wide education can result in increases in vaccination coverage by increasing acceptance and demand for vaccinations among clients.

Review of evidence: effectiveness. Our search identified six studies regarding the effectiveness of community-wide education-only interventions. 38,56,75,132-134 Of these, five^{56,75,132–134} had limited execution and were therefore not included in this review. The qualifying time-series study, conducted with children, found some improvements in the number of measles vaccinations delivered among those aged 6 years but not among those aged 14 to 18 months coincident with a massmedia campaign. The study did not provide substantial information regarding content or intensity of the intervention. Details of the qualifying study are provided at the website: http://web.health.gov/communityguide. No studies were identified evaluating the effect of community-wide education-only interventions regarding knowledge or attitudes.

Review of evidence: other positive or negative effects. No studies evaluating other positive or negative effects of community-wide education-only interventions were sought.

Conclusion. According to the *Guide*'s rules of evidence, available studies provide insufficient evidence to assess the effectiveness of community-wide education-only interventions regarding improving knowledge or attitudes regarding vaccinations or in improving delivery of vaccinations. Only one qualifying study was identified that assessed the effectiveness of community-wide education-only interventions regarding delivery of vaccinations. That study had limitations in design and conduct and found inconsistent results in different subpopulations. No qualifying studies were identified evaluating the effectiveness of community-wide education-only interventions regarding knowledge and attitudes. However, community-wide education is a

component of many effective multicomponent interventions.

Clinic-Based Education Only

Definition. Clinic-based education-only interventions provide information to groups served in a specific medical or public health clinical setting. Interventions that have additional features (e.g., reminders), are used in combination with other interventions (e.g., multicomponent interventions that include education), or are provided in other settings (e.g., schools or child care centers) are reviewed elsewhere in this paper.

Background. Clinic-based education-only interventions might include informational brochures (e.g., "Vaccine Information Statements"), videotapes, or posters that could enable the client to take advantage of available services in the clinic. "Vaccine Information Statements" are commonly used standardized informational statements that are available to all providers of vaccinations and are distributed to clients both to provide information and to obtain consent for vaccination.

Review of evidence: effectiveness. Our search identified five studies regarding the effectiveness of clinicbased education-only interventions. 118,135-138 Of these, two^{136,137} had limited execution and were, therefore, not included in the review. Details regarding the three qualifying studies are provided at the website: http:// web.health.gov/communityguide. One randomized trial¹¹⁸ comparing a combination of printed client educational materials and provider education with provider education only found nonsignificant increases in vaccination coverage of 3% for influenza (baseline, 23%) and 2% for pneumococcal (baseline, 3%) vaccines. Two before/after studies evaluated the effect of "Vaccine Information Statements" regarding parental knowledge and attitudes. One¹³⁵ found a significant increase in client knowledge regarding vaccines and desire to have their child vaccinated; the other study¹³⁸ found no statistically significant effect regarding parental beliefs.

Review of evidence: other positive or negative effects. No information regarding other positive or negative effects was sought in this review.

Conclusion. According to the *Guide*'s rules of evidence, available studies provide insufficient evidence to assess the effectiveness of clinic-based education-only interventions regarding improving vaccination coverage. Only one qualifying study evaluating the effectiveness of printed educational materials regarding improving vaccination coverage was identified. That study found effects regarding coverage that were neither substantial nor statistically significant. Only two studies were identified that evaluated the effects of vaccination information statements regarding client knowledge or attitude

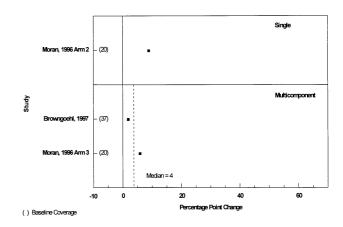


Figure 4. Percentage point change in vaccination coverage attributable to client or family incentives from studies that qualified for inclusion in the review.

toward vaccination. Those studies demonstrated variable effects regarding knowledge and attitudes. No studies were identified evaluating clinic-based educational strategies other than printed educational materials.

Client or Family Incentives

Definition. Client incentives involve providing financial or other incentives to motivate persons to accept vaccinations. Incentives can be either rewards or penalties. Some interventions with aspects of incentives (e.g., WIC programs and child care, school, and college attendance requirements) are reviewed elsewhere in this paper.

Background. Client incentives are based on the assumption that clients will be motivated to seek vaccinations for themselves or their children if they receive rewards (e.g., baby toys, money, or discount coupons for retailers) or to avoid penalties (e.g., being excluded from participating in a program).

Review of evidence: effectiveness. Our search identified three studies regarding the effectiveness of incentives. 33,65,84 All three of those studies were admissible for inclusion in the review, and details regarding those studies are provided in Figure 4 and at the website: http://web.health.gov/communityguide. One additional paper provided more information regarding an already included study. 89

The qualifying studies reported on one intervention arm that evaluated using incentives only and three intervention arms that evaluated incentives used with reminders with or without other interventions. One randomized controlled trial⁶⁵ was conducted among adults in a community health center. That study evaluated the effectiveness of a lottery for a \$50 gift certificate for groceries offered alone or combined with

mailed client reminders to improve acceptance of influenza vaccination. The study found that percentage point changes for influenza were 9% (significant) when the incentive was used alone and 6% (nonsignificant) when combined with reminders; baseline coverage was 20%. A group randomized trial,84 which was conducted in a public health center among children, evaluated a lottery for \$25 to \$100 cash prizes together with mailed client reminders. Change in delivery of at least 1 antigen was 18% during the study period. (This could not be converted to a percentage point change). A retrospective cohort study³³ among parents of children in a Medicaid managed care group gave \$10 gift certificates when vaccinations were obtained in conjunction with a multicomponent strategy that included provider and parent reminders, home visiting, transportation assistance, and provider education. Differences in coverage with DPT, OPV, MMR, and Hib at age 35 months was 2% (nonsignificant); baseline coverage was 37%. No studies of positive incentives other than lottery-type incentives or gift certificates, nor studies of negative incentives, were identified.

Review of evidence: other positive or negative effects.No information regarding other positive or negative effects was sought in this review.

Barriers to intervention implementation. Potential barriers to incentives include ethical concerns regarding the potential for coerciveness of these interventions.

Conclusion. According to the *Guide*'s rules of evidence, available studies provide insufficient evidence to assess the effectiveness of client or family incentives for improving vaccination coverage. Evidence is insufficient because of the (1) small number of available studies; (2) variability in interventions evaluated; and (3) two of the four qualifying studies found results that were neither substantial nor statistically significant.

Client-Held Medical Records

Definition. Client-held medical records that indicate which vaccinations have been received are provided to members of a target population or their families.

Background. Client-held medical records can be used to assess a client's immunization status in medical and other settings and can improve a client's awareness of vaccinations needed or due. State and local health departments and providers have encouraged use of client-held medical records to varying degrees. Client-held medical records could result in improvements in vaccination coverage by (1) increasing client knowledge regarding and demand for vaccinations; (2) reducing missed opportunities to vaccinate in health care settings; or (3) a combination of the two.

Review of evidence: effectiveness. Our search identified eight studies regarding the effectiveness of client-

held medical records. 28,105,117,139-143 Of these, four had limited execution and were not included in the review. 105,139,141,142 Details regarding the four qualifying studies are provided at the website: http://web.health. gov/communityguide. One of the studies compared the combination of a client-held record and a provider reminder with provider reminders only. 143 Other studies evaluated client-held records in conjunction with clinic-based education,117 client reminders,140 or multiple strategies.²⁸ One study¹⁴⁰ reported that "coverages were >45% in both groups" after the intervention and that differences between the groups were not significant. However, that study did not present data that could be expressed as a percentage point change in coverage. The other three studies reported percentage point changes in coverage ranging from 5% to 15%; some findings reached a level of statistical significance but others did not.

Review of evidence: other positive or negative effects. All qualifying studies found increases in the use of some other preventive or clinical services. No information regarding other positive or negative effects were sought in this review.

Barriers to intervention implementation. A potential barrier to the use of client-held medical records includes a possible burden placed on providers. One provider survey found that 80% of providers surveyed reported positive or very positive overall reactions to a "health diary" but 17% of providers believed that such records negatively affected client flow.¹¹⁷

Conclusion. According to the *Guide*'s rules of evidence, available studies provide insufficient evidence to assess the effectiveness of client-held medical records in improving vaccination coverage. Evidence is insufficient because of the: (1) small number of studies; (2) limitations in study design and conduct; (3) variability in interventions evaluated; and (4) several of the reported results were neither substantial nor statistically different from zero.

Research Issues for Increasing Community Demand for Vaccinations

Effectiveness. The effectiveness of recommended and strongly recommended interventions in this section (multicomponent interventions that include education; client reminder/recall; and vaccination requirements for child care, school, and college attendance) is established. However, research questions regarding the effectiveness of these interventions remain.

- What particular characteristics of interventions to increase community demand for vaccinations contribute to increased or lessened effectiveness?
- How do content, specificity, method of delivery, and

frequency of delivery of reminder/recall contribute to effectiveness?

- How do cultural characteristics of clients contribute to increased or lessened effectiveness of different interventions?
- What is the relative effectiveness of reminder and recall systems?
- What are the least and most effective combinations of services in multicomponent interventions?
- How does the effectiveness of vaccination requirements for child care, school, and college attendance vary by specific requirements of legislation and vigorousness of enforcement?
- Do registries provide a functional backbone for effective interventions, including multicomponent interventions that include education or client reminder/recall?

Because the effectiveness of community-wide education-only interventions, clinic-based education-only interventions, client or family incentives, and client-held medical records regarding improving vaccination coverage has not been established, basic research questions remain.

- Are these interventions effective in improving vaccination coverage?
- Do these interventions promote positive or negative attitudes toward vaccination among target populations?
- What attributes of clinic-based or community-wide educational programs—medium, message, intensity—contribute to effectiveness or lack thereof?
- What attributes of incentives (e.g., type or amount) contribute to effectiveness or lack thereof?
- Do multiple competing prevention messages act in ways that are synergistic or interfering?
- Do client-held medical records reduce missed opportunities for vaccination?

Applicability. Each recommended and strongly recommended intervention should be applicable in most relevant target populations and settings. However, possible differences in the effectiveness of each intervention for specific subgroups of the population could not be determined. Several questions regarding the applicability of these interventions in settings and populations other than those studied remain.

- Are these interventions effective in improving vaccination coverage in adolescents?
- Do meaningful differences exist in effectiveness of these interventions based on the level of scale at which they are delivered (i.e., community-wide systems from a registry versus managed care-based systems versus practice-based systems)?

Other Positive or Negative Effects

With the exception of some discussion of improved use of other clinical and preventive care, the studies included in this review did not report on other positive or negative effects of these interventions. Therefore, research regarding the following questions would be useful:

- Do interventions implemented at the community level (e.g., community-wide education-only interventions or multicomponent interventions that include education) result in positive outcomes other than improved vaccination coverage (e.g., community empowerment)?
- Do clinic-based interventions to increase client demand for vaccinations interfere with office flow or efficiency, and if so, how can this effect be minimized?
- Do child care, school, and college vaccination requirements interfere with the other activities of the settings, and if so, how can that effect be minimized?
- Do these interventions result in other positive changes in disease prevention or health care as well as improving vaccination coverage?

