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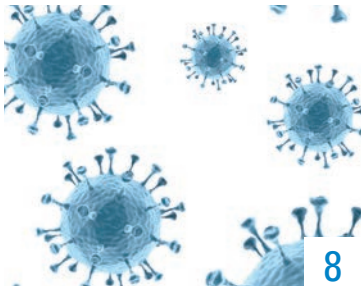
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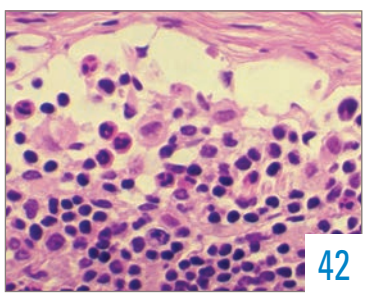
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52

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Staff coverage planning still a challenge during the COVID-19 pandemic

By Linda Wilson
Senior Editor

Given Omicron's transmissibility and resulting surge in COVID-19 cases, the Centers for Disease Control and Prevention (CDC) issued emergency guidance to help healthcare facilities, including laboratories, provide the staff necessary to ensure safe patient care.

During an Omicron-driven surge, the challenge of caring for patients would be complicated by the lack of access to employees in quarantine or isolation from SARS-CoV-2 combined with ongoing vacancies in healthcare positions.

Labs already feel the pain of staffing shortages. Of respondents to *Medical Laboratory Observer's* 2021 salary survey, 80.5% said the current shortage of medical personnel has had a "moderate/large" impact on lab operations, up from 72.7% in 2020.

The CDC's guidance on staffing is contained in two electronic documents: a first webpage addressing isolation after a confirmed infection and quarantine after exposure to the virus; a second webpage discussing contingency- and crisis-management strategies. Among the main points the CDC addressed:

- Healthcare workers with COVID-19 who are asymptomatic can return to work after seven days with a negative test result, and isolation time can be cut further to address staffing shortages.
- Healthcare workers who have received all COVID-19 vaccine doses, including boosters, do not need to quarantine at home following a high-risk exposure to the virus. The CDC defines high risk as an incident in which a healthcare worker's eyes, nose or mouth were exposed to material that may contain SARS-CoV-2.
- Healthcare workers who have not received all vaccine doses and are exposed to the virus may return to work earlier than 14 days if they do not develop symptoms or test positive for COVID-19.

As far as contingency strategies, the CDC recommends canceling elective procedures; addressing social factors that might prevent employees from reporting to work, such as transportation issues; asking staff to postpone time off; and hiring temporary staff. Crisis strategies include transferring patients to other facilities or allowing fully vaccinated, asymptomatic staff who have been exposed to SARS-CoV-2 to work throughout their 14-day quarantine period. These staff members would need to wear a respirator or well-fitting mask. They also would have to report their temperature and symptoms (or lack thereof) before each shift.

"If shortages continue despite other mitigation strategies, as a last resort consider allowing HCP to work even if they have suspected or confirmed SARS-CoV-2 infection, if they are well enough and willing to work, even if they have not met all return-to-work criteria," the CDC said. The agency added that such an option should be implemented only after considering such factors as where workers are in the course of their illness, the types of symptoms they have, and how much patient interaction they will have.

One thing is clear from the CDC's discussion of staffing strategies: As the COVID-19 pandemic rolls into its 3rd year, laboratorians will need to approach staffing strategies with flexibility. They'd also be wise to recognize and reward the ongoing efforts of their exhausted staff members.

I welcome your comments, questions, and opinions – please send them to me at lwilson@mlo-online.com.

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Group Publisher/Executive Editor
Kristine Russell
krussell@mlo-online.com

Senior Editor
Linda Wilson
lwilson@mlo-online.com

Managing Editor
Gail Castanho
gcastanho@endeavorb2b.com

Graphic Artist
Patti Connors
pconnors@endeavorb2b.com

Audience Development/List Rentals
Laura Moulton
lmoulton@endeavorb2b.com

Ad Traffic Coordinator:
Ray Porter
rporter@endeavorb2b.com

eProduct Coordinator
Mary Haberstroh
mhaberstroh@endeavorb2b.com

ADVERTISING

East Coast/Midwest Sales (except IL)
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Carol Vovcsko
(941) 321-2873
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South/West Coast/Illinois Sales
Lora Harrell
(941) 328-3707
lharrell@mlo-online.com

2477 Stickney Point Rd., Suite 221B Sarasota, FL 34231
Phone: (941) 388-7050 Fax: (941) 388-7490
www.mlo-online.com

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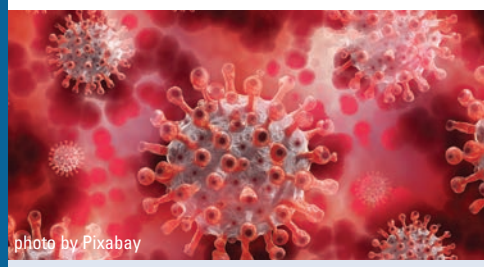
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Fast Facts

Acute COVID-19

Among children and adolescents with SARS-CoV-2 infection admitted to six hospitals during July-August 2021, 915 of them, or 77.9%, were hospitalized for acute COVID-19, the Centers for Disease Control and Prevention (CDC) reported in its Morbidity and Mortality Weekly Report (MMWR).

177

(19.3%) of children had incidental positive SARS-CoV-2 test results (asymptomatic or mild infection unrelated to the reason for hospitalization).

25

(2.7%)YEs, had multisystem inflammatory syndrome in children (MIS-C), a rare but serious inflammatory condition associated with COVID-19.

54.0%

of patients hospitalized for COVID-19 received oxygen support

713

patients hospitalized for COVID-19 (24.7%) were younger than 1 year old.

67.5%

had one or more underlying medical condition, with obesity being the most common (32.4%) among patients aged 12-17 years.

B.1.617.2

is the highly transmissible (Delta) variant of SARS-CoV-2 that causes COVID-19, which was the predominant strain during the study period.

Source: Center for Disease Control and Prevention https://www.cdc.gov/mmwr/volumes/70/wr/mm705152a3.htm?s_cid=mmmm705152a3_w

Severe COVID tied to high risk of death, mostly by other causes, within year

Survivors of severe COVID-19 — especially those younger than 65 years — may be at more than twice the risk of dying within the next year than those who had mild or moderate illness or were never infected, finds a study in *Frontiers in Medicine*, according to a news release from the Center for Infectious Disease Research and Policy (CIDRAP) at the University of Minnesota.

Another finding of the analysis of electronic health records of 13,638 patients who tested positive or negative for COVID-19 is that only 20% of those who had severe COVID-19 (requiring hospitalization) and died did so because of complications of their infection, such as abnormal blood clotting, respiratory failure, or cardiovascular problems.

Rather, 80% were due to different reasons typically considered unrelated to COVID-19.

Of all patients, 178 had severe COVID-19, while 246 were mildly or moderately ill, and the rest tested negative. Among all patients, 2,686 died within 12 months of their COVID-19 diagnosis.

Relative to uninfected patients, those recovered from severe COVID-19 younger than 65 years had a 233% increased risk of dying in the next year. The increased risk was greater than that of survivors of severe COVID-19 who were 65 years or older.

Black men undergoing radiation therapy for prostate cancer have better outcomes than White men

Individual patient data meta-analysis led by UCLA Jonsson Comprehensive Cancer Center researchers found 'unexpected result': Black men may have improved response to initial treatment.

UCLA Jonsson Comprehensive Cancer Center researchers leading a meta-analysis of seven randomized trials found an "unexpected result": Although Black men appeared to have more aggressive disease when they enrolled in clinical trials of radiation therapy for prostate cancer, their treatment outcomes and disease-specific outcomes were better than those of their white counterparts.

"These results provide high-level evidence challenging the common belief that Black men who are diagnosed with prostate cancer will necessarily have a worse prognosis than white men," said Amar Kishan, MD, Associate Professor and Vice Chair of Clinical and Translational Research in the Department of Radiation Oncology at UCLA.

"This is especially important because an unfounded belief can inadvertently contribute to 'cancer injustice,' leading to the use of more aggressive treatments than might be necessary — potentially reducing quality of life — and diverting attention away from other important factors that can influence outcome, including access to more comprehensive healthcare," said Kishan, Chief of the Genitourinary Oncology Service for the Department of Radiation Oncology at the David Geffen School of Medicine at UCLA and the UCLA Jonsson Comprehensive Cancer Center.

In what is believed to be the largest meta-analysis of its kind on the subject, the researchers reviewed individual patient data of 8,814 patients from seven randomized clinical trials on radiation therapy for prostate cancer — studies that enrolled a substantial number of Black men and were conducted by the Radiation Therapy Oncology Group (RTOG)/NRG Oncology. All patients in the trials received either standard or high-dose radiation therapy, and some patients also underwent short- or long-term androgen deprivation therapy.

Of the total, 1,630 men self-identified as Black; 7,184 as white. To investigate associations between race and treatment effectiveness, the researchers extracted and analyzed statistics on recurrence (biochemical recurrence, or BCR), metastasis (distant metastasis, or DM) and prostate cancer-specific mortality, or PCSM, and other, secondary endpoints.

According to the results, Black men were significantly younger and more likely to have high-risk disease at the time of treatment, but they had lower recurrence, metastasis and PCSM rates than White men, even without statistical adjustment. When adjustments were made for age and other factors, "race remained significantly associated with improved BCR, DM and PCSM outcomes," the authors reported in the article. "The fact that Black men had improved early and late disease outcomes when compared with white men is a novel and unexpected result that highlights that Black men may have an improved response to their initial treatment."

Immunotherapy shows promise for children, young adults with recurrent AML

An immunotherapy harnessing the immune system's "natural killer" cells has proven effective in treating acute

myeloid leukemia (AML) in some adults whose cancers return. Researchers at Washington University School of Medicine in St. Louis have shown in a small clinical trial that the same natural killer cells also can help some children and young adults with recurrent AML and few other treatment options.

Results from the phase 1 trial, which included eight patients ages 1 to 30 years, are published online in the journal *Blood*.

"All of the patients enrolled in this study had very aggressive AML," said Jeffrey J. Bednarski, MD, PhD, Assistant Professor of Pediatrics at Washington University School of Medicine in St Louis. "For all of them, their leukemia recurred after stem cell transplantation and was not responsive to several treatment regimens before they were referred to this study. This is a very challenging disease to treat — none of the patients had any curative options. The survival expectation for these patients was essentially zero. That three patients are still alive is very encouraging for this really challenging disease."

Acute myeloid leukemia is a cancer of the blood and bone marrow that results in the overproduction of immature white blood cells, which crowd out healthy blood cells. Standard therapy involves chemotherapy and a stem cell transplant from a donor, which can result in a long-term remission. But for patients whose cancers return after stem cell transplantation, the disease becomes extremely difficult to treat, and most patients ultimately die from progression of their disease within a few months to a year.

Of the eight patients who received the investigational treatment, four achieved complete remission by day 28 after therapy. Two of the four stayed in remission for more than three months. One of these patients remains in remission today, more than two years after the treatment. Three patients who went into remission later relapsed. Of those three, two were able to receive a second stem cell transplant, and they're still alive and doing well. Two other patients had a partial response to the therapy, in that their disease decreased, but they did not go into remission. The remaining two patients did not respond to the therapy.

Study shows how genetic mutation puts women at risk for ovarian cancer

Stem cell scientists have revealed the origins of a common ovarian cancer by modeling fallopian tube tissues, allowing them to characterize how a genetic mutation puts women at high risk for this cancer. The tissues, known as organoids, hold potential for predicting which individuals will develop ovarian cancer years or even decades in advance, allowing for early detection and prevention, according to a news release from Cedars-Sinai.

Ovarian cancer is the leading cause of gynecologic cancer deaths in the U.S., in part, because symptoms are often subtle, and most tumors elude detection until they are in advanced stages and have spread past the ovaries. While the lifetime risk of developing ovarian cancer is less than 2% for the general female population, the estimated risk for women who carry a mutation in the so-called BRCA-1 gene is between 35% and 70%, according to the American Cancer Society.

The new study findings could help physicians pinpoint which of these women are the most likely to deveop ovarian cancer in the future — and which are not — and pursue new ways to block the process or treat the cancer.

To make their discoveries, the research team generated induced pluripotent stem cells (IPSCs), which can produce any type of cell. They started with blood samples taken from two groups of women: young ovarian cancer patients who had the BRCA-1 mutation and a control group of healthy women. Investigators then used the IPSCs to produce organoids, modeling the lining of fallopian tubes, and compared the organoids on the two groups.

Multiple drugs can be tested on the organoids without exposing the patient to them.

Gene therapy could hold promise for sickle cell disease

New research suggests a gene therapy called LentiGlobin could provide a cure for sickle cell disease (SCD), but the work is the early stages, according to researchers at the University of Alabama at Birmingham and reported in a news release.

Julie Kanter, MD, Director of the UAB Adult Sickle Cell Clinic, says patients treated with this therapy are beginning to show signs of producing stable amounts of normal red blood cells containing hemoglobin.

SCD occurs in about one out of every 365 Black or African American births, according to the Centers for Disease Control and Prevention (CDC), and about one in 13 Black or African American babies is born with sickle cell trait.

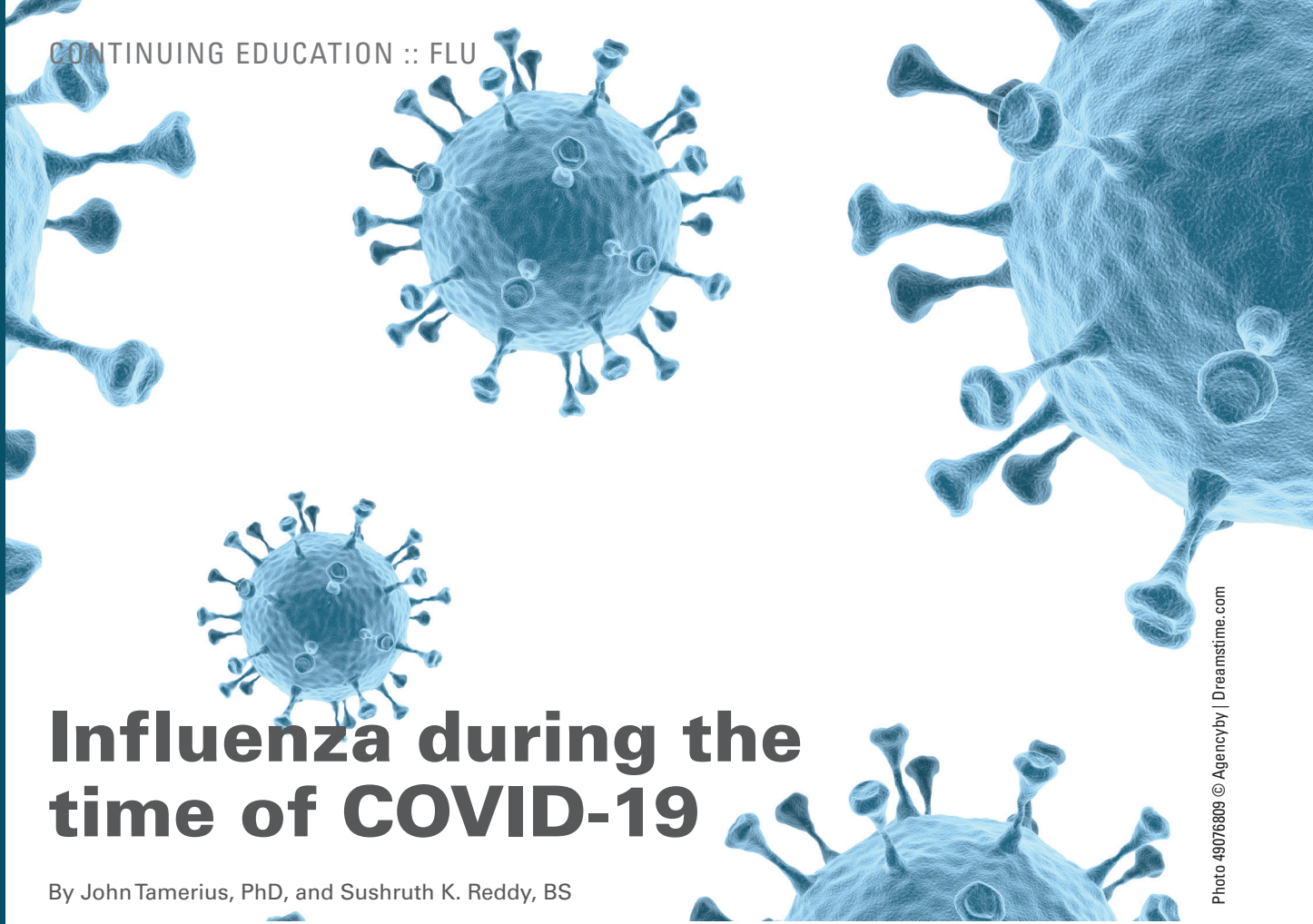
Kanter says there are several types of gene therapy (gene addition/transfer, gene editing, gene correction and gene silencing), but this particular therapy is gene addition or transfer therapy. "In this therapy, we do not change or edit the gene that causes sickle cell disease," Kanter said. "Instead, we use a viral vector to deliver a new gene that will make a healthy hemoglobin — a beta hemoglobin — into the stem cell. This is like coding new instructions into the cell. The old instructions for hemoglobin S are still there, but now the cell can make HbA and HbS. The vector can deliver more than one copy of the instructions to each cell — usually between one and four copies — so the cell can make more HbA than HbS.

