► at Duke University in Durham, North Carolina, says that although the 24-hour genome process is impressive, it is not clear whether genomic sequencing of newborns will soon become standard practice. Many questions remain about who will pay for sequencing, who should have access to the data and how far clinicians should go in extracting genome information that is unrelated to the disease at hand. Then there is the question of how informative the process is. “I think it’s really important that we do these experiments so that we start to see what that yield is,” Angrist says.

So far, only the Kansas City team has been cleared to begin trials, thanks to a waiver from the US Food and Drug Administration (FDA) that allows sequencing of very ill babies. Normally, a test must be experimentally proven before being used to diagnose patients. “These are very pioneering studies,” Kingsmore says. “I think that everybody is keen to see whether this is the start of a new approach at FDA, and whether it will happen in the future with similar studies.”

The other NIH-funded teams are awaiting approval from the FDA or from internal ethics-review boards. In Boston, Massachusetts, a group led by physicians Alan Beggs of Boston Children’s Hospital and Robert Green of the Brigham and Women’s Hospital is planning a study of 240 healthy babies and 240 from NICUs. The team will randomly sequence the exome — the protein-encoding portions of the genome — for half of each group of infants to determine whether those data alone can improve children’s health. Exome sequencing is cheaper, albeit less comprehensive, than whole-genome sequencing.

A third team, led by geneticists Cynthia Powell and Jonathan Berg of the University of North Carolina in Chapel Hill, plans to sequence the genomes of 400 babies with known genetic diseases, such as cystic fibrosis, to see whether they can glean extra information about the disorders. And medical geneticist Robert Nussbaum’s group at the University of California in San Francisco will sequence exomes from 1,400 bloodspots, previously collected from infants at birth, to determine whether this information is useful for diagnosis.

Each team includes ethicists who will grapple with questions such as disclosing information that is unrelated to the diagnosis. “People are sensitive about the power of information in genomics and rightly so,” Green says. Those concerns are magnified when they involve children. ■

“Everybody is keen to see whether this is the start of a new approach.”

A shaman in Ecuador gathers plants to make ayahuasca, which was at the centre of a biopiracy row.

POLICY

Biopiracy ban stirs red-tape fears

Critics worry Nagoya Protocol will hamper disease monitoring.

BY DANIEL CRESSEY

A major international agreement is coming into force to combat ‘biopiracy’ — profiting from biological products while failing to compensate the community from which they originate. The Nagoya Protocol aims to ensure that developing nations benefit when their plants, animals or microbes are used by foreign scientists.

But some researchers fear that the agreement will stymie vital activities, such as conservation or monitoring and treating infectious diseases.

The protocol takes effect on 12 October, four years after it was signed in Nagoya, Japan. Its 92 signatories include Brazil, Japan and the European Union. Notably absent are China and the United States, although researchers in those countries will have to comply with the laws of nations where they collect samples.

Part of the United Nations Convention on Biological Diversity (CBD), the protocol has the stated purpose of ensuring “fair and equitable sharing of benefits arising out of the utilization of genetic resources”, which covers all organisms. Researchers must already obtain permits to collect samples from certain countries, but the protocol means that they will have

to enter into ‘access and benefit sharing’ (ABS) arrangements. These set out who might profit — and how — from the organisms being used, and stipulate how to distribute the benefits fairly, for example through co-authorship of publications, or sharing profits from products such as drugs, vaccines or crops.

Several high-profile cases underscore the need for such rules, says Braulio de Souza Dias, executive secretary of the CBD secretariat. In a case often cited as a victory against biopiracy, a European patent on an antifungal agent derived from neem, an evergreen tree native to India, was revoked in 2000 after a long legal battle, on the grounds that Indian farmers had used the fungicide for decades. Other controversies have involved a US patent on the use of turmeric in wound healing, which was withdrawn, and one on ayahuasca — a hallucinogenic tea made from Amazonian plants — which has now expired.

The importance of the issue also became apparent in 2007, when Indonesia balked at sharing samples from people infected with avian influenza with the World Health Organization, on the grounds that the nation would not benefit from any resulting papers or patents. Indeed, scientists working abroad stand to gain from the

WADE DAVIS/GETTY

protocol, says Dias, because it will build trust between them and local people, which could lead to better access to organisms. In the past, “no one trusted anyone”, he says. The protocol could also help countries to access treatments that are developed using disease samples taken from their own people.

But although scientists understand the need for ABS agreements, many worry that they will have destructive consequences.

