

News in focus

administration proposed cutting the EPA's budget by nearly one-third and laying off more than 20% of its 15,000 staff members. Trump targeted no other major US agency to the same extent.

Ultimately, the US Congress rejected those cuts, but the administration continued its overhaul of the EPA over the next four years. Many senior EPA staff left, and the atmosphere dampened considerably, insiders say.

"There's been an enormous loss of trust; people are exceptionally edgy, and they're not going to bounce back quickly," says one senior EPA scientist. "Biden has a lot of terrific policies he wants to carry out, but the first job will be to bring the agency back to health."

The first step Biden has taken is to appoint a new agency head. On 17 December, he nominated Michael Regan, North Carolina's top environmental regulator, for the post – and EPA observers were thrilled. "Michael Regan will be exactly the kind of administrator that the EPA needs to fix the damage that was done under four years of Trump," says Jeremy Symons, an environmental consultant in Arlington, Virginia, who worked with Regan at the Environmental Defense Fund, an advocacy group based in New York City.

A seat at the table

But one of the most important things Biden can do to boost morale among scientists, insiders say, is to quickly nominate a leader for the agency's main science arm, the Office of Research and Development (ORD). The division houses more than 1,000 scientists and engineers who assess scientific data and conduct research that feeds into regulatory decisions, but it has been without a Senate-confirmed leader since 2012. Although former president Barack Obama nominated a leader for ORD in 2013, Senate Republicans blocked the nominee's confirmation, leaving the division in the hands of acting or deputy assistant administrators; Trump never nominated anyone for the post.

This vacancy has diminished the influence of ORD scientists, says Bob Kavlock, who served as acting head of ORD before retiring in 2017. "It sends a signal when you have somebody who is confirmed by the Senate – they have much more influence," he says. "It puts them at the table with all of the regulatory folks."

Another way to restore EPA scientists' confidence is to strengthen the agency's scientific-integrity policy. Scientists both inside and outside the agency say the policy is strong, but its limitations have become clear under the Trump administration.

In the past few years, according to current and former EPA officials with knowledge of the matter, staff have filed "more than a dozen" complaints against senior political appointees with the EPA's scientific-integrity office, which is responsible for upholding the policy. The

complaints alleged actions such as intimidation of scientists and suppression of science, the officials say. But the EPA's leadership has been "less than cooperative" with the office's investigations, they add – and threatened to withdraw the policy altogether.

EPA officials declined to comment on these allegations.

Many EPA observers also expect Biden's administration to overhaul the network of independent advisory panels – comprised of scientists from academia, industry and state

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or local government – that advise the agency on public-health and environmental issues.

Trump's appointees at the EPA instituted a series of changes that pushed academic scientists off the rosters, often in favour of scientists more sympathetic to industry, says Chris Zarba, who managed activities for the main Science Advisory Board (SAB) before retiring in 2018 and now works with the Environmental Protection Network, an advocacy group of former EPA employees.

Most controversially, in 2017, the administration barred academic scientists with EPA grants from serving on advisory panels, claiming that the grants compromised the scientists' independence. Officials did not apply the same logic to the scientists with ties to industry who took the academics' place, says Zarba.

"It was a thinly veiled attempt to remove particular perspectives so that they could do what they want to do," says Robyn Wilson, a researcher who investigates risk assessment and behavioural science at the Ohio State University in Columbus. She was pushed off the SAB by the rule – and successfully sued over it.

As part of that lawsuit, an appeals court rejected the grants rule altogether. Acknowledging the court's decision, an EPA spokesperson said that scientists with grants weren't kicked off the panels, but rather given a choice about whether to keep their grant or resign – and noted that industry advisers account for only 9% of the SAB's current membership.

But that figure doesn't include consultants with ties to industry or scientists who are known to sympathize with regulated industries, EPA observers contend. According to one analysis, academic scientists occupied 75% of the SAB's seats at the end of Obama's presidency, and that number is now less than 50%.