Economic evaluations. In general, available economic information was sparse; therefore, considerable research is warranted regarding the following questions:

- What are the costs of these interventions?
- How do the costs per additional child vaccinated compare with other interventions to improve vaccination coverage?
- Can strategies that are designed to improve vaccination coverage and other outcomes concurrently improve cost-effectiveness of these strategies?
- How do specific characteristics of these interventions contribute to economic efficiency?
- What are the relative economic consequences of reminder and recall systems?
- What characteristics of reminders or recall (e.g., frequency, content, or method of delivery) are the most cost-effective?
- What combinations of components in multicomponent interventions are most cost-effective?
- What is the cost-benefit or cost-utility of these interventions?

Barriers. How can these interventions be implemented with minimal administrative burden placed on providers or systems?

• Do community-wide registries reduce barriers to use or increase use of these interventions?

Enhancing Access to Vaccination Services

Interventions that enhance access to vaccination services are designed to reduce the cost or to increase the

convenience of obtaining vaccinations. Interventions that enhance access to vaccination services reviewed in this paper include reducing out-of-pocket costs, expanding access in health care settings, and vaccination interventions in non-medical settings, including vaccination programs in WIC settings, home visits, vaccination programs in schools, and vaccination programs in child care centers.

Reducing Out-of-Pocket Costs

Definition. Reducing out-of-pocket costs to families for vaccinations or administration of vaccinations can be implemented by paying for vaccinations or administration, providing insurance coverage, or reducing copayments for vaccinations at the point-of-service.

Background. The out-of-pocket costs of vaccination are commonly cited by clients and providers as a barrier to obtaining vaccinations. Many interventions have been used by the U.S. government (e.g., the Vaccines for Children Program), state governments (e.g., provision of free vaccinations), and managed care organizations (e.g., reducing co-pays) to reduce this barrier. Reducing out-of-pocket costs can result in increases in vaccination coverage either by improving availability of vaccinations or increasing demand for vaccinations.

Review of evidence: effectiveness. Our search identified 26 studies regarding the effectiveness of reducing out-of-pocket costs. ^{28,30,35,56,67,71,76,101,108,110,116,145–159} Two additional papers provided more information regarding an already included study. ^{160,161} Seven studies had limited execution and were therefore not included in the review. ^{56,101,110,116,146,152,155} Details of the 19 qualifying studies are provided at the website: http://web.health.gov/communityguide. Of the qualifying studies, 14 evaluated the effectiveness of reducing out-of-pocket costs regarding improving vaccination outcomes ^{28,30,35,67,71,76,108,147–150,153,156,158}; four evaluated the effectiveness of these interventions regarding improving provider-reported likelihood of referring clients elsewhere for vaccinations, ^{145,151,154,159} and one evaluated both vaccination and referrals. ¹⁵⁷

Of the studies evaluating vaccination outcomes, seven evaluated reducing out-of-pocket costs as a single-component intervention, and eight evaluated multi-component interventions that included reducing out-of-pocket costs. Multicomponent interventions included client reminder/recall, ^{28,30,67,71,76} community-wide education, ^{30,108} expanding access in health care settings, ^{67,156} provider education, ^{30,108} clinic-based education, ²⁸ client-held medical records, ²⁸ WIC interventions, ¹⁴⁸ and provider reminder/recall. ²⁸

Two studies evaluating the effects regarding coverage of single-component interventions suggested increased¹⁵⁰ or earlier¹⁵⁸ vaccination, but did not present results that could be expressed as a percentage point

change in coverage. The remaining 13 studies reported on 15 intervention arms that found median percentage point changes in coverage ranging from -8% to 47% (median, 15%). The five studies of single-component interventions that could be expressed as percentage point changes in coverage reported on six intervention arms that found changes in coverage ranging from -1% to 29% (median, 10%). Eight studies evaluating the effects of multicomponent interventions regarding coverage reported on nine intervention arms and found median percentage point changes in coverage ranging from -8% to 47% (median, 16%). 28,30,67,71,76,108,148,156

Five provider surveys^{145,151,154,157,159} with fair or good execution found that providers reported being more likely to refer children with less public or private insurance coverage to other sites for vaccination. Two of these studies^{154,159} were nationally representative surveys of pediatricians and family physicians.

Review of evidence: applicability. The same body of evidence used to assess effectiveness was used to assess the applicability of these interventions of different settings, populations, and vaccines. Studies have included children^{35,147,148,153,156–158} and adults.^{30,67,71,76,108,149,150} Adolescents have been studied in mother-infant pairs²⁸ but not regarding their own vaccinations. Studies have been performed in urban^{28,67,108,148,156} and rural^{30,149} settings, and in populations with low^{28,148,153,156} and mixed^{150,158} socioeconomic status. Settings in which reduced cost vaccinations were provided included hospitals,^{28,149} clinics,^{147,149} private offices,^{157,158} WIC sites,¹⁴⁸ and emergency departments.¹⁵⁶

Review of evidence: economic. Our search identified one economic evaluation of interventions offering free or discounted vaccinations.⁷¹ Details of this study are provided at the website: http://web.health.gov/communityguide. This study evaluated the cost-effectiveness ratio of a multicomponent intervention offering mailed reminders and free vaccine to encourage influenza vaccination. The adjusted cost-effectiveness ratio of this intervention compared with no intervention on the basis of this study was \$43/additional vaccination.

Review of evidence: other positive or negative effects. Our search did not identify any studies related to the question of whether reducing out-of-pocket costs negatively affects vaccine research and development. No other positive or negative effects of this intervention were sought in this review.

Barriers to intervention implementation. Potential barriers to implementation of reducing out-of-pocket costs include fragmentation of payment mechanisms.

Conclusion. According to the *Guide*'s rules of evidence, strong scientific evidence exists that reducing out-of-pocket costs for vaccinations is effective in improving vaccination coverage.

Expanding Access in Health Care Settings

Definition. Expanding access increases the availability of vaccines in medical or public health clinical settings in which vaccinations are offered by: (1) reducing the distance from the setting to the population; (2) increasing or changing hours during which vaccination services are provided; (3) delivering vaccinations in clinical settings in which they were previously not provided (e.g., emergency departments, inpatient units, or subspecialty clinics); or (4) reducing administrative barriers to obtaining vaccination services within clinics (e.g., developing a "drop-in" clinic or an "express lane" vaccination service).

Background. Surveys of client attitudes and behaviors have identified inconvenience of obtaining vaccinations as a major barrier toward improving vaccination rates in children. ¹⁴⁴ This factor might be particularly important for disadvantaged, low-income families, many of whom have large families and little financial support for child care or transportation.

Review of evidence: effectiveness. Our search identified 25 studies regarding the effectiveness of expanded access. 27,31–33,36,37,57,63,67,72,73,84,101,103,107,110,111,116,119,139,146, 156,162-164 Four additional papers provided more information regarding an already included study. 86,88,89,91 Nine studies were not included in the review because of limited execution. 27,101,103,110,116,119,139,146,163 Details regarding the 16 qualifying studies are provided at the website: http://web.health.gov/communityguide. The qualifying studies provided data regarding two intervention arms that evaluated expanding access only and 15 intervention arms that included expanded access combined with other interventions. Types of expanded access included drop-in clinics, ^{32,57,63,67,72} increased hours on nights and weekends, 31,84,107 providing vaccinations in emergency departments, 156,164 dedicated vaccination clinics,73,111 special vaccination appointments,36,37 vaccination stations for inpatients, 162 and transportation assistance.³³ Most multicomponent interventions included client reminder/recall. 31–33,36,37,57,63,67,72,84 Other components used with expanded access included provider education, 31-33,36,63 clinic-based education, 31,33,36,107 reducing costs, 32,67,156 standing orders, 63,72,162 communitywide education, 32,111 client incentives, 33 WIC interventions,³² home visiting,³³ and assessment and feedback.³⁶

Three qualifying studies^{84,111,162} presented data that could not be expressed as a percentage point change in coverage. The remaining studies presented data regarding 12 multicomponent intervention arms and 2 single-component intervention arms. The overall median percentage point change was 10% (range, -8% to 35%). Two studies that evaluated expanded access only found median percentage point changes of 3% and 7%; only one of these reached a level of statistical significance. Studies that evaluated expanding access in

combination with other interventions found a median percentage point change of 13% (range, -8% to 35%).

Any of several reasons could explain the fact that multicomponent interventions that include expanding access were effective in improving vaccination coverages, whereas expanding access only had less convincing evidence of effectiveness. Possibly, this finding reflects:

- the existence of more studies of multicomponent interventions;
- greater intensity and, thus, greater effectiveness of multicomponent interventions; or
- synergy between components of multicomponent interventions (i.e., the whole is more effective than the sum of the parts).

Another possibility is that only expanding access might not cause large increases in acceptance of vaccinations by itself but could increase the feasibility of using other components (e.g., standing orders or reminders).

Review of evidence: applicability. The same body of evidence used to assess effectiveness was used to assess the applicability of these interventions to different settings, populations, and vaccines. Populations have included adults^{36,37,57,63,67,72,73,162} and children. 31-33,84,111,156,164 Adolescents have been studied in mother-infant pairs but not regarding their own vaccinations. 107 Studies have been conducted in a variety of settings including managed care, 33,63 community clinics, 57,67 Veterans' Administration hospitals and clinics, 72,162 academic settings,^{37,107} private practices,³⁶ public health clinics,^{31,84} and as a part of community-wide interventions. 32,111 Neither of the two studies of emergency department vaccination programs^{156,164} found results that were substantial or significantly different from zero.

Review of evidence: other positive or negative effects. No other positive or negative effects were sought in this review.

Review of evidence: economic. Our search identified one economic evaluation of a multicomponent intervention that included expanding access. ¹²⁰ Details of that study are provided at the website: http://web. health.gov/communityguide. That study estimated the costs of an intervention that included expanding access to vaccination services, multiple education and health promotion activities, and possibly, provider assessment and feedback. The adjusted estimate of average program costs based on that study is \$7.65/vaccination delivered.

Barriers to intervention implementation. Potential barriers to implementation of programs to expand access to vaccination services in medical settings include: (1) difficulties coordinating between settings; (2) lack of appropriate records; (3) clients' difficulty accurately

recalling immunization status; (4) high numbers of clients with contraindications to vaccinations (e.g., high numbers of febrile children in emergency department settings); and (5) lack of a relationship between vaccination programs and primary missions of settings.

Conclusion. According to the *Guide*'s rules of evidence, strong scientific evidence exists that, as a part of multicomponent interventions, expanding access improves vaccination coverage among children and adults and improves vaccination coverage in a range of contexts. Insufficient evidence exists to assess the effectiveness of expanding access by itself because of the: (1) small number of studies; (2) results that are small and statistically nonsignificant; and (3) limitations in study design and execution.

Vaccination interventions in nonmedical settings. Vaccination interventions in nonmedical settings involve efforts to encourage vaccination of important target populations in places where they congregate (e.g., child care centers, schools, and WIC locations). At a minimum, these interventions involve assessment of each child's immunization status and either referral of underimmunized persons to health care providers or provision of vaccinations on-site. Other services can include education, provision of vaccinations, and incentives to accept vaccinations.

Vaccination Programs in the Special Supplemental Nutrition Program for Women, Infants, and Children Settings Definition

Vaccination programs in WIC settings involve efforts to encourage vaccination of a low-income target population in this nonmedical setting. At a minimum, vaccination-promoting strategies in WIC require assessment of each child's immunization status and referral of underimmunized children to a health care provider. Other services can include education, provision of vaccinations, or incentives to accept vaccinations (e.g., monthly voucher pickup, which requires more frequent WIC visits when children are not up-to-date).

