Transforming the Process of Scientific Manuscript Development and Review at CDC: An Interim Report

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ABSTRACT

Objectives: Describe the development, implementation, and evaluation of the initial phase of Scientific Clearance Transformation Initiative (SCTI) at CDC.

Methods: CDC's scientific review and clearance process ("clearance") supports the relevance and quality of CDC's scientific publications. In 2022, CDC launched an agency-wide effort to prioritize strategic science, ensure scientific quality, and improve clearance timeliness. We analyzed data on the time for completing CDC clearance between August 1, 2020 and July 31, 2021 to inform SCTI development. CDC science leaders met monthly throughout 2022 to identify ways to ensure science quality and improve the scientific development and clearance processes. We evaluated the progress by analyzing clearance timeliness data and process indicators (e.g., adoptions of clearance system enhancements) for peer-review journal manuscripts, and qualitative feedbacks about SCTI implementation.

Results: During August 2020 to July 2021, median clearance time was 22 business days for 2519 journal manuscripts (interquartile range: 10-45), and month-by-month median clearance times were similar to overall median time. During 2022, the SCTI implementation year, median clearance time was 16 business days for 2440 manuscripts (interquartile range: 8-30 days); clearance time steadily declined from 25 business days in January to 12 business days in December, representing a 52% reduction. Qualitative feedback highlighted a need to strengthen pre-clearance processes.

Conclusion: SCTI, an ongoing CDC effort, appears to have reduced clearance time during its first year. CDC is committed to further improving processes and systems to facilitate efficient and timely production, dissemination, and communication of high-quality scientific information.

KEYWORDS: Research; Publications/standards; Information dissemination; Peer Review; Process assessment; Public Health; Editorial Policies; Centers for Disease Control and Prevention

INTRODUCTION

Science is the cornerstone of the Centers for Disease Control and Prevention (CDC) mission to save lives and protect against health threats. CDC pledges to the American people to "base all public health decisions on the highest quality scientific data that is derived openly and objectively."[1] To fulfill that pledge, CDC scientists conduct scientific work, ranging from surveillance and program evaluation, to laboratory and epidemiological studies and randomized trials. CDC has a long-standing system of reviewing scientific information products authored and coauthored by its scientists, to ensure scientific rigor, accuracy and integrity, and to ensure adherence to applicable federal laws and policies, such as the Information Quality Act.[2-5] Ultimately, CDC must ensure its scientific publications are high-quality, relevant, timely and actionable, to maximize their impact on public health policy and practice.

CDC's scientific review process, called "clearance," was designed to be the final vetting of a completed manuscript ready for journal submission. Clearance has historically involved successive reviews by subject-matter experts and science managers with programmatic responsibility to ensure that the manuscript's science and conclusions are sound and consistent with CDC's policies and positions. However, clearance practices (e.g., number and type of reviewers and clearance timeline) vary in each center, institute, or office (CIO) at CDC. In many cases, clearance has been used to revise and refine manuscripts that are not yet ready for journal submission, and both authors and reviewers have come to see clearance as a tool for obtaining feedback and identifying errors. Consequently, clearance time for many manuscripts has been longer than intended. Clearance reviewers, in turn, are frustrated by the large amounts of time needed to improve manuscripts that are not ready for clearance. CDC's external partners have also commented that the clearance process can be lengthy and complex, potentially impeding partnerships.[6-8]

In 2021, CDC's scientific leadership assessed the agency's clearance process, leading to the implementation of the Scientific Clearance Transformation Initiative (SCTI) in 2022, designed to enhance the efficiency and quality of the scientific manuscript development, clearance, and review processes.[9] Quality enhancement included an emphasis on scientific rigor and appropriate incorporation of health equity science principles during manuscript development.[9,10] With a strengthened manuscript development process, authors are better prepared to submit high quality

manuscripts that can be rapidly cleared. Senior scientists, scientific leaders, administrators, scientific authors, and reviewers from across CDC participated in the SCTI.