Advocacy groups say the Trump administration stacked the decks on the EPA's boards to such an extent that Biden has little choice but to start again with new appointees. "These were committees that were constituted with an illegitimate process," says Goldman. "They need to start from scratch and reconstitute them with legitimate scientists."

"We have a chance to move forward and restore the role of science in sound public policymaking," says Carol Browner, who headed the agency under former president Bill Clinton. "But this will take time, to rebuild capacity and rebuild the expertise."

IS A BIASED ALGORITHM DELAYING HEALTH CARE FOR BLACK PEOPLE?

Sweeping calculation suggests it could be – but the best way to fix the problem is unclear.

By Jyoti Madhusoodanan

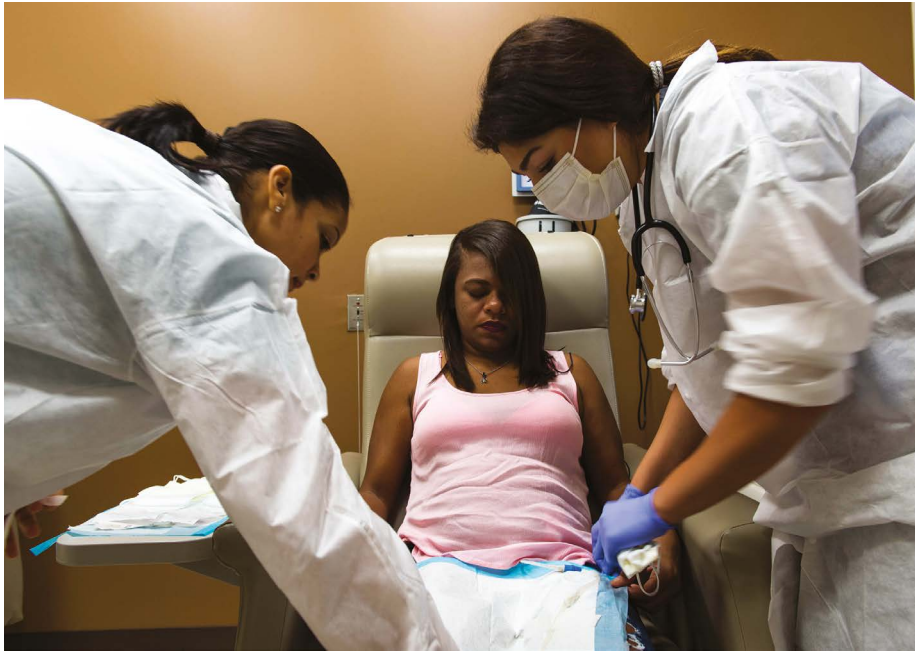
One million Black adults in the United States might be treated earlier for kidney disease if doctors were to remove a controversial 'race-based correction factor' from an algorithm they use to diagnose people, a comprehensive analysis finds.

Critics of the factor question its medical validity and say it potentially perpetuates racial bias – and that the latest study,

published on 2 December in *JAMA*¹, strengthens growing calls to discontinue its use.

"A population that is marginalized and much less likely to have necessary resources and support is the last group we want to put in a situation where they're going to have delays in diagnosis and treatment," says nephrologist Keith Norris at the University of California, Los Angeles, who argues for retiring the correction until there's clear evidence that it's necessary.

On the flip side, others say that the



A woman receives dialysis, a common treatment for people with kidney disease.

correction is based on scientific data that can't be ignored, although they, too, agree that its basis in race is a problem.

Researchers introduced the correction factor² in the late 1990s to take into account results showing that, on average, Black people in the United States tend to have higher blood levels of a molecule called creatinine than do white people – despite having similar kidney function. Creatinine levels are a marker of how well a person's kidneys filter waste from the body. Doctors feed the measurement, along with other information, into algorithms that calculate a person's estimated glomerular filtration rate (eGFR) to evaluate kidney function. High creatinine levels lead to a low eGFR, which is a sign of kidney disease; the correction inserts a multiplier of about 1.2 when calculating the eGFR of Black people, potentially making their kidneys seem healthier than they actually are.

