

Edition 89 - Making HIV, PrEP/PEP, and COVID Vaccination Screenings the Standard of Care in Primary Care Settings - BCPHR Journal



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Making HIV, PrEP/PEP, and COVID Vaccination Screenings the Standard of Care in Primary Care Settings

Abstract

Introduction

Federal policy guidelines regarding clinical screenings play a crucial role in shaping medical practice by providing evidence-based recommendations that ensure patient safety and effective prevention. These guidelines help standardize care, reduce variability, and improve health outcomes by guiding clinicians in adopting the latest and most effective practices. However, these guidelines are often imperfect and do not consider the complexity of varied patient populations as well as the historic systemic inequities that impact health outcomes. With this in mind, we sought to identify and critique policies related to HIV screening, PrEP/PEP screening, and COVID-19 vaccination screening.

Objectives

Three primary goals are associated with this manuscript: First, to review existing policy guidelines from the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) regarding culturally responsive screening for three primary areas of concern: HIV screening, PrEP/PEP eligibility, and COVID-19 vaccination. Second, to convene a National Advisory Board to identify shortfalls in existing guidance to inform recommended changes. Finally, to provide an actionable model for collaborative policy change that other advocates can use to mobilize communities.

Methods

A comprehensive review of the practice guidelines through the CDC and FDA were compiled and analyzed. The results of this analysis informed a policy discussion including primary care practitioners (PCPs), public health officials, academics, policy experts, subject matter experts, patients and advocacy leaders to identify practice shortfalls and develop policy papers highlighting recommended changes to inform clinical practice.

Discussion

Policy change is complex and requires an interprofessional perspective to ensure that recommendations are comprehensive and sustainable. This manuscript provides an overview of these recommendations as well as lessons learned and a practical model for future efforts.

Introduction

Health policies established by federal institutions, primarily the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) through the U.S. Department of Health and Human Services (HHS), establish guidelines for clinical practice and influence how clinicians come to understand health delivery.¹ Beginning in March 2020, the COVID-19 pandemic was declared a global public health emergency which saw a significant deprioritization of HIV prevention efforts in the United States.² This shift in the public health landscape caused harm to historically excluded patient populations (*e.g.*, racial, ethnic, sexual and gender minoritized groups) most significantly.^{3,4} Screening for COVID-19 vaccination status, HIV, and pre-exposure prophylaxis (PrEP)/post-exposure prophylaxis (PEP) eligibility in the primary care setting is critical to reduce the burden and impact of these two pandemics.^{5,6}

As the public health landscape continues to change, the need for robust and inclusive policy guidelines becomes increasingly apparent. Guidelines established by the CDC and the FDA serve as a critical foundation for clinical practice in the United States and, in addition to providing actionable recommendations for clinicians, are developed to enhance patient safety and prevention effectiveness through standardized, evidence-based.⁷ However, existing policies often overlook the nuanced dynamics within our communities and the longstanding inequities that influence health outcomes.⁸ This paper presents a concerted effort to dissect and refine federal policy guidelines, with a focus on improving HIV, PrEP/PEP, and COVID-19 vaccination screening processes for minoritized communities. We propose a multi-faceted approach to reform, involving a comprehensive review of current CDC and FDA guidelines, the assembly of an interdisciplinary team to pinpoint and address deficiencies, and the development of an actionable framework for policy advancement. Our work seeks not only to critique but also to construct – offering a template for collaborative change that underscores the importance of cultural responsiveness and health equity in the design of health policy.

Background

As of 2024, the CDC has published guidelines for HIV screening in primary care practice and counseling regarding the use of PrEP and PEP for HIV prevention, while both the CDC and the FDA have released guidelines regarding screening and counseling for the COVID-19 vaccination.⁹⁻¹³ In reviewing these guidelines, we followed a five-step process of analysis and policy design, as indicated in Figure 1. Across these various guidelines, we 1) reviewed to establish how screening is defined, how frequently the guidelines recommend that clinicians conduct screening, and which communities the guidelines specifically identify as those with greatest exposures to HIV and COVID-19. While doing this work, we also 2) critically reviewed these guidelines to identify areas of shortfalls (detailed at length in this manuscript) and policy recommendations. Following this work, we 3) convened a discussion with an interprofessional National Advisory Board¹⁴ to review our initial comments, provide specific recommendations for policy change, and advise us on appropriate language and framing. The National Advisory Board is a working group made up of experts from primary care, public health, academia, public policy, and patient advocacy. Members of this board were selected based on their background and were invited to provide a diverse set of professional perspectives. We then 4) engaged in an iterative process of drafting and revising updated policy recommendations with members of the National Advisory Board before 5) disseminating these policy recommendations and developing a “call to action” for advocates working in public health and primary care.

Step One: Identifying Existing Policy Guidelines

As previously stated, it is important to identify existing policies to ensure that recommendations for clinical practice are current, situated in evidence-based medicine, and written accessibly for practitioners. The CDC offers evidence-based, comprehensive clinical guidelines across a variety of healthcare domains that are recognized as the standard of care within the medical community. Table 1 represents the initial policy analysis we conducted to inform the work below.

Relevantly, the CDC publishes guidelines for HIV screening, PrEP/PEP eligibility and prescribing, and COVID-19 vaccination screening. We briefly identify the high-level considerations from each guidance document below and provide a deeper assessment of limitations and potential recommendations further in this manuscript (see Tables 2-4).

In the realm of HIV screening, the CDC recommends routine screening of patients aged 13-64 in all healthcare settings at least once in their lives, and at least annual screening for those at higher risk.⁹ The guidelines also recommend that PCPs have regular discussions with their patients regarding lifestyle risks and sexual practices, and counsel patients on preventive screenings.

Regarding PrEP/PEP screening, the CDC provides guidelines for the use of antiretroviral drugs among individuals who are at high risk for HIV infection. Pre-Exposure Prophylaxis (PrEP) is recommended for those who do not have HIV but are at high risk of contracting it, including individuals with an HIV-positive sexual partner, people who inject drugs, and those who engage in unprotected sex.¹¹ Post-Exposure Prophylaxis (PEP), on the other hand, involves taking antiretroviral medication after potential HIV exposure to prevent infection.¹⁰ PEP is only effective if taken within 72 hours of possible exposure to HIV.¹⁵

For COVID-19 vaccination screening, the CDC's guidelines emphasize the stratification of individuals based on risk factors such as age, pre-existing conditions, and availability of different vaccine formulations.¹² These guidelines are regularly updated to reflect the evolving nature of COVID-19, the introduction of new vaccine variants, and the understanding of the long-term efficacy of the vaccines. Importantly, continual guideline updates and varying recommendations based on risk factors and vaccine availability complicates information management for, and timely updates to, clinicians.¹⁶

Step Two: Identifying Shortfalls in Existing Policy

It is important to note that published guidelines are not final; they are designed to be living documents that are revised as new evidence emerges and as medical science evolves. Consequently, those involved in healthcare including clinicians and public health professionals must ensure they remain current on said guidelines. Guidelines must also be adapted to reflect the diversity of our society. In reviewing the published guidelines, we identified several important shortfalls or "policy problems" present in the CDC's recommendations. These, along with corresponding recommendations, are presented in Tables 1-3. Of note, there were multiple unique shortfalls across the three policies however a few important commonalities exist. Namely, none of the three policies adequately define screening, none of them provide guidance on appropriately sensitive counseling for patients, and none of them discuss the importance of regular screening and patient counseling.