Background. The Special Supplemental Nutrition Program for Women, Infants, and Children is a federal grant program administered by the U.S. Department of Agriculture and implemented through state health departments and American Indian and Alaska Native tribal organizations. WIC provides supplemental foods, health care referrals, and nutrition education for low-income women, infants, and children who are found to be at nutritional risk. The program is required to serve as a gateway to, and coordinator for, other health services, including vaccinations. WIC is the single largest point of access to health-related services for low-income preschool children. The program serves over

45% of the U.S. birth cohort and, in some cities, serves up to 80% of low-income infants. In general, participants visit WIC sites every two to three months to receive nutrition services and to pick up food vouchers; more comprehensive health status evaluations are conducted every six to twelve months. Voucher restrictions are used to closely monitor high-risk clients in the WIC program. They require families to return to the WIC site more frequently than would otherwise would have been required, usually monthly. Here, such requirements are referred to as *monthly voucher pick up*.

Review of evidence: effectiveness. Our search identified ten studies regarding the effectiveness of WIC interventions. 32,148,165-172 One additional paper provided more information regarding an already included study. 173 Six studies were not included in the review because of limited execution. 167-172 Details regarding the four qualifying studies are provided at the website: http://web.health.gov/communityguide. Three studies were conducted entirely among WIC clients. One study compared education, assessment, referral, and either escort to a vaccination clinic or monthly voucher pickup with education, assessment, and referral only. Both intervention arms resulted in relatively small (approximately 4% percentage point changes in both groups) but significant improvements in vaccination coverage from baseline coverages of 94%. Two studies compared WIC interventions with no intervention. One of these compared various combinations of education, assessment, referral, free vaccinations, and monthly voucher pickup with usual care and found a 9% percentage point change in the intervention groups relative to the control group and few substantial differences between intervention groups. 166 The other study compared assessment, education, monthly voucher pickup, and free vaccinations plus various combinations of referrals for vaccination or on-site vaccination provision. That study found a 34% percentage point change in vaccination coverage and did not find substantial differences in effectiveness based on specific strategies used for vaccination provision or referral.¹⁴⁸ A final study used WIC interventions as part of a comprehensive multicomponent intervention and found a 12% improvement in coverage attributable to all components combined.³²

Review of evidence: applicability. The same body of evidence used to assess effectiveness was used to assess the applicability of these interventions to different settings, populations, and vaccines. All qualifying studies were conducted in urban areas among disadvantaged, predominantly minority, children. These studies did not include nonurban areas or nonminority populations.

Review of evidence: other positive or negative effects. Many WIC providers are concerned that vaccination requirements or monthly voucher pickup will serve as a disincentive for WIC participation. Two qualifying studies evaluated the effect of WIC programs regarding dropout rates. One of these 165 enrolled 377 children who received assessment and escort, 281 children who received assessment and referral, and 178 children who received assessment and monthly voucher pickup. Nine children (eight at voucher sites) dropped out during the study period. Another study¹⁴⁸ found that dropout rates remained stable over time in the intervention group (average 40%) but increased over time in the comparison group (average 34%). These data (small absolute dropout rates in one study and small absolute differences in dropout rates in another study) do not demonstrate that vaccination interventions in WIC cause substantial increases in WIC dropout.

Review of evidence: ecomonic. Our search identified two economic evaluations of WIC interventions^{148,173} One of these reported cost-effectiveness ratios of three different variations of a WIC intervention differing primarily in methods of referral or vaccination provision.¹⁴⁸ Details of that study are provided at the website: http://web.health.gov/communityguide. Adjusted cost-effectiveness ratios based on that study ranged from \$34 to \$84/fully vaccinated child. Adjusted average cost of assessments based on a second study¹⁷³ were \$2.65/assessment, for interventions using an on-site vaccination nurse, and \$1.28/assessment, for interventions using other strategies to promote vaccination.

Barriers to intervention implementation. Barriers to implementation of a vaccination program in WIC settings might include difficulties coordinating two programs and philosophical objections to monthly voucher pickup policies among some WIC providers and managers.

Conclusion. According to the *Guide*'s rules of evidence, sufficient scientific evidence exists that interventions in WIC settings are effective in improving vaccination coverage.

Home Visits

Definition. Home visits to promote vaccinations involve providing face-to-face services to clients in their homes. Services can include education, assessment of need, referral, and provision of vaccinations. Homevisiting interventions also can involve telephone or mail reminders.

Background. In the United States, home-visiting interventions are usually targeted toward subpopulations that are difficult to reach (e.g., those persons living in public housing communities or persons living in rural areas).

Review of evidence: effectiveness. Our search identified 15 studies regarding the effectiveness of home visits to improve vaccination coverage. 33,73,174-186 One additional paper provided more information regarding an already included study. 89 Of these, eight had limited execution and were therefore not included in the review. 174,177–181,184,185 One study evaluated home visits both as a component of a complex multicomponent intervention and as used alone.³³ The evaluation of home visits only in that study had limited execution; therefore, only the multicomponent intervention from that study is included in this review. Details of the seven qualifying studies are presented at the website: http:// web.health.gov/communityguide. Five studies evaluated home visiting with or without client reminders and case management. 73,175,176, 182,186 Two studies 33,183 evaluated complex multicomponent strategies including home visits. These 7 studies found changes in vaccination coverages ranging from -1% to 49% (median, 10%). Two studies of home-visiting-only interventions found median percentage point changes in coverage of -1% and 10%. Multicomponent interventions demonstrated median percentage point changes in coverage ranging from 2% to 20% (median, 13%).

Review of evidence: applicability. The same body of evidence used to assess effectiveness was used to assess the applicability of these interventions to other settings, populations, and vaccines. Studies included adults^{73,175} and children.^{33,176,182,183,186} Many studies included urban populations^{33,182,183,186} and clients of low socioeconomic status.^{33,182,183,186} One study included rural populations.¹⁸² Home visits have not been studied among adolescents or in interventions to increase delivery of hepatitis B or pneumococcal vaccinations.

Review of evidence: other positive or negative effects. No other positive or negative effects of this intervention were sought in this review.

Review of evidence: ecomonic. Our searches identified four economic evaluations of home visits. ^{179,182,186,187} Two reported cost-effectiveness ratios, ^{182,186} and two reported average costs. ^{179,187} Details of these studies are provided at the website: http://web.health.gov/communityguide. Adjusted average costs based on the data in those studies were \$22/child vaccinated and \$130/vaccination. Adjusted cost-effectiveness ratios based on those studies ranged from \$513 to \$13,020 per additional vaccination.

Barriers to intervention implementation. Potential barriers to implementing home-visiting programs include need for staff training and concerns regarding staff safety.

Conclusion. According to the *Guide*'s rules of evidence, sufficient scientific evidence exists that home-visiting interventions are effective in improving vaccination

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coverage. However, at least when applied only to improve vaccination coverage, home-visiting interventions can be highly resource-intensive relative to other available options for improving vaccination coverage.

Vaccination Programs in Schools

Definition. School-based vaccination interventions are intended to improve delivery of vaccinations to school attendees aged approximately 5 to 18 years. Schoolbased interventions usually include vaccination-related education of students, parents, teachers, and other school staff plus either provision of vaccinations or referral for vaccinations. These interventions can also involve other components (e.g., providing incentives and acquiring written consent from parents or guardians). Vaccination requirements for school attendance are reviewed elsewhere in this paper.

Background. School-based vaccination programs could provide a unique opportunity for reaching adolescents to provide vaccinations and other preventive services because in the United States, approximately 99% of children aged 11 and 12 years attend school. 188 Schoolbased vaccination programs could track each student's immunization status, identify those who have missed doses, and ensure vaccine series completion (e.g., with hepatitis B vaccine) among most students. Schoolbased vaccination programs are often collaborations between schools, local health departments, private hospitals, and community clinics.

Review of evidence: effectiveness. Our search identified four studies regarding the effectiveness of schoolbased vaccination programs for improving coverage.51,75,109,189 Of these, three had limited execution and were not included in the review.^{51,75,109} Details of the single qualifying study are provided at the website: http://web.health.gov/communityguide. The qualifying study¹⁸⁹ evaluated a school-based program to increase delivery of hepatitis B vaccinations to adolescents; the study used multiple components including teacher education, classroom lessons, written client educational materials, and peer and individual incentives to encourage children to bring in their consent forms. Results demonstrated: (1) generally positive attitudes toward vaccinations among students and teachers; (2) significant improvements in client knowledge regarding hepatitis B; (3) faster return of consent forms among schools when incentives were used; and (4) vaccination coverage with three doses of hepatitis B vaccine after the intervention of 66% (comparative data not available).

Review of evidence: other positive and negative effects. No information regarding other positive or negative effects was sought in this review.

Barriers to intervention implementation. Potential barriers to implementation of vaccination programs in schools might include difficulties coordinating between different programs, need for staff training, disruption school routines, and concerns regarding confidentiality.

Conclusion. According to the *Guide*'s rules of evidence, available studies provide insufficient evidence to determine the effectiveness of school-based vaccination interventions. Evidence is insufficient because of (1) the small numbers of available studies; (2) limitations in their design and execution; and (3) lack of comparative studies regarding the effectiveness of these interventions to improve vaccination coverage.

Vaccination Programs in Child Care Centers

Definition. Interventions in child care centers involve efforts to encourage vaccination of children aged <5 years. These interventions require assessment of each child's immunization status at: (1) entry into child care; (2) at some point during the child's enrollment; or (3) at periodic intervals throughout the child's enrollment. Vaccination interventions in child care centers can also include education or notification of parents, referral of underimmunized children to health care providers, and possibly, provision of vaccinations onsite. Vaccination requirements for entry into child care centers are reviewed elsewhere in this paper.

Background. Children in child care centers are at increased risk for communicable diseases. 190 In 1995, approximately 31% of preschool age children were being cared for in child care centers (Report of the Children's Health Working Group, March 1998 Draft). Interventions in child care centers can result in increased attendance in clinical settings through referrals or possibly by directly increasing coverage through delivering vaccinations on-site.

Review of evidence: effectiveness. Our search identified only one study¹⁹¹ regarding the effectiveness of interventions in child care centers to improve vaccination coverage. That study was not included in the review because of limited execution. Absence of qualifying studies does not allow us to make an assessment of the effectiveness of child care center programs.

Review of evidence: other positive or negative effects. No other positive or negative effects were sought in this review.

Conclusion. According to the Guide's rules of evidence, available studies provide insufficient evidence to assess the effectiveness of interventions in child care centers because only one study was identified and it could not be included in this review because of limitations in its design and execution.

Research Issues for Enhancing Access to Vaccination Services

Effectiveness

The effectiveness of recommended and strongly recommended interventions in this section (i.e., reducing out-of-pocket costs, expanding access in health care settings as part of multicomponent interventions, home visits, and vaccination interventions in WIC settings) is established. However, research issues, which contribute to increased or lessened effectiveness, remain regarding the characteristics of these interventions. For example,

- Are programs to reduce out-of-pocket costs similarly effective among persons who are and who are not economically disadvantaged?
- What are the relative effectiveness and economic consequences of strategies that provide home visits for all persons in a defined population versus those that use staged protocols using less-intensive interventions (i.e., reminders) to reach some clients and reserve actual home visits for clients who are hardest to reach?
- What are least and most effective combinations of services in multicomponent interventions that incorporate increasing access to vaccination services in health care settings?
- What are the least and most effective combinations of services in WIC interventions?
- How accurate are vaccination data in WIC settings, and how does data accuracy impact effectiveness?

Because the effectiveness of vaccination programs in child care centers, vaccination programs in schools, and single-component interventions to increase access to vaccination in health care settings has not been established, basic research questions remain.

- Are these interventions effective in improving vaccination coverage?
- Of the range of strategies that have been used to expand access to vaccination services in health care settings, which are the most and least useful?
- What attributes of these programs contribute to effectiveness or lack thereof?

