ASU College of Health Solutions
Arizona State University

Experts Discuss Over-the-Counter Influenza Tests: A Roundtable Discussion

The growth and success of over-the-counter (OTC) tests for COVID-19 diagnosis in recent years have invited discussion about the value and impact of OTC influenza diagnostics. Despite the seasonality of the virus and the staggering number of individuals infected every year, there are still no widely accessible OTC at-home tests for influenza. A virtual roundtable was convened on March 22, 2024, to discuss the benefits and weaknesses of OTC influenza testing as well as issues that need to be considered when developing and commercializing these tests. The 22-member roundtable, moderated by Arizona State University College of Health Solutions faculty, consisted of infectious disease experts, clinical physicians, public health experts, patient advocates, and representatives from retail pharmacies and the diagnostics industry. Specific topics discussed included accessibility to testing; patient, provider, and payor education; and considerations for designing and implementing potential OTC diagnostic influenza tests.

Key Takeaways
Patients Must Have Access to OTC Tests: OTC testing for the flu and other infectious diseases must be made widely available to the general population at a low cost. OTC tests may be distributed through retail and pharmacies as well as trusted community organizations, such as churches and schools.
Patients & Providers Need Education on OTC Tests and Respiratory Illness: Patients and providers need to be educated on the benefits and limits of OTC testing. Patients also need to be educated about the serious nature of respiratory illnesses, the importance of isolating, and the importance of seeking treatment when needed. Physicians need to be educated on strengths and weaknesses of OTC tests.
The Best OTC Tests Will Offer Detection of multiple common respiratory infections (i.e. COVID-19, Flu, etc.) : Multiplexed detection for multiple common respiratory infections is necessary for enhanced clinical use. OTC tests should test for highly preserved sequences and, ideally, be able to detect multiple strains of pathogens. OTC testing may disrupt public health organizations' surveillance of respiratory viruses, so preemptive strategies for assessing the volume of at-home testing must be developed.

Below, we summarize the discussion points organized by the prompt questions during the roundtable.

What are the potential benefits and challenges of a home/OTC flu diagnostic test?

Benefits

Overall, the roundtable agreed that OTC flu testing holds significant promise. Infectious disease experts highlighted the potential for earlier detection of infection, reduction of unnecessary antibiotic/antiviral prescriptions, and reduction of time between diagnosis and treatment, all of which could significantly improve patient outcomes. Public health

experts emphasized the increased accessibility of OTC testing for the general population, especially among individuals who may not otherwise seek or have access to treatment. The importance of testing in school settings was underscored, specifically concerning the potential of OTC tests for helping school nurses better detect and reduce the spread of infections among students. Many other populations where OTC testing would be beneficial were identified, including high density settings including community living centers, long-term care facilities, homeless shelters, as well as with high-risk patient populations. Representatives from retail pharmacies further emphasized the role of OTC testing with products available in pharmacies to help reduce the existing gap between testing and treatment. This would be facilitated by treatment(s) being available without prescription. Specifically, they mentioned that pharmacies can make OTC tests easily available to consumers, pharmacists can answer relevant questions, shortening time between diagnosis and treatment. In an ideal situation, pharmacies would have a space for consumers to perform testing but it is more likely that consumers would perform their test in their car or outside the pharmacy. For pharmacies with integrated health clinics, testing could easily be done on site with treatment quickly available for those testing positive.

Challenges

Considerations for effectively implementing OTC tests were also discussed. Infectious disease experts expressed the need for detection of multiple pathogens within the same OTC test to increase clinical value. Participants did, however, also recognize the challenges of designing, validating, and conducting clinical trials of the OTC tests for

each flu season as strains may differ from year to year. Similar to COVID-19, there may be relevant mutations for both Flu A and B that need to be considered in creating a test. However, mutational changes in flu have not required changes in test chemistry in the past, unlike the need for annual updates for flu vaccine chemistry.