A vector is part of a virus. Kanter compares vectors to envelopes and letters. "I like to think of it as an envelope," she said. "We take out the bad part of a virus (the letter) and leave the empty envelope. We put a new gene (the new letter) with the right instructions into the envelope and send it into the stem cells. The viral parts of the letter are removed so patients don't get the virus itself — they only get the letter coding for the new hemoglobin, called HbAT87Q."

T87Q is a special type of hemoglobin A that is slightly different from regular hemoglobin A and has two advantages:

- The intentional change inserted (called T87Q) makes the hemoglobin even less likely to cause sickling when it is near a hemoglobin S.
- The HbAT87Q can also be measured more accurately inside the cell (since it is slightly different from regular hbA), which allows doctors to know how much of the new hemoglobin a patient is making compared to how much they get from a transfusion.

Kanter says that, although this therapy is providing a significant amount of hope, researchers continue to test to make sure the therapy remains safe.



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Influenza during the time of COVID-19

By John Tamerius, PhD, and Sushruth K. Reddy, BS

In advance of the 2020-2021 influenza in the U.S., public health officials in the Southern Hemisphere provided reports regarding their first influenza season since the official onset of the COVID-19 pandemic. These records indicated a profound drop in the incidence of influenza and other respiratory viral infections compared to previous seasons. This was believed due, in part, to the implementation of nationwide mitigation programs, including social distancing, mask wearing, restrictions on mass gatherings, travel restrictions, and other behavioral precautions that were aimed at limiting the spread of SARS-CoV-2.

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LEARNING OBJECTIVES

Upon completion of this article, the reader will be able to:

1. Compare and contrast the characteristics of influenza A and influenza B in past pre-COVID-19 flu seasons.
2. Discuss the impact of COVID-19 and mitigation measures on the severity of the 2020-2021 influenza season.
3. Discuss the societal and individual actions that might impact the severity of the 2021-2022 flu season.
4. Describe the role of rapid diagnostic testing in managing both COVID-19 and flu outbreaks.

By the end of the Southern Hemisphere's 2020 winter season, there was a dramatic decline (>99%) in incidence of PCR-confirmed cases of influenza in Australia, South Africa, and across South America (**Table 1**).[1] Similarly, the traditional influenza season never developed again in the ensuing 2021 winter season with case levels at 10% or less than typically encountered in most regions of the Southern Hemisphere.[2]

Influenza in the USA from 2015 to December 2021

Forecasting the impact of an approaching flu season is a profoundly difficult task. Data generated in the Southern Hemisphere were certainly clues to what might occur in the U.S. In addition, using the data available from the Centers for Disease Control and Prevention (CDC),[3] epidemiologists were able to examine historical influenza seasonal outcomes and trends that could provide clues about the forthcoming influenza season. The influenza data spanning the period from the onset of the 2015-2016 season (week 40) to December 2021 (week 48) is presented in **Figure 1**.

The CDC data presented here is comprised of influenza test results provided by over 400 clinical laboratories that comprise the nationwide WHO/NREVSS laboratory network.[4] The positivity rates for influenza types A+B combined, or individually, are depicted by respective colors, as shown, and range from about 1% (types A+B combined) to as high as 30%. This figure contains an immense amount of data, so let's look at some of it more closely.

USA 2016 and 2017 influenza epidemic seasons

The 2016-17 and 2017-18 seasons in Figure 1 were "typical" and show, first, the seasonal arrival of influenza A (green),

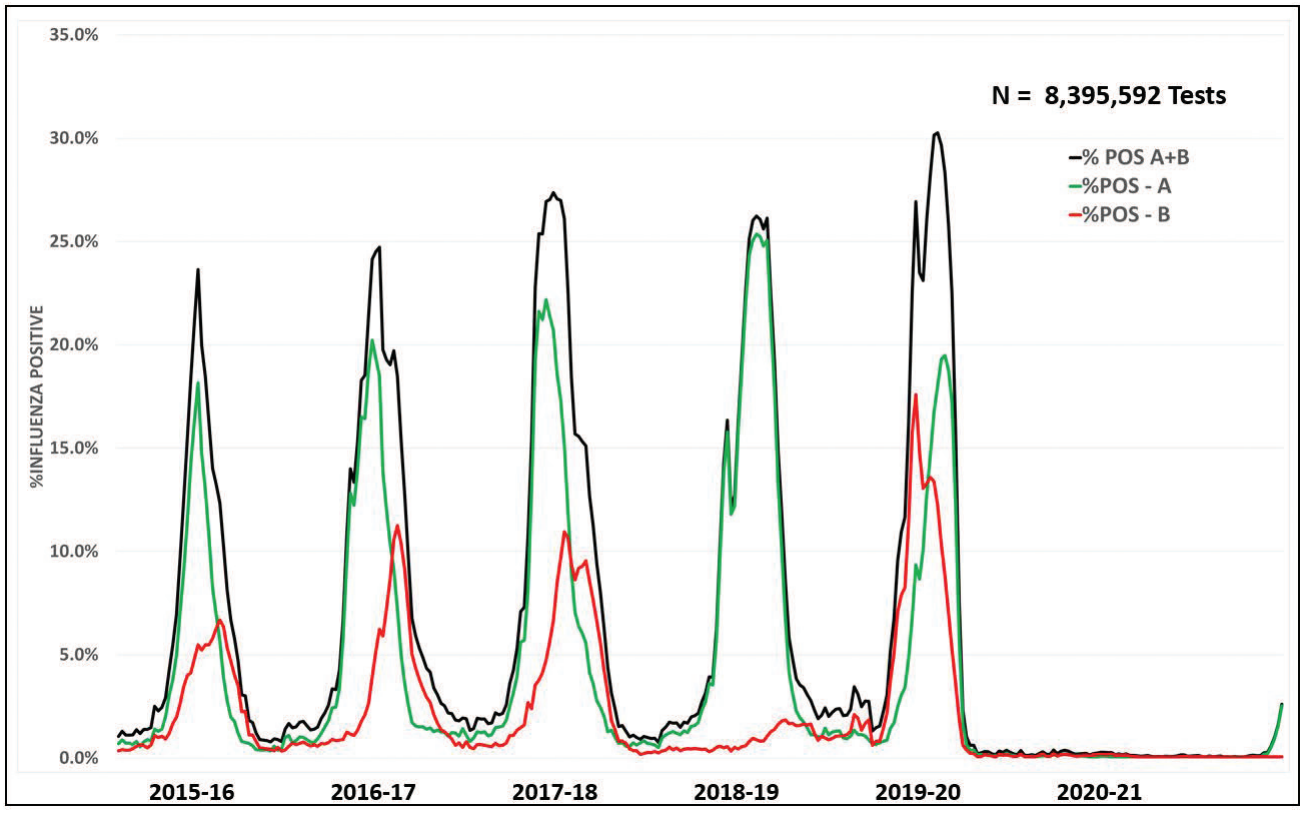

Figure 1. **USA Influenza Status** - 2015 Month 40 to 2021 Month 47

Country	Years of Origin		
	2018	2019	2020
Argentina	1517	4623	53
Chile	2439	5007	12
Australia	925	9933	33
South Africa	711	1094	6

Table 1. Impact of COVID-19 on Incidence of Documented Cases of Influenza in Southern Hemisphere

soon followed by influenza B (red). Conventionally, influenza B reaches its seasonal peak about 5 to 7 weeks after influenza A. This profile is consistent with preceding influenza seasons going back several years.

USA 2018, 2019, and 2020 influenza epidemic seasons

Did this pattern persist into the subsequent three seasons? The answer is "No." The subsequent three seasons each had unusual and distinct profiles, as shown in **Figure 2.** The 2018-19 epidemic in the U.S. was characterized by a particularly strong influenza A season (green) accompanied by remarkably low levels of influenza B (red) with positivity rates always well below 3% across the nation and never peaking anytime during that year's entire epidemic.

Then came the 2019-20 season, with influenza B arriving before influenza A for the first and only time in any season, going back at least to 2008 and achieving a nearly 2-fold higher percent positivity peak than any observed in the preceding three seasons.

As the COVID-19 pandemic arrived, reports demonstrated an abrupt end to the 2019-20 influenza season in the United States, as shown graphically by the sharp, rapid fall of the influenza positivity rates for influenza types A and B in February-March 2020. Indeed, in the subsequent winter, 2020-21, we can argue that there was no influenza season in North America with influenza positivity rates for types A+B combined rarely exceeding 2% for nearly 20 months.

As shown in **Figure 3** below, despite the low influenza positivity rates lasting for 19 months, the number of influenza tests climbed slowly, but steadily, through the largely vacant 2020-21 influenza season. Although episodic cases of influenza were reported across the nation, much of this testing was likely stimulated by the similarity of symptoms for influenza-like-illness (ILI) and COVID-like-illness (CLI). This profile continued until the end of October 2021 when the influenza A positivity rate itself began to rise (see green line in Figures 1 and 2).-

Dramatic decline in influenza-related hospitalizations and deaths in U.S.A

The dramatic decline in positive influenza cases, first reported in the

Seasons	Symptomatic Illnesses	Medical Visits	Hospitalizations	Deaths
2016-2017	29,000,000	14,000,000	500,000	38,000
2017-2018	41,000,000	21,000,000	710,000	52,000
2018-2019	29,000,000	17,000,000	380,000	28,000
2019-2020	35,000,000	16,000,000	380,000	20,000
2020-2021	*	*	*	748

Table 2. U.S. Influenza Disease Burden for Seasons 2016-17 through 2020-21
* CDC 2021 final summary not yet available.

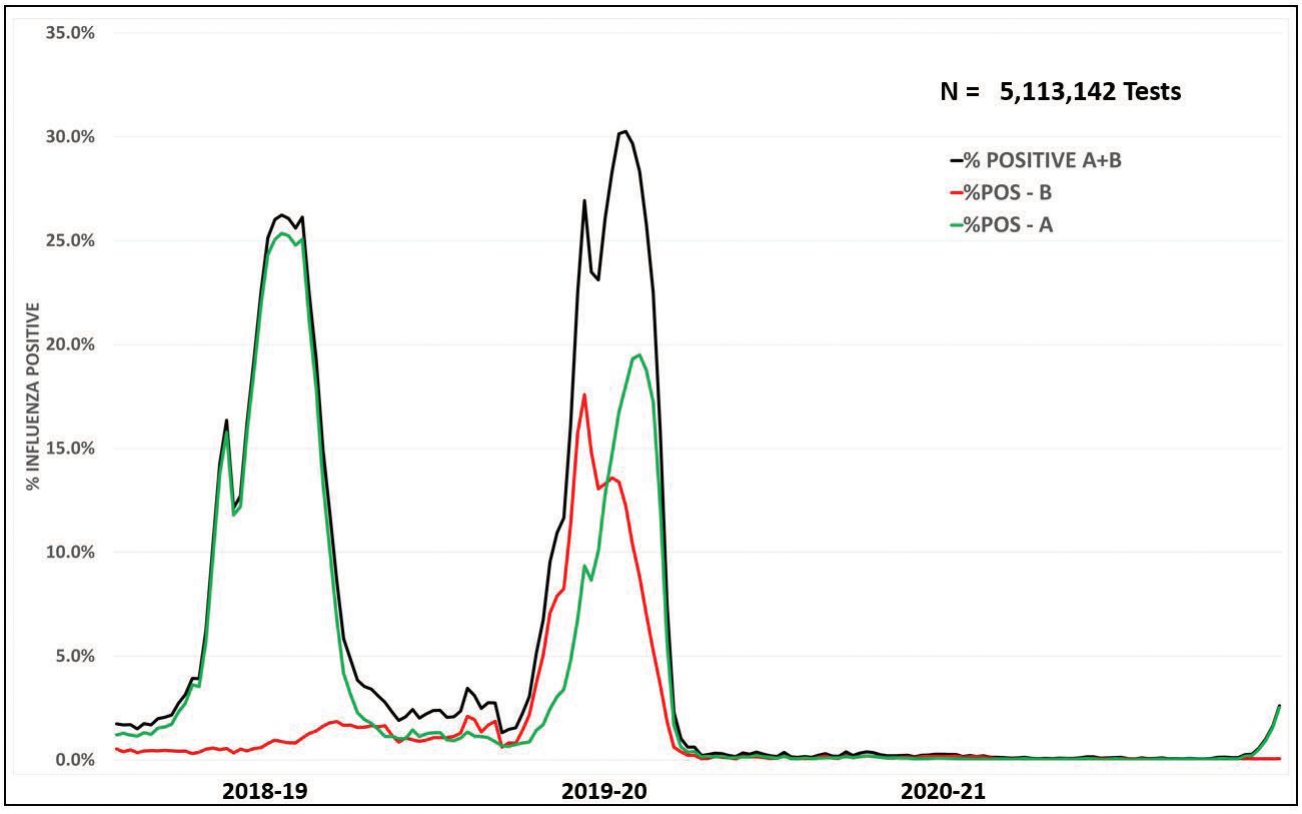

Figure 2. USA Influenza Positivity Rates - 2018 Month 40 to 2021 Month 47

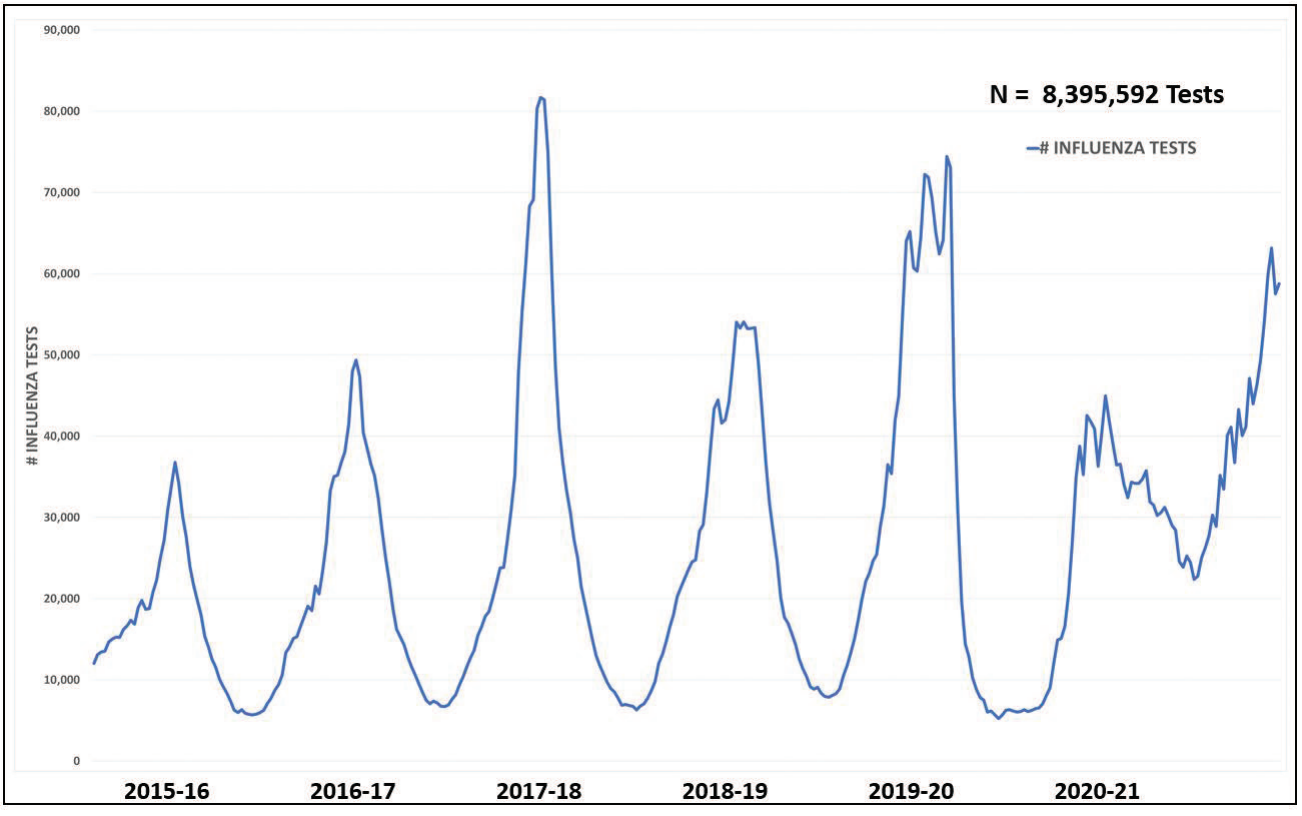

Figure 3. USA Influenza Test Rates-2015 Month 40 to 2021 Month 47

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① U.S. Food and Drug Administration. StatStrip Glucose 510K Notification K181043. Accessed online at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