Step Three: Develop an Interprofessional Team for Review and Consensus

Developing an interprofessional team for the review and development of health policy guidelines is invaluable; this process ensures a diversity of perspectives is considered, leading to more comprehensive and thoughtful guidelines. Table 4 provides an overview of the broad coalition of experts we convened to review our policy recommendations and provide feedback to ensure that they are direct, effective, and meaningful. Importantly,

our team included patients, subject matter experts, PCPs, public health professionals, academics, and policy experts.

The perspective of patients is often overlooked but is necessary to adequately address their dynamic and varied needs. Patients are aware of the psychosocial and cultural factors and stigma that influences how and if they engage in screening conversations. Engaging subject matter experts on HIV and COVID-19 as well as the social determinants of health and health equity is important for ensuring the screening guidelines take into consideration the multifaceted realities of patients' lives.

The perspective of PCPs is crucial. Their experience provides an understanding of the barriers to and facilitators of implementing clinical guidelines into direct patient care, ensuring that policy recommendations are feasible in day-to-day clinical practice. Public health professionals with expertise in epidemiology, disease prevention, and community engagement bring attention to the long-term and population-level impacts of health policy. Importantly, they also ensure that policy development is grounded in the needs of the community. Academics contribute translational research expertise and an understanding of the latest science into policy design. Lastly, federal policy experts offer a strategic perspective on policy implementation, experience in navigating complex legislative environments, and knowledge on drafting policy that is both effective and sustainable.

Together, an interdisciplinary team can design meaningful recommendations for policy change through a balanced consideration of clinical realities, resource needs, ethical considerations, and principles of health equity. This collaborative approach helps to identify shortfalls in existing guidelines and drive innovation in policy development. By drawing on a broad base of knowledge and experience, an interprofessional team can create robust health policy guidelines that are not only scientifically sound but also equitable and adaptable to the changing healthcare landscape and the realities of our healthcare system.

Developing Recommendations for Policy Change

Upon convening this interprofessional National Advisory Board, our charge was to establish meaningful recommendations for updated policy guidelines. These recommendations are reflected in Tables 1-3 above and represent the culmination of a deep dive into existing policies and an analysis of their shortfalls. To ensure meaningful discussion and best use the time of our National Advisory Board, we developed a facilitator's guide to encourage breakout discussions and collaborative change as present in Table 6.

Step Four: Engage in Iterative Review and Policy Design

The process of designing policy recommendations did not immediately end following our policy discussion. The core team for the Two in One Model compiled feedback from our interprofessional National Advisory Board, adjusted our policy recommendations, and collaborated with instructional designers to ensure the final policy papers and recommendations were polished for dissemination. This iterative process involved multiple rounds of revisions, incorporating diverse perspectives and expertise to enhance the robustness and effectiveness of our proposed policies. Additionally, we conducted thorough reviews to ensure that our policy proposals were aligned with current science and anticipated social needs. Ultimately, we produced three policy white papers that were widely disseminated as discussed below. These papers incorporate all the shortfalls and recommended changes as presented in Tables 1-3 but edited to allow for easier navigation, more engaging visuals, and hyperlinks to resources referenced.

Step Five: Dissemination and Calls to Action

Upon completing these three policy papers, our focus shifted towards disseminating these papers and calling for action from partners in advocacy. Leveraging various communication channels including academic

conferences, policy briefings, and strategic video designs and email to various stakeholder groups, we shared our policy recommendations with stakeholders across different sectors (*i.e.* public health, health professions education, and advocacy). Additionally, we organized targeted outreach initiatives to engage academics, primary care practitioners, and clinical advocacy groups to foster dialogue and garner support for our proposed policies. Furthermore, we emphasized the importance of ongoing collaboration and feedback loops to adapt our strategies in response to evolving needs and emerging challenges. These initiatives, including the policy papers and outreach efforts are available on the two in one website at twoinone.smhs.gwu.edu.

Final Policy Papers and Dissemination

The work above resulted in three distinct policy white papers which include a summary of existing CDC guidelines as well as paired policy shortfalls and recommendations developed in consultation with our interprofessional advisory board. These three papers are available in Appendices A-C. Upon completion of the policy papers, we pursued a comprehensive dissemination plan to build a list of “advocates in action,” individuals and organizations interested in changing policy. We began by identifying relevant educational organizations (e.g., Physician Assistant Education Association, American Medical Student Association), professional clinical organizations (e.g., Folx Health, American Academy of Family Physicians, American Public Health Association), and advocacy groups (e.g., Black AIDS Institute, Urban Institute) to design a customized implementation plan. Following this process of identifying relevant partners, we designed three distinct video messages to each collaborator group and created clinician vignettes to generate support for this work. These vignettes feature various clinicians including physicians, physician assistants, and nurses to ensure a broad reach to diverse audiences. Ultimately, this policy dissemination effort allowed us to reach over 75,000 unique individuals.

Discussions and Limitations

This work presents several important implications for primary care practice. First, the policy review and collaborative approach to change was interdisciplinary in nature and highlights the importance of building broad coalitions and engaging in healthcare beyond our typical silos. This work is not without limitations. First, the five-step process model for policy change present in Figure 1 may present challenges in a resource constrained environment. For example, it may not be feasible to call together an interprofessional team like the National Advisory Board when money is unavailable to provide remuneration or when working under time constraints. This model also assumes a distinct endpoint at Stage Five. In other words, the present model describes the work ending upon dissemination when policy work may continue forward through legislative action. We hope to revisit this model as our own work gains momentum and continues forward.

