Shared Decision-Making and Prevention Recommendations: Evolution, Implications, and Challenges for Public Health

Juliana C. Lawrence and Jason L. Schwartz

Keywords: Shared Decision-Making, Vaccination, Prevention, Policy, CDC

Abstract: Recent guidelines and recommendations from government prevention advisory groups endorsing shared clinical decision-making reflect an emerging trend among public health bodies.

In June 2019, revised recommendations for human papillomavirus (HPV) vaccination for adults 27 years and older and for the pneumococcal conjugate vaccine (PCV13) for adults 65 years and older were approved by the Advisory Committee on Immunization Practices (ACIP) to the U.S. Centers for Disease Control and Prevention (CDC). The committee declined in both cases to make a "routine" recommendation for the use of these vaccines in those age groups, instead advising that decisions be made on an individual basis through shared clinical decision-making between patients and health care providers.[1]

These actions reflect an emerging trend among public health bodies to incorporate shared clinical decision-making (SCDM or SDM) into their guidelines and recommendations. But they also raise unique considerations and complexities, particularly for vaccination, where tensions can exist between individual decision-making prerogatives and the population-level consequences of high vaccination rates in communities. SCDM recommendations reframe traditional approaches to evidence-based prevention, affect insurance coverage and patient access to preventive services, and influence patient-provider discussions and subsequent patient decision-making. Understanding the opportunities, challenges, and implications of SCDM recommendations as produced by public health advisory groups is particularly important as their use expands.

Juliana C. Lawrence, M.D., M.M.S., *is a Medicine-Pediatrics resident in the Harvard Brigham and Women's Hospital/Boston Children's Hospital Residency Program. At the time this work was completed, she was a medical student at the Yale School of Medicine.* **Jason L. Schwartz, Ph.D., M.B.E.**, *is an Associate Professor in the Department of Health Policy and Management at the Yale School of Public Health and in the Section of the History of Medicine at the Yale School of Medicine.*

Shared Decision-Making: Origins and Expansion

Since its emergence in the 1980s, shared decision-making — defined by the Department of Health & Human Services (HHS) Agency for Healthcare Research and Quality as "a model of patient-centered care that enables and encourages people to play a role in the medical decisions that affect their health" — has gained broad support in clinical settings due to its dual embrace of patient-centeredness and evidence-based medicine.[2] By facilitating open communication through which health care providers offer information on the benefits and harms of options and patients identify their preferences, both parties are thought to gain a better understanding of patient priorities and values which shape decision-making.[3] Based on the ethical principles of relational autonomy and self-determination, shared decision-making is intended to individualize medical care based on patients' priorities through physician-patient partnership.[4]

The Journal of Law, Medicine & Ethics, 49 (2021): 444-452. © 2021 The Author(s)
DOI: https://doi.org/10.1017/jme.2021.65

In clinical contexts, shared decision-making has been associated with greater patient participation and satisfaction, improved medication adherence, and decreased healthcare utilization.[5] It has been found to be particularly useful in preference-sensitive conditions, where multiple evidence-based treatment options exist but have different benefits and side-effect profiles, such as multiple sclerosis or type 2 diabetes mellitus.[6]

Reflecting its widening appeal, in 2010, the Affordable Care Act (ACA) called for the HHS to encourage shared decision-making and develop related decision aids.[7] The Centers for Medicare & Medicaid Services in 2015 mandated shared decision-making as a condition of coverage for lung cancer screening with low-dose computed tomography, and similar requirements have since been applied to other conditions.[8]

Endorsements of shared decision-making as part of prevention and public health have also gained support and recognition among governmental bodies, advisory committees, and professional organizations. In 2017, the American College of Obstetricians and Gynecologists (ACOG) recommended shared decision-making for patients and providers interpreting the at-times conflicting screening guidelines related to clinical breast exams and screening mammography published by the US Preventive Services Task Force (USPSTF), American Cancer Society, and National Comprehensive Cancer Network.[9] In its guidelines, ACOG highlighted shared decision-making as a mechanism to help patients make informed decisions consistent with their values and preferences.

Similarly, the USPSTF updated its guidelines for prostate-specific antigen (PSA) testing in 2018, recommending that decisions be made on an individual basis by patients in conjunction with their providers, thereby modifying its 2012 recommendation against PSA screening.[10] In its recommendation statement, the USPSTF stated that patients "should have an opportunity to discuss the potential benefits and harms of screening with their clinician and to incorporate their values and preferences in the decision."[11] Another 2018 USPSTF guideline emphasized shared decision-making in recommendations on screening for cervical cancer, encouraging women to make an informed choice among three specified approaches to screening.[12]

Prevention and public health guidelines endorsing SCDM, such as those published by the USPSTF and ACIP, have broad implications for patients, health care providers, payers, and health systems alike. Recommendations based on SCDM aim to embrace the ideals of shared decision-making at the population level, but endorsements of SCDM over traditional prevention recommendations introduce many challenges and complexities. Recent SCDM recommendations regarding vaccination provide a particularly illustrative setting through which to analyze the implications, opportunities, and difficulties posed by SCDM-based prevention recommendations and to identify actions that could improve their contribution to evidence-based disease prevention policy.