Applicability

Each recommended and strongly recommended intervention should be applicable in most relevant target populations and settings. However, possible differences in the effectiveness of each intervention for specific subgroups of the population could not be determined. Several questions regarding the applicability of these interventions in settings and populations other than those studied remain.

- What strategies would be most effective for improving access to vaccinations among adolescents?
- Is effectiveness of WIC interventions in rural areas similar to that described in urban areas?

Other Positive and Negative Effects

In general, studies included in this review did not report on other positive and negative effects of these interventions. Therefore, research regarding the following questions would be useful:

- Do programs to reduce out-of-pocket costs adversely affect development or adoption of new vaccines?
- Do any of these interventions have positive or negative effects regarding subsequent use of primary care?
- Do home visits result in identification of child abuse or neglect?
- Do home visits result in reporting of possible abuse or neglect that is not subsequently confirmed?
- Do WIC interventions result in dropout?
- Do interventions to increase access to vaccinations in health care settings interfere with other functions of these settings, and if so, how can this effect be minimized?
- Do these interventions result in other positive changes in use of preventive services or health care as well as improving vaccination coverage?

Economic Evaluations

In general, available economic information was sparse. Therefore, considerable research is warranted regarding the following questions:

- What are the costs of these interventions?
- How do costs per additional child vaccinated compare with other interventions to improve vaccination coverage?
- Are home-visiting programs cost-effective relative to other interventions to improve vaccination coverage?
- Can strategies that are designed to improve vaccination coverage and other outcomes concurrently improve cost-effectiveness of these strategies?
- Are home-visiting programs that address more than one issue more or less cost-effective than programs addressing vaccinations only?
- How do specific characteristics of these interventions contribute to economic efficiency?
- What are the relative economic consequences of universal programs to reduce out-of-pocket costs versus programs intended for persons whose need is greatest?
- What combinations of components in multicomponent interventions are most cost-effective?
- Are staged home-visit protocols more cost-effective than those that are not?
- What are the most cost-effective combinations of services for WIC programs?

 What is the cost-benefit or cost-utility of these interventions?

Barriers

- How can these interventions be implemented with minimal administrative burden placed on providers or systems and minimal disruption of the settings' primary missions?
- How can reducing out-of-pocket costs be effectively implemented given the fragmentation of payment mechanisms in the United States?
- Can registries help to overcome lack of current immunization status that is sometimes a barrier to implementing these interventions?

Provider-Based Interventions

In the United States, most people accept the need for vaccinations, and they are seen periodically in health care settings. Unfortunately, providers often miss opportunities to vaccinate. Provider-based interventions are implemented primarily through health care systems in settings with the goal of reducing missed opportunities. The provider-based interventions reviewed in this paper include provider recall/reminder, provider assessment and feedback, standing orders, and provider education-only interventions.

Provider Reminder/Recall

Definition. Provider reminder/recall interventions inform those who administer vaccinations that individual clients are due (reminder) or overdue (recall) for specific vaccinations. Techniques by which reminders are delivered—in client charts, by computer, by mail, or other—and content of reminders can vary. Interventions that incorporate elements of both reminders and standing orders are reviewed with standing orders in this paper.

Background. Provider reminder/recall systems make information regarding the client's immunization status available to providers either manually or through a computerized system. This information is then conveyed to the provider before, during, or after a scheduled appointment.

Review of evidence: effectiveness. Our search identified 60 studies regarding the effectiveness of provider reminder/recall. $^{36-38,42,43,52,53,64,69,74,78,102,104,106,110,112-115,139,141,152,155,164,177,182,192-225$ Eight additional papers provided more information regarding an already included study. $^{86,90,92,93,226-229}$ Thirty-one studies were not included in the review because of limited execution $^{69,102,104,110,112,113,115,139,141,152,155,177,193,194,213-218,220}$ or least suitable designs. 53,78,108,192,197,198,202,210,211,224 Details of the 29 qualifying studies are provided at the

website: http://web.health.gov/communityguide. The qualifying studies reported on 21 intervention arms evaluating provider reminder/recall only and 15 evaluating multicomponent interventions including provider reminder/recall. Interventions typically involved chart reminders, checklists, or flowcharts, or computerized reminders made available to providers at the time of client visits. One study evaluated letter reminders sent from an emergency department between clinic visits. He Multicomponent interventions also included client reminder/recall, \$\frac{36,38,42,43,52,74}{36,38,42,114,205}\$ provider assessment and feedback, \$\frac{36,42,182,204,205,209,223}{36,182,209}\$ provider education, \$\frac{36,182,209}{36,182,209}\$ community-wide education, \$\frac{38}{38}\$ and expanded access.

Five qualifying studies presented data regarding one or more intervention arms that could not be expressed percentage point change in coverage. 38,114,164,204,222 Remaining studies provided data regarding 17 single-component intervention arms and 12 multicomponent intervention arms. Overall, the studies found a median percentage point change in coverage of 17% (range, 1% to 67%). Studies that evaluated provider reminder/recall only found a median percentage point change in coverage of 17% (range, 1% to 67%). Studies that evaluated provider reminder/recall as part of a multicomponent intervention found a median percentage point change of 14% (range, 1% to 36%).

Review of evidence: applicability. The same body of evidence used to assess effectiveness was used to assess the applicability of these interventions to different settings, populations, and vaccines. Affected populations included adults, 36,37,42,43,52,60,64,74,114,195,196,199– $201,\!203,\!206-\!209,\!212,\!219,\!225$ adolescents,²⁰⁴ and dren. 38,164,182,205,221 Studies have included a range of providers including residents, 37,43,64,74,114,195,196,204-206, 209,212,219,221-223 physicians who have completed their training, 36,37,64,74,161,173,174,179,190,191 and nonphysician vaccination providers. 36,37,64,74,206,207,207,212,221,222 Physician specialties included internal medicine, 36,43,114,196, 201,206,209,212,219,222 family medicine, ^{36,37,52,64,74,195,203}– ^{205,207,225} and pediatrics. ²²¹ Most studies have been done in outpatient settings, but inpatient settings are also represented. 200,208 Most studies have been done in academic clinical settings, but other settings are also represented including community health centers, 221,225 managed care, 42 private practice, 36,52 community hospitals,²⁰⁰ and community-wide settings.³⁸ Studies have assessed the effectiveness of these interventions to improve vaccination delivery of MMR, 38,164,182,204,205,221 DTP. 164,182,205,221 OPV, 164,182,205,221 Hib, 164,182,221 influenza, 36,37,42,43,64,195,196,199–201,206,207,209,212,222 pneumococcal. 43,196,199,201,206-209,212,212,219 and Td. 43,52,64,74,114, 196,203,222,225 We did not find studies of the effectiveness of this intervention to improve delivery of hepatitis B vaccinations.

Review of evidence: other positive or negative effects. Several qualifying studies that assessed nonvaccination outcomes (e.g., improved delivery of other preventive services or clinical care) found improvements in some outcomes other than vaccination.^{74,196,212,222,223} Other positive or negative effects were not sought in this review.

Review of evidence: economic. Our search identified three studies. 52,93,192 Details of the studies are provided website: http://web.health.gov/communityguide. Data from a study estimating the cost-effectiveness of provider reminders-only documents an adjusted cost-effectiveness ratio of \$0.70/additional vaccination. This cost-effectiveness ratio is probably an underestimate because it does not include the cost of producing reminders. A second study estimated the cost-effectiveness of an intervention that included both client and provider reminders.⁵² The adjusted cost-effectiveness ratio based on that study was \$4/additional vaccination. A final study estimated the cost-effectiveness of a program that assessed the immunization status of hospitalized children by contacting the children's usual physicians, and hospital physicians were reminded to vaccinate the children before they left the hospital. 192 The adjusted cost-effectiveness ratio based on that study was \$300/ fully vaccinated child.

Barriers to intervention implementation. Five studies ^{139,182,207,218,221} found that some settings had difficulty placing reminders in charts or using reminders when provided. This suggests that administrative burden can be a barrier to reminder use. Lack of information infrastructure could also be a barrier to reminder use.

Conclusion. According to the *Guide*'s rules of evidence, strong scientific evidence exists that provider reminder/recall interventions are effective in improving vaccination coverage.

Assessment and Feedback for Vaccination Providers

Definition. Provider assessment and feedback involves retrospectively evaluating the performance of providers in delivering one or more vaccinations to a client population and giving this information to providers. Assessment and feedback interventions can also involve other activities (e.g., incentives or benchmarking [i.e., comparing performance to a goal or standard]).

Background. Provider assessment and feedback can result in improvements in vaccination coverage either by changing provider knowledge, attitudes, and behavior, or by stimulating use of additional changes in the vaccination delivery system (e.g., reminders or standing orders). Evaluation of provider assessment and feedback is timely because (1) information systems are

improving and are increasingly common; (2) most vaccinations are delivered in the private sector; and (3) such quality-assurance approaches as the Health-plan Employer Data and Information Set (HEDIS) are being used more often.

Review of evidence: effectiveness. Our search identified 27 studies regarding the effectiveness of assessment and feedback. 36,42,47,58,69,81,139,182,194,197,204,205,209,211,213,218,220, ^{223,230-238} Four additional papers provided more information regarding an already included study. 86,94,146,239 Thirteen studies were not included in the review because of execution. 69,81,139,194,211,213,218,220,231–233,237,238 Details regarding the 14 qualifying studies are provided at the website: http://web.health.gov/communityguide. Qualifying studies presented data regarding seven intervention arms evaluating assessment and feedback only and nine intervention arms evaluating assessment and feedback used as a part of a multicomponent intervention. Generally, assessment and feedback components of interventions were not described in detail (e.g., content, frequency, method of delivery, or associated characteristics such as benchmarking or incentives). Some studies reported on use of assessment and feedback only; several evaluated assessment and feedback used with financial^{230,234} or nonfinancial²³⁵ incentives. One study found that assessment and feedback to individual physicians might have been more effective than assessment and feedback to the chief of service, but alternative explanations for this finding exist. All but one of the multicomponent interventions⁴⁷ incorporated provider reminder/ recall as well as assessment and feedback. Multicomponent interventions also included provider education, 36,182,197 client reminders, 36,42,47 and clinic-based education. 36,42,205

Three qualifying studies^{204,230,236} presented data that could not be expressed as a percentage point change in vaccination coverage. Remaining studies provided data regarding eight multicomponent intervention arms and five single-component intervention arms. Overall, these studies demonstrated increases in vaccination coverage ranging from 1% to 43% (median, 16%). Studies that evaluated provider assessment and feedback only found a median coverage increase of 16% (range, 9% to 41%). Studies that evaluated provider assessment and feedback as part of a multicomponent strategy found a median percentage point change of 17% (range, 1% to 43%). Several studies have demonstrated that improvements in coverage can be maintained or further improved over several years of follow-up. 197,234,235

Review of evidence: applicability. The same body of evidence used to assess effectiveness was used to assess the applicability of these interventions to different settings, populations, and vaccines. Studies have included adults, ^{36,42,47,58,197,209,223,230,234} adolescents, ²⁰⁴ and children, ^{182,205,235,236} providers including resident

physicians, ^{197,204,205,209,234} physicians who have completed their training, ^{36,42,47,58,205,236} and nonphysician vaccination providers. ²⁰⁵ Physician specialties included internal medicine, ^{36,47,58,197,209,234} family medicine, ^{36,204,205} and general practice. ²³⁶ Studies have been conducted in a range of settings including private practice, ^{36,47,58} managed care, ⁴² public health, ²³⁵ and community health centers, ²³⁰ and academic settings. ^{197,204,205,209,223,234} Studies have assessed the effectiveness of these interventions to improve coverage with MMR, ^{182,204,205,235,236} DTP, ^{182,205,235,236} OPV, ^{182,205,235,236} Hib, ¹⁸² influenza, ^{36,42,47,58,197,209,230,234} pneumococcal, ^{197,223,234} and Td. ^{197,234} The body of evidence did not include studies of interventions to improve delivery of hepatitis B vaccinations.

