

New silk technology stabilizes vaccine and antibiotics so refrigeration is not needed

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Researchers funded by the National Institutes of Health have developed a new silk-based stabilizer that, in the laboratory, kept some vaccines and antibiotics stable up to temperatures of 140 degrees Fahrenheit. This provides a new avenue toward eliminating the need to keep some vaccines and antibiotics refrigerated, which could save billions of dollars every year and increase accessibility to third world populations.

Vaccines and <u>antibiotics</u> often need to be refrigerated to prevent alteration of their <u>chemical structures</u>; such alteration can result in less potent or ineffective medications. By immobilizing their bioactive molecules using <u>silk protein</u> matrices, researchers were able to protect and stabilize both live vaccines and antibiotics when stored at higher than recommended temperatures for periods far longer than recommended.

The research was led by grantees of NIH's National Institute of <u>Biomedical Imaging</u> and Bioengineering (NIBIB), David Kaplan, Ph.D., and Jeney Zhang, Ph.D. candidate, at Tufts University School of Engineering in Medford, Mass. The National Eye Institute and the National Institute of Dental and Craniofacial Research at NIH also contributed to this research. The researchers reported on their findings in the online issue of <u>Proceedings of the National Academy of Sciences</u> on July 9, 2012.

"This truly exciting development is the culmination of years of creative exploration and research focused on a major problem in the delivery of



health care. Dr. Kaplan and his team have done a masterful job at both understanding the key properties of silk, and applying these insights to a global medical challenge," said NIBIB Director Roderic I. Pettigrew, Ph.D., M.D. "This is also a wonderful validation of the type of team science we see in our Biotechnology Resource and Development Centers and their ability to combine <u>cutting edge science</u> in a number of fields to a variety of health needs."

Pettigrew also points out that the next step is to test it in the field.

Keeping medications cold from production until they are used in treatment is a costly process, accounting for as much as 80 percent of the price of vaccinations. The need for a cold chain has been a difficulty for health care providers, aid organizations, scientists and pharmaceutical companies for decades, especially in settings where electricity is limited. Failures in the chain result in the loss of nearly half of all global vaccines, according to researchers.

In an attempt to solve this problem, Kaplan and his lab have been working extensively with silk films that essentially wrap up the live bioactive molecules present in antibiotics and vaccines. This protects these essential bioactive elements, and so can greatly extend the shelflife of the medication. Silk is used because it is a protein polymer with a chemistry, structure, and assembly that can generate a unique environment, making it an attractive candidate for the stabilization of bioactive molecules over extended periods of time.

To test their new silk stabilizers, Kaplan's team stored the measles, mumps, and rubella (MMR) vaccines for six months at the recommended 39.2 degrees Fahrenheit, as well as at 77, 98.6, and 113 degrees Fahrenheit. The results show that encapsulation in the new silk films maintained the potency with minimal loss over time and enhanced stability, even at very high storage temperatures. Similarly, antibiotics



entrapped in silk films maintained near optimal activity even at temperatures as high as 140 degrees. In addition, Kaplan's group found that these silk films had the added benefit of protecting one antibiotic against the detrimental effects of light exposure.

The silk stabilizers are likely to combine well with Kaplan's previously developed silk microneedle system. These tiny needles can deliver medication directly to skin cells that contain a specified antigen. This targeted approach permits administration of lower doses of medication or <u>vaccine</u> and generates longer-lasting immune responses. The combination could prove to be a simple way to stabilize, distribute, and deliver the medication in one system.

Thus, for vaccines and antibiotics, the use of a silk carrier reduces the detrimental effects of heat and humidity.

"New studies are already under way," says Dr. Kaplan. "We have already begun trying to broaden the impact of what we're doing to apply to all vaccines. Based on what we've seen with other proteins, peptides, and enzymes, there's no reason to believe that this wouldn't be universal. This could potentially eliminate the need for a cold-chain system, greatly decreasing costs and enabling more widespread availability of these lifesaving drugs."

More information: "Stabilization of vaccines and antibiotics in silk and eliminating the cold chain," by Jeney Zhang et al. *PNAS*.

Provided by National Institutes of Health

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