CDC Guideline Development and Reporting Checklist

The *CDC Guideline Development and Reporting Checklist* (GDRC) will help you develop guidelines that comply with well-known standards used by most recognized guideline authorities in the world. The World Health Organization (WHO) defines a guideline as:

> *"A guideline is a document that contains recommendations about health interventions, whether they be clinical, public health, or policy interventions. A recommendation provides information about what policy makers, health care providers, or patients should do. It implies a choice between different interventions that have an impact on health and that have ramifications for the use of resources."*[1]

CDC's guidelines and recommendations vary in content, scope, audience, and development methods. The style will also vary depending on how the document is distributed and accessed. Venues for CDC guidelines include *Morbidity and Mortality Weekly Report* (and *Recommendations and Reports*), peer-reviewed journals, and CDC-branded and partner publications. CDC's Office of the Associate Director for Science (OADS) recognizes that one reporting template for all CDC guidelines is neither practical nor sufficient. Yet by identifying key elements that each report should contain, we enhance transparency, clarity, and credibility. These key elements are indicated in the checklist that follows. The elements were adapted from the *CDC Primer*, developed by the CDC Guidelines and Recommendations Work Group in 2012.[2] CDC-OADS clearance officials also use the checklist when reviewing and clearing guidelines and recommendations. Each element includes an example from a published guideline, followed by a text box titled "Type description here." This allows guideline developers to use the checklist as a working document.

Guideline developers should determine the appropriate process for developing the guidelines, such as creating an internal working group or involving subject matter experts outside CDC to develop material or to review and approve the guideline. This may be done ad hoc by creating a larger working group and steering committee or by using a committee already chartered under the Federal Advisory Committee Act (FACA). Guideline developers should first determine whether their proposed guidelines is subject to the Federal Advisory Committee Act (FACA). To find out if FACA applies, contact the MASO Federal Advisory Committee Policy and Oversight Team (CDC) at facmp&o@cdc.gov or by calling (770) 488-4707. Regardless of whether FACA rules apply, guideline developers should follow this checklist to improve the quality of the guidelines and to ensure CDC OADS clearance is obtained.

When reporting guidelines, the style you select will depend on the audience, publication venue, and intended use. Guideline developers must use their best judgment in deciding how to report key

---

[1] World Health Organization (WHO) handbook for guideline development. 2nd Edition. Guidelines as Topic – standards. 2.Review. 3.Meta-Analysis. 4.Peer Review. 5.Evidence-Based Medicine. 6.World Health Organization. I.World Health Organization. ISBN 978 92 4 154896 0 (NLM classification: WA 39).

[2] CDC, Office of the Associate Director for Science. Guidelines and Recommendations: A CDC Primer, 2012.

information. Some information will require detailed description, and presentation format may vary. For example, detailed technical material may be put in appendices. A short-version document may be used to report the recommendations and summarize the methods used, whereas a longer, technical document may be used to report detailed descriptions of searches and evidence tables. Short versions need to provide enough detail so that readers can understand the rationale behind the development process and can locate supplemental information reported in electronic or printed documents.

You may contact the Guidelines and Recommendation Activity Team located in the OADS, Office of Science Quality for a consultation at any stage of the guideline development process.

For more information about the Guidelines and Recommendations Activity, resources and tools, and training, visit the Office of the Associate Director for Science Guidelines and Recommendations Activity site.

Vilma Carande-Kulis, PhD, MS

vcarande-kulis@cdc.gov

404-639-4691

Dyann Matson Koffman, DrPH, MPH, CHES

dmatsonkoffman@cdc.gov

404-639-4783

Farah M Chowdhury, MD, MPH

fchowdhury1@cdc.gov

404-639-3170

Table of Contents: CDC Guideline Development and Reporting Checklist

Scope and Purpose

1. ☒[2] Describe needs and objectives.

Example of overall needs and objectives: *"Annual influenza vaccination is the primary means of preventing influenza and its complications. There are many types of influenza vaccines, and the naming conventions have evolved over time. Routine annual influenza vaccination for all persons aged ≥6 months who do not have contraindications has been recommended by the CDC and CDC's Advisory Committee on Immunization Practices (ACIP) since 2010 (5). This report provides updated recommendations and guidance for vaccination providers regarding the use of influenza vaccines for the 2013–14 season."* Source: Centers for Disease Control and Prevention. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2013–2014. *MMWR Morb Mortal Wkly Rep.* 2013;62(No. RR-07):1–43.

Type description here.

2. ☒ Describe target population and settings.

Example of target population: *"This report contains CDC guidance that augments the 2011 recommendations of the Advisory Committee on Immunization Practices (ACIP) for evaluating hepatitis B protection among health-care personnel (HCP) and administering post-exposure prophylaxis. Explicit guidance is provided for persons working, training, or volunteering in health-care settings who have documented hepatitis B (HepB) vaccination years before hire or matriculation (e.g., when HepB vaccination was received as part of routine infant [recommended since 1991] or catch-up adolescent [recommended since 1995] vaccination)."* Source: Centers for Disease Control and Prevention. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management MMWR 2013;62(RR-10):1–19. ---------- ***Example of setting(s):*** *"This guidance applies but is not limited to HCP in acute-care hospitals, long-term–care facilities (e.g., nursing homes, skilled nursing facilities, and assisted living facilities), physician's offices, dental offices, rehabilitation centers, urgent-care centers, ambulatory surgical centers, dialysis centers, and outpatient clinics, and to persons who provide home health care and emergency medical services."*

[2] A checked off box indicates that element is critical for clearance.

Source: Centers for Disease Control and Prevention. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. *MMWR Morb Mortal Wkly Rep*. 2013;62(RR-10):1–19.