Review of evidence: other positive or negative effects. Several qualifying studies that assessed nonvaccination outcomes (e.g., improved delivery of other preventive services or clinical care) found improvements in some outcomes other than vaccination. ^{197,223,230} Other positive or negative effects were not sought in this review.

Review of evidence: economic. No economic evaluations of assessment and feedback interventions were identified.

Barriers to intervention implementation. Potential barriers to use of assessment and feedback include lack of an adequate information infrastructure and administrative burden on providers and systems.

Conclusion. According to the *Guide*'s rules of evidence, strong scientific evidence exists that assessment and feedback of vaccination coverage information to providers are effective in improving vaccination coverage. The specific characteristics of assessment and feedback interventions (e.g., content, intensity, use of incentives, or benchmarking) that contribute most to effectiveness cannot be determined from available data; however, a variety of assessment and feedback interventions have been consistently effective in a wide range of contexts.

Standing Orders

Definition. Standing orders involve interventions in which nonphysician personnel prescribe or deliver vaccinations to client populations by protocol without direct physician involvement at the time of the interaction. Settings in which this occurs include clinics, hospitals, and nursing homes. Dedicated vaccination clinics often operate under standing orders, but we did not consider standing orders in that context as an intervention for the purposes of this paper.

Background. Requirements for physical examinations and lack of personnel to administer vaccines are two administrative barriers that might contribute to missed opportunities to vaccinate. Empowering nonphysician personnel to deliver vaccinations without physician

involvement at the time of the visit could reduce barriers to vaccination and missed opportunities, resulting in improved vaccination delivery.

Review of evidence: effectiveness. Our search identified 16 studies regarding the effectiveness of standing orders. 36,63,72,110,118,155,162,200,217,240-246 Two additional papers provided more information regarding an already included study. 91,247 Five studies were not included in the review because of limited execution. 110,155,217,241,246 Details of the 11 qualifying studies are provided at the website: http://web.health.gov/ communityguide. Qualifying studies provided data regarding six intervention arms that evaluated standing orders only and five intervention arms that evaluated multicomponent interventions that included standing orders. Multicomponent interventions included expanding access, ^{36,63,72,162} client reminder/recall, ^{36,63,72} clinic-based education, ^{36,118} provider education, ^{36,63} provider reminder/recall, ³⁶ and assessment and feedback.

Two studies presented data that could not be expressed as a percentage point change in vaccination coverage. 162,244 Overall, eight studies of standing orders to improve vaccination coverage in adults found a median percentage point change of 28% (range, 6% to 81%). Studies in which standing orders were used alone found a median percentage point change of 51% (range, 30% to 81%). Studies in which standing orders were used as part of a multicomponent strategy found a median percentage point change of 16% (range, 6% to 26%). Most studies lasted less than a year, but one found continuing improvements over 5 years. 191 A single study in children 1940 found modest declines in missed opportunities to vaccinate at non-well-child visits but no overall improvement in vaccination delivery.

Review of evidence: applicability. The body of evidence used to assess effectiveness of standing orders in adults was used to assess the applicability of these interventions to different settings, populations, and vaccines. Studies have been conducted in community²⁰⁰ and other hospitals,^{72,162,243} nursing homes,²⁴⁵ and a variety of outpatient settings including private practices,³⁶ managed care organizations,⁶³ Veterans' Administration clinics,⁷² and academic clinical organizations. Studies have evaluated the effectiveness of standing orders to improve delivery of both influenza^{36,63,72,118,162,200,242,244} and pneumococcal vaccinations. No studies were found evaluating standing orders to improve vaccination in adolescents or to improve delivery of hepatitis B or Td vaccinations.

Review of evidence: other positive or negative effects. Other positive or negative effects were not sought in this review.

Review of evidence: economic. No economic evaluations of standing orders were identified.

Barriers to intervention implementation. Potential barriers to implementing standing orders could include: (1) difficulties encouraging effective interprofessional communication and shared responsibilities; and (2) the burden of standing orders on providers and systems. One study found that a nurse-guided algorithm to vaccinate children in a busy pediatric clinic could be completed in only 43% of eligible children.²⁴⁰ Alternatively, in some settings, standing orders could reduce the burden on physicians and increase clinic efficiency.

Conclusion. According to the *Guide*'s rules of evidence, strong scientific evidence exists that standing orders are effective in improving vaccination coverage in adults. We concluded that insufficient evidence exists to assess the effectiveness of standing orders to improve vaccination coverage in children based on the following: (1) the greater complexity of vaccination protocols in children as compared with that for adults; (2) the identification of only a single qualifying study of standing orders to increase vaccination coverage in children; (3) limitations in that study's design and conduct; and (4) reported effects regarding vaccination coverage that were not substantially different from zero.

Provider Education Only

Definition. Provider education involves giving information regarding vaccinations to providers to increase their knowledge or change their attitudes. Techniques by which information is delivered can include written materials, videos, lectures, continuing medical education programs, and computerized software. Interventions that have additional features (e.g., provider reminders or assessment and feedback) or that are used in combination with other interventions (e.g., multicomponent interventions that include education) are reviewed elsewhere in this paper.

Background. Provider education is based on the assumption that provider knowledge regarding vaccination will affect physician behavior in a positive manner. Provider education could stimulate them to deliver additional vaccinations, change provider-client interactions to increase client acceptance of vaccinations, or motivate providers to implement other interventions (e.g., reminder/recall systems or standing orders).

Review of evidence: effectiveness. Our search identified six studies regarding provider education-only interventions. 200,216,248–251 An additional paper provided more information regarding an already included study. 229 Two studies had limited execution and were therefore not included in the review. 216,248 Details regarding the four qualifying studies are provided at the website: http://web.health.gov/communityguide. Two studies regarding adults evaluated vaccination coverage as an outcome. One evaluated a fact sheet attached to each client's chart and found small and

nonsignificant percentage point changes and no change in provider knowledge and attitudes. The other study used provider education as the comparison group in a study that evaluated provider reminders and standing orders and found median percentage point changes in coverage of -30% and -7%, compared with standing orders and provider reminders, respectively.

Two studies evaluated the effectiveness of provider education regarding knowledge and attitudes. 250,251 These studies found improvements in provider knowledge and attitudes after dissemination of national guidelines for hepatitis B and implementation of an innovative problem-based learning protocol in medical schools. With one exception, 251 available studies of provider education evaluated interventions that were not very intensive. Available data cannot be generalized to more intensive efforts. Also, provider education is a part of several effective multicomponent interventions, including provider reminders, assessment and feedback, and educational interventions.

Review of evidence: other positive and negative effects.No information regarding other positive or negative effects was sought in this review.

Conclusion. According to the *Guide*'s rules of evidence, available studies provide insufficient evidence to assess the effectiveness of provider education-only interventions in improving vaccination coverage. Evidence is insufficient because of: (1) the small numbers of available studies; (2) limitations in their design and conduct; and (3) small effect sizes.

Research Issues for Provider-Based Interventions Effectiveness

The effectiveness of recommended and strongly recommended interventions in this section (i.e., provider reminder/recall, provider assessment and feedback, and standing orders) is established. However, research issues regarding the effectiveness of these interventions remain.

- Which characteristics of provider-based interventions contribute to increased or lessened effectiveness?
- How do content and method of delivery of provider reminder/recall relate to effectiveness?
- What components of assessment and feedback interventions (e.g., incentives or benchmarking) contribute most to effectiveness?
- How do different practice settings (e.g., independent private practice settings versus hospital management organization settings) contribute to increased or lessened effectiveness of various interventions?
- What is the effectiveness of HEDIS, as a form of assessment, feedback, and benchmarking, in improving vaccination coverage? In independent private-

- practice settings? In hospital management organization settings?
- What intermediate outcomes contribute to the effectiveness of provider assessment and feedback (e.g., provider's knowledge, attitudes, or behavior; additional interventions; or other factors)?
- What are the least and most effective combinations of services in multicomponent interventions?
- Can registries provide a backbone for effective interventions (e.g., provider reminder/recall)?
- How easily can systems for provider reminders or assessment and feedback that encourage the use of one clinical preventive service be adapted for other services?
- What is the relative effectiveness of provider reminders or assessment and feedback that focus on immunizations versus reminders or assessment and feedback that rotate from one clinical preventive service to another?

Because the effectiveness of provider education-only interventions has not been established, basic research questions remain.

- Are these interventions effective in improving vaccination coverage?
- Are these interventions effective in increasing provider knowledge or promoting positive provider attitudes toward vaccination?
- What attributes of provider education-only programs—medium, message, or intensity—contribute to effectiveness or lack thereof?
- Are intensive provider education programs more effective than other programs that are less intensive?

Applicability

Each recommended and strongly recommended provider-based intervention should be applicable in most relevant target populations and settings. However, possible differences in the effectiveness of each intervention for specific subgroups of the population could not be determined. Several questions regarding the applicability of these interventions in settings and populations other than those studied remain.

- Are these interventions as effective in improving vaccination coverage in adolescents as they are in children and older adults?
- Do significant differences exist regarding the effectiveness of these interventions based on the level of scale at which they are delivered (i.e., community-wide provider reminders from a registry versus managed-care-based systems versus office-practice-based systems)?

Other Positive and Negative Effects

With the exception of some discussion of improved use of other clinical and preventive care, studies included in the review did not report on other positive and negative effects of these interventions. Therefore, research regarding the following questions would be useful:

- Do provider-based interventions to increase vaccination interfere with office flow or efficiency, and if so, how can this effect be minimized?
- Do provider-based interventions result in other positive changes in use of preventive or health care as well as improving vaccination coverage?

Economic Evaluations

Generally, available economic information was sparse; therefore, considerable research is warranted regarding the following questions:

- What are the costs of these interventions?
- How do costs per additional person vaccinated compare with other interventions intended to improve vaccination coverage?
- Can strategies that are designed to improve vaccination coverage and other outcomes improve cost-effectiveness of these strategies?
- How do specific characteristics of these interventions contribute to economic efficiency?
- What particular characteristics of provider reminder/recall systems contribute most to costeffectiveness?
- What combinations of components in multicomponent interventions are most cost-effective?
- How do the opportunity costs of multicomponent versus single-component interventions compare?
- What is the cost-benefit or cost-utility of these interventions?

Barriers

- How can these interventions be implemented with minimal administrative burden placed on providers or systems?
- Do community-wide registries reduce barriers to use or increase use of provider reminders, provider assessment and feedback, or provider education?
- For provider reminder/recall and provider assessment and feedback, how can the burden on providers (e.g., data entry) be reduced?
- Can improved sampling strategies be developed and can meaningful information be extracted from small samples of records?
- How can the uptake of these interventions in private practices be encouraged?

We appreciate the contributions of the vaccine-preventable disease evidence review team.