Shared clinical decision-making (SCDM) recommendations reframe traditional approaches to evidence-based prevention, affect insurance coverage and patient access to preventive services, and influence patient-provider discussions and subsequent patient decision-making. Understanding the opportunities, challenges, and implications of SCDM recommendations as produced by public health advisory groups is particularly important as their use expands.

Vaccination Recommendations and the Advisory Committee on Immunization Practices

The ACIP was established in 1964 to assist the CDC in developing guidance for the control of vaccine-preventable communicable diseases.[13] ACIP recommendations become official following approval by the CDC director, typically a pro forma step, and subsequent publication in *Morbidity and Mortality Weekly Report (MMWR)*.[14] ACIP recommendations profoundly impact public health nationwide, functioning as the "gold standard" for evidence-based vaccination practices, shaping patient and provider decision-making, and determining the vaccines covered by private

The Journal of Law, Medicine & Ethics, 49 (2021): 444-452. © 2021 The Author(s)

https://doi.org/10.1017/jme.2021.65 Published online by Cambridge University Press

health insurers and government vaccination programs, as discussed below.

In 2010, the ACIP adopted the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework to systematize its development of evidence-based recommendations.[15] Under this approach, vaccines most often receive a routine recommendation (previously "Category A" or "universal") by which a vaccine is advised for everyone in a specified age- or risk-based population group without a defined contraindication.

In recent years, a growing number of vaccines have instead received a non-routine recommendation in which the committee notes that a vaccine may be administered based on SCDM. (Earlier iterations of this class of recommendation were called "Category B" or "permissive" recommendations.) These SCDM recommendations avoid a general endorsement, instead encouraging shared decision-making between individual patients and health care providers regarding the use of a given vaccine. Several vaccines have both routine and SCDM recommendations for different populations, stratified by age or risk factors.

ACIP recommendations are based on an evaluation of potential benefits and savings in relation to potential harms and costs, considerations which are evaluated through the Evidence to Recommendations (EtR) framework. This analysis integrates critical outcomes, including anticipated benefits and harms of a vaccine as identified through the GRADE framework, as well as disease burden, patient values, acceptability, cost-effectiveness, and feasibility.[16] Routine recommendations for vaccination are issued when the anticipated desirable effects of a vaccine clearly outweigh the predicted undesirable effects for the specified population. Recommendations based on SCDM are adopted for various reasons, including when vaccination of a group is thought to be unlikely to produce substantial population-level impacts, but when some individuals in that group may nonetheless benefit.[17] Additional factors leading to a vaccine receiving a recommendation based on SCDM include lower confidence regarding the effect of vaccination on health outcomes, smaller anticipated net benefit, and lower or uncertain cost-effectiveness.[18]

Recent Vaccine Recommendations Endorsing Shared Clinical Decision-Making

Prior to implementing the GRADE framework, the ACIP at times adopted "permissive" recommendations (which included language such as "may be vaccinated,") instead of routine "universal" recommendations (with "should be vaccinated" language).[19] The terminology of Category A and Category B recommendations were implemented in 2010 alongside the GRADE framework; under this structure, Category B recommendations advised decision-making based on "individual clinical decision making," intending to allow providers and patients to jointly determine whether to pursue vaccination as opposed to making sweeping guidelines for populations.[20] The Category B recommendation was renamed in 2019 to the current "shared clinical decision-making" recommendation, functionally identical but including amended language intended to emphasize physician-patient partnership in decision-making rather than individual responsibility, according to the ACIP.[21]

Initially, recommendations endorsing SCDM (and its "Category B" or "permissive" predecessors) were used by ACIP principally for populations with specific risk factors. For example, the approach was employed in 2011 to recommend that adults 60 years of age and older with diabetes discuss the hepatitis B vaccine with their physicians, in tandem with a traditional recommendation that adults with diabetes less than 60 years of age be vaccinated against hepatitis B at diagnosis. ACIP cited less robust data on the risk for hepatitis B for this older age group as the impetus for these different recommendations.[22]

