DOWNLOAD PDF ADMISSION, DISCHARGE, AND TRANSFER SYSTEM PROTECTION PROFILE (ADT-PP)

Chapter 1 : USA1 - Vaccine Compositions Comprising a Saponin Adjuvant - Google Patents

The set of security functional and assurance requirements is expressed in a format that conforms to the Protection Profile (PP) framework that is the part of the ISO/IEC security calendrierdelascience.com underlying motivation in developing the Admissions, Discharge and Transfer System PP (referred to ADT-PP) is to demonstrate the use of a protection.

Malaria the medicinal preparation containing antigens or antibodies, e. In particular the invention relates to adjuvanted vaccine compositions wherein the adjuvant is a liposomal formulation, comprising a saponin and a lipopolysaccharide. The present invention further relates to influenza vaccine formulations and vaccination regimes for immunizing against influenza disease. As one strategy, adjuvants have been used to try and improve the immune response raised to any given antigen. Lipopolysaccharides LPS are the major surface molecule of, and occur exclusively in, the external leaflet of the outer membrane of gram-negative bacteria. LPS impede destruction of bacteria by serum complements and phagocytic cells, and are involved in adherence for colonisation. LPS are a group of structurally related complex molecules of approximately 10, Daltons in size and consist of three covalently linked regions: The biological activities of LPS, such as lethal toxicity, pyrogenicity and adjuvanticity, have been shown to be related to the lipid A moiety. In contrast, immunogenicity is associated with the O-specific polysaccharide component O-antigen. Both LPS and lipid A have long been known for their strong adjuvant effects, but the high toxicity of these molecules has precluded their use in vaccine formulations. Significant effort has therefore been made towards reducing the toxicity of LPS or lipid A while maintaining their adjuvanticity. The Salmonella minnesota mutant R was isolated in from a culture of the parent smooth strain Luderitz et al. The colonies selected were screened for their susceptibility to lysis by a panel of phages, and only those colonies that displayed a narrow range of sensitivity susceptible to one or two phages only were selected for further study. This effort led to the isolation of a deep rough mutant strain which is defective in LPS biosynthesis and referred to as S. In comparison to other LPS, those produced by the mutant S. LPS is typically refluxed in mineral acid solutions of moderate strength e. Quillaja saponins are a mixture of triterpene glycosides extracted from the bark of the tree Quillaja saponaria. Crude saponins have been extensively employed as veterinary adjuvants. Quil-A is a partially purified aqueous extract of the Quillaja saponin material. By way of example, influenza vaccines and vaccines against human papilloma virus HPV have been developed with adjuvants. Influenza viruses are one of the most ubiquitous viruses present in the world, affecting both humans and livestock. Influenza results in an economic burden, morbidity and even mortality, which are significant. The influenza virus is an RNA enveloped virus with a particle size of about nm in diameter. It consists basically of an internal nucleocapsid or core of ribonucleic acid RNA associated with nucleoprotein, surrounded by a viral envelope with a lipid bilayer structure and external glycoproteins. The inner layer of the viral envelope is composed predominantly of matrix proteins and the outer layer mostly of host-derived lipid material. Influenza virus comprises two surface antigens, glycoproteins neuraminidase NA and haemagglutinin HA , which appear as spikes, 10 to 12 nm long, at the surface of the particles. It is these surface proteins, particularly the haemagglutinin that determine the antigenic specificity of the influenza subtypes. These surface antigens progressively, sometimes rapidly, undergo some changes leading to the antigenic variations in influenza. The influenza virus strains to be incorporated into influenza vaccine each season are determined by the World Health Organisation in collaboration with national health authorities and vaccine manufacturers. HA is the most important antigen in defining the serological specificity of the different influenza strains. This kD protein contains numerous antigenic determinants, several of which are in regions that undergo sequence changes in different strains strain-specific determinants and others in regions which are common to many HA molecules common to determinants. Influenza infection results in various disease states, from a sub-clinical infection through mild upper respiratory infection to a severe viral pneumonia. Typical influenza epidemics cause increases in

