DATE: March 10, 2021

TO: Rochelle P. Walensky, MD, MPH
Director, CDC, and Administrator, ATSDR

FROM: Anne Schuchat, MD (RADM, USPHS, Ret.)
Principal Deputy Director, CDC

SUBJECT: Summary of Guidance Review

BACKGROUND:

As part of your pledge to lead an effort to restore the public's trust in the CDC, you asked me to begin a comprehensive review to ensure that all of CDC's existing guidance related to COVID-19 is evidence-based and free of politics.

In response to the dynamic circumstances of emerging infections and public health emergency responses, CDC has customarily issued "interim" guidance documents that are updated as new information and insights are gained, once novel interventions become available including through emergency use authorization, or once research reveals greater certainty that permits strengthening or rejecting earlier interim recommendations. CDC staff have developed thousands of documents during the COVID-19 response, including foundational guidance documents that address major areas of concern as well as numerous subsidiary tools and resources adapted from the foundational guidance.

At your request, I led a process to rapidly assess the major or foundational guidance the agency had issued in order to identify primary documents that needed updating or removal. I also sought to identify practices that could strengthen the transparency of the evidentiary basis for CDC's COVID-19 guidance. In addition to my own review, I sought review of the process and results from current and former Incident Managers and Principal Deputy Incident Managers of CDC's Emergency Response, as well as key Center Directors. The review also included a general assessment of the approach to cross-clearance within the Incident Management Structure's task forces **(Appendix 1)** as well as how the CDC website alerts readers to changes in guidance and relationships between the evidence-base and various guidance documents.

PROCESS

My review built on processes that were initiated by the CDC's response leadership toward the end of last year. From October 2020 through January 2021, CDC COVID-19 response leadership (I.e., Incident manager and Principal Deputy incident managers) reviewed the existing COVID-19 related guidance documents, considerations and supporting communication materials for areas that needed critical updates, based on several factors such as the accumulation of new evidence . The response leaders used an iterative process which involved requesting that each task force lead review guidance involving their area of expertise, and prioritizing material for major or minor updates as well as documents that should be replaced or removed. Building on this work, I gathered additional insights through key informant interviews with CDC staff, with iterative input from the IMS leaders, as well as input I received from public health stakeholders concerned about the rationale or evidence-base for some guidance.

General observations: There were a variety of issues identified including a) guidance that was not primarily authored by CDC staff; b) reliance on less directive language (e.g., 'considerations') than response leadership felt could be supported by existing evidence; and c) availability of new data or evolving scientific understanding that necessitated updated recommendations. I also found that some recommendations were accompanied by science briefs detailing the evidence-base supporting the guidance, but these supporting science briefs had not yet consistently been produced and/or publicly posted for each major area of guidance. Response leaders told me they had updated internal clearance practices to have reviewers more systematically challenge authors' use of phrases like 'consider' or 'if feasible.' The response leadership team had developed a new template for guidance documents. The document development and clearance procedures were intended to differentiate between CDC recommendations where a sufficiently robust evidence-base existed vs. documents where limited evidence existed so that the latter could be repackaged as "resources" rather than guidance.

Major findings

Guidance removed: By the time of my review in late January and February 2021, two documents developed or finalized outside of the agency had already been removed ("The Importance of Reopening of America's Schools this Fall" posted July 23, 2020 – removed October 29, 2020) or replaced (Overview of Testing for SARS-COV-2 posted August 24, 2020, replaced September 18, 2020). A link to a third document ("Opening up America Again" which was released on April 16, 2020 through a link posted on CDC's web) was removed February 7, 2021 during the process of my review (**Table 1**).

Guidance updates: The review by the task forces and response leadership identified several areas where they prioritized development of updated guidance because of evolving research and observational data from implementation efforts, including: phased prevention linked to epidemiologic thresholds; K-12 school operational guidance; Institutions of Higher Education guidance; Overview of testing guidance linked to more targeted specifications for selected settings (e.g., correctional institutions; non-health care workplaces); duration of exemption from quarantine after natural infection and after vaccination; mask related guidance (orders such as for Federal property and public corridor conveyances and updated guidance to incorporate new information on improvement of fit and filtration), and travel related guidance including the requirement for laboratory testing pre-departure for international arrivals (**Table 2**). Several of these guidance documents have been recently released (**Table 3**) or are expected to complete interagency review, as appropriate, and be completed in the weeks ahead.

Guidance related to COVID-19 vaccines: Given the rapidly evolving trial data and evidence-base on vaccines, a number of guidance documents have been developed related to COVID-19 vaccines, vaccine prioritization, and clinical considerations in conjunction with the FDA's issuance of emergency use authorizations. Multiple recommendations were issued related to vaccines since early December 2020. The Advisory Committee on Immunization Practices uses a formal evidence to recommendations process in their reviews and holds public meetings where the evidence is reviewed before deliberation occurs. This process complements public deliberations carried out by the FDA's Vaccines and Related Biological Products Advisory Committee. Despite the transparency and reliance on scientific data review, public concerns about vaccine recommendations persist, particularly surrounding prioritization in the setting of supply constraints. CDC has been committed to updating the interim considerations for

clarity based on ongoing feedback and expanding evidence. These updates have been vetted with diverse clinical partners in addition to ACIP members.