Type description here.

3. ☒ Describe audience.

Example of intended audience statement:

"These recommendations are meant to serve as a source of clinical guidance for health-care providers; health-care providers should always consider the individual clinical circumstances of each person seeking family planning services. This report is not intended to be a substitute for professional medical advice for individual patients; persons should seek advice from their health-care providers when considering family planning options."

Source: Centers for Disease Control and Prevention. U.S. Selected Practice Recommendations for Contraceptive Use. *MMWR Morb Mortal Wkly Rep.* 2013;62(No. RR-5).

Type description here.

4. ☒ State whether guidelines and recommendations are new or an update; *for updates, indicate how they add to or differ from current guidelines*.

Example of how new guidelines add to or differ from previous guidelines:

"CDC initiated a formal adaptation process to create U.S. SPR, using both the second edition of WHO SPR (6) and the 2008 update (7) as the basis for the U.S. version. Although much of the guidance is the same as the WHO guidance, the recommendations are specific to U.S. family planning practice. In addition, guidance on contraceptive methods not available in the United States has been removed, and four new topics for guidance have been added (the effectiveness of female sterilization, extended use of combined hormonal methods and bleeding problems, starting regular contraception after use of emergency contraception, and determining when contraception is no longer needed)."

Source: Centers for Disease Control and Prevention. U.S. Selected Practice Recommendations for Contraceptive Use. *MMWR Morb Mortal Wkly Rep.* 2013;62(No. RR-5):1–60.

Type response here.

Participants and Competing Interests

5. ☒ State whether a federal advisory committee oversaw the development or approved the recommendations.

Example of statement of federal advisory committee responsible for, overseeing the development, or approving the recommendations: *"ACIP is chartered as a federal advisory committee to provide expert external advice and guidance to the Director of CDC on use of vaccines and related agents for the control of vaccine-preventable diseases in the civilian population of the United States. Recommendations for routine use of vaccines in children and adolescents are harmonized to the greatest extent possible with recommendations made by the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists. Recommendations for routine use of vaccines in adults are reviewed and approved by the American College of Physicians (ACP), AAFP, the American College of Obstetricians and Gynecologists, and the American College of Nurse-Midwives. ACIP recommendations adopted by the CDC Director become agency guidelines on the date published in MMWR."* Source: Centers for Disease Control and Prevention. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2013–2014. *MMWR Morb Mortal Wkly Rep*. 2013;62(No. RR-07):1–43.

Type response here.

6. ☒ List names, credentials, and affiliations of members of the steering committee.[3]

Example of steering committee list: *"U.S. Selected Practice Recommendations for Contraceptive Use Participants CDC Steering Committee: Kathryn M. Curtis, PhD (Chair), Denise J. Jamieson, MD, Polly A. Marchbanks, PhD, Naomi K. Tepper, MD, CDC, Atlanta, Georgia."* Source: Centers for Disease Control and Prevention. U.S. Selected Practice Recommendations for Contraceptive Use. *MMWR Morb Mortal Wkly Rep*. 2013;62(No. RR-5):1–60.

List steering committee members here.

[3] The steering committee are the people who oversaw development and authored, reviewed, and approved recommendations, including contact information for the guideline's corresponding author.

7. ☒ List names, credentials, and affiliations of the members of the work group.[4]

Example of work group list:

ACIP Adult Immunization Work Group

Work Group Chair: Tamera Coyne-Beasley, MD, Chapel Hill, North Carolina (ACIP)

Work Group Members: Tammy Clark, Jackson, Mississippi; Kathleen Harriman, PhD, Richmond, California; Molly Howell, MPH, Bismarck, North Dakota; Laura Pinkston Koenigs, MD, Springfield, Massachusetts; Marie-Michele Leger, MPH, Alexandria, VA; Susan M. Lett, MD, Boston, Massachusetts; Robert Palinkas, MD, Urbana, Illinois; Diane Peterson, Saint Paul, Minnesota; Gregory Poland, MD, Rochester, Minnesota; Laura E. Riley, MD, Boston, Massachusetts; William Schaffner, MD, Nashville, Tennessee; Kenneth Schmader, MD, Durham, North Carolina; Litjen Tan, PhD, Chicago, Illinois; JonathanL. Temte, MD, PhD, Madison, Wisconsin; Richard Zimmerman, MD, Pittsburgh, Pennsylvania.

Work Group Contributors (CDC): Lisa Grohskopf, MD, Craig Hales, MD, Charles LeBaron, MD; Jennifer L. Liang, DVM, Lauri Markowitz, MD; Matthew Moore, MD; Amy Parker Fiebelkorn, MSN, MPH; Sarah Schillie, MD; Raymond A. Strikas, MD, MPH; and Walter W. Williams, MD, Atlanta, Georgia.

Work Group Secretariat (CDC): Carolyn B. Bridges, MD, Atlanta, Georgia

Source: Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices (ACIP) Recommended Immunization Schedules for Persons Aged 0 Through 18 Years and Adults Aged 19 Years and Older—United States. *MMWR Morb Mortal Wkly Rep.* 2013;62(Suppl 1):1–17.

List work group members here.

[4] The members of the work group are the people who planned, searched for, selected, reviewed, summarized, and reported on the evidence, or wrote or approved the CDC guideline.

8. ☒ Disclose competing interests (i.e., financial and other interests)
(Contact the OADS/GRA Team for document: *Developing Disclosure of Competing Interest Statements for CDC Guidelines & Recommendations*).