② US Food and Drug Administration Product Classification. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NBW

③ U.S. Food and Drug Administration. Self-monitoring blood glucose test systems for over-the-counter use. Draft guidance for industry and Food and Drug Administration staff. https://www.fda.gov/media/119828/download

④ US Food and Drug Administration Product Classification. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NBW

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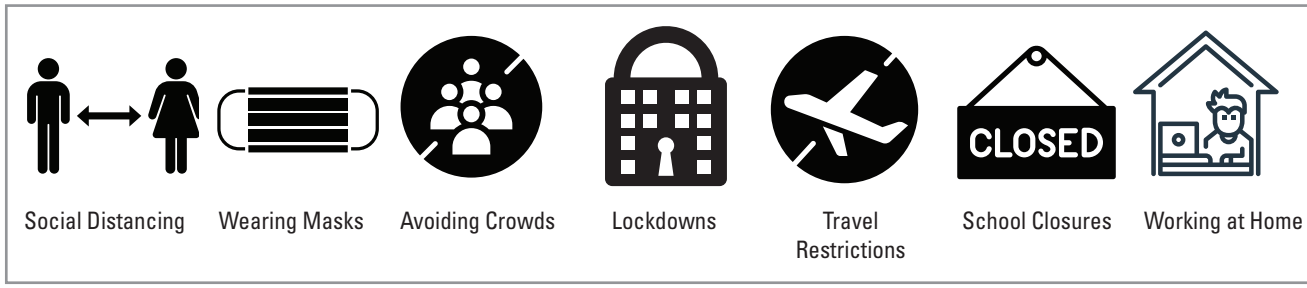

Table 3. Behavioral and Societal Factors Affecting US Influenza Burden (as well as that of COVID-19)

Southern Hemisphere, and observed in the United States, thereafter, profoundly impacted hospitalization and influenza-associated death rates across the nation **(Table 2)**.[5] Although the CDC's full report for the 2020-2021 season is not yet available, participating laboratories have reported testing respiratory specimens from approximately 1.3 million patients of which only 2,136 (0.02%) were positive; there were 748 deaths — only 2% of the average number of deaths for the previous four seasons, according to preliminary reports.[10] What factors influenced these profound changes in influenza seasons across the globe?

Factors influencing the decline of influenza in the 2020-2021 season

- Behavioral and societal factors. Most epidemiologists agree that the continued behavioral and societal precautions (**Table 3**) against the spread of COVID-19 have very likely reduced the appearance and spread of influenza, as well as other respiratory pathogens in the U.S.[6]
- Case isolation, contact tracing, quarantine. In addition, actions by state public health officials to promote and assist in COVID-19 case isolation, such as contact tracing and quarantining of those exposed, have also likely contributed to the decline in influenza.[7]
- Pre-existing herd immunity and vaccinations. Before the pandemic, there already was an existing influenza immunity, due to previous influenza infections and influenza immunizations[8] in the U.S. The combination of this pre-existing herd immunity against influenza and the behavior and societal factors employed to reduce COVID-19, may have reduced influenza cases even further.[9,10]
- Reduced test rate for influenza. Some researchers have argued that the reduced influenza burden is a false perception created by declining influenza tests rates. However, ongoing work by the World Health Organization (WHO) demonstrates that testing rates at sentinel sites remain high, providing for an accurate assessment of influenza burden worldwide.[11]
- Delta and Omicron variants. The arrival of the Delta variant (December 2020) in the U.S., and the growing number of breakthroughs in vaccinated populations, stimulated Americans and their government to reassert mitigation efforts to prevent spread of respiratory disease. Most recently, the arrival of the highly transmissible Omicron variant (November 2021) will likely stimulate similar or even more aggressive steps. The re-

Factors	Consequence
Failure to adhere to behavioral precautions, social distancing, mask wearing, etc.	This could greatly speed up the return and spread of respiratory viruses. Unfortunately, this is occurring in many states. Influenza will likely reoccur as precautions are rescinded.
Opening public schools	Children and schools are primary sources of influenza outbreaks in a community.[14,15] Less than 60% of children have been vaccinated against influenza.[8]
Waning herd immunity	Lack of exposure and even mild influenza infections in the 2020-2021 season diminishes our population's immune preparedness. This decline in herd immunity could result in a more severe influenza epidemic, if it does occur.[10]
Uncertainty about optimal influenza vaccine constituents	Lack of circulating influenza subtypes and lineages in the Southern Hemisphere may have compromised effective vaccine design for this season.[11]
Refusal to receive the influenza vaccine	Lack of herd immunity for influenza increases likelihood of incidence and spread of influenza.[9,16] Influenza vaccination rates are up for adults and down for children this year.[8]
Effective SARS-CoV-2 vaccination program	Elimination or control of COVID-19 incidence could reduce adherence to behavioral precautions.
Failure to test for influenza	Reduced testing for influenza can result in poorly anticipated outbreaks and delay public health intervention.
Episodic influenza positives	Influenza has been reported, but at low levels across the United States for many months. It is poised to reinstate its traditional epidemic behavior.[3]
Climbing positivity rates for influenza, esp. influenza A	In the last six weeks, the incidence of influenza A has climbed steadily, rising to its highest levels in the last 20 months.[3]
Environmental factors	Unpredictable weather events can impact spread of influenza.[17]

Table 4
Some Factors Predisposing to the RETURN of Influenza in 2021-22

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implementation of these precautions could impede the arrival of an influenza epidemic again this winter.[12,13]

Factors favoring a possible return of influenza this winter in the U.S.A.

Obviously, trying to predict what will transpire with influenza this year is a formidable challenge. Even before the arrival of COVID-19, we experienced two very unusual and unpredictable influenza seasons that deviated significantly from previous seasons. As such, there is a growing list of factors that suggest a potential return of influenza this coming season **(Table 4)**.

The fact that influenza and SARS-CoV-2 share so many common signs and symptoms makes differential diagnosis a critical element to effective disease management. Treatments for each pathogen are available, including monoclonal antibody therapy, and recent and other forthcoming emergency use authorizations from the U.S. Food and Drug Administration (FDA) of new oral drugs. However, the timing of therapeutic intervention is very important. Often, the windows for effective therapy are short and require administration as early as possible following onset of symptoms. In addition, we know that, should influenza and COVID-19 both circulate at high levels in the same community, co-infections of influenza and SARS-CoV-2 can occur — with strong negative impact on patient morbidity, mortality, and indisputable need for intense medical interventions.

The availability of high-quality rapid point-of-care diagnostic tests is critically important as the traditional respiratory virus season continues. Perhaps even more important, the competent application of telemedicine, digital health, and at-home COVID-19 tests could have a profound impact on potential resurgence of influenza infections, in the midst of the ongoing COVID-19 pandemic. Distinguishing an ILI patient from a CLI patient is a challenge, but this must be done competently and quickly to save lives. A negative at-home SARS-CoV-2 test for a symptomatic patient must be followed up with an influenza test if a valid influenza season develops. A rapid multiplex test that detects all three viruses would be an excellent alternative — especially if SARS-CoV-2 and one or more influenza types were prominent in a region.

What can we expect this coming Influenza season?

- COVID-19 or influenza or both illnesses will be present.
- The incidence of either, or both, will likely vary dramatically between different regions in the U.S., based on personal and societal behaviors and on environmental factors in different states.
- With onset of ILI and CLI symptoms, there will be uncertainty about the diagnosis without testing for both influenza and COVID-19.
- Physicians will want to test for both viruses — either one at a time or both simultaneously. The test results could enable prompt therapeutic intervention for either disease.
- If testing separately, a positive test for one cannot rule out a co-infection by the other. Although rare, the consequences of missing a dual infection can be devastating.
- For over-the-counter test options, the ability to test for both viruses in the home setting will be an advantage for the patients and members of the household.
- Children will need to be tested if symptomatic or asymptomatic. It is likely that many will be infected in schools. They may have little or no symptoms, but some will shed virus. Serial at-home testing will likely become much more common.
- Depending on environmental conditions, influenza could strike early this winter, especially in areas with high humidity and warmth.

Closing

Making any forecast, as shown with the above background, is almost impossible. But in the U.S., we are poised with a number of excellent platforms for COVID-19 and influenza diagnosis. Over 267 NAATs and 41 rapid antigen tests have received EUAs for COVID-19. The serial use of rapid antigen tests, particularly multiplex tests for detection of influenza viruses and SARS-CoV-2, in POC settings and/or at-home, will continue to give physicians and public health an early warning, enabling early treatment for influenza and for COVID-19 patients, while keeping our public health agencies informed of outbreaks.

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John Tamerius, PhD, is Senior Vice President of Strategic & External Affairs at **Quidel Corporation**

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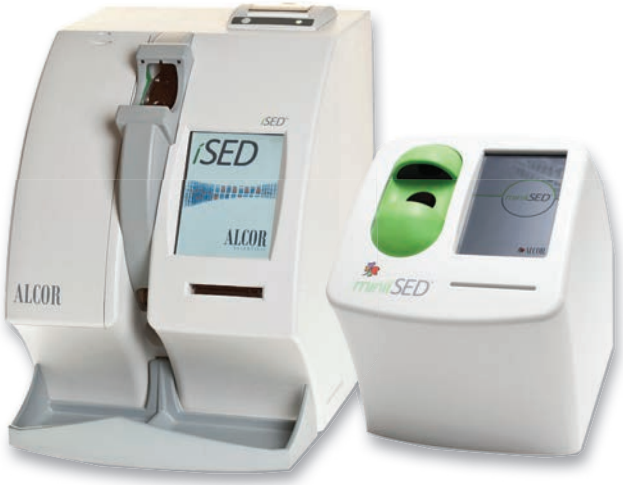

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TEST QUESTIONS

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1. **Since the onset of COVID-19 pandemic, U.S. public health officials in the Southern Hemisphere provided reports regarding their first influenza season, indicating a _____ in the incidence of influenza, compared to previous seasons.**
   - A. profound drop
   - B. slight drop
   - C. slight increase
   - D. profound increase

2. **Which two countries had the smallest number of documented cases of influenza in the Southern Hemisphere, in 2020?**
   - A. Argentina, Chile
   - B. Chile, Australia
   - C. Australia, South Africa
   - D. Chile, South Africa

3. **Using the data available from the CDC, epidemiologists were able to examine historical influenza seasonal outcome/trends that could provide clues about the forthcoming influenza season.**
   - A. True
   - B. False

4. **The positivity rates for influenza types A+B combined, or individually, are depicted by respective colors and range from about ___to as high as ___.**
   - A. 5%, 35%
   - B. 1%, 30%
   - C. 10%, 40%
   - D. 2%, 25%

5. **Influenza B conventionally reaches its seasonal peak about ____weeks after influenza A.**
   - A. 2 to 4
   - B. 3 to
   - C. 5 to 7
   - D. 4 to 8

6. **The 2018-19 epidemic in the U.S. was characterized by a particularly strong influenza A season accompanied by remarkably low levels of influenza B.**
   - A. True
   - B. False

7. **During the 2019-20 season, which influenza virus arrived first?**
   - A. Influenza A
   - B. Influenza B
   - C. None of the above
   - D. Not enough data available

8. **Reports demonstrated an abrupt end to the 2019-20 influenza season in the United States, due to _____.**
   - A.Tthe arrival of the COVID-19 pandemic
   - B. Improved personal hygiene
   - C. Work from home options increased
   - D. All of the above

9. **Throughout the 2020-21 influenza season, the number of influenza tests climbed slowly, but steadily, although episodic cases of influenza were reported across the nation. Why?**
   - A. Much of this testing was likely stimulated by the similarity of influenza-like-illness (ILI) and COVID-like-illness (CLI) symptoms.
   - B. Much of the testing likely contained incomplete information
   - C. Much of this testing was likely stimulated by the similarity of influenza-like-illness (ILI) and measles symptoms.
   - D. Much of this testing was likely stimulated by the differences between influenza-like-illness (ILI) and COVID-like-illness (CLI) symptoms.

10. **In 2020-2021, laboratories reported testing respiratory specimens from 1.3 million patients of which only 2,136 (0.02%) were positive; there were only 2% of the average number of deaths for the previous four seasons. What factors influenced these changes?**
    - A. Behavioral and Societal Factors
    - B. Case isolation, contact tracing, quarantine
    - C. Pre-existing herd immunity and vaccinations.
    - D. All of the above

11. **The arrival of the _____will stimulate Americans to reassert aggressive steps to prevent spread of respiratory disease.**
    - A. Highly transmissible Omicron variant (November 2021)
    - B. Delta variant (December 2020)
    - C. Both
    - D. None of the above

12. **What factor predisposes the return of influenza in 2021-22?**
    - A. Not being prepared for a storm
    - B. Receiving an influenza vaccine
    - C. Failure to adhere to behavioral precautions, social distancing, mask wearing, etc.
    - D. Staying home from school/work if you feel sick

13. **The fact that influenza and SARS-CoV-2 _____ makes differential diagnosis a critical element to effective disease management.**
    - A. do not share any common signs and symptoms
    - B. share so many common signs and symptoms
    - C. share only one symptom
    - D. share only two symptoms

14. **What factor is very important regarding therapeutic intervention?**
    - A. Patient Gender
    - B. Patient Age
    - C. Test location
    - D. Timing

15. **Should influenza and COVID-19 both circulate at high levels in the same community, co-infections of influenza and SARS-CoV-2 can occur – with strong negative impact on patient _____.**
    - A. morbidity
    - B. mortality
    - C. indisputable need for intense medical interventions
    - D. All of the above

16. **The availability of _____ is critically important as the traditional respiratory virus season continues.**
    - A. high-quality rapid POC diagnostic tests
    - B. OTC/at-home COVID-19 tests
    - C. A. and B.
    - D. None of the above

17. **What can we expect this coming influenza season?**
    - A. For OTC, the ability to test for both viruses in the home setting will be an advantage for the patients and members of the household.
    - B. Physicians will want to test for both viruses--either one at a time or both simultaneously. The test results could enable prompt therapeutic intervention for either disease.
    - C. COVID-19 or influenza or both illnesses will be present.
    - D. All of the above

18. **Over ____ NAATs and _____ rapid antigen tests have received EUAs for COVID-19.**
    - A. 267, 41
    - B. 450, 33
    - C. 534, 45
    - D. 289, 63

19. **The serial use of rapid antigen tests, particularly multiplex tests for detection of influenza viruses and SARS-CoV-2, _____, will continue to give physicians an early warning, enabling early treatment.**
    - A. in POC settings
    - B. at-home
    - C. Both A. and B.
    - D. None of above

20. **Depending on_____, influenza could strike early this winter, especially in areas with high humidity and warmth.**
    - A. population controls
    - B. environmental conditions
    - C. social behaviors
    - D. influenza shots