This report describes early lessons from the development, components, and roll-out of SCTI, highlighting CDC's use of administrative data to help design and implement SCTI and monitor its progress. These findings can help inform ongoing efforts at CDC and other federal agencies working to improve scientific information dissemination processes.

SCTI DEVELOPMENT AND IMPLEMENTATION

Timeliness assessment

Initial discussion of strategies to improve CDC's manuscript development and clearance process occurred during August–December 2021, led primarily by a committee of CDC's Associate Directors for Science (ADSs), the agency's senior officials responsible for oversight of the quality of CDC's scientific portfolio.

To inform SCTI planning, CDC's Office of Science analyzed administrative data for 2519 peer-review journal manuscripts that entered CDC "eClearance" between August 1, 2020 and July 31, 2021 (Table 1). eClearance is the internal electronic system that most CDC CIOs use to document their scientific review processes and publication outcomes.[*]

Overall, 50% of these manuscripts took ≥21 business days to clear, while 20% took ≥55 business days to clear; 50% of the manuscript had ≥6 sequential reviewers (maximum: 20 reviewers); 50% of the manuscripts were returned to the authors for revision at least twice (maximum: 15 returns). Of manuscripts that required ≥3 revisions, 50% took ≥49 business days to clear; in comparison, of those requiring <3 revisions, 50% took ≥15 business days to clear. Of manuscripts taking >30 business days to clear, 61% of the time was with authors; in comparison, of those cleared in ≤30 days, 17% of the time was with authors. Some manuscripts covered cross-cutting topics and required "cross-clearance" by subject-matter experts in a different CIO, after being reviewed by the originating Divisions and CIOs. The median time for cross-clearance was 9 business days (IQR: 5-12). In summary, the major contributors to prolonged clearance

[*] Scientific products originating in the CDC Emergency Operations Center (EOC) and the National Institute for Occupational Safety and Health (NIOSH) do not use eClearance to document their scientific review processes and were excluded from all timeliness indicators reported here.

times included the number of sequential reviewers, number of returns for revision, author revision time, and cross-clearance.

Based on these findings and their own experiences, members of the ADS committee recommended improvements in two broad categories: 1) strengthening relevance and quality of scientific products prior to clearance. Specific measures included prioritizing manuscripts for review, encouraging scientific discourse during manuscript development, and establishing a unified set of manuscript quality standards; and 2) developing and implementing enhancements to the clearance process and system. Specific enhancements included minimizing the number of returns for revision during clearance, allowing multiple reviewers to review concurrently instead of only sequentially, removing documents from eClearance if the authors have not made requested revisions promptly, and reducing cross-clearance time. Additionally, in response to concerns expressed by external partners, the ADS committee recommended establishing a rapid alternate clearance pathway for manuscripts that are led by authors external to CDC ("externally-led manuscripts"), with the understanding that the external author bears the major responsibility for these scientific products.[6,7] Workgroups comprised of science leaders from across CDC were formed and met regularly to operationalize these recommendations.

Scientific quality assurance

To strengthen the quality of manuscripts entering eClearance, two main interventions were initiated. First, CIOs implemented a manuscript concept development and approval process (CDAP) as a key component to strengthen quality of scientific products during the idea formulation and development stage. CDAP encourages discussion of manuscript ideas with subject-matter experts–including scientific, program, policy and communications experts–about critical analyses, appropriate data sources, analytic methods, and collaborators prior to manuscript development. One objective of the CDAP is to ensure that proposed manuscripts are aligned with the strategic science priorities of the division and the agency, and staff allocate their time based on these priorities.[10] CDAP also provides an opportunity for early identification of appropriate collaborators and potential opportunities for optimizing the quality, relevance, and impact of manuscripts. Prior to SCTI, a limited number of CDC units employed processes comparable to CDAP. During the SCTI, CDC's Office of Science set a goal that all CIOs implement a CDAP and that 80% of new manuscript submissions would have gone through a

CDAP by November 2022. CIOs were provided guidance describing the major principles for setting up a CDAP, including examples of CDAP approaches, but had the flexibility to implement or continue CDAP in a way that met their own unique needs.