incidence of pneumonia and lower respiratory disease as witnessed by increased rates of hospitalization or mortality. The severity of the disease is primarily determined by the age of the host, his immune status and the site of infection. Individuals with underlying chronic diseases are also most likely to experience such complications. Young infants also may suffer severe disease. These groups in particular therefore need to be protected. Vaccination plays a critical role in controlling annual influenza epidemics. Currently available influenza vaccines are either inactivated or live attenuated influenza vaccine. Inactivated flu vaccines are composed of three possible forms of antigen preparation: These inactivated vaccines are given intramuscularly i. Influenza vaccines, of all kinds, are usually trivalent vaccines. They generally contain antigens derived from two influenza A virus strains and one influenza B strain. An improved single radial immunodiffusion technique for the assay of influenza haemagglutinin antigen: Influenza vaccines currently available are considered safe in all age groups De Donato et al. However, there is little evidence that current influenza vaccines work in small children under two years of age. The effectiveness of an influenza vaccine has been shown to correlate with serum titres of hemagglutination inhibition HI antibodies to the viral strain, and several studies have found that older adults exhibit lower HI titres after influenza immunisation than do younger adults Murasko, , Experimental gerontology, 37, New vaccines with an improved immunogenicity are therefore still needed. Formulation of vaccine antigen with potent adjuvants is a possible approach for enhancing immune responses to subvirion antigens. A sub-unit influenza vaccine adjuvanted with the adjuvant MF59, in the form of an oil-in-water emulsion is commercially available, and has demonstrated its ability to induce a higher antibody titer than that obtained with the non-adjuvanted sub-unit vaccine De Donato et al. However, in a later publication, the same vaccine has not demonstrated its improved profile compared to a non-adjuvanted split vaccine Puig-Barbera et al. By way of background, during inter-pandemic periods, influenza viruses circulate that are related to those from the preceding epidemic. The viruses spread among people with varying levels of immunity from infections earlier in life. In other words, an influenza pandemics occurs when a new influenza virus appears against which the human population has no immunity. Typical influenza epidemics cause increases in incidence of pneumonia and lower respiratory disease as witnessed by increased rates of hospitalisation or mortality. The elderly or those with underlying chronic diseases are most likely to experience such complications, but young infants also may suffer severe disease. At unpredictable intervals, novel influenza viruses emerge with a key surface antigen, the haemagglutinin, of a totally different subtype from strains circulating the season before. It is thought that at least in the past pandemics have occurred when an influenza virus from a different species, such as an avian or a porcine influenza virus, has crossed the species barrier. If such viruses have the potential to spread from person to person, they may spread worldwide within a few months to a year, resulting in a pandemic. For example, in Asian Flu pandemic , viruses of the H2N2 subtype replaced H1N1 viruses that had been circulating in the human population since at least when the virus was first isolated. The features of an influenza virus strain that give it the potential to cause a pandemic outbreak are: A new haemagglutinin may be one which has not been evident in the human population for an extended period of time, probably a number of decades, such as H2. Or it may be a haemagglutinin that has not been circulating in the human population before, for example H5, H9, H7 or H6 which are found in birds. Papillomaviruses are small DNA tumour viruses, which are highly species specific. So far, over individual human papillomavirus HPV genotypes have been described. HPVs are generally specific either for the skin e. HPV-1 and -2 or mucosal surfaces e. HPV-6 and and usually cause benign tumours warts that persist for several months or years. Such benign tumours may be distressing for the individuals concerned but tend not to be life threatening, with a few exceptions. Some HPVs are also associated with cancers. Cervical cancer is the most common malignancy in developing countries, with about , new cases occurring in the world each year. It is now technically feasible to actively combat primary HPV infections, and even established HPVcontaining cancers, using vaccines. For a review on the prospects for prophylactic and therapeutic vaccination against HPV see Cason J. In addition, an upstream regulatory region harbors the regulatory sequences which appear to control most transcriptional events of the HPV genome.

