## Recent publications

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### Induction of protective immunity against H1N1 influenza A(H1N1)pdm09 with spray-dried and electron-beam sterilised vaccines in non-human primates

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Currently, the need for cooled storage and the impossibility of terminal sterilisation are major draw-backs in vaccine manufacturing and distribution. To overcome current restrictions a preclinical safetyand efficacy study was conducted to evaluate new influenza A vaccine formulations regarding thermalresistance, resistance against irradiation-mediated damage and storage stability. We evaluated the effi-cacy of novel antigen stabilizing and protecting solutions (SPS) to protect influenza A(H1N1)pdm09 splitvirus antigen under experimental conditions in vitro and in vivo.Original or SPS re-buffered vaccine (Pandemrix) was spray-dried and terminally sterilised by irradi-ation with 25 kGy (e-beam). Antigen integrity was monitored by SDS-PAGE, dynamic light scattering,size exclusion chromatography and functional haemagglutination assays. In vitro screening experimentsrevealed a number of highly stable compositions containing glycyrrhizinic acid (GA) and/or chitosan.The most stable composition was selected for storage tests and in vivo assessment of seroconversion innon-human primates (Macaca fascicularis) using a prime-boost strategy. Redispersed formulations withoriginal adjuvant were administered intramuscularly.Storage data revealed high stability of protected vaccines at 4◦C and 25◦C, 60% relative humidity,for at least three months. Animals receiving original Pandemrix exhibited expected levels of serocon-version after 21 days (prime) and 48 days (boost) as assessed by haemagglutination inhibition andmicroneutralisation assays. Animals vaccinated with spray-dried and irradiated Pandemrix failed toexhibit seroconversion after 21 days whereas spray-dried and irradiated, SPS-protected vaccines elicitedsimilar seroconversion levels to those vaccinated with original Pandemrix. Boost immunisation with SPS-protected vaccine resulted in a strong increase in seroconversion but had only minor effects in animalstreated with non SPS-protected vaccine.In conclusion, utilising the SPS formulation technology, spray-drying and terminal

sterilisation ofinfluenza A(H1N1)pdm09 split virus vaccine is feasible. Findings indicate the potential utility of suchformulated vaccines e.g. for needle-free vaccination routes and delivery to countries with uncertain coldchain facilities.