Example of a disclosure of competing interest:

"The developers of these guidelines wish to disclose that they have no financial interests or other competing interests with the manufacturers of commercial products or suppliers of commercial services related to vaccines including any related to hepatitis B vaccines, with the following exceptions: D W, MD, wishes to disclose that he served as a consultant and on a speakers' bureau, whether paid or unpaid (e.g., travel related reimbursement, honoraria), for the following vaccine manufacturers: Merck, Sanofi, and Pfizer pharmaceutical companies. A B M, MD, also wishes to disclose that she received grant funding from the following pharmaceutical companies: MedImmune, Sanofi, and Merck."

Source: Adapted from the following published guideline—Centers for Disease Control and Prevention. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. *MMWR Morb Mortal Wkly Rep.* 2013;62(RR-10):1–19.

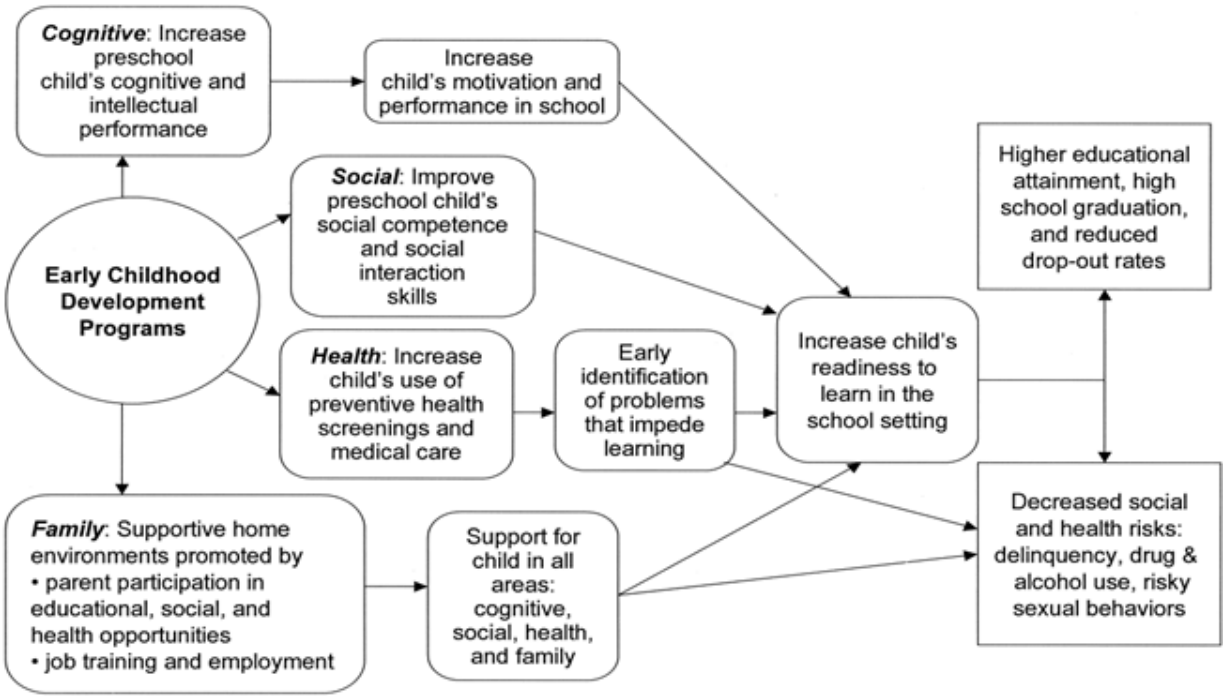
Disclose competing interests here.

Methods Used to Obtain and Summarize the Evidence

9. ☐ Describe logic model or framework linking recommendations to outcomes.

Example of a logic model for Early Childhood Development Programs:

Figure 1, Caption: Early Childhood Development Programs Logic Model Example



Source: Anderson L M, et al. and the Task Force on Community Preventive Services. The effectiveness of early childhood development programs. *American Journal of Preventive Medicine*. 2003;24(3) Suppl:32–46.

Type description here.

10. ☐ Describe questions related to guideline topic for systematic literature review.

Example of questions related to guideline topic for systematic literature review

Figure 2, Caption: Major topic areas and key questions for the systematic literature review concerning HIV, HBV, and HCV transmission through organ transplantation

Major topic area of the guideline	***Question for Systematic Review***
I. Probability of transmission of HIV, HBV, or HCV through solid organ transplantation (SOT)	1. What are the prevalence and incidence rates of HIV, HBV, and HCV among potential solid organ donors? 2. What are the rates of transmission to recipients from donors infected with HIV, HBV, or HCV? Do the rates vary by the organ transplanted or when the donor was infected?
II. Methodology to better estimate donor infection with HIV, HBV, or HCV	3. What behavioral risk factors are associated with an increased probability of infection with HIV, HBV, or HCV? What is the prevalence of these characteristics among potential solid organ donors? 4. What nonbehavioral factors are associated with an increased probability of infection with HIV, HBV, or HCV? What is the prevalence of these factors among potential solid organ donors? 5. What are the test characteristics of the screening methods available to detect HIV, HBV, and HCV in potential solid organ donors? Do test characteristics differ in particular populations and with donor clinical status (i.e., heart beating vs. non-hearting beating donors OR adult vs. pediatric donors)?
III. Donor interventions to decrease transmission of HIV, HBV, or HCV from infected	6. Which donor interventions reduce the probability of pathogen transmission from an organ donor infected with HIV, HBV, or HCV to a previously uninfected recipient?
IV. Potential risks and benefits of transplanting, or not transplanting, solid organs from donors positive for HIV, HBV, or HCV	7. How do the clinical outcomes of recipients of organs from donors infected with HIV, HBV, or HCV compare to those who remain on the transplant list?
V. Potential risks and benefits of transplanting, or not transplanting, solid organs from donors with risk factors for HIV, HBV, or HCV	8. How do the clinical outcomes of transplant recipients who receive organs from donors with behavioral or nonbehavioral risk factors compare to those who remain on the transplant list? 9. What is the impact of excluding potential solid organ donors with behavioral and nonbehavioral risk factor on the organ donor pool? 10. What is the impact of false positive tests on the organ donor pool?