A second SCTI component to strengthen the quality of manuscripts entering eClearance was the creation and implementation of the Domains of Excellence for High-Quality Publications (DOE) framework to support authors in developing high-quality and impact-driven scientific publications. The DOE framework identifies seven areas, or domains, for authors to address during manuscript development—clarity, scientific rigor, relevance, policy, ethics, collaboration, and health equity—as well as specific quality elements within each domain. The DOE framework is intended to reinforce best practices for developing manuscripts and consistency in quality of manuscripts entering eClearance.[11] Since May 19, 2022, the lead author of each manuscript entering eClearance has been required to attest to the application of the DOE, and the lead author' supervisor was asked to affirm the manuscript's readiness for clearance.

System enhancements

Quality improvement and enhancement of CDC's eClearance system are the cornerstones for improving timeliness. Several enhancements to CDC's eClearance platform have been implemented, included enabling concurrent review; creating an alternate pathway with fewer reviewers for most externally-led manuscripts; sending automated email alerts to reviewers and authors whose tasks are overdue; and creating a clearance time metrics dashboard (Table 2). These features were implemented throughout 2022 (Figure 1).

Agency-wide engagement

Agency-wide roll-out of system enhancements began in January 2022. Science leaders and agency leadership engagement lead to dissemination across CIOs, Divisions, and Branches. Five agency-wide webinars were conducted between May 12 and August 4 on SCTI and the establishment and use of the DOE framework, eClearance system enhancements, CDAP and strategic science, and health equity science. Thousands of authors and reviewers of scientific products attended these webinars.

In addition to agency-wide measures, some CIOs implemented their own improvements based on their own specific situations. For example, one CIO set up scientific review forums to address

quality issues during the early stages of the scientific process. Another CIO emphasized the need for supervisors to vet a manuscript's readiness prior to starting formal clearance; trained clearance reviewers on clearly delineated review roles to decrease redundancy and increase reviewer accountability; customized time expectations for each type of review; and trained staff on scientific writing.

Evaluation

To evaluate the impact of the initial phase of SCTI, we assessed clearance data for all manuscripts intended for peer-review journal submission that completed clearance in 2021 and 2022. The year 2021 was used as a pre-SCTI baseline for comparison to 2022. Monthly clearance data during 2022 were analyzed on improvements following SCTI implementation. We calculated the median and interquartile range (IQR) for clearance time in business days. Additionally, we assessed the percentage of manuscripts that went through a CDAP after July 1, 2022, when eClearance started tracking CDAP use during early manuscript development. Finally, we also assessed the proportion of CIOs that had implemented various components of SCTI and analyzed clearance-related qualitative data abstracted from CDC's agency-wide comment and suggestion box, as well as comments during webinars, listening sessions, and ADS meetings.

RESULTS

During 2021–2022, 4849 eligible journal manuscripts were cleared (2409 in 2021; 2440 in 2022). During 2021, the monthly median clearance time fluctuated between 19 and 25 business days; overall for 2021, the median clearance time was 22 business days (IQR: 10-44). During 2022, monthly median clearance time decreased by 52%, from 25 days in January to 12 days in December (Figure 1). Notably, the upper quartile of clearance time reduced sharply in February 2022, right after the implementation of late alerts for authors and reviewers on February 7, 2022. For the entire year of 2022, the median clearance time was 16 business days, a 27% reduction over the 2021 median.

In July 2022, when tracking of CDAP use began, 11% of cleared manuscripts underwent CDAP. CDAP use steadily increased over the next few months. In December 2022, 43% of manuscripts had undergone a CDAP. Also, by December 2022, seven of the 23 CIOs had implemented an

alternate review pathway for externally-led manuscripts. Comparing clearance time before and after implementation of the alternate pathway, CIOs that implemented the alternate review pathway saw median clearance times for these manuscripts cut from 17 to 7 business days pre- and post-implementation. Assessment at the end of 2022 showed that implementation of some components of SCTI, such as CDAP, was uneven across CDC.