Many noted that some physicians and insurance companies do not accept at-home testing results, so education about the validity and purpose of OTC at-home testing is required. Some members of the roundtable also expressed concerns about over-treatment, especially outside of flu season, due to false positive results. Reducing the cost of OTC testing and making it affordable for the average consumer was identified as a priority. Other barriers, such as decreased trust in physicians and pharmacies, were discussed along with potential solutions, such as collaborating with trusted community organizations to deploy OTC tests. Public health experts expressed concern that increased OTC and at-home testing could negatively impact viral surveillance by decreasing the number of samples available. They proposed increasing the public's knowledge of existing initiatives, including the "Make My Test Count" program to combat this issue. However, they also recognized that reporting to "Make My Test Count" may be skewed towards positive results and could be perceived as breaching patient privacy. Patient advocates and industry professionals stated that funding sources for OTC testing in public settings, including schools, must be established to ensure high accessibility.

What role could home flu tests play in managing healthcare resources (i.e., in the clinic and during outbreaks)?

Benefits

Members of the roundtable proposed that reliable OTC testing would create a hybrid care model, in which some patients would conduct at-home tests rather than going to the clinic. They stated that telehealth could be leveraged even more broadly for prescriptions if OTC tests become more accessible. Additionally, roundtable members indicated that OTC tests could motivate individuals who would have never sought care otherwise to seek treatment after a positive result. They also emphasized the importance of isolating when infected with respiratory viruses (including flu) and suggested that OTC testing could help with that — especially if OTC tests can be utilized more rapidly than scheduling a doctor or clinic visit. They also stated that OTC testing may streamline the *test-to-treat* model for patients. Retail pharmacy professionals emphasized that consumer and business models must be proactively developed to ensure an effective response to outbreaks. Additionally, they highlighted retail pharmacies' ability to increase the accessibility of OTC testing due to their strong geographic presence and ability to act as a resource for consumers / patients with basic questions. The possibility of OTC testing in pharmacies and immediate and easy access to treatment, if positive, was also discussed as a potential extension of the *test-to-treat* model. Pharmacists, as noted earlier, can answer questions about the test and the treatment, increasing confidence for the consumer / patient.

Challenges

Some roundtable members expressed the need for more robust scientific evidence on the efficacy of OTC tests before they would be fully confident in the future of OTC testing for flu and other infections. Public health and infectious disease professionals commented on the challenge of collecting patient samples for research if most tests were conducted at home in the future. Specific concerns were the lack of access to patient samples for vaccine development for seasonal viruses like the flu. If OTC testing became the standard, researchers and vaccine developers would need to develop alternative ways to reliably collect patient samples. Additionally, roundtable members pointed out that the cost of OTC tests needs to be affordable across the population. Most believed that the current pricing of OTC tests must be lowered (COVID-19 fluctuates between $10-15 per test; the only OTC flu test, as of the roundtable, is priced at $40 per test). It was noted, however, that diagnostic companies may not invest in technologies that do not have a significant Return on Investment (ROI), indicating that they must balance cost, accessibility, and ROI. The roundtable briefly discussed the potential of government subsidies but believed that they were unlikely without a public health crisis or epidemic.

Would home OTC flu tests increase awareness and education about the flu and its symptoms?

Members of the roundtable expressed the importance of patient education regarding the serious nature of respiratory illnesses and the benefits of vaccination through programs like “Make My Test Count.” They noted that storytelling was often a better way to

educate and engage the general public than scientific jargon. Additionally, they stated that the recent increase in pharmaceutical and OTC advertisements allows for more dialogue, discussion, and education about these topics. Members of the roundtable also emphasized the importance of tailoring education for different audiences. They indicated that education is crucial for patients, healthcare providers, and OTC test manufacturers. They also discussed that it is vital to make sure that individuals using social media know what is accurate to increase the public's scientific literacy and confidence in science in general.

How do you perceive the accuracy of home flu tests compared to tests administered by healthcare professionals?

Infectious disease experts highlighted that some physicians may want to repeat tests in a clinical setting due to past issues with OTC test accuracy, especially due to false negatives. Once again, the ability of a test to detect and discern between multiple respiratory viruses and bacteria to arrive at a diagnosis was mentioned as critical for patient adoption and physician buy-in. (It is also important to note that the concern for test accuracy was raised based on perceptions of COVID-19 OTC tests, as there was only one OTC flu test available at the time of the roundtable. No one on the roundtable had used the test in a controlled setting or in comparison with a lab-based flu test.)