Evidence-base: The availability of scientific briefs (**Table 4**) provides transparency to the evidence-base that supports updated or new guidance. While the response typically reviews new evidence in the process of developing guidance and convenes cross-task force deliberations to review the new evidence, there was not a consistent practice of publicizing the supporting evidence in a scientific brief in conjunction with every major new guidance. We are now committed to providing updated science briefs if there is research to inform guidance updates (see recommendations).

Transparency and credibility in dissemination of guidance: A major update to landing pages and formatting of the CDC's website for COVID-19 was completed during the time period of my review, and this has improved usability of the site. While the response had added a search function for COVID-19 guidance documents in July 2020, and the response's Joint Information Center developed a summary of guidance documents disseminated to partners on a regular basis, this review suggests that additional measures would enhance accessibility of guidance updates for stakeholders and the public. As I conducted my review, I found it difficult to a) tell whether a new document represented a major or very minor update to an existing guidance and b) decipher the core recommendations in long documents. While the version date of previous guidance is noted when updates are posted, the crux of what was new or changed was difficult to find. Further, I determined that a thorough executive summary or abstract highlighting the core features of a guidance document, and a separate 'what has changed' section would help practitioners quickly incorporate new guidance into their ongoing routines without having to review the entire document. Finally, consumers and the public could be more assured of the science-base for guidance if CDC routinely provides scientific briefs, provided a landing spot that listed all recently updated changes or at a minimum, links to appropriate evidentiary support for major new guidance and guidance changes. Additional information on CDC's website describing the general process by which guidance is developed could also support transparency.

Next Steps and Recommendations.

The CDC will finalize production and reviews of remaining prioritized new guidance in the weeks ahead. In order to strengthen CDC's scientific rationale and communication for existing and forthcoming guidance, I recommend:

1. Use of scientific briefs or lists of supporting evidence for major new guidance documents. These need not be exhaustive but should make the scientific rationale for major changes easily accessible.

2. Support transparency in messaging related to areas where the evidence-base is not sufficiently strong or where there are real tradeoffs between theoretic benefits/risks of a course of action and practical implementation barriers to a course of action.

3. Routinely include an abstract or executive summary which briefly outlines key components of new guidance.

4. Routinely provide clear summary of what has changed when updates to guidance are posted, allowing the public to differentiate major from minor changes and the rationale for changes. Incorporate more consistent use of hyperlinks for "reusable elements" (e.g., quarantine period, definition of close contact) that are featured in numerous guidance documents, in order to assure more systematic updating of all guidance that relies on such concepts which themselves are occasionally updated.

5. Plan on media and stakeholder briefings when major guidance is issued. This should allow questions about changes and the scientific rationale to be addressed promptly. Minor guidance updates can be messaged in conjunction with general media briefings, while major guidance updates should be accompanied by more complete roll-out plans to address both public and policymaker concerns and highlight the science or new knowledge that has led to the changes.

6. Plan to review major guidance areas at least every three months during the COVID-19 response to assess when further changes are needed.

7. Reduce the number of adaptations of guidance documents that CDC issues. Encourage partner organizations in collaboration with the CDC to prepare such documents derived from CDC's foundational guidance. This will conserve CDC's scientific and technical resources for the most impactful actions, and permit partners more familiar with each audience to achieve appropriate language and incorporate real world settings more accurately.

8. To the greatest extent possible, incorporate end user input to guidance products to assure recommendations are accessible and easily understood in order to foster accelerated uptake.

Table1. COVID-19 Guidance Documents Removed from CDC Website

Title	Date Posted	Date Removed
The Importance of Reopening of America's Schools this Fall	July 23, 2020	October 29, 2020
Overview of Testing for SARS-COV-2	August 24, 2020	September 18, 2020
Opening up America Again (link on CDC site)	April 16, 2020	February 7, 2021

Table 2. COVID-19 Prioritized Major New or Updated Guidance based on Incident Manager System Leadership Review, October 2020 through January 2021

Title	Released as of March 8, 2021
Recommendations-Phased Prevention Strategies to Reduce SARS-CoV-2 Transmission[1]	
Operational Strategies for K-12 Schools and Childcare Scientific Brief: Transmission of SARS-CoV-2 in K-12 schools	✓ ✓
Overview of Testing for SARS-CoV-2 Guidance Update Supporting testing guidance for specific settings: • Interim Guidance for SARS-CoV-2 Testing in Correctional and Detention Facilities • Guidance-SARS-CoV-2 Testing Strategy for Select Workplaces • Updated Guidance-Testing-Screening-Outbreak Response for IHEs • Interim Guidance for Health Departments for SARS-CoV-2 Testing in Homeless Shelters and Encampments	
Duration of Isolation and Precautions for Adults with COVID-19	✓
Masking Guidance: • Federal property • Public conveyances • Fit and Increase the Filtration	 ✓ ✓ ✓
CDC Guidance for Promoting COVID-19 Safety in Domestic and International Travel for Sea Travel	✓
COVID-19 Critical Infrastructure Sector Response Planning	✓

[1] Prioritized in Fall 2020. Deprioritized guidance in the context of scaling vaccination. Continuing to assemble evidence-base for high risk settings.