Source: ECRI Institute. Solid Organ Transplantation and the Probability of Transmitting HIV, HBV, or HCV: A Systematic Review to Support an Evidence-based Guideline.

Type description here.

11. ☒ Describe the literature search protocol; *cover at least 10 years of most recent published literature and databases used*.

Example of search criteria and sources:

"*The scientific literature was searched through December 2000 by using the MEDLINE database of the National Library of Medicine (started in 1966), the Educational Resources Information Center database (ERIC, 1966), the Cumulative Index to Nursing and Allied Health database (CINAHL, 1982), and Healthstar (1975). The medical subject headings (MeSH) searched were diabetes, case management, and disease management, including all subheadings. Text word searches were performed on multiple additional terms, including care model, shared care, primary health care, medical specialties, primary, or specialist. Abstracts were not included because they generally had insufficient information to assess the validity of the study using Community Guide criteria. A total of 22 dissertations were excluded either because the abstracts contained insufficient information for evaluation or the full text was unavailable. Extracted articles and abstracts were reviewed for relevance; and if deemed relevant, the full-text article was retrieved. We also reviewed the reference lists of included articles, and our consultants provided additional relevant citations.*"

Source: Adapted from: Norris SL, Nichols PJ, Caspersen CJ, Glasgow RE, Engelgau MM, Jack L, Isham G, Snyder SR, Carande-Kulis VG, Garfield S, Briss P, McCulloch D, and the Task Force on Community Preventive Services. The Effectiveness of Disease and Case Management for People with Diabetes: A Systematic Review. *American Journal of Preventive Medicine*. 2002;22(4S).

Type description here.

12. ☒ Provide criteria used to select studies extracted from the literature review.

Example of criteria of select studies

- *English language*
- *Peer-reviewed, full-length publication with original data*
- *Multiple publications of the same study were treated as a single study to avoid double-counting patients*
- *The study included at least one of the following bloodborne pathogens: HIV, HBV, and HCV.*
- *The presence or absence of HIV/HBV/HCV was based on laboratory test(s), not on subjective estimates, physician interviews, or patient interviews.*
- *Additional criteria were applied on a per-question basis, as depicted in Table 1 on the next page. For many questions, an insufficient number of studies were identified to support the development of the guideline. Consequently, in an effort to provide a sufficient amount of relevant information to support the development of the guideline, committee members expanded the inclusion criteria in multiple iterations over several months."*

(Continued on the next page)

Table 1, Caption: Original Question-Specific Inclusion Criteria

Inclusion Criteria*	Questions for Systematic Review									
	1	2	3	4	5	6	7	8	9	10
Pertinent data on at least five people	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Data collected in U.S.A.	✓		✓	✓			✓	✓	✓	
Potential organ donors	✓		✓	✓					✓	
Rates not restricted to actual donors	✓									
Not voluntary reporting	✓									
Regardless of symptoms	✓									
Data collected in year 2000 or later	✓		✓	✓					✓	
Donor seropositive pre-transplant		✓				✓	✓			
Recipient seronegative pre-transplant		✓				✓				
Single type of organ, or separated data on different types of organs		✓				✓	✓	✓		
Waitlist control group							✓	✓		
Systematic review					✓					✓
Addressed test sensitivity and specificity					✓					✓
Experimental group with inactivation procedure						✓				
Control group without an inactivation procedure						✓				
Donor+ for behavioral or clinical factor pre-transplant								✓		

Source: ECRI Institute. Solid Organ Transplantation and the Probability of Transmitting HIV, HBV, or HCV: A Systematic Review to Support an Evidence-based Guideline.

Provide criteria here.

13. ☒ Provide a table of findings that summarizes the body of evidence or a link to websites containing evidence tables.

Example of summary of findings table:

Table 2, Caption: Summary of Findings Table Example

Category	Factor	Citation	Year	Percentage of Infected with Factor	Total Number Infected	Percentage of Uninfected with Factor	Total Number Uninfected	Effect Size*	p-Value**	Comparison Made	Associated in Study?	Population
Tattoo	Tattoo in last 6 months	Orton et al.[104]	2004	4.6%	65	0.5%	225	11 (0.8 to 566)†	0.04	Proportion in HCV+ vs. HCV-	Yes	Blood donors
	Tattoo	Conry-Cantilena et al.[106]	1996	21%	248	4%	131	NR	p <0.001†; NS‡	Proportion in HCV+ vs. HCV-	Yes; uni-variate only	Blood donors init positive on EIA
	Tattoo	Murphy et al.[105]	2000	27%	758	5%	1,039	3.9 (2.5 to 6.1)‡	SS	Proportion in HCV+ vs. HCV- adjusted for IDU	Yes	Blood donors
Piercing	Had body piercing in last 6 months	Orton et al.[104]	2004	4.6%	65	2.2%	225	2.1 (0.3 to 11)†	0.38	Proportion in HCV+ vs. HCV-	No	Blood donors
	Ear piercing among men	Conry-Cantilena et al.[106]	1996	30%	139	0%	83	NR	<0.05‡	Proportion in HCV+ vs. HCV-	Yes	Blood donors init positive on EIA (male only; factor not significant among women)
	Pierced ears/ body parts	Murphy et al.[105]	2000	56%	758	40%	1,039	2.0 (1.1 to 3.7)‡	SS	Proportion in HCV+ vs. HCV- final multivariable logistic regression model	Yes	Blood donors

Source: ECRI Institute. Solid Organ Transplantation and the Probability of Transmitting HIV, HBV, or HCV: A Systematic Review to Support an Evidence-based Guideline. Available at: http://stacks.cdc.gov/view/cdc/12164/.

