



Review article

The interface between U.S. primary care clinics and pharmacies for HPV vaccination delivery: A scoping literature review

Patricia A. Carney^{a,*}, Sarah Bumatay^b, Grace M. Kuo^c, Paul M. Darden^d, Andrew Hamilton^e, Lyle J. Fagnan^a, Brigit Hatch^a

^a Oregon Health & Science University, 3181 S.W. Sam Jackson Park Road, Mail Code: FM, Portland, OR 97239, USA

^b Oregon Rural Practice-based Research Network, 3181 S.W. Sam Jackson Park Road, Mail Code: L222, Portland, OR 97239, USA

^c Oregon State University, 3181 S.W. Sam Jackson Park Road Portland, OR 97239, USA

^d University of Arkansas for Medical Sciences, 4301 W. Markham St. Little Rock, AR 72205, USA

^e Health Science Education and Research Librarian, Oregon Health & Science University, 3171 S.W. Sam Jackson Park Road Portland, OR 97239, USA

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ABSTRACT

Completion of the Human Papilloma Virus (HPV) vaccine series remains low. Partnerships between primary care (PC) clinics and local pharmacies could boost vaccination rates. We conducted a scoping literature review to address what is known and what gaps exist on the interface between U.S. primary care clinics and pharmacies for HPV vaccination. We searched Ovid MEDLINE ALL file and Cumulative Index to Allied Health Literature for articles published between 1/1/2010 and 12/31/2020. Search subjects included: 1) Pharmacy HPV Vaccination, 2) Pharmacy/PC Collaboration, and 3) Pharmacy/PC Collaboration vaccination. We developed an abstraction form to collect information on research methods, settings, strengths, weaknesses and findings. We screened 407 articles for inclusion; 17 met inclusion criteria: 13 (76.5%) reported on observational/descriptive studies; 4 articles (23.5%) reported on intervention studies, none of which were conducted in rural areas. Observational studies focused on willingness to be vaccinated for HPV and facilitators and barriers for vaccination, especially at pharmacies. Many studies concluded that knowledge about and comfort with HPV vaccine administration were needed for all vaccination stakeholders (clinicians, pharmacists, parents, and patients). Intervention studies were small with weak study designs, many of which revealed that pharmacists were not successful in integrating services into broader primary care systems. Challenges included getting physicians to sign standing order protocols, poor service delivery due to engagement barriers, and low parental demand for pharmacists to administer the vaccine. In conclusion, larger more discerning studies are needed to fully understand the potential of primary care and pharmacy interactions for HPV vaccination.

1. Introduction

Each year, nearly 14 million Americans, including teens, become infected with HPV, (CDC, 2021) and HPV is known to cause several types of cancer. (Genital HPV Infection, 2021; Muñoz et al., 2006; Lowy and Schiller, 2012; Koutsky, 2009; Petrosky et al., 2015) Though vaccination against HPV has been available since 2006; vaccination rates fall far short of the Healthy People 2030 Goal of 80% completion by age 13 to 15 years. Overall; in 2020, 75.1% of adolescents 13–17 have

had at least one dose of HPV vaccine and 58.6% have completed the series. (Pingali et al., 2021) Children and youth in rural areas experience disproportionately low HPV vaccination rates compared to their more urban counterparts. Swiecki-Sikora; et al found that HPV vaccination initiation and completion were lower among both girls and boys from rural areas compared to girls from urban areas. (Swiecki-Sikora et al., 2019) Among girls and boys from high-poverty areas; the rural/urban disparity persisted. (Swiecki-Sikora et al., 2019) Reasons for lack of initiation and completion are multifactorial and include patient;

Abbreviations: HPV, Human papillomavirus.

* Corresponding author at: Department of Family Medicine, Oregon Health & Science University, School of Medicine, 3181 SW Sam Jackson Park Rd., Mail Code: FM, Portland, OR 97239, USA.

E-mail addresses: carney@ohsu.edu (P.A. Carney), bumatay@ohsu.edu (S. Bumatay), kuog@ohsu.edu (G.M. Kuo), PMDarden@uams.edu (P.M. Darden), hamiltoa@ohsu.edu (A. Hamilton), fagnanl@ohsu.edu (L.J. Fagnan), adamusb@ohsu.edu (B. Hatch).

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provider, clinic, and community factors as well as insurance coverage, state vaccination policies and pharmacist licensure differences across the U.S.. (Garbutt et al., 2018; [10]; Dingman and Schmit, 2018).

Community-based pharmacies are increasingly utilized for adult vaccinations, and they have been an important source of COVID vaccinations. To date, 108 million of the 374 million COVID-19 doses have been given in retail pharmacies. (Centers of Disease Control and Prevention. *Understanding the Federal Retail Pharmacy Program for COVID-19 Vaccination*. Accessed September 21, 2021) Compared to primary care settings, pharmacies can offer greater convenience and ease of access for vaccination, such as walk-in services, convenient parking, extended hours, and more accessible community-based locations. However, while success in this setting has been reported for vaccination against influenza, pneumococcus, and herpes zoster; the rate of HPV vaccination at pharmacies is low and lags far behind other vaccines. (Hohmeier et al., 2016; Cartmell et al., 2018).

Rationale for lower rates of HPV vaccination at pharmacies is mixed. A few studies indicate that parents are reluctant to use pharmacists as HPV vaccine providers. (Westrick et al., 2016; Calo et al., 2017) Pharmacists believe vaccination is the best protection against cervical cancer (85.3%), but report many barriers to pharmacy administration of HPV vaccination, including insufficient demand (56.5%), lack of insurance coverage (54.8%) and vaccine expiration before use (54.1%). (Hastings et al., 2017) In addition, pharmacists perceive parents have an inadequate understanding about HPV infection (86.6%) and vaccine safety (78.7%), (Hastings et al., 2017) indicating that other sources of patient and family education are needed.

Intervention studies that include only pharmacies have also found many challenges exist. (Calo et al., 2019; Islam et al., 2017) One such study tried implementing HPV vaccines in pharmacies in five U.S. states (North Carolina–n = 2; Michigan–n = 10; Iowa–n = 2; Kentucky–n = 1; and Oregon–n = 0, despite pilot funding). Though efforts were substantial, only 13 HPV vaccine doses were administered to adolescents, and three doses were administered to age-eligible young adults. Parental concerns and lack of an engaged pharmacy staff were the most significant challenges in this study. (Calo et al., 2019).

