REVIEW

Community pharmacies as sites of adult vaccination: A systematic review

Randall C. Burson^a, Alison M. Buttenheim^b, Allison Armstrong^c, and Kristen A. Feemster^d

^aDepartment of Anesthesiology and Critical Care, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA; ^bDepartment of Family and Community Health, University of Pennsylvania School of Nursing, Philadelphia, PA, USA; ^cUniversity of Pennsylvania School of Nursing, Philadelphia, PA, USA; ^dDivision of Infectious Diseases, Children's Hospital of Philadelphia, Philadelphia, PA, USA

ABSTRACT

Vaccine-preventable deaths among adults remain a major public health concern, despite continued efforts to increase vaccination rates in this population. Alternative approaches to immunization delivery may help address under-vaccination among adults. This systematic review assesses the feasibility, acceptability, and effectiveness of community pharmacies as sites for adult vaccination. We searched 5 electronic databases (PubMed, EMBASE, Scopus, Cochrane, LILACS) for studies published prior to June 2016 and identified 47 relevant articles. We found that pharmacy-based immunization services (PBIS) have been facilitated by state regulatory changes and training programs that allow pharmacists to directly provide vaccinations. These services are widely accepted by both patients and pharmacy staff, and are capable of improving access and increasing vaccination rates. However, political and organizational barriers limit the feasibility and effectiveness of vaccine delivery in pharmacies. These studies provide evidence to inform policy and organizational efforts that promote the efficacy and sustainability of PBIS.

ARTICLE HISTORY

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KEYWORDS

community pharmacy services; health services delivery; immunization programs, pharmacies; vaccine policy

Background

Among adults in the United States, approximately 50,000 vaccine-preventable deaths occur each year.¹ However, despite continued public health efforts, adult vaccination rates in the United States remain below the recommended benchmarks for all routinely recommended vaccinations.² The actual adult vaccination rates in both 2000 and 2010 were much lower than the Healthy People 2000 and 2010 targets.^{3,4} Current trends predict vaccination rates will again fall considerably short of the Healthy People 2020 goals.^{5,6} Significant barriers to achieving these goals include a lack of access to a regular source of care and missed opportunities for healthcare providers' to provide preventative health recommendations.⁷ One option to address these persistent shortfalls and barriers is to leverage non-traditional sites of vaccination delivery.^{8,9}

With an estimated 56,000 outlets in the United States, community pharmacies have the potential to dramatically increase adult vaccination rates.^{10,11} Pharmacy-based immunization services (PBIS) are one of a range of primary care services which are increasingly offered by pharmacies.¹²⁻¹⁴ Pharmacies began offering mass-vaccination clinics run by nurses and other visiting healthcare providers in 1984. Over the following decade, this practice became widespread such that in 1997, 5 million doses of influenza vaccine were administered in 15,000 community pharmacies nationwide.15,16 However, the scope and effectiveness of these mass-vaccination clinics were frequently limited by their temporary operation and narrow range of vaccinations offered.^{16,17}

Pharmacists began regularly providing immunizations directly to adults in 1996. Concurrently, an increasing number of states began changing scope-of-practice policies to explicitly allow pharmacists to vaccinate patients.^{15,16,18} The updated regulations facilitated the incorporation of immunization services into the year-round, routine care administered at community pharmacies. However, states adopted these policy changes asynchronously over several years, resulting in the differential adoption of PBIS among states.^{15,16} By 2009 pharmacists in all 50 states, Washington DC, and Puerto Rico were allowed to obtain certification to administer the influenza vaccine, and 46 states allowed pharmacists to administer all adult vaccinations.¹⁹ By 2015 an estimated 280,000 pharmacists had been certified to deliver vaccinations.²⁰ The increased involvement of pharmacists in immunization practice was supported by other traditional immunizers including the American College of Physicians-American Society of Internal Medicine, who have pointed out pharmacists' ability to increase vaccination rates among adults and high risk populations.²¹

PBIS can provide a significant vaccination volume. Pharmacies were the second-most utilized site for influenza vaccination among adults, after physician's offices. Pharmacies delivered 20% of influenza vaccinations in the US in 2011-2012, and up to 25% at the beginning of the 2014-2015 influenza season.²² However, community pharmacies are underutilized as a site of delivery for adult vaccinations such as the pneumococcal; zoster; tetanus, diphtheria, and acellular pertussis (Tdap); and hepatitis A and B vaccines.^{19,23,24} Further insights into barriers that limit the effectiveness of PBIS may strengthen the role of community pharmacies as part of the community-based "immunization neighborhood."18,23-26

CONTACT Randall C. Burson 🖾 Randall.Burson@uphs.upenn.edu 😰 Department of Anesthesiology and Critical Care, Hospital of the University of Pennsylvania, Dulles 680, 3400 Spruce Street, Philadelphia, PA 19104, USA.

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To date, there has been no comprehensive review of the evidence regarding pharmacies as sites of immunization service delivery for adults or the impact of PBIS on vaccination coverage. This is a critical gap in the understanding of how adults access preventative health services, particularly given the emphasis on accessible and affordable primary health care in the Affordable Care Act.²⁷ To assess the current state of PBIS for adult vaccination and its impact,²⁸ we conducted this systematic review to summarize current literature and identify targets for future research.

Methods

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to conduct the review and analysis.²⁹ Searches of the indexed literature were conducted from 1992 through 14 July 2013 in the online databases PubMed, EMBASE, Scopus, Cochrane and LILACS with no language limitations. Google Scholar[©] was also reviewed for gray literature using similar control vocabulary and search criteria. To update the review to reflect developments in the field, a literature search following previously determined criteria was completed for articles published between 15 July 2013 and 20 June 2016. Database searches used relevant terms and control vocabulary that corresponded to our primary research question: immunization; immunization or vaccination services; community or retail pharmacy; community or retail pharmacy services; pharmacist. Population (e.g., pharmacy) and intervention (e.g., immunization services) search terms were constructed according to a population, intervention, control, and outcome (P.I.C.O.) question format.