Conclusions and Next Steps

As we advance the agenda for integrating HIV, PrEP/PEP, and COVID-19 vaccination screenings into primary care settings, several steps are critical: First, it is important to ensure broad and on-going stakeholder engagement. This approach may take many forms at various stages of the policy development process, but at a minimum it is important to engage with policymakers, clinicians, and community leaders to advocate for the adoption of our recommended policy changes. Next, it is important to develop a broad base of advocates who are interested in this work and can join a coalition calling for change. From a practical perspective, this means seeking out individuals in academia, public health, and primary care from a broad geographical base to build a large group of advocates calling for action. Finally, it is important to engage in policy design work with individuals who have the skills and knowledge-base necessary to inform practical change. This requires working with legal experts and policymakers to draft policy language based on our recommendations. Advocating for these changes through direct engagement with legislators and participation in public policy forums is one way

to bring these ideas in front of leadership at the CDC and other health organizations who can call for and enact change.

Figure 1: A Process Map for Developing Clinical Policy Guidance

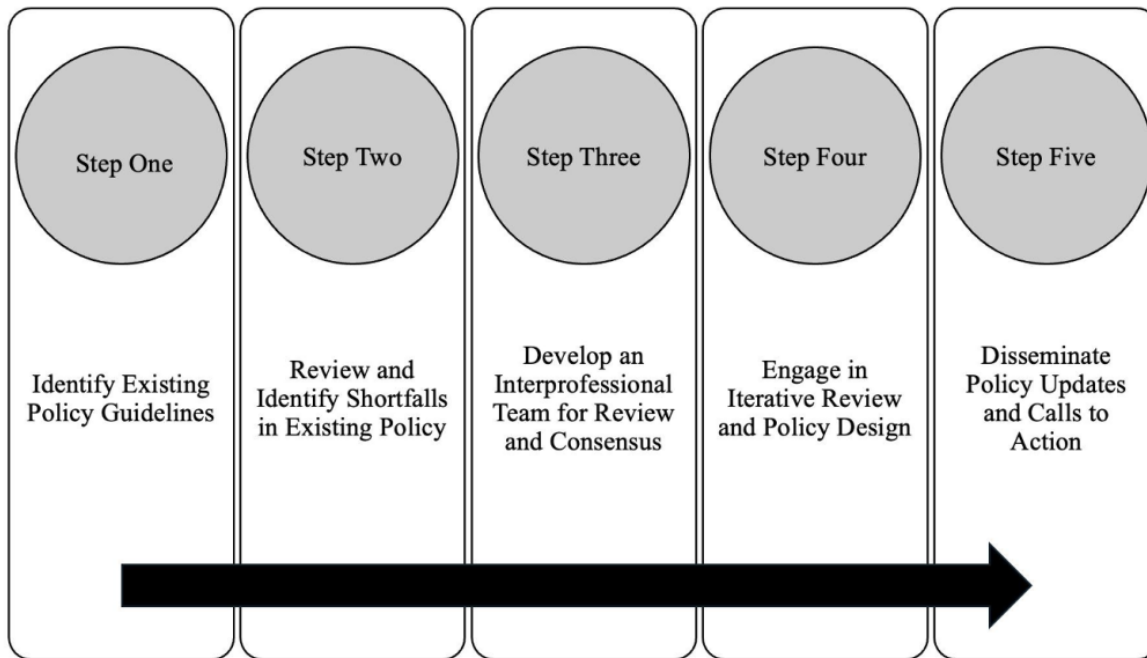


Table 1: Initial Policy Analysis

	<i>Describe the Policy</i>			<i>What kinds of evidence and arguments would you use to assess if the policy would be effective, equitable, and politically feasible?</i>		
What is the Policy	What are the objectives of this policy?	How would the policy work?	Level of Government Involvement	Effectiveness	Equity and Ethics	Feasibility
HIV Screening guidelines	The 2006 guidelines recommend clinicians screen patients at risk for HIV at least once (but 2009 guidelines for pregnant women is routine and 2014 guidelines for MSM is annual)	Perform one diagnostic HIV test on patients between the ages of 13 and 64 in their lifetime (unless pregnant or identified as a MSM)	Federal / CDC	Guidelines leave risk assessment to clinician discretion (it is not universally offered to all patients nor across their lifetime)	Patients assessed for HIV risk are profiled (maintaining stigma) and others with HIV exposures are missed opportunities to get tested, on PrEP, and on treatment	CHCs (and local EDs) serve as a model for how to routinize HIV testing for all patients in a way that is replicable and scalable (as does point-of-care testing in community pharmacies)
PrEP Screening guidelines	New 2021 clinical guidelines and clinical providers supplement	The update includes guidance for recommended initial and	Federal / CDC	CDC now advises all clinicians to talk to their patients who are sexually active, including	Despite PrEP effectiveness, there is low uptake with patient	The SDOH must be considered alongside PrEP initiation research shows

	available	<p>follow-up STI screening, revised HIV testing strategies, and recommended primary care practices for patients being prescribed oral or injectable PrEP.</p> <p>The supplement includes checklists, patient information sheets, and billing codes for both oral and injectable PrEP and includes guidance for counseling patients about adherent PrEP use</p>		<p>adolescents</p> <p>The clinical updates are not widely known or practiced. Even if they are, it still advises discussing PrEP only once in their lifetime and to prescribe the prevention medication to anyone who requests them.</p>	<p>populations that need it most, partly due to delayed screening and because the onus is on patients to request PrEP (and research tells us there are lots of barriers, with stigma and fear among them).</p>	<p>that stigma and housing / food insecurity and IPV serve as deterrents to PrEP compliance.</p>
COVID-19 Vaccine Screening guidelines	Everyone over the age of 6 months is recommended to get vaccinated and boosted	Three vaccine types are currently approved for EUA along with considerations for extended intervals for COVID-19 vaccine primary series doses	<p>Federal / CDC (and informed by Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the CDC; and COVID-19 vaccine approval for emergency Use Authorization by the FDA CDC's Emergency Use Instructions (EUI) for FDA approved vaccines Emergency Use Listing (EUL) of COVID-19 vaccines by the World Health Organization</p>	<p>The clinical guidelines are dynamically changing for specific groups while emergency use authorization is renewed</p>	<p>Clinicians keep up with the science of the guidelines but not the social implications. Since most vaccinations have been community based during the height of the pandemic, screening conversations on the vaccine and boosters have not routinely taken place but presents an important to intervene with patients misinformation</p>	<p>Any PCP can have these conversations on the importance of vaccines and boosters, not just the MD/DO (explaining why this model extends to PA, RNs, NPs, PharmDs)</p>

			(WHO) ACIP's general best practice guidelines for immunization (GBPG) and; Expert opinion).		and limited health literacy	
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Table 2: HIV Screening – Policy Shortfalls and Recommendations