Qualitative feedback from authors and reviewers suggested that the new clearance deadline and automated alerts may have motivated more timely reviews. Removing manuscripts that are not ready for clearance from the eClearance system saves reviewers' time and overall clearance time. Some staff find CDAP helpful in designing papers and encouraging collaboration, which can help drive a much-needed paradigm shift and cultural change that will help enhance science quality and prioritization of important and impactful science. Conversely, staff reported that CDAP was challenging to implement well in Branches that lacked clearly stated near-term priorities and goals. The deadline for review was felt to be too stringent for manuscripts that required many clearance reviewers, especially when the content was cross-cutting and needed clearance in multiple parts of CDC. In some parts of CDC, clearance reviews were performed offline to decrease the clearance day count without lessening the actual amount of review work. Some staff questioned the emphasis on clearance timing when the overall approach of shifting staff attention from clearance to pre-clearance does not necessarily shorten the overall manuscript preparation time. Some authors would like to see enhanced topic prioritization from leadership, accountability and timely support by supervisors, as well as author engagement with supervisors during manuscript development.

DISCUSSION

CDC implemented SCTI in 2022 to reduce clearance time while maintaining or enhancing the quality and impact of its scientific manuscripts. SCTI initially focused on implementing process improvements aimed at reducing clearance times, as well as new tools, such as the CDAP and the DOE framework, to assure scientific relevance and quality early during manuscript development. After the initial phase of SCTI implementation, formal clearance timeliness appeared to have improved. A noticeable drop in the upper quartile of clearance times occurred after the implementation of timeliness alerts for authors and reviewers. Implementation of an alternate pathway was followed by reduced clearance times for externally-led manuscripts. The

effect of concurrent review is unclear as few CIOs have implemented it, and reviewers are still adjusting to this new way of conducting review.

During SCTI, staff were implicitly encouraged to give more attention to the "pre-clearance" phase (i.e., manuscript preparation steps prior to formal clearance), rather than relying on clearance to find and rectify flaws. CDAP was implemented to help produce high-quality manuscripts from the outset, the DOE framework was established to remind authors of quality expectations. These efforts were designed to produce stronger manuscripts entering eClearance, thus reducing time required for formal clearance. Expectedly, qualitative feedback suggested the attention to pre-clearance may have led to longer pre-clearance timelines. We are currently unable to determine how the overall time, from manuscript development to clearance completion, may have been affected, as our quantitative timeliness measures capture only the clearance phase.

Overall, the quantitative and qualitative assessments of the initial phase of SCTI suggest that, while some improvements may have occurred, the initial focus on timeliness needs to be balanced with prioritizing scientific work by CIO and division leadership, leveraging the CDAP to ensure development of impactful manuscripts, and supporting development of high-quality manuscripts prior to clearance. Strengthening early engagement with branch and division leaders during the next phase of SCTI could enhance CDC's strategic science impact.

Some of the strategies employed in SCTI may be relevant to other organizations producing scientific products, even when formal clearance is not needed. For example, CDAP can help the organization improve the relevance of publications while ensuring their quality, and ensure leadership's awareness of staff projects. CDAP can also ensure subject-matter experts are engaged early on, particularly with cross-cutting work, before a project is underway or a manuscript is drafted. Additionally, utilizing CDAP can help manage workload as lower priority work could be paused or stopped. Similarly, the DOE framework can serve as a set of unified quality standards to be used by authors during scientific product development.

Use of administrative data for evaluating the impact of SCTI is subject to multiple limitations. Although the administrative data provides a measure related to timeliness, it does not provide comparable metrics for assessing quality or for capturing timeliness during the manuscript development phase. Further, the longer-term impact of these system enhancements on scientific

quality and clearance efficiency at CDC, and ultimately on the public health impact of the agency's scientific publications, will need to be monitored and assessed.

