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## COMMENTARY

## Shared clinical decision making on vaccines: Nothing has really changed for pharmacists

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## ABSTRACT

Recently the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices has begun utilizing a new recommendation known as "Shared Clinical Decision-Making." This recommendation from Centers for Disease Control and Prevention calls upon health care providers, including pharmacists, to have more engaged conversations with patients regarding their vaccine needs. This commentary is designed to provide pharmacists with clarifications on the intent behind this terminology, and dispel myths that have frequently been attributed to the category of recommendation. Pharmacists must continue to take action to immunize patients and not be confused by a new approach to recommendation terminology.

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For many years, when the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) made recommendations for the use of vaccines, the recommendations were either made for the entire population or for a subset of the population, or the use of particular vaccine was not recommended at all. Recently, the ACIP voted to add an additional option its existing recommendation options: that is, "shared clinical decision making" (SCDM). At the time of this writing, there are 4 vaccines that require the SCDM, which will be discussed later in the paper. One example that pharmacists are most likely to be aware of is the ACIP's decision in October 2019 to implement the SCDM strategy for the administration of pneumococcal conjugate vaccine (PCV-13) in patients over the age of 65 years.<sup>1</sup> The ACIP determined that on the basis of population-based objective data, PCV-13 should no longer be routinely recommended for all patients in this particular age group.

The authors' experience in consulting with pharmacists around the country demonstrates that there is much confusion

about what the CDC and ACIP intend by the term "shared clinical decision making." Even public health departments in some states issued early guidance that seems contrary to the CDC's intent. In an attempt to provide clarification, the CDC published an online guidance document in February 2019, "Frequently Asked Questions," to describe the intent of implementing SCDM.<sup>2</sup> We discuss this guidance and specific implications for pharmacists.

**SCDM: What, Who and How?**

At its core, SCDM indicates that a vaccine provider should engage the patient in a discussion about the risks of infection, given their individual underlying conditions, age, or other risk factors, and the benefits the vaccination may provide in their personal situation. Armed with the facts, the patient and provider can make a shared decision about the vaccination that is in the best interest of the individual. It is equally critical to understand that SCDM is not about vaccine safety. Vaccine safety has been proven in numerous studies over decades. It was never the intention of the ACIP to create doubts about vaccine safety but rather to recognize the benefits that vaccines offer to individual patients even when they may not be beneficial at the population-level with routine immunization of the complete population.

The question of whether pharmacists are qualified to make shared clinical decisions, or even authorized to do so based on state law is one that must be definitively answered. Unequivocally, the CDC specifically lists pharmacists as vaccine providers. All 50 states and all U.S. territories authorize

**Disclosures:** Stephan Foster discloses that he currently serves on the speaker's bureau for Merck and Pfizer, and serves on advisory boards for Sequiris and Dynavax; and is the APhA liaison appointee to the CDC's ACIP. Mitchel C. Rothholz reports that his wife is an employee of Merck. Michael D. Hogue serves on the ACIP COVID-19 Vaccines Workgroup and is the 2020-21 President of APhA.

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**Key Points****Background:**

- The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices has implemented a new approach for select vaccines (HPV, HBV, PCV-13, and MenB) known as "shared clinical decision making" (SCDM).
- This approach was made to recognize the importance of patient-specific clinical decisions for some vaccines in certain populations.

**Findings:**

- Pharmacists are designated by Centers for Disease Control and Prevention as qualified and authorized immunizers, and thus there should be no additional barriers in place to require further authorizations or approvals under SCDM.
- Pharmacists can and should initiate and finalize shared clinical decisions with regard to vaccines.
- SCDM requires that pharmacists must exercise independent judgement and authority on patient-specific recommendations for care related to vaccines. Employers of pharmacists must ensure that systems and processes respect and support the autonomy of pharmacists to make these decisions and appropriately document the care provided and vaccine(s) administered.

pharmacists to administer vaccines, although some do limit the types of vaccines or the ages of patients who may be immunized by pharmacists. Nothing about this has changed with the addition of SCDM as part of vaccine recommendations. It is the CDC's position and ours that pharmacists can and should engage in the process of making shared clinical decisions with their patients and eliminate missed opportunities for vaccination.<sup>2</sup> Nothing is intended or implied in the ACIP's adoption of the SCDM approach that adds any additional approvals or complexity that might delay the complete immunization of patients in need of vaccines. We contend, and the CDC also agrees, that pharmacists are fully capable of making these decisions independently, and therefore, do not have to get approval from another vaccine provider. Again, the ACIP clearly identifies pharmacists as among those capable of initiating and finalizing shared clinical decisions with regard to vaccines.

There is also a misunderstanding that vaccines that are identified as recommended for administration following SCDM are somehow not covered by third party insurance, including Medicare. Nothing could be further from the truth. Vaccines that are recommended for use following SCDM are "recommended." The recommendation requires a discussion with the patient, and the vaccine should not be given routinely to everyone. In fact, responsible clinical practice would point toward patient-provider communication before any treatment or intervention, and immunization is no exception. Pharmacists are advised to document that vaccination was discussed

with the patient and whether it was administered or not as a result of the patient-specific evaluation and discussion. The Affordable Care Act stipulates, and the payers understand, that an ACIP-recommended vaccine must be covered, although such coverage may not be through the pharmacy benefit; the coverage may be through the patient's medical benefit and may require referral of the patient for coverage.<sup>3</sup> It is even possible that a payer may require prior authorization to ensure that the vaccine is being used within the ACIP recommendations. Although the payment process may not be as simple as providers would hope for, vaccines with a recommendation for SCDM are covered at this time.

