GPHIN Daily Report for 2020-09-25

Special section on Coronavirus

Canada

Areas in Canada with cases of COVID-19 as of 24 September 2020 at 07:00 pm EDT
Source: Government of Canada

Province, territory or other	Number of confirmed cases	Number of active cases	Number of deaths
Canada	149,094	11,138	9,249
Newfoundland and Labrador	272	1	3
Prince Edward Island	58	1	0
Nova Scotia	1,087	6	65
New Brunswick	199	0	2
Quebec	69,670	3,917	5,810
Ontario	48,496	3,774	2,836
Manitoba	1,835	449	19
Saskatchewan	1,830	130	24
Alberta	17,190	1,462	261
British Columbia	8,543	1,397	229
Yukon	15	0	0
Northwest Territories	5	0	0
Nunavut	0	0	0
Repatriated travellers	13	0	0

A detailed epidemiologic summary is available.
https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection.html#a1

Canada – Coronavirus disease (COVID -19) Outbreaks and Outcomes (Official and Media)

Canada

Statement from the Chief Public Health Officer of Canada (Epi Report) on September 24, 2020
Source: Canada.ca
ID: 1007907730

[APG]

In lieu of an in-person update to the media, Dr. Theresa Tam, Canada's Chief Public Health Officer, issued the following statement today:
"There have been 147,753 cases of COVID-19 in Canada, including 9,243 deaths. Due the ongoing increase in daily case counts, the proportion of cumulative cases that are still active versus recovered has shifted, with overall the percentage recovered decreasing and currently at 86%. Laboratories across Canada continue to test at a high rate. An average of almost 70,000 people were tested daily last week, with 1.4% of these testing positive. The national daily case count continues to increase, with an average of 1,144 cases reported daily during the past seven days.
Although the pattern of epidemic curves varies by region in Canada, all provinces west of the Atlantic region are showing increasing incidence of COVID-19. The latest data indicate that 12 health regions in four provinces (British Columbia, Alberta, Ontario and Quebec) are experiencing incidence rates of over 50 cases per 100,000 population. In areas where the virus is surging, there are heavy demands on resources for testing and contact tracing to interrupt new chains of transmission. Moreover, our epidemiological analysis and modelling studies show that if the current rate of accelerated growth is not slowed, there will be a large resurgence in these and likely other areas of the country.
However, Canada still has a chance to prevent a large resurgence if we all act together now. As I have said, local public health authorities cannot do this alone, individual actions to prevent exposure and limit the number of close contacts are a must. This is not simply a matter of resources, it is a reality of the current level of accelerated growth. Based on the past week, each new generation of cases is growing at a rate of about 1.3 times in Canada. That means each of the more than 1,000 new COVID-19 cases reported daily will pass the infection to 1.3 others; so, 1,000 cases generates 1,300 cases, which in turn generate 1,700 more cases and so on –unless we all work together to slow the rate of spread!
This is why I am urging everyone to limit their in-person close contacts, as much as is possible for you to do. We all have different pressures and responsibilities but when it comes to close proximity contact with others, remember that every person you encounter brings their whole network of contact history with them. If you can't reasonably reduce your in-person contacts to just your existing household and/or your small, consistent and trusted contacts bubble, there are choices you can make and actions you can take to reduce the risk of each encounter. Close proximity and longer duration can increase the risk, whereas public health controls and policies can reduce the risk. Whenever possible, limit the duration of close contact and opt for lower risk settings/situations where public health measures and policies are in place and always maintain personal protective measures, including physical distancing 2 metres from others, frequent hand washing, and wearing a non-medical mask or face covering as recommended).
If every one of us brings our best effort to bear and we all work together, we can knock the rate of growth back down to get us on the safer slow-burn track once again. We can still "own this pandemic"; read more on COVID-19 information and resources on the actions you can take."
https://www.canada.ca/en/public-health/news/2020/09/statement-from-the-chief-public-health-officer-of-canada-epi-report-on-september-24-2020.html

Canada
Government of Canada announces the Indigenous organizations in Saskatchewan who received funding to address the COVID-19 pandemic in urban areas
Source: Canada.ca
ID: 1007908596

Today, on behalf of the Honourable Marc Miller, Minister of Indigenous Services, the Honourable Jim Carr, Member of Parliament for Winnipeg South Centre announced the 28 Indigenous organizations in the province of Saskatchewan who received approximately $6.1 million in funding through the Indigenous Community Support Fund's off-reserve and urban stream to address the ongoing COVID-19 pandemic.
Since the pandemic began action has been taken at all levels to protect the most vulnerable and to support those who need it most. The Government of Canada is providing funding to Indigenous organizations in Saskatchewan to address the critical needs of urban Indigenous Peoples during this crisis. The funding will aid with food security, mental health support services, homelessness, and required emergency supplies to ensure the health and safety of Indigenous Peoples.
The Saskatoon Yellow Quill Urban Services received $20,000 in funding to provide direct education and teaching tools to support urban Indigenous Peoples to better understand the impacts of COVID-19. The

organization also coordinates activities such as a community garden and home deliveries, ensuring food security, and providing personal protective equipment and sanitation supplies.
As well, the Lac La Ronge Indian Band received $75,000 to help address their COVID-19 Support Plan which will aid their members living off reserve. With this funding, they are addressing food security needs, by ensuring access to grocery financial assistance for approximately 4,200 off-reserve members.
As part of the Indigenous Community Support Fund, the Government of Canada is distributing a total of $90 million to Indigenous organizations and communities providing services to Indigenous Peoples living in urban areas, to support essential services to the most vulnerable and to prevent and respond to potential COVID-19 outbreaks.
On August 12, the Government of Canada announced an additional $305 million for the Indigenous Community Support Fund. This most recent announcement brings the Indigenous Community Support Fund to $685 million in total funding. It will be distributed through a combination of allocations directly to First Nations, Inuit and Métis leadership, and needs-based funding, which will be application driven and extend to Indigenous communities and organizations serving First Nations living off-reserve as well as Indigenous Peoples living in urban centres.
The organizations within Saskatchewan are among approximately 260 Indigenous organizations supported to date by the urban and off-reserve stream of the Indigenous Community Support Fund, to help address the critical needs of Indigenous Peoples living in urban centres across the country impacted by the pandemic.
“I am pleased to announce today the 28 Indigenous organizations in Saskatchewan who received much needed financial support to help them continue to provide the necessary services and programs to stop the spread of COVID-19 and to support Indigenous Peoples living in urban centres and First Nations living off reserve. The safety and health of Indigenous Peoples remain our top priority.”
The Honourable Jim Carr
Prime Minister’s special representative for the Prairies and
Member of Parliament for Winnipeg South Centre
“Today's announcement is another step forward in ensuring the health and safety of Indigenous Peoples. Since the beginning of the pandemic, we've seen incredible action taken by leadership at all levels to protect the most vulnerable and to take collective action to support those who need it most. Their hard work and dedication is saving lives and preventing the spread of COVID-19.”
Pam Damoff
Parliamentary Secretary to the Minister of Indigenous Services and
Member of Parliament for Oakville North—Burlington
“I would like to thank Indigenous Services Canada - ICFS Urban funding for approving and funding opportunities for our Urban members of Yellow Quill First Nations in Saskatoon. This will provide us with the necessary supports for the well-being of our urban members. We welcome any opportunities for the betterment of our communities. This funding will provide support in the second wave of the COVID-19 virus. Once again, thank you for the program.”
Rose Campeau, Board Member
Yellow Quill Urban Services Inc.
"The Lac La Ronge Indian Band has over 11,000 members living in six reserve communities, as well as various other areas, including urban locations. Very often our urban members are away from the supports that have helped to improve the lives of our on-reserve membership. In these times of COVID-19, extra support to our off-reserve members was definitely needed. This world-wide pandemic put extra stress on all families, as well as our own LLRIB membership in urban areas, and we were grateful to receive funding from Indigenous Services Canada, through the Indigenous Community Support Fund, to help alleviate some of the worry of food security in these uncertain times. Through ICFS funding, the Lac La Ronge Indian Band was able to provide members with an amount of groceries and household supplies during the initial stages of the pandemic, and this added support was well received by our members in urban centres. On behalf of the Lac La Ronge Indian Band, I would like to thank the department of Indigenous Services Canada for the extra funding for our members who live off reserve, and to relay to the Minister that the support was appreciated."
Gordon Dupre, Director
Lac La Ronge Indian Band – Economic Development
This support is part of over $2.2 billion that has been committed in specific support to Indigenous and northern communities and organizations in response to the COVID-19 pandemic.

Project funding for the Indigenous Community Support Fund – urban and off-reserve stream was selected through a national Call for Proposals process.
First Nations, Inuit and Métis also have access to other support measures available to Canadian individuals, businesses and industries, through the Government of Canada's COVID-19 Economic Response Plan.
https://www.canada.ca/en/indigenous-services-canada/news/2020/09/government-of-canada-announces-the-indigenous-organizations-in-saskatchewan-who-received-funding-to-address-the-covid-19-pandemic-in-urban-areas.html

Canada

Public health officials call for tighter restrictions, warn COVID-19 could spiral out of control
Source: CBC News
Unique ID: 1007903733

Infectious disease experts say Canadian health authorities must tighten restrictions again or hospitalizations and deaths from COVID-19 will increase exponentially in the coming weeks.
Echoing comments made Tuesday by Chief Public Health Officer Dr. Theresa Tam, who said Canada is at a crossroads in its pandemic battle, experts in public health are urging governments to take decisive action to prevent the current resurgence of the virus from spiralling out of control.
Canada reported 1,248 new cases Wednesday, and on Tuesday the country's most populous province, Ontario, reported its highest number of new cases since early May.
Tam outlined projections that show new cases could climb to 5,000 daily by October if we continue on the current course.
"To date, we're not moving fast enough to get ahead of this," said Dr. Michael Gardam, an infectious disease physician based at a Women's College Hospital in Toronto. "I think we're being lulled into a false sense of security because of the low numbers of hospitalizations and deaths [relative to earlier in the pandemic]. But they will come in the next six weeks or so."
He said asking people nicely to tighten their social circles is not going to be enough.
"I think that appealing to people's better natures — that, hey, you should be careful and you should make sure you limit your contacts — I don't think that that's going to work, to be perfectly frank."
Gardam said Canadians grew fatigued with the restrictions imposed on their social circles earlier in the year and won't be eager to return to them unless pressed.
"I think we're going to have to be a lot more forceful," he said.
Adjusting bubbles
That means demanding Canadians tighten their social circles, and backing that up with enforcement.
"I would argue that we need to be very cautious, like we were back in March, in order to weather the storm from all the increased contacts that we've had."
Right now, "people are playing fast and loose with bubbles all over the place," said Gardam.
If you increase the number of contacts that you have, this is going to go to hell real quick.- Michael Gardam, infectious disease physician, Women's College Hospital
Instead, he says we need to rethink social bubbles now that school is in session again.
"We're all going to have to pay the price because our kids are in school now. So what are we giving up?
"If you want to keep the restaurants open and bars, maybe you have to give up your private gatherings," he said. "Because if you just increase in every dimension, if you increase the number of contacts that you have, this is going to go to hell real quick."
The actions taken in the next two weeks could change the trajectory of the months to come, said Laura Rosella, an associate professor at the University of Toronto's Dalla Lana School of Public Health,
"There's a lot of things with this pandemic that we can't control, but we might be able to control who we interact with, especially socially, and who's in our bubble," said Rosella, who holds a PhD in epidemiology.
"I would encourage everyone to rethink what their bubbles are given the new situation, especially if something's changed, if someone's gone back to work, someone's entering a school situation and especially if vulnerable people are in their bubbles."
Rosella said her advice to Canadians is to "really think through what is absolutely necessary" when it comes to interactions with others.
More than a blip
Rosella said Canadians can't afford to ignore the changes happening with COVID-19.

"We're not in the August situation anymore. There's clearly an uptick of cases," said Rosella, "The fact that we're already on that trajectory tells me that the likelihood of this being just a small blip, that we're not going to notice and we can carry on, is pretty low."
"We are going to experience a significant increase that we're going to have to manage and react to. It could be worse if we do nothing. And if we act, we could minimize the impact of it."
Dr. Samir Gupta, a clinician-scientist at St. Michael's Hospital and an assistant professor in the department of medicine at the University of Toronto, said getting a handle on this COVID-19 surge means returning to restrictions implemented earlier in the pandemic.
Speaking with Heather Hiscox on CBC Morning Live Wednesday, Gupta said Canadians "need to start making similar sacrifices to the ones we made the first time around," which was successful with flattening the curve in the spring.
Without enforcement, "we risk overwhelming our health-care system capacity … [and getting] into real trouble," he said.
"We don't want to have to turn people away and not be able to take care of people who are sick with this virus. And that's the biggest risk we face."
About the Author
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With files from Vik Adopia and Christine Birak
Your daily guide to the coronavirus outbreak. Get the latest news, tips on prevention and your coronavirus questions answered every evening.
https://www.cbc.ca/news/health/covid-19-crossroads-1.5735776

Canada
UPDATE: Three more COVID-19 cases linked to outbreak at Pembroke High School
Source: OttawaMatters.com
Unique ID: 1007903771

Three people who have tested positive for COVID-19 in the Renfrew and Pembroke regions have contracted the virus through connections relating back to the outbreak at Fellowes High School — neither of which are employees or students of the school.
The new cases were found through contact tracing, the Renfrew County and District Health Unit said in a press release Wednesday.
Fellowes High School was the first school in Ontario to close since classes began.
“They have been isolating since being identified as a high-risk contact,” the statement said. “No additional positive tests among students or staff members were received today.”
Until further notice, all staff and students of the school must continue to self-isolate and self-monitor, even if they did received a negative COVID-19 test result, the authority says.
According to Jonathan Laderoute, communications manager of Renfrew County District School Board, as of Wednesday afternoon, Fellowes High School remains closed to all students and staff.
"No additional positive tests among students or staff members were received today," Laderoute said in a statement to 1310 News. "The Renfrew County District Health Unit is still requiring that all staff and students must continue to self-isolate and self-monitor even if they have received a negative COVID-19 test result until further notice." A re-opening of the school has yes to be determined.
https://www.ottawamatters.com/local-news/three-more-covid-19-cases-linked-to-outbreak-at-pembroke-high-school-2738018

Canada
Ontario Investing More Than $1 Billion to Expand COVID-19 Testing and Contact Tracing
Source: Government of Ontario
Unique ID: 1007905937

TORONTO — The Ontario government is building on the largest provincial testing initiative in Canada by providing $1.07 billion to expand COVID-19 testing and case and contact management. The government is also immediately investing $30 million to prevent and manage outbreaks in priority sectors, including the

province's long-term care homes, retirement homes and schools. These investments are part of the province's comprehensive plan to prepare the health system for a second wave of COVID-19.

Details were provided today by Premier Doug Ford, Christine Elliott, Deputy Premier and Minister of Health, and Dr. Barbara Yaffe, Associate Chief Medical Officer of Health.

"We've put over $1 billion on the table to help track, trace and isolate cases of COVID-19 through the largest and most robust pandemic testing initiative in the country," said Premier Ford. "By ramping up our daily testing capacity to 50,000 tests and closely monitoring our long-term care homes and schools, we can quickly respond to any outbreaks and surges and stop the spread of this deadly virus in its tracks."

Expanding testing and case and contact management

A critical part of Ontario's COVID-19 fall preparedness plan is encouraging people to continue to adhere to foundational public health measures and monitor public health trends carefully. That's why the province is investing $1.07 billion to enhance and expand efforts to test, trace and isolate new cases of COVID-19.

"As part of our plan to ensure the health system's readiness for future waves of COVID-19, our government is dramatically expanding our testing capacity, launching more testing locations and adding more case and contact management resources to trace and isolate new cases," said Minister Elliott. "In doing so, we will also support long-term care homes, schools and hospitals to effectively prevent, track and contain outbreaks of COVID-19."

To date, Ontario has maintained adherence to public health measures and established a strong foundation for testing and case and contact management by:
•Establishing a provincial COVID-19 lab network with capacity for more than 40,000 daily tests;
•Establishing over 150 assessment centres;
•Testing long-term care home residents and staff in addition to the ongoing testing of staff and homes in outbreak;
•Providing up to 1,700 more contact tracers to support public health units in contact follow-ups through an agreement with the federal government;
•Launching a new, custom-built case and contact management digital system to improve data quality and timeliness and eliminate the use of the multiple tools being used across the province and the integrated Public Health Information System (iPHIS) for COVID-19;
•Launching COVID Alert, the country's made-in-Ontario exposure notification app; and
•Launching a robust public awareness campaign to educate the public on how to keep them and their families safe, including targeted campaigns to young Ontarians.

Building on these efforts, Ontario will strengthen public health measures and continue to expand testing and case and contact management through the following:
•More Testing Locations: Working with Ontario Health, local public health units and hospitals, Ontario will expand testing locations based on local needs to provide Ontarians with more access to testing and reduce testing wait times. This will include adding more testing locations such as primary care offices, at-home testing for certain home and community care clients, and starting on Friday, September 25, 2020, in participating pharmacies.
•More Testing Options: Ontario will ensure health professionals can provide more people with timely and convenient tests by expanding the methods for COVID-19 testing. Less invasive collection methods, such as throat, nasal swabbing and saliva collection will now be used in addition to nasopharyngeal swabs to test for COVID-19. Starting this week, three Ontario hospitals are offering saliva collection, with more assessment centres offering this option in the coming weeks. The province continues to review innovative technologies, such as rapid and point of care tests, to ensure Ontarians have access to leading and faster testing options.
•More Testing Capacity: Ontario will continue to expand the capacity of the provincial lab network so more tests can be processed and testing targets can be achieved. This includes hiring more lab staff and professional staff and improving data quality through digitizing requisition forms and other automated features. As a first step, the province will increase testing capacity to conduct up to 50,000 daily tests.

•More Case and Contact Managers: Ontario will continue to add case and contact management staff to prevent the spread of the virus. There are currently more than 2,750 case and contact management staff active across all public health units tracing and managing COVID-19 cases, up from approximately 1,500 staff in the spring. An additional 500 Statistics Canada employees are being onboarded this month to assist with contact management and Ontario is hiring an additional 500 contact tracers. In total, there will be more than 3,750 case and contact management staff working to keep Ontarians safe.
•Better Health Behaviour Information: Ontario will conduct health behaviour surveillance to track adherence to public health measures across Ontario and to help understand how to better communicate the importance and benefit of continuing to follow public health measures.

To measure success in these efforts, Ontario will track progress against the following:
•Faster turnaround time for testing: 80 per cent of test results delivered within 48 hours.
•Maintain test positivity rate under three per cent;
•Ensure sufficient case management and contact tracing capacity to continue reaching 90 per cent of cases within 24 hours; and
•Compliance with public health measures (based on health behaviour surveillance data).

In support of these efforts, the province has also released new testing guidance to help focus public resources on where they are needed the most.

Quickly Identify, Manage and Prevent Outbreaks
With the flu and cold season approaching and a potential second wave of COVID-19, Ontario will invest $30 million to build on its efforts to rapidly identify and contain any COVID-19 outbreaks.

To date, Ontario has worked to improve outbreak prevention and management by:
•Deploying hospital infection prevention and control (IPAC) resources to provide ongoing support to long-term care homes;
•Naming Dr. Dirk Huyer as Coordinator of Provincial Outbreak Response to work collaboratively with all ministries, the Chief Medical Officer of Health and public health units to prevent, minimize and manage outbreaks, including in schools, long-term care homes, retirement homes, child care centres, farms and hospitals;
•Developing a COVID-19 surveillance strategy to monitor the disease and detect cases and outbreaks in a timely manner, including in long-term care homes and schools; and
•Launching a new, custom-built case and contact management digital system for rapid identification of cases to speed up outbreak management response times.

Ontario will continue to improve outbreak management through the following:
•More than $510 million provided through the Social Services Relief Fund to municipal Service Managers and Indigenous Program Administrators to protect vulnerable populations, including supporting physical distancing and enhanced infection control measures in congregate settings and isolation facilities;
•Emergency Management Ontario has developed and distributed an outbreak guidance toolkit to support each ministry's outbreak management planning, ensuring strong sector responses; and
•Stress-testing outbreak response protocols and structures through virtual simulation exercises that have been held across the province to address outbreaks in schools, universities and correctional facilities. Additional scenario planning exercises are focusing on Indigenous communities, long-term care homes and retirement homes.

As Ontario works to contain and prevent outbreaks, the province will measure success using the following criteria:
•Rapid containment of outbreaks; and
•Fewer outbreaks in congregate and other high-risk settings, including long-term care homes.

The province's COVID-19 fall preparedness plan, Keeping Ontarians Safe: Preparing for Future Waves of COVID-19, will help the province quickly identify, prevent and respond to any scenario in order to protect communities.

The Keeping Ontarians Safe plan will:
•Maintain strong public health measures, including continued expansion of testing and case and contact management;
•Quickly identify, manage and prevent COVID-19 outbreaks;
•Accelerate efforts to reduce health service backlogs;
•Prepare for surges in COVID-19 cases;
•Recruit, retain, train and support health care workers, while also continuing to engage families and caregivers; and
•Implement the largest flu immunization campaign in Ontario's history.
https://news.ontario.ca/en/release/58515/ontario-investing-more-than-1-billion-to-expand-covid-19-testing-and-contact-tracing

Canada
Ontario Updates COVID-19 Testing Guidelines
Source: Government of Ontario
Unique ID: 1007905714

TORONTO — Today, Dr. Barbara Yaffe, Associate Chief Medical Officer of Health issued the following statement outlining updated COVID-19 testing guidelines for Ontario:

"Throughout the COVID-19 pandemic, Ontario has adhered to public health measures and established a strong foundation for testing and case and contact management that allowed us to rapidly identify and contain any COVID-19 outbreaks. To support this, Ontario established a provincial COVID-19 lab network with capacity for more than 40,000 daily tests.

As the trajectory of the COVID-19 pandemic has changed, the province must also adapt its approach to testing. With the upcoming flu and cold season approaching, we need to ensure Ontario's publicly-funded testing resources are available for those who need them the most, such as school children and others with symptoms of COVID-19. That's why, in consultation with health experts and Ontario's Testing Strategy Expert Panel, Dr. David Williams and I have recommended Ontario update testing guidelines to prioritize those who are at the greatest risk, while shifting away from untargeted asymptomatic testing.

Publicly-funded testing will be available and easily accessible for those who are symptomatic, have had close contact with a confirmed case, or are part of an outbreak investigation. In addition, testing will continue to be available on a targeted basis for specific asymptomatic individuals who are at greater risk due to their health condition or employment, at the direction of the Ministry of Health or the Ministry of Long-Term Care. Evolving our testing guidance in this way will support timely access to testing for those who need it.

Effective immediately, Ontarians should only seek testing at assessment centres if you are:

•Showing COVID-19 symptoms;
•Have been exposed to a confirmed case of the virus, as informed by your public health unit or exposure notification through the COVID Alert app;
•A resident or work in a setting that has a COVID-19 outbreak, as identified and informed by your local public health unit; and
•Eligible for testing as part of a targeted testing initiative directed by the Ministry of Health or the Ministry of Long-Term Care.

Starting on September 25, you can get tested for COVID-19 at select pharmacies if you are not showing symptoms and eligible for testing as part of a targeted testing initiative directed by the Ministry of Health or the Ministry of Long-Term Care.

Our best defence against COVID-19 is still to follow all public health measures like practicing physical distancing, wearing face masks and staying home when ill even with mild symptoms, so we can stop the spread.

As Ontario continues to fight the spread of COVID-19, Ontario's Testing Strategy Expert Panel and Public Health Ontario will continue to actively review testing guidelines.

Testing continues to be available at any of the province's 150 assessment centres currently open, and at participating pharmacies starting this Friday. To find the closest pharmacy or assessment centre, please visit Ontario.ca/covidtest."
https://news.ontario.ca/en/statement/58507/ontario-updates-covid-19-testing-guidelines

Canada

Ontario Extends Critical Delivery Program for Seniors and People with Disabilities
Source: Government of Ontario
Unique ID: 1007905668
TORONTO — The Ontario government is extending the Ontario Community Support Program until March 2021. This will ensure that low-income seniors and people with disabilities, many who are self isolating due to COVID-19, can continue to get meals and other essential supplies delivered to their homes in the upcoming winter months.

The announcement was made today by Raymond Cho, Minister for Seniors and Accessibility.

"Our government is committed to protecting the health and safety of Ontarians. Over the past few months, these deliveries have provided real and meaningful support directly to people with disabilities and seniors in isolation" said Minister Cho. "As we continue to work together to stop the spread of COVID-19, we will ensure that the Ontario Community Support Program will continue to be there for Ontarians with disabilities and older Ontarians when they need it most."

The program was launched in partnership with the Ontario Community Support Association (OCSA) in April. Since then, it has enabled more than 230,000 deliveries of meals and essential supplies across the province, helping seniors and people with disabilities as they stayed home to protect themselves from COVID-19.

"While many Ontarians are returning to work, this pandemic is far from over for vulnerable people who need continued support to stay healthy and safe at home," said Deborah Simon, CEO of the Ontario Community Support Association. "The extension of this program means our members can keep meeting the unprecedented demand for help and support in our communities, and provides certainty and stability for the clients they serve as we head into the second wave of this virus and upcoming flu season."

To access the Ontario Community Support Program and request a service, visit www.ontariocommunitysupport.ca. Those without Internet access or who require service in a language other than English or French, can dial 211 or 1-877-330-3213 (toll free). TTY service is also available by calling 1-888-340-1001.

Quick Facts
•In April, Ontario announced the launch of the Ontario Community Support Program with an $11 million investment to support the delivery of meals, medications and other essentials to low-income seniors and people with disabilities.
•People living with physical disabilities who are in supportive housing or independent living situations, socially isolated and unable to perform activities of daily living without help are eligible to participate in the program.
•Seniors who are low income, socially isolated, with limited or no transportation options are also eligible to participate in the program.
•OCSA is a not-for-profit, community-based organization with a province-wide network providing health and well-being services.

Additional Resources
•Programs and services to help seniors be healthy, active and engaged
•Find out how the province is working to protect Ontarians from COVID-19

https://news.ontario.ca/en/release/58510/ontario-extends-critical-delivery-program-for-seniors-and-people-with-disabilities

Canada
Yukon eyes B.C.'s new spit test for COVID-19
Source: CBC News
Unique ID: 1007905870

'We're working with our B.C. lab partners to see just how we could add this option to our testing in Yukon' Yukon's chief medical officer says the territory is looking to adopt a new method of COVID-19 testing that's being introduced in B.C.

Last week, B.C. announced it was introducing a new mouth rinse, gargle and spit test for students from kindergarten to Grade 12 to help make it easier for children and teenagers to check whether they have COVID-19. The test was developed in that province as an alternative to nasal swabs.

Yukon Chief Medical Officer Dr. Brendan Hanley said the technique seems promising.

"We're working with our B.C. lab partners to see just how we could add this option to our testing in Yukon," Hanley said Wednesday at his weekly pandemic update.

"With this less-invasive test for children, it may be a kinder option for kids who might have to be tested multiple times over the fall and winter months," he said.

B.C.'s Provincial Health Officer Dr. Bonnie Henry says the made-in-B.C. product will reduce her province's dependency on the global supply chain for lab testing. The test can be done without a health professional and by parents or children themselves.

Nova Scotia is also looking to implement the new testing method, but health officials there said right now there aren't enough cases in that province to confirm the testing method.

There is currently one active case in Nova Scotia, and none in Yukon.

Longer hours at testing centre

Meanwhile, Yukon's COVID-19 Testing Centre (CTC) in Whitehorse — formerly referred to as the Respiratory Assessment Centre — will now have longer hours. Hanley says it's one way to prepare for increased demand as the flu season begins.

The centre in Whitehorse will now be open from 8:30 a.m. to 6 p.m., seven days a week. Referrals are no longer required to get a test at the centre.

Hanley also said the health department is working to find more staff for the facility after some shortages.

"There were some challenges this past week with backfilling staff at the CTC," he said.

"The department of Health and Social Services is working with human resources to develop a reliable on-call staffing pool, and we're confident in our ability to provide testing seven days a week."
https://www.cbc.ca/news/canada/north/yukon-covid-spit-test-bc-1.5736468?cmp=rss

Canada, BC
B.C. teacher files claim, says she caught COVID but hadn't been told about student's positive test
Source: National Post - Top Stories
Unique ID: 1007904564

A Vancouver high-school teacher who tested positive or COVID-19 was never contacted by public health officials after a student in her class was confirmed to have the illness, she says.
Renee Willock, West Vancouver Teachers Association president, told CTV that instead, the teacher was alerted by students who were themselves contact-traced and asked to isolate.
As a result the teacher, who works at Sentinel Secondary School in West Vancouver, has filed a claim over the matter with WorkSafeBC, the provincial agency that promotes safe and healthy workspaces.
“The teacher is hugely frustrated,” Willock said. “She could have gone out on Saturday and spread this further and that didn’t need to be the case.”
The teacher stayed home after finding out the student was positive, but she herself began to feel sick the next day. Public health officials are now investigating whether the teacher became infected by the student.

Article content continued
Since the re-opening schools two weeks ago, no confirmed transmission of COVID-19 between a student and a teacher has occurred in Vancouver. But Willock says this case has set off alarms for teachers, as it shows them there are failings in the current system.
Willock said she wants stricter rules imposed for both for mask wearing and physical distancing.
“Just cohorts and contract tracing is not enough,” she said. “We need better preventative measures in schools.”
The teacher’s claim would become the first test case of a teacher filing over the coronavirus with WorkSafeBC.
Teri Mooring, B.C. Teachers Federation president, said there needs to be a process that teachers can count on, to know if there is potential classroom exposure.
“We need to be assured when cases are detected and there are confirmed cases of COVID in schools, that quick and efficient contact tracing happens,” Mooring told CTV.
“This is not leading to confidence in the system unfortunately. Everyone needs to understand there will be quick and efficient notifications when these things happen.”
Mooring feels a real investigation needs to take place into how the teacher was not made aware of the active case in her own classroom, and why staff, parents and the public often aren’t being made aware of cases.
https://nationalpost.com/news/b-c-teacher-files-claim-says-she-caught-covid-but-hadnt-been-told-about-students-positive-test

Canada, ON
Outage that prevented Public Health Ontario from issuing COVID-19 test results fixed, agency says
Source: CBC News
Unique ID: 1007904427

The agency announced the outage on its website on Wednesday afternoon, and it was fixed by Thursday morning. (Public Health Ontario)
An unexpected outage that temporarily prevented Public Health Ontario (PHO) from issuing COVID-19 test results to patients has been fixed, the agency said early Thursday.

"Normal operations have resumed regarding test results reported into the lab information system," PHO said in a statement. "Test results affected by the outage yesterday are now being inputted into the lab information system and will be completed today," it continued.

The agency initially announced the outage on its website Wednesday afternoon, and cautioned that some laboratory test results may be delayed as a result.

PHO continued to collect test samples throughout the outage. The provincial government said earlier this week that it is working to ramp up testing amid an upward trend in COVID-cases, with a goal of reaching 50,000 tests per day.

Officials announced yesterday that testing for asymptomatic people would be rolling out at up to 60 pharmacies provincewide starting Friday. The testing initiative is the second part of the government's fall

pandemic preparedness plan. The first piece involved purchasing millions of seasonal flu shots that the government is encouraging all residents to get.

CBC News has obtained a 21-page draft version of the plan, provided by a government source, in advance of more details being officially revealed later today.
https://www.cbc.ca/news/canada/toronto/public-health-ontario-covid-outage-1.5736332

Canada, QC
Quebec releases scathing reports into long term care homes where dozens died
Source: winnipeg.citynews.ca
Unique ID: 1007905414

MONTREAL _ The owners of a private long-term care home in suburban Montreal where dozens of residents died during the COVID-19 pandemic in March and April displayed “organizational negligence,” according to a new report.
The Quebec government released the report into Residence Herron on Wednesday, as well as a separate report that looked into a public long-term care home north of Montreal where 100 residents died.
In total, 38 people died at Residence Herron between March 26 and April 16, including 23 who died in less than a week between April 5 and 10, the report states.
Commissioned by the provincial government, the investigation concludes that authorities at Herron repeatedly failed to address shortcomings noted in prior inspection reports and in a coroner’s report, largely because of vacancies in key posts and a turnover rate that reached 20 per cent a year.
WATCH, OUR ORIGINAL COVERAGE FROM APRIL: Alleged neglect of seniors at residence in Dorval
“It is clear with such a turnover of staff, things must continually be redone,” the report reads.
The report details the chaos that followed the discovery of a first case of COVID-19 on March 26, and its devastating effects on a residence that was described as ill-prepared to confront a pandemic.
The private facility was placed under government trusteeship after regional health authorities in late March found only three employees on site to care for 133 residents, some of whom were sitting in overflowing diapers and suffering from dehydration.
In the days that followed the first case, residents and staff began showing symptoms. There was no protective equipment until March 28, “except for a few masks,” the report reads. Staff began staying home, either out of fear or because they were told to go into isolation.
On March 29, co-owner Samantha Chowieri texted the local health authority to inform them that the residence was short at least 27 people, including nurses, auxiliaries and care attendants.
A team dispatched from the health authority found dirty floors, air that smelled of urine and feces and residents who were thirsty and dehydrated.
“Several (residents) were soiled, because their incontinence briefs had overflowed and the beds were dirty and the stains suggested it was several days old,” the report says. “When the incontinence briefs were changed, several residents had burns on their skin and the hygiene of the genital areas had not been done adequately.”
In a statement, Herron’s owners said they would take the time to carefully analyze the report before commenting.
The investigator commissioned by the health minister, Sylvain Gagnon, also criticized Herron’s owners for failing to collaborate with health authorities, who eventually sought a court order on the matter.
He concludes that the managers of the facility did not have “malicious” intentions but they did not have full control over their facility and they lacked understanding of what was required to respond to residents’ needs.
“As a result, I must conclude that in the present affair the authorities of the Herron CHSLD demonstrated organizational negligence,” Gagnon writes.
But the investigator reserved some of his harshest criticism for the province’s health-care system, which he says failed to address problems with long-term care and persistent staff shortages across the network.
He was highly critical of the former Liberal provincial government’s health-care reform of 2015, which was supposed to save costs and improve organization but had a negative effect on patient care, he said.
“Were our elders forgotten? Did the authorities at the time lack foresight? We have to answer in the affirmative,” he said.
He also recommended the province study whether private long-term care homes have the resources to adequately meet the needs of people who have serious health conditions or loss of autonomy.

The government also made public a report into the Ste-Dorothee long-term care home in Laval, which had the province's highest death toll in the pandemic.
Investigator Yves Benoit found that pre-existing staff shortages were exacerbated when staff members had to self-isolate due to exposure and agencies refused to send their workers to hot zones.
Asymptomatic employees helped COVID-19 spread through the facility, throwing it into a crisis that resulted in more than 40 per cent of residents testing positive in early April.
Managers at the nursing home criticized health authorities for not setting foot on the site, leading them to feel abandoned.
The report concluded that the workers did the best they could, and the problems at Ste-Dorothee were largely the same as those faced by other long-term care homes: a lack of staff, ineffective management structure and shortages of personal protective equipment.
In a statement, Health Minister Christian Dube said the government has already acted on many of the recommendations in the reports, which were submitted to the government in June and July.
"Not only did the major changes undertaken serve to prepare us for the second wave, our actions are sustainable and their benefits will continue after the pandemic," he said in a statement.
Those changes include mandating that a manager be named to lead each long-term care home, raising salaries, hiring thousands of health-care staff and ensuring infection-control measures are in place in each residence.
In a statement emailed to CityNews, the company that owns the Herron residence said the following:
We will take the time to carefully analyze the conclusions and recommendations of the report. – Katherine Chowieri
manager, Katasa Group.
This report by The Canadian Press was first published Sept. 23, 2020.
https://winnipeg.citynews.ca/2020/09/24/quebec-releases-scathing-reports-into-long-term-care-homes-where-dozens-died/

Canada, ON
Leaked document reveals Ontario's plan to avoid another COVID-19 lockdown
Source: CBC News
Unique ID: 1007907010

Ontario wants to avoid imposing lockdown-style measures to combat a second wave of COVID-19, but is prepared to take 'targeted action" such as closing certain higher-risk businesses, CBC News has learned.
CBC News obtained a copy of Ontario's fall pandemic preparedness plan, still in draft form even as Premier Doug Ford's government is in the midst of announcing some of its elements.
The 21-page draft, provided by a government source this week, acknowledges the recent upsurge in new COVID-19 cases, and lays out three possible scenarios of what the second wave could look like: small, moderate or large.
Whichever scenario plays out, the plan favours responding with targeted restrictions, rather than widespread closures or a lockdown.
"If there is a resurgence of COVID-19, either locally or province-wide, targeted action may be taken to adjust or tighten public health measures," says the document.
"The return to an earlier stage of provincial reopening, or even regional approaches to tightening would be avoided in favour of organization-specific or localized changes."
CBC News asked Ford's office on Wednesday evening for comment about the plan. A spokesperson said the document is an early draft, "which has since evolved considerably.
"It should not be considered complete," said Ford's director of communications, Travis Kann, in an email. "We look forward to continuing to release the full details of the final plan."
Ontario is currently seeing a marked upswing in infections, with the daily numbers of new cases hitting levels not seen in four months. There have been on average 386 new confirmed cases reported daily over the past week, while that figure was 337 in the final week of May.
At that time, all regions were still in Stage 1 of the province's reopening plan, with restaurants and bars shut. Case numbers were on a downward trend.
The draft plan says if cases start rising "a specific workplace or organization could be closed for a period of time or have additional public health measures or restrictions applied, or a certain type of higher-risk business in a local area might be closed until trends in public health indicators improve."