Policy Problems	Policy Recommendations
<p>HIV screening is narrowly defined as diagnostic testing, which does not include the vital priming conversations and counseling that should preface and follow all clinical testing. While there are multiple effective approaches to HIV screening, a persistent barrier for patients regards the stigma associated with HIV (ref, ref, ref). The conversations that occur in a clinical setting between patient and practitioner are a critical part of screening, are necessary to overcome stigma, and are not clearly addressed in any of the guidance documents available through the CDC</p>	<p>We must expand what counts as ‘screening’ beyond HIV diagnostic testing alone to include HIV screening conversations. Such screening conversations must normalize discussing sexual health, use sex-positive language, and rely on a set of standardized questions asked of all patients. The Give-Offer-Ask-Listen-Suggest (GOALS) framework recommends that clinicians introduce sexual history taking as part of primary care that is not focused on risks but on health. In this way, patients may feel more comfortable talking about sex as a natural part of their lives and healthcare. Clinicians can use the sex and STI counseling ICD-10 code (Z70) to bill for time spent posing and fielding questions during limited clinical time. Policy makers can also investigate creating a CPT code and other billing codes for HIV screening discussions.</p>
<p>HIV testing approaches are not implemented in a standardized and comprehensive way. CDC HIV screening guidance calls for a minimum of risk-based HIV testing. With this approach, clinicians use risk-based screening to determine which of their patients are suited for testing. The problem with this approach is that when HIV testing is left to the discretion of clinicians, patients are inherently profiled for their perceived risks. As implemented, risk-based screening increases the stigma associated with having HIV and getting tested for HIV. This approach relies on bias—not just racial, ethnic, sexual, and gender-related bias—but also age and marital status bias.</p> <p>Still, the CDC clinical guidance recommends that the ideal approach to HIV testing is the opt-out method, wherein HIV testing becomes a routine clinical laboratory test patients receive as part of their primary care unless they decline. This approach remains problematic in its implementation because patients are not introduced to HIV testing as an opt-out test nor are these tests prefaced with HIV counseling. In most settings and regions where HIV testing is routine, it is not combined with a sexual history taking. Instead, the HIV test is automatically included in the battery of lab tests run. This is a violation of patient rights to informed refusal. Experiences like these only reinforce patient mistrust and fear.</p>	<p>To eliminate stigma, clinicians must invite all patients to get tested for HIV. Federally qualified health centers and states with opt-out HIV testing demonstrate the high yields of universal (or routine) HIV screening, despite doubts that the costs outweigh the benefit.</p> <p>When implementing HIV universal screening as the standard of care, opt-out discussions and informed refusal need to occur consistently, and as part of sexual history taking and counseling.</p>
<p>The CDC recommends HIV testing at least once for patients between the ages of 13 and 64. For clinicians who work in settings where HIV testing is not the standard of care, patients’ ongoing needs are not accounted for with a once in a lifetime screening recommendation.</p>	<p>Once is not enough. Screening conversations need to occur regularly (at least annually) during primary care practitioner (PCP) visits. To help clinicians remember to engage in sexual history taking and overall sexual health conversations, a reminder can be added to the electronic medical record (EMR) that automatically comes up on the screen. In this way, when clinicians are introducing a range of other preventive screenings and/or managing the health of a medically complex patient, they do not run the risk of forgetting or omitting this critical part of the primary</p>

	<p>care visit.</p> <p>There is also no reason to place an age ceiling on HIV screening. Older Americans are still sexually active and their age over 65 does not protect them from being exposed to HIV.</p>
<p>As current CDC guidelines do not provide language regarding priming conversations and counseling, there is also a gap in guidance as to how PCPs should support minoritized patient populations.</p>	<p>While clinicians should rely on compassionate and nonjudgmental communication for all their patients when discussing sexual health and HIV screening, they need to especially rely on culturally responsive communication when caring for racial, ethnic, sexual, and gender minoritized patients.¹⁷ This form of communication invites clinicians to not only consider their patients' culture but to also do so alongside the culture of medicine, the culture of racism, as well as their own culture. This reflexivity will allow clinicians to practice antiracist and unbiased care. The Two in One Model offers free CME-bearing training on practicing culturally responsive communication.¹⁸</p>
<p>There is currently no focus on the patient experience related to screening and counseling present in CDC guidelines. This gap presents ongoing concerns that emerging policy guidance may continue to perpetuate structural inequities that contribute to health disparities.</p>	<p>Accountable Care Organizations must partner with clinicians and public health practitioners to identify indicators of quality care for patient engagement. One such example may include patient satisfaction.</p>

Table 3: PrEP/PEP Screening – Policy Short Falls and Recommendations

Policy Problems	Policy Recommendations		
PrEP			
<p>PrEP guidelines do not address clinicians' hesitancy to prescribe PrEP; with only 28% reporting sufficient familiarity with PrEP to recommend it to their patients.</p>	<p>Licensing bodies for clinicians (e.g., state medical boards) must require PrEP training/CME coursework to inform clinicians about changing guidelines, PrEP indication, and patient counseling skills. Training programs must teach sexual history taking (see GOALS framework).</p>		
	<p>Insurance companies should create an ICD-10 code, CPT code, and other billing codes for PrEP screening.</p>		
<p>The PrEP guidelines recommend “routinely” taking a sexual history, but there is no concrete recommendation for how frequently clinicians should be talking about PrEP and clinicians are already overwhelmed by annual visit tasks.</p>	<p>To decrease HIV stigma and transmission, the CDC should create guidelines making annual consideration of PrEP part of value-based care guidelines, perhaps through an EMR prompt.</p>		
PEP			
<p>PEP has a time-sensitive 72-hour window, yet the guidance seems to leave it up to the patient to know about PEP and to initiate the discussion.</p>	<p>Licensing bodies for clinicians must require PEP training, so clinicians initiate the discussion and help patients plan for potential exposure.</p>		
	<p>The CDC should create guidelines recommending annual discussions of PEP and clinicians should disseminate this information, so all patients are aware of the option in the event of a potential exposure.</p>		
	<p>Insurance companies should create an ICD-10 code, CPT code, and other billing codes for PEP screening.</p>		