Given the need for improvement in HPV vaccination, particularly in rural areas, and barriers experienced separately by primary care practices and pharmacies, developing and testing interventions that partner vaccination efforts between primary care clinics and community-based pharmacies is a priority. One recent pilot study tested an intervention where the clinic provided the first dose and the pharmacy provided the subsequent dose(s) (Doucette et al., 2019) and found this strategy was feasible and acceptable to pharmacy and clinic staff, though resulted in only 45% of families following through with referral. An improved understanding about the specific gaps in contemporary literature on observational and intervention studies on the interface between primary care clinics and community-based pharmacies, especially in rural areas, will help researchers identify the best next steps in this area of research.

Toward this end, we conducted a scoping literature review designed to answer the question: What is known and what gaps exist in literature that has been published over the last 10 years on the interface between primary care clinics and pharmacies for HPV vaccination delivery, especially in rural settings? We chose this type of review because we wanted to assess the potential size and scope of available research on this topic specifically to identify the nature and extent of research evidence. (Grant and Booth, 2009) Though scoping literature reviews do not typically include an assessment of study quality, we added this component to include the quality of existing studies according to their design, variables collected and the study setting. (Grant and Booth, 2009).

2. Methods

2.1. Literature review procedures

The time period chosen for this review was 1/1/2010 to 12/31/2020, which reflected a ten year interval on this topic to balance recency with stability of published information. We reviewed articles that met the following inclusion criteria: 1) Descriptive, mixed methods, observational, or interventional studies published on the interface between primary care clinics (Pediatrics, internal medicine, family medicine, multidisciplinary) and pharmacies on delivery of HPV vaccines; 2) Studies in rural settings were sub-grouped; and 3) because health systems differ according to country, we included only studies conducted in the United States (U.S.). We excluded papers that did not meet these criteria.

Searches were conducted in the Ovid MEDLINE ALL file, the U.S. National Library of Medicine's bibliographic database, which contains more than 33 million references to journal articles in life sciences with a concentration on biomedicine, (National Library of Medicine. *MEDLINE®: Description of the Database*. Accessed July 27, 2020) and CINAHL (Cumulative Index to Allied Health Literature). (Kamenoff, 1987) Search MESH headings included: Pharmacy HPV Vaccination AND Pharmacy and Primary Care Collaboration AND Pharmacy and PC Collaboration vaccination. We also conducted a broader text-based search of articles using these same terms as subject headings.

We developed an article abstraction form that included capture of the article title, authors, citation, whether the study addressed the research question, whether it met study inclusion criteria, including whether it reported directly on primary care and pharmacy HPV interfaces, and if not, why not. This information was captured for all articles that were screened. Those research articles that addressed the research question and met all inclusion criteria were fully abstracted. The abstraction form underwent six revisions prior to finalization during a testing period conducted between September and November of 2020, based on its actual use to abstract study findings. Revisions involved improvements in data reporting and quality capture, and changes were decided upon during consensus meetings. Full article abstraction captured type of study (descriptive/qualitative, mixed methods, observational, interventional); study design; adequacy of sample size, including survey response rate; type of primary care clinic (pediatrics, internal medicine, family medicine, multidisciplinary); study setting (urban, suburban, rural, mixed); region of the U.S.; pharmacy ownership (independently-owned, corporate-owned, other); and description of the data collection process, variables assessed, findings, study strengths and weaknesses, gaps in the literature not addressed/future research directions, source of funding and research team stakeholders involved in the assessment (e.g., pediatricians, family physicians, pharmacists, public health experts).

Article review and abstraction started in August 2020 and was completed in May 2021. Two independent reviewers, both members of the study team who were public health trained independently conducted the reviews/abstractions of all articles selected for abstract review. Consensus meetings were held weekly to review all abstraction forms and finalize data collected. Data abstracted from full reviews were included in analyses, which focused on study setting, findings, quality of the research conducted to address what is known on this topic and gaps or the need for future research was abstracted to address areas in need of future study.

3. Results

We identified a total of 513 articles using our search terms, library databases and publication years (Fig. A). Of these, 106 duplicates were found and removed leaving 407 articles for screening. Of these, 390 were determined to be ineligible: 206 were excluded because they were not conducted in the U.S., 125 were excluded because they did not focus