The SCDM approach to recommendations was also applied in the early years of human papillomavirus (HPV) vaccination. HPV vaccine was initially recommended for routine use only in females. Following Food and Drug Administration (FDA) approval of an indication for its use in males, the ACIP approved in 2009 a permissive recommendation for the quadrivalent HPV vaccine for males aged 9-26 years.[23] The recommendation noted high efficacy of the vaccine in preventing genital warts in males, good immunogenicity, and minimal adverse reactions, but lower anticipated cost-effectiveness than policies that prioritized vaccination of females.[24]

Recommendations based on SCDM were first applied to a large population group in 2015 when ACIP approved an SCDM recommendation for people aged 16-23 for vaccination against serogroup B meningococcus (MenB), a rare but potentially life-threatening bacterial infection. In its recommendation report, the committee cited a lack of information about the vaccine's long-term effectiveness, the low burden of MenB disease, minimal documented effects of vaccination on MenB carriage, and unfavorable cost-effectiveness modeling as justifications for its narrower recommendation.[25]

The ACIP has continued to adopt SCDM recommendations, most recently at its June 2019 meeting. Updating its previous guidelines on HPV vaccination, the committee recommended routine vaccination of

The Journal of Law, Medicine & Ethics, 49 (2021): 444-452. © 2021 The Author(s)

all persons aged 11-26 years, thereby harmonizing recommendations for males and females; it additionally recommended SCDM for HPV vaccination in adults aged 27-45 years.[26] In the associated GRADE report, ACIP concluded that although the population benefit of vaccination in the 27-45 year age group would be minimal, potential benefits existed for some adults at risk for HPV infections due to waning immunity, inadequate vaccination, or lifestyle-related risk factors.[27]

Also in 2019, ACIP updated guidelines for the pneumococcal conjugate vaccine (PCV13) vaccine against pneumococcus, a major cause of bacterial pneumonia and bloodstream infections, calling for SCDM for people 65 years and older without specified risk factors; this recommendation coexists with a routine recommendations for vaccination of those aged 6 weeks-71 months.[28] For PCV13, ACIP cited an unclear need for vaccination in the general 65+ age group due to the success of childhood vaccination efforts, yet noted that the vaccine may still be beneficial to some members of this older population.[29]

Effects of SCDM Recommendations for Insurance Coverage and Patient Access

ACIP recommendations shape public and private insurance coverage of vaccines, directly affecting patient access and affordability. As part of the ACA, private health insurance plans are required to cover all ACIP-recommended vaccines without patient cost-sharing, including coinsurance, copayments, or deductibles. This requirement includes vaccines recommended based on SCDM in addition to those with a traditional, routine recommendation.[30] New ACIP recommendations are also reflected in coverage updates for the Medicare program for older Americans, most commonly through Medicare Part D, though some are covered by Medicare Part B with no cost-sharing for patients.[31] This coverage requirement for both routine and SCDM recommendations stands in contrast to the coverage implications of narrower recommendations of the USPSTF. Recommendations from that group endorsing shared clinical decision-making ("Grade C") for a specific preventive service do not qualify for first-dollar coverage under the ACA and private insurance coverage is not mandated.[32]

ACIP recommendations additionally have implications for the Vaccines for Children (VFC) program. That federal program purchases all ACIP-recommended vaccines and distributes them via state and local health departments to health care providers at no cost for children through 18 years of age who are eligible for Medicaid, uninsured, underinsured, or American Indian or Alaska Native, representing approximately half of all childhood vaccine doses.[33] The ACIP is empowered to add vaccines to the VFC program and does so immediately following the approval of new recommendations. As with the ACA coverage requirement, the VFC program includes vaccines that are routinely recommended and those recommended based on SCDM.

ACIP recommendations also inform adult vaccine coverage through Medicaid, although the precise mechanisms through which adoption occurs vary among states. Some expressly follow ACIP recommendations, while others include an evaluation of ACIP guidance alongside state health agency recommendations, recommendations from medical professional societies, or the determinations of Medicaid managed care organizations.[34] Recommendations based on SCDM can adversely affect vaccine access for adult Medicaid beneficiaries, unlike those for whom coverage for vaccines comes from other programs. For example, serogroup B meningococcal vaccines are covered by fewer state Medicaid programs than is the meningitis ACWY vaccine, which protects against other types of meningococcal bacteria and is recommended for routine use by the ACIP.[35]

Implications of SCDM-Based Recommendations

By adopting recommendations that endorse SCDM as opposed to more familiar and broader "routine" recommendations, public health agencies and their expert advisory committees aim to acknowledge limited available data or inconclusive findings regarding key considerations such as long-term effectiveness, risk-benefit ratios, or safety; recognize scenarios in which population-level anticipated benefits are modest because of the low prevalence of a condition or other factors; respond to unfavorable economic analyses; and yet preserve financial access through recommendations that facilitate insurance coverage for those interventions.[36]

For the vaccines discussed above, the principal justifications for SCDM-based recommendations varied, yet each case reflects the challenge of generating clear public health guidance in the context of limited evidence of benefit for a low-risk intervention among a specific population. Pending the emergence of additional data regarding vaccine efficacy, immunogenicity, disease burden, or cost-effectiveness, SCDM recommendations present the current evidence but effectively affirm the status quo, since any vaccine approved by the FDA — as all ACIP-recommended vaccines are — is already available for providers to use at their discretion and in discussion with their patients.