The plan commits at least $2.2 billion to the pandemic response. The biggest single item is nearly $1.4 billion on a range of public health measures, including increased capacity in testing, labs, contact tracing, and efforts to prevent transmission of the novel coronavirus.
Other dollar figures in the plan include:
$475 million to prepare the health system for a surge in COVID-19 cases.
$284 million to reduce backlogs in surgeries and other hospital procedures.
$30 million to identify, manage and prevent outbreaks in schools, long-term care and other settings.
$28.5 million for the flu immunization campaign announced on Tuesday.
An additional $90 million is labelled "TBC" (to be confirmed) for a wage enhancement for personal support workers in home and community care.
So far, the government has released two elements of the plan: the upcoming flu vaccination campaign and the expansion of COVID-19 testing to some pharmacies. Ford is expected to reveal more on Thursday, but the full plan was not to be rolled out for several more days.
Parts of the plan that have not been revealed include expanding testing capacity to 50,000 tests per day, with the ability to ramp up to 100,000 tests per day as needed. The plan also says the province will adopt new testing technologies, including saliva tests and tests that can be processed at the point of care.
The document sets out some benchmarks for success in the public health response to COVID-19. The province wants the positive test rate running no higher than three per cent. It's aiming for at least 80 per cent of all test results to be completed within 48 hours.
And it wants 90 per cent of all people who test positive for the virus to be contacted within 24 hours.
There is mixed success with some of these measures right now. The positive test rate province-wide has averaged 1.1 per cent over the past week. The turnaround target for lab tests is currently being met only 68 per cent of the time in Toronto.
The plan does not state any specific benchmarks to trigger tighter pandemic restrictions. The decision would be based on more than just the daily case count, says the document. The number and type of outbreaks, hospitalization data, and the input of local medical officers of health would also be factored in.
Private clinics to help clear surgery backlog
Private medical clinics would be paid to help clear the backlog of thousands of procedures that were postponed during the spring wave of the pandemic as hospitals tried to clear space.
The Ministry of Health will address the backlog in part "through innovative channels such as the use of independent health facilities that can deliver additional publicly funded surgical and diagnostic imaging services," says the document.
It also promises unspecified funding for additional surgeries to take place during extended hours in hospital operating rooms.
The document says the health system is facing challenges that weren't present during the initial spring wave of COVID-19.
Overcrowding at hospitals is one of them, as patient volumes are beginning to returning to pre-pandemic levels. Hospitals and long-term care homes now have less space for patients and residents as they have had to reduce the number of multi-bed rooms to ensure physical distancing.
There's also a shortage of health-care workers, particularly in home and community care, according to the plan.
The draft document says the province will take action on what it calls "health behaviour surveillance" as part of its efforts to slow transmission of COVID-19.
There are no dollar figures attached to this, but the document says the aim is "to track adherence to public health measures across Ontario."
https://www.cbc.ca/news/canada/toronto/covid-19-ontario-fall-pandemic-plan-draft-copy-1.5736538

Canada, ON
ONTARIO: Experts say new testing strategy highlights complexities of second wave
Source: OttawaMatters.com: ottawamatters
Unique ID: 1007906789

Doctors shaping Ontario's pandemic response say the shift is necessary to preserve the province's testing capacity
Medical experts say an abrupt shift in Ontario's testing strategy highlights the complexities of responding to a second wave of the COVID-19 pandemic.

Premier Doug Ford's government announced today that assessment centres would revert back to testing only symptomatic individuals, those who've come into contact with a case and those who work in high-risk settings.
Testing for asymptomatic residents is available at up to 60 pharmacies by appointment starting on Friday.
The move marks a sharp reversal from the message the government touted for months that anyone could obtain a test if they wanted one, regardless of their symptoms or possible exposure level.
Doctors shaping Ontario's pandemic response say the shift is necessary to preserve the province's testing capacity, which has been severely strained in recent weeks as case numbers climb.
Some epidemiologists say the change makes sense and is based on sound science, while others argue it represents the latest in a long line of failed efforts to curb COVID-19 in the province.
This report by The Canadian Press was first published Sept. 24, 2020.
The Canadian Press
https://www.ottawamatters.com/coronavirus-covid-19-national-news/ontario-experts-say-new-testing-strategy-highlights-complexities-of-second-wave-2740067

Canada
COVID-19 outbreak declared at fifth Ottawa school, 52 schools with a COVID-19 case
Source: CTV News
Unique ID: 1007906722

OTTAWA -- A COVID-19 outbreak has been declared at a fifth Ottawa school, while 52 Ottawa schools have at least one confirmed case of COVID-19.
Ottawa Public Health reports the new COVID-19 outbreak is at Lycee Claudel, a French private school in Ottawa. Two students at the school have tested positive for COVID-19.
COVID-19 cases have been reported at 52 schools with the Ottawa Carleton District School Board, Ottawa Catholic School Board, and the French public and catholic school boards.
COVID-19 outbreaks have been declared at the following Ottawa schools:
Ecole elementaire catholique Montfort
Franco-Ouest
Gabrielle Roy Public School
Lycee Claudel
Monsignor Paul Baxter School
Ottawa Public Health ordered Monsignor Paul Baxter School closed for at least two weeks following four cases of COVID-19. Two students and two staff members have tested positive.
Here is a breakdown of the COVID-19 cases in Ottawa's schools:
Ottawa Carleton District School Board: Nine students (eight students, one teacher tested positive)
Ottawa Catholic School Board: 11 schools (14 students, two staff members tested positive)
Conseil des ecole Catholique Centre-Est: 21 schools (32 cases in all schools)
Conseil des ecoles publiques de l'Est de l'Ontario: 11 schools (15 student cases in schools)
https://ottawa.ctvnews.ca/covid-19-outbreak-declared-at-fifth-ottawa-school-52-schools-with-a-covid-19-case-1.5118727

Canada
As coronavirus resurges, ‘now is the time’ to push COVID Alert app: experts
Source: Global News
Relevance: 0.601

Unique ID: 1007906540
Ahead of a second wave of the coronavirus in Canada, experts say its time to talk more seriously about the country’s exposure notification app, COVID Alert.
Since it launched in July, the app has been downloaded more than 2.7 million times. But July was a different time in the pandemic.
When it first launched in Ontario, roughly 80 to 100 people were testing positive each day. Fast-forward eight weeks and those tallies have jumped to upwards of 400, renewing pressure to control the spread.
If anyone still needs an incentive to download the app, this is it, said Emily Seto, an engineer and health technology specialist at the Centre for Global eHealth Innovation at the University of Toronto.

“This could be the time when this app really shows its benefits,” she said. “That is, if people choose to use it.”

Get the message out

COVID Alert has been touted by federal ministers and public health officials as a powerful tool to curtail the pandemic in Canada.

Despite the relatively low number of downloads, Canada’s top doctor, Theresa Tam, said earlier this month that the app needed time to prove its effectiveness.

“As societies open, as schools and colleges and other places restart, now is the time to give it a go,” she said on Sept 3.

The encouragement was echoed by Prime Minister Justin Trudeau, who took to national television Wednesday evening to warn Canadians of a second wave of the COVID-19 pandemic.

He said the app is “one more way to keep ourselves and others safe.”

Seto agrees, but worries the word hasn’t been spread properly. She said now is the time to ensure the messaging is “loud and clear.”

The push for mask-wearing and hygienic practices was broadcast widely and successfully, she said, and “the same tactics can be done regarding COVID Alert.”

“There was a lot of communication around wearing masks for students going back to school, as well as physical distancing. That would have been a good opportunity to get a strong message out about the benefits of the app for parents and also high school students.”

From the day the app rolled out (July 31) to Sept. 22, just 375 people who tested positive for COVID-19 have logged their diagnosis. That’s a far cry from the more than 1,000 new daily cases nationally.

The app does not collect information on how many people have subsequently been notified of exposure, so it’s unclear how far those positive cases have stretched.

However, there has been an apparent increase in activity over the last four weeks. Since Sept 1., 263 people who tested positive for the virus logged their diagnosis to notify others of possible exposure. The app has also been downloaded 490,000 times during the same period, according to the Public Health Agency of Canada.

Given that the recent rise in cases is being driven by young people — often gathering in large groups — the message about the benefit and safety of the app needs to get laser-focused, said Dr. Isaac Bogoch, an infectious disease expert based out of Toronto General Hospital.

“It needs consistent messaging, consistent reminders, and it needs to be done with age, language and culturally appropriate messaging in mind to get the most uptake,” he said.

“Like anything else, if you take your foot off the gas pedal, people will lose interest and might not do it.”

Limitations not binding

Some countries have fared better than others in adopting digital methods.

Germany’s tracing app has been downloaded more than 18 million times since its launch in June and has been touted by the government as a key tool in the country’s effort to contain the virus. Unlike Canada’s, the app can provide users with their COVID-19 test result, sent directly to their smartphone. In its first 100 days, it was used to transmit 1.2 million test results from labs to users.

Seto said this feature is extremely useful and, if possible in Canada, would likely drive up adoption. But the app already has its limits, which Seto said might be a factor in whether people choose to download it in the first place.

The app is only available for download on iPhones with at least iOS 13.5 and Androids with at least version 6. While this limitation has come under criticism, “we’re still very far from having a large percentage of people who have compatible phones actually use it,” said Seto.

Canada’s COVID Alert is strictly voluntary. It uses Bluetooth data to ping any devices that may have had close contact with someone who has tested positive for COVID-19.

The person infected would first have to be tested, then would have to enter that positive diagnosis into their smartphone. The app considers close contact as being an interaction that lasts at least 15 minutes and occurs less than two metres apart, which is determined by the strength of the signal from each device in that interaction.

It retains no identifying personal data. So long as the Bluetooth function is on, users can be notified.

But because the app is voluntary, the onus is on the person who tested positive to log that anonymous information into the app to alert others of potential exposures.

It has also yet to be rolled out or adopted countrywide. It is currently available in Ontario, New Brunswick, Newfoundland and Labrador, and, as of last week, Saskatchewan. It is still in the works in Alberta and Manitoba, though Alberta has used its own provincial app for some time now.
Both Quebec and B.C. have no plans to use the federal app. Quebec has shunned it over supposed privacy concerns, despite the app receiving the blessings of federal and provincial privacy commissioners and endorsements from technology experts.
"We need to remember that 2.2 million isn't really dispersed across Canada, it's primarily focused in Ontario and a couple of other provinces. The denominator isn't Canada's 38 million people," Bogoch said.
"But we've already seen the successes of digital tools in this pandemic. We've also seen the failures of digital tools. But this is something that is simple, free and provides incremental benefit and safety. It's as simple as that."
Chance to relaunch
Since the app initially launched while the COVID-19 situation was improving in Ontario and much of Canada, there's no reason why the government shouldn't consider a re-launch, said Seto.
"It would be of benefit to keep it at the top of people's minds," she said. "Now is the time to do another push in terms of a campaign to get people to download."
But the app is not a panacea to the crisis we're facing, Dr. Susan Bondy, an associate professor at the Dalla Lana School of Public Health at the University of Toronto, said in a previous interview.
She said it's just one piece of a larger puzzle, and that the other classic methods of preventing the virus's spread are just as important. Done in tandem, it can have a significant impact, she added.
"It's just to help curb the incredible workload burden of trying to identify all the contacts of somebody who tested positive," Bondy said.
"People who are risk-averse will take their contacts from two down to zero, and people who are not risk-averse will bring it down from a thousand to merely 10, recognizing that sometimes they will be in a large, untraceable environment like a store or park… That's how this app helps."
You can download the app for iPhone on Apple here and for Android on Google Play here.
— with files from Global News' Amanda Connelly and Beatrice Britneff
https://globalnews.ca/news/7352806/coronavirus-covid-19-second-wave-covid-alert-app/

Canada, ON
Coronavirus: Latest developments in the Greater Toronto Area on Sept. 24
Source: Global News
Unique ID: 1007906465

Here is a roundup of the latest developments on the coronavirus pandemic in the Greater Toronto Area for Thursday:
Ontario reports 409 new coronavirus cases
Ontario is reporting 409 new cases of the novel coronavirus, bringing the provincial total to 48,496.
According to Thursday's provincial report, 151 new cases were recorded in Toronto, 46 in Peel Region, 34 in York Region, 12 in Durham Region and 11 in Halton Region.
More than 30,600 tests were processed in the last 24 hours. Sixty-three per cent of Thursday's cases are people under the age of 40.
Ontario reported one more death and 286 more resolved cases.
Ontario child care centres and schools
Meanwhile, government figures show there have been a total of 210 school-related COVID-19 cases in Ontario — 101 among students and 40 among staff (69 individuals were not identified). This is an increase of 31 more cases since the previous day.
The COVID-19 cases are currently from 178 out of 4,828 schools in the province.
Affected schools are in Toronto, Oakville, Pickering, Ajax, Whitby, Oshawa, Mississauga, Brampton, Caledon, Orangeville, Aurora, Milton, Tottenham, Waterloo, Cambridge, Kitchener, Brantford, Welland, Ancaster, Balmertown, Hamilton, Niagara Falls, Barrie, Orillia, Huntsville, Amherstburg, Thornhill, Maple, Woodbridge, Vaughan, Markham, London, Windsor, Embrun, Orleans, Nepean, Rockland, Ottawa, Kemptville, Kingsville, Elmira, Thunder Bay and Pembroke.
Two schools in Ontario are closed as a result of positive cases, the government indicated.
There have been a total of 107 confirmed cases within child care centres and homes — an increase of three more since the previous day.

Toronto kindergarten class asked to self-isolate after positive case
The Toronto District School Board says an entire kindergarten class has been asked to self-isolate as a result of a staff member who tested positive for coronavirus.
The TDSB said 26 children, one teacher and an early childhood educator are in isolation.
Up to seven classes may have had contact with the sick staff member. However, only one class has been required to self-isolate.
The entire school has been notified and the board is working closely with Toronto Public Health, the TDSB said.
Staff member of Premier Doug Ford's tour team tests positive for coronavirus
Ontario Premier Doug Ford says a junior member of his tour team has tested positive for coronavirus.
Ford posted the news on his Twitter account Thursday morning.
"I had no close contact or prolonged exposure to them and will therefore closely monitor my symptoms and take appropriate action as needed," Ford said in his tweet.
Low-risk, asymptomatic people shouldn't get tests: health officials
Ontario health officials say low-risk individuals who are asymptomatic should not be going to assessment centres for a COVID-19 test.
Associate chief medical officer of health Dr. Barbara Yaffe says that testing needs to be reserved for people with symptoms, or those who have come into contact with someone who has COVID-19.
Previously, the province had encouraged anyone who wanted to get a COVID-19 test to seek one at an assessment centre.
NOTE: This story will be updated throughout the day.
— With files from The Canadian Press
https://globalnews.ca/news/7355243/coronavirus-toronto-peel-york-durham-september-24-covid-19/

Canada
New Brunswick imposes new travel restrictions on Quebec border residents
Source: CTV News Atlantic - Public RSS
ID: 1007907965

FREDERICTON -- New Brunswick is reimposing travel restrictions on residents of Quebec's southern Gaspe area, which has seen its COVID-19 alert level rise.
Premier Blaine Higgs said Thursday only residents of the Listuguj First Nation and Pointe-a-la-Croix, near Campbellton, N.B., will be allowed to make day trips into New Brunswick. The new rule enters into effect Friday.
The move follows last week's decision to reimpose travel restrictions on residents of Quebec's Temiscouata region, which is close to Edmundston, N.B. Residents of southern Gaspe and of Temiscouata are still permitted to make day trips into New Brunswick for essential reasons such as medical appointments, approved work and child custody arrangements.
On Aug. 1, New Brunswick's government had opened its so-called travel bubble, permitting day trips for residents of three border regions in Quebec: the southern Gaspe area, the Temiscouata region, and the Listuguj First Nation.
But following a rise in COVID-19 infections across the Quebec, Higgs began tightening his province's borders once again. On Thursday, Quebec authorities announced the southern Gaspe was moving into the yellow, "pre-alert" stage of the government's COVID-19 alert system.
Aside from residents of Pointe-a-la-Croix and the Listuguj First Nation, anyone from Quebec -- and from outside Atlantic Canada -- who enters New Brunswick for non-essential travel will need to isolate for 14 days.
Higgs said Thursday in a news release there are currently no confirmed COVID-19 cases in Listuguj First Nation or in Pointe-a-la-Croix.
Dr. Jennifer Russell, New Brunswick's chief medical officer of health, said, "Public Health will continue to closely monitor the situation for any changes. We are continuing to ask everyone to take very simple steps to reduce the spread of the disease."
https://atlantic.ctvnews.ca/new-brunswick-imposes-new-travel-restrictions-on-quebec-border-residents-1.5118968

Canada

Vancouver Coastal Health chief says not all COVID-19 exposures in schools will be made public

Source: Global News
ID: 1007907957

Vancouver Coastal Health's top doctor is defending her position on reporting COVID-19 exposures in the region's schools.

Speaking to 980 CKNW's Simi Sara Thursday morning, chief medical health officer Dr. Patricia Daly said VCH will notify the public of COVID-19 exposures when necessary, adding that privacy must be maintained because of the stigma around individuals who contract the coronavirus.

"The expectation is that health authorities and medical health officers will assess cases in school and post as appropriate and that's exactly what we're doing," she said.

"If people think they're going to be outed or that people will find out they have COVID-19, they may not go for testing."

Daly went on to say that VCH officials didn't want to unnecessarily create anxiety in parents if their children are not at risk.

"That's why we have to have a balanced approach," she said. "Certainly, anyone directly exposed as a contact needs to be notified but we also need to reassure all parents that the schools are safe and we hope that they will continue to send their children to school with that confidence."

In a statement issued Friday, Vancouver Coastal Health said all notifications to school administrators, including school exposure and outbreaks, are posted to the VCH school exposure webpage.

Daly said the emphasis needs to be on contact tracing rather than public notifications.

"The most important thing is to identify any close contacts with cases and that is occurring," she said. "So the notification on the webpage does not replace the direct notice notification of any close contacts of patients, whether they're in a school or elsewhere, and that's occurring."

Former Vancouver School Board trustee Patti Bacchus said VCH should list COVID-19 exposures at all schools, just as other health authorities are doing, saying the lack of transparency leads to fear and rumour-mongering.

"Any time you see public officials withholding information and refusing to disclose, it creates suspicion and leads to a lack of trust and speculation," she said.

"My inboxes are full of people sending me rumours that they've heard and copies of screenshots of letters. That's just not the way to be handling information in a public health crisis, but it's what people will do if the public health officials fail to give them the information they would like to see in order to make their own decisions about whether it's safe to be sending their kids to school."

The BC Teachers' Federation said a West Vancouver teacher has filed a claim with WorkSafeBC after officials failed to tell her that a COVID-19 exposure at her school was within her cohort, and she later tested positive herself.

The principal at Sentinel Secondary notified staff and parents on Saturday that someone in the school had tested positive for the coronavirus, according to the West Vancouver Teachers' Association.

Later that day, a number of students in the same cohort as the positive case were told to self-isolate, but the teacher didn't find out until those same students contacted her to ask about remote-learning options, the association said.

A notification about the exposure at the school was not posted on the VCH website until Tuesday.

Asked about the delay, provincial health officer Dr. Bonnie Henry said VCH wanted to ensure the school community was notified first, before the public notification.

When asked about the case at Sentinel Secondary, Daly said she won't comment on specific cases due to privacy concerns, adding that identifying close contacts in a school is no different than any other investigation.

"We know how this virus is transmitted," she said.

"We've been following up thousands of cases in this province since January and we know that those at risk are close contacts. Most transmission occurs, for example, in household settings. We have been doing this now for many months; we have the skills and the expertise needed to identify close contacts."

https://globalnews.ca/news/7356440/vancouver-coastal-health-coronavirus-covid-19-school-exposures/

Canada

Health experts call on province to tighten pandemic restrictions in big cities and hot spots

Source: kitchenertoday.com
ID: 1007907672

A group of 38 health experts have signed an open letter calling for swift and decisive action from the Ontario government

New COVID-19 case numbers in Ontario are rising too quickly and it's time for the province to step in to get them back under control.

That is the message from 38 health experts, including two from Waterloo Region, who have signed an open letter calling for a crack-down.

The letter calls on the Ford government to tighten restrictions on non-essential businesses and activities the signatories say lead to people gathering too closely together.

Those include dine-in restaurants, bars, nightclubs, gyms, theatres, and places of worship. The doctors are also calling for non-essential businesses to return to working from home and for universities and colleges to return to online classes wherever possible.

Dr. Andrew Morris is an infectious diseases specialist at Sinai Health and University Health Network, and a professor at the University of Toronto, he says it's close but not quite a call to return to Stage 2.

"One of the things that we're trying to prioritize is the importance of maintaining kids at schools," said Morris, adding that will be difficult without lowering community numbers or at least keeping them at current levels.

The group of experts say what is happening in the province is entirely predictable.

"Because of the increased numbers that we're seeing, I would anticipate that we're going to see an ongoing rise for the next three or four weeks as a minimum unless there are further public health measures above and beyond altering our testing strategies," Morris said.

Now Morris said there is a fine line to walk between quality of life and keeping people safe.

"And so we really need to get those numbers back down so that we can allow ourselves to normalize," he said. "Unfortunately, one can't even imagine right now increasing our social freedoms."

As for targeting businesses and activities that facilitate social gatherings, Morris said these are the types of places we're seeing most of the spread.

"I think if we could get all members of society minimizing the size of their indoor social interactions, optimizing physical distancing, and wearing masks, we'd really go a far way to getting control of this situation," said Morris, "The challenge we have is that we've provided people with mixed messages around what is safe."

He says people see restaurants and theatres filled with 50 to 100 people and they may ask themselves, if it's okay for a restaurant, what's different with our homes.

"So what ends up happening is we end up having communities that have a psyche that it's okay for us to let our guard down because it's really not so bad," said Morris.

"We want people to socialize," said Morris. "Our challenge is that when people don't socialize responsibly it has effects on the whole community, not just those people who aren't socializing responsibly."
https://www.kitchenertoday.com/local-news/health-experts-call-on-province-to-tighten-pandemic-restrictions-in-big-cities-and-hot-spots-2739910

[APG]

Canada, AB

Edmonton International Airport to pilot rapid-response COVID-19 saliva test

Source: Global News
Unique ID: 1007906449

The Edmonton International Airport is working with a local company on a pilot program to trial a new COVID-19 test that the company says can produce results in seconds.
EIA said it has been selected as the exclusive location to host clinical trials of a coronavirus test that uses a saliva sample from a person and produces a positive or negative result in less than one minute.
The airport hopes the rapid-result test will address the need for a 14-day quarantine period, which is currently in place for any traveller entering the country from outside Canada.
“We all want travel to get back to normal and a rapid COVID-19 test will accelerate this return while enhancing passenger confidence in the safety of our industry,” said EIA president and CEP Tom Ruth in a news release Thursday.
The airport is working with GLC Medical Inc. — located in the Edmonton Research Park — on the trial, which does not yet have a scheduled start date.
The medical company said its saliva test is still undergoing clinical testing as part of the regulatory approval process. But the way it works is the person being tested provides a saliva sample into a testing unit. A graphene surface inside the unit then bonds to the spike protein in the virus, the company explained.
Within one minute, the device will show either a red or green light to indicate if the person is virus-free. GLC Medical said the test does not need to be administered by a medical professional.
“We are very excited to offer the world a graphene-enhanced rapid solution in COVID-19 virus detection,” said Donna Mandau, president and CEO of GLC Medical, in a news release.
“The opportunity to collaborate with EIA, a world-respected airport authority, to enable travel and to bring families back together is very rewarding for us.”
Last week, British Columbia’s provincial health officer announced the province is rolling out a new mouth rinse/gargle test for people ages four to 18.
Dr. Bonnie Henry said the test involves swishing and gargling a sterile saltwater solution, then spitting it into a collection tube. The plan is to eventually make the new test available for everyone.
Alberta’s chief medical officer of health was asked about the saliva test during a COVID-19 briefing last week and said Alberta Health is working with the lab on options such as the mouth rinse and self-saliva sample.
“There are different elements that need to be put in place before that can be used broadly,” Dr. Deena Hinshaw said on Sept. 18.
“We need to make sure that that methodology will work with the way that our lab runs tests. We need to make sure that we have adequate collection containers, all of those different pieces because, of course, all of the hardware and infrastructure that goes along with a new sample methodology needs to be validated to make sure that it does provide an accurate result and that work is underway in Alberta but I don’t have a timeline as to when it might be able to be moved forward.”
The EIA said the next step is to bring the company into the airport and establish a safe and secure test site.
The clinical trial is expected to start at the airport some time this fall and last several weeks.
In late July, global credit rating business DBRS Ltd. suggested passenger volumes at EIA will likely not return to pre-pandemic levels until 2024.
https://globalnews.ca/news/7355724/edmonton-international-airport-covid-19-saliva-test-clinical-trial/

United States - Coronavirus Disease 2019 (COVID-19) - Communication Resources (Official and Media)

United States

Health official says majority of Americans 'remain susceptible' to COVID-19

Source: www.ecns.cn
Unique ID: 1007903808

Special: Battle Against Novel Coronavirus
Robert Redfield, director of the U.S. Centers for Disease Control and Prevention (CDC), said on Wednesday that a majority of Americans remain susceptible to COVID-19.

"CDC is in the process of a very large, sequential study across the entire United States, measuring serology," Redfield told the Senate Health Committee during a hearing. "The preliminary results on the first round show that a majority of our nation -- more than 90% of the population -- remains susceptible."
"It varies in different geographic parts from states," he said. "But it does show that a majority of Americans are still susceptible to this virus," said Redfield.
The remarks came a day after the United States reached over 200,000 COVID-19 deaths, with nearly 7 million infections, both the highest in the world.
Anthony Fauci, director of the U.S. National Institute of Allergy and Infectious Diseases, also attended the hearing and warned of the long-term effects that disease might have on those infected.
Fauci noted that a recent study in non-athletes who have recovered from the virus showed that in their MRIs "they found that about 60 to 70% of them had indication of inflammatory disease in the heart."
"They could wind up when you have inflammation, you could have scarring, that could lead to arrhythmias later on, or that could lead to cardiomyopathies," he said. "It's something we really need to keep our eye out on."
Stephen Hahn, commissioner of the U.S. Food and Drug Administration, and Brett Giroir, assistant secretary for health at the U.S. Department of Health and Human Services, also testified at the hearing.
U.S. President Donald Trump has called the country hitting 200,000 deaths from COVID-19 "a shame." He has also sought to defend his administration's response to the pandemic, which has been under sharp criticism.
http://www.ecns.cn/news/society/2020-09-24/detail-ihaaeqyp8472505.shtml

WHO

Managing the COVID-19 infodemic: Promoting healthy behaviours and mitigating the harm from misinformation and disinformation

Source: WHO
ID: 1007898132

The Coronavirus disease (COVID-19) is the first pandemic in history in which technology and social media are being used on a massive scale to keep people safe, informed, productive and connected. At the same time, the technology we rely on to keep connected and informed is enabling and amplifying an infodemic that continues to undermine the global response and jeopardizes measures to control the pandemic.
An infodemic is an overabundance of information, both online and offline. It includes deliberate attempts to disseminate wrong information to undermine the public health response and advance alternative agendas of groups or individuals. Mis- and disinformation can be harmful to people's physical and mental health; increase stigmatization; threaten precious health gains; and lead to poor observance of public health measures, thus reducing their effectiveness and endangering countries' ability to stop the pandemic.
Misinformation costs lives. Without the appropriate trust and correct information, diagnostic tests go unused, immunization campaigns (or campaigns to promote effective vaccines) will not meet their targets, and the virus will continue to thrive.
Furthermore, disinformation is polarizing public debate on topics related to COVID-19; amplifying hate speech; heightening the risk of conflict, violence and human rights violations; and threatening long-terms prospects for advancing democracy, human rights and social cohesion.
In this context, the UN Secretary- General launched the United Nations Communications Response initiative to combat the spread of mis- and disinformation in April 2020. The UN also issued a Guidance Note on Addressing and Countering COVID-19 related Hate Speech (11 May 2020).
At the World Health Assembly in May 2020, WHO Member States passed Resolution WHA73.1 on the COVID-19 response. The Resolution recognizes that managing the infodemic is a critical part of controlling the COVID-19 pandemic: it calls on Member States to provide reliable COVID-19 content, take measures to counter mis- and disinformation and leverage digital technologies across the response. The Resolution also calls on international organizations to address mis- and disinformation in the digital sphere, work to prevent harmful cyber activities undermining the health response and support the provision of science-based data to the public.
The UN system and civil society organizations are using their collective expertise and knowledge to respond to the infodemic. At the same time, as the pandemic continues to create uncertainty and anxiety, there is an urgent need for stronger action to manage the infodemic, and for a coordinated approach among states,

multi-lateral organizations, civil society and all other actors who have a clear role and responsibility in combatting mis- and disinformation.
We call on Member States to develop and implement action plans to manage the infodemic by promoting the timely dissemination of accurate information, based on science and evidence, to all communities, and in particular high-risk groups; and preventing the spread, and combating, mis- and disinformation while respecting freedom of expression.
We urge Member States to engage and listen to their communities as they develop their national action plans, and to empower communities to develop solutions and resilience against mis- and disinformation.
We further call on all other stakeholders - including the media and social media platforms through which mis- and disinformation are disseminated,researchers and technologists who can design and build effective strategies and tools to respond to the infodemic, civil society leaders and influencers - to collaborate with the UN system, with Member States and with each other, and to further strengthen their actions to disseminate accurate information and prevent the spread of mis- and disinformation.
https://www.who.int/news-room/detail/23-09-2020-managing-the-covid-19-infodemic-promoting-healthy-behaviours-and-mitigating-the-harm-from-misinformation-and-disinformation

PAHO
PAHO urges countries to plan early for COVID-19 vaccinations to reduce deaths
Source: PAHO
ID: 1007900171

PAHO Director warned that it may take time before people are vaccinated and said countries should continue public health measures such as social distancing, handwashing and wearing masks in public

Washington D.C., September 23, 2020 (PAHO) – Countries should not wait for a COVID-19 vaccine to be developed before they start planning and preparing for its arrival, Pan American Health Organization (PAHO) Director, Carissa F Etienne, said today. In the meantime, they must also continue other recommended public health measures to contain the virus.

“Frontline health workers, first responders and those caring for the elderly should be vaccinated first, followed by vulnerable groups such as adults with pre-existing conditions, especially those over 65 years of age,” Etienne said. “The challenge lies in identifying these groups early and determining how to best reach them.”

In a news briefing today PAHO Director warned that even as a vaccine is rolled out “This virus will continue to spread, and people will continue to get sick. So, we cannot pin all our hope on vaccines alone.”

“We’ll still need diagnostics to identify those who are sick and better treatments to care for those that fall ill. We’ll continue to rely on traditional public health measures like tests, contact tracing and quarantines to minimize the spread of this virus. And we’ll continue to count on people exercising social distancing, washing their hands often and wearing masks in public to protect others from getting sick,” the PAHO Director said.

When vaccines become available, the COVAX Facility, convened by GAVI, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO, “will afford countries in our region the best opportunity to fast-track access to COVID-19 vaccines and reduce the impact of the pandemic on people’s lives and our economies. The COVAX facility offers access to a basket of 15 possible vaccines,” she said.

Etienne said nearly 200 COVID-19 vaccine candidates are being studied. “And we hope that one or more of these will prove to be effective, but there is no guarantee. Early vaccines may only provide partial protection or may not work for everyone. We don’t yet know which vaccine will be found safe and effective and how it will work. But we do know that if we don’t prepare now, we will miss the opportunity to benefit from it quickly. The truth is countries can’t wait to have all of the answers before they start planning and preparing to deliver a COVID vaccine.”

The COVAX facility, including the Advanced Market Commitment financing instrument, has signed up 64 self-financing countries and 92 countries eligible for support through that instrument, she said. Through COVAX, participating countries will be guaranteed initial doses to cover at least 3% of their population in the first phases of deployment, as supplies catch up with global demand, eventually reaching 20% of their population – enough to protect those at higher risk for severe COVID-19, Etienne explained.

"Our region has a strong legacy of immunization programs that give us a leg up as we plan for the future," added Etienne.

PAHO is well prepared to offer technical cooperation to countries so they can prepare and implement their vaccination campaigns – "from planning and forecasting to communications, from regulations to the training of health personnel. Another benefit to our member states is that they can rely on our Revolving Fund, the biggest regional mechanism for self-financing countries, for the purchase and delivery of vaccines," she said.

"So, I urge countries around the world to prepare for a coronavirus vaccine, but also to remain realistic, knowing that these preparations do not replace everything else we must do to save lives today," Etienne concluded.
https://www.paho.org/en/news/23-9-2020-paho-urges-countries-plan-early-covid-19-vaccinations-reduce-deaths

ECDC

Rapid risk assessment: Increased transmission of COVID-19 in the EU/EEA and the UK – twelfth update
Source: ECDC
ID: 1007904156

Risk assessment 24 Sep 2020

In this update, we analyse the risk posed to the general population, vulnerable individuals, and healthcare provision by the current increase in COVID-19 case notification rates observed in the EU/EEA and the UK.

Executive summary

Epidemiological developments

COVID-19 case notification rates have increased steadily across the EU/EEA and the UK since August 2020, but this is not having the same impact in all countries. In several countries the observed upsurge correlates with increased testing rates and intense transmission among individuals between 15 and 49 years of age. In such countries most detections concern mild or asymptomatic cases. However, in a number of other countries, the upsurge coincides with high or increasing notification rates in older individuals and, consequently, an increased proportion of hospitalised and severe cases. The observed increased transmission levels indicate that the non-pharmaceutical interventions in place have not achieved the intended effect, either because adherence to the measures is not optimal or because the measures are not sufficient to reduce or control exposure. In addition, the vulnerability of the population to infection remains high, as available data from seroprevalence studies suggest that the level of immunity in the population is <15% in most areas within the EU/EEA and the UK. The current epidemiological situation in many countries is concerning as it poses an increasing risk of infection for vulnerable individuals (individuals with risk factors for severe COVID-19 disease, such as the elderly) and healthcare workers, particularly in primary care, and calls for targeted public health action.

What is the risk being assessed in this update?

In this update, we analyse the risk posed to the general population, vulnerable individuals, and healthcare provision by the current increase in COVID-19 case notification rates observed in the EU/EEA and the UK. In countries observing stable and low notification rates, and low test positivity, the risk of COVID-19 for the general population and for healthcare provision is low, based on a low probability of infection and low impact of the disease. Regarding vulnerable individuals, the overall risk is moderate based on a low probability of infection and very high impact of the disease.

In countries observing high or sustained increase in notification rates, or high test positivity, but with high testing rates and transmission occurring primarily in young individuals, the risk of COVID-19 is moderate for the general population and for healthcare provision, based on a very high probability of infection and low impact of the disease. However, the risk of COVID-19 is very high for vulnerable individuals, based on a very high probability of infection and very high impact of the disease.
In countries observing high or sustained increase in notification rates, or high test positivity, and an increasing proportion of older cases, and/or high or increasing COVID-19 mortality, the risk of COVID-19 is high for the general population, based on a very high probability of infection and moderate impact of the disease.
However, the risk of COVID-19 is very high for vulnerable individuals, based on a very high probability of infection and very high impact of the disease.