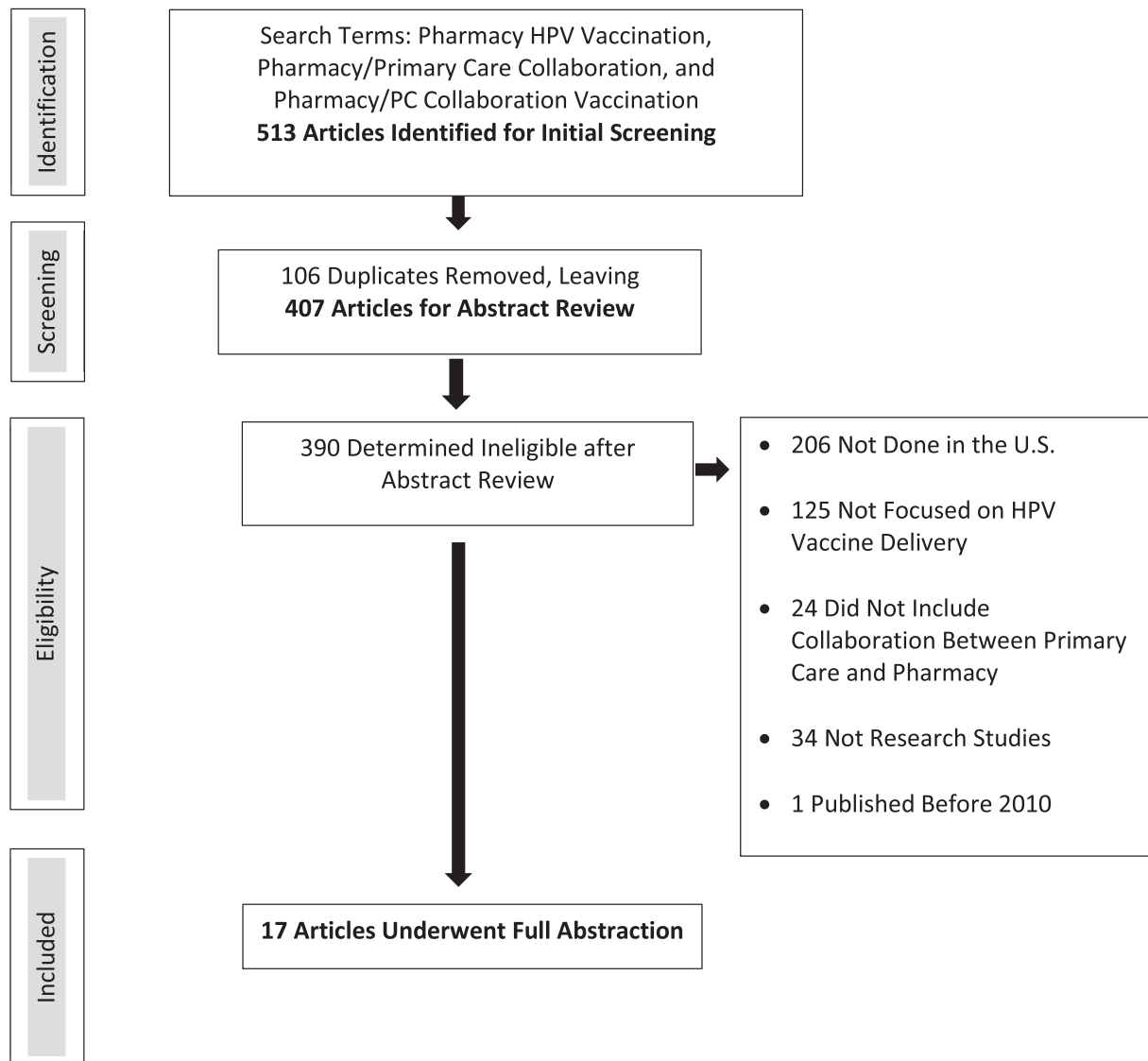


Fig. A. Flow Chart for Review (2010–2020).

on HPV vaccine delivery, 24 did not include information on or mention collaboration between primary care clinics and pharmacy, 34 did not represent research studies (they were commentaries), and one was published before 2010.

Thirteen of 17 fully abstracted articles (76.5%) reported on observational or descriptive studies, two of which were from rural areas (Table A). Four articles (23.5%) reported on intervention studies, none were conducted in rural areas. Seven of the 13 descriptive/observational studies (53.9%) were funded fully or in part by Merck, and one of the four intervention studies was funded by Merck. Other funders included the National Cancer Institute, the Centers for Disease Control and Prevention, the American Cancer Society and the Agency for Healthcare Quality and Research. Some studies were unfunded or the funding source was not noted.

3.1. Descriptive/Observational study findings

Many descriptive and observational studies focused on willingness to be vaccinated for HPV, or facilitators and barriers for vaccination, especially at pharmacies. (Cartmell et al., 2018; Calo et al., 2017; Islam et al., 2017; Kamenoff, 1987; Islam et al., 2019; Navarrete et al., 2014; Koskan et al., 2019; Lutz et al., 2018; Ryan et al., 2020; Skiles et al.,

2011; Ko et al., 2014; Shah et al., 2018; Shah et al., 2018; Shah et al., 2018) Calo et al (Calo et al., 2017) found parents were more willing to get flu shots at pharmacies (62%; n = 778) compared to HPV (29%; n = 364), though parents were more willing to get HPV vaccine at pharmacies if the first shot was given at a physician’s office (OR = 1.45; 95% CI 1.07–1.95). (Calo et al., 2017) Cartmell, et al (Cartmell et al., 2018) found a lack of awareness about HPV in the general public, lack of provider recommendations, concerns about vaccinating for a sexually transmitted disease, insurance and reimbursement issues for pharmacies and administrative barriers at practices affected HPV vaccine delivery. Two papers by Islam et al (Islam et al., 2017; Islam et al., 2019) conducted telephone interviews with 52 pharmacists in 8 states and also found that pharmacy reimbursement/insurance coverage as well as availability of vaccine, vaccine costs/storage and management of adverse reactions were barriers, while parental education, managing parental consent, and pharmacy based marketing were also needed. Navarrete et al (Navarrete et al., 2014) conducted a survey of students seen in an urban southwest college health clinic associated with a community pharmacy to assess knowledge and attitudes towards HPV and its vaccine and found 72.1% did not understand how HPV was transmitted; 87.3% were unaware of when to get HPV vaccine and timing in relation to first sexual act. Eighty-nine students were eligible to

Table A
Abstracted Study Characteristics, Key Findings, Quality and Funders (n = 17).

Author & Publication Year	Study Design	Description	U.S. Region Setting	Variables Collected	Key Findings	Weaknesses	Funders
<i>Descriptive & Observational Studies</i>							
Calo WA, et al (Calo et al., 2017) (2017)	Cross-sectional	National survey study of parents' attitudes about getting children's vaccines at pharmacies (n = 1,255)	Multiple states/ regions	Willingness to get tetanus booster, meningitis, HPV, flu vaccine at pharmacy. Perception of pharmacists' skills administering vaccine compared to physicians' offices.	Parents were most willing to get flu vaccine at pharmacy (62%), Tdap (61%), meningococcal (33%), HPV (29%). Parents more willing to get vaccines at pharmacy with prior HPV shot at physician office (OR = 1.45; 95% CI 1.07–1.95).	Response rate 61%, some response bias likely. Respondents reported higher household income than average American.	Merk Sharm & Dohme NCI Agency for Healthcare Research & Quality
Cartmell KB et al (Cartmell et al., 2018) (2018)	Qualitative key informant interviews	Key stakeholders: state leaders, public health immunization programs, providing organizations, including peds, FM, pharmacies, school nurses, insurers, state quality improvement collaboratives, university faculty, grass root organizations, adolescents, and state legislators) (n = 34).	South Carolina	Barriers, facilitators and strategies for improving HPV vaccination. Best practices for improving HPV vaccination. Key partnerships for developing strategies for HPV vaccination.	Barriers included lack of HPV awareness, lack of provider recommendation, HPV vaccine concerns, lack of access and practice-level barriers. Facilitators included momentum for improving HPV vaccination, school-entry Tdap requirement, pharmacy-based HPV vaccination, state immunization registry, HEDIS measures and HPV vaccine funding. Strategies for improvement: 1) addressing lack of awareness among the public and providers; 2) advocating for policy changes around HPV vaccine coverage, vaccine education, and pharmacy-based vaccination; and 3) coordination of efforts.	Only 34 individuals participated in interviews, so limited generalizability.	NCI
Islam JY, et al. (Islam et al., 2017) (2017)	Cross-sectional	Telephone survey to enrolled pharmacists. 52 closed-ended questions and 26 open ended questions (n = 40).	Eight States included (AL, CA, IN, KY, ME, TN, TX, WA), selected based on variability in vaccination laws-convenience sample of five pharmacists participated in each state.	Challenges or facilitators to administering adolescent and adult vaccines within pharmacies.	Pharmacists indicated reimbursement and insurance coverage issues were greatest challenges. Nearly half indicated availability of vaccination area, vaccine shortage and cost of vaccine storage were challenges. Facilitators include state legislative authority to provide vaccines (51%) Patient education/promotion within the pharmacy (33%) Clear guidelines from corporate management (31%).	100% response rate but used convenience sampling, so limited generalizability	Merck
Islam JY, et al. (Islam et al., 2019) (2019)	Cross-sectional	Telephone survey to enrolled pharmacists. 52 closed-ended questions and 26 open ended questions (n = 40).	Eight States included (AL, CA, IN, KY, ME, TN, TX, WA), selected based on variability in vaccination laws-convenience sample of five pharmacists participated in each state.	Challenges or facilitators to administering adolescent and adult vaccines within pharmacies.	Parental consent (28%), tracking and recall of patients (17%), Education/promotion of vaccination (17%) and stigma about vaccination among parents of adolescents (17%) reported as greatest challenges. Other challenges included cost of vaccine (11%) potential for	100% response rate but used convenience sampling, so limited generalizability	Merck