Recommendations based on SCDM nonetheless promote patients' active participation in discussions

The Journal of Law, Medicine & Ethics, 49 (2021): 444-452. © 2021 The Author(s)

of their values and priorities in the context of an evaluation of the benefits, risks, and uncertainty associated with specific preventive interventions. By encouraging dialogue between patients and providers, these recommendations — if implemented in a manner consistent with their design and intent—work toward the original goals of the shared decision-making movement: patient-centeredness coupled with evidence-based medicine.

However, surveys of health care providers report a general lack of familiarity with SCDM recommendations and difficulty communicating these recommendations to patients. A 2018 survey of pediatric primary care providers found that only 24% could correctly define the Category B vaccination recommendation (prior to its recent renaming).[37] Clear provider recommendations have been found to be highly influential in patient or parental vaccination decisions, and missed opportunities for vaccination are more likely when providers have difficulty communicating relevant recommendations or correctly conveying the implications of a government recommendation for insurance coverage.[38]

Many providers who offer vaccines recommended based on SCDM are not aware of insurance coverage requirements that facilitate access and affordability. In the same survey, 55% of providers did not know that private insurance would pay for vaccines recommended based on SCDM, and 51% did not know that these vaccines were covered by VFC.[39] Because of this knowledge gap, vaccination opportunities may be missed due to unfounded affordability concerns.

Perhaps as a result of these knowledge deficits, recent studies have found that SCDM recommendations are not being implemented as intended. In one survey of providers, only 7% reported using individual clinical decision-making to decide whether to administer vaccines against MenB; instead, most providers simply chose to recommend or not recommend the vaccine to all of their patients or to recommend it only to patients with certain risk factors.[40] Less than half of providers indicated that they "almost always" provided educational materials or discussed that vaccine with their patients.[41]

SCDM recommendations are associated with lower vaccination rates than comparable vaccines or population groups for which traditional, routine recommendations are in place. For example, among individuals with diabetes, hepatitis B vaccination coverage (r3 doses) is 26.3% for individuals aged 19–59 years, the group for whom there is a routine recommendation. For individuals with diabetes aged r60 years — for whom the vaccine is recommended based on SCDM — hepatitis B vaccination rates is 13.9%.[42] Similarly, while 88.9% of adolescents have received 1 or more doses of the routinely-recommended meningococcal serogroups A, C, W, and Y vaccine, which has a routine recommendation, 21.8% of adolescents have received 1 or more doses of the serogroup B meningococcal vaccine, which has a SCDM-based recommendation.[43]

Potential Consequences for Health Disparities and Health Equity

Although vaccination rates in the United States generally remain high, disparities have been observed by race, ethnicity, sociodemographic status, and insurance status for many vaccines among adults and children alike.[44] These findings are consistent with health disparities and health equity concerns identified throughout health care in the United States.[45] Although the VFC program has improved vaccination rates and immunization equity among children, disparities persist, and some, such as those related to income, have increased for certain vaccines.[46] These disparities are thought to be associated with a number of factors including structural inequality, likelihood of seeking or accepting vaccination, disparate attitudes towards immunization and prevention, variations in provider recommendations, and quality of primary care.[47] Ethnic and racial minorities are also more likely to be uninsured or underinsured, adding to financial barriers to vaccination, particularly among adults.[48]

ACIP recommendations are directed toward populations on the basis of age, risk factors, or, in select cases, sex, rather than sociodemographic factors such as race or insurance status. Exceptions to this approach are exceedingly rare, such as the 2019 recommendation for hepatitis A vaccination for individuals experiencing homelessness.[49] However, the real-world implementation of traditional, routine recommendations compared to those prioritizing SCDM may inadvertently affect how prevention is framed and delivered to underserved populations or those with substantial barriers to care. There are well documented associations between such groups and economic status, race, and ethnicity. Understanding the potential effects of SCDM-based recommendations is therefore all the more important as its use increases for vaccination and other preventive services.