What factors should individuals consider when deciding whether to use an OTC / home flu diagnostic test?

Members of the roundtable stated that in school settings, OTC diagnostic tests can allow students to get tested at school rather than at home, where access might be a problem due to health disparities. They also indicated, however, that if drugs like Tamiflu (for Flu) or Paxlovid (for COVID) become available OTC, it may lead to patients taking those medications based on their symptoms, bypassing OTC testing altogether.

What factors should physicians/healthcare professionals consider when deciding whether to recommend a home/OTC flu diagnostic test?

Public health experts stated that false positive rates are relatively low during flu season and that quickly prescribing medications like Tamiflu could help ill or at-risk patients sooner than would happen under traditional healthcare interventions. They indicate that physicians might encounter higher rates of false positives outside of flu season but can retest patients at those times. The need to ensure the accuracy of OTC tests and recording of OTC results for public health purposes was emphasized. Lastly, roundtable members noted that one positive consequence of OTC testing is that it keeps sick patients away from doctor's offices and emergency rooms.

What role should healthcare professionals play in guiding individuals on the appropriate use and interpretation of home flu tests?

Roundtable members indicated that healthcare providers could recommend OTC testing during telehealth visits and prescribe medications as needed. They also highlighted healthcare providers' role as a resource for answering patients' questions about OTC testing.

How can we ensure that individuals using home flu tests are adequately informed about their limitations and when to seek medical attention? How might the widespread use of home flu tests affect the relationship between patients and healthcare providers?

Once again, the ability of OTC testing to allow for early detection and, thus, early treatment was discussed, especially if a visit to the clinic is not required. Members of the roundtable suggested that OTC testing will be even more critical as the coronavirus pandemic dwindles and COVID-19 vaccination rates (and nearly all vaccination rates) decrease. They noted that comprehensive patient and provider education is vital to address misunderstandings and ensure OTC tests are interpreted accurately.

How might advancements in technology and artificial intelligence (AI) impact the accuracy and reliability of home flu tests in the future?

Members of the roundtable stated that OTC testing can help encourage isolation and reduce disease spread, especially during novel disease outbreaks. However, they recognize that the current technology must be improved, discussing issues like decreased sensitivity for viral strains and viral mutations, which may change the target sequences and render single-target tests less effective. Thus, they emphasize the need for developing OTC flu tests that target highly conserved regions of the virus while also detecting strains that may emerge in the future. Lastly, there was a brief discussion on the potential to use technology to learn if a test was used (or not) after purchase. This type of technology, used in some countries outside of the US, records the “opening” of a test box and its contents and assumes that if the test was opened, that it was used.

Notes from the organizers. It was interesting to note that members of the roundtable believed that OTC Flu tests would become broadly available soon. There was little doubt that the technology exists and that test manufacturers would gain regulatory approvals for these types of tests. There was broad agreement on the need for education about the tests and the actions necessary upon learning the results of the tests but all who expressed opinions believed that home testing will be a part of the healthcare ecosystem in the future.

Addendum: As of June 30, 2024, there are six OTC COVID / Flu tests which have been granted an EUA by the FDA.

This paper is brought to you by ASU College of Health Solutions in collaboration with Sanofi Consumer Healthcare.

Authors and Acknowledgements

Mara Aspinall, MBA, Professor of Practice, College of Health Solutions; Co-Founder of Biomedical Diagnostics programs.

Matthew Scotch, PhD, MPH, Associate Dean of Research and Professor, College of Health Solutions**;** Assistant Director, Biodesign Center for Environmental Health Engineering, Biodesign Institute**;** Faculty, Barrett, The Honors College
Visiting Professorial Fellow, University of New South Wales, Sydney, Australia

Srivatsan Swaminathan, BS in Biological Sciences focus in Biomedical Science at Arizona State University; MD candidate, Icahn School of Medicine

Thank you to Cheri Giller and Glenda Heishman, ASU Biomedical Diagnostics master's degree students, for their insights in creating this White Paper.