

# CAREERS

**RESEARCH ETHICS** Team seeks data for integrity-promoting workplaces **p.713**

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Global-health specialist Adrian Hill examines a candidate Ebola vaccine for a ground-breaking clinical trial.

## PUBLIC HEALTH

# Behind a vaccine

*A burgeoning vaccine industry paves paths for scientists to spread their knowledge outside the laboratory.*

BY BRYN NELSON

In August 2014, officials from the World Health Organization (WHO) called global-health specialist Adrian Hill, who is the director of a non-profit vaccine-research centre. They had an urgent question: how soon could the centre launch a clinical trial for an Ebola vaccine?

“They weren’t talking months — they were talking weeks, if not days,” says Hill, who works at the Jenner Institute in Oxford, UK. A non-profit partnership between the University of Oxford and the animal-health-focused Pirbright Institute in Woking, UK, the Jenner

Institute had vaccine-research programmes in progress that targeted nearly 20 human and veterinary diseases — but not Ebola.

Yet within a month of the phone call, the institute had launched an Ebola-research initiative. And six months later, it was testing candidate vaccines, including one in a phase III trial that involved 27,000 people in Liberia.

The rapid implementation of this programme underscores the swift pace and nimble nature of vaccinology, in sharp contrast to other disciplines in which it can take decades to gather results and create practical applications. And although priorities can shift rapidly, the pressing nature of

outbreaks means that researchers can see their ideas implemented quickly to tackle a major disease. “There are not many fields where you can go in as a graduate student to a lab and finish up four years later, and something you’ve made with your own hands at the bench is being used to immunize people in a clinical trial that you are part of,” Hill says.

Early-career scientists with an eye on vaccinology do not necessarily need a PhD. Because the field is geared towards translating research into practice (see ‘Vaccination campaigns must deliver trust first’), many employers value practical lab experience and a humanitarian mindset, and are willing to provide on-the-job training to promising candidates.

Getting a vaccine from the lab to the clinic requires an approach that includes fields from microbiology to chemical engineering. “One of the attractions for a young person coming into this field is that it’s so diverse,” says Hill. “You can head off in different directions.” Opportunities exist throughout industry, the non-profit sector and academia.

## VACCINATION CONTAGION

The global vaccine market has boomed in the past couple decades. Between 2000 and 2013, the market value for vaccines soared from US\$5 billion to almost \$24 billion; by 2025, that value is expected to quadruple. Groups around the world are trying to devise effective vaccines for dozens of diseases, especially the ‘big three’ — HIV/AIDS, malaria and tuberculosis.

In 2000, the Bill & Melinda Gates Foundation in Seattle, Washington, began pouring money into the development and distribution of vaccines for economically disadvantaged nations. After 11 September 2001, the US and other governments began to prioritize vaccine research for diseases that could be used in bioterrorism. And the WHO and other aid organizations have helped to drive home the necessity of controlling diseases in developing countries, such as the ongoing Ebola outbreak in West Africa.

Novavax, a vaccine research-and-development company in Gaithersburg, Maryland, has more than tripled in size over the past 4 years to roughly 300 employees. “Novavax is hiring like crazy,” says Christi McDowell-Patterson, director of upstream process development for the company. Her department, a mix of chemical engineers, cell biologists and other scientists, manages the cell lines and equipment used to create the company’s vaccine candidates, including ones for Ebola, influenza and respiratory syncytial virus. ▶

► Novavax also hires summer interns — mainly undergraduates or recent graduates with bachelor's degrees. "If we like them, we'll try to figure out a way to keep them on," McDowell-Patterson says. Novavax, along with other companies and organizations — such as Sanofi, Novartis and the International AIDS Vaccine Initiative — offers tuition reimbursement to support graduate education for promising young scientists.

Apart from the many perks Novavax offers, ranging from yoga classes to a bowling league, chemist Natalie Thompson was most intrigued by the company's production methods, which use virus-like particles and nanoparticles composed of recombinant proteins. She joined the company in March 2014 after completing a PhD in analytical chemistry and a three-year postdoc during which she used mass spectrometry to study monoclonal antibodies.

At Novavax, she employs analytical methods such as liquid chromatography and mass spectrometry to determine the constituents and quality of the company's vaccine products. "What I enjoy about working in industry is that the final goal is really defined," she says. She also likes the fast pace, and that many different teams work together.

#### A SYMBIOTIC RELATIONSHIP

Many vaccine-development organizations have set up shop near universities to take advantage of local academic expertise, which means that opportunities for budding vaccinologists are often steps away. Gerald Strohmaier, global head of industrial relations and corporate finance at the biotechnology company Valneva, regularly draws talent from the University of Vienna, which hosts the company's main research facility. "We do not have a huge scouting department looking for talent all over the world," he says. "But whatever we can do with students, we do." Although Valneva hires only a few postdocs at a time, scientists who score a position have excellent job prospects — as many as 80% of them secure permanent jobs with the company.

