Recent publications

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Vaccine 2014 April, Volume 32, Issue 19

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 safety and efficacy study was conducted to evaluate new influenza A vaccine formulations regarding thermal resistance, resistance against irradiation-mediated damage and storage stability. We evaluated the efficacy of novel antigen stabilising and protecting solutions (SPS) to protect influenza A(H1N1)pdm09 split virus antigen under experimental conditions in vitro and in vivo. Original or SPS re-buffered vaccine (Pandemrix) was spray-dried and terminally sterilised by irradiation 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 experiments revealed 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 in non-human primates (Macaca fascicularis) using a prime-boost strategy. Redispersed formulations with original 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 seroconversion after 21 days (prime) and 48 days (boost) as assessed by haemagglutination inhibition and microneutralisation assays. Animals vaccinated with spray-dried and irradiated Pandemrix failed to exhibit seroconversion after 21 days whereas spray-dried and irradiated, SPS-protected vaccines elicited similar 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 animals treated with non SPS-protected vaccine. In conclusion, utilising the SPS formulation technology, spray-drying and terminal
sterilisation of influenza A(H1N1)pdm09 split virus vaccine is feasible. Findings indicate the potential utility of such formulated vaccines e.g. for needle-free vaccination routes and delivery to countries with uncertain coldchain facilities.