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Table A (continued)

Author & Publication Year	Study Design	Description	U.S. Region Setting	Variables Collected	Key Findings	Weaknesses	Funders
Koskan AM, et al (Koskan et al., 2019) – published online ahead of print.	Qualitative key informant interviews	Parents of adolescent children (n = 26).	Rural Southwest	Exploration of caregivers' perceptions of receiving adolescent vaccinations, particularly HPV vaccine, at their community retail pharmacy.	adverse reactions (11%). Strategies to overcome challenges providing education to patient and parents (22%). Majority were willing to have child receive vaccines at pharmacy due to convenience and cost savings. 23% of participants preferred having vaccines provided by their primary care providers. Having primary care providers and health departments promote vaccine receipt at pharmacies was recommended	Only 26 participants, though researchers reported thematic saturation was reached.	Not Reported
Lutz CS, et al (Lutz et al., 2018) (2018)	Cross-sectional	National surveys of physicians, nurse practitioners and physician assistants, and pharmacists (n = 1,714 clinicians and 261 pharmacists)	Multiple states/ regions	Practices used to assess, recommend, refer/ administer and document adult vaccines, including HPV.	Most commonly recommended vaccine was influenza (97.1%) FM (77.6% and OB/GYN (91.2%) more likely to recommend HPV vaccine compared to IM (68.6%) 38.7% of Pharmacists recommended HPV vaccine.	Response Rate < 10%	CDC
Navarrete JP, et al. (Navarrete et al., 2014) (2014)	Cross-sectional	Needs assessment survey completed by students and vaccines were administered to income eligible, primarily Hispanic college students (n = 111)	Urban Southwest College Health Clinic	Assessed knowledge and attitudes toward HPV and its vaccine among college students Utilization data for the vaccine clinic from vaccines administered in the pharmacy.	72.1% did not understand how HPV was transmitted. 87.3% were unaware of when to get HPV vaccine and timing in relation to first sexual act. 89 students qualified to receive the vaccine, 79.8% received their 2nd dose and 48.3% completed all 3 doses.	Single study setting, lack of generalizability	Not Reported
Ryan G., et al. (Ryan et al., 2020) (2020)	Qualitative key informant interviews	Of 11 pharmacists from 7 rural Iowa counties	Rural Iowa	Role of rural independent pharmacists in HPV vaccine promotion and update Willingness to educate parents, refer patients and administer the HPV vaccine.	Only 1 participant reported offering HPV vaccine, though 8 of 11 offered other vaccines. Barriers included that HPV vaccines were perceived as not a priority in their workplace due to sensitivity of subject, lack of information and concerns about safety. Most were willing to refer patients to primary care for HPV vaccine	Sample size small, so lack of generalizability	NCI CDC
Skiles MP, et al. (Skiles et al., 2011) (2011)	Qualitative key informant interviews	Of 24 pharmacy directors from 24 states.	Multiple states/ regions	Perceptions of statewide pharmacy practices, personal attitudes and beliefs about adolescent vaccines and consent laws for minors.	58.3% reported that pharmacists vaccinated adolescents in their states. 96% responded that financial barriers affect receipt of HPV vaccine Knowledge of minor consent laws was limited.	Only one respondent per state, so low generalizability	North Carolina Dept of Health & Human Services CDC
Ko KJ, et al, (Ko et al., 2014) (2014)	Multi-Method	Literature review, structured interviews, survey & modified Delphi expert panel	Multiple Regions	Identify the range of barriers and issues associated with developing a pharmacy-based adult vaccine benefit.	2 Way communication via EMR between physicians and pharmacists is needed as the lack of data exchange is a barrier (Faxes and letters have been	Only 12 expert panelists were included, which limits generalizability.	Merck

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Table A (continued)

Author & Publication Year	Study Design	Description	U.S. Region Setting	Variables Collected	Key Findings	Weaknesses	Funders
					ineffective). Physicians should administer the first HPV dose and then refer patients to pharmacy for subsequent doses. Pharmacists should become patient centered medical home providers. Vaccines would improve if pharmacies could offer immunization health benefits designed to incentivize vaccinations, such as premium discounts for those vaccinated.		
Shah PD, et al. (Shah et al., 2018) (2018)	Cross-sectional	Survey of parents of children aged 11–17 from all 50 U.S. States and the District of Columbia (n = 1,504)	Multiple states/ regions	Professionalism, confidentiality and milieu (appealing appearance) in pharmacies were assessed as quality indicators with the outcome measure being parents' willingness to get their child vaccinated.	44% of parents were willing to get their children the HPV vaccines in pharmacies. Willingness was higher if pharmacist was known to parent. Parents who went to independent pharmacies gave higher ratings for service quality than those who went to chain pharmacies (p < 0.001). Parents who went to clinic pharmacies gave lower ratings for milieu compared to chain pharmacies (p < 0.01). Parents who went to independent pharmacies had lower willingness to get the HPV vaccine compared to those who went to chain pharmacies (p < 0.001). No differences in willingness between chain and clinic pharmacies.	Some small response numbers for some pharmacy types limits strong conclusions.	Merk Sharm & Dohme NCI Agency for Healthcare Research & Quality
Shah PD, et al. (Shah et al., 2018) (2018)	Cross-sectional	National surveys of primary care physicians (n = 776) and parents (n = 1,504) of adolescents (aged 11–17).	Multiple states/ regions	The extent to which primary care physicians (PCP) and parents supported pharmacist provided HPV vaccination of 13–17 year-olds who were past due.	79% of physicians and 81% of parents endorsed pharmacist provided HPV vaccination if pharmacists had received proper vaccination training, reported vaccine doses to adolescents' PCPs, and referred adolescents to PCPs for other health services. Family physicians were more likely than pediatricians to support pharmacists providing vaccines (OR = 1.62; 95% CI 1.17–2.22) Parents had increased odds of endorsing trained pharmacists if overall satisfaction with pharmacy services was high (OR = 1.42; 95% CI 1.02–1.19).	Physician response rate was low at 33%, so limited generalizability. Parent response rate was 61%.	Merck/Pfizer AHRQ CDC
Shah PD, et al., (Shah et al.,	Cross-sectional	National survey of parents (n = 1,504) of	Multiple states/ regions	Parents' perceptions of the relative advantage of HPV vaccine delivery in	Parents indicated that doctor's offices offered a better healthcare	Parent response rate was 61%, on the low side.	Merk Sharm & Dohme Agency for