Whereas pharmaceutical and biotech companies focus on more-marketable vaccines, many non-profit institutes are researching vaccines that have less commercial value. Salaries at these institutes are generally lower than those for university or industry jobs, but people do have the potential to make a humanitarian difference in developing countries.

The International Vaccine Institute (IVI), for example, is an independent organization at Seoul National University in South Korea that creates and introduces vaccines for neglected infectious diseases. One of the institute's most-successful developments is a low-cost oral vaccine for cholera. But that vaccine requires two doses given two weeks apart, and IVI researchers are in the process of analysing data from a clinical trial of 200,000 people in Bangladesh to gauge the effectiveness of a

## WORDS BEFORE NEEDLES

### *Vaccination campaigns must deliver trust first*



**Partnerships with health centres in developing countries help to immunize local children.**

Vaccine hesitancy — the reluctance to receive or engage in vaccination — is insidious and alive. In northern India, a polio-vaccination campaign had to dispel rumours about potential side effects. The rumours had been spread by parents who had objected to strangers vaccinating their children. In Kenya, religious leaders who had not been consulted before a tetanus-vaccine initiative revived a 20-year-old rumour that the vaccine would sterilize children.

Heidi Larson has seen countless permutations of this issue. So accustomed was she to dealing with it during her work at the United Nations children's charity UNICEF in New York City that she became known as the director of UNICEF's fire department. The organization sent her around the world to extinguish the fires of distrust and suspicion that often impede the delivery and acceptance of desperately needed vaccines.

An anthropologist by training, she had worked extensively on HIV and AIDS issues affecting adolescents in Nepal and the South Pacific. "I really had thought coming from AIDS into vaccines would be a bit bland," she says. "To my surprise, this whole area of the introduction of new vaccines saw more emotional and political challenge than I ever could have imagined."

Director of the Vaccine Confidence Project at the London School of Hygiene and Tropical Medicine, Larson is mapping the social, cultural and political challenges to vaccination efforts around the world, from northern Nigeria to southern California.

Skills in vaccine introduction, risk management and communication are often overlooked, but groups such as UNICEF and the World Health Organization are increasingly recognizing their value. As a result, career opportunities are emerging

for good communicators with a desire to combine science and public service, helping vaccination teams to earn the support of local communities. "I have more and more people contacting me who want to do masters and PhDs with our group and, at the same time, I have more and more demand for this type of work," Larson says. Some organizations are so desperate for help that Larson is developing a training course that can be completed more quickly than a masters or PhD.

Scientists can also do a graduate programme in public-health communication, and the US National Public Health Information Coalition and the Virtual Immunization Communication Network have compiled tools and training options.

Larson is leading the communication and preparedness effort for an Ebola-vaccine trial in Africa that will involve an initial shot and follow-up boost. She and her colleagues are engaging community leaders to work out acceptable procedures, from how to seek informed consent from the local population to how to distribute and administer the vaccine.

Even small misunderstandings can have profound consequences. The head of one vaccine programme related how ignorance of a local custom — addressing religious leaders and elders with honorifics to show respect — probably contributed to a year-long delay in getting approval for a mass typhoid-vaccination campaign in south Asia. When a colleague corrected the misstep, approval was gained in a few weeks.

For a vaccine trial in Gambia, one of Larson's graduate students modified the informed-consent process to align with the region's oral tradition, replacing written documents with an interactive video in the local language. The approach enhanced comprehension and retention, especially for people who had low levels of literacy.

"There's a real science behind how you introduce a new vaccine. It just doesn't happen by accident," says Peter Jay Hotez, president of the Sabin Vaccine Institute and Texas Children's Hospital Center for Vaccine Development in Houston. Beyond building partnerships, it also requires engaging in public dialogue.

Despite the dearth of formal programmes focused on vaccine outreach and communication, Hotez and other researchers say that those who have the skills and diplomacy can be crucial assets for ensuring that a vaccine-development scheme does not fall short of its goal. **B.N.**

one-dose version to improve compliance. The institute is always on the lookout for research talent, says Sushant Sahastrabudde, a physician who heads the institute's Enteric and Diarrheal Disease Programme. Its international scientific staff of about 50 includes researchers with PhDs, medical doctorates and master's degrees.

The formation of partnerships between non-profit organizations and developing countries is also creating job opportunities. The Infectious Disease Research Institute (IDRI) in Seattle, Washington, employs about 125 people and works with nearly 100 collaborators around the world. It has helped to establish vaccine-formulation centres in South Africa and India. Manufacturing vaccines locally instead of importing them can decrease both the cost and distrust of the product, says Steven Reed, IDRI's founder.