During the next phase of SCTI, the CDC Office of Science will continue to work with CIOs to promote the implementation of these system enhancements, to identify opportunities for additional improvements especially in the areas of science prioritization and pre-clearance quality assurance, to continue to monitor clearance timeliness, and to ensure high-quality and impactful journal submissions. CDC also intends to explore alternative, rapid dissemination mechanisms apart from journal publication, further strengthen and expedite the development, review, and approval process of scientific publications and data, and establishing a tiered clearance prioritization system to further reduce clearance time for scientific information that needs very rapid dissemination. Finally, CDC will continue to promote close collaboration of authors, supervisors, and other scientific leaders on scientific quality throughout the manuscript development process (Table 2).

The goal of strategic public health science is to generate evidence that guides public health practice and informs policy.[12,13] Historically, CDC has prioritized the quality of scientific products to maintain the agency's scientific reputation and ensure fulfillment of our mission to protect public health.[3] High-quality scientific information must be delivered in a timely manner to maximize its public health impact.[12-15] Notably, during the COVID-19 pandemic, there were constant demands for high-quality, up-to-date scientific evidence to inform public health interventions and policies, which presented an unprecedented challenge to CDC to quickly disseminate scientific information while ensuring its quality.

Soon after SCTI implementation, CDC initiated the Moving Forward Initiative to refine and to modernize the agency's structures, systems, and processes for the management of its science and programs.[16] As part of the Moving Forward Initiative, CDC expects to shift from a primarily academically-centric publication model of emphasizing scholarly journal publications to a balanced public health-centric model aimed at delivering high-quality, real-time, impactful scientific products and information via a broader array of dissemination platforms, including scholarly journals, preprint servers, websites, and social media channels. The implementation of the next phase of SCTI will be an integral part of the Moving Forward Initiative.

CONCLUSION

SCTI is an ongoing initiative to improve scientific review and clearance at CDC. Based on input from all levels of its scientific community, CDC is implementing steps to prioritize strategic science, assure scientific quality during early stages of scientific manuscript development, and improve clearance timeliness. CDC is committed to further improving the scientific development and review process to facilitate efficient and timely production, dissemination, and communication of high-quality scientific information, to maximize its public health impact, and to help fulfill CDC's mission to protect America from health, safety, and security threats, both domestic and international.

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Figure 1. Median and interquartile range of time in clearance in business days for manuscripts cleared by the Centers for Disease Control and Prevention, January 2021–December 2022.