Options for response

Preparing for a scenario of widespread transmission - Several countries appear to be now progressing from limited local community transmission towards sustained community transmission. This requires a strong response, focused on both containment and mitigation measures. Geographic areas that did not experience widespread transmission during the first wave may have a higher level of population susceptibility and be less prepared to address the increasing demand for healthcare. Therefore, public health efforts should focus on strengthening healthcare capacity to manage potentially high numbers of COVID-19 patients.
Key target populations - The current epidemiological situation calls for focused public health actions tailored at:
controlling transmission among older children and adults younger than 50 years of age
protecting medically vulnerable individuals
protecting healthcare workers, particularly those involved in providing primary care.
Non-pharmaceutical interventions (NPI) - Until a safe and effective vaccine against COVID-19 is available, NPIs will continue to serve as the main public health tool to control and manage SARS-CoV-2 outbreaks. However, several NPIs can have a negative impact on the general well-being of people, the functioning of society, and the economy. Therefore, their use should be guided by the local epidemiological situation, with the overall goal of reducing transmission and protecting the most vulnerable individuals in society.
Testing strategies – Testing strategies have evolved over the course of the epidemic and should now focus on more widespread testing in the community, prevention of nosocomial transmission, rapid identification and containment of outbreaks and identification of infectious cases to prevent further transmission. Easy access to testing and timeliness of testing is critical for the effectiveness of measures such as contact tracing and isolation of cases.
Contact tracing - Rapid identification, testing regardless of symptoms, and quarantine of high-risk contacts remains one of the most effective measures to reduce transmission. ECDC also recommends the testing of low-risk exposure contacts regardless of symptoms in high-risk settings (e.g. nursing homes), to enable early identification of secondary cases and initiate further contact tracing.
Quarantine - Fourteen day quarantine is recommended for persons who have had contact with confirmed SARS-CoV-2 cases. This can be shortened to 10 days after exposure, if a PCR test at day 10 is negative.
Maintaining strong messaging to promote compliance with key protective behaviours - Risk communication messages should emphasise that the pandemic is far from over, and that the SARS-CoV-2 virus continues to circulate within the community. The overarching messages proposed by ECDC earlier in the pandemic remain valid: ‘This is a marathon, not a sprint’; and ‘We must not drop our guard’. People’s behaviour continues to be the key to controlling the pandemic.
Risk communication for younger people - Reduced compliance by younger people to protective measures is of increasing concern. Communication campaigns specifically targeting young people should ideally be based on insights gained through behavioural research in order to ensure that the messages resonate with and are acceptable to the target population. It is essential that young people see themselves as part of the solution, and that they are actively engaged in strategies to control the pandemic as well as in the recovery effort.
Protecting mental health - While the fall in COVID-19 cases over the summer months and the accompanying lifting of some restrictive measures may have provided respite, the ongoing return to high incidence rates and the consequent potential for a re-imposition of restrictive measures in some countries is likely to lead to renewed stresses. The mental health of people who have had COVID-19 is another issue

of concern, with evidence indicating high rates of psychological ill health after physical symptoms have cleared.
https://www.ecdc.europa.eu/en/publications-data/covid-19-risk-assessment-increased-transmission-twelfth-update
https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-risk-assessment-increased-transmission-12th-update-september-2020.pdf

ECDC

Guidelines for the implementation of non-pharmaceutical interventions against COVID-19
Source: ECDC
ID: 1007904155

Technical report 24 Sep 2020

Non-pharmaceutical interventions (NPI) are public health measures that aim to prevent and/or control SARS-CoV-2 transmission in the community. As long as there is no effective and safe vaccine to protect those at risk of severe COVID-19, NPI are the most effective public health interventions against COVID-19. These ECDC guidelines detail available options for NPI in various epidemiologic scenarios, assess the evidence for their effectiveness and address implementation issues, including potential barriers and facilitators.

Executive summary

General considerations on NPI to control COVID-19

NPI have played a critical role in reducing transmission rates and the impact of COVID-19 in the European Union, European Economic Area (EU/EEA) and United Kingdom (UK). Until a safe and effective vaccine is available to all those at risk of severe COVID-19 disease, NPI will continue to be the main public health tool against SARS-CoV-2.
Most NPI can have a negative impact on the general well-being of people, the functioning of society, and the economy. Therefore, their use should be guided by data on the local epidemiological situation, with the overall goal of protecting the most vulnerable individuals in the society.
Specific recommendations to protect the most vulnerable include enhanced surveillance, comprehensive testing, and intensified infection prevention and control practices in settings that host high-risk individuals, such as long-term care facilities.
In countries/regions/municipalities/communities where sustained control of SARS-CoV-2 has been achieved, as documented by comprehensive surveillance, NPI can be relaxed, allowing society to function almost normally. Under the current exceptional circumstances, imposing travel restrictions on those coming from countries or areas that have not yet achieved transmission control will probably make a meaningful difference to the SARS-CoV-2 epidemiology within the population.
In countries/regions/municipalities/communities that experience community transmission, the authorities should ensure that personal NPI are understood and correctly applied by the population. This includes maintaining physical distance in all settings, hand hygiene and respiratory etiquette, and the wearing of face masks when physical distancing cannot be guaranteed. The use of face masks is recommended both indoors (e.g. supermarkets, shops and public transport) and in crowded outdoor settings. In addition, use of face masks should be strongly recommended for groups at risk of developing severe complications if infected (e.g. individuals in older age groups or with underlying conditions) and for those whose occupations bring them into extensive face-to-face contact with the public when there is ongoing transmission.
Decision-makers responsible for implementing population- and/or environmental-level NPI, either at local or national level, should consider the advice/evidence below when deciding on the combination of measures.

Considerations in the event of community transmission

During the SARS-CoV-2 community transmission phase, the following interventions may be considered, irrespective of incidence level.
Promoting and facilitating physical distancing in all settings is an effective NPI to reduce the levels of SARS-CoV-2 transmission in the community.

Advising the population to voluntarily self-isolate if experiencing COVID-19 compatible symptoms is an essential measure for reducing the number of secondary infections. This should be linked to easy access to testing and rapid contact tracing, testing of high-risk contacts irrespective of symptoms, and the quarantining of contacts.
Advising the population to consistently meet with the same people in 'social bubbles', whether friends or co-workers, can allow for a greater degree of contact between people, while still minimising the risk of SARS-CoV-2 transmission and associated outbreaks.
Limiting the size of indoor and outdoor gatherings decreases the likelihood of SARS-CoV-2 spreading to large numbers of people. Such a measure is more effective if implemented consistently, even for relatively small gatherings (e.g. >10 individuals). Additional organisational measures such as event cancellation, postponement or re-arrangement should be considered, depending on the underlying epidemiological situation.
Promoting teleworking where possible can reduce the risk of outbreaks in the workplace.
Closing selected businesses, such as places where people have limited possibility for physical distancing, could be more effective than closing all businesses, and therefore is a possible option for reducing transmission while avoiding large-scale economic and social impact.
Proactive school closure is not recommended as an effective COVID-19 containment strategy at this stage as there is currently little (and conflicting) evidence on the effect it has on SARS-CoV-2 transmission in the community. Firstly, children (18 years and younger) mostly experience a benign clinical course of COVID-19 and do not seem to have been the main vector of SARS-CoV-2 in the community. Secondly, because the impact of school closure on children's education, families' economies, and on society as a whole is significant and well-documented.
Environmental measures, such as regular cleaning of frequently-touched surfaces and appropriate ventilation of indoor spaces, can lower the risk of disease transmission in the community. Such measures are particularly relevant in healthcare settings to reduce nosocomial transmission and infection of healthcare workers.

Considerations in the event of widespread transmission

During widespread transmission of SARS-CoV-2, when hospitalisation rates, ICU admissions, and/or mortality is increasing, in addition to the NPI above, the following stricter measures can be considered.
Stay-at-home measures are a last-resort option due to their significant impact on both society and individuals. Targeted implementation, both geographically and temporally, is preferred and can be considered to control outbreaks which are not responding to other measures. Available evidence does not prove that stay-at-home measures are more effective than other measures, such as the closing of (some) high-risk businesses.
Population-wide testing strategies (testing all individuals, irrespective of symptoms) may be appropriate in local settings with high incidence. Such an approach would enable public health authorities to identify most of the infectious COVID-19 cases at a given point in time (e.g. including pre-symptomatic, pauci-symptomatic, and asymptomatic cases), allowing for their prompt isolation and the interruption of transmission chains. However, the effectiveness/cost-effectiveness of this approach remains unknown and should not compromise the accessibility or timeliness of testing for those who are symptomatic. Without timely analysis and notification to isolate cases, population-wide testing alone would not be effective in reducing transmission.
Reactive closures of schools may be necessary as a consequence of widespread virus transmission in the community and educational settings. Reactive school and day-care closures will probably not reduce the impact of the epidemic, but may be necessary due to high absenteeism and operational issues, especially if the spread of SARS-CoV-2 coincides with the ongoing influenza season in an EU/EEA country.

Addressing NPI compliance

Support for NPI has varied considerably across countries and in different population groups within the same country: what works to promote safe behaviour in one city, country, culture, or population may be ineffective or otherwise sub-optimal in another. Several EU/EEA countries have therefore been working to incorporate behavioural insights into their COVID-19 response work, using ongoing assessments of public attitudes, behaviour, and beliefs within their own populations. Innovative means have also been developed for collecting anonymised, aggregated data on people's movements, which can act as a proxy for compliance with measures (e.g. stay-at-home measures).

While there is no ‘one-size-fits-all’ approach to promoting NPI compliance, there are nonetheless some key principles that can be applied in all settings, as defined in various theories of behaviour change. The COM-B model is one such theory, based on the common-sense idea that a given behaviour occurs when both the capability and opportunity are present, and when the individual concerned is more motivated to adopt that behaviour than any other. Systematically applying such models can optimise the effectiveness of strategies promoting NPI.
https://www.ecdc.europa.eu/en/publications-data/covid-19-guidelines-non-pharmaceutical-interventions
https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-guidelines-non-pharmaceutical-interventions-september-2020.pdf

International - Coronavirus disease (COVID-19) Outbreak and Outcomes (Media)

United States
Bioethicists condemn DIY COVID-19 vaccine efforts
Source: ABC News
Unique ID: 1007905219

Across the country, a small handful of scientists are brewing up their own homemade and unproven COVID-19 vaccines and giving them to friends, family and themselves. These scientists hail from disparate groups. Some are shadowy and anonymous, while others are highly organized and Ivy-league affiliated.

"It's actually simpler than most recipes in home cookbooks," said Preston Estep, chief scientist and co-founder of a DIY effort backed by a Harvard geneticist. Estep said he hopes that his group's unapproved vaccine, which is inhaled through a nasal spray, might give people sheltering at home more confidence and protection.

"In my view, it is unethical to tell people to wait two years for something that's available today," said another DIY proponent, entrepreneur and microbiologist Johnny Stine, in an email to ABC News. Still, another group says it won't name its handful of members for fear of Food and Drug Administration retribution.

These DIY groups are united in their belief that traditional vaccine development is too long and cumbersome, and society could have access to a potential vaccine now.

Six months into the COVID-19 pandemic, there are at least three vaccines from major pharmaceutical companies in late-stage trials, but we are still months away from having a vaccine widely available.

But there's one problem: none of these DIY enthusiasts know for sure if their vaccine actually protects people from COVID-19, or whether it's safe. And without carefully controlled experiments, they'll never find out.

"I'm not opposed to speed," Arthur Caplan, Ph.D., founding director of the division of medical ethics at New York University Langone Medical Center said. But the DIY vaccine effort, Caplan said, is "reckless, driving drunk."

Now, Caplan is among a growing chorus of bioethicists condemning the DIY vaccine movement.

"A DIY vaccine is a bad idea," said Dr. Ruth Faden, founder of the Johns Hopkins Berman Institute for Bioethics. "Unless -- and this is the big unless -- [it] was connected with some mechanism for moving this into the regular order."

The DIY nature of these experiments means no one is formally keeping track of what happens to people who take these vaccines -- whether they get sick, or if they're protected from coronavirus infection, explained Jennifer Miller, Ph.D., an assistant professor at Yale School of Medicine and founder of Bioethics International and the Good Pharma Scorecard.

That means we're gleaning little meaningful knowledge about whether the vaccines work, Miller said.

"One of the main reasons why it's OK to medically experiment on humans is the potential to create generalizable knowledge and advance the common good," Miller said. But with DIY vaccines, there's no standard ethics review board -- a 21st century safeguard for human experimentation.

"Research on humans is never OK without an ethics review," said Miller. "People tend to think that ethics codes and regulations are for barbarians ... [but] those codes are for everybody. Even if you are a Nobel prize winner, you are not above the ethics codes."

The most recent critique, published Thursday in the journal Science, said these efforts are not only unethical, but if unproven vaccines are sold to consumers they also could also be illegal.

"Taking information that you found in some dark corner of the internet but using it to develop your own materials and needing to ship materials or reagents across state lines -- that is interstate commerce and is what triggers FDA oversight," lead author Jacob Sherkow, law professor at Illinois College of Law, said in a statement. "At that point, that's essentially where the FDA can stop you."

But the proponents of DIY vaccines argue that there's an ethical obligation to release a vaccine that can be used immediately even if unproven for efficacy and safety, rather than waiting for the traditional review process that includes a series of FDA-mandated safety and effectiveness studies that can take years to complete.

"I don't have the millions it takes to even get to the FDA [doorstep] nor would I have the patience to wait two years for a vaccine to a virus that was killing people today," said Stine, who made headlines in May when he was hit with an FDA warning letter for selling his DIY vaccine.

In June, the Washington attorney general filed a lawsuit against Stine, which he later settled without admitting wrongdoing, but he agreed to repay upon request any of the 30 people he had vaccinated.
https://abcnews.go.com/Health/bioethicists-condemn-diy-covid-19-vaccine-efforts/story?id=72862726

United States
Coronavirus (COVID-19) Update: Daily Roundup September 24, 2020
Source: FDA
The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA re-issued an emergency use authorization (EUA) for the Assure COVID-19 IgG/IgM Rapid Test Device, making it the first authorized serology (antibody) test that can be used at the point of care (POC), meaning it is authorized for use in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- The FDA added one new device to the Device Discontinuance List on the Medical Device Shortages During the COVID-19 Public Health Emergency web page. There are no updates to the Device Shortage List. Since the web page was first published, the FDA also updated the web page to clarify how we determine what devices are in shortage, as well as how the analysis informs other measures the FDA uses to help address the public health emergency, including issuing Emergency Use Authorizations (EUAs) and providing enforcement discretion for products that play an important role in meeting demand, as well as working with other federal partners. The FDA will continue to update the lists as the COVID-19 public health emergency evolves.
- FDA developed new health education materials that have been culturally and linguistically tailored for diverse consumers. These materials are intended for health care professionals to share with their patients to help stimulate dialogue and answer pressing questions about FDA’s response to COVID-19. The materials provide information on the

different areas of the FDA's response to the pandemic, including health fraud, medical product supply, therapeutics, vaccine development, and diagnostic and antibody testing.

- Testing updates:
    - As of today, 254 tests are authorized by FDA under EUAs; these include 203 molecular tests, 47 antibody tests, and 4 antigen tests.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-september-24-2020

Japan

8,000 jumbo jets will be required to deliver single COVID-19 vaccine doses to 7.8 billion people

Source: Japan Today
Unique ID: 1007905399

IATA has urged governments to begin careful planning with industry stakeholders to ensure full preparedness when vaccines for COVID-19 are approved and available for distribution. The association also warned of potentially severe capacity constraints in transporting vaccines by air.

Air cargo plays a key role in the distribution of vaccines in normal times through well-established global time-and temperature-sensitive distribution systems. This capability will be crucial to the quick and efficient transport and distribution of COVID-19 vaccines when they are available, and it will not happen without careful planning, led by governments and supported by industry stakeholders.

"Safely delivering COVID-19 vaccines will be the mission of the century for the global air cargo industry. But it won't happen without careful advance planning. And the time for that is now. We urge governments to take the lead in facilitating cooperation across the logistics chain so that the facilities, security arrangements and border processes are ready for the mammoth and complex task ahead," said IATA's Director General and CEO, Alexandre de Juniac.

Facilities

Vaccines must be handled and transported in line with international regulatory requirements, at controlled temperatures and without delay to ensure the quality of the product. While there are still many unknowns (number of doses, temperature sensitivities, manufacturing locations, etc.), it is clear that the scale of activity will be vast, that cold chain facilities will be required and that delivery to every corner of the planet will be needed. Priorities for preparing facilities for this distribution include:

Availability of temperature-controlled facilities and equipment - maximizing the use or re-purposing of existing infrastructure and minimizing temporary builds;

Availability of staff trained to handle time- and temperature-sensitive vaccines; and

Robust monitoring capabilities to ensure the integrity of the vaccines is maintained.

Security

Vaccines will be highly valuable commodities. Arrangements must be in place to keep ensure that shipments remain secure from tampering and theft. Processes are in place to keep cargo shipments secure, but the potential volume of vaccine shipments will need early planning to ensure that they are scalable.

Border Processes

Working effectively with health and customs authorities will, therefore, be essential to ensure timely regulatory approvals, adequate security measures, appropriate handling and customs clearance. This could be a particular challenge given that, as part of COVID19 prevention measures, many governments have put in place measures that increase processing times. Priorities for border processes include:

Introducing fast-track procedures for overflight and landing permits for operations carrying the COVID19 vaccine;

Exempting flight crew members from quarantine requirements to ensure cargo supply chains are maintained;

Supporting temporary traffic rights for operations carrying the COVID19 vaccines where restrictions may apply;

Removing operating hour curfews for flights carrying the vaccine to facilitate the most flexible global network operations;

Granting priority on arrival of those vital shipments to prevent possible temperature excursions due to delays; and

Considering tariff relief to facilitate the movement of the vaccine.

On top of the transport preparations and coordination needed, governments must also consider the current diminished cargo capacity of the global air transport industry. IATA warns that, with the severe downturn in passenger traffic, airlines have downsized networks and put many aircraft into remote long-term storage. The global route network has been reduced dramatically from the pre-COVID 24,000 city pairs. The WHO, UNICEF and Gavi have already reported severe difficulties in maintaining their planned vaccine programs during the COVID19 crisis due, in part, to limited air connectivity.
“The whole world is eagerly awaiting a safe COVID vaccine. It is incumbent on all of us to make sure that all countries have safe, fast and equitable access to the initial doses when they are available. As the lead agency for the procurement and supply of the COVID vaccine on behalf of the COVAX Facility, UNICEF will be leading what could possibly be the world’s largest and fastest operation ever. The role of airlines and international transport companies will be critical to this endeavour,” said Henrietta Fore, UNICEF Executive Director.
The potential size of the delivery is enormous. Just providing a single dose to 7.8 billion people would fill 8,000 747 cargo aircraft. Land transport will help, especially in developed economies with local manufacturing capacity. But vaccines cannot be delivered globally without the significant use air cargo.
“Even if we assume that half the needed vaccines can be transported by land, the air cargo industry will still face its largest single transport challenge ever. In planning their vaccine programs, particularly in the developing world, governments must take very careful consideration of the limited air cargo capacity that is available at the moment. If borders remain closed, travel curtailed, fleets grounded and employees furloughed, the capacity to deliver life-saving vaccines will be very much compromised,” said de Juniac.

https://japantoday.com/category/features/health/8-000-jumbo-jets-will-be-required-to-deliver-single-covid-19-vaccine-doses-to-7.8-billion-people

COVID-19 Vaccine Candidate Launches Phase1/2 Trial for Adolescents, Children
Source: www.contagionlive.com
Unique ID: 1007905280

In recent weeks, the vaccine conversation has transitioned to the readiness of COVID-19 vaccines for children and adolescents. One of the Chinese companies who is developing a vaccine has made a step towards this goal.
Sinovac announced yesterday it had been approved to begin a phase1/2 Trial for adolescents and children for its CoronaVac vaccine. This investigational vaccine is already in phase 1/I2 clinical trial for adults.
Back on September 10, the company reported positive data from that trial. The vaccine showed it was safe and showed an immune response. The vaccine was well tolerated across low, medium, and high dosages and there were no reports of any serious adverse events.
This new trial is a randomized, double-blinded, and placebo-controlled trial among adolescents and children between the ages of 3-17 years old was approved by the Ethics Committee of the Hebei Provincial CDC
In this trial, there will be an administration of a low dosage (300SU/dose) and medium dosage (600SU/dose) vaccines, with a 2-dose immunization scheduled at 28-day intervals.
CoronVac is an inactivated COVID-19 vaccine candidate.
Sinovac has accelerated its vaccine development against the rapid spread of the coronavirus, so as to maximize the safety and health of citizens in China and other select countries around the world. And in recent weeks, the company and countries it is working with have moved swiftly with developments.
Back in the summer, a phase 3 trial was announced in Brazil in conjunction with Instituto Butantan. There were plans to enroll 9000 patients in the health care industry for that study.
On August 11, it was reported a phase 3 trial was being launched in Indonesia. They also reported that in a phase 2 study the vaccine appeared to be safe and induced detectable antibody-based immune responses.
On August 31, according to Reuters the company received emergency use approval for its vaccine under a program in China to vaccinate high-risk groups.
Earlier this month, it was reported by Reuters that Sinovac had vaccinated 90% of its employees and their family members under the country's emergency use program.
To stay informed on the latest in infectious disease news and developments, please sign up for our weekly newsletter.

https://www.contagionlive.com/news/covid19-vaccine-candidate-launches-phase12-trial-for-adolescents-children

France

Sanofi CEO: We'll produce over 1B doses of vaccines worldwide for COVID-19
Source: Theflyonthewall.com
ID: 1007908452

In an interview on CNBC's Mad Money, Paul Hudson said he expects a COVID-19 vaccine to be ready by early next year. It won't be in Phase 3 until November or December, he noted. "We're the only company with two COVID-19 vaccines," Hudson said. The company is increasing its flu vaccine by 15%. According to Hudson, Sanofi's (SNY) partnership with Regeneron (REGN) is "high quality." "We are a completely purpose- driven company," he said. "This isn't a race we need to win - everyone needs to play a part."

China

China's COVID-19 vaccine shows 'no side effects' in Russian trials
Source: ecns
Unique ID: 1007903772

Special: Battle Against Novel Coronavirus
China's candidate coronavirus vaccine caused no side effects among recruits in Moscow as part of large-scale clinical trials, reported Russian English-language newspaper The Moscow Times.
Russia approved Phase 3 trials of the Chinese vaccine developed by CanSino Biologics, a Chinese high-tech biopharmaceutical company, and a research team with the Academy of Military Sciences last month.
"At the moment, the volunteers are doing well. None of them have shown any side effects," Petrovax, the Russian pharmaceutical company working with the vaccine's Chinese developers, announced Monday in a press release.
Petrovax said it has received more than 3,000 applications to get the Ad5-nCoV vaccine so far.
The study's participants will be under direct supervision for nearly a month, with four interim face-to-face examinations, and will undergo a control examination after six months, Petrovax said.
The Russian company said it expects preliminary results sometime in November, according to the Interfax news agency.
Once Russia registers the Chinese vaccine, Petrovax said it will be able to produce more than 4 million doses per month this year and 10 million doses per month in 2021.
China is actively conducting international cooperation on the development of drugs and vaccines against COVID-19.
CanSino announced plans last month to launch Phase 3 trials of the vaccine in Saudi Arabia involving about 5,000 subjects.
http://www.ecns.cn/news/2020-09-24/detail-ihaakvpz4254517.shtml

Switzerland

2,500 Swiss students quarantined for coronavirus after off-campus partying
Source: Global News
Unique ID: 1007906539

Swiss health authorities have ordered a quarantine for a staggering 2,500 students at a prestigious hospitality management school in the city of Lausanne after “significant outbreaks” of the coronavirus that are a suspected byproduct of off-campus partying.
Authorities in Switzerland’s Vaud canton, or region, said all undergraduates at the Ecole Hoteliere de Lausanne, known as the Lausanne Hospitality Management University in English, have been ordered to quarantine both on- and off-campus because the number of COVID-19 outbreaks because targeted closures were not possible.
The World Health Organization, national health authorities and others have cautioned that young people, who tend to have milder COVID-19 symptoms than older demographic groups, have been a key driver for the continued spread of the coronavirus in recent weeks, particularly in Europe.

“Significant outbreaks of infection have appeared at several levels of training, making a more targeted closure impossible that that involving the 2,500 students affected,” the Vaud regional office said in a statement. “Until Sept. 28, the students must stay home. For some, that means not leaving their housing on the hospitality school site.”
It noted that an early investigation showed that “one or more parties was at the origin of these many outbreaks of infection,” and reiterated authorities previous call for a ”responsible attitude” among party-goers such as by wearing masks, tracing their contacts, keeping alert for symptoms, and “social distancing.”
School administrators were taking “all necessary measures” to ensure that classes were continuing online, the statement said.
University spokesman Sherif Mamdouh said Thursday that the situation was “not ideal” but that the university took precautions in recent months. He said that 11 students had tested positive for the coronavirus and none required hospitalization.
Mamdouh said the quarantine affects 2,500 undergraduates. The university has a total student body of about 3,500, including people pursuing advanced degrees. He said hundreds of students living in on-campus dormitories on campus will be subject to the quarantine.
Switzerland is not alone. The latest government figures in neighboring France show that 22 per cent of the country’s currently active virus clusters emerged at schools are universities. The United States has also seen clusters linked to college students.
World Health Organization spokeswoman Margaret Harris said that while it is “unfair to just put it on the young people,” it’s also unsurprising that teenagers and young adults might assume they don’t need to worry about succumbing to the virus.
“Perceptions do indicate that they don’t feel they are as at-risk as older groups” Harris said, particularly in the wake of data showing younger people typically have less-severe cases of COVID-19.
“The message they have heard is: ‘You are out of jail, go out and play,’” she said. “We don’t want to be the fun police, but we want people to have fun safely.”
https://globalnews.ca/news/7355249/2500-students-quarantined-coronavirus-swiss-school/

China

Chinese company says coronavirus vaccine ready by early 2021
Source: tribuneindia.com
ID: 1007907774

A Chinese pharmaceutical company on Thursday said the coronavirus vaccine it is developing should be ready by early 2021 for distribution worldwide, including the United States.

Yin Weidong, the CEO of SinoVac, vowed to apply to the US Food and Drug Administration to sell CoronaVac in the United States if it passes its third and final round of testing in humans. Yin said he personally has been given the experimental vaccine.

“At the very beginning, our strategy was designed for China and for Wuhan. Soon after that in June and July we adjusted our strategy, that is to face the world,” Yin said, referring to the Chinese city were the virus first emerged.

“Our goal is to provide the vaccine to the world, including the US, EU and others,” Yin said.

Stringent regulations in the US, European Union, Japan and Australia have historically blocked the sale of Chinese vaccines. But Yin said that could change.

SinoVac is developing one of China’s top four vaccine candidates along with state-owned SinoPharm, which has two in development, and military-affiliated private firm CanSino.

More than 24,000 people are currently participating in clinical trials of CoronaVac in Brazil, Turkey, and Indonesia, with additional trials scheduled for Bangladesh and possibly Chile, Yin said.

SinoVac chose those countries because they all had serious outbreaks, large populations and limited research and development capacity, he said.

[APG]

He spoke to reporters during a tour of a SinoVac plant south of Beijing. Built in a few months from scratch, the plant is designed to enable SinoVac to produce half a million vaccine doses a year. The bio-secure facility was already busy on Thursday filling tiny bottles with the vaccine and boxing them.

The company projects it will be able to produce a few hundred million doses of the vaccine by February or March of next year.

SinoVac is also starting to test small doses of CoronaVac on children in the three countries because of the high rate of infection among young people there.

Yin said the company would prioritize distribution of the vaccine to countries hosting human trials of CoronaVac.

While the vaccine has not yet passed the phase 3 clinical trials, a globally accepted standard, SinoVac has already injected thousands of people in China under an emergency use provision.

Yin said he was one of the first to receive the experimental vaccine months ago along with researchers after phase one and two of human trials showed no serious adverse effects. He said that self-injecting showed his support for CoronaVac.

“This is kind of a tradition of our company,” Yin said, adding that he had done the same with a hepatitis vaccine under development.

Earlier this year, China permitted “emergency use” of vaccine candidates for at-risk populations like border personnel and medical workers if companies could show “good safety and good antibodies” from tests of about 1,000 people, Yin said.

SinoVac received that approval in June along with SinoPharm and CanSino, and was able to provide tens of thousands of doses of CoronaVac to Beijing’s municipal government, Yin said.

SinoVac employees qualified for emergency use of the vaccine because an outbreak inside the company would cripple its ability to develop a vaccine, he said.

About 90% of the company’s staff have received it.

“We are confident that our research of the COVID-19 vaccines can meet the standards of the US and EU countries,” Yin said. — AP
https://www.tribuneindia.com/news/world/chinese-company-says-coronavirus-vaccine-ready-by-early-2021-145976

United Nation
UN implores nations to find ways to bring 300,000 stranded mariners home
Source: nydailynews.com
ID: 1007908607

The United Nations chief on Thursday implored countries to cooperate in repatriating 300,000 stranded mariners who have been stuck at sea throughout the pandemic, some of whom have not been home in a year or more.

Working back-to-back 12-hour shifts, often without weekends, the merchant mariners are buckling under the strain — which could have a disastrous effect on the global supply chain, UN Secretary-General Antonio Guterres said Thursday.

Meanwhile, on land, the lack of ability to get onto the ships has stranded an equal number of mariners who would like to report for duty, Guterres said.

“I remain very concerned about the growing humanitarian and safety crisis facing hundreds of thousands of these indispensable workers,” Guterres said in a statement, speaking of the 2 million people who transport 80% of the world’s goods. “Despite the unprecedented conditions brought about by the pandemic, seafarers have continued to tirelessly support the often-invisible global logistics chain. Physically and mentally exhausted, away from their families and loved ones, their time at sea has now been extended far beyond the standards stipulated in international conventions, with some tours of duty now stretching more than 17 months. Fatigued seafarers cannot operate indefinitely, and disruptions to international shipping would have devastating consequences.”

The stranded mariners are caught in the middle.

“When the pandemic broke out, life onboard became difficult almost immediately,” said Captain Hedi Marzougui, at the meeting between shipping executives and government officials this week, a side event to the U.N. General Assembly.

He recounted how crew changes, shore leave and medical leaves “were suspended or became very difficult to perform” and urged those in attendance to picture “if you had worked every day for 12 hours with no weekend without seeing your loved ones,” he said. “Now add that you have to do that with no idea when you will be repatriated.”

Previous accounts have detailed harrowing scenarios of captains pulling teeth, and looming collective mental health crises.

France proposed compiling a global UN list of ports that can be secured to accommodate crew changes, the Associated Press reported. Kenya called for sharing costs globally for a rapid testing plan for major ports.

Guterres noted that there are plenty of options, and implored the international community to work together. Designating marine personnel as essential workers, and implementing protocols developed by UN agencies along with the International Chamber of Shipping and the International Transport Workers' Federation would allow “stranded seafarers to be repatriated and others to join ships,” Guterres said.

Keeping them healthy and functioning is vital, business leaders said in a letter to Guterres signed by members of the Consumer Goods Forum, a coalition of leaders from 400 retailers, manufacturers and service providers.

“Seafarers are essential workers that keep global supply chains functioning,” said Unilever’s Chief Supply Chain Officer, Marc Engel, in a statement from Global Compact, the UN consortium of business leaders seeking sustainable commerce. “Without them, there are no masks, no COVID tests, no hand sanitizers, or other essential goods. There is no food, there is no medicine. These supply chains are on the verge of serious disruption.”

Echoing the humanitarian concerns of Guterres, the Consumer Goods Forum warned, “The situation has also inadvertently created a modern form of forced labor.”
https://www.nydailynews.com/coronavirus/ny-coronavirus-united-nations-300000-stranded-mariners-bring-home-20200925-waw4uzlkbjekbg5jvwhwl7q5h4-story.html

China

Two cases of asymptomatic infection were found in Qingdao, who had loaded and unloaded imported frozen seafood
Source: flutrackers.com
ID: 1007908656

At 23:57 on the 24th, the Qingdao Health and Health Commission notified that during the regular routine inspections of the employees of Qingdao Port Dagang Company, it was discovered that two loading and unloading workers were infected with the new crown virus and were asymptomatic. The two patients were workers in the same class. They unloaded imported frozen seafood during the night shift on September 19, and the nucleic acid test was positive 5 days later.

At present, 132 close contacts have been investigated and 129 people have been tested, all of which are negative. All products involved in the epidemic have been sealed, and some positive samples have been detected.

Two patients are workers in the same class
Loading and unloading imported frozen seafood tested positive after 5 days
According to reports, the 2 cases of asymptomatic infections were both middle-aged males. They were stevedores of Qingdao Port Dagang Company and had a history of common exposure. The two men loaded and unloaded frozen seafood imported from abroad on the night shift on the 19th, and the nucleic acid test result was positive on the 24th.
Among them, the patient Dong XX lives with his wife (working in Qingdao Fourth Middle School canteen) and son (schooling in Shanghai Zhilu Primary School). He and his family have been to supermarkets, morning markets, vegetable markets and other public places. At present, his wife and The son's nucleic acid test results are all negative; the patient Chen Moumou has two colleagues living in the same room, and the current nucleic acid test result is negative.

Newly added asymptomatic infection Dong XX
Male, 40 years old, living at No. 13 Tieshan Road, Shibei District, is a loading and unloading worker of Qingdao Port Dagang Company, and is a person included in the regular inspection of the city's "all inspections required". On September 8, Dong’s routine nucleic acid test was negative; on September 19, Dong’s night shift loaded and unloaded frozen seafood imported from abroad; on September 24, the testing agency reported that Dong’s nucleic acid test was positive and reported to Qingdao Municipal Diseases The control center's nucleic acid retest was positive. At present, Dong Moumou consciously has no symptoms. The expert team determined that he was asymptomatic and has been transferred to a designated hospital for isolation, observation and treatment.

Dong Moumou walks to and from get off work on weekdays and lives with his wife (working in the canteen of Qingdao No. 4 Middle School) and son (schooling in Shanghai Zhilu Primary School). Both his wife and son have negative nucleic acid test results. At present, we are organizing an orderly study on the residential area of Dong Moumou, No. 13 Tieshan Road, Shibei District, Dagang Port District where he works, the frozen fish storage area in Licang District, Qingdao No. 4 Middle School where his wife works, and Shanghai where his son is studying. The branch road elementary school, as well as the relevant personnel in the activity areas of Liaoning Lu Jiajiayue Supermarket, Jilin Road Morning Market, Leling Road Youke Supermarket, Xiaobaodao Vegetable Market, etc., where Dong Moumou and his family have visited, carried out full nucleic acid tests. And kill the environment.
New asymptomatic infection Chen XX

Male, 45 years old, living in the single dormitory of Dagang Company, Dagang Road, Dagang Road, Shibei District. He commutes to work by bicycle on weekdays. He is a stevedore in the same class with Dong Moumou. He has a history of common exposure. On September 8, Chen’s routine nucleic acid test was negative; on September 19, Chen’s night shift loaded and unloaded frozen seafood imported from abroad; on September 24, the Qingdao Center for Disease Control and Prevention had a positive nucleic acid test, and Chen consciously did not have any Symptoms, the expert group determined as asymptomatic infection, has been transferred to designated hospitals for isolation observation and treatment.

Chen XX had two colleagues living in the same room, and the test result was negative. Other close contacts are being investigated and tracked overnight, and the circulation and testing results will be announced in time.
132 close contacts and 228 close contacts have all been quarantined and observed.

[APG]

The notification stated that as of now:
132 close contacts have been investigated and all have been quarantined;
129 people have been tested and all the test results are negative;
228 close contacts of close contacts have all collected samples and sent them to the laboratory for testing, and have all implemented centralized isolation and observation;
There were 4341 people in general contacts and community investigations. 3497 samples have been collected and 1,502 results have been obtained, all of which are negative.
All products involved in the epidemic have been sealed
Some positive samples have been detected
The notification mentioned that the batch of imported products involved in the epidemic has not yet entered the market and has been sealed up. A total of 1,440 samples involving cold chain products and the environment have been collected and submitted for inspection, and some positive samples have been detected.
https://www.sohu.com/a/420714648_362042
https://flutrackers.com/forum/forum/china-other-health-threats/china-covid-19-sept-13-2020-may-31-2021/894083-china-more-imported-frozen-seafood-samples-test-positive-for-covid-19-coronavirus-2-human-cases-confirmed-asymptomatic-4-341-contacts-being-investigated-qingdao-shandong-province-september-24-2020

Finland

Dogs used to detect coronavirus in pilot project at Helsinki airport | World | News |
Source: The Chronicle Herald
Unique ID: 1007903735

HELSINKI (Reuters) - Dogs trained to detect the novel coronavirus began sniffing passenger samples at Finland's Helsinki-Vantaa airport this week, authorities said, in a pilot project running alongside more usual testing at the airport.
The dogs' efficiency has not been proven in comparative scientific studies so passengers who volunteer to be tested and are suspected as carrying the virus are instructed to also take a swab to confirm the result.
A team of 15 dogs and 10 instructors are being trained for the job in Finland by volunteers, sponsored by a private veterinary clinic. Among them is Kossi, a rescue dog from Spain, who was trained as a sniffer dog in Finland and who has worked before detecting cancers.
"What we've seen in our research is that the dogs will find (the disease) five days before they (patients) get any clinical symptoms," Anna Hielm-Bjorkman, who is Adjunct Professor at the University of Helsinki and spesialised in clinical research for companion animals, told Reuters.
"They are very good (at it). We come close to 100-percent sensitivity," she said, referring to the dogs's ability to detect cases of the virus.
In the canine test, a passenger swipes their neck with a gauze, places it in a can which is then handed over to another room for a dog to sniff and to deliver an immediate result.
A few months ago, authorities in the United Arab Emirates embarked on similar canine testing at Dubai International Airport using police dogs.
"In the future, it's also possible... that these dogs go around passengers in a similar way to customs dogs," Vantaa deputy mayor Timo Aronkyto, said.
(Reporting by Anne Kauranen and Attila Cser; Editing by Alexandra Hudson)
https://www.thechronicleherald.ca/news/world/dogs-used-to-detect-coronavirus-in-pilot-project-at-helsinki-airport-501214/

Iraq

COVID-19 outbreak in Baghdad is “very alarming”
Source: reliefweb.int
ID: 1007907722

The COVID-19 pandemic has become very alarming in Iraq, with the country currently reporting close to 4,000 new cases every day and around 500 deaths a week.