The need to bolster public-health infrastructure in developing regions has become increasingly important. "There's minimal, almost zero, capacity to develop vaccines in the Middle East, north Africa and sub-Saharan Africa," says Peter Jay Hotez, president of the non-profit Sabin Vaccine Institute and Texas Children's Hospital Center for Vaccine Development in Houston. "And yet these are the places where we're going to see the next generation of catastrophic emerging infections." The US Department of State named Hotez as a US Science Envoy, a role designed to help promote international partnerships. For his project, he is pushing to expand vaccine infrastructure in Africa and the Middle East by focusing on countries such as Saudi Arabia and Morocco, which have an established scientific culture and PhD-level scientists. If he succeeds, programmes that increase vaccine production in these places could lead to more jobs for local scientists, as well as for international consultants.

For him, vaccinology provides the "perfect confluence" of humanitarian values and biomedical and social science. And as Hill can attest, the work is seldom boring. The past six months have been particularly "invigorating and energizing", he says, with regular enquiries about the Ebola trials from the British Prime Minister's office and other top government officials. "Going to the highest level of government with what you assayed yesterday," he says, "is pretty exciting." ■

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## WORKPLACE CLIMATE

# Metrics for ethics

*Focus on perceived working conditions could help graduate schools to train responsible researchers.*

BY MONYA BAKER

Training in research ethics is mandatory for many US graduate students and postdocs, but there is little evidence that formal classes prompt scientists to conduct research ethically. However, the workplace climate — which includes perceptions of regulatory committees, data confidentiality and treatment of trainees — influences research practices and can spawn behaviours such as poor record-keeping or plagiarism.

An interdisciplinary team has developed a survey to assess work conditions in research institutions, with a long-term goal of establishing a baseline for measurements of workplace climate across disciplines and universities. The SOuRCe (Survey of Organizational Research Climate) is a 32-question survey that divides workplace climate into seven categories, including integrity norms (such as giving due credit to others' ideas), integrity inhibitors (such as inadequate access to material resources) and adviser–advisee relations. The team hopes that such data will help institutions to craft policies that will improve research conduct.

The survey illuminates differences in attitudes held by faculty members and trainees, says Karen Klomprens, dean of the graduate school at Michigan State University (MSU) in East Lansing. When the school ran versions of the survey in 2009 and 2014, clusters

of respondents reported feeling ill-equipped to judge whether university policies support responsible research — which suggests that those topics are not discussed in meaningful ways, she says. Klomprens used the results to spur faculty members in specific departments to talk to trainees about norms in authorship, data management and peer review. "Because we use the survey data by graduate programme and by discipline, we can make recommendations," she says. To encourage participation, she emphasized to respondents that the tool is not intended to shame or punish, and responses are stripped of identifying information.

Brian Martinson studies research integrity at the non-profit HealthPartners Institute for Education and Research in Bloomington, Minnesota, and helped to develop the survey at 40 academic health centres (B. C. Martinson *et al. Sci. Eng. Ethics* 19, 813–834; 2013). He has also worked on it in a separate project with MSU, Pennsylvania State University and the University of Wisconsin–Madison. A poor workplace climate correlates with many undesirable research behaviours, even extreme forms such as data falsification, he explains (see 'Ethics in the environment'). Still, he thinks that institutions could boost integrity most effectively by focusing on common, less-attention-grabbing behaviours that are tightly tied to workplace climate, such as sloppy record-keeping. "They lower the standards that people are following over the long run," he says.

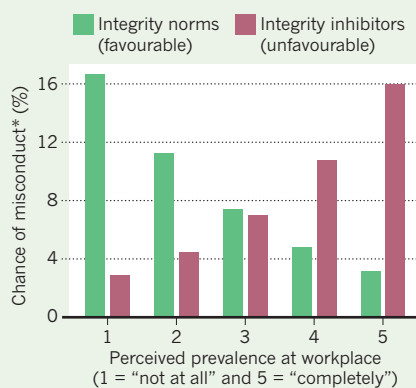
The dearth of robust, real-world research has long hampered efforts to improve integrity, says C. K. Gunsalus, director of the National Center for Professional and Research Ethics in Urbana, Illinois, who is working with Martinson's team to distribute the study online. "The climate survey provides actual empirical data," she says.

Gunsalus and others aim to aggregate results in a central database, so that a physics department at one institution, for instance, will be able to compare its climate scores with those of similar departments elsewhere.

Analysing workplace climate could be a powerful way to promote integrity, says Nicholas Steneck, a consultant for the US Office of Research Integrity in Rockville, Maryland, although he fears that institutions might find it tough to apply SOuRCe results to policy. But Gunsalus thinks that broad, quantitative survey results could make the issue more difficult to neglect. "The best thing that gets traction with scholars and scientists," she says, "is data." ■

## ETHICS IN THE ENVIRONMENT

The level of self-reported fraud, fabrication and plagiarism increases as perceptions of 'integrity norms' fall and of 'integrity inhibitors' rise.



\*Predicted likelihood that an individual would report engaging in fraud, fabrication or plagiarism, according to regression analysis of a large survey on research behaviour and workplace climate during the past three years.