Opting against routine recommendations in favor of the flexibility, provider discretion, and meaningful patient-provider dialogues envisioned by SCDM-based recommendation leaves open the possibility of differences in vaccination practices among health care providers that may increase already-present disparities in vaccination rates. The substantive discussions of evidence, values, and preferences envisioned by SCDM recommendations are increasingly difficult to

The Journal of Law, Medicine & Ethics, 49 (2021): 444-452. © 2021 The Author(s)

perform in today's primary care settings, where time constraints and multiple competing health concerns are among the many factors that may limit opportunities for such dialogues. This risk is particularly acute among low-income, Medicaid-eligible, and minority populations that already face numerous obstacles to the delivery of recommended care, preventive or otherwise.[50] A recent study found an association between patient ethnicity and the likelihood of receiving a meningitis B vaccination, for example, with Hispanic and African-American patients less likely to receive the vaccine.[51]

Provider knowledge regarding financial coverage for vaccines with an SCDM recommendation could also disproportionately affect patients who are underinsured or uninsured, potentially exacerbating existing vaccination disparities among those with public, private, or no insurance.[52] Patient insurance type has also been associated with the probability of adolescents receiving a meningitis B vaccine, despite the provisions common to public and private insurance programs that facilitate patient affordability among its target age group.[53]

Strengthening the Effectiveness of Shared Decision-Making Recommendations in Prevention

Shared clinical decision-making recommendations aim to offer balanced, evidence-based guidance and to apply the ideals of shared decision-making to public health and prevention. However, additional efforts are required for these recommendations to achieve the goals of their proponents and to support public health and prevention efforts most effectively.

Formally Reassess SCDM-Based Guidelines on a Regular Basis

The work of advisory bodies such as ACIP and USPSTF in developing rigorous, accurate, evidence-based guidelines is complicated by uncertainty and limited or evolving evidence. Periodically and formally revisiting guidelines in light of new evidence is therefore essential to ensuring that recommendations reflect current evidence and best practices. However, there is currently no regular timeline or cycle for individual recommendations to be reviewed or revisited by the ACIP. While the committee on occasion commits to revisiting a recommendation in select cases, as occurred for the PCV13 vaccine at its 2014 committee meeting, it generally reviews existing recommendations periodically on an as-needed basis and as its workload permits.[54]

Timely reassessment is especially important for vaccines recommended based on SCDM, as uncertainty or limited evidence regarding the effects of vaccination on health outcomes, duration of protection, or cost-effectiveness may contribute to the initial adoption of such a recommendation.[55] Implementing a formal schedule for revisiting SCDM recommendations (such as every 5 years) would ensure that guidelines reflect the most up-to-date evidence on vaccine effectiveness, disease burden, vaccination-related effects on disease incidence, and uptake, permitting the ACIP to determine whether the SCDM recommendation is still appropriate. Additionally, formal reassessment cycles would provide an opportunity to synthesize recent research and to explicitly articulate specific factors — such as patient characteristics, exposures, and comorbidities — that providers should note with their patients as part of shared decision-making conversations.

Support Research Examining Potential Associations Between SCDM Recommendations and Disparities in Vaccination Coverage

To ensure that recommendations endorsing SCDM are promoting health equity, government public health agencies whose advisory bodies are responsible for these guidelines should support and facilitate research examining the potential effects of SCDM recommendations on disparities in access to vaccines and other interventions. Evaluating the administration of vaccines and other interventions recommended for SCDM stratified by sociodemographic factors such as race, ethnicity, and insurance status would enhance the evidence base regarding potential differences in delivery, insurance coverage effects, and disparate provider practices associated with these recommendations. Such research would enable the CDC, ACIP, USPSTF, and other public health bodies to better understand effects of their recommendations in specific groups and to amend or clarify them, as needed.

By providing a more comprehensive and nuanced understanding of current vaccination disparities specifically associated with SCDM-based recommendations, such research findings could support targeted investments of additional resources — financial, educational, or otherwise — to communities most impacted by disparate vaccination uptake.

Enhance Provider Education Through Updated and Expanded Continuing Medical Education Offerings

In order for guidelines based on SCDM to achieve their intended objectives, providers must be informed about this class of recommendations, their translation to practice, and their implications for patient access and affordability through public and private insurance or inclusion in government-supported programs.

The Journal of Law, Medicine & Ethics, 49 (2021): 444-452. © 2021 The Author(s)

Public health bodies like the CDC, with support from medical and public health professional societies, should offer and expand continuing medical education (CME) activities that discuss SCDM-recommendations and their relevance for patients and providers. Such educational programs should be updated regularly to reflect current evidence and provide information regarding consequences of these recommendations for patient coverage through health insurance or federal programs.