PrEP & PEP	
The CDC guidelines do not offer a clear definition of screening, sometimes using it to mean HIV or other STI testing and at other times, conversations with patients.	CDC guidelines should rely on a consistent definition of screening. We suggest the following: PrEP and PEP screening involves clinicians (1) informing patients about PrEP and PEP, (2) asking about sexual activity or intravenous drug use, (3) asking about “substantial risk” factors like partners who are HIV-positive or shared injection equipment, (4) assessing for signs of living with HIV infection, and (5) offering a diagnostic test for HIV.
PrEP and PEP screening (defined above) are complex, yet the 2021 CDC guidelines do not offer clarity or support on navigating screening conversations.	Due to the multiple actions asked of clinicians when screening for PrEP/PEP, the CDC guidelines should include resources, not just for information to be gathered, but also for <i>how</i> to engage with patients to collect that information and support them through the screening process, such as the From Risk to Reasons guide .
Racial, ethnic, sexual, and gender minoritized patients are disproportionately affected by HIV <i>and</i> experience more microaggressions from their clinicians, yet the CDC guidelines do not offer resources for adapting screening conversations for these patient populations.	CDC guidelines should offer resources such as the Two in One CME bearing culturally responsive communication model and training .
Many clinicians are unaware of the updated CDC guidelines and perhaps are still influenced by the former guidelines that specifically call out populations like “men who have sex with men” or “transgender persons.” Nevertheless, they are (a) not screening more broadly and (b) still screening some patient groups disproportionately.	Clinicians must not continue to stigmatize minoritized patients. The CDC must work more robustly with partners like clinician licensing bodies to advertise these changing guidelines and offer resources to accompany them like our culturally responsive communication model and trainings , so clinicians working with minoritized patients can shift from singling out specific patients to building rapport and trust across all patients.
While improved, the new guidelines remain stigmatizing because they still distinguish between “high prevalence groups or communities” and others, even though this distinction does not guide care recommendations.	CDC guidelines should not mention specific communities if they are not also offering different recommendations for those communities.
There is currently no focus on the patient experience related to screening and counseling present in CDC guidelines. This gap presents ongoing concerns that emerging policy guidance may continue to perpetuate structural inequities that contribute to health disparities.	Accountable Care Organizations must partner with clinicians and public health practitioners to identify indicators of quality care for patient engagement. One such example may include patient satisfaction.

Table 4: COVID-19 Vaccination Screening – Policy Short Falls and Recommendations

Policy Problem	Policy Recommendation
The CDC does not have any guidelines on COVID-19 vaccination screening as we have noted above. Moreover, screening frequency, information, and conversations are done at the discretion of the clinician. The conversations that occur in a clinical setting between patient and practitioner are a critical part of screening and are not clearly addressed in any of the guidance documents available through the CDC.	The CDC should develop guidance for clinicians on compassionate and nonjudgmental communication for all their patients. When discussing COVID-19 vaccines, clinicians need especially to rely on culturally responsive communication when caring for racial, ethnic, sexual, and gender minoritized patients. This reflexivity will allow clinicians to practice antiracist and unbiased care.

<p>Patients are individually responsible for keeping up with COVID-19 vaccine recommendations and booster guidance. Americans are constantly bombarded with vaccine information, misinformation, and disinformation, and must navigate when and where to get vaccinated. Many Americans receive their vaccine information from social media or other media outlets or are unreached by vaccine information.</p>	<p>Conversations around COVID-19 and COVID-19 vaccines should occur regularly between all patients and PCPs to eliminate stigma. EMRs should include COVID-19 vaccination status as well as prompts and recommendations for COVID-19 vaccinations and boosters (at least annually).</p>
<p>Practitioners do not have updated vaccine guidelines consistently communicated to them either through the government or academic / professional organizations. As with patients, practitioners are required to seek information and determine its relevance and timeliness.</p>	<p>Collaboration between state and local public health departments and major healthcare practitioners is critical for successful screening guidance and vaccine rollout. Many patients rely on their PCP to receive vaccines. Collaboration between the state and primary care clinics is essential to reaching these patients.</p>
<p>Policy documents do not address the many complexities of COVID-19 vaccination. COVID-19 vaccines pose unique challenges for vaccination in a primary care clinic due to storage and distribution requirements. PCPs are the main source of immunizations for many Americans, and, unfortunately, most PCPs are not administering COVID-19 vaccines. Patients must navigate the barriers to receiving vaccines outside of their PCP visits. Additionally, patients who receive a COVID-19 vaccine outside of the organization of their PCP must bring their vaccination card to be manually entered into the EMR.</p>	<p>CDC guidance should indicate that clinicians who are unable to provide the COVID-19 vaccine should still screen patients for vaccination status and refer patients to vaccination sites nearby. Clinician recommendation is an influential factor in vaccine acceptance. Clinicians may direct patients to Vaccine.gov or go as far as schedule the appointment with the patient.</p>
<p>Current CDC guidelines direct patients to their healthcare clinician or vaccine provider for any information or concerns regarding the COVID-19 vaccines. There are currently ICD-10 codes for clinicians to utilize when screening or discussing COVID-19 vaccines with patients. But, on average, PCPs only have 15 minutes with each patient and are not incentivized to take the time to navigate the difficult conversations around COVID-19 vaccines when they are specifically unable to bill for these discussions.</p>	<p>There must be a unique billing code created by the WHO, AMA, and other relevant agencies to incentivize health delivery service organizations to allow clinicians time to have discussions about the COVID-19 vaccines with patients. Billing codes improve health care costs and ensure fair reimbursement policies. In addition to financially incentivizing PCPs to screen for COVID-19 vaccines, billing codes facilitate the collection and storage of data that can be utilized by patient organizations, policy-makers, and insurers.</p>
<p>There is currently no focus on the patient experience related to screening and counseling present in CDC guidelines. This gap presents ongoing concerns that emerging policy guidance may continue to perpetuate structural inequities that contribute to health disparities.</p>	<p>Accountable Care Organizations must partner with clinicians and public health practitioners to identify indicators of quality care for patient engagement. One such example may include patient satisfaction.</p>

Table 5: Composition of the Two in One Model’s Interprofessional Policy Team

Advisory Board #	Professional Role	Policy Paper
Member 1	PCP	HIV
Member 2	Public Health Practitioner & Academic	HIV
Member 3	Public Health Practitioner & Policy Expert	HIV
Member 4	Communications Expert & Patient	HIV
Member 5	PCP	PrEP/PEP
Member 6	Public Health Practitioner & Academic	PrEP/PEP
Member 7	Advocacy Expert & Academic	PrEP/PEP

Member 8	PCP	COVID-19
Member 9	Policy Expert	COVID-19
Member 10	Public Health Student	COVID-19

Table 6: Facilitator’s Guide to National Advisory Board Discussion and Policy Development

NOTE: You may either print this document or have it open on a separate screen so that you can use this as a guide while sharing your screen with Advisory Board members to follow along with your policy recommendations.

Summarize the background of your assigned screening guidelines.

Elicit any clarifying questions regarding the existing policy guidelines.

Read the problem statements for your assigned screening (i.e., what shortfalls exist with the current policy guidelines). Ask:

Do they agree with the identified problems?

Are there any other problems we have yet to address?

Are the problems identified meaningful for PCPs?

Read the policy recommendations for your assigned screening. Ask:

Do they agree with the proposed recommendations? Are these feasible?

Are there any other potential recommendations we should offer?

Would it be helpful for us to visually arrange the problems and recommendations next to each other in a table or does this bulleted list work?