Study selection

Duplicate studies were removed from the results, and titles and abstracts were screened by the first author using the following inclusion criteria: articles reporting original research on the administration of vaccines routinely recommended for adults, 18 y or older, in community pharmacies in the United States and Territories. Community pharmacies, hereafter referred to simply as pharmacies, were defined as community-based locations that provide pharmaceutical services to the public, and are distinct from hospital or industrial pharmacy settings. Routinely-recommended vaccines refer to vaccines recommended to adults by the Advisory Commission on Immunization Practices (ACIP) that are part of standard immunization needs.³⁰ Studies were excluded if they: 1) were conducted in countries other than the United States; 2) focused on vaccinations delivered at sites other than pharmacies; 3) referred to only child or adolescent vaccinations or 4) referred to only non-standard immunization needs, such as travel vaccinations or pandemic/ emergency responses. The co-authors confirmed the preliminary screening of titles and abstracts, with disagreements between reviewers resolved by consensus.

Quality screen and data extraction

Given the variety of study designs, one of 3 quality screens were applied to selected papers. Experimental study designs were assessed using the Effective Public Health Practice Project (EPHPP) tool for quantitative studies.³¹ Case control and cohort studies were evaluated using the Newcastle-Ottawa rating system.³² Observational cross-sectional studies were assessed using the National Institute of Health's National Heart, Lung and Blood Institute (NHLBI) Quality Assessment Tool for Observational Cohort and Cross-sectional Studies.³³ All screened studies met basic quality requirements, so no studies were excluded. Models, case studies and qualitative studies did not undergo quality assessment, and were included in the review.

Data were extracted from included studies using a data extraction template developed by the authors. The first author extracted data from eligible articles, and the co-authors independently reviewed and confirmed extracted data and quality screening results for a subset of papers. Authors resolved outstanding questions and discrepancies through consensus. Data elements extracted included study design, sample, study period, location, main outcome, and key findings. Results were extracted and coded for the 3 principal topics of the review: feasibility, acceptability and effectiveness of PBIS. Studies were further coded to one or more sub-categories created from emergent themes that arose through iterative review of the data.

Results

Database searches yielded 397 results, and Google Scholar® generated an additional 816 results for a total of 1213 publications (Fig. 1). Following review of titles and abstracts, 136 articles underwent screening based on inclusion criteria and study design and an additional 79 studies were excluded. The remaining 57 articles underwent full text review, quality screen, and data abstraction. Of these, 21 studies that did not meet inclusion criteria or met one or more of the exclusion criteria were discarded from the review. Scanning bibliographies of all included studies revealed 4 additional studies that met eligibility criteria. The updated literature search revealed an additional 7 studies, yielding a final total of 47 articles which were included in the review (Table 1). A majority of studies used a cross-sectional study design (n = 25 studies, 53%); the remainder includes 4 cohort studies (8.5%), 4 case studies (8.5%), 4 experimental studies (8.5%), 3 modeling studies (6.5%), and 7 studies of singular design (15%). Results are presented here by outcome theme, including feasibility (n = 30 studies), acceptability (n = 11 studies), and effectiveness (n = 27 studies).

Feasibility

Results from studies evaluating the feasibility of pharmacies as a site for adult vaccination clustered around 4 main themes: pharmacist scope of practice (n = 15 studies); certification and training (n = 16 studies); setting and affiliations (n = 15 studies); and reimbursement (n = 9 studies). Sustainability of services, a measure of long-term feasibility, was also observed (n = 5 studies).

The utilization of pharmacies for adult vaccination has been facilitated by an expansion of pharmacists' scope of practice as immunizers. State-level policy changes that allowed pharmacists to directly administer vaccinations to patients were

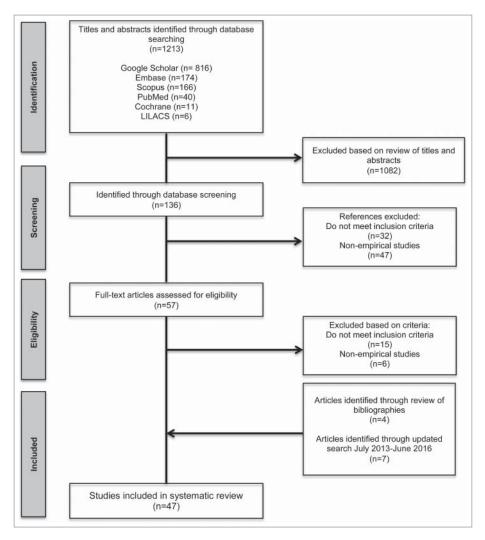


Figure 1. Flow diagram documenting systematic search conducted to identify studies on community pharmacies as sites for adult vaccination.

associated with significantly increased pharmacy-^{17,34,35} and state-level^{36,37} vaccination rates. Additional regulations in some states that required pharmacists to inform the patient's provider prior to³⁸ or following³⁸⁻⁴¹ vaccination delivery were viewed as barriers by pharmacy staff. Other barriers frequently expressed by pharmacists included concerns about the limiting effect of scope-of-practice policies,⁴² legal liability,^{1,43} and ability to treat potential adverse effects.²