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Table A (continued)

Author & Publication Year	Study Design	Description	U.S. Region Setting	Variables Collected	Key Findings	Weaknesses	Funders
2018) (2018)		adolescents (aged 11–17).		pharmacies and doctors' offices.	environment than pharmacies for privacy (70%) and safety (65%). Parents indicated that pharmacies offered convenience with needing no appointment (70%) and having convenient hours (60%). Parents more willing to have child receive vaccine in pharmacy if accessibility was rated as more important than the healthcare environment (p < 0.001).		Healthcare Research & Quality
<i>Interventional Studies</i>							
Calo WA, et al. (Calo et al., 2019) (2019)	Mixed methods	Five small pilot studies conducted in five states (NC, MI, KY, IA, OR)	Multiple states/ regions	Methods for vaccine delivery along with service penetration, acceptability, appropriateness, feasibility, adoption and sustainability	Pharmacists were not successful in integrating their services into the broader primary care eco system. Pharmacy billing for vaccines precluded many physicians from signing a standing order protocol, and many physicians would not sign these for children. In NC, physician referrals to pharmacies worked well as well as nurses providing the vaccines in the clinic on a walk in bases. Service penetration was poor due to engagement barriers, low parental demand, and engagement among pharmacy staff. Feasibility, adoption and sustainability was poor due to lacking third party reimbursement, limited integration into primary care systems. Only 13 HPV vaccine doses were administered. The pilot projects struggled in all five states.	Pilot strategies varied according to state.	Merk Sharm & Dohme NCI Agency for Healthcare Research & Quality American Cancer Society
Cebollero J, et al. (Cebollero et al., 2020) (2020)	Repeated measures pre-post	Three phases: 1) captured baseline data, 2) active pharmacist led intervention in clinic with patient and healthcare provider education, added a prompt to EMR and clinic staff administered vaccines; 3) evaluated the durability of interventions.	Single Southeast Urban adult family planning clinic	Number of patients aged 18–26 who visited clinic and the number of 9vHPV vaccines administered in the clinic in the pre and posttest time periods.	No HPV doses were administered during the pre-intervention phase. 80 female patients were eligible for vaccination, 34 (42.5%) of whom received their first dose (n = 23), second dose (n = 5), or third dose (n = 6) of 9vHPV vaccine while at the clinic. 46 (57.5%) patients were not vaccinated. HPV vaccination rates dropped after the intervention period was over.	Single site study that included a family planning clinic. No males included. Age group was young adults, so limited generalizability.	Unfunded
Doucette WR, et al (Doucette et al.,	Repeated measures pre-post	Intervention included work flow planning for identification of eligible patients,	Suburban Midwest single clinic (n = 20 providers) and single pharmacy	Workflows for identification, delivery and documentation of	51 patients were referred to pharmacy for HPV vaccine. Of these 23 received a total of 25	Only 1 clinic and 1 pharmacy included, so lack of generalizability.	CDC American Cancer Society

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Table A (continued)

Author & Publication Year	Study Design	Description	U.S. Region Setting	Variables Collected	Key Findings	Weaknesses	Funders
2019) (2019)		administration of the first HPV dose at the clinic and option of receiving subsequent doses at clinic or at pharmacy 2 miles away.		HPV vaccinations for 12 month period	vaccinations. All 23 completed their HPV series. Average age was 13.4 (S. D. = 1.4) and 78.3% were female. Payments to pharmacy included 56.5% commercial payers and 43.5% Vaccines for Children. Challenges included few interested patients, workflow challenges. Benefits included improved communication between providers and pharmacists.		
Hohmeier KC, et al (Hohmeier et al., 2016) (2016)	Multi-disciplinary mixed methods	Included pharmacies, local physicians' offices and the general public. Interventions included flagging patients receiving acne control or birth control medications in the pharmacy, placing flyers and posters on HPV in the pharmacy, and visiting local physicians' offices (FM, Peds, OB/GYN) and providing HPV education and posters	Southeast (TN)	HPV vaccination rates among 9–26 year olds. Patient/parent survey (convenience sample) on comfort level with the vaccine, information seeking about HPV	During 2014 control period, no HPV vaccines were administered. During 2015, 21 surveys administered. 10 patients indicated they were vaccinated at the pharmacy, with 9 receiving first doses. Patients most likely to choose pharmacy due to no appointment needed and convenient hours.	Only 1 pharmacy included. Patient surveys with bias due to convenience sampling. Small sample size. Intervention period only 8 weeks	Unfunded

be vaccinated, all received their first shots, 79.8% received the second shots, but only 48.3% received all 3 doses, all of which were provided at the pharmacy associated with the health clinic. (Navarrete et al., 2014).

Koskan et al conducted qualitative interviews with 26 parents of adolescents in the rural southwest, and found that 69.2% would be willing to have their children receive vaccines at pharmacies (only 23% preferred to get these at their physicians' offices) because of convenience and perceived cost savings. (Koskan et al., 2019) Lutz et al (Lutz et al., 2018) conducted a national cross-sectional survey with 1,714 clinicians and 261 pharmacists on practices used to assess, recommend and refer/administer adult vaccines including HPV. They found the most commonly recommended vaccine was influenza (97.1%) and that family physicians and obstetrician/gynecologists were more likely to recommend HPV compared to internal medicine (77.6%, 91.2% and 68.6% respectively), while only 38.7% of pharmacists recommended the HPV vaccine. (Lutz et al., 2018).