The protocol has the potential to hamper disease monitoring, according to the London-based biomedical research charity the Wellcome Trust. Red tape could make it harder to quickly share samples across borders, which in turn could cripple efforts to monitor drug resistance in malaria, for example, or outbreaks of *Escherichia coli*. “There need to be equitable arrangements for sharing benefits, but it is absolutely critical that policy-makers ensure they do not hinder these international partnerships that are so vital to protect global public health,” says David Carr, a policy adviser at the Wellcome Trust.

The new rules will also present challenges for synthetic biologists, who combine genetic code from many different organisms to create

drugs or sensors. This could require dozens of ABS arrangements for a single product, says Tim Fell, chief executive of Synthace, a biotechnology company in London. Such bureaucracy could push European companies to countries — particularly the United States — that are not signatories, he adds.

“If I compare two sequences, is that utilization? I don’t know.”

International research collaborations may face a bureaucratic challenge if their members operate under different laws, says the London-based BioIndustry Association.

There is also uncertainty about the protocol’s reach, particularly for genetic sequences. A possible interpretation of the rules is that anyone who uses sequence data would have to complete ABS paperwork. Christopher Lyl, who studies weevils at London’s Natural History Museum, helps to run a CBD website that provides advice about the protocol. Even he is unsure of how it will affect him: “If I compare two sequences to reach a conclusion on identification, is that utilization? I don’t know.”

The BioIndustry Association also says

that the threat of criminal charges for non-compliance — the UK government is considering jail terms of up to two years — could have a chilling effect on research.

Some researchers think that the protocol could even hurt the countries it is intended to help. Kazuo Watanabe, director of the Gene Research Center at the University of Tsukuba in Japan, fears that red tape surrounding access to and exchange of specimens will hinder field studies in disciplines such as taxonomy and ecology. This, in turn, will make it harder to help conservation efforts.

Dias acknowledges the potential problems, but says that people will have to deal with them: “There will be a cost for a transition phase, yes, but it should be for the better.”

Elisa Morgera, who specializes in global environmental law at the University of Edinburgh, UK, agrees. There may be uncertainty in the short term, with “difficult negotiations and possible missteps”, she says, but the protocol offers a way to rebuild trust. “Those genuinely interested in the long-term viability and reputation of bio-based research and innovation would be well advised to constructively contribute to this process,” she says. ■

INFECTIOUS DISEASE

Ebola obstructs malaria control

Outbreak is shutting down prevention and treatment programmes in West Africa.

BY ERIKA CHECK HAYDEN

As the Ebola death toll spirals into the thousands in West Africa, the outbreak could have a spillover effect on the region’s deadliest disease. The outbreak has virtually shut down malaria control efforts in Liberia, Guinea and Sierra Leone, raising fears that cases of the mosquito-borne illness may start rising — if they haven’t already.

So far, at least 3,000 people are estimated to have died of Ebola in Guinea, Sierra Leone and Liberia in the current outbreak, although World Health Organization (WHO) staff acknowledge that official figures vastly underestimate the total. By contrast, malaria killed more than

6,300 people in those countries in 2012, most of them young children. Overall, malaria deaths have fallen by about 30% in Africa since 2000 thanks to national programmes supported by international funding agencies such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the US Agency for International Development and the WHO’s Roll Back Malaria initiative. The schemes distribute free bed nets to protect sleeping children from mosquitoes, train health workers to find malaria cases and offer tests and treatment at no charge to patients.

But the Ebola outbreak has brought those efforts to a standstill in the three affected countries. “Nobody is doing a thing,” says Thomas Teuscher, acting executive director of the Roll

Back Malaria Partnership, based in Geneva, Switzerland.

He says that malaria drugs are sitting in government warehouses, especially in Liberia and in Guinea, where medical supply trucks have been attacked by people angry with the government’s handling of the Ebola outbreak. Liberia had planned a national campaign to distribute bed nets this year, but Teuscher says that it may be difficult to launch that now.

Routine health care has collapsed during the outbreak, because both patients and providers have shunned clinics for fear of infection. As a result, tens of thousands of people could die from treatable causes, says Estrella Lasry, a tropical-medicine specialist for medical

**MORE
ONLINE**

TOP STORY

Physicists manage to squeeze quantum data for the first time
go.nature.com/nb7vqv

MORE NEWS

- Earth has water older than the Sun go.nature.com/ft3jwn
- ‘Weak nuclear force’ explains life’s asymmetry go.nature.com/lqhngq
- Nobel laureates want Iranian physicist freed from Teheran prison go.nature.com/1htceb

EXPLAINER

Were warnings of Japan eruption missed?
go.nature.com/xntje5