Such a vaccine can comprise the L1 antigen as a monomer, a capsomer or a virus like particle. Methods for the preparation of VLPs are well known in the art, and include VLP disassembly-reassembly approaches to provide enhanced homogeneity, for example as described in WO and U. Such particles may additionally comprise L2 proteins. There is still a need for improved vaccines, especially in the case of influenza and in particular influenza pandemics and for the elderly population, or in the case of HPV vaccines. Adjuvants containing combinations of lipopolysaccharide and Quillaja saponins have been disclosed previously, for example in EP It has now been found that good adjuvant properties may be achieved with combinations of lipopolysaccharide and quillaja saponin as immunostimulants in an adjuvant composition even when the immunostimulants are present at low amounts in a human dose. In a second aspect of the present invention, there is provided an immunogenic composition comprising an influenza virus or antigenic preparation thereof, in combination with a saponin adjuvant presented in the form of a liposome. In a specific embodiment of this aspect, the immunogenic composition further comprises a Lipid A derivative, such as 3D-MPL. Suitably the saponin adjuvant in the form of a liposome according to the invention comprises an active fraction of the saponin derived from the bark of Quillaja Saponaria Molina, such as QS21, and a sterol, such as cholesterol, in a ratio saponin: In particular, said immunogenic composition comprises an antigen with a CD4 T cell epitope. Alternatively, said immunogenic composition comprises an antigen with a B cell epitope. In another aspect there is provided the use of a an antigen or antigenic preparation thereof, and b an adjuvant as hereinabove defined in the manufacture of an immunogenic composition for inducing, in a human, at least one, or at least two, or all of the following: In particular said antigen is an influenza virus, HPV, Cytomegalovirus CMV , Varicella zoster virus VZV , Streptococcus pneumoniae or malaria antigen or antigenic preparation thereof, and said human is an immuno-compromised individual or population, such as a high risk adult, an elderly adult or an infant. In a specific embodiment, there is provided the use of an antigen or antigenic preparation thereof and an adjuvant as herein defined in the preparation of an immunogenic composition for vaccination of human, in particular a human elderly adult, against the pathogen from which the antigen in the immunogenic composition is derived. Specifically said antigen is an influenza virus, human papilloma virus, Cytomegalovirus, Varicella Zoster virus, Streptococcus pneumoniae, Plasmodium parasite, antigen or antigens or antigenic preparation thereof. There is also provided a method of vaccination comprising delivery of an antigen or antigenic composition, in particular an influenza virus or HPV, Cytomegalovirus, Varicella Zoster virus, Streptococcus pneumoniae, Plasmodium parasite, or antigenic preparation thereof and an adjuvant as hereinabove defined to an individual or population in need thereof. In a specific embodiment, the immunogenic composition is capable of inducing an improved CD4 T-cell immune response against said antigen or antigenic preparation thereof, and in particular is further capable of inducing either a humoral immune response or an improved B-memory cell response or both, compared to that obtained with the un-adjuvanted antigen or antigenic composition. Specifically said humoral immune response involves the induction of a cross-reactive humoral immune response. In a further embodiment, there is provided a method or use as hereinabove defined, for protection against infection or disease caused by a pathogen which is a variant of the pathogen from which the antigen in the immunogenic composition is derived. In another embodiment, there is provided a method or use as hereinabove defined for protection against infections or disease caused by a pathogen which comprises an antigen which is a variant of that antigen in the immunogenic composition. In a specific embodiment, there is provided the use of an antigen, in particular an influenza or HPV, or antigenic preparation thereof in the manufacture of an immunogenic composition for revaccination of humans previously vaccinated with an immunogenic composition comprising an antigen, in particular an influenza or HPV or antigenic preparation thereof, in combination with an adjuvant as herein described. In a specific embodiment, the composition used for the revaccination may additionally contain an adjuvant. In another specific embodiment, the immunogenic composition for revaccination contains an antigen which shares common CD4 T-cell epitopes with an antigen or antigenic composition used for a previous vaccination. Specifically, the immunogenic composition for revaccination contains an influenza virus or

antigenic preparation thereof which shares common CD4 T-cell epitopes with the influenza virus or virus antigenic preparation thereof used for the first vaccination. In one aspect, the revaccination is made in subjects who have been vaccinated the previous season against influenza.

Chapter 2 : Patient Identification Bands - Manufacturer from Mumbai

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