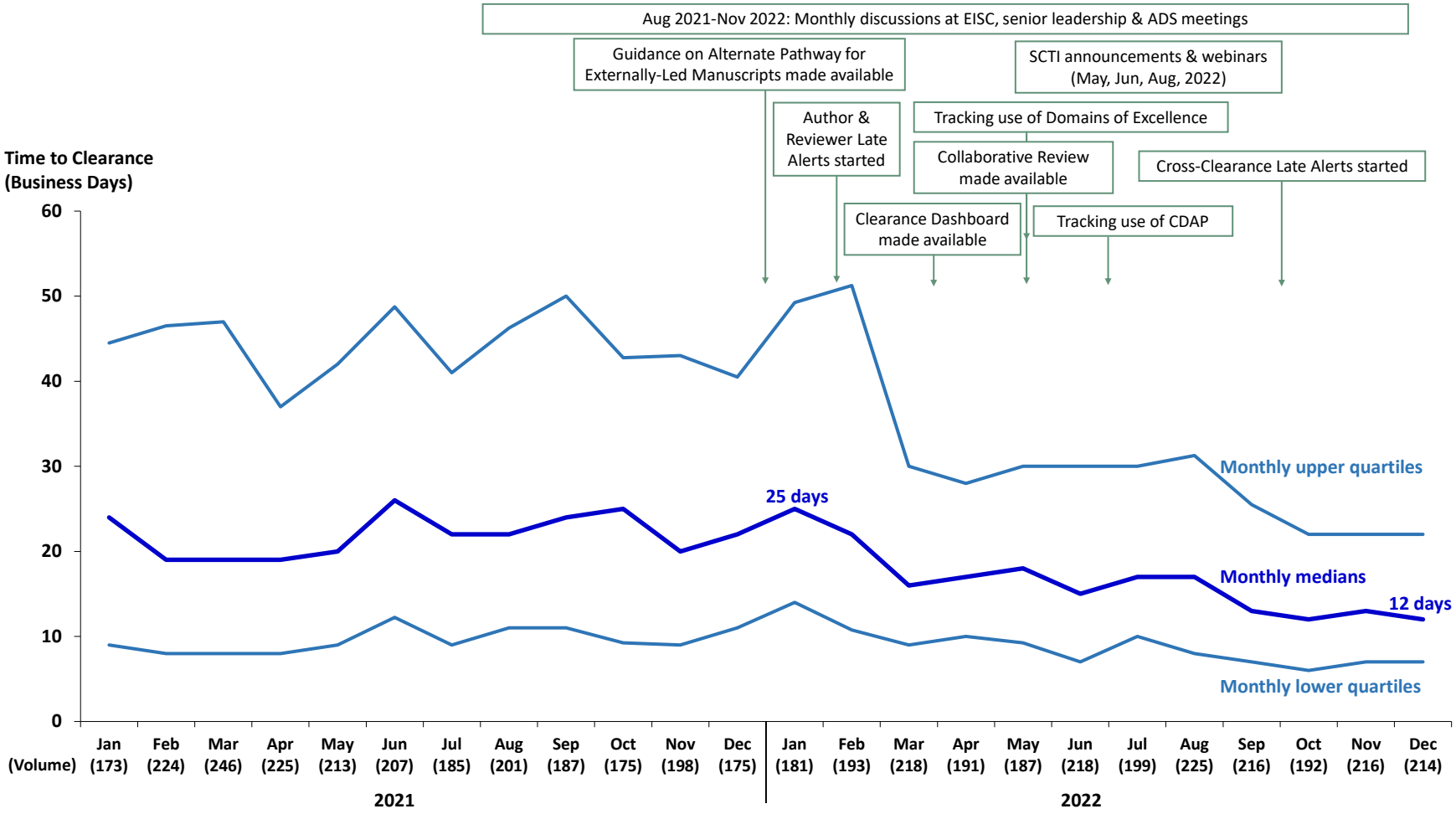

Table 1. Clearance metrics for 2519 peer-review journal manuscripts that entered CDC clearance system from August 1, 2020 – July 31, 2021 (prior to the Scientific Clearance Transformation Initiative)

Clearance metric	
Clearance time, CDC overall	
Median (IQR*) clearance time† (business days)	21 (10-45)
80th percentile of clearance time (business days)	55
Number of sequential reviewers per manuscript	
Median (range)	6 (1-20)
Number of returns for revision per manuscript	
Median (range)	2 (0-15)
Median clearance time (business days) by number of returns for revisions	
≥3 returns	49
<3 returns	15
% of time with authors, by clearance time (business days)	
Overall	53
≥30 days	61
<30 days	17
Cross-clearance time	
Median (IQR*) (business days)	9 (5-12)

* IQR: Interquartile range.

† Defined as interval between entry and completion of formal clearance.

Table 2. CDC Scientific Clearance Transformation Initiative (SCTI): Transformative Actions and Future Plans

Key Areas	Initial Actions	Next Steps
Strategic science	• Establishment and implementation of CDAP*	• Prioritize manuscript development based on strategic science • Make CDAP nimble, efficient, and user-friendly • Promote agency-wide adoption of CDAP
Quality assurance	• Creation of DOE framework[†11]	• Conduct training on DOE framework • Make DOE framework available for CDC's external partners
eClearance system enhancements	• Established alternate review pathways for externally led manuscripts • Implemented automatic late alerts for authors and reviewers • Established a system for concurrent manuscript review • Implemented use of a dashboard to track clearance time metrics	• Establish a tiered system for manuscript review based on strategic science, with accelerated timelines for high-priority manuscripts • Promote alternate review pathways for externally led manuscripts • Improve efficiency and timeliness of cross-clearance • Enforce the designation of comment level (e.g., required, recommended, suggested) • Conduct training for reviewers and authors • Utilize preprint servers to accelerate dissemination • Updating CDC clearance

* Concept Development and Approval Process
† Domains of Excellence for High Quality Publications

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