Involving other pharmacy personnel also supported the implementation of immunization service offerings. Immunization-certified pharmacy students can support PBIS through direct administration of vaccines,⁴⁴ assistance with program organization,⁴¹ and patient education.⁴⁵ However, in 2009, 2 y after regulatory changes allowed Arkansas pharmacy students to provide supervised immunizations, only half of practicing Arkansas pharmacists reported they were aware of this training opportunity, and only 33% of pharmacists had allowed a pharmacy student to administer immunizations.⁴⁰ Pharmacies have employed nurses as immunizers for single-day mass vaccination clinics in pharmacies without PBIS, or operated alongside pharmacists as alternative immunizers. ^{1,41,43} However, limited frequency of mass vaccination clinics yielded fewer average vaccinations delivered per influenza season for nurses (91–233 doses per pharmacy per season) versus pharmacists (528–807

doses per pharmacy per season).¹⁷ Trained pharmacy technicians can also support PBIS through managing workflow, such as processing patient information or billing.⁴¹ However pharmacies with greater numbers of pharmacy technicians were associated with fewer total service offerings.⁴⁶

In studies that discussed pharmacist training, the percentage of pharmacists aware that vaccination was within their scopeof-practice ^{1,2,42,43} or who were interested in offering vaccinations varied.^{46,47} A number of studies reported less than 40% of pharmacists were immunization certified,^{2,38,40,48} however there was considerable variation in certification rates across groups of surveyed pharmacists.^{39,49,50}

Not surprisingly, 3 studies found formal training to be an important factor in incorporating immunization services into community pharmacies.^{2,48,51} Pharmacists who believed that the ability to vaccinate advanced their field were 7 times more likely to be immunization certified.⁴⁰ Conversely, non-certified pharmacists commonly cited lack of knowledge or training as a major barrier to participating in immunization services when compared to certified pharmacists.³⁸

In-pharmacy training and formal certification programs, such as those offered by the American Pharmacists Association, are used to train and educate pharmacy students⁴⁴ and practicing pharmacists⁵¹ about immunization practice. Furthermore,

Summary of Main Y Findings	Both self-directed and coaching groups had significant increases in pneumococcal vaccination rates; pharmacies in the coaching group completed a greater number of process indicators.	Due to a limited sample size, the effect of a motivational interviewing (MI) intervention on vaccination rates was inconclusive; pharmacists considered MI to be an effective	Communication root. The total direct cost for the influenza, pneumococcal, and zoster vaccinations were cheaper at pharmacies than other sites. Patients paid the least out-of-pocket cost for influenza and menumocorcal at harmacies	After a herpes zoster educational intervention led by pharmacy students, 72.5% of unvaccinated patients were interested in speaking with a pharmacist/doctor. Patients who had received a healthcare provider's recommendation were more likely to he varcinated	Pharmacies and the second of t	Two different pharmacoeconomic models both indicated that a herpes zoster vaccine program at a local harmacy chain vielded a net nordt	30.5% of all adult vaccines delivered at the protect national pharmacy chain were administered during off-hours (i.e. nights, weekends, and	Automatysy Automated telephone messaging to at-risk patients significantly increased herpes zoster varcination rates hatwaen the 2 cohorts	Personal selling techniques were more effective than passive methods at increasing herpes zoster vaccination commitments and delivered vaccinations	Pharmacy-based flyers and letter-based interventions increased herpes zoster vaccination rates and increased acts of	Significant racial disparities between black and white responders were found for both community pharmacy and non-pharmacy populations. Community pharmacy patients reported higher overall influenza vaccination rates.
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Main Outcome C	Number of pneumococcal vaccination administered; program evaluation indicators	Number of vaccines delivered at pharmacy chain; pharmacists attitudes	Vaccine administration costs	Vaccination rates; patient characteristics and knowledge	Wayne County, MI Pharmacy characteristics and service offerings	Financial gains and losses for vaccines administered per pharmacy site	Date and time of vaccines administered	Number of vaccines administered	Patient commitments to vaccinate and attitudes; time spent with pharmacist	Vaccination rates; patient knowledge	Vaccination rates; patient characteristics
Location	US	Atlanta, GA	US	AL & FL	Wayne County, Ml	Kansas City, KA	US	GA & TN	OM	Z	ns
Study Period	2013-2015	September 2013-April 2014	2010	Summer 2013	February 2011	September 2011- January 2012	August 2012-July 2013	December 2006- May 2007	November 2010 - February 2011	February 2008 - March 2008	2009
Sample	96 Community pharmacies	1 Pharmacy; 19 customers received motivational interviewing intervention	2 Health insurance databases, representing 48.7 million patients	688 Pharmacy patients, 65 y or older	503 Community pharmacies	19 Pharmacies from one chain	National pharmacy chain	16 Pharmacies; 9650 prescription holders received	745 Pharter incluses received personal selling in experimental group, 614 in control crown	3 Pharmacy strong 2 Pharmacy sites; 16,121 during February control, 16,062 during intervention	71,135,249 Survey responders from the Medicare Expenditure Survey
Design	Cluster-randomized experimental design	Pilot evaluation	Cross-sectional	Cross-sectional	Cross-sectional	Cost Analysis Model	Cross-sectional	Randomized Control Trial	Pre/post with comparison group	Prospective Intervention; Pre/ post Design	Cross-sectional
Study	Westrick et al. (2016) ⁵⁷	Brackett et al. (2015) ⁷³	Singhal and Zhang (2014) ²³	Teeter et al. (2014) ⁴⁵	Erickson and Workman (2014) ⁷⁶	Hedden et al. (2014) ⁶⁹	Goad et. al (2013) ²⁴	Hess (2013) ⁷²	Bryan et al. (2013) ⁷⁰	Wang et al. (2013) ⁶⁶	Wang et al. (2013) ⁷⁷

Table 1. Summary of characteristics of included studies with results relevant to PBIS, organized in reverse chronological order. Principal category labels: F-Feasibility, A-Acceptability, E-Effectiveness.