In the past few years, institutions including Beth Israel Deaconess Medical Center in Boston, Massachusetts, have dropped the correction factor. None of them has yet released data on the action's impact. In August, the American Society of Nephrology in Washington DC and the National Kidney Foundation in New York City convened a task force to evaluate whether the medical community should stop using it. The group's initial recommendations are expected by the end of the month, with a final decision on whether to continue using the correction due in the first half of next year.

Those who want to abolish the correction say it perpetuates the problematic idea that people of different ethnicities have different biology. Also, the eGFR algorithms are just an estimate of kidney function that describe a collection of “noisy data”, says nephrologist

Rajnish Mehrotra of the University of Washington in Seattle, one of the institutions that has dropped the correction. The question, he says, is whether you're willing to perpetuate the false idea that race reflects biological differences for a “small gain in precision” that you might get from using it to evaluate kidney function.

Others worry that simply removing the correction could cause harm. Mathematical analyses such as the one in *JAMA*, they say, do not represent real-world health outcomes: it's unclear whether removing the race multiplier would actually help or hurt the health of the one million Black adults who would

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be affected. Neil Powe, an internal-medicine specialist at the University of California, San Francisco, and a co-author of the study, points out that removing the factor could lead to over-diagnosis of kidney disease in Black people, causing burdens such as extra medical bills and denying them access to medicines, such as diabetes drugs considered too risky for those with unhealthy kidneys. The correction arose because of creatinine data, he says – and as long as creatinine alone is used as a biomarker to gauge kidney function, researchers can't just ignore those data, which have been replicated³ for US study participants multiple times.

In the United States, Black people are currently almost four times as likely as white

people to experience kidney failure. It's tough to tell whether – or how much – the race-corrected algorithm has worsened this crisis, because the rate of disease is affected by other factors influenced by systemic racism, including socio-economic inequalities and a lack of health insurance, scientists say. “Race corrections to eGFRs are most likely contributing, but it's not reasonable to expect that removing the race correction will automatically solve all inequities for Black Americans with chronic kidney disease,” says Nwamaka Eneanya, a nephrologist at the University of Pennsylvania in Philadelphia who advocates dropping the correction.

Assessing a correction

In the latest analysis, researchers including Powe aimed to assess what would happen if they removed the race-based correction factor for a representative group of people. The team examined the medical records of 9,522 Black people included in the National Health and Nutrition Examination Survey, a programme run by the US Centers for Disease Control and Prevention that maintains a national database of health statistics.

Although it was unsurprising that dropping the correction would increase the number of Black people diagnosed with kidney disease, “the size of the effect surprised us”, says Arjun Manrai, a computational health researcher at Harvard Medical School in Boston, who led the study. Removing it would lead to a change in diagnosis for 3.5% of Black adults from ‘disease free’ to having early-stage kidney disease (in the US population, this would be equivalent to one million Black adults). Removing it would also shift the status of 29% of Black patients from having early-stage to advanced disease.

Andrew Levey, a nephrologist at Tufts University in Boston, is one of the researchers who originally established the correction factor. Although he has come to question whether the multiplier should be used, he isn't certain that dropping it is the answer.

A better solution, says Levey, might be to develop an algorithm that relies on biomarkers beyond creatinine. On 7 December, he and his colleagues published an eGFR algorithm that has no race-based correction factor and instead uses multiple biomarkers, in addition to creatinine⁴.

Until such algorithms are vetted for wider clinical use, Levey and others suggest talking to patients about how their race might be used in clinical decisions. He adds: “I don't think that we have been transparent in speaking with our patients about how we do this.”

1. Diao, J. A. et al. *J. Am. Med. Assoc.* <https://doi.org/10.1001/jama.2020.22124> (2020).
 2. Levey, A. S. et al. *Ann. Int. Med.* **130**, 461–470 (1999).
 3. Peralta, C. A. et al. *Am. J. Nephrol.* **31**, 202–208 (2010).
 4. Inker, L. A. et al. *Am. J. Kidney Dis.* <https://doi.org/10.1053/j.ajkd.2020.11.005> (2020).