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Appendix A

Methods

In the Guide to Community Preventive Services; Systematic Reviews and Evidence-Based Recommendations, evidence is summarized regarding: (1) the effectiveness of interventions; (2) the applicability of effectiveness data (i.e., the extent to which available effectiveness data might apply to other populations and settings); (3) other positive or negative effects of the intervention, including positive or negative health and nonhealth outcomes; (4) economic impact; and (5) barriers to implementation of interventions. The process that was used to systematically review evidence and then translate that evidence into conclusions made in this paper involved:

- forming an evidence review and *Guide* chapter development team;
- developing a conceptual approach to organizing, grouping, and selecting interventions;
- selecting interventions to evaluate;
- searching for and retrieving evidence;
- assessing the quality and summarizing the body of evidence of effectiveness;
- translating the body of evidence of effectiveness into conclusions;
- considering data regarding applicability, other effects, economic impact, and barriers to implementation; and
- · identifying and summarizing research gaps.

This appendix summarizes how these methods were used in developing the vaccine-preventable disease evidence reviews. The *Guide's* methods for systematic reviews and linking evidence to recommendations are explained in detail elsewhere (see Briss PA, et al. "Developing an Evidence-Based *Guide to Community Preventive Services*" pp. 35–43 in this issue). The vaccine-preventable disease intervention reviews were developed by a multidisciplinary team representing a variety of perspectives (see authorship and acknowledgment lists). The conceptual approach for the vaccine-preventable disease evidence reviews is described in the second section of the body of the text.

Search for Evidence

Electronic searches for literature were conducted of MEDLINE, Embase, Psychlit, CAB Health, and Sociological Abstracts. The team also reviewed reference lists in articles and consulted with immunization experts. To be included in the review, a study had to:

- have a publication date of 1980–1997;
- address universally recommended adult, adolescent, or childhood vaccinations;
- be a primary study rather than, for example, a guideline or review;
- take place in an industrialized country or countries;

- be written in English;
- meet the evidence review and *Guide* chapter development team's definition of the interventions; provide information on one or more outcomes related to the analytic frameworks; and
- compare a group of persons who had been exposed to the intervention with a group who had not been exposed or who had been less exposed. In addition, we excluded studies with least suitable designs for two interventions (provider reminder/recall and client reminder/recall) where the literature was most extensive (see Briss PA, et al. pp. 92–96 in this issue for a description of the study designs included and their definitions).

Studies were also reviewed that did not meet these criteria but had been recommended by one or more experts as having potential to change a preliminary assessment of effectiveness. For example, unpublished studies of interventions involving the Special Supplemental Nutrition Program for Women, Infants, and Children and 1998 publications on home visits were reviewed.

Assessing the Quality and Summarizing the Body of Evidence of Effectiveness

Each study meeting the inclusion criteria was read by two reviewers who used a standardized abstraction form to record information from the study. Any disagreements between two reviewers were reconciled by consensus among the development team members.

Quality of study execution was systematically assessed (see Briss PA, et. al. pp. 35–43 in this issue). For this review we used a slightly earlier version of the data abstraction form (see Zaza S, et al. "Data Collection Instrument and Procedure for Systematic Reviews in the *Guide to Community Preventive Services*," pp. 44–74 in this issue) that organized potential limitations in execution into the following eight categories:

- definition and selection of study and comparison population(s);
- definition and measurement of exposure and intervention;
- assessment of outcomes;
- follow-up and completion rates;
- bias;
- data analysis;
- · confounding; and
- miscellaneous criteria (e.g., lack of statistical power).

Execution of each study was characterized as good, fair, or limited based on the total number of categories with limitations. Good studies had zero or one limitation; fair studies, two to four; and limited studies, five or more. Studies with limited execution did not qualify for the review.

We abstracted information from the studies regarding one or more outcomes of interest:

- measures of vaccination (i.e., vaccination coverage or doses delivered);
- disease outcomes, when available; and
- other outcomes (e.g., knowledge or attitudes for educational interventions), if available and relevant.

In general, we reported data regarding disease outcomes and other nonvaccination outcomes (e.g., knowledge and attitudes) as they were reported by the authors, without attempting to transform these measures. We then summarized them qualitatively.

Where possible, we represented results of each study as point estimates for change in vaccination coverage attributable to the interventions. We then calculated percentage point changes and baselines using the following formula:

• For studies with before/after measurements and concurrent comparison groups:

$$(Ipost - Ipre) - (Cpost - Cpre); baseline = Ipre$$

For studies with post-only coverage measurements and concurrent comparison groups:

For studies with before/after measurements but no concurrent comparison:

Ipost - Ipre; baseline = Ipre, where

Ipost = last reported coverage in the intervention group after the intervention.

Ipre = reported coverage in the intervention group immediately before the intervention.

Cpost = last reported coverage in the comparison group after the intervention. And,

Cpre = reported coverage in the comparison group immediately before the intervention.

In the studies, vaccination coverages could have been measured as series-complete (i.e., proportion of persons up-to-date with each of several vaccinations) or as one or more individual vaccinations. When a study presented more than one vaccination result (but not a series-complete measure), we used an equally weighted average of percentage point changes. Studies without coverage outcomes, or for which percentage point changes were not calculable, were not included in descriptive statistics or in figures; however, these studies are described in the text.

We often had to select among several possible effect measures. When available, we used measures adjusted for potential confounders in multivariate analyses in preference to crude effect measures. In children, we used outcome measures among children closest to age 2 years. In studies that made comparisons between multiple groups, we compared each intervention group with the group that received no intervention or the least intensive intervention. We included separate effect measures where possible for children, adolescents, and adults, but did not otherwise report different effect measures for different subpopulations.

To summarize the findings regarding the effectiveness of an intervention across multiple studies, we displayed results of individual studies in tables and figures and reported median and range of effect measures. We summarized the strength of the body of evidence based on numbers of available studies, strength of their design and execution, and size and consistency of reported effects.

Other Effects

Guide reviews routinely seek information on other effects (i.e., positive and negative health or nonhealth "side effects"). We sought evidence of potential harms of these population-based interventions if they were mentioned in the effectiveness literature or thought to be of importance by the evidence review team. For example, we sought evidence of dropout from WIC programs, which has been suggested as a potential effect of WIC interventions.

Although vaccines are generally safe and effective, none is 100% safe or effective. Universally recommended vaccines have been documented in other reviews to have benefits for individuals that outweigh the risk of serious health effects. Therefore, this review did not evaluate possible positive or negative effects of the vaccines themselves.

Economic Evaluations

Review of economic evaluation studies was performed if the intervention was effective (see Carande-Kulis VG, et al. "Methods for Systematic Reviews of Economic Data for the *Guide to Community Preventive Services*," pp. 75–91 in this issue). To be included in the reviews, a study had to:

- use an economic analytical method (e.g., cost analysis, cost-effectiveness analysis, cost-benefit analysis, or cost-utility analysis);
- have a publication date of 1980–1998;
- address universally recommended adult, adolescent, or childhood vaccinations;
- be a primary study rather than, for example, a guideline or review;
- be performed in the Established Market Economies as described by the World Bank¹;
- be written in English;
- meet the evidence review and *Guide* chapter development team's definition of one or more interventions;
- provide an economic evaluation of an intervention as described in the evidence reviews rather than economic evaluation of a vaccine; and

 report sufficient information so that an adjusted estimate of cost, cost-effectiveness, cost-utility, or cost-benefit could be made.

A standardized abstraction form (see Carande-Kulis VG, et al., pp. 75-91 in this issue) was used for abstracting and adjusting data to meet the reference case suggested by the panel on cost-effectiveness in health and medicine.² Using the abstraction form, costs were adjusted to 1997 U.S. dollars. The cost-effectiveness ratio was defined, for the vaccine-preventable disease evidence reviews, as the cost of the program per additional vaccination or cost per fully vaccinated child. Average cost was defined as cost of the program per person or vaccination. Where possible, cost of vaccinations were excluded to avoid overestimating costs of the intervention themselves. Ratios and averages ≤10 were cited with two decimal points. Ratios and averages ≥11 were rounded to the nearest integer. For interventions with four or more cost-effectiveness ratios, ratio distribution was described by the median and range (Appendix C).

Summarizing Barriers to Implementation of Interventions

Information regarding barriers to implementation of the interventions are described in the main text. Information on barriers did not affect Task Force recommendations.

Summarizing Research Gaps

Systematic reviews in the *Guide* identify existing information on which to base public health conclusions. An important additional benefit of these reviews is identification of areas where information is lacking or of poor quality. However, the reader should note that many major areas of vaccine-preventable disease research (e.g., epidemiology of vaccine-preventable diseases, clinical and laboratory features of vaccine-preventable diseases, and vaccine development and efficacy) and some areas of intervention research were not reviewed and are thus not represented in the sections on research gaps. To develop these sections, we used the following process:

- We identified remaining research questions for each intervention evaluated.
- In cases of interventions for which evidence of effectiveness was sufficient or strong, we summarized remaining questions regarding effectiveness, applicability, other effects, economic consequences, and barriers.
- In cases of interventions for which evidence of effec-

tiveness was insufficient, we summarized remaining questions regarding effectiveness and other effects. We summarized applicability issues only if they affected the assessment of effectiveness. We decided that identifying research gaps in barriers or economic evaluation before effectiveness was demonstrated would be premature.

• For each category of evidence, we identified issues that had emerged from the review, based on the informed judgement of the evidence review team. Several factors influenced that judgement.

General

- We avoided addressing downstream issues if we could not address upstream issues. For example, if no study had answered whether the intervention was effective, we did not ask what might increase effectiveness. Similarly, if cost-effectiveness data were unavailable, we did not ask how efficiency might be improved.
- If no information or inadequate information existed to draw a conclusion regarding effectiveness, applicability, other effects, or economic evaluations, we listed these as evidence gaps.
- When a conclusion was drawn regarding evidence, we applied team judgement regarding whether additional issues remained.

Effectiveness

- We did not necessarily identify studies that would simply change a body of evidence from sufficient to strong as evidence gaps.
- If effectiveness was demonstrated using some but not all outcomes, we did not necessarily list all other possible outcomes as evidence gaps.

Applicability

 If available evidence was thought to generalize, we did not necessarily identify all subpopulations or settings where studies had not been done as evidence gaps.

Following the reviews of individual interventions, we considered whether overriding methodologic issues existed.