These CME offerings should additionally include state-specific information related to Medicaid coverage to provide more tailored information about access for adults. Improving provider education would address the knowledge gaps and divergent interpretations of SCDM recommendations identified in recent research.

Develop Shared Decision-Making Aids to Better Inform Discussions Between Patients and Health Care Providers

CDC should collaborate with medical professional societies to develop shared decision-making tools that facilitate informed conversations between patients and providers for any vaccine with an SCDM recommendation. Similar resources should be produced or supported by other entities issuing comparable recommendations, including the USPSTF. Assisting providers with approaches to meaningful shared decision-making is essential to such recommendations functioning as intended and minimizing associated disparities.[56]

Potential shared decision-making tools include accessible, interactive decision aids describing risks and benefits of specific vaccines or other preventive interventions. In other contexts, decision aids have been shown to improve patient knowledge, encourage patient engagement, and decrease distress related to medical decision-making.[57] Additional resources could include in-office decision aid handouts for patients, patient education materials, and short videos or informational brochures guiding health care providers on facilitating shared decision-making conversations with patients for SCDM-recommended interventions.

Through these materials, patients would be better positioned to have productive conversations with health care providers regarding SCDM-recommended interventions, and providers would have additional resources available to them to facilitate those discussions. Materials developed to support shared clinical decision-making for vaccines and other types of prevention should be systematically studied to assess their effects on patient understanding and decision-making.

Conclusion

Prevention recommendations that endorse shared clinical decision-making seek to extend to areas of public health the enthusiasm and possibilities of shared decision-making initially found in the context of clinical care. When applied to national guidelines and recommendations for vaccines and other preventive interventions, they allow for greater flexibility and accommodation, particularly when evidence is limited or benefits are likely only for portions of a recommended population.

However, calls for shared decision-making instead of more familiar, routine recommendations for the use of vaccines or other preventive interventions present unique challenges and complexities, including decreased provider familiarity and understanding, potential access barriers, and the potential to exacerbate existing health disparities. As the prominence of shared decision-making in prevention and public health guidelines grows, additional efforts would be valuable in strengthening the effectiveness of these recommendations for public health policy-makers, expert advisory committees, health care providers, and patients alike.

Acknowledgements

Support for this publication came from the Yale School of Medicine Medical Student Fellowship, the Jane Danowski Weiss Family Foundation Fund, and the G. D. Hsiung, Ph.D. Student Research Fellowship.

Note

The authors have no conflicts of interest to disclose.

References

1. E. Meites, P. G. Szilagyi, and H. W. Chesson, et al., "Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices," *Morbidity and Mortality Weekly Report (MMWR)* 68, no. 32 (2019): 698-702; A. Matanock, G. Lee, and R. Gierke, et al., "Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged >/=65 Years: Updated Recommendations of the Advisory Committee on Immunization Practices," *Morbidity and Mortality Weekly Report (MMWR)* 68, no. 46 (2019): 1069-1075.
2. T. C. Hoffmann, V. M. Montori, and C. Del Mar, "The Connection Between Evidence-Based Medicine and Shared Decision Making," *JAMA* 312, no. 13 (2014): 1295-1296; Agency for Healthcare Research and Quality, *The CAHPS Ambulatory Care Improvement Guide* (Washington, DC: Agency for Healthcare Research and Quality: 2017).
3. G. Elwyn, D. Frosch, and R. Thomson, et al., "Shared Decision Making: A Model for Clinical Practice," *Journal of General Internal Medicine* 27 (2012): 1361-1367.
4. *Id.*
5. D. Flynn, M.A. Knoedler, and E .P. Hess, et al., "Engaging Patients in Health Care Decisions in the Emergency Department Through Shared Decision-Making: A Systematic Review," *Academic Emergency Medicine* 19, no. 8 (2012): 959-967; F. Legare, M. Labrecque, and M. Cauchon, et al., "Train-

The Journal of Law, Medicine & Ethics, 49 (2021): 444-452. © 2021 The Author(s)

https://doi.org/10.1017/jme.2021.65 Published online by Cambridge University Press