The second rural study was conducted in rural Iowa and involved key informant interviews with 11 pharmacists from 7 rural counties, which found that only one pharmacist (9.1%) offered HPV vaccines while 73% of pharmacists offered other vaccines. (Ryan et al., 2020) Pharmacy professionals perceived HPV vaccination was not a priority due to parental sensitivities and concerns about safety. Skiles, et al (Skiles et al., 2011) conducted telephone interviews with 24 pharmacy directors in 24 U.S. states and found that 58.3% vaccinated adolescents, 96% reported that financial barriers were problematic and pharmacists' knowledge of consenting minors was low. Ko, et al (Ko et al., 2014) conducted interviews using a modified Delphi approach with an expert panel of physicians, pharmacists and health insurers and determined that full agreement on approaches to address HPV vaccination improvements would need to include: 1) two-way communication via electronic medical record (EMR) between physicians and pharmacists

for optimal and timely data exchange; 2) clinic administration of the first dose and then referral to pharmacy for subsequent dose(s); 3) pharmacists becoming members of the patient centered medical home team; and 4) pharmacies offering immunization health benefits designed to incentivize vaccinations, such as premium discounts for those vaccinated.

Shah et al (Shah et al., 2018; Shah et al., 2018; Shah et al., 2018) published three papers from the same study involving an online survey of 1,504 parents of children aged 11–17 from all 50 states and the District of Columbia on their willingness to have their children receive the HPV vaccine at pharmacies. Briefly, investigators found that 44% of parents reported willingness to get their children the HPV vaccines in pharmacies, and willingness was higher if the pharmacist was known to the parent. Parents who went to independent pharmacies had lower willingness to get the HPV vaccine compared to those who went to chain pharmacies (p < 0.001). (Shah et al., 2018) They also found that 79% of physicians and 81% of parents endorsed pharmacist provided HPV vaccination, if pharmacists had received proper vaccination training, reported vaccine doses to adolescents' PCPs, and referred adolescents to PCPs for other health services. (Shah et al., 2018) Parents had increased odds of endorsing trained pharmacists if overall satisfaction with pharmacy services was high (OR = 1.42; 95% CI 1.02–1.19), (Shah et al., 2018) though parents did indicate that doctor's offices offered a better healthcare environment than pharmacies for privacy (70%) and safety (65%); that pharmacies offered better convenience with needing no appointment (70%) and having convenient hours (60%); and parents were more willing to have child receive vaccine in pharmacy if accessibility was rated more important than the healthcare environment (p < 0.001). (Shah et al., 2018).

3.2. Interventional study findings

All four of the intervention studies were small assessments with pre-post repeated measures. Calo, et al (Calo et al., 2019) conducted a mixed-methods set of small pilot studies in five states (NC, MI, KY, IA, and OR) and found that, overall, pharmacists were not successful in integrating their services into the broader primary care ecosystem. Challenges occurred with getting physicians to sign standing order protocols, service penetration was poor due to engagement barriers, low parental demand, and engagement among pharmacy staff, and only 13 HPV vaccine doses were administered. These pilot projects demonstrated this approach is not feasible. Cebollero et al (Cebollero et al., 2020) studied the number of patients aged 18 to 26 who visited an urban area adult family planning clinic following a pharmacist led educational intervention. While no HPV doses were administered during the pre-intervention phase, 80 female patients were eligible for vaccination during the intervention period, 34 (42.5%) of whom received their first dose, 23 (28.8%) received the second dose, and six (7.5%) received the third dose, while at the clinic, and 46 (57.5%) patients were not vaccinated. Unfortunately, HPV vaccination rates dropped after the intervention period was over.

Doucette et al (Doucette et al., 2019) studied an intervention that included workflow redesign to identify eligible patients and deliver the vaccine as part of a partnership between a single primary care clinic and a local pharmacy (2 miles away). As a result, 51 patients were referred to pharmacy for HPV vaccination, and of these 23 received their initial vaccine and all 23 completed their HPV series. Payments to pharmacy included 56.5% commercial payers and 43.5% Vaccines for Children. Additional benefits included improved communication between providers and pharmacists. Hohmeier et al (Hohmeier et al., 2016) studied a single pharmacy and several local physicians' offices using an intervention that involved flagging patients receiving acne and birth control treatment, posting flyers and other information in the pharmacy and meeting with local physicians. They used a convenience sample of surveys from 21 patients/parents to assess the impact of the intervention and found that among the 21 surveys administered, 10 indicated that they received at least one dose at the pharmacy and that the pharmacy was chosen by patients who appreciated that no appointment was needed and the hours were convenient.

3.3. Indications for Future research directions

All studies were abstracted for future research directions (Table B). Overwhelmingly, researchers reported that future research is needed to understand practical issues around HPV vaccine storage and delivery and how best to coordinate services between primary care and pharmacy (Cartmell et al., 2018; Calo et al., 2017; Islam et al., 2017; Islam et al., 2019; Navarrete et al., 2014; Koskan et al., 2019; Lutz et al., 2018; Ryan et al., 2020; Skiles et al., 2011; Ko et al., 2014; Shah et al., 2018; Shah et al., 2018; Shah et al., 2018) and that public health agencies should also be included. (Lutz et al., 2018; Ryan et al., 2020; Ko et al., 2014; Shah et al., 2018) Researchers also recommended that more research needed on vaccine delivery in rural areas as these studies are so limited. (Koskan et al., 2019; Ryan et al., 2020) And virtually all the intervention studies indicated the more rigorous study designs, much larger studies, and much longer follow-up periods are needed to more fully understand the efficacy interventions designed to improve vaccine delivery and that these should include improved communication among stakeholders, including between primary care providers and pharmacists (Hohmeier et al., 2016; Calo et al., 2019; Islam et al., 2017; Doucette et al., 2019; Islam et al., 2019; Koskan et al., 2019; Lutz et al., 2018; Ryan et al., 2020; Skiles et al., 2011; Ko et al., 2014; Shah et al., 2018; Shah et al., 2018; Shah et al., 2018; Cebollero et al., 2020) and sustainable interventions (Cebollero et al., 2020) that will continue after the intervention period is over.

Table B
Abstracted Study Indications for Future Research Directions.

