Reimagining our Shared Approach to Fall Respiratory Virus Seasons: New Strategies for Transmission Reduction and Population-Level Benefit

November 14, 2023
12:30 p.m. – 4:30 p.m. ET

Duke | MARGOLIS CENTER *for* Health Policy

Welcome and Opening Remarks

Mark McClellan

Director, Duke-Margolis Center for Health Policy

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Workshop Agenda

12:30 PM	**Welcome and Overview**
12:40 PM	**Public Health Priorities for the Fall Respiratory Virus Season**
12:55 PM	**The Burden and Spread of Respiratory Viruses in Fall 2023**
1:45 PM	**A Framework for Incorporating Population-Level Benefits**
2:45 PM	**Break**
2:55 PM	**Regulatory, Coverage, and Payment Policy Steps**
3:45 PM	**Alignment on a Coordinated, Public-Private Strategy**
4:25 PM	**Summary**

Public Health Priorities for the Fall Respiratory Virus Season

Mandy Cohen

Director, Centers for Disease Control and Prevention

The Burden and Spread of Respiratory Viruses in Fall 2023

Caitlin Rivers

Senior Scholar, Johns Hopkins Center for Health Security

Moderated Discussion and Q&A

Moderator: **Mark McClellan**, Duke-Margolis Center for Health Policy

Panel:

Anne Zink, Alaska Department of Health and Association of State and Territorial Health Officials

Siddharth Tenneti, CVS Health

Brandon Webb, Intermountain Health

Christian Ramers, Family Health Centers of San Diego

Caitlin Rivers, Johns Hopkins Center for Health Security

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A Framework for Incorporating Population-Level Benefits in Regulatory and Reimbursement Processes

Mark McClellan

Director, Duke-Margolis Center for Health Policy

Why Are We Focusing on Transmission Reduction?

- Advancements in biomedical innovation have reduced the impact of respiratory viruses and can progress to further contain the spread of disease by reducing disease transmission.
- While the potential benefits of *transmission reduction* for population health have long been recognized, U.S. and global public policies do not have clear, consistently-applied frameworks for assessing, valuing, and supporting the development and use of biomedical innovations.
- Current regulatory, coverage, and payment policies help encourage use of diagnostics, vaccines, and therapeutics which reflect individual benefits and risks.
- However, current products may not fully reflect potential population health benefits of more widespread use of a growing range of biomedical products that may do more to prevent infections and limit spread when used voluntarily.

Goals for Today's Meeting and Our White Paper: Encouraging Biomedical Innovation and Product Use for Transmission Reduction

- Clarifying whether and how policy reforms across stakeholders that target transmission reduction can facilitate greater access to and voluntary uptake of current diagnostics, vaccines, and therapeutics – resulting in improved population health outcomes.
- Identifying opportunities to create pathways and incentives for the continued development of next-generation medical technologies that more substantially reduce disease transmission, and thus enable greater population health benefits in the U.S. and globally.

A Framework to Reduce Transmission for Population Benefits

- Developing guidance on the use of current and next-generation products requires the use of **a framework to incorporate the population benefits of transmission reduction** in the current policy environment.
- There are also implications for policies that affect use of existing products and that encourage transmission reduction in future product development.
- This framework defines key dimensions of population benefits to support policies that explicitly account for the value of transmission reduction *and* individual benefits in the development and use of medical products.

Key Questions to Account for the Potential Value of Population Health Benefits

- Under what circumstances is a more explicit focus on population benefits of transmission reduction likely to be worthwhile, and what policy steps would be most effective in achieving these benefits?
- How can such benefits best be measured and validated?
- Do current regulatory policies provide a clear pathway for products that block or significantly reduce transmission, even if they have relatively modest or no benefits compared to existing treatments for individuals?
- Do current coverage and payment policies reflect the transmission reduction benefits of products, including greater likelihood of containing spread in high-risk settings, beyond a product's expected individual benefits and risk from use?

A Framework for Analysis of Population Health Impacts

- Products to diagnose, prevent, or treat infectious disease have the potential to confer benefits beyond those to the individual.
- Products that prevent infection or reduce the duration or intensity of infectiousness have valuable benefits from reducing transmission:
  - **Clinical benefits** from preventing sickness in congregate facilities and reducing the use of health care resources so that they are distributed across other disease areas.
  - **Economic benefits** from preventing sickness in populations that include workers and reducing burdens on health care infrastructure.
  - **Social benefits** by maintaining health and social infrastructures, keeping students/staff in school, and improving quality of life at a population level.
- An examination of reduction in infection transmission, beyond the individual benefit-risk analysis.
  - **Measures of transmission reduction**, e.g. evidence on reduced spread in different types of risk settings.
  - **Validated markers of transmission reduction** that may vary across threats, e.g., diminished symptoms, diminished viral loads.
  - **Modeling and policy simulations** of net impact of policies reforms related to transmission reduction on disease spread, population benefits and costs.