ing Family Physicians in Shared Decision-Making to Reduce the Overuse of Antibiotics in Acute Respiratory Infections: A Cluster Randomized Trial," *Canadian Medical Association Journal* 184, no. 13 (2012): E726-734; K. M. Kew, P. Malik, and K. Aniruddhan, et al., "Shared Decision-Making for People with Asthma," *Cochrane Database of Systematic Reviews* 10 (2017): CD012330.
6. E. Colligan, A. Metzler, and E. Tiryaki, "Shared Decision-Making in Multiple Sclerosis," *Multiple Sclerosis* 23, no. 2 (2017): 185-190; A. C. Shillington, N. Col, and R. A. Bailey, "Development of a Patient Decision Aid for Type 2 Diabetes Mellitus for Patients Not Achieving Glycemic Control on Metformin Alone," *Patient Preference Adherence* 9 (2015): 609-617.
7. Patient Protection and Affordable Care Act, 42 USC 18001, §3506 amended in §936 [42 USC §299b-36] (2010).
8. F. M. Merchant, N. W. Dickert, Jr., and D. H. Howard, "Mandatory Shared Decision Making by the Centers for Medicare & Medicaid Services for Cardiovascular Procedures and Other Tests," *JAMA* 320, no. 7 (2018): 641-642.
9. Committee on Practice Bulletins — Gynecology, "Practice Bulletin Number 179: Breast Cancer Risk Assessment and Screening in Average-Risk Women," *Obstetrics Gynecology* 130, no. 1 (2017): e1-e16.
10. U. S. Preventive Services Task Force, D. C. Grossman, S. J. Curry, et al., "Screening for Prostate Cancer: US Preventive Services Task Force Recommendation Statement," *JAMA* 319, no. 18 (2018): 1901-1913.
11. U.S. Preventive Services Task Force, D. C. Grossman, S. J. Curry, et al., "Screening for Prostate Cancer: US Preventive Services Task Force Recommendation Statement," *JAMA* 319, no. 18 (2018): 1901-1913.
12. U.S. Preventive Services Task Force, S. J. Curry, A. H. Krist, et al., "Screening for Cervical Cancer: US Preventive Services Task Force Recommendation Statement," *JAMA* 320, no. 7 (2018): 674-686.
13. J. L. Schwartz and A. Mahmoud, "A Half-Century of Prevention — The Advisory Committee on Immunization Practices," *New England Journal of Medicine* 371, no. 21 (2014):1953-1956.
14. L. K. Pickering, H. C. Meissner, and W.A. Orenstein et al., "Principles of Vaccine Licensure, Approval, and Recommendations for Use," *Mayo Clinic* Proceedings 95, no. 3 (2020): 600-608.
15. G. Lee, W. Carr, and ACIP Evidence-Based Recommendations Work Group, "Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices," *Morbidity and Mortality Weekly Report (MMWR)* 67, no. 45 (2018): 1271-1272.
16. Centers for Disease Control and Prevention, "Evidence to Recommendations Frameworks," *Advisory Committee on Immunization Practices (ACIP)* 2020, *available at* <https://www.cdc.gov/vaccines/acip/recs/grade/etr.html> (last visited July 21, 2020).
17. U.S. Department of Health & Human Services, ACIP Shared Clinical Decision-Making Recommendations, 2020, *available at* <https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html> (last visited August 22, 2021).
18. F. Ahmed, J. L. Temte, and D. Campos-Outcalt, et al., "Methods for Developing Evidence-Based Recommendations by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC)," *Vaccine* 29, no. 49 (2011): 9171-9176.
19. A. Kempe, M. A. Allison, and J. R. MacNeil, et al. "Knowledge and Attitudes Regarding Category B ACIP Recommendations Among Primary Care Providers for Children," *Academic Pediatrics* 18, no. 7 (2018): 763-768.
20. See *supra* note 18.
21. Advisory Committee on Immunization Practices, "Summary Report," Paper presented at Meeting of the Advisory Committee on Immunization Practices, June 2019, in Atlanta, Georgia. Copy in author's personal files.
22. Centers for Disease Control and Prevention, "Use of Hepatitis B Vaccination for Adults with Diabetes Mellitus: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *Morbidity and Mortality Weekly Report (MMWR)* 60, no. 50 (2011): 1709-1711.
23. Centers for Disease Control and Prevention, "FDA Licensure of Quadrivalent Human Papillomavirus Vaccine (HPV4, Gardasil) for Use in Males and Guidance from the Advisory Committee on Immunization Practices (ACIP)," *Morbidity and Mortality Weekly Report (MMWR)* 59, no. 20 (2010): 630-632.
24. *Id.*
25. J. R. MacNeil, L. Rubin, and T. Folaranmi, et al., "Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices," *Morbidity and Mortality Weekly Report (MMWR)* 64, no. 41 (2015): 1171-1176.
26. Meites et al., *supra* note 1.
27. *Id.*
28. Matanock et al., *supra* note 1.
29. *Id.*
30. Kempe et al., *supra* note 19.
31. Centers for Disease Control and Prevention, "Resources for Adult Vaccination Insurance and Payment" *available at* <https://www.cdc.gov/vaccines/hcp/adults/for-practice/insurance-payment.html> (last visited August 21, 2021).
32. H. Bauchner, P. B. Fontanarosa, and R. M. Golub, "Welcomes the US Preventive Services Task Force," *JAMA* 315, no. 4 (2016): 351-352.
33. B. Walsh, E. Doherty, and C. O'Neill, "Since The Start Of The Vaccines For Children Program, Uptake Has Increased, And Most Disparities Have Decreased," *Health Affairs (Millwood)* 35, no. 2 (2016): 356-364; J. L. Schwartz and J. Colgrove, "The Vaccines for Children Program at 25 — Access, Affordability, Sustainability," *New England Journal of Medicine* 382, no. 24 (2020): 2277-2279.
34. A.M. Stewart, M. C. Lindley, and K. H. Chang, et al., "Vaccination Benefits and Cost-Sharing Policy for Non-Institutionalized Adult Medicaid Enrollees in the United States," *Vaccine* 32, no. 5 (2014): 618-623.
35. C. J. Granade, R. F. McCord, and A.A. Bhatti, et al., "State Policies on Access to Vaccination Services for Low-Income Adults," *JAMA Network Open* 3, no. 4 (2020): e203316.
36. Meites et al., *supra* note 1; Matanock et al., *supra* note 1; Advisory Committee on Immunization Practices, Summary Report, *supra* note 21; MacNeil et al., *supra* note 25.
37. Kempe et al., *supra* note 19.
38. J. L. Moss, P.L. Reiter, and B. K. Rimer, et al., "Collaborative Patient-Provider Communication and Uptake of Adolescent Vaccines," *Social Science & Medicine* 159 (2016): 100-107.
39. Kempe et al., *supra* note 19.
40. L. Huang, A. Goren, and L. K. Lee, et al., "Disparities in Healthcare Providers' Interpretations and Implementations of ACIP's Meningococcal Vaccine Recommendations," *Human Vaccines & Immunotherapeutics* 16, no. 4 (2020): 933-944.
41. *Id.*
42. W.W. Williams, P.J. Lu, and A. O'Halloran, et al., "Vaccination Coverage Among Adults, Excluding Influenza Vaccination — United States, 2013," *Morbidity and Mortality Weekly Report (MMWR)* 64, no. 4 (2015): 95-102.
43. L.D. Elam-Evans, D. Yankey, and J. A. Singleton, et al., "National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2019," *Morbidity and Mortality Weekly Report (MMWR)* 69 (2020): 1109–1116.
44. P. J. Lu, A. O'Halloran, and W. W. Williams, et al., "Racial and Ethnic Disparities in Vaccination Coverage Among Adult Populations in the U.S.," *American Journal of Preventive* Medicine 49, no. 6 (Supplment 4) (2015): S412-425; H. A. Hill, D. Yankey, and L. D. Elam-Evans, et al., "Vaccination Coverage by Age 24 Months Among Children Born in 2016 and 2017 - National Immunization Survey-Child, United States, 2017-2019," *Morbidity and Mortality Weekly Report (MMWR)* 69, no. 42 (2020): 1505-1511.