Over the past month alone, more than 100,000 cases have been identified in the country. And on 23 September, 5,055 new COVID-19 cases were confirmed, representing the highest daily rate in the country since the beginning of the pandemic. The Iraqi capital Baghdad is the worst-hit city, with almost 30 per cent of the country's reported cases .

To respond to the escalating emergency and support local health authorities, Médecins Sans Frontières (MSF) has started working in Al-Kindy hospital in Baghdad. The hospital is receiving large numbers of severe and critical COVID-19 patients.

During the past two months, our teams have been helping in the respiratory care unit (RCU), providing bedside training for staff, including ventilation use, drug use, and techniques adapted for the treatment of COVID-19. Given the high number of patients, we plan to expand our services in Baghdad by opening a new COVID-19 ward in Al-Kindy hospital.

Despite efforts to tackle the virus, the growing number of severe and critical cases has recently overwhelmed Al-Kindy and other health facilities treating people with COVID-19. The RCU in Al-Kindy hospital has 52 beds, all of which are currently full.

"Every moment of every day we're seeing more and more severe COVID-19 cases in Baghdad," explains Dr Pedro Serrano Guajardo, a doctor working with MSF as an intensive care unit specialist.

"Many patients stay in the RCU for 15 to 20 days to be treated, meaning that sometimes new patients are put on the waiting list for two, maybe three days, until they can get the treatment they need. By the time we have a free bed, patients are in really bad shape. It is really distressing to watch these people wait for a bed."

The waiting lists and lack of bed capacity are not the only issues in Baghdad.

"Some people in the city do not appreciate the gravity of the situation, and they are not taking prevention measures," says Dr Guajardo. "They are also waiting to come to the hospital when it's almost too late to seek treatment. We receive cases in acute respiratory distress, and it is very hard to treat them when they reach that point."

These people seem to be avoiding treatment due to the heavy social stigma associated with COVID-19 in the community.

"I think many people sometimes only realise how bad the situation is when they or a loved one is brought to the hospital. They see patients dying, very quickly, every day. Then they realise the reality [of the situation]."

Iraqi health workers have also been very badly affected, with almost 15,000 cases since the start of the outbreak. This comes on top of existing shortages of human resources in several hospitals in Baghdad, further complicating an already critical situation.

"We're trying to do our best to support the efforts of Iraqi health authorities in tackling the virus in Baghdad, even though our capacity is limited," says Gwenola Francois, MSF's head of mission in Iraq.

"Even with the high number of patients we see at the moment, we are not sure where we are on the curve of the epidemic. From what we can see the situation is deeply worrying. We're currently preparing additional means of support with the health authorities to alleviate the suffering of people in Baghdad."

"The most stressful thing is to see a patient dying and know that I don't have an available ventilator for them," says Dr Guajardo. "When you can see them fade away minute by minute, it is frustrating because I know that if people were taking measures to protect themselves – like wearing a mask when they go out and washing their hands, or coming to hospital earlier rather than later – then the situation could improve."

[APG]

https://reliefweb.int/report/iraq/covid-19-outbreak-baghdad-very-alarming

Russia

Cheaper Than Remdesivir: Russia to Supply Anti-COVID Avifavir to 17 Countries
Source: sputniknews.com
ID: 1007907781

In late May, Russia registered the world's first anti-COVID-19 drug, based on favipiravir, an antiviral medication. The medicine has been extensively used in Russian clinics to treat coronavirus disease since June, and has since been obtained by hospitals in Belarus, Kazakhstan, Bolivia and a number of other countries.

The Russian Direct Investment Fund (RDIF), the investor which funded the development of the world's first vaccine against coronavirus, and Moscow-based ChemRar Group have agreed to supply the anti-COVID drug Avifavir to 17 countries.

Avifavir, the world's first favipiravir-based drug to be approved for the treatment of COVID-19, will now be delivered to Saudi Arabia, Brazil, Bulgaria, Serbia, Argentina, Chile, Colombia, Ecuador, El Salvador, Honduras, Kuwait, Panama, Paraguay, Slovakia, South Africa, the UAE and Uruguay.

After being first registered in Russia on 29 May 2020, it has already been used for COVID-19 treatment in more than 70 Russian regions and subsequently purchased by Belarus, Bolivia, Kazakhstan, Kyrgyzstan, Turkmenistan and Uzbekistan. The efficacy of favipiravir against COVID-19 has been confirmed by Japan's Fujifilm Holdings Corp, several months after Avifavir trials in Russia.

Avifavir as the Leading Anti-Covid Drug in the Russian Market
RDIF notes that in comparison to other Russian manufacturers of favipiravir, Avifavir has proven to be more effective when treating more than 400 patients, who fell ill with the coronavirus disease since April. The drug has now been approved by European, Middle Eastern and Asian regulators, becoming Russia's number one anti-coronavirus medication for export.

According to RDIF, it is also a much cheaper option in comparison to Remdesivir, a favipiravir-based drug produced in the United States.

"When we registered the first anti-coronavirus drug in the world based on favipiravir, there was a lot of scepticism as people were wondering how we could register it when Japan had not registered it yet," says Kirill Dmitriev, CEO of the Russian Direct Investment Fund. "Now five months after our clinical trials, we see that Japan has confirmed the clinical efficacy of favipiravir."

Russia-based Avifavir drug is being delivered to Russian regions
© SPUTNIK / THE RUSSIAN DIRECT INVESTMENT FUND (RDIF)
Russia-based Avifavir drug is being delivered to Russian regions
The RDIF CEO stresses that apart from clinical trials which were conducted at 35 medical centres in Russia, Avifavir's efficiency has also been tested by 940 patients in observational post-registration studies, which made it "the largest clinical trial of a favipiravir-based drug against coronavirus in the world".

"Based on our extensive clinical trials and the research in Japan confirming favipiravir's efficacy against coronavirus we believe that Avifavir and other favipiravir-based products will be the leading antiviral medicines against COVID-19 in the world," Dmitriev adds. "In addition to proven efficacy and safety Avifavir is also three to four times cheaper than Remdesivir."
Trials Confirm Avifavir's Efficiency
According to the results of post-registration clinical trials, those patients taking Avifavir recovered more quickly from COVID-19 symptoms, as in 30% of cases the virus was eliminated at an early stage, while the level of oxygen saturation in the patient's blood was also restored to normal two times more quickly than when traditional therapy was applied. No adverse effects from the drug's use have been reported.

[APG]

Meanwhile, the third phase of clinical trials of the Japanese favipiravir-based drug Avigan also showed a shorter time of recovery among patients with non-severe pneumonia, according to the results published on 23 September.

RDIF, Russia's sovereign wealth fund, has also been involved in the development of the world's first anti-coronavirus vaccine, dubbed Sputnik V, which was registered in Russia on 11 August. The country has now received a request for 1 billion doses of the vaccine from at least 20 countries, including the UAE, Saudi Arabia, Indonesia, Philippines, Mexico, Brazil and India.
https://sputniknews.com/russia/202009241080559270-cheaper-than-remdesivir-russia-to-supply-anti-covid-avifavir-to-17-countries/

Sweden
Signs COVID cases rising in Sweden again 'worrying' says PM Lofven
Source: TheChronicleHerald.ca
ID: 1007907993

STOCKHOLM (Reuters) - Some areas of Sweden are seeing a worrying resurgence of coronavirus infections because many people seem to have set aside months of caution in favour of full-on social life once again, its prime minister said on Thursday.
Unlike most countries, Sweden eschewed a mandatory national lockdown against the pandemic, instead calling for personal responsibility, social distancing and good hygiene to slow rather than eradicate a disease seen as here to stay.
Though still with a COVID-19 caseload much lower than in many other European countries, Sweden has recorded a gradual rise in new infections in recent weeks. On Thursday 533 new ones were reported, the highest daily number since early July.
Prime Minister Stefan Lofven said Swedes had recently become too relaxed about heeding anti-COVID guidelines.
"In Sweden, the situation is comparatively...stable, but we also see signs that the number of infections is increasing in certain areas in our country. That's worrying," he told a news conference.
"The caution that existed in the spring has more and more been replaced by hugs and parties, bus trips in rush-hour traffic, and an everyday life that, for many, seems to return to normal.
"What we do right now, we will be glad of later. What we do wrong now, we will suffer for later," Lofven added.
He urged Swedes to adhere to social distancing and good hygiene standards, warning the government was ready to introduce stricter measures if needed to curb the spread of the virus.
"Unfortunately, we are seeing a small upturn in Sweden," Chief Epidemiologist Anders Tegnell told reporters.
"It is moving slowly but surely in the wrong direction, something we talked about that could happen in the autumn when we returned to workplaces."
Sweden reported two new deaths from COVID-19 on Thursday, taking the Total to 5,878 since the start of the pandemic.
That toll is many times more per capita than in its Nordic neighbours, but also well below countries like Spain and Italy that opted for hard national lockdowns.
The government also said on Thursday it had decided to extend a loan guarantee scheme for small and mid-sized businesses until the end of the year.
https://www.thechronicleherald.ca/news/world/signs-covid-cases-rising-in-sweden-again-worrying-says-pm-lofven-501289/

Studies Related to Coronavirus disease (COVID -19) Outbreak (Media)

Canada
Less than 250 people carried COVID-19 in Quebec in the spring
Source: rcinet.ca
ID: 1007907771

As few as 247 people could have carried COVID-19 into Quebec during the spring, according to a genome sequencing study published by the Institut national de santé publique du Québec (INSPQ) and the McGill Genome Centre.

The study looked at 734 genome sequences in the province that were obtained between mid-February and April 1, and compared those sequences with 21,935 sequences from elsewhere in Canada and around the world.

“This is the first of many analyses that will look not only at how the virus was first introduced into the province but also at how it has been spreading. Indeed, it is surprising to see how widely the virus had been dispersed at such an early stage.”
Dr. Guillaume Bourque, professor at the department for human genetics and head of the Canadian Center for Computational Genomics
According to a dataset examined by the research team, travel history data also suggested that 32.7 per cent of COVID-19 infections came from Europe, with France having the highest amount at 12.1 per cent. Another 31 per cent came from the Carribean and Latin America, and 23.9 per cent came from the United States. The data found that only 1.2 per cent of COVID-19 infections came from Asia and none from China.
“Our research indicates that [the] origin of the outbreak in Quebec was mostly via Europe and the Americas, and not from Asia. Most of the early introductions of the virus into Quebec did not give rise to sustained transmission, but a barrage of introductions just after spring break eventually gave rise to the tens of thousands of cases we have seen since.”
Dr. Jesse Shapiro, associate professor at the department of microbiology and immunology at McGill University
Quebec reported its first presumptive case of COVID-19 on Feb. 27, and since then has had a total of 69,670 infections and 5,810 deaths, according to the most recent report from the provincial government.
“The data confirms the importance of public health measures,” said Dr. Sandrine Moreira, head of genomics and bioinformatics at the INSPQ. “With such few cases leading to community-based transmission, we all need to remain vigilant.”
https://www.rcinet.ca/en/2020/09/24/study-suggests-that-less-than-250-people-carried-covid-19-in-quebec-in-thespring/

United States

Scientists discover genetic and immunologic underpinnings of some cases of severe COVID-19
Source: nih.gov
ID: 1007907441

New findings by scientists at the National Institutes of Health and their collaborators help explain why some people with COVID-19 develop severe disease. The findings also may provide the first molecular explanation for why more men than women die from COVID-19.
The researchers found that more than 10% of people who develop severe COVID-19 have misguided antibodies—autoantibodies—that attack the immune system rather than the virus that causes the disease. Another 3.5% or more of people who develop severe COVID-19 carry a specific kind of genetic mutation that impacts immunity. Consequently, both groups lack effective immune responses that depend on type I interferon, a set of 17 proteins crucial for protecting cells and the body from viruses. Whether these proteins have been neutralized by autoantibodies or—because of a faulty gene—were produced in insufficient amounts or induced an inadequate antiviral response, their absence appears to be a commonality among a subgroup of people who suffer from life-threatening COVID-19 pneumonia.
These findings are the first published results from the COVID Human Genetic Effort, an international project spanning more than 50 genetic sequencing hubs and hundreds of hospitals. The effort is co-led by Helen Su, M.D., Ph.D., a senior investigator at the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH; and Jean-Laurent Casanova, M.D., Ph.D., head of the St. Giles Laboratory of Human Genetics of Infectious Diseases at The Rockefeller University in New York. Major contributions were made by Luigi Notarangelo, M.D., chief of the NIAID Laboratory of Clinical Immunology and Microbiology (LCIM); Steven Holland, M.D., director of the NIAID Division of Intramural Research and senior investigator in the NIAID LCIM; clinicians and investigators in hospitals in the Italian cities of

Brescia, Monza and Pavia, which were heavily hit by COVID-19; and researchers at the Uniformed Services University of the Health Sciences in Bethesda, Maryland.
The wide variation in the severity of disease caused by SARS-CoV-2, the virus behind COVID-19, has puzzled scientists and clinicians. SARS-CoV-2 can cause anything from a symptom-free infection to death, with many different outcomes in between. Since February 2020, Drs. Su and Casanova and their collaborators have enrolled thousands of COVID-19 patients to find out whether a genetic factor drives these disparate clinical outcomes.
The researchers discovered that among nearly 660 people with severe COVID-19, a significant number carried rare genetic variants in 13 genes known to be critical in the body's defense against influenza virus, and more than 3.5% were completely missing a functioning gene. Further experiments showed that immune cells from those 3.5% did not produce any detectable type I interferons in response to SARS-CoV-2.
Examining nearly 1,000 patients with life-threatening COVID-19 pneumonia, the researchers also found that more than 10% had autoantibodies against interferons at the onset of their infection, and 95% of those patients were men. Biochemical experiments confirmed that the autoantibodies block the activity of interferon type I.
Article
Q Zhang et al. Inborn errors of type I IFN immunity in patients with life-threatening COVID-19. Science DOI: 10.1126/science.abd4570 (2020).
P Bastard et al. Auto-antibodies against type I IFNs in patients with life-threatening COVID-19. Science DOI: 10.1126/science.abd4585 (2020).
Who
NIAID Director Anthony S. Fauci, M.D., NIAID Senior Investigator Helen C. Su, M.D., Ph.D., and Luigi Notarangelo, M.D., chief of the NIAID Laboratory of Clinical Immunology and Microbiology, are available for interviews.
https://www.nih.gov/news-events/news-releases/scientists-discover-genetic-immunologic-underpinnings-some-cases-severe-covid-19

United States

Update: Characteristics of Health Care Personnel with COVID-19 - United States, February 12-July 16, 2020
Source: CDC Morbidity and Mortality Weekly Report (MMWR)
ID: 1007907667

Health care personnel (HCP) are essential workers at risk for COVID-19.
What is added by this report?
HCP with COVID-19 who died tended to be older, male, Asian, Black, and have an underlying medical condition when compared with HCP who did not die. Nursing and residential care facilities were the most commonly reported job setting and nursing the most common single occupation type of HCP with COVID-19 in six jurisdictions.
What are the implications for public health practice?
Continued surveillance is vital to understand the impact of COVID-19 on essential workers. Ensuring access to personal protective equipment and training, and practices such as universal use of face masks at work, wearing masks in the community, and observing social distancing remain critical strategies to protect HCP and those they serve.
Article Metrics
As of September 21, 2020, the coronavirus disease 2019 (COVID-19) pandemic had resulted in 6,786,352 cases and 199,024 deaths in the United States.* Health care personnel (HCP) are essential workers at risk for exposure to patients or infectious materials (1). The impact of COVID-19 on U.S. HCP was first described using national case surveillance data in April 2020 (2). Since then, the number of reported HCP with COVID-19 has increased tenfold. This update describes demographic characteristics, underlying medical conditions, hospitalizations, and intensive care unit (ICU) admissions, stratified by vital status, among 100,570 HCP with COVID-19 reported to CDC during February 12–July 16, 2020. HCP occupation type and job setting are newly reported. HCP status was available for 571,708 (22%) of 2,633,585 cases reported to CDC. Most HCP with COVID-19 were female (79%), aged 16–44 years (57%), not hospitalized (92%), and lacked all 10 underlying medical conditions specified on the case

report form† (56%). Of HCP with COVID-19, 641 died. Compared with nonfatal COVID-19 HCP cases, a higher percentage of fatal cases occurred in males (38% versus 22%), persons aged ≥65 years (44% versus 4%), non-Hispanic Asians (Asians) (20% versus 9%), non-Hispanic Blacks (Blacks) (32% versus 25%), and persons with any of the 10 underlying medical conditions specified on the case report form (92% versus 41%). From a subset of jurisdictions reporting occupation type or job setting for HCP with COVID-19, nurses were the most frequently identified single occupation type (30%), and nursing and residential care facilities were the most common job setting (67%). Ensuring access to personal protective equipment (PPE) and training, and practices such as universal use of face masks at work, wearing masks in the community, and observing social distancing remain critical strategies to protect HCP and those they serve.

Data from laboratory-confirmed and probable COVID-19 cases, voluntarily reported to CDC from state, local, and territorial health departments during February 12–July 16, 2020, were analyzed. COVID-19 cases are reported using a standardized case report form, which collects information on demographic characteristics, whether the case occurred in a U.S. health care worker (HCP status), symptom onset date, underlying medical conditions, hospitalization, ICU admission, and death. HCP occupation type and job setting were added to the case report form in May, enabling prospective and retrospective entry of these elements. Case surveillance data were enriched with additional cases from a COVID-19 mortality-focused supplementary surveillance effort in three jurisdictions§ (3). Descriptive analyses were used to examine characteristics by vital status. HCP occupation type and job setting were reported by a subset of jurisdictions with at least five HCP cases for each variable. Analyses were conducted using Stata (version 15.1; StataCorp) and SAS (version 9.4; SAS Institute).

Among 2,633,585 U.S. COVID-19 cases reported individually to CDC during February 12–July 16, HCP status was available for 571,708 (22%) persons, among whom 100,481 (18%) were identified as HCP. Data completeness for HCP status varied by jurisdiction; among jurisdictions that included HCP status on ≥70% of cases and reported at least one HCP case (11), HCP accounted for 14% (14,938 of 109,293) of cases with HCP status available and 11% (14,938 of 132,340) of all reported cases. Case report form data were enriched with 89 additional HCP cases using supplementary mortality data; thus, the final HCP case total for analysis was 100,570 (Table 1).

Among HCP with COVID-19 overall, the median age was 41 years (interquartile range = 30–53 years); 79% of cases were in females. Among 69,678 (69%) HCP cases with data on race and ethnicity, 47% were in non-Hispanic Whites (Whites), 26% were in Blacks, 12% were in Hispanics or Latinos of any race (Hispanics), and 9% were in Asians. Of persons with known hospitalization or ICU admission status, 8% (6,832 of 83,202) were hospitalized and 5% (1,684 of 33,694) were treated in an ICU. Vital status was known for 67% (67,746) of HCP with COVID-19; among those, 641 (1%) died. Deaths among HCP with COVID-19 were reported in 22 jurisdictions. Compared with those who survived, decedents tended to be older (median age = 62 versus 40 years), male (38% versus 22%), Asian (20% versus 9%), or Black (32% versus 25%).

Among HCP cases with data on one or more of 10 underlying medical conditions specified on the case report form, 17,838 (44%) persons had at least one condition. The most common were cardiovascular disease (18%), chronic lung disease (16%), and diabetes mellitus (13%). The vast majority (92%) of fatal HCP cases were among HCP with an underlying medical condition. More than one half had cardiovascular disease (61%) or diabetes mellitus (52%), conditions known to increase the risk for severe COVID-19¶; 32% were reported to have both conditions (Table 1).

Six jurisdictions reported the occupation type** or job setting†† for at least five HCP with COVID-19 (Table 2). Among HCP with COVID-19 in these jurisdictions, occupation type was available for 59% (5,913 of 9,984) and job setting for 41% (6,955 of 17,052). Health care support workers accounted for the largest overall group of occupation types (32%), and nurses constituted the largest single occupation type (30%) (Table 2). Within this subset of HCP cases, two thirds (67%) were in persons reported to work in nursing and residential care facilities.

Discussion

State, local, and territorial health departments voluntarily submit COVID-19 case notification data to CDC, and these critical data help provide a national picture of cases. The first report on HCP with COVID-19 using national case surveillance data in April 2020 (2) described characteristics of 9,282 HCP cases and 27 deaths among approximately 315,000 total cases. As of July 16, 2020, among approximately 2.5 million reported U.S. COVID-19 cases, 100,570 cases in HCP and 641 deaths among HCP with COVID-

19 have been reported to CDC. Continued national surveillance is vital to evaluate the effect of the pandemic on HCP, and this update emphasizes the ongoing impact on this essential working population. Among reported HCP with COVID-19, age and sex distributions remain comparable to those of the overall U.S. HCP workforce§§; however, compared with nonfatal COVID-19 cases in HCP, fatal HCP cases were more common among older persons and males. Similar to findings described in the overall population (4,5), HCP with underlying medical conditions who developed COVID-19 were at increased risk for death. Almost all reported HCP with COVID-19 who died had at least one of 10 underlying conditions listed on the case report form, compared with fewer than one half of those who survived. Asian and Black HCP were also more prevalent among fatal cases; disproportionate mortality of persons from some racial and ethnic groups among cases has also been described in the general population (3). Long-standing inequities in social determinants of health can result in some groups being at increased risk for illness and death from COVID-19, and these factors must also be recognized and addressed when protecting essential workers in the workplace, at home, and in the community. Ensuring adequate allocation of PPE to all HCP in the workplace is one important approach to mitigating systemic inequalities in COVID-19 risk (6). As the COVID-19 pandemic continues in the United States, HCP are faced with increasing fatigue, demands, and stressors. HCP who are at higher risk for severe illness and death from COVID-19 should maintain ongoing communication with their personal health care providers and occupational health services to manage their risks at work and in the community.

In this update, most HCP with COVID-19 were reported to work in nursing and residential care facilities. Large COVID-19 outbreaks in long-term care facilities suggest that transmission occurs among residents and staff members (7,8). During the COVID-19 pandemic, multiple challenges in long-term care settings have been identified, including inadequate staffing and PPE, and insufficient training in infection prevention and control. As the pandemic continues, it is essential to meet the health and safety needs of HCP serving populations requiring long-term care. Importantly, HCP cases were also identified from a variety of other health care settings. Therefore, increased access to resources, appropriate training, and ongoing support are needed across the health care spectrum to protect all HCP and their patients.

HCP with COVID-19 were reported among a diverse range of occupations. Nurses represented 30% of HCP cases with known occupation type, but account for only approximately 15% of the total U.S. health care and social assistance workforce.¶¶ Nurses and health care support workers often have frequent, close contact with patients and work in settings that might increase their risk for acquiring SARS-CoV-2, the virus that causes COVID-19. HCP who do not provide direct patient care, such as administrative staff members and environmental service workers, were also reported to have COVID-19. Risk to HCP can occur through pathways other than direct patient care, such as exposure to coworkers, household members, or persons in the community. HCP who acquire SARS-CoV-2 can similarly introduce the virus to patients, coworkers, or persons outside the workplace. Thus, practices such as universal use of face masks at work, wearing masks in the community, observing social distancing, and practicing good hand hygiene remain critical strategies to protect HCP and the populations they serve. Screening HCP for illness before workplace entry and providing nonpunitive sick leave options remain critical practices.

The findings in this report are subject to at least five limitations. First, although reporting completeness increased from 16% in April to 22% in July (2), HCP status remains missing for most cases reported to CDC. HCP might be prioritized for testing, but the actual number of cases in this population is most certainly underreported and underdetected, especially in asymptomatic persons (9,10). Second, the amount of missing data varied across demographic groups, underlying medical conditions, and health outcomes; persons with known HCP status and other information might differ systematically from those for whom this information is not available. Third, details of HCP occupation type and job setting were not included on the CDC case report form until May 2020, and only six jurisdictions reported these data. Fourth, testing strategies and availability can vary by jurisdiction and health care setting, influencing the numbers and types of HCP cases detected. Finally, this report does not include information on whether exposure to SARS-CoV-2 among HCP cases occurred in the workplace or in other settings, such as the household or community.

As of July 16, 2020, 100,570 COVID-19 cases in HCP and 641 deaths among HCP with COVID-19 were reported in the United States. Information on COVID-19 among essential workers, including HCP, can inform strategies needed to protect these populations and those they serve, including decisions related to COVID-19 vaccination, when available. Factors such as demographics, including race and ethnicity, underlying health conditions, occupation type, and job setting can contribute to the risk of HCP acquiring COVID-19 and experiencing severe outcomes, including death. Given the evidence of ongoing COVID-19

infections among HCP and the critical role these persons play in caring for others, continued protection of this population at work, at home, and in the community remains a national priority.***
* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html ; https://www.cdc.gov/coronavirus/2019-ncov/covid-data/faq-surveillance.html ; https://www.cdc.gov/coronavirus/2019-ncov/php/reporting-pui.html .
† Underlying medical condition status was classified as “known” if any of these 10 conditions, specified on the standard case report form, were reported as present or absent: diabetes mellitus; cardiovascular disease (includes hypertension); severe obesity (body mass index ≥40 kg/m2); chronic renal disease; chronic liver disease; chronic lung disease; immunosuppressive condition; autoimmune condition; neurologic condition (including neurodevelopmental, intellectual, physical, visual, or health impairment); and psychologic/psychiatric condition.
§ The supplementary mortality surveillance effort, which included persons with laboratory-confirmed COVID-19 who died during February 12–April 24, 2020, identified 89 additional HCP and two additional deaths among known HCP from three jurisdictions: Michigan, New Jersey, and New York City.
¶ https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html .
** Seventeen HCP occupation type categories: health care support worker (includes nursing assistant, medical assistant, and other care provider or aide); nurse; administrative staff member; environmental services worker; physician; medical technician; behavioral health worker; first responder; dietary services worker; dental worker; laboratorian; occupational, physical, or speech therapist; pharmacy worker; respiratory therapist; phlebotomist; physician assistant; and other; data were reported in five jurisdictions (Alaska, Kansas, Minnesota, North Carolina, and Utah).
†† Three HCP job setting categories: nursing and residential care facility (includes long-term care facility [nursing home/assisted living facility], rehabilitation facility, and group home); hospital; ambulatory health care service (includes outpatient care center, home health care service, and dental facility); data were reported in five jurisdictions (Alaska, Kansas, Michigan, Minnesota, and Utah).
Suggested citation for this article: Hughes MM, Groenewold MR, Lessem SE, et al. Update: Characteristics of Health Care Personnel with COVID-19 — United States, February 12–July 16, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1364–1368. DOI: http://dx.doi.org/10.15585/mmwr.mm6938a3external icon .

https://www.cdc.gov/mmwr/volumes/69/wr/mm6938a3.htm?s_cid=mm6938a3_x

United States

US health experts says COVID-19 outbreaks not spreading in American schools
Source: Republic World
Unique ID: 1007905592

US researchers said that the students and teachers contracted the disease mostly from outside and there was little evidence of the outbreak inside the schools.
As the US announced the reopening of the schools last month, and concerns about the coronavirus outbreak among children grew, US health experts have confirmed that the rates of infection inside the building remained significantly lower than the public premises. According to an ANI report, the students and teachers contracted the disease mostly from outside and there was little evidence of the outbreak inside

the schools. It was found that the US schools may not be as risky as many believed they were during the pandemic.
“Everyone had a fear there would be explosive outbreaks of transmission in the schools. In colleges, there have been. We have to say that, to date, we have not seen those in the younger kids, and that is a really important observation,” director of the Center for Infectious Disease Research and Policy at the University of Minnesota, Michael Osterholm said.
This implies that the experts have found no concrete proof of the school environment being unsafe. Although the medical experts did not totally rule out the possibility and suggest zero risks of contracting the coronavirus in the schools. The research suggested that the buildings and institutions did not make the staff or the students “more vulnerable” with adherence to health safety measures and remote teaching. Data gathered by the experts from the smaller communities, however, indicated that the onset of the flu season and with the arrival of the winters, the equation might perhaps change and may put the staff and the students at greater risks.
According to the researchers at Brown University, working in collaboration with school administrators, the data uploaded on the National COVID-19 School Response Data Dashboard indicated low levels of infection among teachers and students, an ANI report confirmed. In a sample collected by the authorities over the course of a two-week period beginning from August 31, it was found that only 0.23 per cent of students were either confirmed or presumptive cases of the novel coronavirus.
Read: US: GOP Senators See Political, Principle Gain In Court Fight
23 COVID-19 cases across 20 schools
"These numbers will be, for some people, reassuring and suggest that school openings may be less risky than they expected," said Emily Oster, an economics professor at Brown University, who created the disease tracker. She said, "I do not think that these numbers say all places should open schools with no restrictions or anything that comes close to that. Ultimately, school districts are going to have different attitudes toward risk.”
"We are not seeing schools as crucibles for onward transmission. It is reasonable to say that it looks promising at this point," said Sara Johnson, associate professor of paediatrics at the Johns Hopkins University School of Medicine.
Additionally, a non-profit advocacy organization named The Network for Public Education tracked at least 37 school districts in Connecticut, New York, and Pennsylvania and found similar results. Only 23 confirmed COVID-19 cases were detected across 20 schools, with no proof of spread in the school premises, Carol Burris, the network's executive director was quoted as saying by ANI. While over 14 deaths from the novel disease have been reported among the teachers, principals, and counsellors, there has been no evidence of any casualties contracting the virus at the institutions, the research indicated.
(Images Credit: AP)
https://www.republicworld.com/world-news/us-news/us-health-experts-covid-19-outbreaks-not-spreading-in-us-schools.html

United States
Falling COVID-19 viral loads may explain lower rates of ICU use, deaths
Source: CIDRAP
ID: 1007908234

The findings of two studies presented at this week's virtual European Society of Clinical Microbiology and Infectious Diseases (ESCMID) Conference on Coronavirus Disease suggest that patients' loads of SARS-CoV-2, the virus that causes COVID-19, declined as the pandemic progressed, which may help explain falling rates of coronavirus-related intensive care unit (ICU) use and deaths.

Both unpublished studies were observational, however, so they cannot determine cause and effect, only highlight the association.

Measuring the progress of the pandemic
The first study, conducted by Wayne State University researchers in Detroit, involved a retrospective analysis of 708 initial nose-throat swabs from hospitalized coronavirus patients tested from Apr 4 to Jun 5 using reverse transcription polymerase chain reaction (RT-PCR). The goal was to better describe the effects of changing viral loads—which is a measure of virus density—at a population level.

In the first week of the study, 48.7% of viral loads were characterized as intermediate, versus 25.5% in both the low and high viral load categories. Thereafter, the percentage of high and intermediate loads progressively fell at the same time as the proportion of low viral loads rose.

Five weeks into the study, 70% of the samples showed a low initial viral load, corresponding to a decrease in the death rate; 45% of patients with high viral loads died, in contrast with 32% in those with intermediate loads and 14% in those with low loads.

At week 5 the rate of patients with an intermediate load was around 18%, and about 12% had high viral loads. By week 6, no patients had high viral loads.

The authors concluded that the downward trend in viral load may indicate that the pandemic is becoming less severe, implementation of physical distancing and lockdowns may have decreased overall exposure to the coronavirus, and analyzing viral loads over time may be a good way to assess pandemic progress.

"Though confounding variables have not been evaluated, this suggests an association between initial viral load and mortality," they said in an ESCMID press release.

Severity of signs, symptoms
The second unpublished study, conducted by researchers in Italy, suggests that as pandemic lockdowns in that country began, resulting in lower case numbers, COVID-19 patient viral loads on nose-throat swabs tested by RT-PCR also fell from March to May. The authors said that their findings may account for lower percentages of patients needing intensive care and dying of their infections over time.

Researchers analyzed data from 373 COVID-19 patients in an emergency department in the northern city of Negrar to assess a possible association between the severity of coronavirus signs and symptoms with viral load as the pandemic transitioned from high to low transmission.

As patient viral loads declined over the course of the pandemic, the percentage of patients admitted to the ICU declined substantially from March (6.7%) to April (1.1%), and May (0.0%).

"As the epidemiological context changed from high to low transmission setting, people were presumably exposed to a lower viral load, which has been previously associated to less severe clinical manifestations," the authors wrote.
https://www.cidrap.umn.edu/news-perspective/2020/09/falling-covid-19-viral-loads-may-explain-lower-rates-icu-use-deaths

United Kingdom
Oxford's OpenABM-Covid19 mathematical model helps to control the coronavirus epidemic
Source: medicalxpress.com
Unique ID: 1007904937

A team of mathematical modelers and epidemiologists at Oxford University's Nuffield Department of Medicine release the latest model of a population responding to the coronavirus epidemic. The model—OpenABM-COVID19—provides public health decision-makers with the ability to review the potential progression and outcome of the coronavirus, including fluctuations in infected individuals, hospitalisations, intensive care unit (ICU) admissions and deaths, and assess the impact of test and trace programs.
OpenABM-COVID19 supports public health services, including the UK's NHS England and NHS Wales, to forecast the epidemic and decide on the best balance and scale of epidemic control interventions over the coming months. Modeled interventions include digital contact tracing (exposure notification system), testing, ongoing physical distancing, self-isolation, mask wearing and further localized or national lockdown measures.
Ming Tang, director of data and analytics at NHS England and NHS Improvement, says: "Essential NHS services have been available throughout the pandemic, and this open-source model from Oxford University is providing the NHS in England with yet another tool to help understand potential demand on hospital

services across the country, and ensure we can continue to offer care to patients and anyone concerned about worrying symptoms."

The UK's latest demographic and coronavirus data feed into the model, providing a tool which is fast, adjustable and scalable and can be updated with any country or regional demographic data and contact networks. Infectious individuals are not randomly spread throughout a population, and the networks on which they interact have a profound effect on the dynamics of the epidemic and the final number of people infected. Various sized populations are modeled using real world interactions—each person with routine and random encounters in settings such the workplace, with family and friends, at school or university. The severity of the disease, including the probability of hospitalization and death, increases with age. Higher levels of transmission within households, and mild or asymptomatic individuals, are also factored into the simulations.

Professor Christophe Fraser, scientific advisor to the Department of Health & Social Care and Group Leader in Pathogen Dynamics at Oxford University's Nuffield Department of Medicine, says: "The fact that COVID-19 affects different population groups, and that we live and interact in distinct ways, needs to be integrated into our understanding of the potential effect of different public health measures. The UK and other national governments are adjusting our Oxford model to evolving policy scenarios, new measures and the latest scientific evidence. Our model supports decision making as countries ease or scale-up policies as the epidemic continues to evolve and as we try to return to the workplace, school, visit friends and family, and consider how to manage safe social activities."

The Oxford team is also supporting the development and deployment of digital contact tracing. As apps and exposure notification systems are tested and rolled out in different countries, the model can be adjusted to see the impact of notifying contacts based on different test result timing and digital contact tracing configurations, such as community-level testing or not, or change configurations to respond to adjusted guidance on self-isolation duration. The model helps to gage the number of tests required with different notification approaches, allowing for testing delays or surges in incidence.

Professor Mark Briers, program director at The Alan Turing Institute and Department of Health & Social Care advisor, says: "OpenABM-COVID19 has been instrumental in helping us to understand the potential implications of the contact tracing app as a non-pharmaceutical intervention, providing a scientific basis for the exploration of relevant policy options. Scientists at Oxford University's Nuffield Department of Medicine have provided continual expert scientific advice, delivering significant impact to the UK, helping to reduce the negative health consequences and societal implications of COVID-19."