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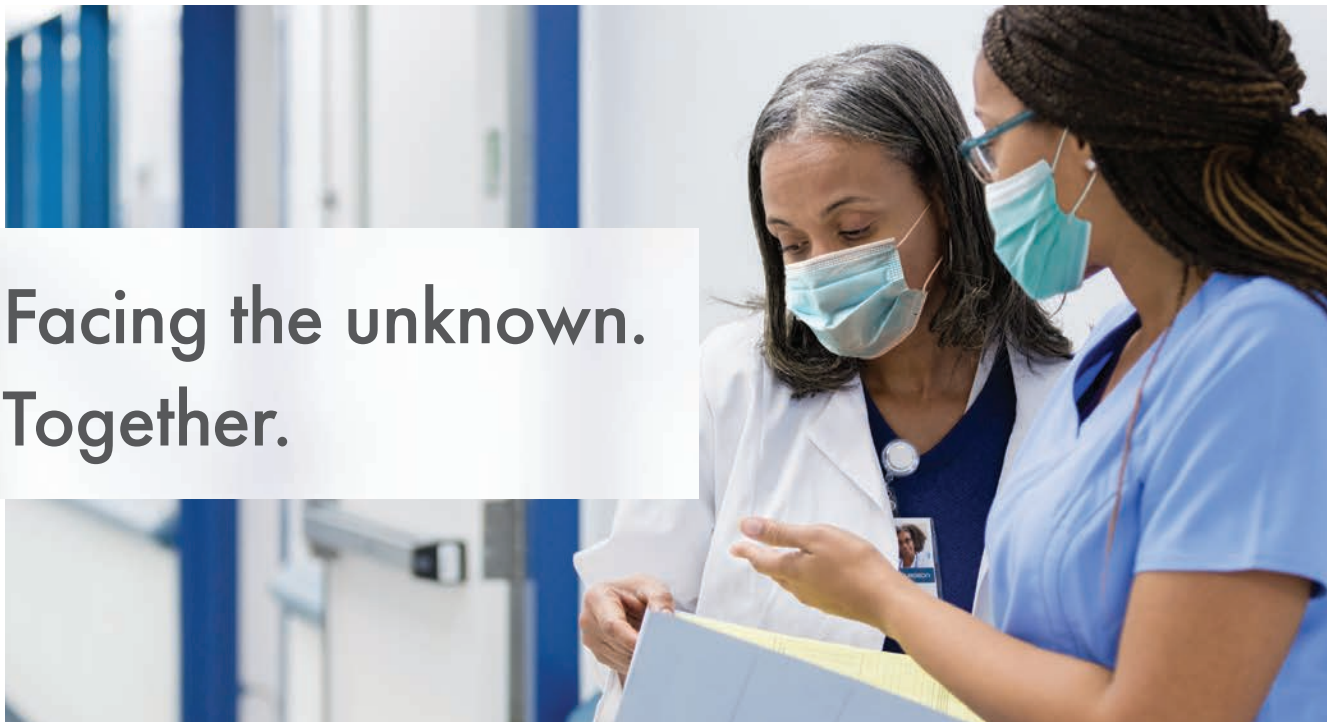

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Sample to Insight

Improving red blood cell usage at an academic medical center

By Colleen Hinrichsen, SBB, and Jean Fede, DO

Blood Utilization has become a more focused effort over the last decade. Accrediting bodies like the Joint Commission have asked hospitals and health systems to actively monitor overutilization of patient therapies. One of the top five most commonly overutilized therapies has been blood transfusions, as identified by the American Medical Association.[1] The American Board of Internal Medicine's Choosing Wisely program addresses waste in healthcare. One of the Choosing Wisely initiatives "Why choose two when one will do?" is to teach clinicians to only order blood products when truly necessary, and only one unit at a time.[2]

The Department of Health and Human Services National Blood Collection and Utilization Survey (NBCUS) has identified a decreased trend in blood collections over most of the last decade.[3] Evidence supports that this trend is most likely due to the decreased utilization of blood transfusions in hospitalized patients in the United States since 2011 because of nationwide efforts to help quell the use of blood products when they may not be medically necessary.[4]

A multitude of studies have supported the Choosing Wisely recommendations of a more restrictive, rather than liberal, transfusion practice in stable patients. The studies have found this approach to be more effective, and ultimately leading to better patient outcomes.[5,6,7,8]

Penn Medicine Princeton Medical Center began an aggressive real-time blood utilization program in July 2016.
Photo Courtesy of Penn Medicine Princeton Medical Center

Orthopedics specialties, for example, have seen substantial decreases in the use of perioperative blood transfusions since implementing wide use of an inexpensive drug called tranexamic acid, which helps decrease bleeding associated with certain surgeries.[9]

Not without risk, blood transfusions can lead to other problems, namely transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI), and other transfusion-specific adverse events; immunomodulation; increased rates of healthcare associated infections; and increases in the hospital length of stay.[4,5] Increased hospital stays can lead to poor patient outcomes, decreased Medicare reimbursement rates, and an overall increase in patient-care costs.

The roles of institutional blood utilization committees — in addition to monitoring usage/wastage statistics and cross-match/transfusion ratios — have evolved in recent years in response to the utilization efforts discussed here.

Like other institutions, Penn Medicine Princeton Medical Center, formerly known as the University Medical Center of Princeton at Plainsboro, also has a committee that focuses on the overutilization of blood products. Historically, the committee has achieved its goals by:

- Peer-to-peer discussions, which help to educate providers on the most effective uses of blood products or alternatively, treating the patient medically (i.e., using iron therapy in applicable patients as a first line therapy rather than transfusing the patient with red blood cells)
- Evaluating blood product utilization by individual provider
- Real-time intervention on blood orders that do not meet established transfusion criteria
- Asking providers to help justify possible unsubstantiated use of blood products

The use of electronic blood ordering and added layers of control, like clinical decision support (CDS) or a 'best practices alert' (BPA), may be the next growing trend to support a restrictive transfusion approach.[5,1,7] Best practice alerts prompt providers to think about whether their orders meet transfusion criteria while they are placing an order. BPAs may include hard stops if a blood transfusion order has not met criteria, such as if the laboratory level (i.e., hemoglobin) at which transfusion is recommended is not met. These hard stops provide immediate feedback to the clinicians. For those institutions utilizing house staff or hospitalists to help manage hospitalized patients, follow-up reports provide feedback to attending physicians, who are ultimately responsible for treatment orders.[2] Stanford University, for example, reported a 24% reduction in RBC transfusions once CDS was implemented.[1] Studies show that a restrictive blood transfusion strategy also leads to equivalent, or better outcomes, such as a reduction in cardiac events, repeat bleeding, bacterial infection, and total mortality.[10,11]

Our program

Penn Medicine Princeton Medical Center began an aggressive real-time blood utilization program in July 2016, which has been shown to be one effective approach to better blood utilization.[12] Prior to initiating our utilization program, like many hospital transfusion services, the 355-bed nonprofit, academic medical center had an existing type-and-screen transfusion policy,

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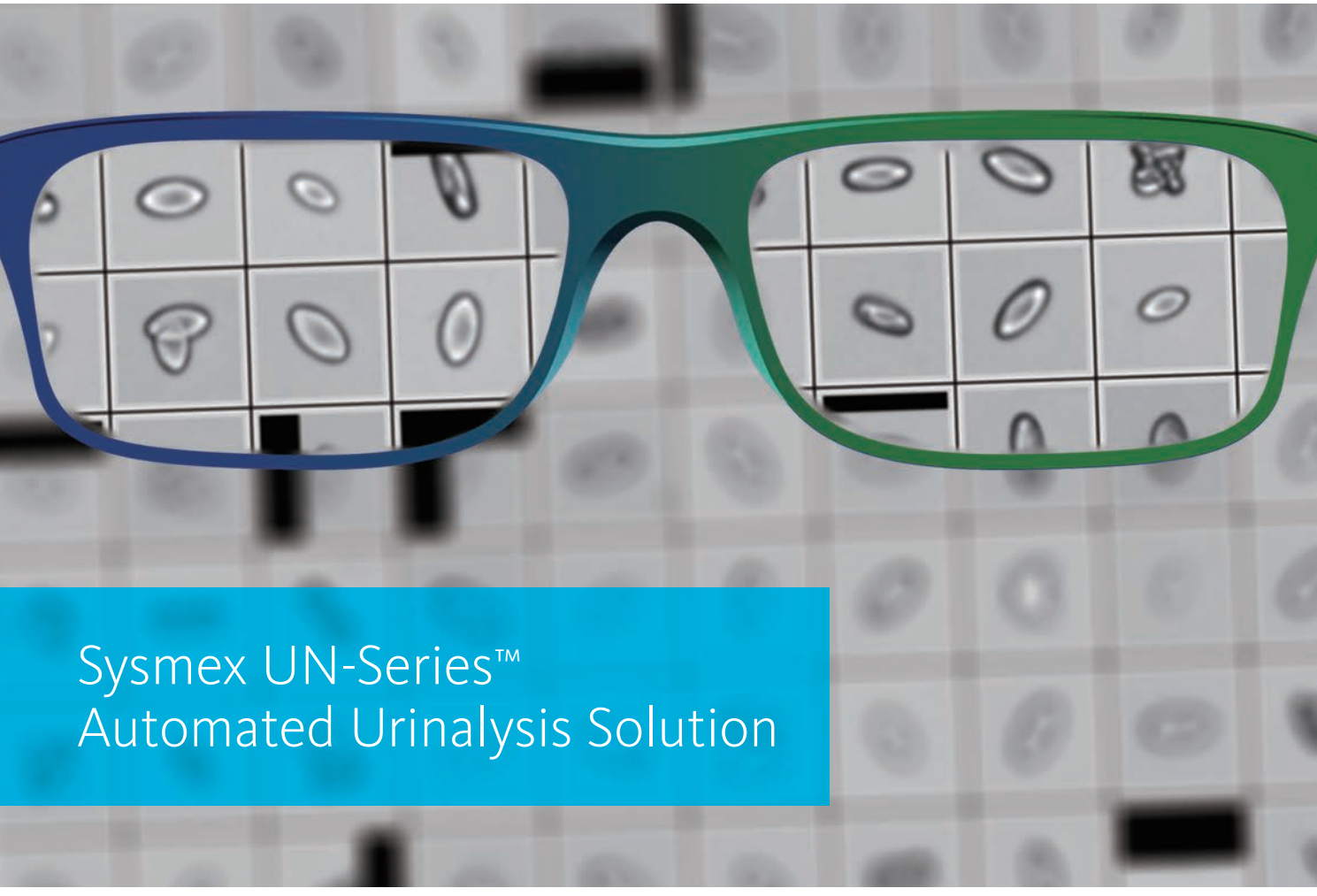

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shown to be effective in more efficient inventory management and, therefore, decreased blood product wastage.[8] Without the benefit of clinical decision support, our transfusion service team members added the real-time program to actively screen blood transfusion orders to determine if established transfusion guidelines are met. The medical director of the transfusion service provides a phone consultation with the ordering provider each time a blood product is ordered for transfusion if the guidelines for transfusion criteria are not met. At the conclusion of the consultation, a recommendation to transfuse (or not) is made.

Our hospital uses the following transfusion guideline criteria for non-bleeding inpatients:

- Red Blood Cells: patient Hgb </= 7 g/dL
- Platelets: patient platelet count <= 10,000/µL
- Plasma: patient INR >/= 1.6

At one-year post-implementation of this program, red blood cell utilization had decreased by 17%.

In addition to the real-time screening, we retrospectively review a report from our laboratory information system (LIS) each workday, which lists all blood transfusions, along with pre- and post-transfusion lab values (i.e., hemoglobin, INR, fibrinogen).

Finally, we gather monthly LIS reports on blood utilization sorted by physician, and the committee recommends which providers may need further review, and after further chart review, possibly asking the provider to write a letter justifying the reasons for transfusion.

In addition to our ongoing work to improve usage of RBCs for transfusion, we developed a formal study.

Our goals were to find out if:

- The trend of RBC transfusion reduction has continued to trend downward over a two-year study period compared with the six-month baseline.
- There had been a corresponding trend of increased inpatient iron therapy during the same timeframe.
- There had been a corresponding increase in utilization of laboratory anemia-related tests.

We collected data for the study from July 2016 to June 2018, comparing it to baseline data, which we collected from January 2016 to June 2016.

While improving transfusion medicine services was the primary goal, another benefit of this project and formal study may be an increased awareness about the roles of pathologists,

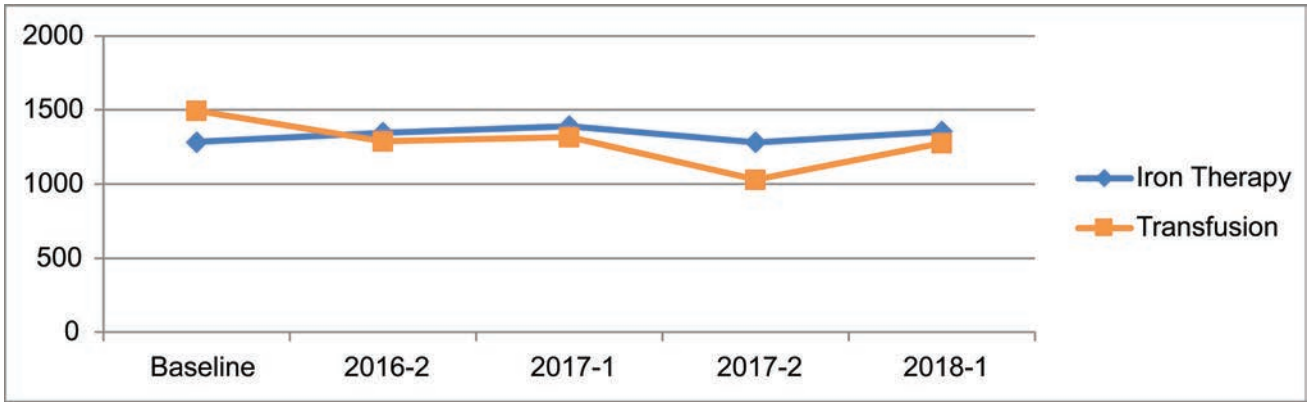

Figure 1. There has been an overall increase in iron therapy usage corresponding with a decrease RBC transfusion usage during the 2-year study period compared to baseline.

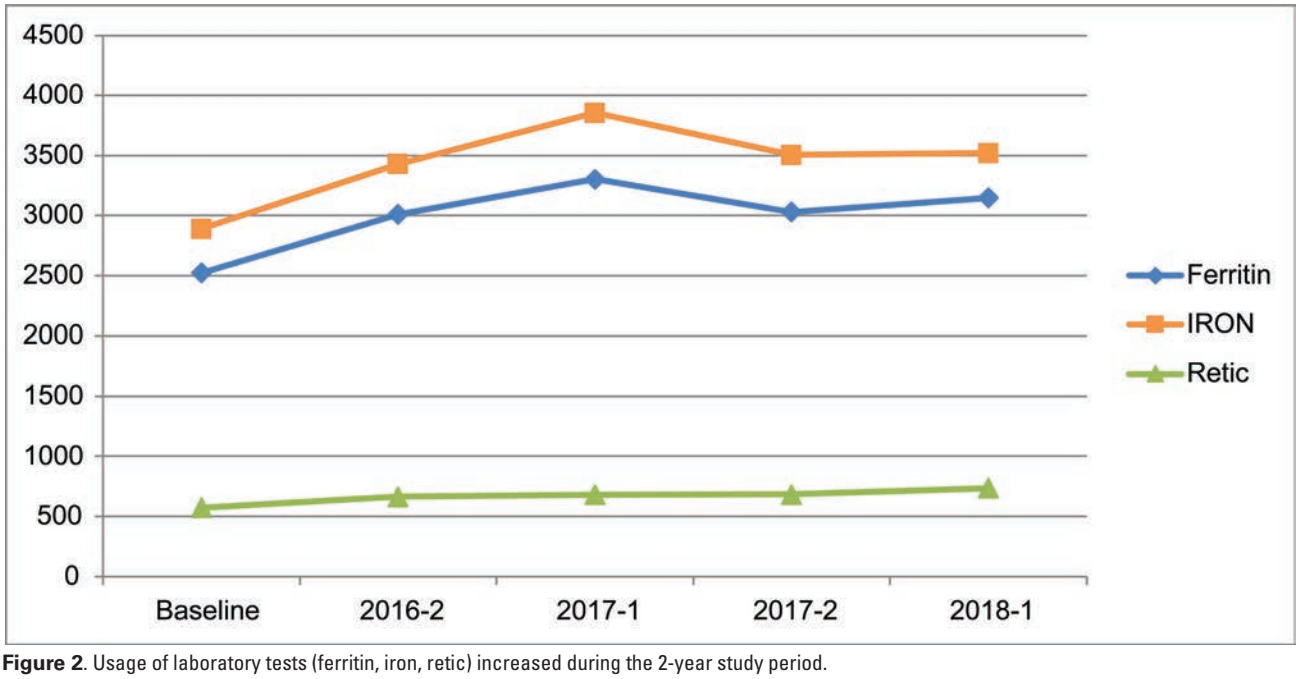

Figure 2. Usage of laboratory tests (ferritin, iron, retic) increased during the 2-year study period.