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Table	

Study	Design	Sample	Study Period	Location	Main Outcome	Category	Summary of Main Findings
Doucette et al. (2012) ⁷⁵	Case Report	1 Independent community pharmacy	2008–2010	lowa City, IA	Profitability of pharmacy services	ш	Influenza and herpes zoster immunizations yielded a net profit, while pneumococcal vaccines chowed a part hose during the study nariod
Murphy et al. (2012) ²⁵	Cross-sectional	6936 Walgreens pharmacies, over 18,000 pharmacists	September 2009-February 2010	US	Number of influenza vaccinations provided in medically-underserved areas	A, E	A single national pharmacy cump ine scup period. A single national pharmacy chain served 43.2% of medically underserved areas (MUAs), and 37.7% of the chain's total influenza vaccines were delivered in MIIAs
Crawford et al. (2011) ⁵⁹	Cross-sectional	103 Pharmacy sites, 437 pharmacy staff	January 2008-March 2009	New York, NY	Individual and neighborhood characteristics of staff, staff support for PBIS	F, A, E	Pharmacists working in pharmacies that provided other public-health services were more supportive of PBIS. Pharmacists working in high-minority communities were significantly less supportive
Taitel et al. (2011) ⁷⁸	Cross-sectional	1,343,571 At-risk patients	August 2010 - November 2010.	US	State-level vaccination rates	ш	Pharmactes were successful at identifying at-risk patients, and providing additional vaccinations. At-risk patients were accinated against pneumococcal at significantly higher rates than adults usion traditional care. (A 88% vs. 2 00%)
Penfold et al. (2011) ⁴²	Qualitative	65 Flu vaccine stakeholders; 7 pharmacy stakeholders	January 2009 - June 2010	US	Stakeholder perceptions of barriers and solution to community delivery of influence varcines	ш	Pharmacies cited barriers in but chaoties of insurance reimbursement, and legal constraints based on scone-of-martice
Pace et al. (2010) ⁴⁰	Cross-sectional	122 Pharmacists or pharmacy managers	February - March 2009	AR	Practice site characteristics and demographics; pharmacist involvement; perceived barriers	ш	A majority of pharmacists believed pharmacist- delivered vaccinations advanced the field and increased access to care. Cited barriers varied
Pilisuk et al. (2010) ³⁹	Mixed Methods; Cross-sectional	Representatives from 8 chain pharmacies, 2,500 store locations	2006–2007	СА	Pharmacy policies and protocols; practice site characteristics and demographics	ш	by planmacy seturity. Representatives reported that all chains offered adult immunization services. Maintaining records with patients' medical home was cited as one of the hirdnest challendes
Westrick (2010) ⁵⁰	Cohort	155 Pharmacies responded to both survey stages.	2003, 2004, 2006–2007	MM	Pharmacy and immunization service characteristics	ш	Type of pharmacy and time since implementation of vaccination programs affected the scale and pharmacist-involvement in PBIS.
Westrick (2010) ⁵⁵	Cross-sectional	106 Pharmacies included	2003–2004	M	Pharmacist characteristics and attitudes; pharmacy organizational factors	ш	Pharmacrustor intervention of pharmacrust-delivered and out-sourced vaccination services were correlated with decisions to adopt or discontinue services
Westrick et al. (2009) ⁵³	Cross-sectional	1704 Pharmacists or pharmacy managers	July 2005- February 2006	AL, AZ, ID, MD, MS, I MT, NM, NY, OK, OR, PA, SD, TN, TX, WA, WI, WV	AL, AZ, ID, MD, MS, Pharmacist involvement and MT, NM, NY, OK, characteristics OR, PA, SD, TN, TX, WA, WI, WV	ш	Pharmacies affiliated with pharmacy schools were significantly more likely to participate in public health services. However, affiliation was non- significant when the presence of a certified pharmacist or positive attitudes were
Grabenstein (2009) ¹⁷	Retrospective Cohort Study	13 Pharmacies in Oregon and 11 1997 and 1998 pharmacies in Washington	1 1997 and 1998	OR & WA	Number of vaccines administered per pharmacy site	F, E	Pharmacists offering daily vaccinations administered more vaccinations over an influenza season than nurses operating single- day clinics
Westrick and Breland (2009) ⁵⁶	Cross-sectional	206 Key informants of pharmacies	2006	WA	Practice site characteristics; pharmacy organizational factors	ш	Compatibility between the site and immunization services was found to be key to sustainability. Two paths to compatibility are discussed.