Dr. David Bonsall, advisor to the Department of Health & Social Care, clinician and senior researcher at Oxford University's Nuffield Department of Medicine, says: "We need the best data and latest analyses to retain control of COVID-19. Our epidemic model can be updated to ensure we optimize the speed and effectiveness of contact tracing and testing. Contact tracing apps / Exposure notification systems should be introduced alongside other fast and effective disease control measures to help save lives, protect people, reduce the need for widespread lockdowns and enable us to return to more normal activities."

The model supports public health decision-makers anywhere in the world to look at the progression and outcome of infection and how different measures affect the population. It also demonstrates the impact of policy decisions on people's lives and health systems, including the number of people in quarantine. The model has been further enhanced in partnership with Google Research, including studies to assess the uptake needed for Exposure Notification Systems (contact tracing apps) in the U.S.. Thanks to the Python interface for the model, developed in close collaboration with the IBM UK team, it can be used and adapted by others.

Dr. Nicole Mather, life sciences lead at IBM UK Services, says: "IBM UK developed the Python interface which allows the OpenABM-COVID19 to be run by third parties. It has allowed public health authorities to use the model not only for digital contact tracing development, but also to support resource management and epidemic response planning for health services and other institutions. It has been important to enable a wider range of contributors to aid the building of OpenABM-COVID19—we are delighted to help broaden access to this model."

Craiger Solomons, technical advisory cell for the Welsh Government, says: "We've adapted the Oxford University model to reflect the impact of COVID-19 on Wales. With support from the team at Oxford University, the Welsh Government has integrated Welsh data and considered different policy scenarios based on the differing contact ratios; including random, workplace and school interactions. These data were not available for Wales previously, they're now informing the evidence base used by Welsh Ministers to consider national and local policy actions."

Dr. Robert Hinch, first co-author of the paper and senior researcher at Oxford University's Nuffield Department of Medicine, says: "Our Oxford model can be adjusted to other coronavirus epidemic settings. Digital exposure notification systems based on the Google-Apple API are being developed in many countries across Europe, Africa and in the US. It is critical that we have the ability to analyze the possible effects of different public health interventions using national or regional-specific demographic and contact network data. We hope this model will continue to contribute to our response options now, and strengthen our preparedness efforts for future pandemics."
Provided by University of Oxford
https://medicalxpress.com/news/2020-09-oxford-openabm-covid19-mathematical-coronavirus-epidemic.html

United Kingdom

Sensitive Detection of SARS-CoV-2–Specific Antibodies in Dried Blood Spot Samples
Source: CDC
ID: 1007905375
Volume 26, Number 12—December 2020
Dispatch

Abstract

Dried blood spot (DBS) samples can be used for the detection of severe acute respiratory syndrome coronavirus 2 spike antibodies. DBS sampling is comparable to matched serum samples with a relative 98.1% sensitivity and 100% specificity. Thus, DBS sampling offers an alternative for population-wide serologic testing in the coronavirus pandemic.

A confirmed diagnosis of acute coronavirus disease (COVID-19) depends on the detection of RNA from the causative pathogen, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). In contrast, although serologic testing is less useful for diagnosing the acute stages of infection, it can aid in diagnosing atypical manifestations of SARS-CoV-2 infection (M. Perez-Toledo et al., unpub. data, https://doi.org/10.1101/2020.06.05.20123117External Link) and in determining prior virus exposure at a population level (*1*), knowledge which could substantially influence public health and social policies (*2*,*3*). Currently, antibody testing for SARS-CoV-2 uses serum or plasma collected by venipuncture. The use of such sampling in large-scale seroepidemiologic studies is limited by logistic challenges, resources, and costs, as well as the risk for SARS-CoV-2 exposure from direct patient contact. In contrast, dried blood spot (DBS) sampling is simple, inexpensive, and can be self-collected and then sent by postal services to laboratories for processing (*4*). It is a well-established method for detecting antibodies against various infections (*5*,*6*), and antibodies collected by DBS are stable for prolonged periods (*7*). Moreover, DBS sampling provides a solution to widening access to serologic platforms in low- and middle-income countries. Nevertheless, the potential role of DBS sampling in studying SARS-CoV-2 seroprevalence has not been fully explored, and knowledge regarding the recovery of antibody from the DBS is limited. We describe the validation of DBS samples against matched serum in a highly sensitive and specific SARS-CoV-2 ELISA.

The Study

We collected 87 samples from 80 volunteers at the University Hospitals Birmingham NHS Foundation Trust (under approved protocol for blood donations use in clinical assays, UK Research Ethics Committee reference no. 2002/201 and Clinical Immunology Service Reference no. ERN_16-178) during May 18–June 3, 2020. Three matched samples were from SARS-CoV-2 serum antibody–negative volunteers. The remaining samples were from SARS-CoV-2 serum antibody–unknown volunteers; 5 volunteers provided duplicate and 1 volunteer provided triplicate matched samples (Appendix Figure). To refine negative thresholds, we included 17 pre–August 2019 DBS-only samples (UK Research Ethics Committee reference no. 2002/20, Integrated Research Application System reference no. 132132, University Hospitals Birmingham project reference no. RRK4136). Volunteers were healthy at the time of sampling. Thirty-one matched samples (31/87 [35.6%]) were from PCR-positive volunteers, on average, 54 days (SD + 17 days) from reported symptom onset and 45 days (SD + 15 days) from PCR testing. All participants were anonymized, and SARS-CoV-2 PCR status was recorded as positive or unknown.
For DBS collection, we collected capillary blood samples onto forensic-grade 226 DBS cards (Ahlstrom Munksjo, https://www.ahlstrom-munksjo.comExternal Link) by using finger-prick lancets (*4*,*8*). We stored DBS cards at room temperature in individual sample bags with desiccant. Concomitantly, we collected

venous blood from volunteers and separated serum by using centrifugation at 9,700 × *g* for 5 min at room temperature. Laboratory analysis was blinded to PCR status, and we reported SARS-CoV-2–specific antibody results as positive, negative, or equivocal.

To elute antibody from DBS cards, we isolated individual preperforated DBS spots by using a sterile pipette tip and placed them into a universal tube at a ratio of 1 spot to 250 µL 0.05% phosphate-buffered saline (PBS)–Tween 20 (PBS-T) (PBS, Oxoid; Tween-20; Sigma-Aldrich, https://www.sigmaaldrich.comExternal Link). We briefly vortexed and incubated tubes overnight at room temperature. We then harvested DBS eluate into a microtube and centrifuged it at 10,600 × *g* for 10 min at room temperature. We stored eluate at 4°C for <14 days in accordance with standard protocols (*4*). We quantified total IgG, IgA, and IgM concentrations in matched serum and DBS eluate, plus pre–August 2019 DBS samples, with nephelometry by using the automated COBAS 6000 (Roche, https://www.roche.comExternal Link).

We performed a highly sensitive and specific in-house ELISA (now under peer review) to measure IgG, IgA and IgM against soluble, stabilized, trimeric SARS-CoV-2 spike (S) glycoprotein (*9*,*10*), as previously described (S.E. Faustini et al., unpub. data, https://doi.org/10.1101/2020.06.16.20133025External Link). In brief, we coated Nunc 96-well plates (ThermoFisher, https://www.thermofisher.comExternal Link) with 50 µL of 2 µg/mL S glycoprotein (M. Perez-Toledo et al.; S.E. Faustini et al.). We blocked plates and diluted samples with 2% BSA 0.1% PBS-T (PBS, Oxoid; Tween-20 and BSA, Sigma-Aldrich) at starting dilutions of 1:3 DBS eluate and 1:15 serum, with 3-fold serial dilutions; or single dilutions of 1:10 DBS eluate and 1:100 serum. We diluted mouse monoclonal anti–human horseradish peroxidase conjugated antibodies (anti–IgG R-10 1:8,000, anti–IgA MG4.156 1:4,000, and anti–IgM AF6 1:2,000; Abingdon Health, https://www.abingdonhealth.comExternal Link) in 0.1% PBS-T. We developed plates with TMB Core (Bio-Rad, https://www.bio-rad.comExternal Link) and stopped them after 5 min with 0.2M H_2SO_4 (Sigma-Aldrich). We recorded optical densities at 450 nm (OD_{450}) by using the Dynex Revelation (Dynex Technologies, https://www.dynextechnologies.comExternal Link). We reported results as SARS-CoV-2 S antibody positive, negative, or equivocal. The cutoff for negativity was less than the highest negative control (DBS 0.399 OD_{450} and serum 0.449 OD_{450}), and for positivity, the mean of the negative controls +3 SD (DBS 0.444 OD_{450} and serum 0.62 OD_{450}); a result between this range was considered equivocal.

We performed statistical analyses by using Prism 8 (GraphPad, https://www.graphpad.comExternal Link) and assessed correlations between continuous data by using Spearman's rank test ($p<0.05$ was considered statistically significant). We assessed DBS sample ELISA performance, relative to the serum assay, by calculating the comparative sensitivity, specificity, and positive and negative predictive values, with 95% CIs. We assessed the agreement between DBS and serum ELISA results by determining the Cohen κ coefficient and Bland-Altman mean-difference.

Figure 1

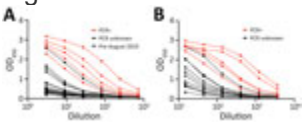

Figure 1. Elution of SARS-CoV-2 anti-spike glycoprotein antibodies from DBS samples, showing 3-fold DBS eluate (A) (initial 1:3 dilution) and serum (B) (initial 1:15 dilution) titrations. Dashed line indicates pre–August 2019 DBS samples...

We performed quantification of total immunoglobulin concentrations in serum and DBS eluate. We observed 7- to 11-fold reduction in mean immunoglobulin concentration (IgG, IgA, and IgM) in DBS eluate compared with matched serum (Table 1). Matched serum and DBS titration curves showed the detection of SARS-CoV-2 S glycoprotein antibodies in both serum and DBS eluate with the limits of detection and the optimal detection dilution indicated (1:10 for DBS eluate and 1:100 for serum). PCR-positive matched samples showed higher responses, whereas pre–August 2019 DBS samples were negative across all dilutions (Figure 1).

Figure 2

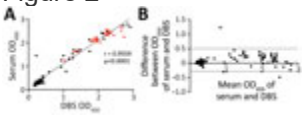

Figure 2. Effectiveness of DBS sampling for SARS-CoV-2 anti-spike glycoprotein detection. A) Correlation between matched DBS eluate (1:10) and serum (1:100) OD_{450} ELISA results (n = 87). Red circles indicate PCR-positive samples (n...

We measured OD_{450} detected by ELISA for matched DBS eluate (diluted 1:10) and serum (diluted 1:100). We observed a significant correlation between matched serum and DBS samples (r = 0.96 [95% CI 0.93–0.97]; p<0.0001) (Figure 2, panel A) and minimal differences in results observed by sample type (Bland-Altman bias 0.11 + 0.20) (Figure 2, panel B). Discordance occurred between only 1 matched sample (κ = 0.975). Relative to serum samples, DBS samples achieved 98.11% sensitivity and 100% specificity for detecting S glycoprotein antibodies (Table 2); 100% of the PCR-positive samples (n = 31) were also antibody-positive in DBS eluate.

Conclusions

We show that DBS samples can be used for the detection of SARS-CoV-2–specific antibodies with results comparable to serum samples, supporting the findings of recent preliminary studies (*11*,*12*). Although individual laboratories should optimize DBS-derived antibody detection, considering dilution-factor and cutoff thresholds for their relevant downstream assay, these results demonstrate that DBS sampling could complement venipuncture for serologic assessments, such as seroprevalence studies, during the COVID-19 pandemic.

A current limitation of antibody assays is the necessity for venipuncture by skilled phlebotomists; DBS sampling overcomes this limitation and introduces the opportunity for wider population-level testing and improved surveillance in groups at heightened risk for infection. For example, DBS could be delivered using postal services (*4*) to patients with chronic conditions, the immunocompromised, and the elderly, all of which are groups disproportionately affected by COVID-19 (*13*). Furthermore, the DBS method is simple and inexpensive (*4*), which could enhance sampling in low- and middle-income countries, among groups where venipuncture is culturally unacceptable or in a geographically dispersed population.

Dr. Morley is a clinician specializing in public health, currently undertaking her PhD research, which is focused on humoral immunology, at the University of Birmingham. She worked on SARS-CoV-2 diagnostics and research during the COVID-19 pandemic at the University of Birmingham.

Acknowledgments

We would like to thank the University of Birmingham Clinical Immunology Service for their invaluable support in sample collection and processing. We also thank Cynthia D'Aguilar and Julie Williams for logistic support in sample collection. We are grateful for the expertise of Margaret Goodall in generating the mouse monoclonal anti–human horseradish peroxidase conjugated antibodies.

This work was supported by the Wellcome Trust and the National Institute for Health Research Birmingham Biomedical Research Centre at the University Hospitals Birmingham NHS Foundation Trust and the University of Birmingham. The views expressed are those of the authors and not necessarily those of the National Institute for Health Research or the Department of Health and Social Care. This project was supported by the Saving Lives Charity (UK Charity Commission no. 1144855) who kindly provided the dried blood spot collection cards. The work, conducted in Max Crispin's laboratory, was funded by the International AIDS Vaccine Initiative, Bill and Melinda Gates Foundation through the Collaboration for AIDS Vaccine Discovery (grants nos. OPP1196345/INV-008813, OPP1084519, and OPP1115782), the Scripps Consortium for HIV Vaccine Development (National Institutes of Health National Institute for Allergy and Infectious Diseases grant no. AI144462), and the University of Southampton Coronavirus Response Fund. S.T. is the medical director of the Saving Lives Charity. M.T.D. and M.G. report stocks in Abingdon Health (outside the submitted work).

Figures

- **Figure 1**. Elution of SARS-CoV-2 anti-spike glycoprotein antibodies from DBS samples, showing 3-fold DBS eluate (A) (initial 1:3 dilution) and serum (B) (initial 1:15 dilution) titrations. Dashed line indicates pre–August 2019...
- **Figure 2**. Effectiveness of DBS sampling for SARS-CoV-2 anti-spike glycoprotein detection. A) Correlation between matched DBS eluate (1:10) and serum (1:100) OD_{450} ELISA results (n = 87). Red circles indicate PCR-positive...

Tables

- **Table 1**. Mean concentrations of SARS-CoV-2 IgG, IgA, and IgM measured in matched DBS eluate and serum samples
- **Table 2**. 4x4 table of DBS eluate SARS-CoV-2 ELISA sensitivity and specificity, relative to serum samples

Top

Suggested citation for this article: Morley GL, Taylor S, Jossi S, Perez-Toledo M, Faustini SE, Marcial-Juarez E, et al. Sensitive detection of SARS-CoV-2–specific antibodies in dried blood spot samples. Emerg Infect Dis. 2020 Dec [*date cited*]. https://doi.org/10.3201/eid2612.203309
DOI: 10.3201/eid2612.203309
Original Publication Date: September 24, 2020
[1]These senior authors contributed equally to this article.
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https://wwwnc.cdc.gov/eid/article/26/12/20-3309_article?ACSTrackingID=USCDC_333-DM38928&ACSTrackingLabel=Latest%20Expedited%20Articles%20-%20Emerging%20Infectious%20Diseases%20Journal%20-%20September%2024%2C%202020&deliveryName=USCDC_333-DM38928

Domestic Events of Interest

Canada, BC
Overdose deaths hit new record during dual public health emergencies
Source: Powell River Peak
Unique ID: 1007903727

While many have been focused on the COVID-19 pandemic, British Columbia has been dealing with a second public health emergency: overdose deaths.
B.C. now has a record of six straight months with over 100 illicit drug toxicity deaths. Emergency health services have also received a record number of overdose calls over the summer, and in the first eight months of 2020, there have been more overdose deaths than in all of 2019.
In August, there was a 71% increase in the number of overdose deaths compared with the same time last year. However, after peaking at 181 deaths in June, the number of overdose deaths has fallen for the past two consecutive months, dipping 16% in August from July.
Fentanyl appears to be playing a larger role in B.C.'s drug overdose crisis, with the number of overdose deaths showing signs of extreme fentanyl concentrations nearly doubling to 14% in April 2020 to August 2020, from 8% from January 2019 to March 2020.
Men continue to make up the majority of overdose deaths, accounting for 81% of all overdose deaths to date in 2020; however, in August 2020, overdose rates for women returned to average levels. While Vancouver, Surrey and Victoria have the highest number of cases, the highest overdose rates are in the Northern Health region, where there are 40 overdose deaths per 100,000, compared with 31 across the province.
Vancouver had the second highest overdose rate at 36 overdoses per 100,000. While overdose rates in Vancouver Coastal Health and Island health declined in August, rates in the Northern Health region have remained high.
Despite the increase in deaths, there have been no reported deaths at supervised consumption or drug overdose prevention sites.
BIV
https://www.prpeak.com/overdose-deaths-hit-new-record-during-dual-public-health-emergencies-1.24208146

Canada, QC
Public health warns of possible Legionnaires' disease outbreak in LaSalle
Source: montrealgazette.com
ID: 1007908246

The Montreal regional public health department issued a call for caution to the health network on Thursday after a possible outbreak of Legionnaires' disease in LaSalle.

Seven cases of Legionnaires' disease were reported to the public health authority between Sept. 9 and Sept. 22, it said in a press release. The call for caution is a warning to the health network to watch for cases of Legionnaires' disease since its symptoms may be confused with those of COVID-19.

Legionnaires' disease is a respiratory infection that can be caused by breathing in fine water droplets in the air that are contaminated with Legionella bacteria.

Legionella bacteria occur naturally in low quantities in fresh water and wet soils and can mostly be found in artificial water sources, especially hot water. The sources include hot water heaters, shower heads, sink faucets, spas, hot tubs, whirlpools, home humidifiers and water cooling towers.

Preventive measures in the home include ensuring the temperature of electric hot water heaters is set to 60 degrees Celsius.

The disease mostly affects people 50 or older with chronic conditions, smokers and people who drink a lot of alcohol. It does not spread from person to person.

The public health department says it's investigating to determine whether the seven people in LaSalle were exposed to the same environmental source and then to identify it and correct it. The department said it's investigating all possible sources, including water fountains and construction sites.

"A public health team has also been sent to the area located south of the Canal de l'Aqueduc to identify other potential sources," the press release said. "Some citizens may be called upon to assist with this activity."

The public health department said the latest cases of Legionnaires' disease are probably not linked to seven cases that were identified in the southwest sector of Montreal this summer.

Every year, it said, about 50 Montrealers contract Legionnaires' disease.
https://montrealgazette.com/news/local-news/public-health-authority-warns-of-possible-legionnaires-disease-outbreak-in-lasalle

International Events of Interest

United States

Mushrooms link in 41 Salmonella cases in 10 States – California hardest hit
Source: foodpoisonjournal.com
ID: 1007908077

As of September 24, 2020, a total of 41 people infected with the outbreak strain of Salmonella Stanley have been reported from 10 states – Arizona, California, Connecticut, Georgia, Illinois, Louisiana, New Jersey, New York City, Pennsylvania and Wisconsin.

Illnesses started on dates ranging from January 21, 2020, to August 26, 2020. Ill people range in age from 2 to 74 years, with a median age of 27. Sixty-two percent of ill people are female. Of 32 ill people with information available, 4 hospitalizations have been reported. No deaths have been reported.

Epidemiologic and traceback information show that wood ear mushrooms distributed by Wismettac Asian Foods, Inc., are the likely source of this outbreak.

In interviews, ill people answered questions about the foods they ate and other exposures in the week before they became ill. Of 18 people with information, 16 (89%) reported eating ramen at a restaurant in the week before their illness started. Several people reported eating at the same ramen restaurants, showing they may be part of illness clusters.

A foodborne illness cluster is defined as two or more people who do not live in the same household who report eating at the same restaurant location, attending a common event, or shopping at the same location of a grocery store in the week before becoming ill. Investigating illness clusters can provide critical clues about the source of an outbreak. If several unrelated ill people ate or shopped at the same location of a restaurant or store within several days of each other, it suggests that the contaminated food item was served or sold there.

Four illness clusters were identified at restaurants serving ramen in three states. Eight (89%) of the nine ill people linked to restaurant clusters reported eating wood ear mushrooms or ramen containing wood ear mushrooms in the week before their illness started.

FDA and states are conducting a traceback investigation to identify the source of the wood ear mushrooms eaten by ill people. Review of records collected to date identified that Wismettac Asian Foods, Inc., supplied wood ear mushrooms (dried fungus) to the illness cluster restaurants.

The California Department of Public Health collected dried fungus at one of the restaurants linked to an illness cluster for testing. Testing identified Salmonella in a sample of dried fungus distributed by Wismettac Asian Foods, Inc. WGS analysis is being done to determine if the Salmonella identified in the dried fungus is the same as the Salmonella from ill people.

On September 24, 2020, Wismettac Asian Foods, Inc., issued a recallof all Shirakiku imported dried fungus after the California Department of Public Health found Salmonella in the product.

Restaurants should not sell or serve recalled wood ear mushrooms distributed by Wismettac Asian Foods, Inc.

Salmonella: Marler Clark, The Food Safety Law Firm, is the nation's leading law firm representing victims of Salmonella outbreaks. The Salmonella lawyers of Marler Clark have represented thousands of victims of Salmonella and other foodborne illness outbreaks and have recovered over $750 million for clients. Marler Clark is the only law firm in the nation with a practice focused exclusively on foodborne illness litigation. Our Salmonella lawyers have litigated Salmonella cases stemming from outbreaks traced to a variety of foods, such as cantaloupe, tomatoes, ground turkey, salami, sprouts, cereal, peanut butter, and food served in restaurants. The law firm has brought Salmonella lawsuits against such companies as Cargill, ConAgra, Peanut Corporation of America, Sheetz, Taco Bell, Subway and Wal-Mart.

If you or a family member became ill with a Salmonella infection, including Reactive Arthritis or Irritable bowel syndrome (IBS), after consuming food and you're interested in pursuing a legal claim, contact the Marler Clark Salmonella attorneys for a free case evaluation.

United States
Outbreak Investigation of Salmonella Stanley: Wood Ear Mushrooms - Dried Fungus (September 2020)
Source: US FDA
ID: 1007908003

The FDA, along with CDC and state and local partners, is investigating an ongoing multistate outbreak of Salmonella Stanley infections likely linked to wood ear mushrooms imported by Wismettac Asian Foods, Inc. of Santa Fe Springs, CA. Wood ear mushrooms are a dried mushroom, also commonly labelled or referred to as Kikurage, Dried Black Fungus, Dried Fungus, or Mu'er/Mu Er/Mu-Err.

In interviews, ill people answered questions about the foods they ate and other exposures in the week before they became ill. According to the CDC, of 18 people with information, 16 (89%) reported eating ramen at a restaurant in the week before their illness started. Four illness clusters were identified at restaurants serving ramen in three states. Eight (89%) of the nine ill people linked to restaurant clusters reported eating wood ear mushrooms or ramen containing wood ear mushrooms in the week before their illness started.

As part of this investigation, the California Department of Public Health collected a sample of wood ear mushrooms, imported by Wismettac Asian Foods, Inc., from one of the restaurants where ill patients reported eating. This sample was reported positive for the presence of Salmonella. This sample is undergoing genetic testing, or whole genome sequencing, to determine if the Salmonella present in the sample has the same genetic fingerprint as the outbreak strain. More information will be provided as it becomes available.

Wismettac Asian Foods, Inc. acted quickly upon being notified of the positive test result and recalled all wood ear mushrooms within shelf life on September 23, 2020. This product was labeled as Shirakiku brand Black Fungus (Kikurage) with UPC Code 00074410604305, imported from China. Product was distributed in six packs of five-pound bags to restaurants in AR, CA, CO, CT, DE, DC, FL, GA, HI, IA, IL, IN, LA, MA, MD, MI, MN, MO, MS, NC, NV, NJ, NY, OH, OR, PA, SC, TN, TX, VA, WA, WI, and Canada.

Recommendation
Wood ear mushrooms imported by Wismettac Asian Foods, Inc. were only sold to restaurants and were not available directly to consumers. Although these items have been recalled, concerned or high-risk individuals should check with their restaurant to confirm that any wood ear mushrooms that have been used or are being used are not part of this recall.

Restaurants should not sell or serve recalled wood ear mushrooms distributed by Wismettac Asian Foods, Inc. Additionally, restaurants that received recalled products should use extra vigilance in cleaning and sanitizing any surfaces that may have come in contact with recalled product, to reduce the risk of cross contamination.

Restaurants should discard and not sell or serve wood ear mushrooms if they cannot tell where they came from.

Product Images
Outbreak Investigation of Salmonella Stanley in Wood Ear Mushrooms (September 2020) - Photos of Recalled Shirakiku Dried Fungus
Recall Information
On September 23, 2020, Wismettac Asian Foods, Inc. recalled Shirakiku brand imported dried fungus. This product was labeled as Shirakiku brand Black Fungus (Kikurage) with UPC Code 00074410604305, imported from China. Product was distributed in six packs of five-pound bags to restaurants in AR, CA, CO, CT, DE, DC, FL, GA, HI, IA, IL, IN, LA, MA, MD, MI, MN, MO, MS, NC, NV, NJ, NY, OH, OR, PA, SC, TN, TX, VA, WA, and WI.

General Food Safety Tips for Dried Mushrooms

Dried mushrooms, that have not been recalled due to potential contamination, should always be reconstituted using boiling water to kill any pathogens. This advice does not apply to recalled products, which should be thrown out.

Case Counts
Total Illnesses: 41
Hospitalizations: 4
Deaths: 0
Last Illness Onset Date: August 26, 2020
States with Cases: AZ (1), CA (25), CT (1), GA (1), IL (5), LA (1), NJ (2), NY (1), PA (2), WI (2)
Product Distribution*: AR, CA, CO, CT, DE, DC, FL, GA, HI, IA, IL, IN, LA, MA, MD, MI, MN, MO, MS, NC, NV, NJ, NY, OH, OR, PA, SC, TN, TX, VA, WA, WI
*States with confirmed distribution; product could have been distributed further
https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-salmonella-stanley-wood-ear-mushrooms-dried-fungus-september-2020

United States

First-ever 'Yellow Fever' mosquito detected in Butte County

Source: krcrtv
Unique ID: 1007903736

CHICO, Calif. — For the first time in Butte County the mosquito commonly known as the yellow fever mosquito has been found.
The invasive species was discovered September 17 in northeast Chico in the area of East Avenue and Mariposa Avenue.
The Aedes aegypti mosquito has been detected previously in other areas of California, but never in Butte County. Aedes aegypti have the potential to transmit viruses such as chikungunya, dengue, yellow fever, and Zika, that are not known to be transmitted by Butte County's native mosquitoes, and to date, have not been detected in Aedes aegypti in California.
"The District is working to evaluate the extent of the infestation and we plan to do everything we can to eradicate this mosquito and to protect our residents from the potential disease risk of these invasive mosquitoes," said Matt Ball, District Manager. "Our goal is to control and eliminate this species of mosquito so that it does not become established in our community."
The same invasive species was detected in Shasta County in August.
To prevent an increase in mosquitos make sure to drain any standing water from your property.
https://krcrtv.com/news/local/first-ever-yellow-fever-mosquito-detected-in-butte-county

Turkey

A dangerous species of mosquito appeared in Turkey

Source:VZ
Unique ID: 1007899163

An Asian tiger mosquito capable of carrying yellow fever and the zika virus has begun to spread rapidly in Turkey, According to Turkish media.

Clusters of these animals were found in large areas of Istanbul, previously they were not common in Turkey, RIA Novosti reports citing HabberTurk.

According to scientists, these mosquitoes are well adapted to the new conditions.

"This species attacks all day long, especially when a person is outdoors. It is much more aggressive than other mosquitoes and can tolerate diseases such as yellow fever and the zika virus," explained Kerem Ether, an associate professor at Istanbul University.

According to him, mosquitoes can not only infect people with serious diseases, but also increase allergic reaction with their bites.

In August, Rospotrebnadzor reported that tropical bugs were seen in the European part of Russia, their number is increasing every year.

Ilya Gomyranov, a spokesperson for the Moscow State University's zoological museum, said in a commentary to the newspaper Vzglyad that such bedbugs can transmit dangerous diseases to humans.

You can comment on the materials of the newspaper Vzglyad by registering on the website of the
https://vz.ru/news/2020/9/23/1061961.html

Researches, Policies and Guidelines

United States

Acanthamoeba acquired via contaminated soil while potting plants: NEJM

Source: outbreaknewstoday.com
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Images in Clinical Medicine published today in the New England Journal of Medicine, Emory University researchers describe a case of Granulomatous Amebic Encephalitis (GAE) caused by the free-living amoeba, Acanthamoeba.

They report the 82-year-old man likely contracted the parasite via exposure to soil from potted-plant maintenance.

He was hospitalized and died after a week. An autopsy showed “liquefactive necrosis” in part of his brain.

Acanthamoeba cysts and trophozoites were detected microscopically and by PCR.

The Centers for Disease Control and Prevention (CDC) says Acanthamoeba is a microscopic, free-living ameba, or amoeba (single-celled living organism), that can cause rare, but severe infections of the eye, skin, and central nervous system. The ameba is found worldwide in the environment in water and soil.

Acanthamoeba case in Michigan with Shahzad Mian, M.D.

The three diseases caused by Acanthamoeba are:

Acanthamoeba keratitis – An infection of the eye that typically occurs in healthy persons and can result in permanent visual impairment or blindness.

Granulomatous Amebic Encephalitis (GAE) – A serious infection of the brain and spinal cord that typically occurs in persons with a compromised immune system.

Disseminated infection – A widespread infection that can affect the skin, sinuses, lungs, and other organs independently or in combination. It is also more common in persons with a compromised immune system.
http://outbreaknewstoday.com/acanthamoeba-acquired-via-contaminated-soil-while-potting-plants-nejm-82225/
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United States

Meningococcal Vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020
Source: CDC

Summary

This report compiles and summarizes all recommendations from CDC’s Advisory Committee on Immunization Practices (ACIP) for use of meningococcal vaccines in the United States. As a comprehensive summary and update of previously published recommendations, it replaces all previously published reports and policy notes. This report also contains new recommendations for administration of booster doses of serogroup B meningococcal (MenB) vaccine for persons at increased risk for serogroup B meningococcal disease. These guidelines will be updated as needed on the basis of availability of new data or licensure of new meningococcal vaccines.

ACIP recommends routine vaccination with a quadrivalent meningococcal conjugate vaccine (MenACWY) for adolescents aged 11 or 12 years, with a booster dose at age 16 years. ACIP also recommends routine vaccination with MenACWY for persons aged ≥2 months at increased risk for meningococcal disease caused by serogroups A, C, W, or Y, including persons who have persistent complement component deficiencies; persons receiving a complement inhibitor (e.g., eculizumab [Soliris] or ravulizumab [Ultomiris]); persons who have anatomic or functional asplenia; persons with human immunodeficiency virus infection; microbiologists routinely exposed to isolates of Neisseria meningitidis; persons identified to

be at increased risk because of a meningococcal disease outbreak caused by serogroups A, C, W, or Y; persons who travel to or live in areas in which meningococcal disease is hyperendemic or epidemic; unvaccinated or incompletely vaccinated first-year college students living in residence halls; and military recruits. ACIP recommends MenACWY booster doses for previously vaccinated persons who become or remain at increased risk.

In addition, ACIP recommends routine use of MenB vaccine series among persons aged ≥10 years who are at increased risk for serogroup B meningococcal disease, including persons who have persistent complement component deficiencies; persons receiving a complement inhibitor; persons who have anatomic or functional asplenia; microbiologists who are routinely exposed to isolates of N. meningitidis; and persons identified to be at increased risk because of a meningococcal disease outbreak caused by serogroup B. ACIP recommends MenB booster doses for previously vaccinated persons who become or remain at increased risk. In addition, ACIP recommends a MenB series for adolescents and young adults aged 16–23 years on the basis of shared clinical decision-making to provide short-term protection against disease caused by most strains of serogroup B N. meningitidis.

Introduction

Meningococcal disease is a serious bacterial infection that primarily presents as meningitis, bacteremia, or both. Three quadrivalent (serogroups A, C, W, and Y) meningococcal conjugate (MenACWY) vaccines and two serogroup B meningococcal (MenB) vaccines are licensed and available in the United States and are recommended by CDC's Advisory Committee on Immunization Practices (ACIP) for the prevention of meningococcal disease caused by these serogroups (Table 1) (Box 1) (1–13). Details about groups recommended to receive meningococcal vaccination, number of vaccine doses, dosing regimens, contraindications, precautions, and special circumstances are described elsewhere in this report.

This report compiles and summarizes all previously published ACIP recommendations for use of meningococcal vaccines in the United States (Box 2) (1–15). It also clarifies certain existing recommendations and contains new recommendations for administration of booster doses of MenB vaccine among persons aged ≥10 years at increased risk for serogroup B meningococcal disease. This report is intended for use by clinicians and public health providers for guidance regarding the use of meningococcal vaccines.

Methods

ACIP provides recommendations for the prevention and control of meningococcal disease in the United States. The ACIP Meningococcal Vaccines Work Group met by teleconference once per month during 2005–2020, except during brief periods of hiatus. Work group membership included voting members of ACIP, representatives of ACIP ex-officio and liaison organizations, and scientific consultants with expertise in public health, vaccinology, medical specialties, vaccine research, and assessments of vaccine efficacy and safety. Work group discussions included topics such as meningococcal disease surveillance and epidemiology and meningococcal vaccine safety, immunogenicity, effectiveness, coverage, program feasibility, and cost-effectiveness. Presentations were requested from invited experts, and published and unpublished data were discussed. These data were summarized by the work group and presented to ACIP to help establish recommendations. When evidence was lacking, the recommendations incorporated expert opinion from ACIP. Meeting minutes and information on ACIP membership and conflicts of interest are available on the ACIP website (https://www.cdc.gov/vaccines/acip). This report updates and replaces previously published ACIP recommendations for meningococcal vaccines (9–13,16).

Grading of Recommendations, Assessment, Development and Evaluation (GRADE) was adopted by ACIP in 2010 (17). Recommendations using the GRADE approach include the use of MenACWY oligosaccharide diphtheria CRM197 conjugate vaccine (MenACWY-CRM) among children aged 2–23 months at increased risk for meningococcal disease, use of a MenACWY vaccine among persons infected with human immunodeficiency virus (HIV), all MenB vaccine recommendations, and use of a MenACWY tetanus toxoid vaccine (MenACWY-TT) among persons aged ≥2 years (9–11,13). GRADE evidence tables for these recommendations are available (https://www.cdc.gov/vaccines/acip/recs/grade/table-refs.html). In 2018,

ACIP adopted the Evidence to Recommendations (EtR) framework to facilitate the assessment and ensure transparency of additional factors considered in developing vaccine recommendations, including target population values, stakeholder acceptability, and feasibility of implementation (18). Recommendations for MenB booster doses among persons aged ≥10 years at increased risk for meningococcal disease and use of MenACWY-TT among persons aged ≥2 years were further evaluated using the EtR framework (19). The EtR frameworks for these recommendations are available (https://www.cdc.gov/vaccines/acip/recs/grade/etr.html). ACIP did not use GRADE or EtR for updates of evidence related to recommendations made before implementation of these approaches.

ACIP votes were held when a new routine or risk-based recommendation was under consideration, with new age indications or dosing regimens for a vaccine, or when additional groups were identified as being at risk for meningococcal disease. An ACIP vote was not required for use of newly licensed products (e.g., MenACWY-TT in persons aged ≥2 years) when no changes in recommendations for vaccine use in terms of dosing and schedules were made.

For this report, a systematic literature search was completed to review all available evidence on the immunogenicity, effectiveness, and safety of U.S.-licensed MenACWY and MenB vaccines among age groups for which the vaccines were approved, including separate reviews to assess evidence related to MenB booster doses and MenACWY-TT. PubMed, Medline, Embase, CINAHL, Scopus, Cochrane Library, and ClinicalTrials.gov were searched for clinical trials or observational studies published during 2000–2018 without language or geographic restrictions. The following search terms were used: "(quadrivalent meningococcal conjugate or tetravalent meningococcal conjugate or meningococcal ACWY or MCV4 or MCV-4 or MenACWY or MenACWY-D or MenACWY-CRM or Menactra or Menveo or serogroup B meningococcal or meningococcal serogroup B or meningococcal B or meningococcal group B or group B meningococcal or MenB or Bexsero or MenB-4C or rMenB+OMV NZ or 4CMenB or Trumenba or rLP2086 or MenB-FHbp or FHbp or Factor H binding protein)" and "vaccin*" and "(immunogenicity or efficacy or effectiveness or impact or safety or adverse event*)." For the review specific to MenB booster vaccination, the same MenB vaccine search terms plus the term "booster" were used to capture all studies related to booster doses. To identify evidence related to MenACWY-TT, licensed after the original systematic literature search was conducted, as well as newly available evidence related to other meningococcal vaccines, search results were supplemented by data (using updated search terms to include "MenACWY-TT," "MenACYW-TT," and "MenQuadfi") published in 2019–2020 or identified by work group subject matter experts, or unpublished data provided by the vaccine manufacturers.