Author	Description	U.S. Setting/Region	Future Research Directions
<i>Descriptive & Observational Studies</i>			
Calo WA, et al (Calo et al., 2017) (2017)	Cross-sectional National survey study of parents' attitudes about get children's vaccines at pharmacies (n = 1,255)	Multiple states/regions	Researchers should seek better understanding of practical issues around providing HPV vaccines in pharmacies in terms of work flow, ease of vaccine dose recording and reporting to state immunization information systems and coordinating with primary care physicians.
Cartmell KB et al (Cartmell et al., 2018) (2018)	Interviews with key stakeholders on barriers, facilitators and strategies for improving HPV vaccination.	South Carolina	Studies of how to coordinate and sustain efforts are needed that include contextually appropriate strategies to address patient awareness, diverse vaccine delivery modes (e.g., primary care, pharmacy, schools), and robust stakeholder involvement.
Islam JY, et al. (Islam et al., 2017) (2017)	Cross-sectional study that involved administering a telephone survey to enrolled pharmacists. 52 closed-ended questions and 26 open ended questions.	Eight States included (AL, CA, IN, KY, ME, TN, TX, WA).	Research is needed on the collaborative efforts between pharmacists, primary care providers and policy makers to expand pharmacists' role in providing vaccines.
Islam JY, et al. (Islam et al., 2019) (2019)	Cross-sectional study that involved administering a telephone survey to enrolled pharmacists. 52 closed-ended questions and 26 open ended questions.	Eight States included (AL, CA, IN, KY, ME, TN, TX, WA).	Intervention research in needed on strategies to improve adolescent in-pharmacy vaccination update.
Koskan AM, et al (Koskan et al., 2019) – published online ahead of print.	Deductive qualitative content analysis of 26 key informant interviews of parents of adolescent children.	Rural Southwest	Intervention research is needed to foster the delivery of vaccines by pharmacists in rural areas, which is perceived to be more convenient and cost effective.
Lutz CS, et al (Lutz et al., 2018) (2018)	National cross-sectional internet surveys of physicians, nurse practitioners and physician assistants, and pharmacists.	Multiple states/regions	Future research is needed to determine how to close the gaps that currently exist in recommended adult vaccines across the spectrum of provider specialties. Research needs to include best practices for stocking vaccines.
Navarrete JP, et al. (Navarrete	Cross-sectional needs assessment survey completed by students	Urban Southwest	Studies need to focus on better informing minority college age

(continued on next page)

Table B (continued)

Author	Description	U.S. Setting/ Region	Future Research Directions
et al., 2014 (2014)	and vaccines were administered to income eligible, primarily Hispanic college students.	College Health Clinic	students and strategies to get them vaccinated.
Ryan G., et al. (Ryan et al., 2020) (2020)	Key informant interview of pharmacists	Rural Iowa	Research on partnership development between pharmacists, state public health agencies and academic institutions is needed to study how best to increase HPV vaccine update in rural areas by overcoming barriers.
Skiles MP, et al. (Skiles et al., 2011) (2011)	Telephone interviews conducted with pharmacy directors (n = 24 directors from 24 states).	Multiple states/regions	Research is needed on the role pharmacists could play in expanding HPV vaccination, which needs to include retail commitment to adolescents, vaccine storage, handling and financing, and legal issues regarding minors consenting.
Shah PD, et al. (Shah et al., 2018) (2018)	Online survey of parents of children aged 11–17 from all 50 U.S. States and the District of Columbia	Multiple states/regions	More research is needed on pharmacist-patient communication as a mechanism to improve pharmacy delivered HPV vaccine.
Shah PD, et al. (Shah et al., 2018) (2018)	Cross-sectional National surveys of primary care physicians and parents of adolescents (aged 11–17).	Multiple states/regions	Research is needed on informing parents about pharmacist delivered HPV vaccine Stakeholder input is needed to improve pharmacy services, including HPV vaccine delivery.
Shah PD, et al., (Shah et al., 2018) (2018)	Cross-sectional National survey of parents (n = 1,504) of adolescents (aged 11–17).	Multiple states/regions	Future research should focus on how different combinations of vaccine delivery features may improve adoption of pharmacy delivered vaccinations.
Ko KJ, et al., (Ko et al., 2014) (2014)	Literature review, structured interviews, survey & modified Delphi expert panel	Multiple Regions	Future research should include studying approaches that make pharmacists providers withing the broader contexts of preventive care.
<i>Interventional Studies</i>			
Calo WA, et al. (Calo et al., 2019) (2019)	Mixed methods intervention small pilot studies conducted in five states (NC, MI, KY, IA, OR)	Multiple states/regions	Future research should involve integration strategies that will connect primary care

Table B (continued)

Author	Description	U.S. Setting/ Region	Future Research Directions
Cebollero J, et al. (Cebollero et al., 2020) (2020)	Repeated measures pre-post study design with pharmacist led intervention in clinic with patient and healthcare provider education, prompt to EMR and clinic staff administered vaccines.	Single Southeast Urban adult family planning clinic	and pharmacies in diverse settings. Future research should focus on iterative processes needed to sustain complete vaccine delivery.
Doucette WR, et al (Doucette et al., 2019)	Repeated measures pre-post design. Intervention included work flow planning for identification of eligible patients, administration of the first HPV dose at the clinic and option of receiving subsequent doses at clinic or at pharmacy 2 miles away.	Single Suburban Midwest clinic (n = 20 providers) and single pharmacy	Future research must address multiple clinic-pharmacy teams using a more rigorous study design and assessments of patient satisfaction with vaccine delivery at pharmacies.
Hohmeier KC, et al (Hohmeier et al., 2016) (2016)	Multidisciplinary mixed methods study that included pharmacies, local physicians' offices and the general public.	Southeast	Future research needs to include longer intervention and follow-up periods, more rigorous study designs and more pharmacy partners.

4. Discussion

We conducted this scoping review to determine what is known and what gaps exist in literature published over the last 10 years on the interface between primary care clinics and pharmacies for HPV vaccination delivery, especially in rural settings. We found a total of 17 papers that addressed interactions between primary care clinics and community pharmacies for HPV vaccination; however, only four of these reported on interventions. Two papers reported on rural areas and both of these studies were observational. One study by Ko et al, (Ko et al., 2014) noted the need for transfer of information between pharmacies and primary care clinics which is facilitated by use of state immunization registries. The role of state health policy and legislative authority was mentioned as a facilitator in another study. (Islam et al., 2017).