About one third of vaccines purchased by pharmacies are administered in pharmacies, while the remaining two-thirds are distributed to other vaccinators	A financial analysis of the first 11 months of a herpes zoster immunization program resulted in a net profit.	Perceived benefit, perceived compatibility, and perceived complexity of PBIS independently predicted adoption of pharmacist-delivered immunization services; when considered together, perceived benefit was the only significant predictor.	There are wide state-level variations in pharmacies' stages of involvement in PBIS	Only 22% of responding pharmacists were immunization certified, and 52% had immunized in the last year. Barriers were analyzed based on involvement with immunization services.	The mean cost of vaccinations and the cost to prevent a case of influenza were both lower in pharmacies than physician's offices and mass vaccination clinics.	2nd and 3rd year pharmacy students delivered an estimated 5,000 and 15,000 vaccines in community pharmacies. Self-confidence to administer increased and was maintained a year later.	Doc	Immunization services were the most commonly offered non-dispensary services (15.1% of pharmacies). Three or more pharmacists on duty, and pharmacy innovativeness were positively associated with greater service offerings.	Sur	Following a pharmacist-led educational intervention, patients demonstrated greater influenza vaccination knowledge and higher rates than the control group. (Continued)
ш	ш	ш	ш	ц Ц	ш	ш	F, A, E	ш	F, A	ш
AL, AZ, ID, MD, MS, Number of vaccines purchased, MT, NM, NY, OK, administered, and distributed to OR, PA, SD, TN, other sites TX wAA wit ww	Financial gains and losses for PBIS	Immunization service characteristics	AL, AZ, ID, MD, MS, Pharmacy and immunization service MT, NM, NY, OK, characteristics OR, PA, SD, TN, TX, WA, WI, WV	Characteristics and perceived barriers of PBIS and practice sites	Health benefits and financial costs	Number of vaccines administered; pharmacy student and mentor attitudes	Number of influenza and pneumococcal vaccines delivered at a pharmacy chain	Type and frequency of pharmacy services	Pharmacist-perceived barriers to PBIS	Vaccination rates; patient knowledge
AL, AZ, ID, MD, MS, MT, NM, NY, OK, OR, PA, SD, TN, TX, WA, WI, WV	lowa City, IA	WA	AL, AZ, ID, MD, MS, F MT, NM, NY, OK, OR, PA, SD, TN, TX, WA, WI, WV	NC	n/a	Denver, CO	VA	N	НО	Puerto Rico
July 2005- February 2006	February 2007- January 2008	2004 and 2006–07	July 2005- February 2006	January- February 2007	n/a	2004-2005	1998–2005	2004	February 2005	June-July 2000
1704 Pharmacists, 301 offered pharmacist-delivered vaccination services	1 Independent community pharmacy	115 Pharmacies participated in both stages II and III.	1707 Community pharmacists	1,274 Active pharmacists	Cost breakdowns by population, n/a health status, and age group	Cohort; Cross-sectional 2nd and 3rd year pharmacy students (n=121–125, and n=123)	29 Grocery stores, 23 with pharmacies	611 Pharmacists, of which 290 community pharmacists	43 Pharmacists	50 Pharmacy patients in experimental group with educational activity, and 50 in control group
Cross-sectional	Retrospective Cost Analysis	Cohort	Cross-sectional	Cross-sectional	Cost Decision Model; Qualitative	Cohort; Cross-sectiona	Case series	Cross-sectional	Cross-sectional	Controlled Clinical Trial
Westrick et al. (2009) ⁵⁴	Wood et al. (2009) ⁶³	Westrick and Mount (2009) ⁵⁸	Westrick et al. (2008) ⁴⁷	Kummer and Foushee (2008) ³⁸	Prosser et al. (2008) ⁷⁴	Turner et al. (2007) ⁴⁴	Goode et al. (2007) ⁴⁹	Doucette et al. (2006) ⁴⁶	Capurso and Powers (2006) ²	Marrero et al. (2006) ⁷¹

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Table 1. (Continued)	(p						
Study	Design	Sample	Study Period	Location	Main Outcome	Category	Summary of Main Findings
Bearden and Holt (2005) ³⁷	Cross-sectional	All pharmacies with immunization programs: 56 in 2001, 88 in 2002, 132 in 2003	2001-2003	OR	Pharmacy-based vaccination rates and characteristics	Е Г	In the 3 y following regulatory changes that allowed pharmacist vaccination, the number of adult influenza vaccinations delivered and participating pharmacies increased each year. Over one quarter of vaccines were delivered in rural counties.
Steyer et al. (2004) ³⁶	Quasi-experimental Matched Pair	Sixteen states; 8 that passed legislation in 1997 allowing pharmacist-administered vaccination, and 8 that did not pass until after 2000	1995 and 1999	States with legislation (AR, KS, NE, ND, OK, TN, TX, VA) and Those without (LA, MO, IA, WY, UT, WY, FL, MD) in 1997	State vaccinations rates	E, E S	States that allowed pharmacist-vaccination had significantly higher influenza vaccination rates for adults 65 y and older, after controlling for policy changes.
Neuhauser et al. (2004) ⁴⁸	Cross-sectional	90 Immunization-certified pharmacists and 169 pharmacists for control	Not Reported	Ϋ́	Practice site characteristics and demographics; pharmacist involvement and satisfaction	F, A O	Certified pharmacists were more involved in PBIS than non-certified pharmacists in some capacity. Seventy-four percent of certified pharmacists administered vaccines.
Kamal et al. (2003) ¹	Cross-sectional	1266 Immunization-certified Pharmacists	Fall 2001	SU	Characteristics and perceived barriers of PBIS; pharmacist involvement	Е Н	From 1998 to the updated survey in 2001, nurse- and pharmacist-administered adult vaccinations increased (16.2% to 30.2% and 2.2% to 6.8%, respectively).
Kamal et al. (2003) ⁵¹	Cross-sectional	194 Immunization-certified pharmacists	Prior to August 2001	SU	Pharmacist involvement and satisfaction	F 9	92.3% of pharmacists would recommend the certification course. Barriers were assessed for both immunizing and non-immunizing pharmacists.
Grabenstein et al. (2002) ³⁵	Retrospective Cohort	80,462 Pharmacy prescription recipients from 24 Fred Meyer chain pharmacies, 11 in WA and 13 in OR, 4403 pharmacy patients.	1999	OR & WA	Customers' vaccination status, choice of immunization provider, and attitudes	F, A R	Responders were most likely to return to their previous vaccine provider. Convenience and provider experience were the 2 most influential factors in determining the choice of vaccine provider.
Grabenstein et al. (2001) ³⁴	Cohort	2090 Adult by accurate the second patients in Spring 1999 either Washington or Oregon, and either age 21– 64 with chronic conditions or age >65	Spring 1999	OR & WA	Customers' vaccination status and choice of immunization provider	F, E C	Of the success adults age 21–64 with chronic conditions, and patients who were unvaccinated the year prior had significantly higher vaccination rates in Washington state, which offers PBIS.
Ernst et al. (2001) ⁶⁷	Cross- s ectional	11 Physician offices and 16 community pharmacies, 25 pharmacy customers per site	January 1999	A	Patient history and attitudes toward immunizations	A, E P	Pharmacists were the second most supported immunizer behind physicians. Patients with prior experience receiving a vaccination at non- traditional sites were more likely to support immunization at pharmacies.
Grabenstein et al. (2001) ⁶⁵	Cross-sectional	90 Participating pharmacists, 21 August 1998-January 1999 pharmacies returned surveys from 17 cities in 10 states.	August 1998-January 1999	AL, AR, IA, ID, MI, NE, TN, TX, VA, WI	Patient characteristics, history and attitudes toward vaccinations	A, E V	Vaccine recipients reported they were treated respectfully, and considered pharmacies to be advantageous because of access, proximity, and/or convenience.
Madhavan et al. (2001) ⁴³	Cross-sectional	1348 Pharmacists	Not Reported	ns	Characteristics and perceived barriers of PBIS	F, A, E P	Pharmacist involvement in vaccination counseling and promotion were high, while delivery was low. Those who attended educational programs were more involved and perceived barriers to be less problematic.

