occurs, the appropriate secretary — the home secretary when an NAS member is accused, and the foreign secretary when a member without US citizenship is accused — would examine the evidence presented as part of the complaint. If incidents being reported seem to violate the NAS code of conduct, the secretary appoints a committee, which then gathers statements from the complainant and the accused, allows each to respond, and makes a recommendation on what disciplinary measures the NAS should take.

The NAS does not have the resources to conduct its own formal investigations, unless the complaint that's been filed is about internal NAS matters, according to McNutt. So the policy stipulates that complaints must be based on public documentation of resolved cases investigated elsewhere, such as a university report detailing harassing behaviour or a statement that a professor has been dismissed for violating an ethics policy.

The change to the NAS's by-laws, announced in early June 2019, came amid renewed scrutiny of sexual harassment at professional institutions as part of the #MeToo movement. Before the change, the academy had no mechanism for removing members. Even a 1997 prison sentence for child molestation did not prompt the NAS to oust physician Daniel Gajdusek from its ranks. He was still a member when he died in 2008.

A prestigious award

Eighty-four per cent of the NAS's membership ultimately voted to adopt the new policy, which required only a simple majority to pass. "I was very happy to see the vote come out as it did," says Meg Urry, an astrophysicist at Yale University in New Haven, Connecticut, who became an NAS member in 2016. Urry has long spoken out against sexual harassment in academia.

Election to the NAS — a lifetime appointment — is often considered one of the highest honours a US scientist can receive. But membership of the academy isn't just a line in a scientist's awards list: the academy takes an active role in advising the federal government on scientific issues, so members are often recruited to serve on panels. The National Academies Press publishes more than 200 reports each year that weigh in on issues such as the implications of climate change and equitable vaccine distribution.

It is problematic for someone who has committed sexual harassment to have such an influential, national role, says Kathleen Treseder, an ecologist at the University of California, Irvine. Treseder was one of four women at the university who filed sexual-harassment complaints against Ayala in November 2017.

Membership of the academy is a signal that, by some measure, a person is a great scientist. But mentoring young people and fostering their growth as scholars is also part of being a great scientist, Urry says, and that's why harassers should not be allowed to stay. "It's not just that you've done something bad, it's that you've poisoned the well."

Radio silence

Why no one has used the new NAS system to file a harassment complaint is an open question. One possibility is that the NAS has not properly communicated its new policy and process for reporting harassers to its members and to the wider community. "As far as I understand it, the process hasn't been finalized," Urry told *Nature* when contacted about this issue.

Bill Kearney, a spokesperson for the NAS, says that the change to the policy was widely covered in the media last year and was disseminated to the NAS's members.

Some might also question why the NAS leadership can't proactively move known harassers into the queue for consideration by a committee, even if no individual has filed a complaint. McNutt cannot, because under the policy, she would be the arbiter if there were an appeal, presenting a conflict of interest. As for other members of the NAS's governing council or leadership, Kearney confirmed that they could bring forward complaints so long as they excused themselves from the rest of the proceedings.

And those who have already reported harassers to other organizations might be feeling fatigue. "Do I have to do everything? I've already sacrificed enough," Treseder says about why she hasn't filed a complaint with the NAS. "Everybody else has this information. Somebody else could do it." She adds: "I could not be more disappointed in the National Academy of Sciences as an institution and every single National Academy of Sciences member who has allowed the sexual harassers to stay."

McNutt says that the NAS members who are known harassers have been keeping a low profile since the by-laws changed. "They are not being appointed to committees or panels or anything like that," she says. "Their influence in the academy is non-existent."

Jane Willenbring, a geologist at Stanford University in California, who successfully pushed the Geological Society of America to institute a similar policy after someone who harassed her was named a fellow of the organization in 2017, says that these scientists' lack of participation in academy activities is not enough. Their continued presence as members — even inactive ones — sends a signal that "we don't have to take an active role in telling harassers that they have no place in science", she says. "I don't think that's a healthy way to create the important change that we need to see."

CONCERNS INTENSIFY OVER UPCOMING COVID-VACCINE RESULTS

Jabs now in trials could stumble on safety, be subject to political interference or fail to meet expectations.

By Smriti Mallapaty & Heidi Ledford

Several ongoing coronavirus-vaccine trials could announce game-changing results next month. But as anticipation grows, concerns are building about whether the vaccines will clear safety trials, what they will achieve if they do and the risk that the approval process will be influenced by politics, or at least seem to be.

Three weeks ago, the UK trial of a leading vaccine candidate developed by the University of Oxford and pharmaceutical company AstraZeneca restarted after a six-day pause to investigate safety concerns. Halted trials of the same vaccine in South Africa and Brazil have also since resumed, but the US Food and Drug Administration (FDA) has not yet given the green light for US studies to start again. The trials' sponsors have so far released few details about what caused the pause. Some scientists say this lack of transparency could erode public trust in the vaccine.

In the background, fears have intensified that political meddling could see a vaccine approved for emergency use without sufficient evidence that it works. US President Donald Trump has said he wants a vaccine ahead of his country's presidential election in November.