Remind them that we will debrief the ‘call to action’ as a group and thank them for their time.

Appendix A: HIV Screening Policy Paper



CDC: Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings; Policy Background and Recommendations

Maranda C. Ward, Abigail Konopasky, Leah Hoey, Patrick G. Corr

Background

The Centers for Disease Control and Prevention (CDC) last updated their human immunodeficiency virus (HIV) screening guidelines for all adults, adolescents, and pregnant women in 2006. The updated



pregnant women in 2006. These clinical guidelines state that all people between the ages of 13 and 64 years should be screened for HIV at least once in their lives. This same guidance notes that individuals at higher risk for HIV infection (e.g., gay, bisexual, and men who have sex with men [MSM]) should be rescreened at least annually while sexually active).

In 2017, the CDC released brief guidance advising clinicians to screen patients more frequently based on individual risk factors (e.g., sexual activity), local HIV rates, and local policies.

This policy brief reviews current definitions of HIV screening, outlines the **problems** with current practice around HIV screening, and offers specific **policy recommendations** for addressing these problems.

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notes that HIV testing should be an element of all prenatal testing and occur during the third-trimester of pregnancy in regions with high HIV transmission rates, unless they opt-out of testing. The guidance further notes that clinicians do not need to request separate written consent from patients to provide this screening.¹

A stakeholder group including Primary Care Practitioners (PCPs), policy experts, public health practitioners, and academics vetted the following policy recommendations which address existing problems with the CDC's HIV Screening Guidelines.



Gap 1: HIV Screening Omits Discussion

HIV screening is **narrowly defined** as diagnostic testing, which **does not include the vital priming conversations and counseling** that should preface and follow all clinical testing. This is especially salient since the HIV screening guidelines rely on more than one HIV testing approach. The conversations that occur in a clinical setting between patient and practitioner are a critical part of screening and are not clearly addressed in any of the guidance documents available through the CDC.

Recommendation 1: Include Discussion

Updated HIV screening guidelines for adults, adolescents, and pregnant women

HIV Screening, Defined

The CDC defines HIV screening as HIV diagnostic testing for patients, specifically "performing an HIV test for all persons in a defined population".¹ The CDC notes that all adolescents and adults should receive HIV screening at least once unless they decline the test (i.e., opt-out of testing). CDC guidance

Policy Recommendations

- Include Discussion
- Reduce Bias
- Increase Testing
- Support Practitioners
- Focus on Patients

patients. The Give-Offer-Ask-Listen-Suggest (GOALS) framework² recommends that clinicians introduce sexual history taking as part of primary care that is not focused on risks but on health. In this way, patients may feel more comfortable talking about sex as a natural part of their lives and healthcare. Clinicians can **use the sex and STI counseling ICD-10 code (Z70)** to bill for time spent posing and fielding questions during limited clinical time. Policy makers can also investigate creating a CPT code and other billing codes for HIV screening discussions.

Gap 2: Testing Is Discretionary

HIV testing approaches are not implemented in a standardized and comprehensive way. CDC HIV screening guidance calls for a minimum of risk-based HIV testing. With this approach, clinicians use risk-based screening to determine which of their patients are suited for testing. The problem with this approach is that **when HIV testing is left to the discretion of clinicians, patients are inherently profiled for their perceived risks.** As implemented, risk-based screening increases the stigma associated with having HIV and getting tested for HIV. This approach relies on bias- and not just racial, ethnic, sexual, and gender-related

We must expand what counts as 'screening' beyond HIV diagnostic testing alone to **include HIV screening conversations**. Such screening conversations must **normalize discussing sexual health, use sex-positive language, and rely on a set of standardized questions asked of all**

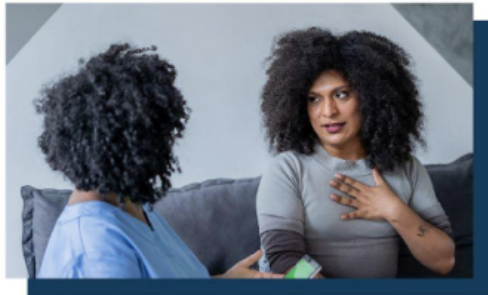


bias- but also age and marital status bias.

Still, the CDC clinical guidance recommends that the ideal approach to HIV testing is the opt-out method, wherein HIV testing becomes a routine clinical laboratory test patients receive as part of their primary care unless they

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decline. This approach remains problematic in its implementation because **patients are not introduced to HIV testing as an opt-out test nor are these tests prefaced with HIV counseling**. In most settings and regions where HIV testing is routine, **it is not combined with a sexual history taking**. Instead, the HIV test is automatically included in the battery of lab tests run. **This is a violation of patient rights to informed refusal**. Experiences like these only reinforce patient mistrust and fear.



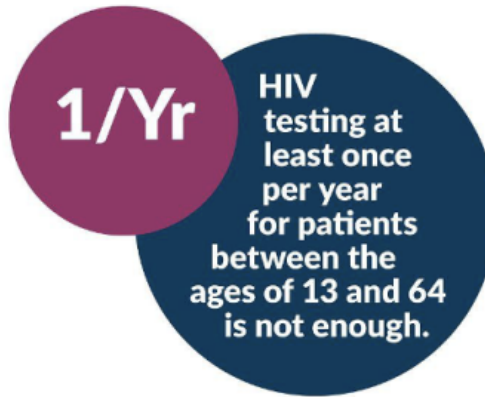
Recommendation 2: Reduce Bias

To eliminate stigma, clinicians must **invite all patients to get tested for HIV**. Federally qualified health centers and states with opt-out HIV testing demonstrate the high yields of universal (or routine) HIV screening, despite doubts that the costs outweigh the benefit.³

When implementing HIV as the standard of care as a universal screening, **opt-out discussions and informed refusal needs to occur consistently, and as part of sexual history taking and counseling**.

Gap 3: Testing Is Insufficient

Recommending HIV testing at least once for patients between the ages of 13 and 64 is not enough. For clinicians who work in settings where HIV testing is not the standard of care, patients' **ongoing needs are not accounted for with a once in a lifetime screening recommendation**.



Recommendation 3: Increase Testing

Screening conversations need to occur regularly (at least annually) during PCP visits. To help clinicians remember to engage in sexual history taking and overall sexual health conversations, **a reminder can be added to the electronic medical record that automatically comes up on the screen**. In this way, when clinicians are introducing a range of other preventative screenings and/or managing the health of a medically complex patient, they do not run the risk of forgetting or omitting this necessary part of the primary care visit.

Gap 4: Guidance Is Lacking

As current CDC guidelines do not provide language regarding priming conversations and counseling, there is also **a gap in guidance as to how PCPs should support minoritized patient populations**.