Provide table here.

14. ☒ Describe methods used to assess evidence quality, whether they be GRADE, Cochrane, USPSTF, Community Guide, or other methods.

Example of description of methods used to assess evidence quality:

"We used the GRADE evidence rating methodology, which has been developed for treatment comparisons (Questions 6, 7 and 8)[1] and diagnostics (Question 5).[2] The GRADE system determines the quality of the evidence for a single outcome of a single comparison based on nine factors. 'Quality' here encompasses not only quality in terms of how well the study was designed, but also eight additional factors including inconsistency, indirectness, and imprecision of the evidence base (evidence base being all studies included for that outcome). The first factor (study design) sets the starting GRADE, in which randomized studies start at High, observational studies start at Low, and all other study designs start at Very Low. The next four factors can only be used to downgrade from this starting level (study quality limitations, inconsistency, indirectness, imprecision). The other four factors are grouped under 'Other considerations,' and they are reporting bias (which can only be used to downgrade), large magnitude of effect, all plausible confounders would have reduced the effect, and dose-response association (these latter three factors can only be used to upgrade, if applicable). Ultimately, the GRADE system yields an overall rating for each outcome, which ranges from 'very low' to 'high.' The interpretation of these ratings is summarized in Table 6.3. The details of the application of the GRADE system for each question are described in those sections. GRADE methodology has not been developed for the questions on epidemiology (Question 1), transmission (Question 2), risk factors (Questions 3 and 4), and the impact of exclusions on the donor pool (Questions 9 and 10). For these, we created GRADE methodology as follows. For Questions 1 and 2, no randomized trials are necessary to address the questions, therefore the starting evidence grade was high and we applied the other components of the GRADE system as appropriate. For Questions 3 and 4, we used a starting evidence grade of Low because risk factor studies are by nature observational. Portions of Questions 3 and 4 involve the prevalence of risk factors; these were graded similarly as Question 1 (epidemiology). For Questions 9 and 10, it was not necessary to develop new GRADE methodology, because for Question 9 there was only one study and it had already been graded in Question 8, and for Question 10 there were no included studies."

Figure 3, Caption: "Table 6.3: Interpretation of GRADE Ratings"

Table 6. Interpretation of GRADE Ratings

Quality Rating	Interpretation
High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very Low	Any estimate of effect is very uncertain

Note: These interpretations are from Box 2 of Guyatt et al. (2008).[3]

Source: ECRI Institute. Solid Organ Transplantation and the Probability of Transmitting HIV, HBV, or HCV: A Systematic Review to Support an Evidence-based Guideline.

Type description here.

15. ☒ Describe methods used to obtain and summarize expert opinions regarding the scientific evidence.[5]

Example of methods to assess expert opinion: *"In August 2011, CDC convened a 2-day consultation with work group members to 1) review and evaluate the quality of the evidence for the proposed birth cohort-based strategy, 2) consider benefits versus harms of patient-important outcomes, 3) weigh the variability between the values and preferences of HCV testing among potential patients, and 4) consider resource implications. During the consultation, a summary of findings table addressing each patient important outcome was presented to consultation attendees for discussion (Appendix B). Work group members later provided input on the quality of the evidence and strength of the recommendations. Following the consultation, the DVH Steering Committee and other DVH representatives reviewed the information and reached a decision regarding the strength of the recommendations. At that time, a recommendations statement and qualifying remarks were developed in accordance with GRADE methodology."* Recommendations for the identification of chronic hepatitis C virus infection among persons born during 1945–1965. *MMWR Morb Mortal Wkly Rep*. 2012;61(RR-4):1–32.

Type description here.

[5] Methods used to obtain expert opinions may include focus groups, surveys, interviews, or questionnaires.

16. ☐ Describe methods used to obtain and assess economic data.

Example of methods to obtain and assess economic data:

To examine the cost-effectiveness of various strategies for assessing HCP protection from hepatitis B, two economic models that yielded calculations of the incremental cost per quality-adjusted life-year (QALY) saved were developed. One model represented an approach in which anti-HBs is measured on a pre-exposure basis, and HCP with anti-HBs <10 mIU/mL receive an additional dose of HepB vaccine, followed by repeat anti-HBs measurement. If anti-HBs remains <10 mIU/mL after the first revaccination dose, the HCP receives two additional revaccination doses of HepB vaccine followed by repeat anti-HBs measurement. Another model represented a postexposure management approach; at the time of exposure, the HCP is tested for anti-HBs and the source patient is tested simultaneously for HBsAg, and postexposure prophylaxis would be administered on the basis of these results. Results from the two models were compared. A decision-tree analysis was used to combine all parameters and calculate the total intervention costs and probability of infection. In addition, HBV infection-related costs and QALY loss (accounting for acute and asymptomatic infections and a 6% probability of chronic infection) were determined from an existing model (89) and were considered for the HCP's remaining lifetime. The intervention time frame included a 1-year analysis and a multiyear analysis covering up to 10 years of exposure. A 3% annual discount rate was used, and all final cost figures were converted to 2010 U.S. dollars using the Medical Consumer Price Index. The baseline cost-effectiveness models assumed that an ideal 95% of HCP have initial and sustained protection against HBV infection after a primary ≥3-dose HepB vaccine series, irrespective of the presence of detectable anti-HBs. Ninety-five percent protection was derived from the proportion of persons aged <40 years, including term newborns that have measurable anti-HBs ≥10 mIU/mL soon after a primary vaccination series. Approximately 18–25 years after vaccination, approximately 20% of HCP (vaccinated at age <1 year) or approximately 80% of HCP (vaccinated at age ≥1 year) retain anti-HBs ≥10 mIU/mL. The model did not account for unrecognized exposures, as probability data for unrecognized exposures are not available or suboptimal vaccine coverage that exists among HCP.