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pharmacists, and laboratorians in performing interdepartmental patient care. Care of the patient — with appropriate laboratory testing, iron therapy, and when necessary, RBC transfusions — may result in better outcomes and shorter lengths of stay.

In addition, during our program evolution, we have discovered that our pathology group is one of very few such groups in the U.S. currently billing a professional component for this important work in appropriate patient care.

Proper role of transfusions

Many studies and journal reviews in recent years note a focus on smarter blood utilization; that is, reserving the precious blood supply for patients who need it most, when other therapies have failed, rather than using blood transfusion as a first-line therapy to treat anemia in hospitalized patients. These studies and other efforts, like the Choosing Wisely program, have helped curb overutilization of laboratory testing and blood transfusions, leading to an overall decrease in blood collection in the U.S. and a concurrent decrease in demand for those products. There are some concerns that a negative result of this downward trend may be a more fragile blood supply. That could be a problem if the nation's blood supply cannot meet temporary increases in demand, such as when disasters occur, resulting in numerous massive transfusions.

Study methods

We measured the total number of RBC transfusions monthly, gathering data from the LIS and capturing it in an Excel file. The total number of iron therapy patients was measured monthly by culling information from the pharmacy information system and capturing it in an Excel file. The total number of laboratory tests, including iron, retic count, and ferritin, were measured monthly from the LIS and captured in an Excel file. All data points (RBC usage, iron therapy usage, laboratory test data) were compared to baseline data in six-month increments, and overall.

We wanted to answer the following questions:

- Has iron therapy increased during the study period, compared to baseline?
- Have red blood-cell transfusions decreased during the study period, compared with baseline?
- Has the usage of anemia-related laboratory tests increased during the study period, compared with baseline?

Anticipated Complications

Complications of completing the study are limited to the resources available for data gathering and organizing. In addition, the hospital information system was upgraded in June 2018, which corresponded with the final month or our study. As such, pharmacy data for June 2018 was tallied from two separate computer systems: the legacy system for June 1-8 and the new system for June 9-30.

Conclusions

Our study data showed that iron therapy has increased on average 4.2%, compared to baseline. Blood utilization decreased 17%, compared to baseline, over the 2-year study period. (See **Table 1**). In addition, there was an increase in medically related assessment of patients compared with baseline, over the 2-year study period.

All laboratory tests showed consistent increases in usage, with an average of 22.8% compared with baseline, when looking at all three tests: ferritin, iron, and retic count combined (see **Table 2**).

Overall, our blood utilization program has been effective in both decreasing unnecessary transfusions and increasing use of laboratory testing that can help guide providers to possibly choose more effective treatment options for patients. In future studies, it may be valuable to look at patient length of stay and overall morbidity and mortality to better understand the relationships before and after implementation of a blood utilization program.

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Colleen Hinrichsen, SBB, is the Transfusion Medicine Supervisor at Penn Medicine Princeton Medical Center.

Jean Fede, DO, has been working as a board certified Anatomic and Clinical Pathologist at Pathology Associates of Princeton for the last 14 years. In addition, she currently serves as the Medical Director of the Blood Bank and Transfusion Medicine Service for Penn Medicine Princeton Medical Center. As a Pathologist, she has considerable experience diagnosing a wide range of tumors as well as overseeing and coordinating the molecular testing required as part of that diagnostic process.

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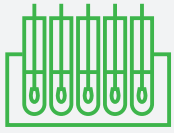

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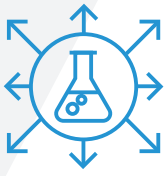

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How far and how well will your data travel?

By Mehdi Nassiri, MD

In today's world, with the ease of travel and individual mobility, healthcare data must travel with its owners (patients). However, nearly one third of patients are burdened with providing their own health record when seeking care. The goal of interoperability in healthcare is to make the right data available, to the right people, at the right time, across products and organizations in a way that can be relied upon and meaningfully used by recipients.

The other benefit of sharing data is creating venues for innovative research. Consumer electronics, with a variety of sensors, are tracking elements that affect our health, and more people are using apps to help manage their diet and exercise goals. Investigators are using this data to create solutions to several issues, but there are too many hurdles in making patient data portable, in a secure manner. The coronavirus disease 2019 (COVID-19) pandemic has exposed huge challenges in data sharing with which healthcare institutions had to comply. [1,2]

Labs first

As laboratorians, we were the first to deal with information systems. Our instruments do not print data on a piece of paper anymore. Building interfaces and laboratory information systems (LIS) is part of our job. In fact, we are responsible for creating most of the data in a healthcare system. We also were the first to use and implement standards. Although we go to great lengths to make sure we correctly run our assays, we report them differently, even when using the same instruments. Not to mention that the reference range for any test with numerical results is different from one laboratory to another. We have very few assays with portable results between labs due to lack of availability of an international reference.

Focus on molecular pathology

The more complex a test is and the more data it generates, the more difficult the transmission of data to an information system becomes. Molecular testing is the cornerstone of therapeutic decision-making in the care for cancer patients, not only for choosing drugs but also to adjust drug dose. Clinicians rely on genetic tests results. Molecular assays are the most complex in our arsenal, considering the number of steps for data analysis and the different file types involved. Like most assays, we only provide an interpretation and do not share intermediary files in the electronic health record (EHR). Currently, there is no mechanism to share regions of the genes being tested and variants in an interrogable fashion. There should be a mechanism for reevaluating the results in context of new clinical and biologic information. None of these requirements can be accomplished with the static text-based report that we currently generate.

In late 2019, the Association for Molecular Pathology (AMP) Board of Directors called for the formation of an Electronic Health Record Interoperability for Clinical Genomics Working Group with

Current state of interoperability.

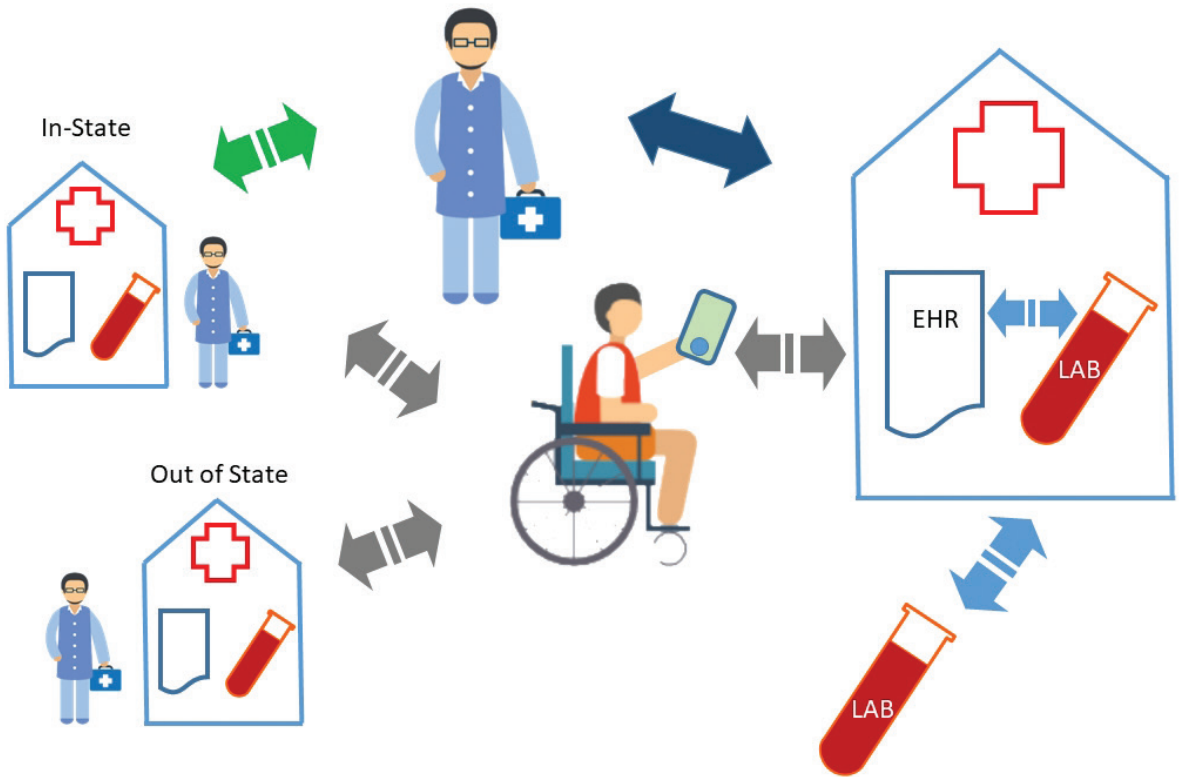

Figure 1. Since April 2021, under 21st Century Cures Act, patients have access to their health records (gray), although access is, at best, limited to a portal at the healthcare institution and not portable data. In most states, there is a statewide data exchange in place (green), but it is fragmented and there are no interstate data exchange. Lack of standards prevent complete data sharing from LIS, with EHR, and from reference labs. In an ideal interoperable state, the broken arrows will be solid. Elements are from Shared Nationwide Interoperability Roadmap (https://www.healthit.gov/infographic/shared-nationwide-interoperability-roadmap-journey-better-health-and-care)

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Level	Issue	Summary
Upstream of the laboratory	Orders: Improvements for Electronic Orders	EHRs are not yet ready to send accurate, coded, clinical history, signs, symptoms, family history, and other broad sets of data elements to laboratories without generating significant burden on providers.
Laboratory	Data Transfers: The Existing HL7 Standard and the FHIR Effort	Despite the improved ability for FHIR to handle data transfer of hierarchical and genomic data, its implementation has been limited between EHRs and laboratories due to cost and lack of a mandate.
	Discrete Variant Data: The Foundational Architecture of Enabling Genomic Medicine	Transfer and storage of standardized variant data structures from the LIS to the EHR is the key enabling feature for future use of genomic data in the EHR
Downstream of the laboratory	Display of Genomic Test Results: Providing Sufficient yet Usable Data.	Genomic reports between laboratories are variable, and even when they include complete information, they may be difficult for providers and patients to understand, due to either lack of genomic expertise or usability or both.
	Display of Aggregated Results across Different Tests	The EHR should provide functionality for clear longitudinal display of data and a way to compare gene and gene region content for each NGS panel. A tiered approach, presenting the complexity of genomic data with a dynamic and integrated report, is the preferred approach. Such integrated reports should include hyperlinks to additional curated content for specific variants.
	Display of Reclassified Variants	Consensus guidelines on best practice for requesting and providing reclassification of variants is a top priority. The different rationales for reclassification and their impact on clinical management and laboratory workflows need to be carefully considered.
	Display of Genomic Results to Patients	There are distinct regulatory requirements and information needs for patients' access to genomic results, as compared with providers, that should be supported in the EHR.
	Clinical Decision Support Rules (CDS)	Discrete genomic data will facilitate scalable drug-genome alerts and other forms of CDS, and international recommendations for CDS are needed for safety and consistency in practice.
	Cross-Functional Requirements and Standards	Effective use of genomic data in EHRs depends on integration of appropriate, safe, and functional international standards for interoperability and data retrieval.
	Reporting Genomic Results to Outside Organizations	Discrete genomic data with appropriate interpretation attributes will facilitate interoperability between systems and organizations. Patient education and informed consent, as well as cybersecurity measures, are paramount to keeping patients informed and their data safe from unauthorized access.

Table 1. Summary of AMP Electronic Health Record Working Group findings. (Adapted from reference 3.)

expertise in molecular pathology and clinical informatics to recommend solutions about ways to resolve the current problems associated with the display and use of genomic data in EHRs. The working group performed a comprehensive examination of current problems and barriers to the display and use of genomic data in EHRs. Multiple problems were categorized and described in detail by the working group members.[3] The problems and opportunities were classified as EHR capabilities, upstream source and downstream recipient of data, and inherent issues of the LIS specifically related genomics and molecular pathology. Major themes were the lack of standards and consensus in current processes. **(Table 1)**

Role of FHIR

The article also reviewed, in detail, current initiatives and solutions. Noteworthy among these tools is FHIR (Fast Healthcare Interoperability Resources). It allows flexibility in the development of task-specific apps to interact with the EHR, which have[4,5] become monolithic and the domain of only a few companies. FHIR adopts nonproprietary web technology called application programming interfaces (APIs)/web services. FHIR can be used as a stand-alone data exchange standard but can also be used with existing standards. However, HL7 FHIR and currently deployed HL7 version 2 are significantly different, and it will be costly for vendors and laboratories to switch to FHIR. In addition, there are no legal mandates requiring that communications between EHRs and laboratories use FHIR, unlike the older version 2 of HL7, which is required for use by certified EHR technology in the United States.

In summary, standards and tools are becoming available to create viable processes for interoperability and data sharing. However, reaching consensus and universal adoption of them takes time, resources, and capital.

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Mehdi Nassiri, MD, is Associate Professor of Pathology and Laboratory Medicine, **Indiana University School of Medicine, Indiana University Health.**

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Omicron can complicate SARS-CoV-2 diagnostics

By Gail Castanho

Since the early days of the COVID-19 pandemic, labs, and other healthcare settings, have used molecular and antigen diagnostic tests to detect SARS-CoV-2, the virus that causes COVID-19, in patients' specimens.

Then came Omicron. After the variant's arrival in late 2021, public health and government officials began to analyze the impact of Omicron on test results.

The concern centers around the number of mutations in Omicron, compared with earlier variants and the original virus. Many of these occur in the spike protein, which the Centers for Disease Control and Prevention (CDC) said,"is characterized by at least 30 amino acid substitutions, three small deletions, and one small insertion. Notably, 15 of the 30 amino acid substitutions are in the receptor binding domain (RBD). There are also a number of changes and deletions in other genomic regions."

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Experts say Omicron is more easily spread among people than earlier versions of the virus. This has been confirmed by the World Health Organization (WHO), where Omicron's overall risk remains classified as "very high risk." Indeed, the Centers for Disease Control and Prevention (CDC) reported recently that Omicron now accounts for 95% of COVID-19 cases in the United States, compared with 5% for Delta.

The WHO also said that "the rapid growth rate is likely to be a combination of both immune evasion and intrinsic increased transmissibility of the Omicron variant."

Upon investigation, what seems to be significant with testing for SARS-CoV-2, when the Omicron variant is present, is two-fold.

First, there is the potential impact on molecular tests. The Food and Drug Administration (FDA) has published lists of diagnostic tests that have been potentially impacted by SARS-CoV-2 variants. The issue is whether a diagnostic test will produce accurate results if a mutation occurs in the virus in the gene target that the test is designed to detect. If a test detects multiple gene targets, it will still detect the presence of SARS-CoV-2 via the other targets and produce accurate test results, the FDA said.

However, if the test is a single-target or multiple-target assay in which all of its targets are impacted by mutations, it will fail to detect Omicron, leading to false negative test results. The FDA has created a list of such tests.

Originally, the DTPM COVID-19 RT-PCR test from Tide Laboratories was on the list. However, the manufacturer has since modified the test, and the FDA reissued an emergency use authorization (EUA) for the test in late December 2021.

"The original test was a single target test that was expected to fail to detect the SARS-CoV-2 Omicron variant (B.1.1.529) due to a nine-nucleotide deletion in the N-gene, spanning positions 28370-28362, which is within the portion of the N-gene that the single target covered," the FDA explained. However, the manufacturer has since modified the test, which is now a multiplex test with an added reverse primer to detect the Omicron variant.

A bioinformatics analysis demonstrated a 100% match with Omicron and Delta variant sequences, the FDA said.

Several other single-target tests remain on the list of tests expected to fail to detect Omicron.

The FDA noted that other tests may have one genetic target, with reduced sensitivity, due to a mutation in the Omicron variant related to the S gene, but test results should not be impacted because the tests detect multiple genetic targets in the virus. Those tests are included in a list of "Tests with Detection Patterns that May Be Associated with the SARS-CoV-2 Omicron Variant."

The agency also said some of these may have an unintended benefit: the tests may signal that the Omicron variant is present in a sample, meaning that these specimens should be prioritized for sequencing.

Examples of those types of tests are Thermo Fisher Scientific's PCR TaqPath COVID-19 Combo Kit and TaqPath COVID-19 CE-IVD RT-PCR Kit. The tests detect SARS-CoV-2 infections "by identifying the presence of three gene targets from the orf1a/b, S, and N regions of the virus. By surveying across multiple genes, the test can report accurate results even in the case where one of the targets (the S gene target) is impacted by a mutation," the company said. It added that "the overall accuracy of the TaqPath COVID-19 assays is not impacted." Thermo Fisher has been touting its tests as useful for providing an early indication of the possible presence of Omicron in a sample.