To assuage concerns, the drug companies behind the three leading coronavirus vaccines in phase III trials — AstraZeneca, Pfizer and Moderna — have released documents describing how their tests are being conducted. These trial protocols include benchmarks for safety and success, and details that had not been made public before, including how soon the vaccines' preliminary results could be reported and how the companies might stop

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Protesters call for an end to COVID-19-based restrictions in Sacramento, California.

trials early to get fast-tracked approval. Here are three areas that scientists are watching closely.

Safety and transparency

Initially, researchers weren't too concerned when the media reported that enrolment in the UK trial of the Oxford vaccine had been paused on 6 September because of an adverse reaction in a participant. Adverse reactions in clinical trials are quite common and often unrelated to the treatment — which some researchers say is probably the case with the Oxford vaccine, given how soon UK regulators let the trial resume. Some media outlets have reported that the participant developed transverse myelitis, an inflammation of the spinal cord, but AstraZeneca and the University of Oxford have not released information on the person's condition.

Some scientists criticized this lack of information, especially when it emerged that this was the second pause in enrolment because of an adverse reaction. Information sheets given to participants in July noted that the trial had previously been halted when a member was initially reported to have developed symptoms of transverse myelitis. AstraZeneca says the person was later diagnosed with multiple sclerosis, and an independent panel decided the condition was unrelated to the vaccine.

If it turns out that two people have developed transverse myelitis, given the relatively small number of people who have received the vaccine, that is notable, says Raina MacIntyre, an epidemiologist at the University of New South Wales in Sydney, Australia. "If there's another case, it's going to be very hard for this trial to recover from that."

To rule out a link between the vaccine and the conditions, researchers must run statistical analyses that compare rates of the conditions in participants who received the vaccines with those in people who got the placebo. This is probably what the FDA is still investigating before it decides whether to allow the US trials to resume, says MacIntyre.

More details about why the trials were paused and then later resumed should be made public, says Hilda Bastian, who studies evidence-based medicine at Bond University in the Gold Coast, Australia.

The University of Oxford did not respond to questions about calls for greater transparency. But AstraZeneca chief executive Pascal Soriot said during a panel discussion hosted by the World Economic Forum on 24 September that clinical-trial guidelines recommend against disclosing information about individual participants, to avoid compromising their privacy and the integrity of the study.

Role of politics

Public trust in coronavirus vaccines is already wavering, particularly in the United States. There, a pathway for fast-tracking urgently needed treatments — an FDA Emergency Use Authorization (EUA) — has been part of the concern. This sidesteps the usual drug-approval process and allows treatments to be used if they "may be effective". "In being vague and non-transparent, it's potentially susceptible to the appearance of political influence," says Herschel Nachlis, who studies health policy at Dartmouth College in Hanover, New Hampshire.

So when companies released clinical-trial protocols for the three leading vaccine candidates, researchers were quick to pore over the details. Overall, the protocols looked normal, says David Benkeser, a biostatistician at Emory University in Atlanta, Georgia.

But one feature stood out, says Benkeser. In Pfizer's protocol, external experts assigned to monitor the trial's safety are allowed to take a peek at the interim data more often than they are in the other two companies' protocols. This means that an analysis of early results could be carried out after the trial has accrued data from just 32 people who become infected across its vaccine and placebo arms. This milestone could be reached in as little as three months from the trial's July start date — potentially before the US election.

If early analysis found that the vaccine was convincingly effective at reducing infections in that small sample size, the trial could be stopped and the company could apply for an EUA. But although it would be possible to show that the vaccine meets the FDA's standard at that early stage, it would not allow for long-term follow-up to assure the vaccine's safety, says Kurt Viele, director of modelling and simulation at Berry Consultants, which advises on clinical-trial designs, in Lexington, Kentucky. Three months is also too short to get a good sense of how long immunity from the vaccine lasts, he notes. Pfizer did not respond to questions about whether it plans to continue safety monitoring if a trial is stopped early.

It will be crucial for the company to continue collecting safety data — and make it public — even if the trial is stopped early, says Viele.

The FDA is rumoured to be beefing up its EUA process for COVID-19 vaccines, according to a 22 September report in *The Washington Post*. The FDA declined to comment on the specifics of the news story, but Trump has already said that he might block such measures.

Vaccine goals and efficacy

Even if regulators do approve the three front-runner vaccines, researchers warn that the jabs might not do what the public expect.

The AstraZeneca, Pfizer and Moderna protocols revealed that the trials are designed to test whether the vaccines reduce total cases of symptomatic COVID-19, not just cases of severe disease, such as those that require hospitalization and can end in death.

MacIntyre and other researchers say it would have been better to test whether the vaccines reduced severe disease and death. If a jab can successfully reduce the risk of serious complications, then the virus might have a similar effect on vaccinated people as does the common cold, she says.

The current phase III trials are each enrolling several tens of thousands of participants. But a trial that tried to establish whether a vaccine reduces incidence of severe COVID-19 would need more — and so would take more time, says Thomas Lumley, a biostatistician at the University of Auckland in New Zealand. The current trials chose a middle path between establishing whether vaccines prevent any infection with the virus and testing whether they prevent severe infection, he says.