To further assess vaccine safety, data were evaluated from the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD), two postlicensure surveillance systems for adverse events. VAERS is a national passive public health surveillance system operated by CDC and the Food and Drug Administration (FDA) and accepts reports from anyone, including health care professionals, vaccine manufacturers, patients, and caregivers (20). Health care providers and patients are encouraged to report clinically important or unexpected adverse events, even if unsure whether the event is vaccine related, and to provide medical documentation for reports of serious adverse events (e.g., death, life-threatening health event, hospitalization, or lasting disability after vaccination) (20). VAERS can identify rare adverse events and detect possible safety problems quickly, generating vaccine safety hypotheses to be evaluated by other sources; however, VAERS data cannot be used to determine whether a vaccine caused an adverse event. VSD is a collaboration between CDC and eight health care organizations that conducts active public health surveillance and epidemiologic research about vaccine safety. VSD collects individual-level data, including medical and vaccine records, on approximately 10 million persons annually (approximately 3% of the U.S. population) (21). This allows for population-based observational studies with longitudinal follow-up that can be used to calculate rates and relative risks of vaccine adverse events. Therefore, VSD data can be used for surveillance to identify vaccine safety signals or for hypothesis testing to evaluate signals originating from other sources such as VAERS.

Background

Meningococcal disease includes the spectrum of invasive infections caused by Neisseria meningitidis, a gram-negative diplococcus. Meningococcal disease usually presents clinically as meningitis, bacteremia,

or both (22). Meningococcal disease also can present as other invasive syndromes such as bacteremic pneumonia, arthritis, and pericarditis. Noninvasive infections such as pneumonia without bacteremia, conjunctivitis, or urethritis also might occur. Meningococcal disease develops rapidly, often among previously healthy persons, and results in high morbidity and mortality. Even with appropriate antimicrobial therapy, the overall case-fatality ratio in the United States is 15%, and 10%–20% of survivors have long-term sequelae such as neurologic disability, limb or digit loss, or hearing loss (22,23).

N. meningitidis is classified into 12 serogroups according to the composition of its polysaccharide capsule; serogroups A, B, C, W, X, and Y cause most of the disease globally (24). N. meningitidis colonizes mucosal surfaces of the nasopharynx and is transmitted through direct contact with large-droplet respiratory tract secretions from patients or asymptomatic carriers. Nasopharyngeal carriage rates are highest in adolescents and young adults, who serve as reservoirs for transmission of N. meningitidis (25). Invasive disease is an infrequent consequence of nasopharyngeal colonization.

Epidemiology of Meningococcal Disease in the United States

Since the late 1990s, the incidence of meningococcal disease has steadily decreased in the United States, from 1.2 cases per 100,000 population in 1996 to an historic low of 0.1 cases per 100,000 population in 2018. During 2015–2018, approximately 360 cases occurred annually in the United States, representing an average annual incidence of 0.11 cases per 100,000 population (26). Incidence is highest among infants aged <1 year, followed by children aged 1 year and adolescents and young adults aged 16–20 years (23). During 2015–2018, the primary serogroups that caused disease were B and C, causing 42% and 26% of cases in which serogroup was known, respectively; serogroups W and Y and nongroupable strains each caused 9%–14% of cases (26). Decreases in meningococcal disease incidence began before the introduction of MenACWY and MenB vaccines and have been observed across all age groups and for the predominant disease-causing serogroups in the United States (23). Outbreaks account for approximately 5% of meningococcal disease cases across age groups in the United States (27). In recent years, several outbreaks of serogroup B meningococcal disease among university students and serogroup C meningococcal disease among men who have sex with men (MSM) have been reported (28,29).

Groups at Increased Risk for Meningococcal Disease

Risk factors for meningococcal disease include antecedent viral infection, household crowding, and smoking (30–34). In addition, certain groups are at increased risk for meningococcal disease, including the following:

•Persons with persistent complement component deficiencies: Persons who have persistent (e.g., genetic) deficiencies in the complement pathway (e.g., C3, C5–C9, properdin, factor D, or factor H) have up to a 10,000-fold increased risk for meningococcal disease (35). Persons with complement deficiencies might experience recurrent disease and inherited disorders might affect additional family members; therefore, testing for complement deficiency should be considered for patients with meningococcal disease (36–38).

•Persons who use complement inhibitors: Use of complement inhibitors (e.g., the currently licensed eculizumab [Soliris] and its long-acting derivative ravulizumab [Ultomiris] monoclonal antibody therapies that block C5) is associated with a substantially increased risk for meningococcal disease (39,40). Eculizumab use is associated with an approximately 2,000-fold increased incidence of meningococcal disease (41). Complement inhibitor recipients remain at risk for meningococcal disease even after meningococcal vaccination; therefore, CDC guidance indicates that providers could consider treating patients with antimicrobial prophylaxis for the duration of complement inhibitor treatment (42).

•Persons with anatomic or functional asplenia: Persons with anatomic or functional asplenia (including sickle cell disease) appear to be at increased risk for meningococcal disease and, compared with healthy persons, have a higher mortality rate (40%–70%) from the disease (43–45).

•Persons living with HIV infection: In studies from the United States, United Kingdom, and South Africa, persons living with HIV infection or acquired immunodeficiency syndrome have an elevenfold to twenty-four-fold increased risk for meningococcal disease (46–50). Among persons living with HIV infection, low CD4 count or high viral load are associated with greater risk (48). Most meningococcal cases reported among persons living with HIV infection in the United States are caused by serogroups C, W, or Y (47).

•Microbiologists routinely exposed to N. meningitidis isolates: The annual attack rate of laboratory-acquired meningococcal infection among microbiologists who routinely work with N. meningitidis isolates has historically been estimated to be 13 per 100,000 persons, which is manyfold higher than the rate for adults among the general population (51). This increased risk is likely related to mechanical manipulation of isolates that generates droplets or aerosols; increased risk was not observed among laboratory workers who handle clinical specimens but not isolates (51).

•Persons at increased risk during an outbreak of meningococcal disease: Approximately 5% of U.S. cases are outbreak related (27). Outbreaks can occur in community or organizational settings (52). During outbreaks, the median attack rate is up to 1,400-fold higher than in the nonoutbreak setting (27).

•Travelers to countries where meningococcal disease is hyperendemic or epidemic: Travelers to countries where meningococcal disease is hyperendemic or epidemic, such as the meningitis belt of sub-Saharan Africa, are at increased risk for exposure, and thus, disease. Historically, serogroup A was the predominant meningococcal pathogen in the meningitis belt. However, after the implementation of a meningococcal serogroup A conjugate vaccine (MenAfriVac), serogroup A disease has been nearly eliminated in the meningitis belt (53). Endemic meningococcal disease and outbreaks are now most commonly caused by serogroups C, W, and X (54).

•College students: Historically, college freshman living in residence halls were identified as being at increased risk for meningococcal disease (55). With improved control of serogroups C, W, and Y disease after widespread use of MenACWY vaccine among adolescents, the risk for meningococcal disease among college students is greatest for serogroup B, with a relative risk of 3.5 compared with persons not attending college, although serogroup B disease incidence among this population is low (0.17 cases per 100,000 population) (56). Risk factors for serogroup B meningococcal disease among undergraduate college students include age 18–20 years, attendance at a 4-year college, freshman class year, and on-campus residence (56,57). Although not assessed outside of outbreak settings, participation in a fraternity or sorority is an additional risk factor during serogroup B meningococcal disease outbreaks (57).

•Military recruits: Historically, new military recruits were identified as being at increased risk for meningococcal disease and outbreaks, most likely related to the crowded living conditions among persons originating from different geographic areas carrying diverse N. meningitidis strains (58,59).

•Men who have sex with men: Several outbreaks of serogroup C meningococcal disease have been reported among MSM in the United States (28). MSM have also been shown to be at increased risk for meningococcal disease outside of outbreaks, although the incidence of disease remains low. HIV infection might be an important factor for this increased risk in the United States, particularly in nonoutbreak settings (60).

Clinical and Public Health Management of Meningococcal Disease

Early recognition of meningococcal disease is important for prompt diagnosis and initiation of antimicrobial therapy. Symptoms of meningitis include sudden onset of high fever, headache, nuchal rigidity, altered mental status, photophobia, nausea, and vomiting. Meningococcemia might present as fever; malaise; cold hands and feet; leg or other body pain; vomiting; diarrhea; and maculopapular, petechial, or purpuric rash (61). The diagnosis of confirmed meningococcal disease is made either through isolation of N. meningitidis or detection of N. meningitidis–specific nucleic acid in a specimen obtained from a normally sterile body site (e.g., blood or cerebrospinal fluid) (62). Culture is the preferred confirmatory test because it allows for further characterization of the strain; however, serogroup-specific polymerase chain reaction testing using

a validated assay is a sensitive method for identifying N. meningitidis, particularly in situations in which antimicrobial therapy was initiated before specimen collection (63). Because N. meningitidis infections typically are severe, antibiotics should be started immediately for a patient with suspected meningococcal disease without waiting for laboratory confirmation. Several antibiotics are available for the treatment of meningococcal disease, including ceftriaxone, cefotaxime, and, when the diagnosis is confirmed, penicillin (64).

Antimicrobial chemoprophylaxis of close contacts of a patient with meningococcal disease is important to prevent secondary cases. Several antibiotics are recommended for chemoprophylaxis, including ciprofloxacin, rifampin, and ceftriaxone; azithromycin can be used in areas with sustained ciprofloxacin resistance (currently rare in the United States). Additional information on identification of close contacts and administration of chemoprophylaxis is available in CDC's Manual for the Surveillance of Vaccine-Preventable Diseases (65).

The investigation of and response to meningococcal disease outbreaks rely on comprehensive epidemiologic and laboratory investigation of cases, identification of persons at increased risk for meningococcal disease as a result of the outbreak and, in certain situations, implementation of vaccination campaigns and use of expanded antimicrobial chemoprophylaxis. Additional information is available in CDC's Guidance for the Evaluation and Public Health Management of Suspected Outbreaks of Meningococcal Disease (52).

Meningococcal Vaccines

Three quadrivalent meningococcal conjugate (MenACWY) vaccines are currently licensed and available in the United States: 1) meningococcal groups A, C, W, and Y polysaccharide diphtheria toxoid conjugate vaccine (MenACWY-D) (Menactra); 2) meningococcal groups A, C, W, and Y oligosaccharide diphtheria CRM197 conjugate vaccine (MenACWY-CRM) (Menveo); and 3) meningococcal groups A, C, W, and Y polysaccharide tetanus toxoid conjugate vaccine (MenACWY-TT) (MenQuadfi) (Table 1). Additional information is available in the package inserts (66–68).

In addition, two serogroup B meningococcal (MenB) vaccines are licensed and available in the United States: 1) MenB-FHbp (Trumenba) and 2) MenB-4C (Bexsero) (Table 1). MenB-FHbp consists of two purified recombinant lipidated FHbp antigens, one from each FHbp subfamily (A and B). MenB-4C consists of three recombinant proteins (neisserial adhesin A [NadA], factor H binding protein [FHbp] fusion protein from subfamily B, and neisserial heparin binding antigen [NhbA] fusion protein) and outer membrane vesicles (OMVs) containing outer membrane protein porin A (PorA) serosubtype P1.4. Additional information on MenB vaccines is available in the package inserts (69,70).

Two additional licensed meningococcal vaccines are no longer available in the United States: 1) a quadrivalent (serogroups A, C, W, and Y) meningococcal polysaccharide vaccine (MPSV4) (Menomune – A/C/Y/W-135) and 2) a combined Haemophilus influenzae type b and meningococcal serogroups C and Y conjugate vaccine (Hib-MenCY-TT) (MenHibrix) (71,72).

Evaluation of Efficacy of Meningococcal Vaccines

Because of the low incidence of meningococcal disease in the United States, vaccine efficacy estimates supporting U.S. licensure of the current meningococcal vaccines are based on demonstration of specific immune responses (e.g., immune correlate of protection through serum bactericidal activity [SBA]) and not direct evidence of clinical effectiveness). Protection against invasive meningococcal disease is mediated by bactericidal antibodies to meningococcal capsular polysaccharides or protein antigens in the presence of complement. This complement-dependent bactericidal activity is measured by use of an SBA assay with a human (hSBA) or baby rabbit (rSBA) complement source (73). SBA activity has been demonstrated to correlate with immunity against meningococcal disease and thus is accepted as the correlate of protection (74). Because meningococci have greater susceptibility to lysis by rabbit complement, antibody titers measured by an rSBA assay are elevated compared with those from an hSBA assay; thus, antibody titers measured by these two assays are not directly comparable (74). An hSBA titer ≥1:4 (although a threshold

of ≥1:8 also has been used to account for assay variability) or an rSBA titer ≥1:8 and/or a fourfold rise in rSBA or hSBA titers have been used to infer vaccine-mediated immunologic protection against meningococcal disease (73).

For the purposes of U.S. licensure, immunogenicity was assessed as the proportion of persons who achieved an SBA titer above a predefined threshold or fourfold rise in SBA titers for serogroups A, C, W, and Y and serogroup B strains tested. For MenACWY vaccines, efficacy was inferred using either rSBA or hSBA. For MenB vaccines, efficacy was inferred using hSBA. MenB vaccines are not expected to protect against all strains of serogroup B N. meningitidis because their mechanism of action is against subcapsular proteins and not the polysaccharide capsule (75,76). Because laboratory evaluation of vaccine efficacy against all serogroup B meningococcal strains would be impossible because of their antigenic and genetic diversity, efficacy of MenB vaccines was inferred using hSBA titers against selected strains (77).

Because MenB vaccines do not protect against all strains of serogroup B N. meningitidis, assays have been developed to provide additional insight into breadth of strain coverage. For MenB-FHbp, a flow cytometric meningococcal antigen surface expression (MEASURE) assay was developed to quantify the level of FHbp expressed in serogroup B strains through mean fluorescence intensity. On the basis of this assay, 91% of U.S. and European serogroup B strains expressed sufficient FHbp to be susceptible to MenB-FHbp–mediated bactericidal killing (75). The meningococcal antigen typing system (MATS) was developed to predict MenB-4C strain coverage using genotyping for PorA and enzyme-linked immunosorbent assays for FHbp, NhbA, and NadA. Using MATS, 91% of U.S. serogroup B meningococcal disease strains are predicted to be covered by MenB-4C, with FHbp and NhbA the greatest contributors to U.S. strain coverage (76). A complementary strain coverage prediction method using genotyping (gMATS) also has been developed (78), as has the Bexsero antigen sequence type (BAST) scheme to facilitate genomic surveillance of MenB-4C antigen variants in invasive meningococcal disease isolates (79).

Serogroups A, C, W, and Y Meningococcal Vaccines

MenACWY-D (Menactra)

MenACWY-D was first licensed in the United States in 2005. Clinical trials have demonstrated immunogenicity of MenACWY-D among persons aged 9 months–55 years, although antibody waning is observed during the 3–5 years after primary vaccination (67,80–104). Booster vaccination elicits a robust immune response, and data in adolescents demonstrate persistence for at least 4 years after a booster dose (105,106). Clinical trials have demonstrated an acceptable safety profile, with injection site pain and erythema as the most common local reactions; irritability and drowsiness are the most common systemic adverse events among infants and children, and myalgia, headache, and fatigue are the most common systemic adverse events among adolescents and adults (67,80,81,85,87–90,92–96,98–103). Most adverse events are mild to moderate and resolve within 3 days. Early postlicensure surveillance raised the concern of a potential risk for Guillain-Barré syndrome (GBS), but subsequent evaluations have not identified an increased risk for GBS after MenACWY-D vaccination (107–110). No other vaccine safety concerns have been identified in postlicensure surveillance (111–114).

MenACWY-D Immunogenicity

Infants and Children

In clinical trials among infants who received MenACWY-D as a 2-dose series at ages 9 and 12 months, 89%–96% achieved an hSBA titer ≥1:8 against serogroup A, ≥98% against serogroup C, 81%–92% against serogroup W, and 95%–97% against serogroup Y 1 month after completion of the series (80,98). Administration of MenACWY-D simultaneously with routine vaccines did not result in reduced immune responses to meningococcal serogroups A, C, W, or Y or measles, mumps, rubella, or varicella antigens; however, when MenACWY-D was administered simultaneously with seven-valent pneumococcal conjugate vaccine (PCV7) (Prevnar), noninferiority criteria were not met for three of seven pneumococcal serotypes (98). By 3 years after primary series completion, substantial MenACWY-D waning occurred, with 13%–46%

of recipients having an hSBA titer ≥1:8 across serogroups, although this proportion increased to ≥98% 1 month after a single booster dose (80).

Among toddlers receiving a 2-dose primary series at ages 12 and 15 months, 85% achieved an hSBA titer ≥1:8 against serogroup A and ≥96% against serogroups C, W, and Y at 1 month after the primary series (80). In another study in which MenACWY-D was administered at ages 12 and 18 months, ≥96% achieved rSBA titers ≥1:8 for all serogroups (95). In this study, administration of MenACWY-D simultaneously with routine vaccines did not result in reduced immune responses to meningococcal serogroups A, C, W, or Y or tetanus, diphtheria, pertussis, poliovirus, or H. influenzae type b antigens.

Among children aged 2–10 years, the rate of seroresponse (defined as a greater than fourfold rise in hSBA or a titer ≥1:8 among persons with baseline titers <4) was highest for serogroup A (80%) and lower for serogroups C, W, and Y (42%–57%) at 1 month after a single dose (88). Studies using rSBA demonstrated a higher proportion of seroresponse across serogroups (≥86%) using different thresholds (either a greater than fourfold rise in titers among persons with baseline titers <1:8 or a titer ≥1:8) (91,93,96,104). Among children aged 4–6 years, administration of MenACWY-D simultaneously with routine vaccines did not result in reduced immune response to meningococcal serogroups A, C, or W or diphtheria, tetanus, or poliovirus antigens; however, the noninferiority criteria were not met for serogroup Y and one pertussis antigen (anti-fimbriae) (67). Because no clinical correlates of protection are available for pertussis antigens, the clinical significance of this finding is unknown. When MenACWY-D was administered 30 days after diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine (DAPTACEL), significantly lower geometric mean titers (GMTs) were observed for all meningococcal serogroups (67). Among children aged 4–6 years vaccinated previously at age 2–3 years, the proportions maintaining an rSBA titer ≥1:128 were 75%, 52%, 61%, and 90% for serogroups A, C, W, and Y, respectively (97).

Adolescents and Adults

Among adolescents and adults aged 10–55 years, 64%–71% achieved an hSBA titer ≥1:8 against serogroup A, 72%–99% against serogroup C, 64%–90% against serogroup W, and 39%–82% against serogroup Y at 1 month after vaccination with a single dose (81,87,89,99). In studies assessing immunogenicity using rSBA, ≥80% and ≥88% achieved seroprotection across serogroups when the thresholds of ≥1:128 and ≥1:8 were used, respectively (85,90,92,102,104). Administration of MenACWY-D simultaneously with routine vaccines did not result in reduced immune responses to meningococcal serogroups A, C, W, or Y or tetanus, diphtheria, pertussis, human papillomavirus (HPV), MenB-FHbp, or typhoid antigens (67,94,100–103).

Persistence studies conducted among adolescents and adults demonstrated antibody waning after primary vaccination; however, serogroup-specific degree of waning varied between the studies. In one study, antibody waning was observed for all serogroups, particularly serogroup A, by 22 months postvaccination and titers remained stable thereafter at 3 and 5 years postvaccination; 21%–34% of recipients achieved an hSBA titer ≥1:8 for serogroup A, 58%–62% for serogroup C, 71%–74% for serogroup W, and 53%–54% for serogroup Y between 22 months and 5 years postvaccination (83,84,86). In another study, antibody waning was observed by 4–6 years postvaccination but was more marked for serogroups C and Y (44% and 39% achieved an hSBA titer ≥1:8, respectively) compared with serogroups A and W (65% and 69%, respectively) (105). In a separate study, serogroup A waning was most pronounced, although for the other serogroups the proportion of recipients with hSBA titers ≥1:8 was higher than that observed in previously mentioned studies and was stable at 1, 3, and 5 years postvaccination with 32%–44% seroprotected against serogroup A, 73%–81% against serogroup C, 76%–85% against serogroup W, and 87%–91% against serogroup Y (82). Thus, although antibody waning after primary vaccination of adolescents and adults was observed across studies, time points assessed and patterns of waning by serogroup were not consistent. In a study of adolescents who received a booster dose of MenACWY-D, ≥99% achieved hSBA titers ≥1:8 against all serogroups at 1 month postvaccination; this proportion remained ≥90% 4 years later (105,106).

MenACWY-D Safety

Clinical Trials

Among infants vaccinated at ages 9 and 12 months and toddlers vaccinated at ages 12 months and 15 or 18 months, the most commonly reported local reactions after either of the doses were injection site pain (35%–59%) and erythema (23%–43%) (80,95,98). The most commonly reported systemic adverse events were irritability (49%–72%) and drowsiness (27%–44%); fever was reported in 11%–50% of recipients. Adverse events among infants were similar when MenACWY-D was administered alone or simultaneously with other vaccines (98). After receipt of a booster dose 3 years after vaccination as an infant, rates of local and systemic adverse events were similar to those observed for the primary series (115). Similar adverse events were observed among children aged 2–10 years after a single dose, although typically at a slightly lower rate; injection site pain (32%–48%), induration (11%–22%), and erythema (10%–30%) were the most commonly reported local reactions, and drowsiness (9%–26%), irritability (7%–35%), and fever (2%–11%) were the most common systemic adverse events (67,88,93,96).

Among adolescents and adults aged 11–55 years who received a single dose, injection site pain (31%–69%) was the most common local reaction, followed by induration (9%–20%), erythema (3%–20%), and swelling (1%–14%) (81,85,87,89,90,92,99,102). Myalgia (15%–26%), headache (11%–45%), fatigue or malaise (10%–28%), and diarrhea or other gastrointestinal symptoms (11%–17%) were the most commonly reported systemic adverse events; fever was observed in <8%. Similar types and rates of adverse events were observed after a booster dose administered 4 years later (105). In general, MenACWY-D administered simultaneously with HPV vaccine, tetanus and reduced diphtheria toxoids and acellular pertussis vaccine (Tdap), MenB-FHbp, or typhoid vaccines was well tolerated, although rates of some adverse events (e.g., headache and fatigue) were slightly higher with simultaneous administration compared with MenACWY-D administered alone (67,94,100–103). Across age groups, whether MenACWY-D was administered alone or simultaneously with other vaccines, adverse events were mild to moderate and typically resolved within 3 days.

Postlicensure Safety Monitoring

After licensure of the vaccine in 2005, several cases of GBS after MenACWY-D vaccination were reported to VAERS (116). ACIP reviewed the available data and determined that the benefits of meningococcal vaccination outweighed the small potential increased risk for GBS (107). By 2010, two retrospective evaluations had been conducted in which no GBS cases were observed in the 6 weeks after 2.3 million doses of MenACWY-D were administered (108,110). The excess risk for GBS after vaccination, if it exists, is estimated to be <0.66 cases per 1 million adolescents vaccinated (110). In 2010, ACIP voted to remove the precaution for persons with a history of GBS from the ACIP recommendations, although it continues to be listed as a precaution in the package insert (16,67). Evaluations of VSD data through 2014 and VAERS data through 2016 have since been conducted, identifying no new GBS-related concerns (CDC, unpublished data, 2020).

In addition to assessing risk for GBS, data from VAERS and VSD have been evaluated to assess for other potential postvaccination adverse events. In a comprehensive review of VAERS reports received from 2005 through June 2016, during which approximately 70 million MenACWY-D doses were distributed, no new safety concerns were identified (CDC, unpublished data, 2020). A total of 13,075 adverse events related to MenACWY-D were reported, of which 846 (6.5%) were serious. Reports predominantly related to adolescents aged 11–18 years simultaneously vaccinated with MenACWY-D and other vaccines. The most commonly reported events were injection site erythema, fever, and headache, consistent with findings from clinical trials.

An analysis of VSD during 2005–2014, when 1.4 million doses, including 245,000 booster doses, were administered, was conducted to evaluate prespecified outcomes (CDC, unpublished data, 2020). Although rates of syncope and medically attended fever increased after MenACWY-D vaccination, no new safety concerns were identified. Furthermore, tree-temporal scan data mining through VSD of primary doses administered to 1.2 million adolescents aged 11–18 years during the same period identified no new or unexpected adverse events within 42 days after MenACWY-D administration (114). Several smaller studies, including VSD- and manufacturer-sponsored studies conducted during 2005–2014, similarly did

not identify any additional safety concerns for MenACWY-D among infants, children, adolescents, or adults (111–113).

MenACWY-CRM (Menveo)

MenACWY-CRM was first licensed in the United States in 2010. MenACWY-CRM has been demonstrated to be immunogenic among persons aged 2 months–55 years (88,89,99,117–130). Antibody waning occurs by 3–5 years after primary vaccination, and booster vaccination elicits a robust immune response (83,84,131–133). No consistent or clinically relevant concerns about MenACWY-CRM administered simultaneously with other vaccines have been identified (134–136). Clinical trials have demonstrated an acceptable safety profile, with injection site pain and erythema as the most common local reactions (88,118–124,126,127,129,137). Irritability and sleepiness were the most commonly reported systemic adverse events among infants and toddlers. Among children, irritability, myalgia, headache, and sleepiness were the most commonly reported systemic adverse events, whereas myalgia, headache, and fatigue were the most commonly reported systemic adverse events among adolescents and adults. Most adverse events were mild to moderate and resolved within 3 days. One study observed an increased risk for Bell's palsy among adolescents after MenACWY-CRM vaccination, although this was based on a small number of cases and the importance of this finding is uncertain (138). No additional safety concerns have been identified in postlicensure surveillance, although administration errors appear more common than with other vaccines, predominantly because of the need to reconstitute the vaccine using lyophilized and liquid components (139,140).

MenACWY-CRM Immunogenicity

Infants and Children

Among infants vaccinated at ages 2, 4, and 6 months with MenACWY-CRM and routine vaccines, 76%–89% achieved an hSBA titer ≥1:8 for serogroup A and ≥94% for serogroups C, W, and Y 1 month after the third dose (119,124,128,130,141). Antibody titers waned by age 12 months, particularly for serogroup A. Following the fourth dose in the infant series at age 12–17 months, the proportions of infants with an hSBA titer ≥1:8 were 89%–96% for serogroup A and ≥95% for serogroups C, W, and Y. Administration of MenACWY-CRM simultaneously with routine vaccines did not result in reduced immune responses to meningococcal serogroups A, C, W, or Y or diphtheria, tetanus, hepatitis B, poliovirus, measles, mumps, rubella, varicella, H. influenzae type b, or most pneumococcal antigens (136). For the few pneumococcal serotypes for which noninferiority criteria were not met, results were not consistent across studies and age of administration (136). Noninferiority was not consistently met for pertussis antigens across studies when MenACWY-CRM was administered with routine vaccines; however, the clinical relevance is unclear because of the lack of clinical correlates of protection for pertussis antigens. By age 2 years, or 1 year after completion of a 4-dose MenACWY-CRM series, 88%–89% achieved an hSBA titer ≥1:8 for serogroups W and Y, 61% for serogroup C, and 39% for serogroup A (141). By age 40 months, most children still had an hSBA titer ≥1:8 for serogroups W and Y (76% and 67%, respectively), although this proportion was only 34% for serogroup C and 10% for serogroup A. By age 60 months, similar but slightly lower proportions were observed; following a single booster dose, ≥96% of recipients achieved hSBA titers ≥1:8 across all serogroups.

After a 2-dose series among older infants and toddlers at either ages 7–9 months and 12 months or 12 and 15 months, the proportions who achieved an hSBA titer ≥1:8 1 month after the second dose were 88%–97% for serogroup A and ≥96% for serogroups C, W, and Y (125,130). Administration of MenACWY-CRM simultaneously with routine vaccines did not result in reduced immune responses to meningococcal serogroups A, C, W, or Y or measles, mumps, rubella, or varicella antigens (136). Among children who received the 2-dose primary series at ages 12–13 and 15 months, serogroup-specific antibody waning patterns similar to those among infants also were observed; however, the proportion of recipients with an hSBA titer ≥1:8 was higher at age 40 months (85%, 79%, 55%, and 31% for serogroups W, Y, C, and A, respectively) among this group (131). Similar results were observed by age 60 months; after a single booster, all subjects achieved hSBA titers ≥1:8 for all serogroups (131).

Among children who received a single dose at age 2–10 years, the proportions who achieved hSBA titers ≥1:8 (≥1:4 in one study) were 72%–89% for serogroup A, 68%–94% for serogroup C, 90%–96% for serogroup W, and 65%–91% for serogroup Y (88,118,120,121,123,126). No data are available on MenACWY-CRM administered simultaneously with routine vaccines among this age group. Twelve months after the primary dose, the proportion with seroprotective titers declined, particularly for serogroups A and C (118,123). Five years after a primary dose administered at age 2–10 years, 14%–22% of recipients remained seroprotected against serogroup A, 32%–56% against serogroup C, 74%–80% against serogroup W, and 48%–53% against serogroup Y; these proportions were lower among those vaccinated at age 2–5 years compared with age 6–10 years. One month after a single booster dose, all recipients achieved hSBA titers ≥1:8 for all serogroups (132).

Adolescents and Adults

One month after a single MenACWY-CRM dose among adolescents and adults aged 11–75 years, 66%–92% of recipients achieved an hSBA titer ≥1:8 for serogroup A, 79%–98% for serogroup C, 84%–99% for serogroup W, and 79%–96% for serogroup Y (89,99,117,120–122,126,127,129). In one study that reported immunogenicity separately for adults aged ≥55 years, those aged 56–65 years had results similar to those aged 19–55 years (129). Administration of MenACWY-CRM simultaneously with other vaccines did not result in reduced immune responses to meningococcal serogroups A, C, W, or Y or tetanus, diphtheria, HPV, hepatitis A, hepatitis B, typhoid, yellow fever, Japanese encephalitis, or rabies antigens (117,135,142–146). After simultaneous administration of MenACWY-CRM and MenB-4C, a robust immune response to meningococcal serogroups A, C, W, and Y and to select meningococcal serogroup B strains was observed, although the majority of persons had high prevaccine hSBA titers across serogroups (134). Noninferiority criteria were not met for two pertussis antigens (i.e., pertussis toxoid and pertactin) when MenACWY-CRM and Tdap were administered simultaneously, although the clinical relevance of this is unclear (135).

By 12–22 months postvaccination, substantial antibody waning was observed for serogroup A, though the majority of recipients remained seroprotected for serogroups C, W, and Y (86,122). After this initial decline, hSBA titers remained relatively stable at 3 and 5 years postvaccination, with 28%–32% of recipients having an hSBA titer ≥1:8 against serogroup A, 59%–76% against serogroup C, 72%–82% against serogroup W, and 64%–76% against serogroup Y (83,133). One month after a single MenACWY-CRM booster dose administered at 3–6 years after the primary dose, ≥94% of subjects achieved an hSBA titer ≥1:8 across all serogroups. Booster vaccination elicited a robust immune response whether MenACWY-CRM or MenACWY-D was used for the primary dose (83,147). By 2 years after the booster dose, the proportion of recipients with an hSBA titer ≥1:8 decreased to 79% for serogroup A but remained at ≥95% for serogroups C, W, and Y (84).

MenACWY-CRM Safety

Clinical Trials

Among infants and toddlers vaccinated with a MenACWY-CRM series (4-dose and 2-dose series, respectively) administered with routine vaccines, injection site pain (19%–39%) and erythema (12%–22%) were the most common local reactions after the third or fourth infant doses and second toddler dose (119,124,137,141). Irritability (36%–50%), sleepiness (22%–31%), and decreased appetite (15%–20%) were the most common systemic adverse events; fever was reported in 5%–9% of recipients. Reactogenicity among infants and toddlers vaccinated with a 4- or 2-dose series, respectively, did not increase with subsequent MenACWY-CRM doses. Among children aged 2–10 years vaccinated with a single dose, injection site pain (<40%) and erythema (<32%) were the most commonly reported local reactions (88,118,120,121,123,126). Irritability was reported in 7%–26%, myalgia in <29%, headache in <21%, and fatigue in <21%. Adverse events were similar whether vaccination was administered at ages 2–5 or 6–10 years. Adverse events were similar after a booster dose administered 5 years after primary vaccination (132).

Among adolescents and adults aged 11–75 years who received a single MenACWY-CRM dose, injection site pain occurred in 8%–54%, erythema in <39%, and induration in <24%. Commonly reported systemic adverse events include headache (8%–41%), myalgia (<43%), and fatigue (3%–23%) (99,120–122,126,127,129,148). When MenACWY-CRM was administered simultaneously with HPV and Tdap vaccines, headache, malaise, myalgia, and arthralgia occurred more often than when MenACWY-CRM was administered alone (117). In addition, adverse events after a booster dose administered 4–6 years after primary vaccination were similar to those among persons receiving a first dose. Across age groups, whether MenACWY-CRM was administered alone or simultaneously with other vaccines, adverse events were mild to moderate and typically resolved within 3 days.

Postlicensure Safety Monitoring

In a manufacturer-sponsored cohort study of approximately 49,000 vaccinated adolescents aged 11–21 years with a self-controlled case series analysis, a statistically significant increased risk for Bell's palsy during the 84 days after vaccination was observed when MenACWY-CRM was administered simultaneously with other vaccines but not when MenACWY-CRM was administered alone (138). However, this finding was based on only eight patients, most of whom received simultaneous vaccine administration, and several were noted to have had conditions or infections that might precede Bell's palsy. Thus, the importance of this finding remains uncertain. No other safety signals were observed among the other predefined events of interest in this evaluation (138). No increased risk for Bell's palsy or any other new safety concerns were observed in smaller studies conducted in the same health system among children aged 2 months–10 years (140,149).

A comprehensive review of VAERS reports from 2010 through 2015, during which 8.2 million MenACWY-CRM doses were distributed, was conducted with no new safety concerns identified (139). A total of 2,614 reports about MenACWY-CRM were received, primarily related to adolescents aged 11–18 years in whom MenACWY-CRM was administered simultaneously with other vaccines. Reported adverse events were consistent with the findings from prelicensure studies. The reporting rate of GBS or Bell's palsy was proportionate to the rate reported for other vaccines. However, administration errors were reported more commonly for MenACWY-CRM, predominantly because of administration of only one component (most commonly the liquid component) rather than reconstituting the vaccine by mixing the liquid and lyophilized components together before administration.

MenACWY-TT (MenQuadfi)

MenACWY-TT was first licensed in the United States in 2020 for the prevention of meningococcal disease caused by serogroups A, C, W, and Y in persons aged ≥2 years (68). As a result, relatively limited data on MenACWY-TT safety and immunogenicity are available compared with other licensed meningococcal conjugate vaccines. MenACWY-TT has been administered to nearly 5,000 persons aged ≥2 years to date through clinical trials, with demonstrated immunogenicity in this age group and elicitation of a boost response among adolescents vaccinated with MenACWY-TT who previously received MenACWY-D or MenACWY-CRM (68,150–155). No clinically relevant concerns about MenACWY-TT administered simultaneously with HPV or Tdap vaccines among adolescents have been identified (151). Clinical trials have demonstrated an acceptable safety profile, with injection site pain as the most common local adverse event, and myalgia, headache, and malaise as the most commonly reported systemic adverse events across age groups (68,150–155). Most adverse events were mild to moderate (68,150–155).

MenACWY-TT Immunogenicity

Infants and Children

Because MenACWY-TT is currently only licensed for persons aged ≥2 years in the United States, immunogenicity and safety data for children aged <2 years are not presented in this report. Among children who received a single dose at age 2–9 years, the proportions who achieved hSBA titers ≥1:8 1 month after vaccination were 86% for serogroup A, 98% for serogroup C, 95% for serogroup W, and 99% for serogroup Y (155). MenACWY-TT seroresponse rates were demonstrated to be noninferior to those observed for

MenACWY-CRM (155). No data are available on MenACWY-TT administered simultaneously with routine vaccines or on persistence of the immune response to MenACWY-TT among this age group; data will be reviewed as they become available to inform vaccine recommendations.