Second, antigen tests may be less sensitive to Omicron than molecular PCR tests. Preliminary data, from the FDA suggests that antigen tests detect Omicron, but may be less sensitive. The FDA updated the SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests web page to share new information about the impact of the SARS-CoV-2 Omicron variant on antigen diagnostic tests. The update includes preliminary study results of some antigen tests using patient samples containing live virus.

In addition to the FDA's research, a small real-world study by the COVID Sports and Society Workgroup finds antigen tests fail to detect Omicron during early days of infection. The study found that the median time, from the first positive PCR test to the first positive antigen test, was three days.

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Individual FDA EUAs for Molecular Diagnostic Tests

Company Name	Last Updated (and Original Date EUA Issued)	Name of Test	Type of Test	Authorized Settings
3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.	06/24/2021 (06/18/2020)	TRUPCR SARS-CoV-2 Kit	Real-time RT-PCR, Saliva	H
Abbott Diagnostics Scarborough, Inc.	08/27/2021 (03/27/2020)	ID NOW COVID-19	RT, Isothermal amplification	H, M, W
Abbott Molecular Inc.	11/22/2021 (03/18/2020)	Abbott RealTime SARS-CoV-2 assay	Real-time RT-PCR	H
Abbott Molecular Inc.	11/05/2021 (05/11/2020)	Alinity m SARS-CoV-2 assay	Real-time RT-PCR, Pooling, Screening	H,M
Abbott Molecular Inc.	07/01/2021 (03/04/2021)	Alinity m Resp-4-Plex	Real-time RT-PCR, Multi-analyte	H, M
Abbott Molecular Inc.	07/-1/2021 (03/04/2021)	Alinity m Resp-4-Plex	Real-time RT-PCR, Multi-analyte	H,M
altona Diagnostics GmbH	07/15/2021 (04/22/2020)	RealStar SARS-CoV02 RT-PCR Kits U.S.	Real-time RT-PCR	H
Applied BioCode, Inc.	12/15/2021 (12/15/2021)	BioCode CoV-2 Flu Plus Assay	RT-PCR, Multi-analyte	H
Applied BioCode, Inc.	12/15/2021 (12/15/2021)	BioCode CoV-2 Flu Plus Assay	RT-PCR, Multi-analyte	H
BillionToOne, Inc.	06/23/2021 (09/04/2020)	qSanger-COVID-19 Assay	Sequencing	H
BioFire Defense, LLC	08/25/2021 (03/23/2020)	BioFire COVID-19 Test	RT, Nested multiplex PCR, Pooling, Saliva	H, M
BioFire Diagnostics, LLC	08/30/2021 (10/02/2020)	BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)	RT, Nested multiplex PCR, Multi-analyte	H,M,W
BioFire Diagnostics, LLC	08/30/2021 (10/02/2020)	BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)	RT, Nested multiplex PCR, Multi-analyte	H, M, W
BioGX, Inc.	06/29/2021 (06/29/2021)	BioGX Xfree COVID-19 Direct RT-PCR	Real-time RT-PCR	H
Biomeme, Inc.	06/22/2021 (08/11/2020)	Biomeme SARS-CoV-2 Real-Time RT-PCR Test	Real-time RT-PCR, Pooled Serial Screening - Swab, Pooled Serial Screening - Media	H
Centers for Disease Control and Prevention (CDC)	08/05/2021 (07/02/2020)	Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay	Real-time RT-PCR, Multi-analyte	H
Centers for Disease Control and Prevention's (CDC)	07/21/2021 (02/04/2020)	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC)	Real-time RT-PCR, Pooling	H
Cepheid	10/20/2021 (09/10/2021)	Xpert Xpress CoV-2/Flu/RSV plus	Real-time RT-PCR, Multi-analyte	H,M,W
Clinomics USA Inc.	06/24/2021 (02/04/2021)	Clinomics TrioDx RT-PCR COVID-19 Test	Real-time RT-PCR	H
DiaSorin Molecular LLC	07/22/2021 (03/19/2020)	Simplexa COVID-19 Direct assay	Real-time RT-PCR	H, M
Enzo Life Sciences, Inc.	07/16/2021 (07/07/2020)	AMPIPROBE SARS-CoV-2 Test System	Real-time RT-PCR, Pooling	H
Gencurix, Inc.	08/26/2021 (06/23/2020)	GenePro SARS-CoV-2 Test	Real-time RT-PCR	H
GenMark Diagnostics, Inc.	07/28/2021 (10/07/2020)	ePlex Respiratory Pathogen Panel 2	RT-PCR and electrochemical detection, Multi-analyte	H, M
GK Pharmaceuticals Contract Manufacturing Operations	08/27/2021 (09/18/2020)	GK ACCU-RIGHT SARS-CoV-2 RT-PCR KIT	Real-time RT-PCR	H
Hologic, Inc.	10/26/2021 (05/14/2020)	Aptima SARS-CoV-2 assay	TMA, chemiluminescent, Pooling, Screening	H
Hologic, Inc.	10/26/2021 (12/16/2020)	Aptima SARS-CoV-2/Flu assay	Real-time TMA, chemiluminescent, Multi-analyte	H
Hologic, Inc.	07/23/2021 (03/16/2020)	Panther Fusion SARS-CoV-2 Assay	Real-time RT-PCR, Pooling, Screening	H
INVITES BIOCORE CO., LTD.	08/18/2021 (05/21/2020)	BioCore 2019-nCoV Real Time PCR Kit	Real-time RT-PCR	H
KimForest Enterprise Co., Ltd.	07/15/2021 (09/21/2020)	KimForest SARS-CoV-2 Detection Kit v1	Real-time RT-PCR	H
Laboratory Corporation of America (Labcorp)	09/30/2021 (09/30/2021)	Labcorp SARS-CoV-2 & Influenza A/B Assay	Real-time RT-PCR, Multi-analyte, Home Collection	H
Life Technologies Corporation (a part of Thermo Fisher Scientific Inc.)	10/22/2021 (07/30/2021)	TaqPath COVID-19 Fast PCR Combo Kit 2.0	Real-time RT-PCR, Saliva	H
LMSI, LLC (dba Lighthouse Lab Services)	10/14/2021 (10/14/2021)	CovidNow SARS-CoV-2 Assay	Real-time RT-PCR, Home Collection, Screening	H
LumiraDx UK Ltd.	11/30/2021 (10/14/2020)	LumiraDx SARS-CoV-2 RNA STAR Complete	RT, qSTAR amplification, Home Collection, Screening, Pooling	H
Mammoth Biosciences, Inc.	07/07/2021 (08/31/2020)	SARS-CoV-2 DETECTR Reagent Kit	RT-LAMP, CRISPR	H
OSANG Healthcare	06/24/2021 (04/18/2020)	GeneFinder COVID-19 Plus RealAmp Kit	Real-time RT-PCR	H
PathogenDx, Inc.	07/22/2021 (04/20/2021)	DetectX-Rv	RT-PCR, DNA Microarray Hybridization	H

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SD-COM-ART-00130

Individual FDA EUAs for Molecular Diagnostic Tests

Company Name	Last Updated (and Original Date EUA Issued)	Name of Test	Type of Test	Authorized Settings
PerkinElmer, Inc.	12/14/2021 (10/06/2021)	PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1	Real-time RT-PCR, Multi-analyte	H
PerkinElmer, Inc.	12/14/2021 (10/06/2021)	PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1	Real-time RT-PCR, Multi-analyte	H
PerkinElmer, Inc.	12/10/2021 (03/24/2020)	PerkinElmer New Coronavirus Nucleic Acid Detection Kit	Real-time RT-PCR, Pooling, Screening, Saliva	H
PlexBio Co., Ltd.	08/19/2021 (06/25/2020)	IntelliPlex SARS-CoV-2 Detection Kit	RT-PCR	H
QIAGEN GmbH	07/29/2021 (03/30/2020)	QIAstat-Dx Respiratory SARS-CoV-2 Panel	Real-time RT-PCR, Multi-analyte	H, M
Quest Diagnostics Nichols Institute	12/14/2021 (03/17/2020)	Quest SARS-CoV-2 rRT-PCR	Real-time RT-PCR, Home Collection, Pooling	H
Quest Diagnostics Nichols Institute	12/14/2021 (07/15/2020)	Quest Diagnostics PF SARS-CoV-2 Assay	Real-time RT-PCR, Home Collection	H
Quest Diagnostics Nichols Institute	12/14/2021 (07/15/2020)	Quest Diagnostics RC SARS-CoV-2 Assay	Real-time RT-PCR, Home Collection, Pooling	H
Quest Diagnostics Nichols Institute	12/14/2021 (07/15/2020)	Quest Diagnostics HA SARS-CoV-2 Assay	TMA, chemiluminescent, Home Collection	H
Quest Diagnostics Nichols Institute	12/14/2021 (12/04/2020)	Quest Diagnostics RC COVID-19+Flu RT-PCR	Real-time RT-PCR, Multi-analyte, Home Collection	H
Rheonix, Inc.	07/01/2021 (04/29/2020)	Rheonix COVID-19 MDx Assay	RT-PCR, Saliva	H
Roche Molecular Systems, Inc.	10/20/2021 (09/03/2020)	cobas SARS-CoV-2 & Influenza A/B	Real-time RT-PCR, Multi-analyte	H,M
Roche Molecular Systems, Inc.	06/24/2021 (09/14/2020)	cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System	Real-time RT-PCR, Multi-analyte	H, M, W
Roche Molecular Systems, Inc. (RMS)	10/20/2021 (03/12/2020)	cobas SARS-CoV-2	Real-time RT-PCR, Pooling, Screening	H, M, H-Pooling
Spectrum Solutions LLC	08/04/2021 (10/08/2020)	SDNA-1000 Saliva Collection Device	Saliva Collection Device	N/A
STS Lab Holdco (a subsidiary of Amazon.com Services LLC)	12/17/2021 (08/11/2021)	Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test	Real-time RT-PCR, Home Collection, Pooling, Screening	H
STS Lab Holdco (a subsidiary of Amazon.com Services LLC)	12/17/2021 (03/25/2021	Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2	Real-time RT-PCR, Home Collection, Pooling, Screening	H
STS Lab Holdco (a subsidiary of Amazon.com Services LLC)	12/17/2021 (05/28/2021	Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Pooling, Screening	H
Talis Biomedical Corporation	11/10/2021 (11/05/2021)	Talis One COVID-19 Test System	RT, Isothermal amplification	H, M, W
Thermo Fisher Scientific	08/03/2021 (02/10/2021)	TaqPath COVID-19, FluA, FluB Combo Kit	Real-time RT-PCR, Multi-analyte	H
Thermo Fisher Scientific Inc.	10/12/2021 (04/09/2021)	Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit	Real-time RT-PCR, Saliva	H
Thermo Fisher Scientific Inc.	09/01/2021 (07/08/2021)	TaqPath COVID-19 RNase P Combo Kit 2.0	Real-time RT-PCR, Serial Screening, Home Collection	H
Thermo Fisher Scientific, Inc.	10/12/2021 (03/13/2020)	TaqPath COVID-19 Combo Kit	Real-time RT-PCR, Home Collection	H
Trax Management Services Inc.	06/25/2021 (07/13/2020)	PhoenixDx SARS-CoV-2 Multiplex	Real-time RT-PCR	H
Twist Bioscience Corporation	06/25/2021 (03/23/2021)	SARS-CoV-2 NGS Assay	Sequencing	H
UCSD BCG EXCITE Lab	12/17/2021 (12/17/2021)	UCSD EXCITE COVID-19 Test	Real-time RT-PCR, Home Collection, Screening	H
Vela Operations Singapore Pte Ltd	06/24/2021 (08/05/2020)	ViroKey SARS-CoV-2 RT-PCR Test	Real-time RT-PCR	H
Vela Operations Singapore Pte. Ltd.	07/08/2021 (09/22/2020)	ViroKey SARS-CoV-2 RT-PCR Test v2.0	Real-time RT-PCR	H
Verily Life Sciences	11/08/2021 (09/08/2020)	Verily COVID-19 RT-PCR Test	Real-time RT-PCR, Pooling, Home Collection	H
Visby Medical, Inc.	08/31/2021 (09/16/2020)	Visby Medical COVID-19	RT-PCR, Pooling	H, M

Source: U.S. Food and Drug Administration

Individual FDA EUAs for Antigen Diagnostics Tests

Company Name	Last Updated (and Original Date EUA Issued)	Name of Test	Type of Test	Authorized Settings
Abbott Diagnostics Scarborough, Inc.	04/20/2021 (08/26/2020)	BinaxNOW COVID-19 Ag Card	Lateral Flow, Visual Read	H, M, W
Abbott Diagnostics Scarborough, Inc.	03/31/2021 (03/31/2021)	BinaxNOW COVID-19 Ag 2 Card	Lateral Flow, Visual Read, Non-prescription Testing, Serial Screening	H, M, W
Access Bio, Inc.	12/02/2021 (10/08/2020)	CareStart COVID-19 Antigen test	Lateral Flow, Visual Read, Serial Screening	H, M, W
ANP Technologies, Inc	09/24/2021 (09/24/2021)	NIDS COVID-19 Antigen Rapid Test Kit	Lateral Flow, Visual Read, Serial Screening	H, M, W
Becton, Dickinson and Company (BD)	12/10/2021 (07/20/2020)	BD Veritor System for Rapid Detection of SARS-CoV-2	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening	H, M, W
Becton, Dickinson and Company (BD)	03/24/2021(03/24/2021)	BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B	Chromatographic Digital Immunoassay, Instrument Read, Multi-analyte	H, M, W
Celltrion USA, Inc.	09/01/2021 (04/16/2021)	Celltrion DiaTrust COVID-19 Ag Rapid Test	Lateral Flow, Visual Read, Serial Screening	H, M, W
Celltrion USA, Inc.	10/23/2020 (10/23/2020)	Sampinute COVID-19 Antigen MIA	Magnetic Force-assisted Electrochemical Sandwich Immunoassay (MESIA)	H, M
DiaSorin, Inc.	07/12/2021 (03/26/2021)	LIAISON SARS-CoV-2 Ag	CLIA	H, M
Ellume Limited	07/08/2021 (07/08/2021)	ellume.lab COVID Antigen Test	Lateral Flow, Fluorescence, Instrument Read	H, M, W
GenBody Inc.	11/17/2021 (07/13/2021)	GenBody COVID-19 Ag	Lateral Flow, Visual Read, Serial Screening	H, M, W
iHealth Labs, Inc.	12/22/2021 (11/05/2021)	iHealth COVID-19 Antigen Rapid Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W
InBios International Inc.	11/22/2021 (11/22/2021)	SCoV-2 Ag Detect Rapid Self-Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W
InBios International, Inc.	09/03/2021 (05/06/2021)	SCoV-2 Ag Detect Rapid Test	Lateral Flow, Visual Read, Serial Screening	H, M, W
Luminostics, Inc.	12/07/2020 (12/07/2020)	Clip COVID Rapid Antigen Test	Lateral flow immunoluminescent assay, instrument read	H, M, W
LumiraDx UK Ltd.	10/29/2021 (08/18/2020)	LumiraDx SARS-CoV-2 Ag Test	Microfluidic Immunofluorescence Assay, Instrument Read, Screening	H, M, W
Nano-Ditech Corp.	12/06/2021 (12/06/2021)	Nano-Check COVID-19 Antigen Test	Lateral Flow, Visual Read, Serial Screening	H, M, W
OraSure Technologies, Inc.	11/01/2021 (06/04/2021)	InteliSwab COVID-19 Rapid Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W
OraSure Technologies, Inc.	06/04/2021 (06/04/2021)	InteliSwab COVID-19 Rapid Test Rx	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W
OraSure Technologies, Inc.	06/04/2021 (06/04/2021)	InteliSwab COVID-19 Rapid Test Pro	Lateral Flow, Visual Read, Serial Screening	H, M, W
Ortho Clinical Diagnostics, Inc.	11/16/2021 (01/11/2021)	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack	Chemiluminescence Immunoassay, Instrument Read	H, M
PHASE Scientific International, Ltd.	11/15/2021 (07/28/2021)	INDICAID COVID-19 Rapid Antigen Test	Lateral Flow, Visual Read, Serial Screening	H, M, W
Princeton BioMeditech Corp.	10/27/2021 (02/04/2021)	Status COVID-19/Flu A&B	Lateral Flow, Visual Read, Multi-analyte	H, M, W
QIAGEN GmbH	08/05/2021 (08/05/2021)	QIAreach SARS-CoV-2 Antigen	Digital Lateral Flow, Fluorescence, Instrument Read	H, M
Qorvo Biotechnologies, LLC.	04/13/2021 (04/13/2021)	Omnia SARS-CoV-2 Antigen Test	Bulk Acoustic Wave (BAW) Biosensor, Instrument Read	H,M
Quanterix Corporation	12/21/2021 (01/05/2021)	Simoa SARS-CoV-2 N Protein Antigen Test	Paramagnetic Microbead-based Immunoassay, Serial Screening, Saliva	H, M
Quidel Corporation	11/09/2021 (12/18/2020)	QuickVue SARS Antigen Test	Lateral Flow, Visual Read, Serial Screening	H, M, W
Quidel Corporation	06/11/2021 (05/08/2020)	Sofia SARS Antigen FIA	Lateral Flow, Fluorescence, Instrument Read, Serial Screening	H, M, W
Quidel Corporation	10/02/2020 (10/02/2020)	Sofia 2 Flu + SARS Antigen FIA	Lateral Flow, Fluorescence, Instrument Read, Multi-Analyte	H, M, W
Salofa Oy	12/17/2021 (05/20/2021)	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette	Lateral Flow, Visual Read	H, M, W
Xtrava Health	10/12/2021 (10/21/2021)	SPERA COVID-19 Ag Test	Lateral Flow, Visual Read	H, M, W

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Hba1C testing and age factors

By Linda Wilson

Measuring the amount of HbA1c in the blood is a common laboratory test for both diagnosing and monitoring diabetes.