The Journal of Law, Medicine & Ethics, 49 (2021): 444-452. © 2021 The Author(s)

45. A. F. Brown, G. X. Ma, and J. Miranda, et al., "Structural Interventions to Reduce and Eliminate Health Disparities," *American Journal of Public Health* 109, supplement 1 (2019): S72-S78.
46. Walsh et al., *supra* note 33.
47. Lu et al, *supra* note 44.
48. *Id*.
49. M. Doshani, M. Weng, and K. L. Moore, et al., "Recommendations of the Advisory Committee on Immunization Practices for Use of Hepatitis A Vaccine for Persons Experiencing Homelessness," *Morbidity and Mortality Weekly Report (MMWR)* 68 (2019): 153–156.
50. A. H. Pieterse, A. M. Stiggelbout, and V. M. Montori, "Shared Decision Making and the Importance of Time," *JAMA* 322, no. 1 (2019): 25-26.
51. Huang et al., *supra* note 40.
52. Lu et al., *supra* note 44.
53. Huang et al., *supra* note 40.
54. P. Sacco, K. Myers, and C. Poulos, et al., "Preferences for Adult Pneumococcal Vaccine Recommendations Among United States Health Care Providers," *Infectious Diseases and Therapy* 8, no. 4 (2019): 657-670.
55. Ahmed et al., *supra* note 18.
56. Huang et al., supra note 40.
57. A. M. O'Connor, D. Stacey, and R. Rovner, et al., "Decision Aids for People Facing Health Treatment or Screening Decisions," *Cochrane Database of Systematic Reviews* 3 (2001): CD001431.

The Journal of Law, Medicine & Ethics, 49 (2021): 444-452. © 2021 The Author(s)