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Appendix B
Studies of the Effectiveness of Client Reminder/Recall

Author, Reference Number, Study Period	Design, Category, Execution	Study Location, Setting Type, Population Description	Interventions Studied, Comparisons, (Number of Participants)	Outcomes and Effect Measures, Including Percentage Point Change Unless Otherwise Noted (Statistical Significance)
		Effects o	Effects of Client Reminders/Recall Only	
Alemi Ref. 1 1993–94	Nonrandomized trial, greatest suitability, fair	Cleveland, Ohio; clinics/offices; clients — aged <6 months; urban; 81%–88% black; low socioeconomic status	 Computer-generated client telephone reminders and recalls versus Comparison group of usual care (Total study population, 213 participants) 	Up-to-date with DTP/OPV/MMR/Hib vaccinations, 1 versus 2 = 25% change (p < 0.005)
Alto Ref. 2 1991	Randomized trial, greatest suitability, fair	Colorado; family practice residency clinic; clients — aged >2 months and <7 years; 17% Hispanic; urban; 51% male; low socioeconomic status	 Mailed and telephone client reminders versus Comparison group of usual care (Total study population, 464 participants before randomization) 	Up-to-date with DTP/OPV/MMR/Hib vaccinations, 1 <i>versus</i> 2 = 8% change (p < 0.011)
Barnas Ref. 3 Time not reported	Randomized trial, greatest suitability, fair	Milwaukee, Wisconsin; primary- care clinic; clients — aged ≥65 years, mean 74 years; urban/suburban; 51% black; 70% female	Mailed client reminder for influenza plus reminders to attend clinic versus Comparison group receiving reminder to attend clinic (Total study population, 804 participants)	Influenza, 1 <i>versus</i> 2 = -7% change (p < 0.04)
Brimberry Ref. 4 1984–85	Randomized trial, greatest suitability, fair	Little Rock, Arkansas; family practice residency clinic; clients — adults; urban/suburban/rural; otherwise, not well-described	 Mailed client reminder versus Telephone client reminder versus Comparison group of usual care (Total study population, 787 participants) 	Influenza, 1 <i>versus</i> 3 = 5.9% change (p < 0.02); 2 <i>versus</i> 3 = 5.5% change (p < 0.02); no difference between mail and telephone reminders
Buchner Ref. 5 1984	Randomized trial, greatest suitability, fair	Seattle, Washington; private practice offices; clients — aged ≥65 years, mean 76 years; suburban/rural; 66% female; low/middle socioeconomic status	 Mailed client remainder versus Comparison group of usual care (Total study population, 540 analyzed) 	Influenza, 1 <i>versus</i> 2 = 1% change (nonsignificant)
Campbell Ref. 6 Time not reported	Randomized trial, greatest suitability, good	Rochester, New York; pediatric community clinic at Strong Memorial Hospital; clients — aged birth—13 months; urban; 49%—55% female; 60%—67% black; low socioeconomic status	 Mailed letter reminders for well child care (87 participants) versus Mailed postcard reminders (96) versus Comparison group of usual care (105) 	DTP by age 7 months, 1 <i>versus</i> 3 = 6% change; 2 <i>versus</i> 3 = 2% change (p = 0.72 for differences between the three groups)
				Table B-1 Continued

Author, Reference Number, Study Period	Design, Category, Execution	Study Location, Setting Type, Population Description	Interventions Studied, Comparisons, (Number of Participants)	Outcomes and Effect Measures, Including Percentage Point Change Unless Otherwise Noted (Statistical Significance)
Carter Ref. 7 Time not reported	Randomized trial, greatest suitability, fair	Seattle, Washington; ambulatory clinic at VA hospital; clients — adults, urban; not vaccinated in the year before the intervention	Standard client reminder letter plus brochure (66 participants) versus Augmented client reminder letter plus brochure (55) versus Augmented client reminder letter (57) Comparison group of standard client reminder letter (57)	Influenza, 1 <i>versus</i> 4 = 13% change (p < 0.05); 2 <i>versus</i> 4 = 23% (p < .05), 3 <i>versus</i> 4 = 7% (nonsignificant); influenza, combined 1 and 2 <i>versus</i> 3 and 4 = 13% (p < 0.025)
CDC Ref. 8 1994	Group randomized trial, greatest suitability, fair	Montana and Wyoming; communitywide; clients — aged ≥ 65 years; mostly rural	 Mailed "personal letter" reminders (87 participants) versus Mailed brochure reminders (96) versus Comparison group of usual care (105) All groups received public service announcements and provider reminders 	Influenza, 1 and 2 combined <i>versus</i> 3 = 6.1% (Cl = 5.5%-6.7%)
Grabenstein Ref. 9 1993	Randomized trial, greatest suitability, good	Durham County, North Carolina; community pharmacies; clients — mean age 67 years; 62% female, 79% white, socioeconomic status mid/high	Mailed letter on pharmacy stationary relating risk and availability of vaccination (242 participants) versus Mailed letter regarding "poison proofing" home (240) Both groups received reminder letter 2–3 weeks later	Influenza, 1 <i>versus</i> 2 = 10% (CI = 1%–19%)
Larson Ref. 10 1978–79	Randomized trial, greatest suitability, fair	Seattle, Washington; University of Washington Family Medicine Center; clients — mean age 67 gears; 68% female	 Neutral card stating availability of vaccinations versus Health belief model card versus Personal card signed by physician versus Comparison group of usual care (Total study population, 283 participants) 	Influenza, 1 <i>versus</i> 4 = 5% change; 2 <i>versus</i> 4 = 31% (p < 0.001); 3 <i>versus</i> 4 = 21% (p < 0.025); 2 <i>versus</i> 1 = 26% (p < 0.01); 3 <i>versus</i> 1 = 16% (p < 0.1)
Lieu Ref. 11 1994–95	Randomized trial, greatest suitability, fair	Northern California; managed care organization; clients — aged 20–24 months; middle/upper socioeconomic status	 Computer-generated personalized letter client recalls (172 participants) versus Comparison group of usual care (149) 	MMR by age 24 months, 1 <i>versus</i> 2 = 1.7% change (p < 0.001)
				Table B-1 Continued

Author, Reference Number, Study Period	Design, Category, Execution	Study Location, Setting Type, Population Description	Interventions Studied, Comparisons, (Number of Participants)	Outcomes and Effect Measures, Including Percentage Point Change Unless Otherwise Noted (Statistical Significance)
Tucker Ref. 20 1980–83	Time-series, moderate suitability, fair	Syracuse, New York; family practice residency model office, faculty private office, clients — aged >65 years; otherwise, not well-described	 Mailed client reminder letter from residency director (856 clients of model office) versus Same but stronger wording and signed by client's physician (1251 clients of model office, 249 clients of private office) versus Prior usual care (75 clients of model office, 75 clients of private office) 	Model office — Influenza, 1 <i>versus</i> 3 = 7% change (nonsignificant); 2 <i>versus</i> 3 = 7% (nonsignificant); private office — influenza, 2 <i>versus</i> 3 = 7% (nonsignificant)
		Effects of Client Remind	of Client Reminder/Recall in Combination with Other Interventions	
Barton Ref. 21 1983–87	Time-series, moderate suitability, fair	Boston, Massachusetts; clinic/provider's offices; clients — aged >65 years; urban	 Client reminders plus client education plus provider reminders versus Same plus feedback to individual physicians versus Previous usual care (Total study population, 647 participants) 	Influenza, 1 <i>versus</i> 3 = 18% change; 2 <i>versus</i> 3 = 36% (statistical significance not reported)
Becker Ref. 22 1986–87	Randomized trial, greatest suitability, fair	Charlottesville, Virginia; University of Virginia medicine clinic; providers: residents; clients — aged 40–60 years, mean 51–52; 64%–72% female; 50%–60% black; low socioeconomic status	Physician and client reminders (168 participants) versus Physician reminders (203) versus Comparison group (192)	Influenza, pneumococcal, and Td, 2 <i>versus</i> 3 = 9%, 2%, and 6% change; 1 <i>versus</i> 3 = 16%, 1%, 8% (analysis of variance for groups 1, 2, and 3 only significant for Td)
Browngoehl Ref. 23 Kennedy Ref. 24 1992–93	Retrospective cohort study; moderate suitability; fair	Philadelphia, Pennsylvania; Medicaid managed care group; clients — aged 30–35 months (control group) and 18–24 months (study group); low socioeconomic status	 Tracking and reminders plus provider education and incentives plus parent education and incentives plus transportation assistance plus home visits (1,254 participants) versus Control group of older children (1,257) 	4 DTP/3 OPV/1 MMR at age 35 months, 1 versus 2 = 7% change (p < 0.05); 4 DTP/3 OPV/1 MMR/1 Hib at age 35 months, 1 versus 2 = 2% change (nonsignificant) Higher coverage in children who received home visits (significance not given)
Buffington Ref. 25 1989	Randomized trial, greatest suitability, fair	Rochester, New York; private physician offices; clients — aged ≥65 years; urban/suburban; otherwise, target population not well-described	 Provider feedback versus Provider feedback plus mailed client remainders versus Comparison group of usual care (Total study population, 10,525 participants) 	Influenza, 1 <i>versus</i> 3 = 16% change (p < 0.001); 2 <i>versus</i> 3 = 17% (p < 0.001)

Table B-1 continued

Author, Reference Number, Study Period	Design, Category, Execution	Study Location, Setting Type, Population Description	Interventions Studied, Comparisons, (Number of Participants)	Outcomes and Effect Measures, Including Percentage Point Change Unless Otherwise Noted (Statistical Significance)
Nichol Ref. 34 1987 Nichol Ref. 35 1987–92	Other designs with concurrent comparison groups, greatest suitability, time-series study, moderate suitability, both fair	Minneapolis, Minnesota, <i>versus</i> other midwestern cities; VA outpatient services; clients — veterans	 Standing orders, walk-in "flu-shot" clinics, vaccination stations in busy clinic areas, mailing to all outpatients (378 participants) versus Usual care at 3 other midwestern academic hospitals (997) 	Influenza, 1 versus 2 = 26% change (p < 0.00001); time-series data found that coverage rates continued to increase for 5 years; additional 15% among all clients (p < 0.0001)
O'Sullivan Ref. 36 Time not reported	Randomized trial, greatest suitability, fair	Eastern United States; large urban teaching hospital; clients — maternal aged ≤17; 100% black; low socioeconomic status	Education and rigorous follow-up relating to family planning, parenting behaviors, return to school, health education, recall phone calls/letters, client-held vaccination records, lower costs versus Usual care	Children aged 18 months, 1 <i>versus</i> 2 = 15% change in up-to-date vaccination coverage (p < 0.02); mothers, clinic attendance and repeat pregnancy rates better in intervention group; return to school and emergency room use did not differ
Oeffinger Ref. 37 Time not reported	Nonrandomized trial, greatest suitability, fair	McLennan County, Texas; family practice residency program in hospital and clinic; clients — aged <1 year with 35%—39% adolescent mothers; 28%—36% Hispanic; 33%—47% black	 Client education at clinic plus client reminder letter (nonspecific) 2 months after birth versus Comparison group of usual care 	Up-to-date with 3 DTP vaccination/2 OPV by 12 months, 1 versus 2 = -4% (p = 0.41)
Ohmit Ref 38 1989–92	Time-series study, moderate suitability, fair	Seven counties in southwest Michigan; clients — aged ≥65 years; otherwise, not described	Communitywide education of physicians and clients plus free vaccination plus provider education plus client education plus aniled postcard client reminders plus outreach in senior centers (evaluated in 1,315 and 1,663 participants in 1990–91 and 1991–92, respectively) versus Prior usual care (client numbers not given)	Influenza, 1 versus 2 = 16% change (statistical significance not reported)
Paunio Ref. 39 1982–86	Time-series study, moderate suitability, fair	Finland; communitywide; target population — aged birth–11 years	 Registry plus mass-media reporting of local data regarding vaccination coverage plus provider reminders plus parent reminders versus Usual care before registry 	MMR, 1 versus 2 = 8% change (no significance testing) Fitted weekly time-series models of number of MMR delivered 1 versus 2, no effect on number of vaccinations administered to children aged 14–18 months; mass-media might have increased vaccinations administered to children aged 6 years, all three interventions increased numbers of children aged 6 years who received first MMR
				Table B-1 Continued