Adolescents and Adults

One month after a single MenACWY-TT dose among adolescents and adults aged 10–55 years, the proportions who achieved hSBA titers ≥1:8 were 94%–96% for serogroup A, 94%–99% for serogroup C, 95%–99% for serogroup W, and 97%–99% for serogroup Y (151,154). Among adults aged ≥56 years, these proportions were 89%–94%, 75%–90%, 77%–80%, and 81%–92% for serogroups A, C, W, and Y, respectively (152,153). Across these age groups, MenACWY-TT seroresponse rates were noninferior to those of the comparator meningococcal vaccines (68,151,153). MenACWY-TT administered simultaneously with HPV and Tdap vaccines in adolescents did not result in reduced immune responses to meningococcal serogroups or tetanus, diphtheria, or HPV antigens (151). Noninferiority criteria were not met for three pertussis antigens when MenACWY-TT and Tdap were administered simultaneously, although the clinical relevance of this is unclear. No data are available on persistence of the immune response to MenACWY-TT. When available, data will be reviewed to inform booster dose recommendations for persons primed with MenACWY-TT. Among adolescents and adults aged ≥15 years primed with MenACWY-D or MenACWY-CRM 4–10 years previously, >99% achieved an hSBA titer ≥1:8 across all serogroups at 1 month after booster vaccination with MenACWY-TT (150).

MenACWY-TT Safety

Clinical Trials

Among children aged 2–9 years vaccinated with a single MenACWY-TT dose, injection site pain occurred in 39%, erythema in 23%, and swelling in 14%; systemic adverse events included malaise in 21%, myalgia in 20%, headache in 13%, and fever in 2% within 7 days of vaccine administration (68). Among adolescents and adults aged 10–55 years, the most common local adverse event was injection site pain (35%–45%); erythema and swelling occurred in 5% and 4%–5%, respectively (68,151). Systemic adverse events included myalgia (27%–36%), headache (27%–30%), and malaise (19%–26%); fever occurred in 1% (68,151). Rates of local and systemic adverse events were typically similar in adults aged ≥56 years compared with other age groups: injection site pain (26%–31%), erythema (5%–12%), swelling (5%–8%), myalgia (22%–35%), headache (19%–24%), malaise (15%–22%), and fever (2%). When MenACWY-TT was administered simultaneously with HPV and Tdap vaccines in adolescents, rates of local and systemic adverse events were typically similar to those when MenACWY-TT was administered alone, although myalgia occurred more frequently (151). In addition, adverse events after a MenACWY-TT booster dose administered 4–10 years after primary vaccination with either MenACWY-D or MenACWY-CRM were similar to those among persons receiving a first MenACWY-TT dose (150). Across age groups, whether MenACWY-TT was administered alone or simultaneously with other vaccines, adverse events were mild to moderate (68,150–155).

Postlicensure Safety Monitoring

Given the recent licensure of MenACWY-TT, no postlicensure data were available at the time of publication of this report. Data from VAERS and VSD will be monitored as part of postlicensure safety monitoring. (See Reporting of Vaccine Adverse Events for information on how to report MenACWY-TT adverse events to VAERS.)

MenACWY Vaccine Immunogenicity and Safety in Persons with Underlying Medical Conditions

Complement-mediated bactericidal activity is important for protection against meningococcal disease; opsonophagocytic killing elicited by meningococcal antibodies is another defense against infection and is the presumed primary mechanism for vaccine-induced protection against meningococcal disease among persons with complement deficiency (35,156). No data about immunogenicity of U.S.-licensed MenACWY vaccines (MenACWY-D, MenACWY-CRM, or MenACWY-TT) are available for persons with complement

deficiency. Antibody titers after vaccination with MPSV4, a vaccine that is no longer available in the United States, are similar among persons with late complement deficiency compared with healthy persons and the antibodies produced are capable of eliciting opsonophagocytosis; however, antibody titers might wane more rapidly among persons with complement deficiency and higher antibody levels might be needed for opsonophagocytosis to function (35,157–160). Data are lacking to establish the efficacy of meningococcal conjugate vaccines among persons with complement deficiency. Thus, persons with complement deficiency are at increased risk for meningococcal disease even if they develop antibodies postvaccination (66–68).

Limited data are available about efficacy of meningococcal vaccines among persons taking complement inhibitors. However, some studies suggest that opsonophagocytic killing of meningococci in the presence of eculizumab in sera from persons vaccinated with MenACWY either does not occur or is insufficient to prevent meningococcal proliferation (161). In addition, reports of meningococcal disease despite recent vaccination among persons taking eculizumab indicate that meningococcal vaccines do not provide complete protection among persons taking complement inhibitors, even if antibodies develop after vaccination (42,66–68,161).

Although no data are available for U.S.-licensed MenACWY vaccines (MenACWY-D, MenACWY-CRM, or MenACWY-TT), adults with anatomic asplenia had a reduced immunologic response compared with healthy persons after 1 dose of a serogroup C meningococcal conjugate vaccine; after a second dose, most persons achieved seroprotection (162–164). Among children and adolescents vaccinated with a conjugate MenACWY-TT vaccine licensed outside the United States, similar immune responses were observed in children with functional or anatomic asplenia compared with healthy controls after each of 2 doses (165). However, antibodies appear to wane rapidly after serogroup C meningococcal conjugate vaccination among children with functional asplenia due to sickle cell disease, particularly among those who received primary vaccination at age <2 years (166).

Among adolescents with HIV infection, immunogenicity to MenACWY-D is reduced compared with adolescents without HIV infection. By 4 weeks postvaccination with a single dose, 52%–73% of HIV-infected adolescents had a greater than fourfold increase in rSBA across the meningococcal serogroups. Lower CD4 percentage, higher viral load, and a more advanced clinical stage were inversely associated with seroprotection against serogroup C (167). By 72 weeks subsequent to a second dose, a significantly greater proportion of adolescents with a CD4 percentage ≥15% had seroprotective rSBA titers, although this proportion was lesser for serogroup C than other serogroups, compared with those with a CD4 percentage of <15%, among whom seroprotection rates for all serogroups was reduced (168). Among children aged 2–10 years with HIV infection and a CD4 percentage ≥25%, antibody titers against serogroup C waned substantially by 72 weeks after vaccination (169). Similar trends were observed subsequent to vaccination of HIV-infected children and adolescents with serogroup C meningococcal conjugate vaccine (170–173).

Although data are limited, vaccination of persons with asplenia or HIV infection appears to be safe and well tolerated, with similar types of adverse events as reported among healthy controls or during clinical trials (165,167,169,171). Among HIV-infected children and adolescents vaccinated with MenACWY-D, rates of adverse events typically were lower than those reported during clinical trials of healthy children and adolescents, although these lower adverse event rates were not consistently observed among those vaccinated with a serogroup C meningococcal conjugate vaccine (80,167,169–171). Among children with asplenia who received a conjugate MenACWY-TT vaccine licensed outside the United States, an acceptable safety profile was observed among all age groups, although higher rates of adverse events were reported compared with healthy controls; however, the small study size limits the interpretation of this finding (165,170,171).

MenACWY Vaccines in Pregnant Women

Adverse outcomes (e.g., spontaneous abortion or birth defects) are risks for all pregnancies, occurring in approximately 15%–20% and 3%, respectively, of clinically recognized pregnancies in the United States (174,175). Although evidence is limited, rates of these outcomes after MenACWY vaccination during

pregnancy are consistent with the estimated background rates, and no additional concerning maternal or neonatal safety patterns have been identified (66,67,112,139,176,177).

No controlled trials have been conducted to specifically assess the safety of meningococcal vaccination among pregnant women and birth outcomes of vaccinated women. However, among approximately 2,000 pregnant Malian women vaccinated during the third trimester with MenACWY-D as a control group in an influenza vaccine trial, rates of local and systemic adverse events were lower than those observed during MenACWY-D clinical trials of adolescents and adults and serious obstetric and nonobstetric adverse events were rare, with similar rates between MenACWY-D and influenza vaccination groups (176). In the MenACWY-D vaccinated group, 98% of pregnancies resulted in live births, and among infants, 0.3% had low birthweight and 0.2% had a congenital malformation; no differences in these outcomes were observed among women who received influenza vaccine.

Among approximately 5,000 adolescent or adult females enrolled in MenACWY clinical trials, pregnancy was reported in 43 women during the 6 months postvaccination (37 who received MenACWY-CRM and six who received MenACWY-D) (66,67). Of these, seven (19%) MenACWY-CRM recipients reported spontaneous abortion (estimated dates of conception were 5 days before vaccination for one woman, 6–17 weeks postvaccination for five women, and 6 months postvaccination for one woman). Congenital anomaly (hydrocephalus) was reported in the infant of one MenACWY-D recipient with an estimated conception date 15 weeks after vaccination.

Although data are limited, no concerning safety signals have been identified through postlicensure surveillance. In reviews of VAERS, 127 pregnancy-associated reports were identified during the periods evaluated: 113 for MenACWY-D (2005–2011) and 14 for MenACWY-CRM (2010–2015); the differences in number of reports by vaccine type probably reflect differences in numbers of doses administered during these periods (139,177). The majority of vaccine administrations occurred during the first trimester. Among the 113 pregnant women who received MenACWY-D, spontaneous abortion was reported in 17% and congenital anomaly was reported in <1% of VAERS reports (177). Following MenACWY-CRM vaccination in pregnancy, only three VAERS reports had information on birth outcome, with no adverse events reported (139). Among patients in a large health care organization, one spontaneous abortion was identified among 18 MenACWY-D exposures during pregnancy with known outcome (112).

Manufacturers of MenACWY vaccines maintain registries that monitor pregnancy outcomes of women exposed to MenACWY during pregnancy. Among 87 pregnant women exposed to MenACWY-D during 2005–2016 from 30 days before or at any time during pregnancy who had known pregnancy outcome and who were enrolled in the registry before outcome being known, spontaneous abortion was reported in 7% and major congenital anomalies in 2% (67). Among 82 pregnant women exposed to MenACWY-CRM during 2014–2017 from 28 days before or at any time during pregnancy who had known outcome, spontaneous abortion was reported in 12% and congenital anomaly in 4% (GlaxoSmithKline, unpublished data, 2019). No information is available from the MenACWY-TT pregnancy registry because of the recent licensure of the vaccine.

Effectiveness of MenACWY Vaccines

Overall vaccine effectiveness of a single dose of MenACWY-D against meningococcal disease caused by serogroups A, C, W, or Y among adolescents in the United States is estimated at 69% (95% confidence interval [CI]: 51%–80%) in the 8 years after vaccination: 77% (95% CI: 57%–88%) against serogroup C and 51% (95% CI: 1%–76%) against serogroup Y (178). Effectiveness was 79% (95% CI: 49%–91%) in the first year but decreased to 69% (95% CI: 44%–83%) 1 to <3 years postvaccination and 61% (95% CI: 25%–79%) 3 to <8 years postvaccination. No data are available on the effectiveness of MenACWY-CRM or MenACWY-TT.

Vaccination and Meningococcal Disease Incidence

Measuring the association between adolescent MenACWY vaccination on rates of meningococcal disease has been challenging because of the low and decreasing incidence of meningococcal disease among all

age groups. However, from MenACWY introduction through 2017, adolescents experienced the greatest percentage decreases (>90%) in meningococcal disease incidence due to serogroups C, W, or Y combined compared with other age groups (179). In the setting of 85% coverage with at least 1 dose of MenACWY-D or MenACWY-CRM among U.S. adolescents aged 13–17 years and 44% coverage with at least 2 doses among adolescents aged 17 years by 2017, a twofold to threefold increase in the rate of decline in incidence was observed during the postvaccination period compared with the prevaccination period among adolescents, suggesting that vaccination with MenACWY-D or MenACWY-CRM is associated with reductions in disease rates in adolescents (179,180). No data are available for MenACWY-TT.

Vaccination and Oropharyngeal Carriage

Although vaccination with a serogroup C meningococcal conjugate vaccine in Europe and a serogroup A meningococcal conjugate vaccine in sub-Saharan Africa has been associated with reductions in oropharyngeal carriage of these N. meningitidis serogroups and resulted in herd immunity in the population (181–183), data are limited for MenACWY vaccines. In the United States, carriage prevalence of meningococcal serogroups C, W, or Y combined among college students in the setting of high MenACWY vaccination coverage is now extremely low (<1%); however, no direct evidence exists that this low prevalence is a result of vaccination (184–186). In a small observational study of Polish military recruits, those vaccinated with a MenACWY vaccine 1–3 years earlier had lower rates of meningococcal carriage compared with unvaccinated recruits (187). In a randomized controlled trial of United Kingdom university students, those who received MenACWY-CRM had significantly lower carriage prevalence than controls for serogroup Y (39% carriage reduction) and serogroups C, W, and Y combined (36% carriage reduction) at 2 months postvaccination, although no differences in carriage acquisition rates were observed (188). In contrast, in a study conducted in a different United Kingdom university population vaccinated with MenACWY-CRM in response to rapid expansion of a serogroup W clone in England, serogroup W carriage of this clone increased despite relatively high vaccination coverage (189). However, because carriage acquisition among university students is known to rapidly increase at the beginning of the academic year (190), the majority of serogroup W transmissions might have occurred simultaneously with vaccination activities (i.e., during September).

Cost-Effectiveness of MenACWY Vaccines

Cost-effectiveness of MenACWY vaccines in the United States was last assessed in 2010 using Monte Carlo simulation (191). In this evaluation, cost per quality-adjusted life year (QALY) of vaccinating at ages 11 and 16 years was similar to vaccinating at either age 11 or 15 years ($212,000–$256,000), although the estimated number of cases and deaths averted among the vaccinated cohort was substantially higher with a 2-dose strategy (184 and 22, respectively) compared with a single-dose strategy (94–115 and 11–14, respectively) (16).

Serogroup B Meningococcal Vaccines

MenB-FHbp (Trumenba)

MenB-FHbp is only licensed for persons aged 10–25 years in the United States; therefore, immunogenicity and safety data for children aged <10 years are not presented in this report. Available data for this age group have recently been summarized elsewhere (192).

Clinical trials have demonstrated that although vaccination of adolescents and young adults with either a 2- or 3-dose schedule of MenB-FHbp is immunogenic, antibody titers wane substantially by 1 year postvaccination and then remain stable for up to 4 years (94,193–199). Subsequent to booster vaccination 4 years after primary series completion, a robust response is observed and persistence at 26 months after the booster dose is superior to the response at a comparable period after primary series completion for both 2-dose and 3-dose primary series recipients (19,200). No clinically relevant concerns related to MenB-FHbp administered simultaneously with other vaccines have been identified (94,196,201). MenB-FHbp is safe and well tolerated, although more reactogenic than MenACWY (94,194–199,201). In clinical trials, the most common local reactions were injection site pain, induration, and erythema, and the most common

systemic adverse events were headache, fatigue, and myalgia. Symptoms typically resolved within 5 days (94,194–199,201). Adverse events reported through postlicensure safety surveillance are consistent with the clinical trial data, and no new safety concerns have been identified (202).

MenB-FHbp Immunogenicity

Clinical trials for MenB-FHbp immunogenicity against four reference strains, each expressing an FHbp antigen different from those included in the vaccine, among persons aged 10–25 years were conducted using several dosing schedules, including the licensed formulations of a 3-dose schedule (0, 1, and 6 months or 0, 2, and 6 months) and a 2-dose schedule (0 and 6 months). By 1 month after completion of either of the 3-dose schedules, the proportion of persons with hSBA titers ≥1:8 or at or above the lower limit of quantification (LLOQ) of the assay (LLOQ: ≥1:8 or ≥1:16 depending on the strain) was 91%–98% for test strain A22, ≥99% for A56, 81%–95% for B24, 86%–96% for B44, and 84%–94% for the composite response (i.e., response against all test strains) (94,193–199). The proportions of persons with seroprotective hSBA titers were similar between 0-, 1-, and 6-months and 0-, 2-, and 6-months schedules. In the study that assessed the 2-dose schedule (0 and 6 months), the proportion with hSBA titers ≥LLOQ was 97% for A22, 99% for A56, 81% for B24, 78% for B44, and 77% for the composite response (182,198). Administration of MenB-FHbp simultaneously with other vaccines did not result in reduced immune response to MenB-FHbp antigens, meningococcal serogroups A, C, W, or Y or diphtheria, tetanus, or pertussis antigens (94,201). Noninferiority criteria were not met for HPV 18 antigen, although the GMTs were high and for each of the four HPV types in the quadrivalent HPV vaccine (including type 18), ≥99% of persons seroconverted (197).

By 6 months postcompletion of a 3-dose (0, 2, and 6 months) schedule among adolescents aged 11–18 years, the proportions with hSBA titers ≥LLOQ were 60% for A22, 89% for A56, 57% for B24, 37% for B44, and 26% for the composite response (193). By 12 months postcompletion of any 3-dose series, the proportion with hSBA titers ≥LLOQ was 41%–54% for A22, 69%–76% for A56, 41%–55% for B24, 23%–29% for B44, and 22% for the composite response (193,198). These proportions remained relatively stable thereafter (at 18, 24, 36, and 48 months postprimary series) (range: 35%–59% for A22, 47%–73% for A56, 41%–57% for B24, 17%–27% for B44, and 16%–19% for the composite response) (193,198). After a 2-dose schedule, the proportion of recipients with hSBA titers ≥LLOQ was slightly lower than that observed for the 3-dose series but similarly stable 12–48 months after series completion (range: 36%–48% for A22, 54%–60% for A56, 31%–37% for B24, 16%–20% for B44, and, by 48 months, 16% for the composite response) (193,198).

One month after a booster dose administered 48 months after primary series completion, 94%–98% of persons who received a 2-dose primary series and ≥97% of those who received a 3-dose primary series achieved an hSBA titer ≥1:4 against the four test strains (19). Twelve months after MenB-FHbp booster administration, 62%–82% of those who received a 2-dose primary series and 73%–93% of those who received a 3-dose primary series achieved hSBA titers ≥1:4 across the test strains (composite response of 63% for both groups). By 26 months postbooster, further antibody titer waning was observed among persons who received a 2-dose series but not among those who received a 3-dose series: 59%–67% and 71%–90% achieved an hSBA titer ≥1:4 for the four test strains, respectively, although decreases were observed in the composite response for both groups (42% and 46%, respectively).

In addition to these trials demonstrating immunogenicity to the four test strains, several evaluations have assessed immunogenicity against genetically diverse and clinically relevant strains. In one of the clinical trials, 63%–99% of persons vaccinated with a 2-dose primary series at 0 and 2 months and 75%–99% vaccinated with a 3-dose primary series achieved an hSBA titer ≥LLOQ against 10 additional strains (195). In a manufacturer-sponsored evaluation, hSBA responses measured against 27 clinically relevant strains (including strains from four U.S. university outbreaks) demonstrated that ≥32% of persons vaccinated with 2 doses and ≥56% vaccinated with 3 doses achieved an hSBA titer ≥1:8 against all test strains (203). The proportion of persons who achieved seroprotective hSBA titers was greater for strains expressing the most common FHbp variants in the United States (B24 and A22) at ≥81% and 88%–95%, respectively, after the third dose. In another manufacturer-sponsored study, 1 month after the third MenB-FHbp dose ≥73% of adolescents achieved an hSBA titer ≥1:4 against eight French serogroup B outbreak strains (204). In an independent study among vaccinated U.S. health care workers, ≥93% achieved an hSBA titer ≥1:4 against

14 serogroup B strains (including strains from six university outbreaks) by 1 month after the third dose; by 9–11 months postvaccination, 27%–90% remained seroprotected against nine strains tested (205).

MenB-FHbp Safety

Clinical Trials and Research Studies

Among adolescents and young adults, injection site pain (72%–93%), induration (21%–37%), and erythema (10%–24%) were commonly observed local reactions after any dose in either a 2- or 3-dose series (94,194–197,199). Headache (27%–67%), fatigue (30%–66%), myalgia (21%–40%), and arthralgia (11%–33%) were the most commonly reported systemic adverse events; fever was reported in 2%–23% of recipients. Reactogenicity did not increase with increasing number of doses. Rates and types of adverse events subsequent to a booster dose administered 4 years after primary series completion were similar to those observed after the primary series (198). Most adverse events were mild to moderate, and symptoms typically resolved within 5 days of onset (94,194–199).

Because MenB-FHbp contains factor H binding protein, a theoretical risk exists for development of factor H autoantibodies (implicated in diseases such as atypical hemolytic uremic syndrome and C3 glomerulonephropathy) postvaccination (206,207); however, whether factor H autoantibodies develop after MenB-FHbp vaccination and, if so, whether they are clinically significant is not known. Among persons who received MenB-FHbp in clinical trials, the proportion with a newly diagnosed autoimmune disease during the trial or during the 6-month follow-up period was low (0.14%) and similar to unvaccinated controls (208). Furthermore, the onset of symptoms consistent with the diagnosis occurred before the first vaccination in most of these persons.

Postlicensure Safety Monitoring

In a comprehensive review of VAERS reports from licensure in 2014 through June 2018, no new safety concerns were identified (CDC, unpublished data, 2020). A total of 1,719 reports involving MenB-FHbp were identified; among these reports, the median patient age at vaccination was 17 years, and 36% involved simultaneous administration with other vaccines. The most common adverse events reported were fever, headache, and injection site pain. Reported adverse events (e.g., headache, fever, chills, and myalgia) are consistent with those identified in clinical trials. No safety signals related to autoimmune or renal diseases were detected.

After a MenB-FHbp mass vaccination campaign in response to a serogroup B meningococcal disease outbreak on a university campus in which approximately 10,000 doses were administered, adverse events were solicited via survey subsequent to each of the 3 doses (202). Among survey respondents, rates of injection site pain, fatigue, myalgia, fevers, and chills were similar to those reported during clinical trials, and no new safety concerns were identified.

MenB-4C (Bexsero)

MenB-4C was first licensed in the United States in 2015. MenB-4C is licensed for persons aged 10–25 years in the United States; therefore, immunogenicity and safety data for children aged <10 years are not presented in this report. Available data for this age group have been summarized elsewhere (209).

Among adolescents and young adults, a 2-dose MenB-4C primary series is immunogenic (148,210–213). Although antibody persistence is difficult to assess because of heterogeneous results by vaccine antigens (FHbp, NhbA, NadA, and PorA) or between studies, different points assessed in different studies, and elevated baseline titers in certain studies, antibody titers appear to wane by 2 years postvaccination (148,213–216). A robust immune response is demonstrated after either a MenB-4C or investigational serogroups A, B, C, W, and Y (MenABCWY) vaccine booster dose administered 2, 4, or 7.5 years after a MenB-4C primary series (215,217). Although data are limited, persistence after a booster dose likely lasts for several years based on observed and modeled data (218). MenB-4C vaccine is safe and well tolerated, although more reactogenic than MenACWY (188,210–213). In clinical trials, the most common local

reactions were injection site pain, erythema, and swelling and the most common systemic adverse events were headache, fatigue, and myalgia. In postlicensure safety surveillance, local and systemic adverse events reported are consistent with the clinical trial data (219–221).

MenB-4C Immunogenicity

Clinical trials were conducted to assess immunogenicity to four test strains among persons aged 10–25 years using a 2-dose primary series schedule (0 and 1–2 months), with seroprotection defined as an hSBA titer ≥1:4 or ≥1:5. One month after the second dose, ≥98% of recipients achieved seroprotection against FHbp, ≥97% against NadA, ≥75% against PorA, and ≥68% against NhbA (148,210–213). At 5–6 months after the primary series, ≥82% remained seroprotected against FHbp, ≥93% against NadA, and ≥75% against PorA (NhbA was not assessed) (148,213). Antibody persistence at further points was variable between studies. In a study conducted among United Kingdom college students, in which the proportion of persons with baseline (prevaccination) titers ≥1:4 ranged from 57% to 69% for FHbp, NadA, and PorA, 85%–97% of vaccinated students remained seroprotected for these antigens at 11 months postcompletion of the primary series (148). In a study of Chilean adolescents, in whom baseline titers were also elevated, 75%–93% were seroprotected against FHbp, NadA, and PorA by 18–23 months after the primary series and 29%–84% had seroprotection at 7.5 years (215,216). However, the proportion seroprotected at 7.5 years was not significantly different from baseline for three of the four antigens in the original study cohort, although higher than an age-matched unvaccinated population for three of four antigens. Among participants in two different clinical trials in which most had low baseline titers, results at 2 years (United States and Poland) and 4 years (Canada and Australia) postvaccination were relatively consistent: 30%–34% seroprotection against FHbp, 84%–94% against NadA, 9%–16% against PorA, and 50%–75% against NhbA (214,215). In a small clinical trial of adult laboratory workers, in which most participants had high baseline hSBA titers to serogroups A, C, W, and Y and select serogroup B strains, simultaneous administration of MenACWY-CRM and a 3-dose MenB-4C series resulted in robust immune responses through 4 months after the second dose and 1 month after the third dose (134).

In extension studies conducted in Chile, Canada, and Australia, a MenB-4C booster was administered either 4 or 7.5 years after completion of the primary series (215). One month after booster administration, ≥93% of persons achieved an hSBA titer ≥1:4 across the four vaccine antigens. No data on persistence of the immune response after a booster dose are available for this cohort. However, modeling of the clinical trial data demonstrates that persistence likely lasts for several years (218). In an extension of the U.S.-Poland study, 11 persons previously vaccinated with a MenB-4C primary series were randomized to receive an investigational pentavalent (serogroups A, B, C, W, and Y) vaccine, in which the serogroup B component was identical to the components of the licensed MenB-4C product, as a booster dose 2 years postcompletion of the primary series (217). One month postbooster, ≥91% of persons achieved an hSBA titer ≥1:5 against FHbp, NadA, and NhbA, and 82% achieved an hSBA titer ≥1:5 against PorA. At 12 months postbooster, all recipients achieved an hSBA titer ≥1:5 against NadA, 82% against FHbp and NhbA, and 45% against PorA, although confidence intervals were wide because of the small study size (217).

In addition to clinical trials, several observational immunogenicity studies have been undertaken. After a 2013 mass MenB-4C vaccination campaign at a U.S. university in response to a serogroup B meningococcal disease outbreak caused by a strain predicted by the MATS assay to be covered by both the FHbp and NhbA antigens in MenB-4C, 66% of serosurvey participants achieved an hSBA titer ≥1:4 against the outbreak strain at 2 months after receipt of the 2-dose series; immunogenicity against two vaccine antigen reference strains was high (222). Antibody titers against the outbreak strain appeared to wane rapidly postvaccination; by 20 months postvaccination, 24% of recipients remained seroprotected (223). Antibody titer waning also was observed among students vaccinated with MenB-4C during a different U.S. university outbreak. The proportion of students with an hSBA titer ≥1:4 against the outbreak strain and three additional university outbreak strains ranged from 53% to 93% 1.5–2 months after completion of the series, and this proportion decreased to 31%–86% at 7 months (224). In another evaluation using sera from vaccinated adults, hSBA activity against 18 genetically diverse serogroup B strains (including three reference strains and six university outbreak strains) demonstrated that at 1 month postvaccination, ≥85% of recipients achieved an hSBA titer ≥1:4 against most strains; however, this proportion decreased to 70%

for 14 of the strains and 45%–62% for the remaining four strains (two from outbreaks) by 4–6 months postvaccination (225).

MenB-4C Safety

Clinical Trials and Research Studies

Among adolescents and adults, injection site pain (82%–98%), erythema (35%–68%), swelling (26%–47%), and induration (10%–48%) were commonly reported local reactions after primary vaccination (188,210–213). Headache (21%–65%), fatigue and malaise (18%–73%), myalgia (17%–75%), arthralgia (8%–42%), and nausea (8%–35%) were commonly reported systemic adverse events; fever was reported in 1%–10% of recipients. In a clinical trial conducted among laboratory workers in which MenB-4C was administered simultaneously with MenACWY-CRM, local injection site adverse reactions were more common in the arms in which MenB-4C was administered compared with MenACWY-CRM; nausea and headache were more frequently reported when the two vaccines were administered simultaneously compared with MenB-4C administration alone (134). After a MenB-4C or investigational MenABCWY booster dose, rates of local or systemic adverse events typically were similar to those observed among persons who received doses as part of primary vaccination (215,217).

As with MenB-FHbp, MenB-4C contains components that include factor H binding protein. Animal models and an evaluation in humans demonstrated that antibodies generated after MenB-4C vaccination were cross-reactive with human factor H (226–228). In the human study, a small proportion of persons vaccinated with MenB-4C had transient development of factor H autoantibodies, although factor H function was unaffected (228). Although these findings do not suggest that factor H autoantibodies from MenB vaccination are likely to cause factor H–associated autoimmune conditions, the clinical significance remains uncertain, and additional postlicensure safety surveillance will be important. In FDA's review of MenB-4C clinical trial data, among study participants with an autoimmune disorder diagnosed during the study follow-up period, the onset of symptoms consistent with the disorder occurred before the first vaccination in most trial participants (70).

Postlicensure Safety Monitoring

MenB-4C safety surveillance was conducted as part of several mass vaccination campaigns in the United States and Canada (219–221). MenB-4C mass vaccination campaigns were implemented in response to outbreaks at two U.S. universities (approximately 31,000 doses administered), under an expanded access investigational new drug protocol before U.S. licensure of the vaccine, and one university in Canada (approximately 5,000 doses administered) (220,221). The most commonly reported adverse events were consistent with findings from clinical trial data (e.g., fever, injection site pain, and arm pain), although 0.88 syncopal events per 1,000 persons in the U.S. evaluation were reported. Similarly, safety surveillance for mass vaccination to control increased incidence of serogroup B meningococcal disease in a region of Quebec, Canada, in which nearly 60,000 doses were administered to persons aged ≤20 years, demonstrated local and systemic adverse events consistent with those described in clinical trials, although adverse event–related absenteeism or medical consultations were frequent (219). However, four cases of likely idiopathic nephrotic syndrome were identified in vaccinated children aged 2–5 years during the 1-year postvaccination safety monitoring period (229). Because of the small number of cases and wide confidence intervals of risk estimates, whether this finding represents a safety signal is unclear.

In a comprehensive review of VAERS reports from licensure in 2015 through June 2018, no new safety concerns were identified (CDC, unpublished data, 2020). A total of 1,470 reports involving MenB-4C vaccination were received; the median patient age was 17 years, and 39% involved simultaneous administration with other vaccines. The most commonly reported adverse events were injection site pain, fever, and headache. Transient decreased mobility of the arm where the vaccine was injected was disproportionately reported for MenB-4C compared with other vaccines. Overall, the reported adverse events were consistent with the findings from clinical trials. No autoimmune or renal disease–related safety signals were detected.

MenB Vaccine Immunogenicity and Safety in Persons with Underlying Medical Conditions

Immunogenicity of MenB-4C was assessed in children and adolescents aged 2–17 years with certain underlying conditions (230). One month postcompletion of a 2-dose primary series, the proportion of persons with complement deficiency or complement inhibitor use with hSBA titers ≥1:5 was 87% for FHbp, 95% for NadA, 68% for PorA, and 73% for NhbA when exogenous complement was used. Among those with asplenia, ≥84% had seroprotection against these four antigens, which was similar to the proportion observed in healthy control participants. However, among complement-deficient persons, when endogenous complement was used, only 41%–68% had seroprotection against the four antigens; among those with terminal component deficiencies or complement inhibitor use, only 17% demonstrated any bactericidal activity postvaccination. In addition, a lack of opsonophagocytic killing of meningococci in the presence of eculizumab in sera from persons vaccinated with MenB-4C has been observed, and cases of serogroup or genogroup B meningococcal disease have been reported despite recent vaccination among persons using eculizumab (161,231,232). Although data are limited for MenB-FHbp, similar concerns exist for the lack of complete protection in vaccinated persons (69). Thus, persons with complement deficiency or complement inhibitor use might remain at increased risk for meningococcal disease even if they develop antibodies postvaccination (69,70,94,201).

The safety profile of MenB-4C among children and adolescents aged 2–17 years with certain underlying medical conditions was similar to that observed in healthy controls (230). In a small Spanish evaluation in adults with complement deficiency, eculizumab use, asplenia, and history of meningococcal disease, plus a microbiologist with an immunodeficiency, the reactogenicity profile of MenB-4C was similar to that reported in clinical trials in adolescents and adults except for a slightly higher rate of fever (13%).

Vaccination in general might activate complement. Thus, patients with complement-mediated diseases, such as those in whom complement inhibitors are used for treatment (e.g., paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome), might experience increased signs and symptoms of their underlying disease after vaccination. In a safety review of patients treated with eculizumab in Canada, an increased risk for anemia or hemolysis was observed when patients receiving eculizumab were vaccinated with MenB-4C, particularly in those who received an eculizumab dose within 2 weeks of vaccination (233). The Canadian package insert for eculizumab was updated with the manufacturer's recommendation that patients be vaccinated (with any recommended meningococcal vaccine, not specifically MenB-4C) before or at the same time as eculizumab initiation; those receiving eculizumab treatment are recommended to be vaccinated only when their disease is controlled and the eculizumab concentration in the blood is considered to be high (234). No similar safety concerns have been identified in the United States to date; however, meningococcal vaccination is likewise recommended at least 2 weeks before complement inhibitor initiation (39,40).

MenB Vaccines in Pregnant Women

Data on safety of MenB vaccines in pregnant women are limited. No controlled trials have been conducted to specifically assess the safety of MenB vaccination among pregnant women and birth outcomes of vaccinated women. Among approximately 6,000 adolescent or adult females enrolled in MenB-FHbp clinical trials, pregnancy was reported during the trial or in the follow-up period in 34 women who had received at least 1 dose (94,194–199,201). Among these, four (12%) spontaneous abortions were reported. Among approximately 2,000 adolescent or adult females enrolled in MenB-4C clinical trials, no pregnancies were reported in the published literature (188,210–213,215). Evaluation of VAERS through June 2018 identified three reports related to MenB-FHbp vaccination during pregnancy, with no maternal or fetal adverse events reported, and four related to MenB-4C, with one spontaneous abortion reported (CDC, unpublished data, 2020). Both manufacturers maintain pregnancy registries to collect information on birth outcomes after maternal vaccination; however, no data are available (GlaxoSmithKline and Pfizer, personal communications, 2019).

Effectiveness of MenB Vaccines

After a mass vaccination program among persons aged 2 months–20 years in a region of Canada experiencing increased incidence of serogroup B meningococcal disease due predominantly to a single clone, MenB-4C vaccine effectiveness among all target age groups was estimated at 79% (95% CI: −231% to 99%) in the 4 years postvaccination, although the wide confidence intervals encompassing the null effect value limit the interpretation of the finding (235). No additional data on MenB-4C effectiveness are available for adolescents and adults. In the United Kingdom, where infants are vaccinated with MenB-4C at ages 2, 4, and 12 months, vaccine effectiveness among children who completed the series was estimated at 59.1% (95% CI: −31.1% to 87.2%) for all serogroup B strains in the 3 years after vaccination (236). No data are available on MenB-FHbp vaccine effectiveness in any age group.

Vaccination and Meningococcal Disease Incidence

No information is available on the association between MenB vaccination and meningococcal disease incidence in the United States. This association cannot be assessed because of the low incidence of serogroup B meningococcal disease and low vaccination coverage after the 2015 ACIP recommendation that adolescents be vaccinated on the basis of shared clinical decision-making (22% of adolescents aged 17 years received ≥1 MenB dose in 2019) (237).

Vaccination and Oropharyngeal Carriage

Current evidence suggests that MenB vaccines probably do not have a substantial effect on the prevalence or acquisition of N. meningitidis oropharyngeal carriage. In a large randomized controlled trial in Australia, MenB-4C vaccination of adolescents did not result in a reduction of carriage with N. meningitidis serogroup B or other disease-causing N. meningitidis serogroups (238). In a smaller randomized controlled trial of United Kingdom university students, no immediate reduction in meningococcal carriage was observed in the 1 month after MenB-4C vaccination. By 3 months postvaccination, significantly lower carriage of any meningococcal strain and of capsular groups B, C, W, and Y was observed; however, no specific effect of MenB-4C on serogroup B carriage was observed (188). No data from large randomized controlled trials for MenB-FHbp are available. However, two observational carriage evaluations after vaccination of U.S. university students primarily with MenB-FHbp during serogroup B outbreaks demonstrated stable serogroup B carriage rates before and after vaccination, suggesting that MenB-FHbp does not have a large or rapid effect on carriage (185,186).

Cost-Effectiveness of MenB Vaccines

Cost-effectiveness of MenB vaccines among U.S. adolescents was first assessed in 2015 and most recently evaluated in 2018 (10,239). Vaccination strategies included a MenB primary series at age 11 years with a booster at age 16 years, a series at age 16 years, a series at age 18 years, and a series among college students. Cost per QALY saved for these four strategies ranged from $9.6 million to $12.7 million, with the number needed to vaccinate to prevent a case ranging from 152,000 to 305,000 and the number needed to vaccinate to prevent a death ranging from 1.6 million to 2.8 million (239).