F, E Documents the implementation of pharmacist- and nurse-operated immunization services. The program increased the number of vaccines administered in the years after implementation.	Th	Model indicates that a pharmacist-written letter campaign advocating influenza vaccination could prevent hospitalizations and deaths, and yield a net savings to Medicare.
ц Ц	А, Е	ш
Number of influenza and pneumococcal vaccines delivered by pharmacists	Accessibility of influenza vaccines	Financial gains and losses for vaccine- advocacy letters; vaccination rates
VA	Rural IA	n/a
September-December 1998	Fall 1996	n/a
27 Chain pharmacies	1 Independent community pharmacy	n/a
Cross-sectional	Implementation Study; Cross- sectional	Grabenstein et al. Cost Analysis Model (1992) ⁶⁸
Weitzel and Goode (2000) ⁴¹	Ernst et al. (1997) ⁶⁴	Grabenstein et al (1992) ⁶⁸

immunization certification is now a required element of any accredited Doctor of Pharmacy curriculum.⁵² Studies found that following in-clinic training, pharmacy students were more selfconfident in administering adult vaccinations.⁴⁴ Pharmacists who had received immunization-related educational training were more willing to vaccinate than those who had not, and found common barriers to be less problematic.^{43,51} Similarly, immunization-certified pharmacists were much more likely to be involved in some aspect of immunization (99%) than noncertified pharmacists (24%).48 The presence of one or more immunization-certified pharmacists was correlated with the pharmacy offering immunization services,⁵³ and with a transition from no or outsourced services to a pharmacist-delivered immunization system.47,54 However, the number of years a pharmacist has been practicing may be associated with immunization participation. A 2010 study found that pharmacists who had practiced for less than a decade were less likely to have administered vaccinations in the previous year when compared to pharmacists who had practiced for more than 10 y.⁴⁰

Several studies considered the relationship between the type of pharmacy ownership (e.g. chain, independent, etc.) and feasibility of providing immunization services. Community pharmacies that had a greater number of certified pharmacists were more likely to offer immunization services.⁴⁶ Certified pharmacists were more likely to work in independent community pharmacies and mass merchandising pharmacies.⁴⁸ Independent pharmacies were more likely than chain and mass merchandiser pharmacies to be associated with increased and sustained public health service offerings, including PBIS,^{46,50} and more frequent vaccination administration.¹ However, in one study, over half of independent pharmacies abandoned outsourcing immunization services to an external workforce (e.g., visiting nurse vaccinators) and did not adopt in-pharmacy services. The same study found that half of chain and massmerchandising pharmacies, and a majority of supermarket pharmacies, maintained an outsourcing model of immunization services without further adoption of PBIS.55

Studies of pharmacies' organizational structure determined that compatibility between implementing immunization services and pharmacy structure is necessary for PBIS to become part of standard pharmacy practice.56,57 Staff and management support were considered important for the success of a vaccination program, with lack of support cited as a barrier.^{40,48} Lack of time and inability to fit immunization services into the workflow was another frequently cited barrier to the adoption of PBIS.^{1,2,38,40,41,43} Pharmacy staff also expressed concerns about privacy during the vaccination process and lack of space needed to offer the services.^{2,38,43} Factors such as participation in other public health services like HIV testing and needle exchange, and perceived benefit of PBIS were predictors of in-pharmacy immunization service adoption.^{50,55,56,58,59} These factors were also associated with the decision to either outsource immunization services to other health professionals or implement inpharmacy services.^{46,47} A multi-state survey indicated that a high percentage of pharmacies either lacked interest in or information about how to implement pharmacist-delivered immunization services.47

While many pharmacist-administered vaccines are covered under a number of private insurance plans, as well as Medicare Part B and D,⁶⁰⁻⁶² reimbursement and insurance logistics were cited as barriers for both patients and pharmacists.^{38,46} Pharmacists reported that the level of insurance reimbursement was a barrier in their provision of vaccinations.^{1,43} Similarly, insurance coverage and out-of-pocket costs were perceived as 2 potential barriers for patients.^{1,39,43,63} Moreover, patients reported that insurance coverage and their perceived ability to pay were important factors in selecting their vaccination site.^{35,39} Several strategies, including the implementation of an insurance assessment step prior to vaccination, were reported to simplify the reimbursement and billing processes for patients.^{42,63}

The sustainability of PBIS is a key determinant of the effectiveness and future outcomes of pharmacies as sites of adult vaccination. Compatibility of PBIS with pharmacy services or pharmacist and staff attitudes toward offering immunization services were influential in determining program sustainability.^{50,55,56,58} Two main pathways to sustain practice-site innovations were identified: 1) a continuous process of assessment, modification and adaptation; or 2) having an "operational champion" with insider knowledge of the organizational structures to ensure PBIS fit within existing structures.⁵⁶ Discontinuation of in-pharmacy services was commonly reported when challenges or barriers to PBIS outweighed perceived benefit or revenue; state-level discontinuation rates ranged from 3 to 23%.⁴⁷