Source: Centers for Disease Control and Prevention. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. *MMWR Morb Mortal Wkly Rep.* 2013;62(RR-10):1–19.

Type description here.

17. ☐ Summarize the evidence of economic efficiency for proposed recommendations.

Example of narrative of economic efficiency:

"For pre-exposure anti-HBs testing followed by revaccination and retesting, if necessary, compared with doing nothing, the incremental cost per QALY saved was $4,542,467 for trainees and $3,149,183 for nontrainees at year one, and decreased to $893,619 and $796,140, respectively, over 10 years. This approach is expected to result in 3.7 and 1.6 visits to occupational health for trainees and nontrainees, respectively. The expected number of infections is 0.7 per 100,000 and 0.4 per 100,000 for trainees and nontrainees, respectively. For an approach relying upon postexposure management, compared with doing nothing, the incremental cost per QALY saved was $2,270,801 for trainees and $1,610,998 for nontrainees at year one, and decreased to $917,859 and $1,114,364 respectively, over 10 years. The expected number of infections is 3.0 per 100,000 and 1.7 per 100,000 for trainees and nontrainees, respectively. Although an approach relying upon postexposure management might be less costly per QALY saved initially for many institutions, pre-exposure anti-HBs testing with possible revaccination becomes more cost-effective compared with a postexposure approach over time. Sensitivity analyses demonstrated that cost-effectiveness improves in settings where a greater proportion of source patients are HBsAg-positive and among HCP with higher risk for exposure (e.g., surgeons). Cost-effectiveness can change as new antivirals become available for treatment of HBV infection. Vaccinating previously unvaccinated HCP trainees followed by postvaccination serologic testing, compared with doing nothing, has an incremental cost per QALY saved of $374,646 at year one and $51,537 over 10 years, accounting for direct costs to the health-care system and direct medical costs of hepatitis B-related illness and complications."

Source: Centers for Disease Control and Prevention. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. *MMWR Morb Mortal Wkly Rep*. 2013;62(RR-10):1–19.

Type description here.

Methods Used to Develop Recommendations

18. ☒ Present recommendations and supporting evidence in a simple and easy to find format. If the recommendations are an update, indicate how they add to or differ from existing recommendations. Recommendations must be linked to the evidence.[6]

Example of linking the recommendation to the evidence:

Recommendations:

- *Amenorrhea does not require any medical treatment. Provide reassurance. If a woman's regular bleeding pattern changes abruptly to amenorrhea, consider ruling out pregnancy if clinically indicated.*
- *If amenorrhea persists and the woman finds it unacceptable, counsel her on alternative contraceptive*

Evidence Summary:

During contraceptive counseling and before insertion of the implant, information about common side effects such as unscheduled spotting or light bleeding and amenorrhea, especially during the first year of use, should be discussed. A pooled analysis of data from 11 clinical trials indicate that a significant proportion of etonogestrel implant users had relatively little bleeding: 22% of women experienced amenorrhea and 34% experienced infrequent spotting, although 7% reported frequent bleeding and 18% reported prolonged bleeding (121). Unscheduled bleeding or amenorrhea is generally not harmful. Enhanced counseling about expected bleeding patterns and reassurance that bleeding irregularities are generally not harmful has been shown to reduce discontinuation in clinical trials with other hormonal contraceptives (i.e., DMPA) (101,102). A systematic review and four newly published studies examined several medications for the treatment of bleeding irregularities with primarily LNG contraceptive implants (122–126). Two small studies found significant cessation of bleeding within 7 days of start of treatment among women taking oral celecoxib (200 mg) daily for 5 days or oral mefenamic acid (500 mg) 3 times daily for 5 days compared with placebo (124,125). Differences in bleeding cessation were not found among women with etonogestrel implants taking mifepristone but were found when women with the implants combined mifepristone with either ethinyl estradiol or doxycycline (126,127). Doxycycline alone or in combination with ethinyl estradiol did not improve bleeding cessation among etonogestrel implant users (126). Among LNG implant users, mifepristone reduced the number of bleeding or spotting days but only after 6 months of treatment (128). Evidence also suggests that estrogen (129–131), daily COCs (129), levonorgestrel pills (130), tamoxifen (132), or tranexamic acid (133) can reduce the number of bleeding or spotting days during treatment among levonorgestrel implant users…."

Source: Centers for Disease Control and Prevention. Adapted from – U.S. Selected Practice Recommendations for Contraceptive Use. *MMWR Morb Mortal Wkly Rep*. 2013;62(No. RR-5):1–60.

Type description here.

[6] Place evidence summary and citations either near the recommendations as shown in example, a page number in the document, or a citation or website where the corresponding evidence is found.

19. ☒ Describe methods used to formulate recommendations (e.g., group discussion, consensus).