Recommendation 4: Support Practitioners

While clinicians should rely on compassionate and nonjudgmental communication for all of their patients when discussing sexual health and HIV screening, **they need to especially rely on culturally responsive communication** when caring for racial, ethnic, sexual, and gender minoritized patients. This form of communication **invites clinicians to not only consider their**

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patients' culture but to also do so alongside the culture of medicine, the culture of racism, as well as their own culture. This reflexivity will allow clinicians to practice antiracist and unbiased care. The **Two in One Model** offers free CME-bearing training on practicing culturally responsive communication.



Gap 5: Patients Are Disengaged

There is currently **no focus on the patient experience** related to screening and counseling present in CDC guidelines. This gap presents ongoing concerns that emerging policy guidance may continue to perpetuate structural inequities that contribute to health disparities.

Recommendation 5: Focus on Patients

Accountable Care Organizations must partner with clinicians and public health practitioners to identify indicators of quality care for patient engagement. One such example may include patient satisfaction.

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Acknowledgements

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Appendix B: PrEP/PEP Screening Policy Paper





Testing Model

Screening for Preexposure Prophylaxis (PrEP) and Post-exposure Prophylaxis (PEP) for the Prevention of HIV Transmission in the United States, 2021 Guidelines: Policy Background and Recommendations

Abigail Konopasky, Maranda C. Ward, Leah Hoey, Patrick G. Corr

Background

Pre-exposure Prophylaxis (PrEP)

The Centers for Disease Control and Prevention's (CDC) 2021 guide recommends routinely taking a sexual history and **informing all adolescents and adults** who are sexually active or use intravenous drugs about daily use of PrEP and **recommending it to those with substantial risk** to help prevent HIV infection. Screening can occur virtually (e.g., phone- or web-based consultations with clinicians).¹

Post-exposure Prophylaxis (PEP)

The CDC's 2016 guide recommends use of PEP within 72 hours for anyone who has been exposed to HIV to help prevent HIV transmission.²

This policy brief reviews current definitions of PrEP and PEP **screening**, outlines the **problems** with current practice around PrEP and PEP screening, and offers specific **policy recommendations** for addressing these problems.

Policy Recommendations

- Licensing bodies should require clinician training
- Insurance compaines should create new billing codes
- Clarify and expand the definition of screening
- Require more frequent discussions with patients
- Include resources for clinicians on not stigmatizing patients

PrEP and PEP Screening, Defined

For PrEP, HHS and the CDC recommend clinicians **initiate a conversation** around HIV transmission in order to determine whether patients have "substantial risk": a sexual partner who is HIV positive, a recent sexually transmitted infection, history of inconsistent condom use, or

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sharing drug injection equipment. If substantial, the next step is to perform a **diagnostic** test for HIV and, if negative, to **recommend** PrEP.

PEP guidance describes how patients must seek care **within 72 hours** of exposure.

A stakeholder group including primary care practitioners (PCPs), policy experts, public health practitioners, and academics vetted the following policy recommendations which address existing problems with the PrEP/PEP Screening Guidelines.

Policy Gaps	Recommendations
PrEP Screening	
<ul style="list-style-type: none"> • Many clinicians are hesitant to prescribe PrEP with only 28% reporting sufficient familiarity with PrEP to recommend it to their patients.³ 	<ul style="list-style-type: none"> • Licensing bodies for clinicians (e.g., state medical boards) must require PrEP training/ CME coursework to inform clinicians about changing guidelines, PrEP indication, and patient counseling skills. Training programs

- The PrEP guidelines recommend “routinely” taking a sexual history, but there is no **concrete recommendation for how frequently clinicians should be talking about PrEP** and clinicians are already overwhelmed by annual visit tasks.

must teach sexual history taking (see GOALS framework).

- Insurance companies should create an **ICD-10 code, CPT code, and other billing codes** for PrEP screening.
- In order to decrease HIV stigma and transmission, the CDC should create guidelines making **annual consideration of PrEP part of value-based care guidelines**, perhaps through an electronic medical record (EMR) prompt.

PEP Screening

- PEP is time-sensitive (i.e., a 72-hour window), yet the guidance seems to leave it **up to the patient to initiate the discussion**.

- Licensing bodies for clinicians must **require PEP training**, so clinicians initiate the discussion.
- The CDC should create **guidelines recommending annual discussions of PEP** and clinicians should disseminate this information so all patients are aware of it.
- Insurance companies should create an **ICD-10 code, CPT code, and other billing codes** for PEP screening



Policy Gaps and Recommendations for Both PrEP & PEP Screening Guidelines

Gap 1: Clarify Definition of Screening

The CDC guidelines do not offer a clear **definition of screening**, sometimes using it to mean HIV or other STI testing and, other times, conversations with patients.

Recommendation 1: Use Our Definition

CDC guidelines should **use our screening definition**: Drawing from the guidelines (which do not have an explicit definition of screening), we define PrEP and PEP screening as clinicians: (1) **informing** patients about PrEP and PEP, (2) **asking about** sexual activity or intravenous drug use, (3) **asking about** “substantial risk” factors like partners who are HIV-positive or shared injection equipment, (4) **assessing** for signs of living with HIV infection, (5) offering a **diagnostic test** for HIV.

Gap 2: No Support for Conversations

PrEP and PEP screening (defined above) are complex, yet the 2021 CDC **guidelines do not offer clarity or support on navigating screening conversations**.



Gap 3: Clinicians Screening Some Patients Disproportionately

Many clinicians are **unaware of the updated CDC guidelines** and perhaps are still influenced by the former guidelines that specifically call out populations like “men who have sex with men” or “transgender persons.”⁴ Nevertheless, they are (a) **not screening more broadly** and (b) **still screening some patient groups disproportionately**.

While better, the new guidelines are stigmatizing because they still **distinguish between “high prevalence groups or communities” and others**, even though this distinction does not guide care recommendations.

Racial, ethnic, sexual, and gender minoritized patients are disproportionately affected by HIV and experience more microaggressions from their clinicians, yet the **CDC guidelines do not offer resources for adapting screening conversations for these patient populations.**

Recommendation 2: Include Resources

Due to the multiple actions asked of clinicians when screening for PrEP/PEP, the CDC guidelines should **include resources**, not just for information to be gathered, but also **for how to engage with patients to collect that information and support them** through the screening process, such as the [From Risk to Reasons guide](#).

CDC guidelines should **offer resources** such as our CME bearing [culturally responsive communication model and training](#).



Recommendation 3: Help Clinicians Screen Broadly

Clinicians must not continue to stigmatize minoritized patients. Instead, CDC guidelines should **provide resources** like our [culturally responsive communication model and trainings](#), so clinicians working with minoritized patients can shift from singling out specific patients to building rapport and trust across all patients.