Acceptability

The included studies captured 2 main sub-categories of acceptance: pharmacist or pharmacy staff's comfort providing PBIS (n = 5 studies), and patient's acceptance of PBIS (n = 6 studies). Pharmacists^{48,49} and pharmacy staff⁵⁹ both generally had positive attitudes about PBIS. However, several studies cited pharmacists' discomfort with carrying out different aspects of immunization services,² including administering vaccinations, managing any adverse events, billing procedures, and patient counseling.⁴³

Several factors influenced patient acceptance of pharmacies as sites for vaccination, including convenience, accessibility, and expanded hours of operation.^{25,35,64,65} Most patients felt comfortable with pharmacists delivering vaccinations in pharmacies, with pharmacists ranked the second most highly trusted immunizers^{65,66} after physicians.⁶⁷ Overall, patients were more likely to return to the same vaccination sites as previous vaccinations, including patients who used pharmacies or other non-traditional immunizers.^{35,67}

Effectiveness

Twenty studies reported the effect of PBIS on patient vaccination rates as a primary outcome measure. Other outcome measures including the cost-effectiveness of PBIS (n = 5 studies), and their impact on health disparities and access among medically at-risk or underserved populations (n = 19 studies).

The implementation and expansion of immunization programs in community pharmacies generally increased the number of vaccinations administered.^{17,37,41,43,49,57,65} In particular, pharmacy-based vaccination appears to have been effective in increasing influenza vaccination rates among patients who had missed the previous year or who would not have otherwise received an influenza vaccine.^{34,35,64,65}

In addition to administering vaccines, pharmacist participation in vaccination counseling and advocacy increased from 1998 to 2001.¹ An early cost analysis model predicted that letters from pharmacists that prompted patients to receive vaccinations could hypothetically decrease influenza healthcare utilization costs through increased vaccination rates among letter recipients.⁶⁸ Subsequent studies demonstrated that advertising pharmacy immunization programs was correlated with increased profits for pharmacies due to increased vaccine administration and the profitability of vaccination delivery.⁶⁹ Active or personalized methods (e.g., direct communication with customers, personalized letters, and educational interventions) were shown to be more effective at increasing immunization rates than passive or general methods.45,66,70,71 Other methods of advertising, such as flyers and automated voice messages, were shown to increase vaccination rates to varying degrees. 66,68-70,72,73

Several studies examined the cost-effectiveness of PBIS. A recent study of 2 major health insurance claims databases revealed that, on average, the total cost of influenza and pneumococcal vaccination were lower in pharmacies than in physician offices for both patients and insurers; however, the zoster vaccine had a lower cost in physicians' offices.²³ When examining the costs of immunization programs in individual pharmacies, studies show more variability. The maintenance of pharmacy services were largely cost-effective for influenza ^{74,75} and herpes zoster vaccination programs.^{63,69,75} One study cited a net loss for pneumococcal vaccinations at a single independent pharmacy.⁷⁵ Prosser et al. (2008) determined that pharmacies were more cost-effective sites of vaccination than physicians' offices due to decreased time spent waiting and lower operation costs.⁷⁴

PBIS are uniquely positioned to improve access to vaccines through non-traditional service offerings. Community pharmacies offered more consistent hours and days of operation, and more flexible scheduling than physicians' offices or public health clinics.^{17,41,64,65} One study of a national pharmacy chain found that 30.5% of the more than 6 million vaccines doses dispensed were administered during nights, weekends and holidays. Additionally, more than one million vaccinations (17.5% of all vaccinations) were administered during lunch hours (11am-1pm). Uninsured patients were more likely to be vaccinated during these off-clinic hours than individuals with insurance.²⁴

There is mixed evidence about the potential for PBIS to reduce geographic and socioeconomic disparities in vaccine access. A study of pharmacy offerings in Wayne County, Michigan reported that pharmacies located in lower income ZIP codes and areas with a higher percentage of minorities were less likely to offer PBIS.⁷⁶ A 2012 study of a large national chain pharmacy highlighted that 41% of the chain's locations service medically underserved areas throughout the United States, and 37.7% of influenza vaccines delivered were administered in medically underserved areas.²⁵ Similarly, patients living in smaller towns were more likely to receive vaccinations in non-traditional settings, such as pharmacies.⁶⁷ Another study

examining PBIS in New York City found that pharmacy staff at pharmacies located in predominately racial and ethnic minority neighborhoods were significantly less likely to be supportive of PBIS, while pharmacies located in neighborhoods with greater numbers of immigrants were only marginally supportive of these services.⁵⁹ Finally, a 2013 study reported that both white and black community pharmacy patients had significantly higher influenza vaccination rates than responders who did not fill prescriptions at community pharmacies, but racial disparities between these groups of patients were significant in both pharmacy and non-pharmacy populations.⁷⁷

Pharmacies may also effectively reach medically high-risk populations. Pharmacy staff are capable of identifying patients who meet the recommendation criteria for certain vaccinations based on the patient's health status and prescription history.^{37,64,78} Vaccine promotion practices at pharmacies were able to increase herpes zoster vaccination ^{45,66,70,72} and influenza vaccination rates^{36,64} in 2 target populations for this vaccine: patients 65 y or older and patients between the ages of 18–64 with co-morbid chronic conditions.^{34,49}

Discussion

Our review of published literature shows that pharmacies are capable of successfully implementing cost-effective inhouse immunization services, which in turn can increase adult vaccination rates. We found that policy changes have expanded pharmacy services, while training programs have engaged pharmacists and pharmacy staff in immunization practices. Pharmacies are uniquely positioned as vaccination sites. For patients, they offer a convenient and accessible alternative for immunization services. Results also indicate that PBIS are an effective method of increasing vaccination rates at both the pharmacy- and state-level, particularly among medically underserved populations. Furthermore, as pharmacies continue to expand primary and preventative care services, PBIS offer cost-effective business opportunities. Yet, despite these benefits, many legal, organizational, and attitudinal barriers hinder the feasibility and effectiveof pharmacy immunization initiatives. Targeted ness research interventions and innovative approaches to overcome these barriers can improve the implementation and sustainability of PBIS.