Example of methods used to formulate the recommendations:

"During October 4–7, 2011, CDC convened a meeting in Atlanta, Georgia, of 36 experts who were invited to assist in guideline development and provide their perspective on the scientific evidence presented and the discussions on potential recommendations that followed. The group included obstetrician/ gynecologists, pediatricians, family physicians, nurse-midwives, nurse practitioners, epidemiologists, and others with research and clinical practice expertise in contraceptive safety, effectiveness, and management. Participants received all of the systematic reviews before the meeting. During the meeting, the evidence from the systematic review for each topic was presented, and participants discussed the evidence and the translation of the scientific evidence into recommendations that would meet the needs of U.S. health care providers. In particular, participants discussed whether and how the U.S. context might be different from the global context and whether these differences suggested any need for modifications to the global guidance. CDC gathered the input from the experts during the meeting and finalized the recommendations in this report. The document was peer reviewed by meeting participants, who were asked to comment on specific issues that were raised during the meeting. Feedback also was received from an external review panel, composed of health care providers who had not participated in the meetings. These providers were asked to comments on the accuracy, feasibility, and clarity of the recommendations, as well as to provide other comments. Areas of research that need additional investigation also were considered during the meeting (31)."

Source: Centers for Disease Control and Prevention. U.S. Selected Practice Recommendations for Contraceptive Use. *MMWR Morb Mortal Wkly Rep*. 2013;62 (No. RR-5):1–60.

Type description here.

20. ☒ Describe factors that influenced the strength of the recommendations including how expert opinion, values, and preferences supported the recommendations.

Examples of factors influencing the strength of the recommendations:

"To evaluate the evidence on reducing transmission of HIV, HBV, and HCV, we examined data addressing 10 key questions within five major topic areas (Figure 1). A sixth topic area includes questions addressed by expert opinion (Figure 2). We drew upon subject-matter experts to draft summaries related to these questions, as a preliminary scan of the literature showed that a systematic review would likely yield insufficient data. Recommendations related to the 10 key questions were based on a targeted systematic review of the best available evidence, with explicit links between the evidence and recommendations. To accomplish this review, we used a modified Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach for evaluating quality of evidence and determining strength of recommendations.[14–18] If weighing the critical outcomes for a key question resulted in a net benefit or a net harm, then a Category I recommendation was formulated to recommend strongly for or against the given intervention, respectively. If weighing the critical outcomes for a key question resulted in a trade-off between benefits and harms, then a Category II recommendation was formulated to recommend that providers or institutions consider the intervention when deemed appropriate. In addition to a category rating, recommendations were also assigned a level rating (A through D) to reflect the quality of the evidence base underlying the recommendations. Level A represents high- to moderate-quality evidence and Level B represents low- to very low-quality evidence. No recommendations were assigned a Level A rating. Level C represents required practices by state or federal regulations, regardless of evidence quality. "Level D represents recommendations from previously published guidelines or reports for topics not directly addressed by the systematic review of the evidence, but deemed critical to the target user; in this level, critical outcomes were determined to result in net benefits, regardless of evidence quality. It is important to note that the strength of a Category IA recommendation is equivalent to that of a Category IB, IC, or ID recommendation; it is only the quality of the evidence underlying the Category IA recommendation that makes it different. Recommendations related to the three expert opinion questions were based on the expert opinion summaries and are designated either as IB if they represent a strong recommendation or IIB if they represent a weak recommendation."

Source: Seem DL, Lee I, Umscheid CA, Kuehnert MJ. PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation. Public Health Reports 2013;(128):247–304.

Example where values and preferences were taken into account:

"Factors determining the strength of a recommendation included the following: (1) the values and preferences used to determine which outcomes were critical, (2) the harms and benefits that emerged by weighing the critical outcomes, and (3) the overall GRADE of the evidence base. A fourth factor, resource use, was not systematically considered."

Source: Seem DL, Lee I, Umscheid CA, Kuehnert MJ. PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation. *Public Health Reports.* 2013;(128):247–304.

Type description here.

21. ☐ Describe other considerations that informed the recommendations (e.g., applicability, feasibility, barriers to implementation).

Example of assessment of applicability of the recommendation:

"The same body of evidence used to assess effectiveness was used to assess the applicability of smoking bans and restrictions to different settings and populations. Smoking bans and restrictions were evaluated in a variety of settings, including hospitals and medical centers,[28,57,72] offices of health care providers,[57] workplaces in the government or public sector,[35,47,55] and a university.[42] Studies on representative samples of employed people in California [31,61,79,80] and in Missouri[36] demonstrated that smoking bans and restrictions reduced self-reported exposure to ETS in workplaces community-wide. Studies included representative samples of indoor workers in the states of California [31,61,79,80] and Missouri, [36] large, diverse samples of government employees in Texas, [47] and health maintenance organization (HMO) employees in Oregon.[57] The evidence of effectiveness in these studies should extend to most indoor workers in the United States."

Example of barriers to implementation of the intervention:

"A major barrier to efforts by local governments to adopt smoking bans is pre-emption, which is the passage or presence of a state law with weaker smoking restrictions that prevents implementation and enforcement of stronger local laws.[91,92] Eliminating pre-emption statutes is one of the tobacco objectives of Healthy People 2010.[19] Another major barrier to the adoption of local, state, and national smoking bans is political opposition by smokers, businesses concerned about potential changes in revenue, and tobacco industry–sponsored groups.[93]"

Source: Hopkins DP, Briss PA, Ricard CJ, Husten CG, Carande-Kulis VG, Fielding JE, Alao MO, McKenna JW, Sharp DJ, Harris JR, Woollery TA, Harris KW, and The Task Force on Community Preventive Services. Reviews of Evidence Regarding Interventions to Reduce Tobacco Use and Exposure to Environmental Tobacco Smoke. *American Journal of Preventive Medicine*. 2001; 20(2S):16–66.

Type description here.

22. ☒ Describe benefits and harms associated with recommendations and how those benefits and harms might have influenced the recommendations.

