Pandemic vaccine enters clinical trials

The majority of the seasonal flu vaccine has already been shipped ahead of flu season in the Northern Hemisphere, but candidate vaccines against pandemic H1N1—which had killed nearly 1,800 people as of August—are just entering clinical trials. Health officials predict that the first doses should be available, at the earliest, in September.

"The hope is that we will have vaccine available in time to still have a substantial impact in terms of preventing cases during what would normally be the peak season," says Art Reingold, head of the epidemiology division at the University of California in Berkeley and a member of the World Health Organization's Strategic Advisory Group of Experts on Immunization.

The planned clinical trials of H1N1 vaccine, which will involve about 30,000 people in at least nine countries, will provide short-term safety data and help health officials decide whether one or two doses will be needed, how large each dose needs to be and whether the seasonal flu shot should come before, after or alongside the pandemic vaccine. Seven of these trials are being sponsored by the US National Institute of Allergy and Infectious Diseases (NIAID) to test inactivated H1N1 vaccines from Sanofi-Aventis, the world's largest flu vaccine manufacturer, and Australia-based manufacturer CSL Biotherapies. Other companies, including Novartis, GlaxoSmithKline and Baxter, are conducting their own trials as well.

One manufacturer, China-based Sinovac, already has preliminary results. On 18 August, the company announced that data from a trial of 1,600 people in Beijing suggest that its vaccine against H1N1 is safe and that one dose will be sufficient. As this issue of *Nature Medicine* went to press, the company had not yet specified the dose needed to raise an immune response.

Even with manufacturers working round the clock, vaccine supplies might outstrip initial demand. Growing the vaccine virus in chicken eggs—the conventional method of flu vaccine production—is a time-consuming process, and the seed strain for H1N1 has been growing more slowly than anticipated. A new method involves growing vaccine virus in cell culture, but this process has not been approved in the US. Anthony Fauci, head of NIAID, says that cell-based vaccines would only be used "if we run into an emergency where we don't have enough of the egg-based vaccines."

Although manufacturers of the inactivated H1N1 vaccine are reporting lower than expected yields, MedImmune, a subsidiary of AstraZeneca, is getting higher than expected yields of its live nasal mist vaccine—about 80 doses per egg compared to 1 or 2 doses per egg for the inactivated vaccines. "There is a possibility that a much larger quantity of the live vaccine will be available early. And this could be used very advantageously by immunizing healthy schoolchildren and working adults," says W. Paul Glezen, a flu expert at Baylor College of Medicine in Houston, Texas. "Those are the groups that spread the virus in the community."

Cassandra Willyard, New York

New plan seeks to accelerate African diagnostic capacity

Africa is home to 60% of the world's HIV/AIDS burden, 90% of its malaria cases and nearly a quarter of the globe's tuberculosis sufferers, but only a handful of clinical laboratories can properly identify and treat patients. That could soon change, however, thanks to an ambitious accreditation initiative unveiled on 27 July that seeks to double Africa's diagnostic laboratory capacity over the next two years.

Supported by the World Health Organization Regional Office for Africa (WHO/AFRO) and the US President's Emergency Plan for AIDS Relief (PEPFAR), the new initiative is built upon a five-step framework that scientists believe will be crucial for its success.

Previously, African laboratories had to achieve full accreditation to be recognized. These standards sometimes seemed "ridiculously overwhelming," leading many labs to give up before even starting the process, explains Deborah Birx, director of the Global AIDS Program at the US Centers for Disease Control and Prevention (CDC), which is helping to implement the new framework. The new initiative is built on a tiered approach that promotes encouragement. "It gives you a roadmap to implement improvement," Birx says.

According to John Nkengasong, chief of the International Laboratory Branch at the CDC's Global AIDS Program, labs from any of the 46 African countries that are part of the WHO/AFRO network can take part, irrespective of the diseases on which they focus. In November, the CDC and the WHO plan to host a workshop to train scientists on the proposed management tools so that they can educate other scientists in their regions. Within two years, Nkengasong hopes that as many as 60 labs in sub-Saharan regions other than South Africa will be accredited, doubling the 28 that are today.

The initiative "is affordable, it's scalable, it's effective and it's not disease specific," Nkengasong says. "All of these elements allow for sustainability."

Melinda Wenner, New York

Sealants get specific

Researchers from the Massachusetts Institute of Techology say they have new insights into how a glue-like material might be tailored to work with specific tissues and organs. The authors of the paper, published online this summer, think that the current surgical sealants used to repair wounds have not reached their true potential. "The structure, surface properties and internal architecture of different organs can vary dramatically, and the idea that one material is ideal for all tissues and applications is simplistic," says Elazer Edelman, the lead investigator on the paper (*Adv. Mater.*, doi:10.1002/adma.200900340; 2009).

Edelman notes that even organs that reside in the same body cavity are subject to varying mechanical forces, have different surface chemistry, are exposed to different pH and react to sealants in different manners. In the new research, his group examined the performance of a sealant composed of polyethylene glycol and dextran aldehyde when applied to heart, lung, liver and duodenum tissues from rats. On the basis of this, they propose ways to modify the sealant's reactivity with various tissues.

Zaverio Ruggeri of the Scripps Research Institute in California says that, although the proposed sealant has not yet been shown to be superior to currently available sealants, the concept of tissue specificity addressed in this study is "stimulating" and new. "Surgeons might need a whole collection of different glues depending on the organs involved in the operation," he adds.

Nayanah Siva, London