It also is an important test because diabetes is a major chronic condition. In 2018, 34.2 million Americans, or 1 in 10, had diabetes and 88 million American adults, or 1 in 3, had prediabetes, according to the Centers for Disease Control and Prevention (CDC). In addition, 7.3 million adults aged 18 years or older who met laboratory criteria for diabetes were not even aware that they had the disease.[1]

HbA1c tests measure the amount of HBA1c in red blood cells over the lifespan of those cells, or about 120 days. The test has numerous advantages over other methods. It does not require fasting or ingesting a concentrated glucose drink followed by a waiting period before testing. In addition, HbA1c can be measured multiple times per month, if necessary, making it ideal for not only diagnosing diabetes but also monitoring the disease.

Reversing an earlier position, the World Health Organization (WHO) recommended HbA1c as a diagnostic marker for diabetes in 2011 "provided that stringent quality assurance tests are in place and assays are standardized to criteria aligned to the international reference values, and there are no conditions present which preclude its accurate measurement."[2]

The American Diabetes Association endorsed HbA1c testing in 2010.[3]

Image by Ahmad Ardity from Pixabay

Relationship between HbA1c and age

However, there are some situations in which interpreting HbA1c test results should be approached cautiously, such as with older adults.

The concentration of HbA1c in blood increases as people age. The rates of diabetes and prediabetes also are higher in older age groups.

Among adults 18-44 years of age, 3% have been diagnosed with diabetes, compared with 12.4% of adults 45-64, 21.4% of adults 65-75, and 21.8% of adults 75 or older, according to an analysis by the Kaiser Family Foundation (KFF).[4]

Similarly, the CDC found that 24.3% of people 18-44 years old were diagnosed with prediabetes, increasing to 41.7% in people 45-64 years old, and 46.6% in people 65 years and older.[5]

Numerous researchers have examined the relationship between age and measures for diagnosing diabetes, such as HbA1c.

For example, a 2008 article in *Diabetes Care* found an association between HbA1c levels and age in patients without diabetes.[6] The relationship held even after excluding study participants with impaired fasting glucose and impaired glucose tolerance. The analysis was based on information from 2,473 participants from the Framingham Offspring Study and 3,272 participants from the National Health and Nutrition Examination Survey (NHANES) 2001–2004 population.

A more recent study is described in a 2019 article in *BMC Endocrine Disorders* in which the authors confirmed an association between increasing HbA1c concentration in the blood and age in non-diabetic study participants. The relationship held up in lean, overweight and obese study participants.[7]

However, official guidelines do not suggest different reference values based on age. (An HbA1c level of 6.5% is the currently established cutoff point for diagnosing diabetes.) The authors of the *BMC* study said that the one-size-fits-all reference value could impact the quality-of-care for patients. "Consequently, with respect to usage of a global cutoff for diagnosis of diabetes, disregarded age-related changes of HbA1c independent of disease might bear the risk of misdiagnosis in the elder population. Similarly, the HbA1c reference values for the monitoring of glycemia in patients with diabetes do not take the age of the individual into account potentially leading to unnecessary overtreatment with severe consequences," the authors note.[7]

Prediabetes and the elderly

Another recent study focused on measures of prediabetes in the elderly.[8] The cohort study followed 3,412 older adults without diabetes living in a community setting for 6.5 years. The mean age was 75.6 years and included both frail and non-frail older adults.

During the study period, 1,490 participants, or 44%, met the definition of prediabetes, with HbA1c levels of 5.7% to 6.4%, while 1,996, or 59%, met the criteria for prediabetes with fasting glucose levels (FGLs) of 100-125 mg/dL. A total of 1,004, or 29%, met both the HbA1c and IFG criteria.[8]

By the end of the study period, however, few of the participants with prediabetes had become diabetic. Among those who met the criteria for prediabetes by HbA1c concentrations, 97, or 9%, progressed to diabetes and 148, or 13%, lowered their glycemia levels to a normal level. Of those with IFG at baseline, 112 (8%) progressed to diabetes and 647 (44%) achieved normal glycemia levels.[8]

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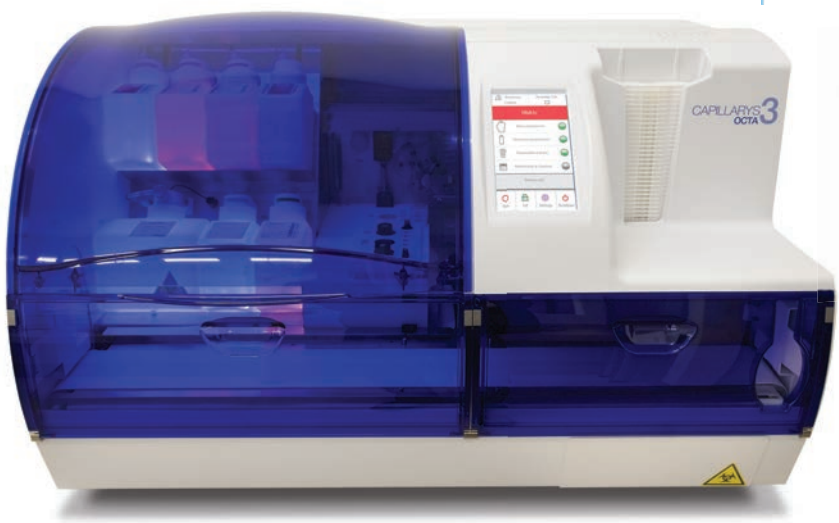

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The authors said the findings suggest that these measures of prediabetes may not be meaningful for guiding patient care in older adults.

Reasons for the relationship

What is the reason behind the relationship between age and HbA1c?

That is not entirely clear, explains Priya Sivaraman, PhD, HPLC Product Manager at Tosoh Bioscience."Age seems to be an independent criterion that affects A1c levels, meaning it's not dependent on factors such as glucose levels and insulin resistance. Very few studies have looked into the mechanism that can potentially explain the cause of elevated A1c in the elderly. There are few studies that conclude the elevated A1c has to do with changes in the rate of glycation, however, the studies had their share of limitations."

Priya Sivaraman, PhD

One of the studies she points to was described in a 1993 article in *Clinica Chimica Acta* on the acceleration of hemoglobin glycation with aging.[9]

Meanwhile, a 2017 study conducted in China showed that the relevance of HbA1c as a measure for diabetes decreased with age, which the authors said happens because of decreases in red blood cell (RBC) counts as people age. But how this occurs is unclear, the authors said.[10]

However, they speculated about how decreasing RBC counts could impact HbA1c as a diagnostic test. They wrote,"We put forward two possible explanations. First, the decreased RBC count caused by the decreased cell turnover could result in the increased RBC lifespan with aging, increasing the levels of HbA1c. Second, previous studies have reported that the cellular damage caused by aging, including altered enzyme activity, decreased membrane lipids and increased cell fragility, promoting the acceleration of hemoglobin glycation. Under these conditions, the HbA1c level could not truly reflect the average blood glucose concentration in the elderly, resulting in the decreased diagnostic efficiency with aging."[8]

Advice for diagnosis and clinical practice

All of this information begs the question: How should HbA1c results be interpreted in older adults, and what does this mean for clinical practice?

Sivaraman said,"Since the data available today on the effect of age on A1c levels is limited, laboratories need to exercise caution when using A1c as a sole diagnostic marker in the elderly. It is important to look at the individual's history and complement the A1c with other tests that can help arrive at a robust diagnosis. Attention needs to be paid specifically to individuals who flank the decision-making point wherein age could possibly play a role in the change in diagnosis as the individual ages."

Authors of the 2019 article in *BMC Endocrine Disorders* focusing on the relationship between HbA1c and age suggested age-stratified reference ranges for Caucasians. For people aged 20-39 years, the authors propose an upper reference limit for HbA1c of 6.0%, compared with 6.1% for people 40-59 years, and 6.5% for people who are 60 years or older.

In a podcast interview with *JAMA Internal Medicine*, Elizabeth Selvin, PhD, Professor of Epidemiology at Johns Hopkins Bloomberg School of Public Health and an author of the prediabetes study, suggested how to respond to HbA1c test results indicating prediabetes in elderly patients."I think we need to rethink definitions of prediabetes in older adults," Selvin said."They simply don't have the same prognostic meaning as they have in younger individuals.[11]

Rather than focusing on a diagnosis of prediabetes, Selvin recommends that clinicians counsel their older patients about the broad health benefits of a healthy lifestyle, including eating healthy food, reducing consumption of processed foods, quitting smoking, and getting regular exercise, such as walking or lifting weights. [11]

However, she emphasized that prediabetes is still an important concept overall."Identifying people prior to the onset of diabetes, especially in middle age, is really critical. Preventing the onset of diabetes can then help us prevent the onset of major complications."[11]

Diabetes is a Major Chronic Illness

- More than 34 million people in the United States have diabetes
- More than 88 million adults have prediabetes.
- The disease is the 7th leading cause of death in the United States
- Medical costs and lost work and wages for people with diabetes total $327billion annually.
- In the last 20 years, the number of adults diagnosed with diabetes has more than doubled.

Source: Centers for Disease Control and Prevention
https://www.cdc.gov/diabetes/basics/quick-facts.html

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COVID-19 and HIV co-infection: The importance of vigilant and advanced detection and diagnostic capabilities

By Marc Tordjeman, PhD

Since the World Health Organization (WHO) officially announced the coronavirus (COVID-19) outbreak as a pandemic on March 11, 2020, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has continued to present a global challenge. Healthcare systems are still under immense pressure in many regions as some countries continue to battle severe waves of the virus. Globally, as of November 9, 2021, there have been 250,154,972 confirmed cases of COVID-19, including 5,054,267 deaths, reported to WHO. As of November 8, 2021, a total of 7,084,922,999 vaccine doses have been administered.[1]

The global effort to contain COVID-19 has resulted in extraordinary and unprecedented worldwide collaborative efforts from healthcare workers, researchers, industry bodies, and governments. The scientific community continues to respond to the ongoing threat of COVID-19 by learning as much as possible about how the disease spreads, how it affects people and communities, the long-term impact on the body after infection, and the incidence of concomitant infection with other pathogens.

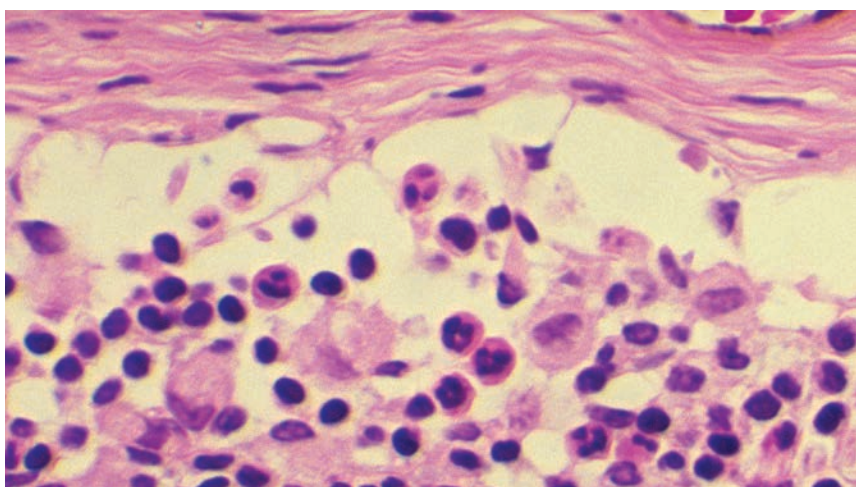

Photo Courtesy of CDC

However, as COVID-19 has a variety of clinical manifestations, it may be challenging to distinguish co-infections which share clinical features, such as human immunodeficiency virus (HIV). It's vitally important to quickly detect co-infection in COVID-19 patients with HIV and accurately identify causative pathogens to deliver effective treatment.

COVID-19 research developments

An increasing amount of research is uncovering the true impact of secondary bacterial, fungal, and viral infections in COVID-19 patients. Microbiologists, epidemiologists, virologists, and pathologists have generated vast bodies of research investigating the structure of SARS-CoV-2, its mechanism of infection, the COVID-19 disease pathway and how it affects individuals differently, studying the long-term effects of COVID-19 and, more recently, studying and tracking mutations that could lead to new viral variants.

Another important but complex area of research is SARS-CoV-2 co-infection, where an individual may be infected with the virus and one or more additional pathogens concomitantly. SARS-CoV-2 infection leads to both innate and adaptive immune responses, which, in some cases of severe disease, can become dysfunctional and cause significant lung and systemic pathology. [2] This lung damage and dysregulated immune response in severe COVID-19 pneumonia puts these patients at an increased risk of secondary infection. In addition, individuals with pre-existing conditions could be more susceptible to severe COVID-19 disease if infected.

Rapid diagnosis is critical to identifying and diagnosing such infections and determining the correct course of treatment, as quickly as possible. However, several factors can complicate patient diagnosis and treatment in the case of co-infection. Secondary infection could be more easily missed and go undiagnosed in the face of a SARS-CoV-2 primary infection, especially if symptoms overlap. Diligent testing of COVID-19 patients for other infectious diseases is, therefore, vital. Importantly, patients with severe COVID-19 disease in intensive care units (ICUs) are at increased risk of nosocomial infection and should be carefully monitored as rapid treatment decisions are required, particularly in the case of multi-drug-resistant (MDR) microorganisms.

COVID-19 outcomes for patients with HIV

Although the reported incidence of bacterial, fungal, and viral co-infections in hospitalized COVID-19 patients is relatively low [3] when present, they may cause severe diseases with poorer outcomes. For example, many studies have reported a higher incidence of secondary infections in patients admitted to the ICU,[4,5] and those diagnosed with secondary infections had lower discharge rates and higher mortality rates than those without secondary infection.[6] Researchers are still looking to determine whether this outcome is a function of longer ICU stays, concomitantly administered medications (e.g., antibiotics, immunomodulators), the immunocompromising effects of severe COVID-19 itself, or other factors.[7]

People living with HIV (PLHIV) who have a compromised immune system, including those with a low CD4 count or high viral load, may be less able to cope with infectious diseases, such as COVID-19 and any bacterial or fungal co-infections. However, the rate of COVID-19/HIV co-infection and impact on patient outcomes is not clear, and reports differ over morbidity and mortality rates. Studies are often limited by small patient groups — many including a single case report of HIV co-

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infection — and results depend heavily on HIV epidemiology in specific geographies.

For example, one study of a cohort of patients from Western Cape Province, South Africa, reported that HIV was associated with a doubling of COVID-19 mortality risk,[8] whereas a systemic literature review found that PLHIV is largely affected by similar features of disease risk and progression as those without HIV,[9] and studies from the UK,[10] Germany,[11] and the United States[12] report no excess morbidity or mortality in HIV patients.

Researchers are also working to understand the impact of tuberculosis and HIV co-infected patients on COVID-19 pathogenesis. The interaction between TB and HIV has been extensively studied: without ART, the risk of latent TB infection progressing to active TB disease in PLHIV is greater than in immunocompetent individuals.[13] In addition, management of MDR TB in people living with HIV is complicated by higher rates of drug toxicities that may be exacerbated in the setting of COVID-19 co-infection.[14]

HIV drug resistance (HIVDR) is a growing concern that, if not addressed, could jeopardize the successful scale up of ART that has been seen in recent years. An increased incidence of HIVDR could limit the possible protection that antiretroviral drugs afford HIV patients infected with COVID-19.