Building on Regulatory Considerations for Population Benefit

- FDA regulatory decision-making focuses on benefits to the individual that outweigh risk from product use, though FDA often considers impact of an anti-infective product on disease transmission.
- Two complementary avenues can build on precedent to consider benefits beyond the individual in regulatory approvals for products with potentially large impacts on infection/infectiousness relative to individual health:
  - Providing guidance for the explicit assessment of potential population health benefits for relevant infectious disease products.
  - Supporting pre- and post-market assessments of safety and efficacy for population-level benefits.

Building on Coverage and Reimbursement Considerations for Population Benefit

- Many COVID-19 PHE policies established precedent for minimizing access barriers to products that prevent contraction or reduce infectiousness in order to reduce widespread transmission in addition to providing individual benefits – e.g., population level procurement models for vaccines, therapies, and diagnostics; elimination of usual copays.
- Such policies have mostly not been retained or applied to other products besides vaccines to address public health threats.
- Coverage and payment policies have not been developed for vaccines that may differ in reducing transmission, or for diagnostics and therapeutics that do so too.
- Health care payment reforms in the US and other countries are also creating more accountability and supports for health care providers to improve population health goals - e.g., more use of effective preventive services and “test to treat” models to achieve measurable improvements in covered populations and communities.

Applying a Population Benefit Framework through Practical Policy Steps: Addressing the Threat of Respiratory Viruses

- How can this framework be further developed and applied to policies for approval, coverage, and payment of products to better contain spread and reduce health burden of respiratory viruses?
  - Supporting more effective voluntary use of existing products.
  - Clarifying and advancing the development and adoption pathway for next-generation products.
- Implementation considerations for development include:
  - The role of Federal, state, and local strategies to incorporate biomedical products that reduce infection transmission.
  - The involvement of frontline health care and community leaders to provide information and encourage appropriate access, delivery, and uptake.
  - The role of the commercial sector in producing and delivering products at-scale.

Regulatory Reforms to Realize a Population Benefit Framework

Diagnostics	Vaccines & Therapeutics
• Leveraging population health benefits of better diagnostic tests through more robust wastewater surveillance infrastructure • Establishing incentives to adapt diagnostics to public health purposes during disease surges • Fostering innovation with challenge programs modeled after RADx to enhance development, commercialization, uptake of products. • Providing subsidies to create a warm-based manufacturing capacity of current and next-generation products	• Creating a post-market evidence generation infrastructure that incorporates clinical trials with simplified processes and adaptable platform style approaches • Utilizing more traditional randomized controlled trials that have facilitated label expansion for past products • Supporting a better infrastructure for post-market studies to confirm larger population benefits

Reimbursement Reforms to Realize a Population Benefit Framework

Diagnostics

- Establishing differential payment rates for laboratory diagnostic tests with population benefits
- Establishing coverage policies to support the use of multiplex testing in various clinical settings
- Utilizing alternative payment arrangements to incentivize development and ensure robust supply
- Facilitating an enhanced surveillance infrastructure through payment adjustments for participation
- Developing standardized validated outcome measures of transmission reduction to capture population-level benefit in payer decision-making

Vaccines & Therapeutics

- Utilizing value-based payment arrangements to address outstanding evidence questions and support coverage
- Incorporating outcome measures that reflect use of products with population health benefits in CMMI models and CMS ACOs
- Establishing more comprehensive reimbursement infrastructure that reflects the added value of transmission reducing products
- Utilizing bulk purchasing agreements to maintain a steady supply of products

Better Evidence Development on Population-Level Benefits

- A more robust evidence generation infrastructure is needed to develop evidence on claims of transmission reduction through both efficient randomized studies and observational data analyses.
- Products must generally demonstrate favorable individual risk-benefit evidence for approval, which may include promising or validated surrogate markers for population health benefits.
- Real-world epidemiologic research and population-based randomized trials (including challenge and cluster-randomized trials) have provided guidance and examples how to assess for vaccines and diagnostic testing.
- Products might receive regulatory approval for individual benefits with post-market support and guidance to facilitate label expansion claims related to demonstrated population health benefits.

Moderated Discussion and Q&A

Moderator: **Mark McClellan**, Duke-Margolis Center for Health Policy

Panel:

Blythe Adamson, Infectious Economics LLC

Marc Lipsitch, Harvard T.H. Chan School of Public Health

Emanuel Petricoin, George Mason University, Center for Applied Proteomics and Molecular Medicine

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Break

Workshop will resume at **2:55 p.m. EST**

Policy Steps to Realize a Population Benefit Framework

Moderator: **Christina Silcox,** Duke-Margolis Center for Health Policy

Panel:

Danielle Scelfo, ClearNote Health

Lee Fleisher, University of Pennsylvania Perelman School of Medicine/Duke-Margolis Center for Health Policy

Coleen Klasmeier, Roche Diagnostics

Haider Andazola, Foley Hoag LLP

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Opportunities for a Coordinated Strategy to Contain Respiratory Viruses

Moderator: **Mark McClellan**, Duke-Margolis Center for Health Policy

Panel:

Peter Marks, U.S. Food and Drug Administration

David Boucher, Administration for Strategic Preparedness and Response

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Summary and Closing

Mark McClellan

Director, Duke-Margolis Center for Health Policy

Thank You!

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