CDC guidelines should **not mention specific communities** if they are not also offering different recommendations for those communities.

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Gap 4: Structural Inequities Continue

There is currently **no focus on the patient experience** related to screening and counseling present in CDC guidelines. This gap presents ongoing **concerns that emerging policy guidance may continue to perpetuate structural inequities** that contribute to health disparities.

Recommendation 4: Monitor Quality

Accountable Care Organizations must **partner with clinicians and public health practitioners to identify indicators of quality care** for patient engagement. One such example may include patient satisfaction.



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Acknowledgements

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Appendix C: COVID-19 Vaccination Screening Policy Paper



HIV + COVID Screening & Testing Model

CDC Guidelines on COVID-19 Vaccine Screening; Policy Background and Recommendations

Patrick G. Corr, Leah Hoey, Abigail Konopasky, Maranda C. Ward

Background

The Centers for Disease Control (CDC) offers **varying guidelines** based on age, health status, priority populations, and the vaccine type. **All individuals over the age of six months are eligible** for most COVID-19 vaccines, with the exception of Johnson & Johnson (recommended for patients older than 18).¹

The CDC's Advisory Committee on Immunization Practice (ACIP) maintains a **repository** of all past and present COVID-19 vaccine guidance including guidelines for **bivalent booster doses** of the COVID-19 vaccines and for **initial vaccination** of children aged six months to five years, six to 11 years, 12 to 18 years, and people older than 18 years of age. **There are four existing** COVID-19 vaccines: Pfizer-BioNTech, Moderna, Novavax, and Johnson & Johnson's Janssen. These four vaccines have **distinct guidelines** based on the classification of the vaccine, recommended amount of doses, effectiveness, and risk.¹

This policy brief reviews current definitions of COVID-19 vaccine **screening**, outlines the **problems** with current practices, and offers specific **policy recommendations** for addressing these problems.

Policy Recommendations

- Provide guidance on compassionate communication
- Use EMRs to prompt more frequent conversations
- Increase collaboration in disseminating guidance to PCPs
- Clinicians to still screen even if not vaccinating
- Create billing codes specifically for discussing vaccination
- Focus on patient by monitoring care quality

COVID-19 Vaccine Screening, Defined

The CDC does not provide a **definition** of screening in their COVID-19 vaccine guidelines.

Screening in the literature has been described as the process of **asking questions** about the patients' health status, contraindications, and precautions before administering a vaccine.

A stakeholder group including primary care practitioners (PCPs), policy experts, public health practitioners, and academics vetted the following policy recommendations which address existing problems with the CDC's COVID-19 Screening Guidelines.

Gap 1: No CDC Screening Guidelines

The CDC does not have any guidelines on COVID-19 vaccine screening as we have noted above. Moreover, screening frequency, information, and conversations are done at the discretion of the provider. The conversations that occur in a clinical setting between patient and practitioner are a critical part of screening and are not clearly addressed in any of the guidance documents available through the CDC.

Recommendation 1: Develop Guidelines

The CDC should develop guidance for clinicians on compassionate and nonjudgmental communication for all of their patients. When discussing COVID-19 vaccines, clinicians need especially to rely on culturally responsive communication when caring for racial, ethnic, sexual, and gender minoritized patients. This reflexivity will allow clinicians to practice antiracist and unbiased care.

Gap 2: Patients Need More Reliable Information

Patients are individually responsible for keeping up with COVID-19 vaccine recommendations and booster guidance. Americans are constantly bombarded with vaccine information, misinformation, and disinformation, and have to navigate when and where to get vaccinated. Many Americans receive their vaccine information from social media or other media outlets or are unreached by vaccine information.²

Recommendation 2: Increase Conversations

Conversations around COVID-19 and COVID-19 vaccines should occur regularly between all patients and PCPs to eliminate stigma. Electronic Medical Records (EMR) should include COVID-19 vaccination status as well as prompts and recommendations for COVID-19 vaccinations and boosters (at least annually).



Gap 3: PCPs Not Updated

Practitioners do not have updated vaccine guidelines consistently communicated to them either through the government or academic/professional organizations. As with patients, practitioners are required to seek information and determine its relevance and timeliness.

Recommendation 3: More Collaboration

Collaboration between state and local public health departments and major healthcare providers is critical for successful screening guidance and vaccine rollout. Many patients rely on their PCP to receive vaccines. Collaboration between the state and primary care clinics is essential to reaching these patients.



Gap 4: Most PCPs Not Vaccinating

COVID-19 vaccines pose unique challenges for vaccination in a primary care clinic due to storage and distribution requirements. PCPs

Gap 5: PCPs Can't Bill for Discussions

Current CDC guidelines direct patients to their healthcare or vaccine provider for any information or concerns regarding the

are the main source of immunizations for many Americans, and, unfortunately, most PCPs are not administering COVID-19 vaccines. **Patients must navigate the barriers to receiving vaccines outside of their PCP visits.** Additionally, patients who receive a COVID-19 vaccine outside of the organization of their PCP have to bring their vaccination card to be manually entered into the EMR.

Recommendation 4: PCPs Should Still Screen

CDC guidance should indicate that **clinicians who are unable to provide the COVID-19 vaccine should still screen patients for vaccination status and refer patients to vaccination sites nearby.** Provider recommendation is an influential factor in vaccine acceptance. Providers may direct patients to [Vaccines.gov](https://www.vaccines.gov) or go as far as schedule the appointment for the patient.



COVID-19 vaccines. There are currently ICD-10 codes for providers to utilize when screening or administering COVID-19 vaccines with patients. **But, on average, primary care providers only have 15 minutes with each patient and are not incentivized to take the time to navigate the difficult conversations around COVID-19 vaccines when they are specifically unable to bill for these discussions.**

Recommendation 5: Create Billing Codes

There must be a **unique billing code created by the WHO, AMA, and other relevant agencies to incentivize health delivery service organizations to allow clinicians time to have discussions about the COVID-19 vaccines with patients.** Billing codes improve health care costs and ensure fair reimbursement policies. In addition to financially incentivizing PCPs to screen for COVID-19 vaccines, billing codes facilitate the collection and storage of data that can be utilized by patient organizations, policy-makers, and insurers.³

Gap 6: Focus on the Patient Is Lacking

There is currently **no focus on the patient experience** related to screening and counseling present in CDC guidelines. This gap presents ongoing concerns that **emerging policy guidance may continue to perpetuate structural inequities that contribute to health disparities.**

Recommendation 6: Monitor Quality

Accountable Care Organizations must **partner with clinicians and public health practitioners to identify indicators of quality care for patient engagement.** One such example may include patient satisfaction.



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