Vaccine Administration

MenACWY-D, MenACWY-CRM, MenACWY-TT, MenB-FHbp, and MenB-4C are all administered intramuscularly at a dose of 0.5 mL. However, for MenACWY-CRM, the lyophilized MenA component must be reconstituted with the liquid MenCWY component immediately before administration. If the liquid MenCWY component is inadvertently administered alone without the lyophilized MenA component, revaccination is not necessary for persons who are not planning to travel internationally because serogroup A meningococcal disease is rarely reported in the United States. However, revaccination is necessary if the person plans to travel internationally, particularly to a region where serogroup A meningococcal disease is endemic, or where vaccination is required, such as to the Hajj pilgrimage. In this case, a dose prepared according to the manufacturer's instructions should be administered as soon as feasible. Additional information on meningococcal vaccine administration is available in the package inserts (66–70).

Recommendations for Use of Meningococcal Vaccines

Adolescents and Young Adults

ACIP recommends routine administration of a MenACWY vaccine for all persons aged 11–18 years (Table 2). In addition, ACIP recommends a MenB vaccine series for persons aged 16–23 years on the basis of shared clinical decision-making to provide short-term protection against most strains of serogroup B meningococcal disease (Table 2). The preferred age for MenB vaccination is 16–18 years.

MenACWY Vaccines

ACIP recommends a single dose of MenACWY at age 11 or 12 years followed by a booster dose administered at age 16 years (Table 2). Children who received MenACWY at age 10 years do not need an additional dose at age 11–12 years but should receive the booster dose at age 16 years. Children who received MenACWY before age 10 years and with no ongoing risk for meningococcal disease for which boosters are recommended should still receive MenACWY according to the recommended adolescent schedule, with the first dose at age 11–12 years and a booster dose at age 16 years. For example, a healthy child who received MenACWY at age 9 years because of short-term travel to a country where meningococcal disease is hyperendemic or epidemic and who is not otherwise at increased risk should receive the MenACWY at age 11–12 years according to the recommended ACIP adolescent vaccination schedule. Children who received MenACWY before age 10 years and for whom boosters are recommended because of an ongoing increased risk for meningococcal disease (e.g., those with complement deficiency, HIV infection, or asplenia) should follow the booster schedule for persons at increased risk.

Adolescents who receive their first dose at age 13–15 years should receive a booster dose at age 16–18 years; the booster dose can be administered at any time, as long as a minimum interval of 8 weeks between doses is maintained. Adolescents who receive a first dose after their 16th birthday do not need a booster dose unless they become at increased risk for meningococcal disease. Persons aged 19–21 years who have not received a dose after their 16th birthday can receive a single MenACWY dose as part of catch-up vaccination. MenACWY vaccines are interchangeable; the same vaccine product is recommended, but not required, for all doses. MenACWY vaccines can be administered simultaneously with other vaccines indicated for this age group, but at a different anatomic site, if feasible. MenACWY-TT, which is conjugated to tetanus toxoid, is only licensed for the prevention of meningococcal disease; use of this vaccine does not replace doses or affect the dosing intervals of routinely recommended tetanus toxoid–containing vaccines in any age group.

MenB Vaccines

MenB vaccination is not routinely recommended for all adolescents. Instead, ACIP recommends a MenB series for persons aged 16–23 years (preferred age 16–18 years) on the basis of shared clinical decision-making (240) (Table 2). Shared clinical decision-making refers to an individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian. Considerations for shared clinical decision-making for vaccine administration and timing of administration might include

•the serious nature of meningococcal infections, with high rates of death and permanent sequelae in those who develop invasive disease;

•the low number of serogroup B meningococcal disease cases (average of 34 serogroup B cases annually among persons aged 16–23 years in the United States during 2015–2018);

•the increased risk among college students, especially those who are freshmen, attend a 4-year university, live in on-campus housing, or participate in sororities and fraternities;

•the protection provided by MenB vaccines against most strains of serogroup B N. meningitidis;

•the estimated relatively short duration of MenB protection (antibody waning within 1–2 years postcompletion of the primary series); and

•the evidence to date suggesting that MenB vaccination has no effect on meningococcal carriage (i.e., MenB vaccines might provide individual protection against serogroup B disease but herd protection is unlikely).

For adolescents who are not otherwise at increased risk for meningococcal disease (e.g., due to complement deficiency or asplenia), a 2-dose series of MenB vaccine should be administered as follows: 2 doses of MenB-FHbp administered at 0 and 6 months or 2 doses of MenB-4C administered at 0 and ≥1 month. If the second dose of MenB-FHbp is administered earlier than 6 months after the first dose, a third dose should be administered at least 4 months after the second dose. Either of the MenB vaccines can be used when indicated; ACIP does not state a product preference. However, MenB vaccines are not interchangeable, and the same vaccine product must be used for all doses. If one MenB dose was received but the vaccine product is unknown, the series must be restarted with either product to ensure completion of a 2-dose series using the same product. If 2 doses were administered using different MenB products, one product should be selected for administration of an additional dose at an appropriate interval to ensure valid completion of a MenB series; the dose from the product not selected for series completion should be considered invalid. For situations in which a MenB dose or doses must be repeated, a minimum interval of 4 weeks should be used between any 2 doses. MenB vaccines can be administered simultaneously with other vaccines indicated for this age group, but at a different anatomic site, if feasible.

Persons at Increased Risk for Meningococcal Disease

Persons at increased risk for meningococcal disease are recommended to receive routine meningococcal vaccination. Vaccine product, number of doses, and booster dose recommendations are based on age and risk factors (Tables 3, 4, 5, 6, 7, 8, 9, and 10). Although evidence suggests that vaccination might not adequately prevent meningococcal infections among persons with certain complement deficiencies or those using a complement inhibitor (66–70), these persons should continue to be vaccinated according to recommendations because of a possible benefit among persons at high risk for infection (Table 4). Persons using complement inhibitor should be vaccinated at least 2 weeks before complement inhibitor initiation unless the risks for delaying treatment outweigh the risks for developing meningococcal disease. Among unvaccinated patients for whom complement inhibitor therapy cannot be delayed, antimicrobial prophylaxis (e.g., penicillin) should be administered alongside meningococcal vaccination and continued for 2 weeks after vaccine administration (39,40). In addition, providers might consider antimicrobial prophylaxis for the duration of complement inhibitor therapy. Among persons undergoing elective splenectomy, meningococcal vaccines should be administered at least 2 weeks before surgery, if possible; otherwise, they should be administered after the procedure as soon as the patient's condition is stable (241).

MenACWY Vaccines

Children at increased risk for meningococcal disease caused by serogroups A, C, W, or Y (Box 1) who received MenACWY at age <11 years and for whom booster vaccination is recommended because of an ongoing increased risk should follow the booster dose schedule (Tables 4, 5, 6, 7, 8, and 9), not the routine adolescent schedule. For example, a child with HIV infection who received MenACWY at age 9 years should receive the next dose at age 14 years. Booster doses administered to children aged <15 years, repeated booster doses, and booster doses administered at an interval of <4 years are not licensed in the United States and are considered off-label (Table 11).

Because of the high risk for invasive pneumococcal disease, children with functional or anatomic asplenia or HIV infection should not be vaccinated with MenACWY-D before age 2 years to avoid interference with the immune response to 13-valent pneumococcal conjugate vaccine (PCV13); MenACWY-CRM should be used in this group. If MenACWY-D is used in persons of any age with these conditions, it should not be administered until at least 4 weeks after completion of all PCV doses.

In addition, MenACWY-D should be administered either before or at the same time as DTaP to avoid interference of DTaP with the immune response to meningococcal vaccine among children at increased risk for meningococcal disease. If MenACWY-D cannot be given before or at the same time as DTaP, it should be administered 6 months after DTaP, unless the child is at increased risk for meningococcal disease because of travel to an area where disease is hyperendemic or epidemic or where an outbreak is occurring, in which case MenACWY-D should be administered regardless of timing of DTaP receipt. If MenACWY-D is inadvertently administered in the 6 months after DTaP administration, the dose does not need to be repeated.

If a healthy person aged ≥2 years previously vaccinated with a single dose of MenACWY develops an underlying condition for which meningococcal vaccination is recommended as a 2-dose primary series, a second dose should be administered as soon as possible, provided that an 8-week minimum interval between doses is maintained. For example, a person who received a single MenACWY dose before travel and then years later developed asplenia should receive another dose as soon as possible to complete the 2-dose series recommended for persons with asplenia; restarting the 2-dose series is not required. Booster doses should then be administered according to the schedule (Tables 4, 5, and 6), with the first dose administered either 3 or 5 years after completion of the primary series, depending on age. MenACWY vaccines are interchangeable; the same vaccine product is recommended, but not required, for all doses. Administration of MenACWY-D or MenACWY-CRM in persons aged ≥56 years, a 2-dose MenACWY primary series in persons aged ≥2 years at increased risk for meningococcal disease, administration of >1 booster dose, and administration of a booster dose in persons aged <15 years or at an interval of <4 years since the last dose are not licensed in the United States and are considered off-label ACIP recommendations (Table 11).

First-year college students living in residence halls should receive at least 1 dose of MenACWY within 5 years before college entry. The preferred timing of the most recent dose is on or after their 16th birthday. If only 1 dose of vaccine was administered before the 16th birthday, a booster dose should be administered before enrollment. Adolescents who received a first dose after their 16th birthday do not need another dose before college entry unless >5 years have elapsed since the dose.

MenB Vaccines

For persons at increased risk for meningococcal disease (Box 1), including during serogroup B meningococcal disease outbreaks, either a 3-dose MenB-FHbp series or 2-dose MenB-4C primary series should be administered. For persons who previously completed a MenB primary series who become or remain at increased risk for meningococcal disease, booster vaccination should be administered according to the dosing schedule (Tables 4, 5, 7, and 8). Primary series vaccination in persons aged ≥26 years and booster vaccination in persons at increased risk for meningococcal disease are not licensed in the United States and are considered off-label (Table 11).

For the MenB-FHbp primary series, the 3-dose series (at 0, 1–2, and 6 months) should be administered to provide earlier protection and maximize short-term immunogenicity. If the second dose is administered at an interval of ≥6 months, a third dose does not need to be administered. If the third dose is administered earlier than 4 months after the second dose, a fourth dose should be repeated at least 4 months after the third dose. For MenB-4C, doses should be administered at 0 and ≥1 months. The two MenB vaccines are not interchangeable; the same vaccine product must be used for all doses, including booster doses. Because efficacy has not been established for persons receiving MenB vaccines interchangeably, every effort should be made to determine vaccine product for all received doses, including booster doses, because receiving mismatched MenB vaccine products might result in inadequate protection (see Vaccination of Adolescents and Adults). For situations in which a dose or doses must be repeated, a

minimum interval of 4 weeks should be used between any 2 doses. MenB vaccines can be administered simultaneously with other vaccines indicated for this age group, but at a different anatomic site, if feasible.

Establishment of Vaccine-Mediated Immunity

ACIP does not recommend evaluation of antibody titers against meningococcal serogroups for the purposes of establishing immunity or the need for vaccination. Commercially available immunoglobulin (e.g., IgG) testing should not be used to infer individual seroprotection against meningococcal disease.

Precautions and Contraindications

Because postvaccine syncope can occur with all injectable vaccines, procedures should be in place to prevent falling injuries and manage syncopal reactions. Vaccine providers, particularly when vaccinating adolescents, should consider observing patients (with patients seated or lying down) for 15 minutes after vaccination to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve (241). Similarly, anaphylaxis can occur after any vaccination. Furthermore, because the tip caps of prefilled MenB-4C syringes contain natural rubber latex and might cause allergic reactions, latex sensitivity is included as a precaution for MenB-4C (70). Appropriate medical treatment must be available should an acute allergic reaction, including an anaphylactic reaction, occur. In addition, because apnea after intramuscular vaccination has been observed in some infants born prematurely, prematurity is a precaution for MenACWY-CRM vaccination (66). Finally, although postlicensure data have not established a risk for Guillain-Barré syndrome after MenACWY-D vaccination, previous history of Guillain-Barré syndrome is listed as a precaution for MenACWY-D in the package insert (67).

For all meningococcal vaccines, severe allergic reaction to a previous dose or any component of the vaccine is a contraindication to vaccination (66–70). For MenACWY-D and MenACWY-CRM, severe allergic reaction to any diphtheria toxoid– or CRM197–containing vaccine is also a contraindication (66,67). For MenACWY-TT, severe allergic reaction to a tetanus toxoid–containing vaccine is also a contraindication (68).

Pregnancy and Lactation

Pregnant and lactating women should receive MenACWY vaccine if indicated. Because limited data are available for MenB vaccination during pregnancy, vaccination with MenB should be deferred unless the woman is at increased risk and, after consultation with her health care provider, the benefits of vaccination are considered to outweigh the potential risks.

Reporting of Vaccine Adverse Events

Adverse events that occur in a patient following meningococcal vaccination can be reported to VAERS. Reporting is encouraged for any clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.govexternal icon or by calling 1-800-822-7967.

Future Directions in Meningococcal Vaccination

Although meningococcal disease incidence in the United States is low and decreasing, continued surveillance and evaluations are needed to assess the safety and effectiveness of MenB vaccines, including repeated booster doses among persons at increased risk for meningococcal disease. In addition to MenB, continued monitoring of MenACWY use is necessary to help evaluate the meningococcal vaccination program and provide information about the need and strategy for additional meningococcal vaccines, such as investigational serogroups A, B, C, W, and Y (MenABCWY) vaccines, in the United States (210,242). Furthermore, efforts are under way to reduce the global incidence of meningococcal disease and other causes of meningitis through a strategy that includes optimizing the use of current vaccines as well as

developing additional vaccines, such as an expanded conjugate vaccine that includes serogroups A, C, W, Y, and X for use in sub-Saharan Africa (243,244).
https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm?s_cid=rr6909a1_e&ACSTrackingID=USCDC_921-DM38861&ACSTrackingLabel=This%20Week%20in%20MMWR%20-%20Vol.%2069%2C%20September%2025%2C%202020&deliveryName=USCDC_921-DM38861

United States

Trends in Diagnosis of HIV Infection, Linkage to Medical Care, and Viral Suppression Among Men Who Have Sex with Men, by Race/Ethnicity and Age — 33 Jurisdictions, United States, 2014–2018
Source: CDC

Summary

What is already known about this topic?
Men who have sex with men (MSM) account for two thirds of annual diagnoses of human immunodeficiency virus (HIV) infection. Increased linkage to care and viral suppression among MSM with HIV infection can prevent transmission.

What is added by this report?
During 2014–2018, diagnoses of HIV infection among MSM in 33 jurisdictions decreased 2.3% per year overall, but Black, Hispanic/Latino, and younger (aged 13–19 years) MSM experienced a small or no decrease. Linkage to care within 1 month and viral suppression within 6 months of diagnosis increased overall (2.9% and 6.8% per year, respectively) and among all racial/ethnic groups.

What are the implications for public health practice?
Intensified prevention efforts for Black, Hispanic/Latino, and younger MSM are needed.
During 2018, gay, bisexual, and other men who have sex with men (MSM) accounted for 69.4% of all diagnoses of human immunodeficiency virus (HIV) infection in the United States (1). Moreover, in all 42 jurisdictions with complete laboratory reporting of CD4 and viral load results,* percentages of MSM linked to care within 1 month (80.8%) and virally suppressed (viral load <200 copies of HIV RNA/mL or interpreted as undetected) within 6 months (68.3%) of diagnosis were below target during 2018 (2). African American/Black (Black), Hispanic/Latino (Hispanic), and younger MSM disproportionately experience HIV diagnosis, not being linked to care, and not being virally suppressed. To characterize trends in these outcomes, CDC analyzed National HIV Surveillance System† data from 2014 to 2018. The number of diagnoses of HIV infection among all MSM decreased 2.3% per year (95% confidence interval [CI] = 1.9–2.8). However, diagnoses did not significantly change among either Hispanic MSM or any MSM aged 13–19 years; increased 2.2% (95% CI = 1.0–3.4) and 2.0% (95% CI = 0.6–3.3) per year among Black and Hispanic MSM aged 25–34 years, respectively; and were highest in absolute count among Black MSM. Annual percentages of linkage to care within 1 month and viral suppression within 6 months of diagnosis among all MSM increased (2.9% [95% CI = 2.4–3.5] and 6.8% [95% CI = 6.2–7.4] per year, respectively). These findings, albeit promising, warrant intensified prevention efforts for Black, Hispanic, and younger MSM.

CDC used data reported to the National HIV Surveillance System by December 2019 to identify cases of HIV infection that met CDC's HIV infection case definition among MSM, including MSM aged ≥13 years who inject drugs (3). Multiple imputation was used to adjust for unknown or missing transmission category (15.6% of cases) (4). At the time of diagnosis, all MSM resided in one of 33 jurisdictions§ with complete laboratory reporting for each year during 2014–2018. Linkage-to-care analyses included MSM with HIV infection diagnosed during the calendar year when the diagnosis was first made. Linkage to care was defined as one or more CD4 or viral load tests performed within 1 month of diagnosis. Viral suppression within 6 months of diagnosis was measured for MSM whose infection was diagnosed during the outcome year and who resided in any of the 33 jurisdictions at the time of diagnosis of HIV infection. Viral suppression was defined as a viral load result of <200 copies/mL or a viral load test interpretation value of undetected.

Results are presented by race/ethnicity (Black, Hispanic, other, and White) and age group (13–19, 20–24, 25–34, 35–44, 45–54, and ≥55 years). The estimated annual percentage change (EAPC) was calculated

for each MSM group. Because of unknown population denominators, case counts were used to analyze diagnoses by transmission category; the EAPCs in case counts were calculated by using a Poisson distribution. EAPCs indicate the per-year change, on average, in the number of diagnoses, percentage linked to care, or percentage virally suppressed. EAPC p-values <0.05 indicated statistically significant trends, whereas p-values ≥0.05 indicated no significant change. Analyses were conducted using SAS (version 9.4; SAS Institute).

During 2014–2018, the number of diagnoses of HIV infection among all MSM decreased 2.3% (95% CI = 1.9–2.8) per year (from 19,789 to 18,034), on average (Table 1). Among Black MSM, diagnoses decreased 1.3% per year overall and 6.0% and 5.6% among those aged 20–24 and 45–54 years, respectively. Diagnoses did not significantly change among Black MSM aged 13–19, 35–44, and ≥55 years, but increased 2.2% annually among those aged 25–34 years. Among Hispanic MSM, diagnoses did not significantly change overall or among those aged 13–19, 35–44, 45–54, and ≥55 years. Diagnoses decreased 3.7% per year among Hispanic MSM aged 20–24 years but increased 2.0% among those aged 25–34 years. Among White MSM, diagnoses decreased 4.8% per year overall and 5.6%, 2.1%, 7.8%, and 9.3% among those aged 20–24, 25–34, 35–44, and 45–54 years, respectively. Diagnoses did not significantly change among White MSM aged 13–19 or ≥55 years.

The percentage of all MSM who were linked to care within 1 month of diagnosis increased 2.9% per year, on average, from 2014 (66.2%) to 2018 (74.4%). Among Black MSM, the percentage linked to care increased 3.8% per year overall, and it increased among those aged 13–19, 20–24, and 25–34 years. It did not significantly change among those aged 35–44, 45–54, and ≥55 years. Among Hispanic MSM, the percentage linked to care increased 3.2% per year overall, and it increased among those aged 20–24, 25–34, 35–44, and 45–54 years. However, the percentage linked to care did not significantly change among those aged 13–19 and ≥55 years. Among White MSM, the percentage linked to care increased 1.8% per year overall, and it increased among those aged 20–24 and 25–34 years but did not significantly change among all other age groups.

The percentage of all MSM who achieved viral suppression within 6 months of diagnosis increased 6.8% per year, on average, from 2014 (51.1%) to 2018 (67.2%) (Table 2). Among Black MSM, the percentage who achieved viral suppression increased 9.4% per year overall, and it increased among those aged 13–19, 20–24, 25–34, 35–44, and 45–54 years. The percentage virally suppressed did not significantly change among Black MSM aged ≥55 years. Among Hispanic MSM, the percentage who were virally suppressed increased 6.8% per year overall, and it increased among those aged 20–24, 25–34, 35–44, and 45–54 years; it did not significantly change among those aged 13–19 or ≥55 years. The percentage of White MSM who achieved viral suppression increased 4.4% per year overall, and it increased among those aged 13–19, 20–24, 25–34, 35–44, and 45–54 years; it did not significantly change among those aged ≥55 years.

Discussion

Annual diagnoses of HIV infection among MSM in the 33 analyzed jurisdictions decreased during 2014–2018. However, the rate of annual decrease among Black MSM (1.3%) was less than that among White MSM (4.8%), diagnoses did not significantly change among Hispanic MSM or any MSM aged 13–19 years, and diagnoses increased among Black and Hispanic MSM aged 25–34 years. In addition, more diagnoses occurred overall among Black MSM than among other racial/ethnic MSM groups. CDC recently reported that racial/ethnic disparities in estimated rates of diagnosis of HIV infection among MSM increased during 2010–2015, and Black MSM had an HIV diagnosis rate that was 9.3 times that of White MSM in 2015 (5). These data warrant intensified prevention efforts for Black and Hispanic MSM, especially those aged 25–34 years, and all MSM aged 13–19 years.

Increased linkage to care promotes viral suppression, which effectively prevents HIV transmission. During 2014–2018, linkage to care within 1 month and viral suppression within 6 months of diagnosis increased (2.9% and 6.8% per year, respectively). Increases were highest among Black and Hispanic MSM. However, among all MSM included in the 2018 analysis, only 67.2% achieved viral suppression within 6 months of diagnosis. Moreover, during 2018, proportionally fewer Black MSM were linked to care and achieved viral suppression than did other racial/ethnic MSM groups. Limited health care access, housing instability,

poverty, and systemic racism commonly impede linkage to care and viral suppression (6,7). Addressing these factors might improve outcomes.

The findings in this report are subject to at least two limitations. First, only 33 of the 51 U.S. jurisdictions had complete laboratory reporting of CD4 and viral load results during 2014–2018. Therefore, data do not represent all diagnoses of HIV infection among MSM during 2014–2018. Second, using EAPCs with p-values <0.05 to identify trends might result in clinically meaningful temporal changes being deemed as having no significant change.

Providing antiretroviral therapy for both HIV preexposure prophylaxis and treatment can prevent HIV infection and, subsequently, the need for linkage to care and viral suppression among MSM (8,9). However, during 2017, Black and Hispanic MSM who had discussed preexposure prophylaxis with a medical provider were less likely than were White MSM to receive prescriptions for preexposure prophylaxis in 23 jurisdictions (8). Providers' implicit racial biases toward Blacks and Hispanics often promote treatment nonadherence (10), which inhibits viral suppression (9). Therefore, interventions might need to address systemic racism and concomitant racial biases within health care systems (7). CDC encourages use of interventions that address social determinants of health¶ that underlie the high risk for HIV infection among MSM of all races/ethnicities and ages. Such interventions might help prevent HIV infection and eliminate racial/ethnic disparities in HIV infection among MSM.
https://www.cdc.gov/mmwr/volumes/69/wr/mm6938a1.htm?s_cid=mm6938a1_e&ACSTrackingID=USCDC_921-DM38861&ACSTrackingLabel=This%20Week%20in%20MMWR%20-%20Vol.%2069%2C%20September%2025%2C%202020&deliveryName=USCDC_921-DM38861

Democratic Republic of the Congo
Ebola Response Priorities in the Time of Covid-19
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On April 10, 2020, a total of 53 days after the last patient with Ebola virus disease (EVD) had been isolated and more than 23 months since the start of the 10th EVD outbreak in the Democratic Republic of Congo (DRC), a new confirmed case was reported in the Beni health zone. This case, and the six that followed, brought the total to 3462 cases — the second-largest Ebola outbreak in history. Although the outbreak was declared over on June 25, 2020, additional cases attributable to persistently infected survivors may occur. Therefore, surveillance and rapid-response capacity should be maintained, not only for a duration equivalent to two incubation periods (42 days) after the last confirmed case tested negative, but also for at least 90 additional days of enhanced surveillance.

In the 2013–2016 Ebola epidemic in West Africa, there were at least eight flare-ups from persistently infected survivors, which extended the required response for 11 months after the first declaration of Ebola-free status by the Liberian Ministry of Health.1 During the 10th DRC outbreak, a single relapsed case of EVD resulted in at least 74 additional infections in 13 health areas in six health zones, extending the need for the full response effort by several months.2 Missed Ebola cases and reignition of the 10th outbreak, when the impact may be amplified by a lack of attention and resources due to the Covid-19 pandemic and the declaration of the 11th DRC Ebola outbreak in Equateur Province, could be devastating for DRC and neighboring countries.

As ongoing transmission in the 10th outbreak narrowed to two health zones in late February 2020, the Ebola response operation decommissioned 4 of its 10 local coordination units. The responsibility for Ebola activities was transferred to the provincial health authorities without clear operational plans or provision of training, staff, or resources. In addition, the national leadership for the Ebola response was also tasked with overseeing the DRC Covid-19 response, and many Ebola-response staff members were shifted to Covid-19 activities. The loss of technical capacity, resources, and focus puts the quality of ongoing EVD surveillance at risk.

To maintain the ability to rapidly detect and respond to new EVD cases, we recommend that the response partners, including U.S. government agencies, initiate or strengthen the critical strategies discussed below. Where possible, these activities should be broadened to include surveillance and detection of Covid-19 cases and to strengthen provincial capacity for surveillance and infection prevention and control generally.

First, health care facility–based (HCF) surveillance should be prioritized. Such surveillance is the cornerstone of routine systems for reportable diseases. Between October 2019 and March 2020, some 44% of HCF surveillance alerts met the EVD case definition, as compared with 4% of community-based surveillance alerts (according to an analysis of the DRC EVD response alert database by the Centers for Disease Control and Prevention). HCF surveillance also required fewer staff members and less funding than community-based surveillance. Strengthening HCF surveillance could also improve reporting for all outbreak-prone diseases, including Covid-19. To maximize its impact, this activity could be focused in areas with recent EVD transmission, relatively weak surveillance, and large concentrations of survivors.

Second, postmortem surveillance for EVD should be implemented using rapid diagnostic tests (RDTs) approved for emergency use. Before the outbreak, EVD surveillance was challenging, as evidenced by the 3-month lag between the likely start of the outbreak in April 2018 and the first laboratory confirmation of an Ebola case. Though the response team implemented comprehensive EVD surveillance, it was developed in parallel to the local public health structure. As resources diminish and responsibility transfers back to local authorities, postmortem testing could be an effective strategy for EVD case detection. RDTs performed at, or in proximity to, the place of death, could allow for bodies that test negative to be given back to families more quickly, thereby reducing community resistance to other EVD response measures. Using point-of-care RDTs, rather than a polymerase-chain-reaction (PCR) test, would also free up laboratory personnel, resources, and facilities for Covid-19 and other testing.

Third, new close contacts of EVD survivors should be vaccinated. The potential for sexual transmission of EVD from male survivors continues for at least 500 days after disease onset.3 In addition, EVD relapse has been documented.2 Since survivors may have different sexual or household contacts over time, their contact networks should be continually reassessed at survivor clinics. Vaccination of new close contacts of survivors would increase their level of protection and reduce potential onward transmission. Depending on vaccine availability, this effort could be narrowed to sexual contacts of male survivors with a positive PCR test.

Fourth, catch-up vaccination should be provided to health care workers. There were 60,423 frontline workers who received the rVSV-ZEBOV vaccine under compassionate-use protocols during the response. Even though nosocomial transmission was a major driver of the outbreak, only 5% of confirmed cases were in health care workers.4 However, a portion of health care workers remain unprotected, possibly because of staff turnover, reluctance to receive an investigational vaccine, or the logistic and financial burden of traveling to a vaccination site. Although the total duration of protection from the vaccine is unknown, it has been documented that virus-specific antibodies persist for up to 2 years.5 Catch-up vaccination of health care workers will protect them for at least the longest period known to have elapsed between disease onset and relapse or sexual transmission.

Fifth, real-time genetic sequencing should be integrated with epidemiologic investigations. By early August 2020, the Institut National pour la Recherche Biomedicale had publicly shared 765 genetic sequences derived from clinical specimens obtained during the 10th EVD outbreak. Linking genetic sequences with epidemiologic data in real time, however, proved challenging. On the basis of epidemiologic links, a large cluster of cases that began in late November 2019 was erroneously assumed to be one transmission chain, until months later when genetic sequencing revealed that a number of the specimens were most likely from separate chains. Real-time integration of genetic sequencing with epidemiologic data would help focus investigations and provide testing of transmission hypotheses, which could in turn lead to the identification of additional contacts for vaccination and monitoring.

Sixth, the United States should develop an operational strategy for outbreak response in conflict zones. Northeastern DRC has suffered from decades of conflict, with the proliferation of nonstate armed groups

and community-based militia, and a worsening humanitarian crisis. The use of security forces for protection of Ebola response workers, allegations of improper use of funds, and community mistrust of United Nations peacekeepers, the national government, and nonlocal Congolese impeded response activities. In late August 2018, the U.S. government evacuated its staff to the periphery of the Ebola outbreak area because of security concerns. Some other foreign governments followed suit. Numerous attacks on health care facilities and response workers occurred in areas with active transmission. However, outbreaks will continue to occur in insecure areas and, as Covid-19 has demonstrated, global health will continue to be a national security issue. These realities underscore the importance of developing a U.S. operational strategy for responding to outbreaks in conflict zones that enables public health experts to rapidly deploy to these areas during emerging health crises. This strategy should include appropriate risk-mitigation measures and evacuation plans that allow early, safe, and continuous access to the outbreak area.

The likelihood of new EVD cases, combined with the understandable pivot of national and international staff and attention to Covid-19 and the new Ebola outbreak, makes it imperative that we build sustainable capacity to detect and rapidly respond to Ebola in eastern DRC. Integrating the activities outlined above with the fundamental EVD control strategies of case investigation, contact tracing, isolation, and safe burials will help ensure that DRC's 10th outbreak does not reignite, while serving as a blueprint for strengthening the response to the 11th and future outbreaks.
https://www.nejm.org/doi/full/10.1056/NEJMp2025512

Russia

Unique natural antibiotic discovered in Russia
Source: vz.ru
Unique ID: 1007899151

Scientists at Tyumen State University (TumSU) have discovered a universal natural antibiotic that overcomes the resistance of pathogens to drugs, the authors of the discovery in a study published in the journal Applied Biochemistry and Microbiology report.

One of the tasks of pharmacology today, as noted in the article tyumen scientists, is to find natural antibiotics that can fight microorganisms that have multiple (multi-drug resistant, MDR) or absolute (extreme-drug resistant, XDR) antibiotic resistance available on the market.

For the first time in the world, TumSU researchers demonstrated the unique ability of peptide Emhisillipsin A, secreted from the alkalophilic mycellial fungus Emericellopsis alkalina. According to experts, the substance suppresses the ability of bacteria to form biofilms, so that the resistance of these pathogens to antibiotics is negated.

As explained by the authors of the study, the main therapeutic feature of the studied substance - the universality of the impact. In the case of emericilipsin A are not only MDR- and XDR-shaped bacteria, but also almost any pathogenic eukaryotes - for example, mycellial mushrooms and yeast.

"Emericillixin A acts on eukaryotes and prokaryotes due to different molecular mechanisms. Eukaryotes - fungi and tumor cells - die due to the destruction of their cell membrane by the peptide, and the virulence of prokaryotes is suppressed by preventing the formation of biofilms," Evgeny Rogozhin, a senior researcher at the X-BIO Antimicrobial Resistance Laboratory, told RIA Novosti.

As noted by the authors of the study, among the pathologies with which emehisillipsin A will fight - tumors, as well as all sorts of bacterial and fungal infections.

Emericillipsin A, according to the scientists of TumSU, is promising both as an independent treatment, and as an element of complex drugs. The therapy can be carried out either by injection or locally, by direct treatment of the affected tissues.

The study was conducted in close cooperation with colleagues from the Research Institute on the research

of new antibiotics by G.F. Gause, the Central Research Institute of Epidemiology of Rospotrebnadzor and the Institute of Bioorganic Chemistry by M.M. Shemyakin and Yuri Ovchinnikov RAS.

In the future, the team of scientists intends to move from working with cellular models to laboratory tests of the drug.

Recall, the Ministry of Health warned that unlimited prescribing of antibiotics may soon lead to the fact that none of the existing antibacterial drugs will not work.
https://vz.ru/news/2020/9/23/1061802.html

Germany
Key genetic clue missing in fight against superbugs
Source: phys.org
Unique ID: 1007905069

For the first time, researchers have discovered how antibiotic resistance genes are spreading, at a continental scale, via bacterial plasmids in the hospital superbug, Klebsiella pneumoniae.

Researchers from the Center for Genomic Pathogen Surveillance, based jointly at the Wellcome Sanger Institute and the Big Data Institute, University of Oxford, together with their collaborators used genome sequencing technology to analyze plasmids—genetic structures in bacteria that can carry antibiotic resistance genes—as well as bacterial chromosomes from K. pneumoniae samples taken from European hospital patients.

The findings, published today (24th September) in Proceedings of the National Academy of Sciences, reveal three different pathways by which antibiotic resistance genes spread via plasmids through bacterial populations. Researchers say it is critical that plasmids are included when tracking antibiotic resistance in order to have the best chance of stopping superbugs.

Members of the Enterobacteriaceae family of bacteria can become resistant to last-line antibiotics called carbapenems, and are listed as a critical threat in the World Health Organization's list of priority pathogens. Within this family, Klebsiella pneumoniae is an opportunistic pathogen that causes serious diseases, including pneumonia and meningitis.

K. pneumoniae becomes resistant to carbapenems by acquiring antibiotic resistance genes, known as carbapenemase genes, which code for an enzyme that chews up the antibiotic.

In K. pneumoniae, these carbapenemase genes are usually found on plasmids—smaller circular pieces of DNA that are additional to the bacterial chromosome. Plasmids can jump between different strains and species of bacteria, meaning antibiotic resistance genes can quickly spread and drive the rapid rise in antibiotic resistant bacterial infections worldwide.

Therefore, researchers must include plasmids when tracking the evolution and spread of bacteria to get a true picture of how antibiotic resistance genes are spreading. However it has previously been difficult to use genome sequencing to reliably track plasmid evolution, due to the variability in size and structure of their genetic sequences.

Now with long-read sequencing technology researchers are able to read and reconstruct complete sequences for plasmids.

In a new study, researchers from the Center for Genomic Pathogen Surveillance and their collaborators conducted long-read genome sequencing on 79 K. pneumoniae samples from patients, taken from a Europe-wide survey.

The team generated complete plasmid sequences from these samples, and studied them along with more than 1700 previously short-read sequenced K. pneumoniae samples from the same survey to understand

how antibiotic resistance genes are spreading through the bacterial population in European hospitals. Dr. Sophia David, first author from the Center for Genomic Pathogen Surveillance said: "To fully understand how antibiotic resistance is spreading, we need to consider the role of plasmids. In this study, which is the first to analyze the genetic sequences of plasmids at a continental scale, we discovered three primary routes by which antibiotic resistance genes are spreading via plasmids through the K. pneumoniae population."

The three pathways of transmission involve one plasmid jumping between multiple strains, multiple plasmids spreading among multiple strains, and multiple plasmids spreading within one strain of K. pneumoniae.

Professor Hajo Grundmann, co-lead author from the University of Freiburg in Germany, said: "These new insights into the three routes of spread of antibiotic resistance genes in K. pneumoniae are critical for controlling outbreaks of antibiotic resistant infections. Knowing these transmission strategies enables tailoring of interventions, either to control the dominant plasmid, control the dominant strain, or in complicated situations, control both. For example, if there was a hospital outbreak and the strain carried a high-risk plasmid, there's a chance this plasmid might jump into other bacterial strains or species, which would need to be monitored."

The team also found that plasmids encoding carbapenemase genes were most successful in spreading when acquired by a high-risk strain. This reinforces the importance of preventing transmission of high-risk strains through early detection and rigorous infection control in healthcare environments.

Professor David Aanensen, co-lead author and Director of the Center for Genomic Pathogen Surveillance said: "When tracking certain antibiotic resistant bacteria, plasmids are one of the missing parts of the puzzle.

Analyzing the genetic sequences of both bacterial chromosomes and plasmids can give us a more detailed picture of how antibiotic resistance genes and mechanisms spread in a population. Genomic surveillance of bacteria should include plasmids and other mobile elements in order to tackle the rise in antibiotic resistant infections."

More information: Sophia David et al. Integrated chromosomal and plasmid sequence analyses reveal diverse modes of carbapenemase gene spread among Klebsiella pneumoniae, Proceedings of the National Academy of Sciences (2020). DOI: 10.1073/pnas.2003407117
https://www.pnas.org/content/early/2020/09/18/2003407117

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