Example of description of benefits and harms *"Review of evidence: other positive or negative effects:* *Potential benefits of education to reduce ETS exposure in the home include changes in tobacco use behaviors such as an increase in cessation attempts and successful cessation. No harms of community education to reduce ETS exposure in the home were identified in the literature or by the chapter development team."* Source: Hopkins DP, Briss PA, Ricard CJ, Husten CG, Carande-Kulis VG, Fielding JE, Alao MO, McKenna JW, Sharp DJ, Harris JR, Woollery TA, Harris KW, and The Task Force on Community Preventive Services. Reviews of Evidence Regarding Interventions to Reduce Tobacco Use and Exposure to Environmental Tobacco Smoke. *American Journal of Preventive Medicine*. 2001;20(2S):16–66.

Type description here.

Future Research Needs

23. ☐ Describe evidence gaps showing opportunities for future research.

Example of description of areas for future research *"The systematic review for this guideline revealed numerous gaps in the evidence that affected the guideline's ability to adequately address many of the key questions reviewed. Additional gaps in evidence were identified from other sources, such as comments submitted during the public comment period or in review following public comment. The following are 20 specific areas recommended for further study. These recommendations are arranged to correspond to the order of the 10 key questions followed by the three expert opinion questions; they are not listed in priority order.* *1. Estimate the incidence and prevalence of HIV, HBV, and HCV among deceased potential organ donors in the U.S. (Key Question 1)* *2. Collect, analyze, and report national data on HIV, HBV, and HCV infection transmission rates annually based on donor and recipient testing to inform policy decisions and future screening recommendations. (Key Question 2)* *3. For transplant candidates who are HBV-uninfected and receive a non-hepatic organ from an HBV-infected donor who is anti-HBc positive only, evaluate transmission rates where IgM and IgG testing is performed and where various prophylaxis measures, including vaccination, are used as a way to improve knowledge of best practices to minimize transmission risk. (Key Question 2)"*

Source: Seem DL, Lee I, Umscheid CA, Kuehnert MJ. PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation. *Public Health Reports.* 2013;(128):247–304.

Type description here.

Review and Vetting

24. ☒ Describe who (people and organizations) reviewed and commented on the recommendations, if the comments influenced and resulted in a revision of the recommendations.

Example of how individuals and organizations review the recommendations

"After a draft of the tables, narrative summaries, and recommendations was completed, the guideline authors shared the draft guideline with the Expert Panel and Review Committee and made revisions to the guideline based in part on their feedback. The draft guideline was then posted on the Federal Register for public comment. The PHS Guideline Revision Working Group participated in the revision of the guideline recommendations in consideration of public comment and provided feedback on the full document. The draft guideline was then shared with the Expert Panel and Review Committee for technical considerations. Finally, the Office of the Assistant Secretary for Health (OASH) submitted the guideline for review and approval by HHS. The opinions of individual members of the Expert Panel or Review Committee might not be fully reflected in this document, as the guideline represents the position of the PHS agencies and is not a consensus document."

Source: Seem DL, Lee I, Umscheid CA, Kuehnert MJ. PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation. *Public Health Reports.* 2013;(128):247–304

Type description here.

Approach to Updating Content

25. ☒ Explain when the guidelines and recommendations will be updated.

Example of language used to report on updating the guideline: *"Future revisions to this guideline will be dictated by new research and technological advancements for preventing the transmission of HIV, HBV, and HCV through organ transplantation."* Source: Seem DL, Lee I, Umscheid CA, Kuehnert MJ. PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission through Organ Transplantation. *Public Health Reports.* 2013; (128):247–304.

Explain when guidelines and recommendations will be updated here.

Additional Resources

CDC Resources

CDC, Office of the Associate Director for Science. Guidelines and Recommendations: A CDC Primer, 2012.

Conference on Guideline Standardization

Shiffman RN, Shekelle P, Overhage JM, et al. Standardized reporting of clinical practice guidelines: A proposal from the Conference on Guideline Standardization. *Annals of Internal Medicine*. 2003;139(6):493–498.

AGREE Next Steps Consortium

Appraisal of Guidelines for Research and Evaluation (AGREE) Instrument II

PRISMA

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)

Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Loannidis JPA., Clarke M., Devereaux PJ, Kleijnen J., and Moher D. (2009). The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: Explanation and elaboration. *BMJ.* 2009;339:b2700.

Moher D, Liberati A, Tetzlaff J, Altman DG, & The PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: The PRISMA Statement. *PLoS Medicine.* 2009;6(7):1–6.

MOOSE

Meta-analysis of Observational Studies in Epidemiology (MOOSE)

Stroup DF, Berlin JA, Morton SC, et al. Meta-analysis of observational studies in epidemiology: A proposal for reporting. *JAMA.* 2000; 283(15):2008–12.

Task Force for Community Preventive Services

Community Guide Reviews—Topic Index

Community Guide Reviews—Systematic Review Methods

US Preventive Services Task Force

USPSTF Procedure Manual

Cochrane Collaboration

Cochrane Handbook for Systematic Reviews of Interventions

Cochrane Systematic Reviews

GRADE Working Group

List of GRADE Working Group publications and presentations

Institute of Medicine

IOM. *Finding What Works in Health Care: Standards for Systematic Reviews*. Washington, DC: National Academies Press. 2011.

IOM (2011). *Clinical Practice Guidelines We Can Trust*. Washington, DC: National Academies Press. 2011.

National Institute for Health and Clinical Excellence (NICE)

Methods for the Development of NICE Public Health Guidance (2nd Ed.); Appendix L.

NICE Guidelines Manual; Chapter 10. 2009.