Despite the policy changes that allowed pharmacists to administer vaccinations, state scope-of-practice policies such as the variety of vaccines offered, and Medicare Part B and D reimbursement methods, continue to shape PBIS feasibility and impact.^{18,60,79} While these regulations help to maintain complete and accurate patient records, they may unintentionally lead to "missed opportunities" to vaccinate. Moreover, the additional demands placed on pharmacists and their staff to complete these requirements may ultimately pose a barrier for pharmacy involvement in immunization services.^{38,39,41} Several studies have documented the potential effects of past scope-ofpractice regulatory expansions that allowed for pharmacists to immunize, yielding higher state-level vaccination rates and increased access.^{36-39,41,43} Yet, there is scant research on the impact of current policies on vaccination rates or PBIS service offerings. Further research may provide a better understanding of these effects and identify regulations that better facilitate the implementation of PBIS.

While many of the reviewed studies reveal that PBIS are feasible and acceptable, barriers at many levels still persist. Future research and interventions to address these remaining impediments can target 3 potential areas. First, efforts can be made to ensure that pharmacists and other personnel involved in PBIS are able to provide vaccinations effectively. Immunization training is a necessary prerequisite to providing PBIS and can help decrease the burden of certain barriers.^{43,51} However, this is not sufficient to ensure or maintain pharmacists' participation in PBIS, as evidenced by immunization-certified pharmacists who are not actively involved with PBIS or who have discontinued offering immunizations due to difficulties encountered after certification.38,40,55 In order to maintain immunization services, additional resources beyond certification are needed to efficiently train pharmacists, such as the RxVaccinate program which provides training and tools for PBIS implementation.⁵⁷ Evidence indicates that the integration of pharmacy technicians and students into immunization delivery can relieve the strain of organizational barriers and led to greater health promotion and administration of vaccinations.^{41,45} These experiences allow pharmacy students to gain clinical exposure to immunization services while strengthening the connection between pharmacy schools and the surrounding community pharmacies.53 Initiatives to involve nurses and physicians in PBIS may further promote collaborative approaches to improving primary and preventative care services for patients.

The second target area for increasing the effectiveness of PBIS is addressing organizational and logistical concerns to increase perceived compatibility between PBIS and the pharmacy. An existing body of evidence has identified several determinants of successful and sustainable pharmacy innovations^{50,55,58} that can inform future interventions. Further research is needed on how to tailor pharmacy-based immunization services to match heterogeneous practice sites.⁴³ Planning and implementation should occur at multiple levels by preparing individual personnel, adapting PBIS to the specific pharmacy site, and addressing organizational and attitudinal barriers.^{57,79}

Lastly, interventions to increase effectiveness can leverage the potential financial benefits of PBIS. PBIS represent a financially feasible alternative to traditional immunization sites; however, efforts should be made to address the existing billing and reimbursement barriers to mitigate lost opportunities to provide vaccinations. There has been little research into optimal financing mechanisms and billing procedures;⁷⁹ our results indicate that streamlining PBIS billing and reimbursement could improve feasibility.

In the era of the Affordable Care Act (ACA), pharmacies are well-positioned to provide affordable, accessible preventative health services, including vaccination.^{14,79} The ACA instituted measures to increase access and funding for preventative health services including mandated insurance coverage of ACIP-recommended vaccinations when delivered by in-network providers.^{80,81} However, pharmacies are still largely considered out-of-network providers and the ACA did not change the terms of Medicare Part D coverage, which create additional challenges for both patients and pharmacists pursuing insurance coverage

and reimbursement. Higher rates of insured adults and a greater emphasis on providing services through patient-centered medical homes will likely influence the utilization and sustainability of PBIS. Further evaluation of the effect of the ACA on pharmacy-based programs and vaccination delivery is needed to support the long-term effectiveness of PBIS.

Limitations

There are several limitations to consider in this review. Due to the asynchronous expansion of states' scope-of-practice regulation and differential adoption of PBIS in pharmacies, the included studies report pharmacy practices at different stages of implementation and operation. The rapidly changing nature and variability of PBIS creates a temporal aspect that should be considered in the interpretation of results and conclusions. Our conclusions are drawn primarily from observational studies, limiting our ability to infer casual relationships or fully account for confounders or biases. Additionally, community pharmacies were largely analyzed as homogenous practice settings, both in the literature and in this review, despite differences in ownership, management structure, geographic location and time period that may potentially influence practice. Therefore, further studies addressing these confounding factors are needed.

Conclusions

The certification of pharmacist immunizers and integration of immunization programs into the daily routine of pharmacy services greatly facilitates pharmacies as sites of adult vaccination. The studies we analyzed support PBIS as cost-effective innovations that have made considerable contributions to adult vaccination rates. This effect is particularly notable in pharmacies' ability to engage under-vaccinated populations that have been difficult to reach through traditional methods. The sustainability of pharmacy-based immunization programs depends on individual pharmacy characteristics and attitudes of pharmacists and pharmacy management. Remaining barriers to immunization services are multifactorial, and will require strategic interventions and approaches that address the individual-, pharmacy-, and state-level factors. This review provides a critical perspective on the feasibility, acceptability, and effectiveness of PBIS, as well as recommendations for future research and practice of immunization delivery in community pharmacies.

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Author contributions

R. Burson conducted the systematic review and study selection (including title review, abstract review, and full-text review), carried out quality assessment, data extraction and analysis, drafted the article, and prepared

figures and tables. K. Feemster and A. Buttenheim originated and guided the study, reviewed data extraction and quality assessment. All authors contributed to the article through critical revision. All authors approved the final article. The authors of this study reported no financial disclosures.

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