More studies are needed on HPV vaccination in rural settings because nationally initiation and series completion rates among those aged 13–17 are lower in rural areas (64.2%; 95% CI 61.2–67.2) versus urban areas (73.8%; 95% CI 71.5–75.9, p < 0.05), and 47.3% (95% CI 44.2–50.4, p < 0.05, respectively). Several studies have reported less knowledge, awareness and parental attitudes regarding HPV vaccination. (Cates et al., 2009; Sperber et al., 2008) An additional finding is that there is a lower prevalence of provider recommendations in non-MSA areas for giving the HPV vaccine. (Burson et al., 2016) Although 48 states and the District of Columbia and Puerto Rico allow pharmacists to administer the HPV vaccine, specific requirements vary. (Shah et al., 2018) Overall, we found study quality was limited due to a lack of multivariable analyses as well as small sample sizes and low survey response rates, making generalizability very limited.

Still, some important themes emerged. Collaboration between primary care providers and pharmacists appears to be desirable, and perceived success would require: 1) clear lines of timely bi-directional electronic communication regarding HPV vaccine deliver; 2)

designated vaccination champions to take ownership of interactions between the clinic and the pharmacy; 3) sustainable infrastructures for ongoing promotional HPV vaccine education for parents, adolescents and young adults in both clinic and pharmacy settings; and 4) outcomes data on receipt of vaccines and characteristics of those unvaccinated would help identify additional strategies to improve vaccination.

There was also consensus that additional knowledge and willingness were needed by all stakeholders in the vaccination process – healthcare providers, pharmacists, parents, and patients. A recent systematic review underscores the successes of delivery of adult vaccines by pharmacists, which provides a model for HPV vaccine delivery to children and youth with primary care collaboration, as long as the significant issues including reimbursement, political and organizational barriers can be overcome. (Burson et al., 2016) This message is underscored in a recent paper by Koskan, et al, which found that pharmacist delivered HPV vaccination was convenient in having children complete the series, issues related to lack of HPV vaccine stocking, and lack of insurance for pharmacist-administered vaccinations impede this approach as a delivery model. (Koskan et al., 2022).

One prior review study was published by Fava et al in 2017, (Fava et al., 2017) and focused on barriers to administration of HPV vaccines. The authors identified four things that were needed to improve HPV vaccination, including: 1) a united team approach including vaccine experts, electronic reminders, social media messages, community engagement; 2) HPV vaccine delivery teams include primary care clinics, pharmacies, and public health departments; that 3) primary care vaccination team members give HPV Dose #1 with additional doses given based on location convenience; and 4) that vaccination team members should refer hesitant patients to a community champion or motivational specialist. (Fava et al., 2017) These findings were consistent with the findings presented from our review. Although the authors' focused on identification of barriers, rather than assessment of interventions and the review methodology was not described in detail.

Our findings for successful vaccine action plans are consistent with the guiding principles from the World Health Organization, including to add more focus from health systems and primary health care perspective to community-led processes. (Conference, 2021) In addition to facilitators and barriers for collaboration between clinic and community pharmacy, interventions within individual entities are also important (e.g., workflow redesign, vaccine storage, cost, management of vaccine reactions, business model, or staff empowerment). We agree with Dowell AC, et al that community engagement and applications of both complexity and implementation science are essential to innovate routine practice such as vaccinations, if we expect to see successful adaptive outcomes. (Dowell et al., 2019) Similar to findings from a feasibility study conducted by Garbutt JM, et al, which used a theory-informed, multi-component implementation strategy to improve HPV vaccine use, our findings suggest that intervention implementation could effectively make large improvements in HPV vaccinations. (Garbutt et al., 2018).

Successful collaboration between primary care clinics and pharmacies emerged as an effective model to increase HPV vaccinations; however, of considerable concern is the number of community pharmacy closures in recent years, especially in rural areas, which have been shown to include independent pharmacies, chain pharmacies (e.g., Walgreens), supermarket pharmacies and mass merchandiser pharmacies (e.g., Wal-mart). (Todd et al., 2013) Data from the National Council for Prescription Drug Programs were used to assess pharmacy closures between 2006 and 2010 and found that residents had to travel an average of 20 miles to reach their nearest pharmacy, the size of communities that lost their only pharmacy ranged from 163 to 1,996 residents with about 307 residents aged 65 or older. (Todd et al., 2013) Thus, there is a need to understand the impact of losing pharmacies in rural settings on the feasibility of pharmacies to become a part of the local immunization delivery system.

Most importantly, this scoping review highlights the limited extent

of current research in this area and the need for rigorously designed large intervention studies with adequate follow-up to fully assess their impact. In addition, many studies were funded completely or partially by drug companies, which may be influenced by biases. The quality of the studies that we abstracted was also limited, which underscores the need for robust future research. Moving forward, solutions for HPV and other vaccines likely rest in primary care clinics and community-based pharmacies, and understanding implementation strategies for effective collaborations between these groups is of utmost importance. Though the healthcare system is currently strained by the COVID-19 pandemic, this research is especially timely as creative solutions for vaccinations of all types are critically needed.

4.1. Conclusion

In conclusion, this scoping literature review indicates more intervention research is needed to fully understand how to reach the full potential of HPV vaccination, and this should focus on partnerships between primary care and pharmacies, how best to connect these two settings with digital information and documentation systems and how to overcome vaccine hesitancy, which has implications for many vaccines, not just HPV.

Declarations.

- Funding: The American Cancer Society funded this work (RSG-18-022-01-CPPB).

- Ethics approval: Oregon Health & Science University Reviewed the proposal related to this scoping literature review and determined it was not human subjects research.

- Consent to participate – Not Applicable.

- Consent for publication – Not Applicable.

- Availability of data and material – Not Applicable.

- Code availability – Not Applicable.

- Authors' Contributions

Patricia A. Carney, PhD, MS Conceptualization, Funding acquisition, Methodology, Data curation, Formal analyses, Project administration, Resources, Supervision, Validation, Visualization, Writing - original draft.

Sarah Bumatay, BS Methodology, Data curation, Formal analyses, Writing - review & editing.

Grace M. Kuo, PharmD, MPH, PhD Writing - review & editing.

Paul M. Darden, MD Writing - review & editing.

Andrew Hamilton, MLS, MS Methodology, Data curation, Writing - review & editing.

Lyle J. Fagnan, MD Writing - review & editing..

Brigit Hatch, MD, MPH Writing - review & editing..

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.pmedr.2022.101893>.

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