Table 3. COVID-19 Major Guidance Documents Released or Updated since January 20, 2021 as of March 8, 2021

Date Released	Title
3/8/21	Interim Public Health Recommendations for Fully Vaccinated People This is the first set of public health recommendations for fully vaccinated people.
2/16/21	Return to Work Criteria for Healthcare Personnel with SARS-CoV-2 Infection (Interim Guidance) Changes to more closely align guidance with updates to the Decision Memo: HCP who are severely immunocompromised, could remain infectious more than 20 days after symptom onset. Consultation with infectious diseases specialists is recommended; use of a test-based strategy for determining when these HCP may return to work could be considered.
2/16/21	Discontinuation of Transmission-Based Precautions and Disposition of Patients with SARS-CoV-2 Infection in Healthcare Settings Changes to more closely align guidance with updates to the Decision Memo: • Patients who are severely immunocompromised could remain infectious more than 20 days after symptom onset. Consultation with infectious diseases specialists is recommended; use of a test-based strategy for determining when to discontinue Transmission-Based Precautions could be considered.
2/16/21	Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19) • New information on potential for under-detection of occult hypoxemia by pulse oximetry, especially among persons with dark skin • New information on dermatologic manifestations associated with COVID-19 • New information on prolonged shedding of replication-competent SARS-CoV-2 in severely immunocompromised persons • New information on reports of reinfection with variant viruses
2/12/21	Operational Strategy for K-12 Schools through Phased Mitigation Updated to incorporate the best available evidence at this time. The indicators and thresholds in the operational strategy replace the core indicators in the Indicators for Dynamic School Decision-Making.
2/10/21	Maximizing Fit for Cloth and Medical Procedure Masks to Improve Performance and Reduce SARS-CoV-2 Transmission and Exposure, 2021 Added new evidence on two ways of improving the fit of medical procedure masks: fitting a cloth mask over a medical procedure mask, and knotting the ear loops of a medical procedure mask and then tucking in and flattening the extra material close to the face. Each modification substantially improved source control and reduced wearer exposure.
2/5/21	Requirement for Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States Updated to include Order
2/4/21	Requirement for Face Masks on Public Transportation Conveyances and at Transportation Hubs Updated to include Order

Table 4. COVID-19 Science Briefs Containing Evidence-Base in Support of Updated Guidance

Category	Title	Date Updated
Potential Airborne Transmission	Science Brief: SARS-CoV-2 and Potential Airborne Transmission	10/5/20
Use of Cloth Masks	Science Brief: Community Use of Cloth Masks to Control the Spread of SARS-CoV-2	11/20/20
Options to reduce Quarantine	Science Brief: Options to Reduce Quarantine for Contacts of Persons with SARS-CoV-2 Infection Using Symptom Monitoring and Diagnostic Testing | CDC	12/2/20
Vaccine Allocation	The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020	12/3/20
Mitigation	Summary of Guidance for Public Health Strategies to Address High Levels of Community Transmission of SARS-CoV-2 and Related Deaths, December 2020	12/11/20
Pfizer COVID-19 Vaccine	Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Pfizer-BioNTech COVID-19 Vaccine	12/13/20
Moderna COVID-19 Vaccine	Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Moderna COVID-19 Vaccine	12/20/20
Evidence for Vaccine Allocation	Evidence Table for COVID-19 Vaccines Allocation in Phases 1b and 1c of the Vaccination Program	12/20/20
Emerging SARS-CoV-2 Variants	Science Brief: Emerging SARS-CoV-2 Variants | CDC	1/28/21
Transmission of SARS-CoV-2 in K-12 schools	Science Brief: Transmission of SARS-CoV-2 in K-12 schools	2/12/21
Duration of Isolation and Precautions for Adults with COVID-19	Interim Guidance on Duration of Isolation and Precautions for Adults with COVID-19	2/13/21
Janssen COVID-19 Vaccine	Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Janssen COVID-19 Vaccine	3/1/21
Fully vaccinated People	Science Brief: Background Rationale and Evidence for Public Health Recommendations for Fully Vaccinated People	3/8/21

Appendix 1: Task Forces within CDC's COVID-19 Incident Management Structure, March 2021

Task Force Name
Epidemiology & Surveillance
Data, Analytics & Visualizations
Laboratory & Testing
Global Migration
State, Territorial, Local, Tribal (STLT) Support
International
Community Interventions & Critical Populations
Health Systems & Worker Safety
Vaccine