**Vaccines under SCDM**

We also want to address the reasoning behind the ACIP's approach to shared clinical decisions relative to the 4 vaccines for which the Committee's recommendation were adopted for SCDM by the CDC. The vaccines include the PCV-13 vaccine, human papillomavirus (HPV) vaccine, hepatitis B virus (HBV) vaccine, and meningococcal B (MenB) vaccine. Pharmacists are perhaps most aware that the CDC has taken this approach with the PCV-13 vaccine. The ACIP strives to make its recommendations based on population-based objective data using the Evidence to Recommendations (EtR) framework.<sup>4</sup> Previous data for this vaccine and its use in patients aged 65 years and above showed that immunizing all patients in this age group would prevent a substantial number of hospitalizations and deaths and represented a cost-effective public health intervention with overall societal benefit.<sup>5</sup> Thankfully, because of reduced pneumococcal carriage and infection rates resulting from a successful pediatric immunization program over the past decade, the rate of invasive pneumococcal disease in the older population has markedly declined since the routine immunization strategy of seniors was adopted in 2014. After reviewing more recent data, the ACIP found that, as a societal proposition, it was no longer beneficial for everyone over the age of 65 years to receive the vaccine.<sup>1</sup> Yet the ACIP did identify certain patients within this age group for whom, as individuals, substantial personal benefit might be realized. These patients may include those with diabetes, lung, heart, liver, or renal disease, or multiple chronic conditions that may worsen substantially when pneumococcal pneumonia strikes. Others who may benefit include individuals who smoke, those who reside in nursing homes or long-term care facilities, and those who live in settings where there is low pediatric PCV-13 vaccine uptake. A complete list of those considerations is found in Box 1 of the 2019 recommendations published in the Morbidity and Mortality Weekly Report.<sup>1</sup> Ultimately, the vaccine provider must assess this risk, discuss the risks with the patient, make a clear recommendation, and then vaccinate.

A different example of SCDM is with the HPV vaccine. In 2019 the ACIP stated, "Routine recommendations for HPV vaccination of adolescents have not changed. Catch-up HPV vaccination is now recommended for all persons through age 26 years. For adults aged 27 through 45 years, public health benefit of HPV vaccination in this age range is minimal; SCDM is recommended because some persons who are not adequately vaccinated might benefit." In these circumstances, data indicate that the greatest risk of contracting HPV is from

the first sexual contact, with the risk decreasing as one ages. While population-based strategies for routine immunization would provide little broad public health benefit, individuals who may have not been sexually active before the age 27 or who have had few sexual partners, or who may have been newly engaged in higher risk sexual activity may benefit from vaccination. This needs to be an individual decision based on patient-specific factors and an engaged conversation with the patient to determine the risks.

Another area where this strategy has been employed since 2018 is HBV vaccine in patients with diabetes. According to the CDC, adults with diabetes have a 60% higher prevalence of HBV infection and twice the chance of acquiring acute HBV as compared with the patients who do not have diabetes.<sup>6</sup> The risk of contracting HBV, even among patients with diabetes, declines sharply after the age of 60 years. As a result, the recommendation to vaccine providers is to “immunize at the discretion of the treating clinician” for those having diabetes and over the age of 60, while those having diabetes and younger than 60 years should be routinely immunized with the HBV vaccine.<sup>6,7</sup> This is simply another example of SCDM, meaning that the clinician must use his or her clinical judgment based on patient’s specific factors when determining if vaccination is appropriate for a subset of the population.

The fourth vaccine for which SCDM is part of the recommendations of the ACIP is the MenB vaccine. In fact, this vaccine was the first to implement the strategy of recommending that the vaccine provider and the patient or caregiver enter into an active process of evaluating infection risks and the benefits vaccination may provide. Dating back to April 2017, the ACIP calls this a “Category B” recommendation using a system called GRADE.<sup>8</sup> With the adoption of the EtR Framework described earlier, the ACIP no longer uses the alpha system for recommendations.<sup>4</sup> Nevertheless, a Category B recommendation for the MenB vaccine indicates that individual clinical decision making should be used in determining if the vaccine should be administered to individuals in the 16-23-year age group who are not at increased risk for meningococcal disease.<sup>9</sup> To determine the risks, a vaccine provider and the patient or parent should engage in conversation to assess the individual risk. The vaccine provider then needs to make a firm recommendation to administer the vaccine if determined appropriate.

## Conclusion

Recommendations from the CDC to use SCDM is an affirmation that the conversations we have with patients or caregivers are important. Even within the current CDC guidance on immunization activities during the severe acute respiratory syndrome coronavirus 2 (commonly referred to as COVID-19) pandemic, language regarding consideration of benefit versus risk is included, and discussion with patients or caregivers is the central element within SCDM.<sup>10</sup> Arguably, this approach encourages all vaccine providers to have more of these conversations. While some may be more comfortable with concrete algorithms for the vaccination of populations, this new approach by the CDC truly does emphasize the importance of professional autonomy. Pharmacists are health professionals who must exercise independent judgment and authority on patient-specific

recommendations for care, including vaccination decisions, as part of the Pharmacist Patient Care Process.<sup>11</sup> Employers of pharmacists must ensure that the systems and processes, many of which may be adopted at a corporate level, respect and support the autonomy of pharmacists to make these decisions, and allow pharmacists to appropriately document the care provided and vaccine(s) administered.<sup>12</sup> SCDM for vaccines, while a new approach by the CDC, is exactly what health care providers (including pharmacists) have done for decades. Pharmacists and other vaccine providers should not let a new approach slow down their efforts to prevent vaccine-preventable diseases and ensure every patient is fully immunized with every health care encounter, as recommended within the National Vaccine Advisory Committee’s Adult Immunization Practice Standards and other standards.<sup>13</sup> Failing to proactively engage in these important conversations is also a decision, one with potentially serious negative consequences leading to poor patient outcomes or worse. When in doubt, vaccinate.

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