Viral load testing

According to European Union (EU) recommendations, timely and accurate COVID-19 laboratory testing is an essential part of the management of COVID-19. Testing helps fight the pandemic, supports decisions on infection control strategies and patient management at healthcare facilities, and detects asymptomatic cases that could spread the virus further, if not isolated. Early testing, diagnosis, and intervention significantly increase the likelihood of an individual's recovery — where a gain in minutes or hours can mean the difference between life and death. Reducing the need for prolonged and often invasive ICU treatment, the chance of recovery is greater and vital resources are available more quickly for the next patient.

A swift and accurate diagnosis establishes the correct course of action straight away, which ultimately means fewer lives will be lost. Fast and simple HIV viral load testing is needed to appropriately monitor HIV patients and ensure ART programs are followed to minimize comorbidity with COVID-19.

With clinical laboratories across the globe under intense pressure to deliver increased demand for test results, advances in molecular and diagnostic systems offer a rapid response. Modern real-time PCR kits are designed to improve rapid, targeted results in clinical areas that suffer from poor culture sensitivity, or where organism growth rate has an impact on clinical care and health economic outcomes. Results from real-time PCR are used together with clinical patient observations to provide a clearer picture of the infectious disease etiology, diagnosis, and the best course of treatment.

Clinical microbiology solutions are key for early identification of bacterial or fungal diseases that can affect COVID-19 patients with weakened immune systems, such as those who may be also suffering from HIV or related complications. A next-generation PCR thermal cycler and reader, together with assays, can enable fast HIV viral load testing to facilitate successful ART. By using the same automated extraction protocol as COVID-19 assays, labs can quickly implement these assays with minimal training.

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Future considerations

The volume of literature surrounding COVID-19 research continues to grow at a significant pace, as the scientific community endeavors to deepen its knowledge of the virus' epidemiology, understand public health and mental health impacts, gather data on hospital mortality, and develop better diagnostics and therapies. In addition, more research is unfolding to better understand the challenges of diagnosing and managing co-infections, such as HIV/AIDS.

However, research remains in the early stages, and there is not yet a clear picture of how co-infection impacts clinical outcomes or if existing infections predispose individuals to poorer COVID-19 resilience. Rapidly identifying secondary pathogens, and diagnosing such co-infections, is vital to determining the correct course of treatment and improving patient outcomes. Microbial detection and identification tools are not only contributing to research discoveries but allow clinical microbiologists to make fast and well-informed treatment decisions that, for critically ill COVID-19 patients, can make all the difference.

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Marc Tordjeman, PhD, started Biocentric, a French Biotech company that is now part of **Bruker Microbiology and Diagnostics.** In 2005, resulting from a collaborative work with the French National AIDS Research Agency (ANRS), a commercial, reliable, and affordable HIV viral load on open PCR platform was launched with the objective to give low resource-countries access to HIV viral load.

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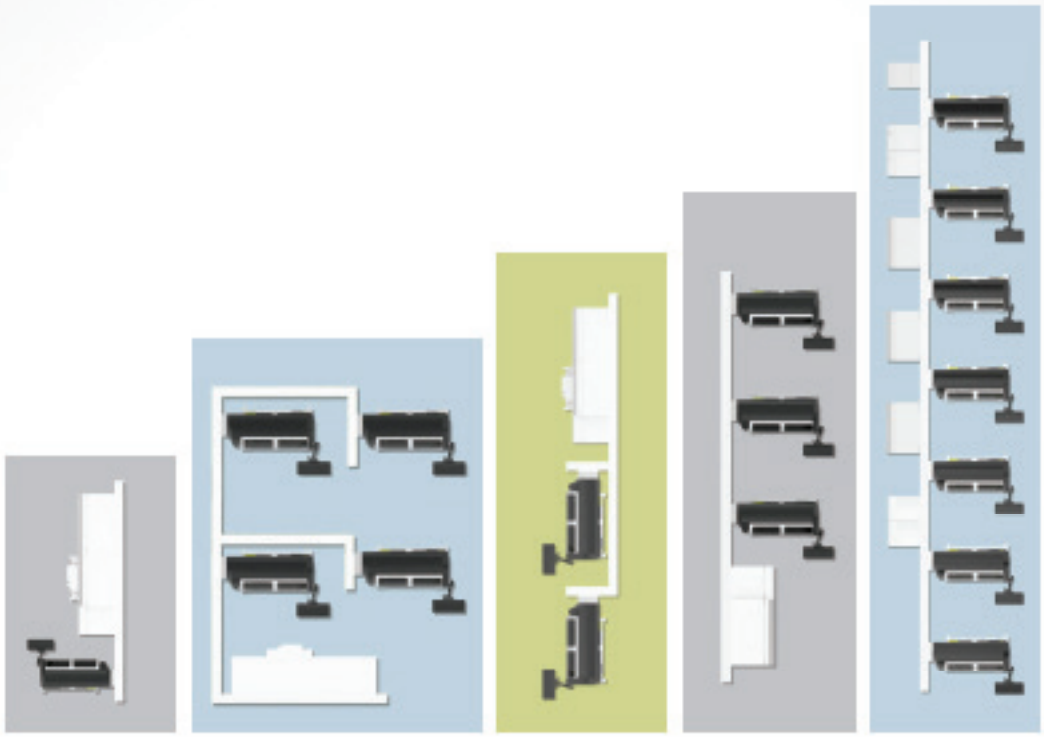

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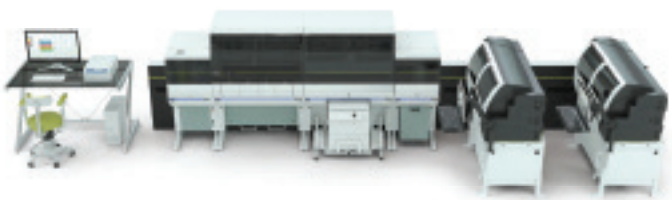

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Gambino's career focused on testing quality and patient safety

By Harvey Kaufman, MD

Salvadore Raymond "Ray" Gambino, MD, 1926-2022, passed away on January 1, 2022, after a brief illness. He was a remarkable person and one of the leading figures in the development of modern clinical laboratory medicine.

Salvadore Raymond "Ray" Gambino, MD

He also played a critical role in the launch of *Medical Laboratory Observer (MLO) and Clinical Laboratory Reference (CLR)*, where he was clinical editor from 1969-1978.

Storyteller

To teach, Gambino was a keen storyteller. In a March 20, 1976, op-ed in T*he New York Times* he wrote, "During my professional career, I have been responsible for three serious errors: a wrong unit of blood, a wrong autopsy, and a wrong gas (carbon monoxide). How could anyone make such errors? I don't have the final answer, but I think the following case histories will tell something about the genesis of error."

One lesson from the case studies he presented is we see what we expect to see. Another lesson is that despite multiple check points, everyone assumes someone else checked first. "Two heads aren't always better than one," Gambino wrote.

These stories of errors and "near misses" help us learn and create solutions to ensure patient safety and reliable laboratory services. Gambino concluded his *The New York Times* piece with advice to always place safety first, "Safety will have to come before cost effectiveness."

Lab leader

Gambino was a leader in quality for clinical laboratories throughout his career. He delivered innumerable seminars on laboratory operations and quality throughout the United States. He was Editor-in-Chief of American Society for Clinical Pathology (ASCP) Check Sample, a self-education program, from 1969-1992. Gambino started his own newsletter "Lab Report" in 1979 and was its editor through 1998.

In 1990, Gambino received the ASCP Ward Burdick Award for Distinguished Service to Pathology. In 2009, he was designated as a Mastership, an honor for distinguished ASCP members who have made significant contributions to the field of pathology and laboratory medicine and to ASCP.

With Robert Galen, MD, Gambino wrote Beyond Normality: The Predictive Value and Efficiency of Medical Diagnoses. This classic book was instrumental in the industrywide adoption of the concepts of sensitivity, specificity, and predictive values.

Gambino's career began after he graduated from Antioch College in 1948 and University of Rochester Medical School in 1952.

But it was during his tenure (1961-1969) as the laboratory director at Englewood (NJ) Hospital that Gambino shocked the hospital's medical staff by restricting the ordering of tests he considered inappropriate. He offered unlimited consultations to help guide appropriate laboratory utilization. His model was, "one clinician and one patient at a time."

He held numerous other prestigious roles in laboratory management:

- Director of Clinical Chemistry, Presbyterian Hospital, New York, NY (1969-1978)
- Director of Laboratories and Chief Pathologist, St. Luke's Hospital Center New York, NY (1978-1980)
- Director of Laboratories and Chief Pathologist, St. Luke's-Roosevelt Hospital Center New York, NY (1980-1983)
- Executive Vice President and Chief Medical Officer, MetPath (precursor of Quest Diagnostics) Teterboro, NJ (1983-1993), and Executive Vice President and Chief Medical Officer Emeritus, Quest Diagnostics (1994-2014)

Gambino trained many medical residents throughout his career, including some who went on to become industry leaders themselves, such as James Powell, MD, Founder of what became LabCorp; Paul Brown, MD, Founder of MetPath; and Joseph O'Brien, MetPath's long-lasting Laboratory Director. Another resident, Richard Axel, MD, Professor at Columbia University Medical Center, was awarded the 2004 Nobel Prize in Physiology or Medicine.

Role at *MLO*

In addition to his work in the laboratory and teaching residents, Gambino also was involved in the founding of *Medical Laboratory Observer*.

Gambino described his role in a 2009 article in *MLO*. He said two unexpected visitors from *Medical Economics* arrived at his office in Englewood, NJ. They wanted to create a controlled-circulation magazine for laboratorians.

"My immediate response was positive. Yes, we needed such a magazine, but their options were limited. They could either emulate *Scientific American* or emulate *Medical Economics*. Personally, I favored emulating *Medical Economics*.

I said, 'Why not just create for laboratorians what you are now doing for practicing physicians?'

They did! Soon thereafter, I was asked if I would be willing join them as an editorial consultant for a new bi-monthly publication to be called *Medical Laboratory Observer*. I said, "Yes!"

Gambino was a force of nature full of ideas, explorations, and knowledge that directly influenced many lives. He was never afraid to raise his voice when he thought patient care could be improved. Gambino's impact will last a long time and will always be associated with Quest Diagnostics' top quality award, the Gambino Award. His long life was a novel full of stories with lessons that, when applied, improve patient safety and clinical laboratory testing and services. Thank you, Ray Gambino.

Harvey Kaufman, MD, a board-certified pathologist, is Senior Medical Director at **Quest Diagnostics.** A 29-year veteran of Quest Diagnostics, Kaufman was an original, and still active, member of the Laboratory Working Group of the National Institute of Diabetes and Digestive and Kidney Diseases, NIH (formerly the National Kidney Disease Education Program).

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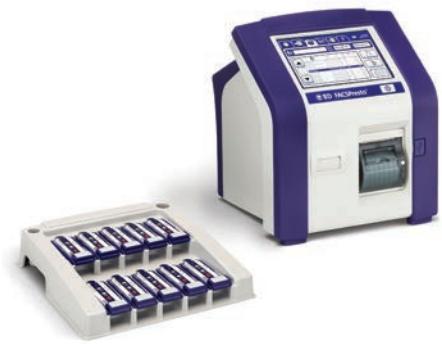

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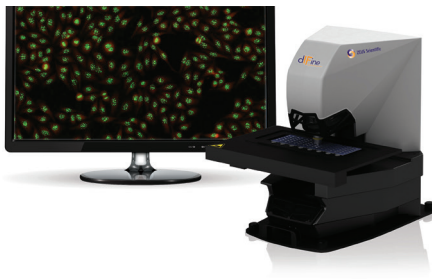

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LABORATORY INNOVATOR

Shepherding rural Michigan through the COVID-19 pandemic

By Linda Wilson

Nicholas Decker, MLS (ASCP), is the Laboratory Director at 161-bed **Memorial Healthcare** in Owosso, MI, which has 26 satellite offices in a largely rural area in central Michigan. A graduate of Michigan State University, Decker began his career in the hematology department of the clinical laboratory.

Why did you choose to pursue a career in clinical laboratory management? What appealed to you about a specialization in hematology testing?

I chose to pursue clinical laboratory management because of the fast-paced environment. I enjoyed the meaningful nature of the work, and the constant challenge of the market. With hematology specifically, it was something I connected with due to the manual nature of some of the work. It is a fine blend of art and science while being very technical and yet also subjective. I felt it demanded constant focus, so I chose to seek out a hematopathology role early on in my career.

When the COVID-19 pandemic first erupted in Michigan in 2020, what steps did the clinical laboratory at Memorial Healthcare take to respond? When did the lab introduce SARS-CoV-2 testing?

Memorial Healthcare rapidly identified the best method, equipment, and approach that fit our laboratory and our community. We purchased, installed, validated equipment, and were operational within about 17 days. During this same time period we established a triage center on our main campus for all respiratory patients and built a drive-thru test site at the hospital that we continue to operate to this day. We began testing for COVID-19 on March 23, 2020, and we have been performing 100% of our COVID-related testing since that time.

What key lessons did you learn in the lab's response early in the COVID-19 pandemic that you've applied to the subsequent surges in cases and demand for testing?

We quickly learned that no sole vendor can keep up with pandemic level demands. We currently have five vendors for this testing alone. As recently as a month ago, we brought in a new vendor. We also learned how to adapt to the lack of testing product availability. So instead, we validated numerous swabs, including 3-D printed models, and many types of liquid medias for transport, including our own version brewed on-site with the World Health Organization's recipe. This helped Memorial Healthcare combat the immense shortages early on with both of these key products.

Our spaces also quickly needed to be adjusted. We converted our cytology office to testing space and our manager's office to storage space. We relocated our pathologist's office outside of the primary lab area, so we could convert the previous office space to refrigerated and frozen storage of testing supplies and specimens. We also gained many new friends and colleagues between sharing supplies and supporting each other with the hard-to-find items that are causing testing bottlenecks. None of this was on the radar before COVID-19.

As a regional healthcare center, will you describe the role your lab has played in the state of Michigan's response to the pandemic?

Memorial Healthcare supported our community immediately. And true to our nature as a local independent facility, we ensured we could handle everything locally first but then expanded to support other systems as well. For example, we supported external emergency rooms, pre-procedure testing needs for other facilities, as well as overflow testing from schools, skilled nursing facilities, and jails. We also have partnered with new clients to support their outreach needs, specifically for SARS-COV-2 and other diagnostic needs.

How many SARS-CoV-2 tests does your lab perform daily — on average? What is the range of daily SARS-CoV-2 tests performed at your lab?

We currently perform 300-500 tests daily for SARS-COV-2 detection. This varies throughout each surge, but our highest single day test count reached approximately 700. We offer multiplex assays, rapid testing, and RT-PCR SARS-COV-2 specific assays as well.

What is the current vacancy rate at your lab? What strategies have you found to be successful in recruiting and/or retaining staff?

We have, like many labs, vacancies at both the scientist level as well as at the phlebotomy level. Overall, we lack approximately 5.0 full-time equivalents (FTEs) from our fully staffed budget. However, something that was important to Memorial Healthcare, which was successful, was to continue student training during the pandemic. This preserved our new employee pipeline and encouraged students to enter the laboratory field. We also have started a clinical rotation for individuals with bachelor's degrees, so they would be eligible, with clinical experience, to sit for certification.

For retention purposes, we have been very flexible with our staff to preserve work-life balance and avoid burnout. We've supported the challenges of being a parent during the pandemic. For example, we converted to compressed scheduling (i.e., seven days on and seven days off or four 10-hour workdays) to help working parents balance daycare needs and remote instruction for their school-aged children. This has been a challenging time in the staffing area for sure. Prior to the COVID-19 pandemic, we had nearly no vacancies at the scientist level, and minimal openings in the phlebotomy department.

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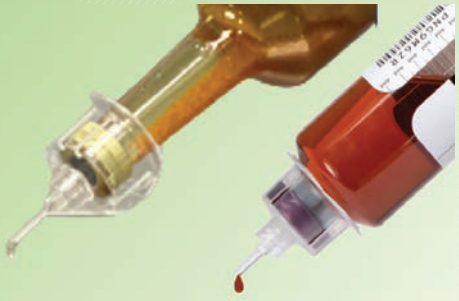

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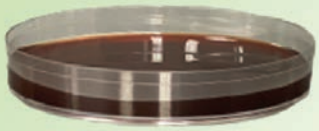

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