



TEMPERATURE STABLE VACCINES

Stable vaccines without the need for cold chain storage



TECHNOLOGY

A research team at the University of Bath has developed an award-winning method to protect biopharmaceuticals at room temperature, in particular vaccines, potentially removing the need for cold chain storage. Biological substances based on proteins, including vaccines, antibodies, and enzymes degrade at room temperature due to denaturation. As a consequence their storage and distribution relies on continuous cold chain refrigeration; this is costly and not always effective.

Our new method, called ensilication, relies on application of silica layers on individual biologicals, such as proteins, viruses, peptides and others. By using a silica “cage” grown around the protein molecules we can render them stable against long term ambient temperatures for storage and transport. Proteins preserved through the ensilication method can be released intact, retaining their structure and function. Ensilication offers the prospect of a solution to the “cold chain” problem for biological materials, especially for vaccines, antibodies and other biopharmaceuticals.

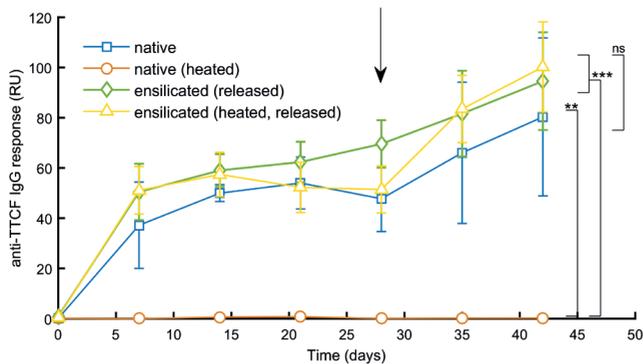
To show the potential of the technology we have evaluated ensilication of thirteen targets: lysozyme, a well-characterised protein with enzymatic activity; horse haemoglobin, a heterotetrameric protein with a complex

tertiary and quaternary structure; tetanus toxin C-fragment (TTCF), a vaccinogenic tetanus fragment, part of the commonly used DTP vaccine, small peptides such as insulin and others.

While ensilicated, these proteins have been subjected to heating at 100°C under dry and wet conditions, chilled up to -20°C, and stored for up to 3 years at ambient conditions. They have then been released from silica, and both their structure and function have been preserved. Data at ambient conditions show that ensilication is as good as lyophilisation at room temperatures, but considerably better than lyophilisation at low temperatures.

In vivo mice responses indicate similar immune response from ensilicated TTCF that was heated and sent by normal (non-cold chain) postage, where unprotected TTCF denatured in similar conditions and failed to incite any immune response.

The results demonstrate that proteins in solution can be encased in a covalently bonded silica network, transported without cold chain, and subsequently released back into solution without loss of structure and function. This has the potential to transform the vaccine market, removing our dependence on cold chain.



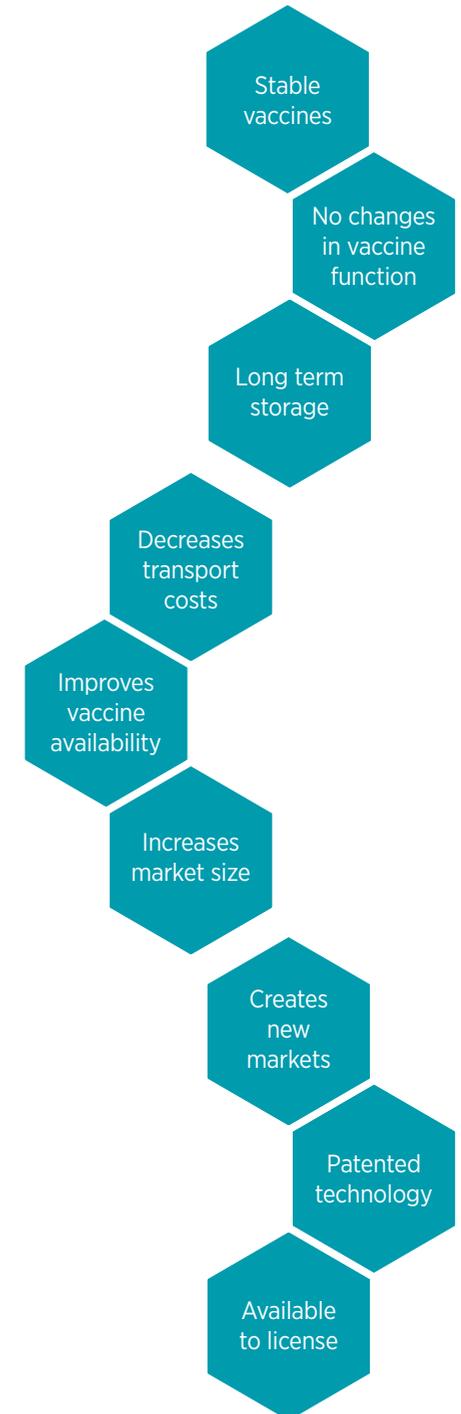
Serum IgG response from mice immunised with TTCF after ensilication. From *Scientific Reports* 10, 9243, 2020.

BENEFITS

- An award-winning method to protect biopharmaceuticals, especially vaccines, at room temperature
- Stable against long term ambient temperatures
- No changes in vaccine function
- Improves vaccine availability
- Enables long term storage
- Significantly decreased transport costs
- Increases the size of current markets
- Creates new markets

FURTHER INFORMATION

- Sartbeava et al 2020. *RCS Advances*, 10, 29789.
- Sartbeava et al 2020. *Sci. Reports* 10, 9243.
- Sartbeava et al 2019. *Sci. Reports* 9, 11409.
- Sartbeava et al 2017. *Sci. Reports* 7, 46568.
- Sartbeava 2018. *The Chemical Engineer*, 921, 24-29. IChemE Hansen Medal received April 2019.
- Sartbeava and Doekhie 2020. *The conversation*. theconversation.com/vaccines-often-degrade-in-the-heat-heres-how-our-new-chemical-casing-could-save-lives-118361
- Awards: IChemE Biotechnology Award, 2017; Biggest Game changing award, Innovate UK-SetSquared, 2016; Hanson Medal, iChemE, 2019; Emerging Technologies Competition, 2020.
- The research outlined has been developed by Dr Asel Sartbeava from the University of Bath



CONTACT

The University of Bath is looking for partnerships to help develop this technology for a variety of sectors. If you are interested to discover more then please get in contact.

TECHNICAL

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