Table B-1 Continued

Author, Reference Number, Study Period	Design, Category, Execution	Study Location, Setting Type, Population Description	Interventions Studied, Comparisons, (Number of Participants)	Outcomes and Effect Measures, Including Percentage Point Change Unless Otherwise Noted (Statistical Significance)
Ornstein Ref. 45 1988–89	Group randomized trial (by practice group), greatest suitability, fair	South Carolina; family medicine center at University of South Carolina; providers — faculty, residents, and fellows in family medicine; clients aged >18 years, mean age 40 years; urban; 61% female; 61% black; low socioeconomic status	 Computerized physician reminders on chart (1,988 participants) versus Client reminders (1,925) versus Physician and client reminders (1,908) versus Comparison group of usual care (1,576) 	Td, 1 versus 4 = 6.7% change; 2 versus 4 = 5.7%; 3 versus 4 = 8.2%; significant improvements in 3 of 4 other preventive services
Satterthwaite Ref. 46 Time not reported	Randomized trial, greatest suitability, fair	Aukland, New Zealand; general practices; clients — aged >65 years; otherwise, target population not described	 "Personal" client reminder letter (931 participants) versus Same plus free vaccination offered in letter (930) versus Comparison group of usual care (930) 	Influenza, 1 <i>versus</i> 3 = 10% change (p < 0.001); 2 <i>versus</i> 3 = 28% (p < 0.001)
Yokley Ref. 47 Time not reported	Group randomized trial by family, greatest suitability, fair	Akron, Ohio; public health clinic; clients aged ≤5 years, mean 37 months; 50% female; 64% white	 Mailed general client reminder (195 participants) versus Mailed specific client reminder (190) versus Mailed specific client reminder plus special off hours clinics (185) versus Mailed specific client reminder plus parent incentive lottery (183) versus Comparison group of usual care (191) 	Vaccinated with at least 1 antigen after 3 months, 1 versus 5 = 3% change (not significant); 2 versus 5 = 13% (not significant); 3 versus 5 = 16% (significant); 4 versus 5 = 18% (significant)

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Studies of the Effectiveness of Client or Family Incentives

Outcomes and Effect Measures, Including Percentage Point Change Unless Otherwise Noted (Statistical Significance)	4 DTP/3 OPV/1 MMR at age 35 months, 1 versus 2 = 7% change (p < 0.05); 4 DTP/3 OPV/1 MMR/1 Hib at age 35 months, 1 versus 2 = 2% change (nonsignificant) Higher coverage in children who received home visits (significance not given)	Influenza, 1 <i>versus</i> 4 = 16% change; 2 <i>versus</i> 4 = 9%; 3 <i>versus</i> 4 = 6%; multivariate analysis odds ratios, 1 = 2.29% (Cl = 1.45%-3.61%, 2 = 1.68% (Cl = 1.05%-2.68%, 3 = 1.41% (Cl = 0.88%-2.27%)	Vaccinated with at least 1 antigen after 3 months, 1 versus 5 = 3% change (nonsignificant); 2 versus 5 = 13% (nonsignificant); 3 versus 5 = 16% (significant); 4 versus 5 = 18% (significant)
Interventions Studied, Comparisons, (Number of Participants)	Tracking and reminders <i>plus</i> provider education and incentives <i>plus</i> parent education and incentives <i>plus</i> transportation assistance <i>plus</i> home visits (1,254 participants) <i>versus</i> Control group of older children (1,257)	Mailed client reminders versus Lottery-type client incentive versus Both versus Comparison group of usual care (Total study population, 797 participants) All groups received walk-in vaccinations, free vaccinations, and health fair	Mailed general client reminder (195 participants) versus wailed specific client reminder (190) versus Mailed specific client reminder plus special off hours clinics (185) versus Mailed specific client reminder plus parent incentive lottery (183) versus Comparison group of usual care (191)
Study Location, Setting Type, Population Description	Philadelphia, Pennsylvania; Medicaid managed care group; clients — children aged 30-35 months (control group) and 18-24 months (study group); low socioeconomic status	Boston, Massachusetts; community health center; clients 2. – adults, mean age 66 years; urban; 33%-35% male; low socioeconomic status	Akron, Ohio; public health clinic; 1. clients — aged ≤5 years, mean 37 months; 50% female; 64% 3. white 4.
Design, Category, Execution	Retrospective cohort study; moderate suitability; fair	Randomized trial, greatest suitability, fair	Group randomized trial (by family), greatest suitability, fair
Author, Reference Number, Study Period	Browngoehl Ref. 1 Kennedy Ref. 2 1992-93	Moran Ref. 3 1991	Yokley Ref. 4 Time not reported

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Appendix C Economic Evaluations of Client Reminder/Recall

Author, Reference Number, Study Period	Analytic Method, Reported or Calculated Summary Measure	Study Location, Setting Type, Population Description,	Interventions Studied, Comparisons	Base Year, Costs Included, Reported Summary Measure, Coverage Baseline and Increase	Adjusted Base Year, Summary Measure Adjusted Value, Notes
Buchner Ref. 1 1984	Cost-effectiveness; cost-effectiveness ratio in dollars per additional vaccination	Seattle, Washington; general practice, adults aged >65 years; influenza	 Mailed client reminder Control 	1984 US\$; costs included direct costs of mailing reminders, including postage, printing, and envelopes; CE ratio of 1 versus 2 = \$30/additional vaccination; baseline coverage = 54%; change in coverage = 1%	1997 US\$; CE ratio of 1 versus 2 = \$46.35/additional vaccination
Chiu Ref. 2 1994–96	Cost-analysis; average cost in dollars per child	Jacksonville, Florida; hospital nurseries and communitywide; children aged <18 months; vaccines not specified	"Shots by Two" Project; volunteers "adopt" a baby, introduce themselves, and provide four postcard and phone reminders from the child's birth to age 18 months No control	1994 (assumed) US\$; estimates do not specify whether per child or per reminder and do not include in-kind contributions of volunteer time; AC = \$0.60 /child; county baseline coverage = 64.3%; change in coverage = 16.5% (Entire increase in coverage cannot be attributed to the intervention)	1997 US\$; AC = \$0.65/child AC is an underestimate because costs do not include in-kind contribution of volunteer time
Frame Ref. 3 1991–92	Cost-effectiveness; cost- effectiveness ratio in dollars per additional vaccination	Dansville, New York; rural; family practice; adults aged ≥21 years; Td booster	Computer-generated provider and client reminders and tracking Manual tracking	1992 US\$; costs included staff, materials, and postage; cost of installing computer-based system not included; CE ratio = \$3.71/additional vaccination; baseline coverage = 20%; change in coverage = 21%	1997 US\$; CE ratio of 1 <i>versus</i> 2 = \$4.41/Additional vaccination This intervention also increased provision of other preventive care; therefore, CE ratio probably underestimates overall CE
Frank Ref. 4 1981–82	Cost-effectiveness; cost-effectiveness ratio in dollars per additional vaccination	Hamilton, Ontario, Canada; urban community health center; adults aged >65 years; influenza	Mailed client reminders Follow-up telephone calls to nonrespondents Prior usual care	1982 (assumed) Canadian\$; costs included materials, labor, and postage; CE ratio of 1 versus 3 = \$2.16-\$2.50/Additional vaccination; CE ratio of 2 versus 1= \$5.00-\$8.00/Additional vaccination; baseline coverage = 17%; change in coverage attributable to 1 = 26%; additional change in coverage attributable to 2 = 12%	1997 US\$; CE ratio of 1 versus 3 = \$2.80-\$3.20/Additional vaccination; CE ratio of 2 versus 1 = \$6.40-\$10.37/Additional vaccination
					Table C-1 Continued

Adjusted Base Year, Summary Measure Adjusted Value, Notes	1997 US\$; CE ratio of 1 versus 2 = \$13.00/Additional vaccination	1997 US\$; CE ratio of 1 versus 3 = \$4.10/Additional vaccination; CE ratio of 2 versus 3 = \$2.18/Additional vaccination Assumes same effectiveness for autodialer system in increasing coverage that was observed for recall letters	Table C-1 Continued
Base Year, Costs Included, Reported Summary Measure, Coverage Baseline and Increase	1990 US\$; costs included materials, labor, and professional fees; CE ratio of 1 <i>versus</i> 2 = \$10.68/Additional vaccination; baseline coverage = 54%; coverage increase = 10%	1996 US\$; costs included computer costs, printing, clerical labor, postage, and stationary; baseline coverage = 86%; change in coverage = 4% for both 2 and 3 compared with 1; CE ratio of 1 versus 3 = \$4.04/Additional vaccination; CE ratio of 2 versus 3 = \$2.14/Additional vaccination	
Interventions Studied, Comparisons	. Two mailed reminders regarding risk of influenza and availability of vaccinations No reminders	Computer-generated personalized client reminders Autodialer telephone system Control group with no reminder	
Study Location, Setting Type, Population Description, Vaccine	Durham County, North Carolina: pharmacy- based; adults aged >64 years; influenza	Northern California; managed care organization; children 2. aged 20-24 months; MMR 3.	
Analytic Method, Reported or Calculated Summary Measure	Cost-effectiveness; cost- effectiveness ratio in dollars per additional vaccination	Cost-effectiveness; cost- effectiveness ratio in dollars per additional vaccination	
Author, Reference Number, Study Period	Grabenstein Ref. 5 1990	Lieu Ref. 6 1994–95	

Adjusted Base Year, Summary Measure Adjusted Value, Notes	1997 US\$; CE ratio of 1 versus 4 = \$4.06/Additional vaccination; CE ratio of 2 versus 4 = \$10.00/Additional vaccination; CE ratio of 3 versus 4 = \$50.73/Additional vaccination	1997 US\$; CE ratio of 1 <i>versus</i> 3 = \$22.10/Additional vaccination; CE ratio of 2 <i>versus</i> 3 = \$43.00/Additional vaccination	1997 US\$, CE ratio of 1 versus 4 = \$0.70/Additional vaccination; CE ratio of 2 versus 4 = \$8.75/Additional vaccination; CE ratio of 3 versus 4 = \$9.75/Additional vaccination
Base Year, Costs Included, Reported Summary Measure, Coverage Baseline and Increase	1991 (assumed) US\$; costs included graphic development, printing, prizes, postage, and clerical labor; costs of vaccine, software, tracking hardware, and student personnel not included; CE ratio of 1 versus 4 = \$3.45/Additional vaccination; CE ratio of 2 versus 4 = \$8.74/Additional vaccination; CE ratio of 3 versus 4 = \$43.06/Additional vaccination; baseline coverage = 20%; coverage increase 1 = 16%, 2 = 9%, and 3 = 6%	1995 US\$; costs included postage and vaccination administration; CE ratio of 1 <i>versus</i> 3 = \$21,00/Additional vaccination; CE ratio of 2 <i>versus</i> 3 = \$40.50/Additional vaccination; includes price of vaccine; baseline coverage = 25%; coverage increase 1 <i>versus</i> 3 = 24%; 2 <i>versus</i> 3 = 47%	1985 Canadian\$ (assumed); direct costs, including medical and nonmedical staff labor, postage, and stationary; cost of producing provider reminders not included; CE ratio of 1 versus 4 = \$0.43/Additional vaccination; CE ratio of 2 versus 4 = \$5.00/Additional vaccination; CE ratio of 3 versus 4 = \$6.50/Additional vaccination; baseline coverage = 3%; change in coverage, 1 = 20%; 2 = 21%, and 3 = 27%
Interventions Studied, Comparisons	2. Lottery-type incentive 3. Both educational brochure and incentive 4. Control group of usual care	 Mailed invitation for vaccination Mailed invitation plus free vaccination Comparison group of usual care 	 Physician reminder Telephone reminder by nurse Letter reminder Randomized control
Study Location, Setting Type, Population Description, Vaccine	Boston, Massachusetts; urban community health center; poor tower income; aged ≥65 years or <65 years but at high-risk; influenza	Denmark; general practices; adults aged ≥65 years; influenza	Ottawa, Canada; University of Ottawa Family Medicine Center at Civic Hospital; adults aged >20 years; tetanus booster
Analytic Method, Reported or Calculated Summary Measure	Cost-effectiveness; cost- effectiveness ratio in dollars per additional vaccination	Cost-effectiveness; cost- effectiveness ratio in dollars per additional vaccination	Cost-effectiveness; cost- effectiveness in dollars per additional vaccination
Author, Reference Number, Study Period	Moran Ref. 9 1991	Nexøe Ref. 10 1995	Rosser Ref. 11 1983–86

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