Medication error led to fatal adverse reactions: 42 case reports

In a study of post-marketing individual case safety reports submitted to EudraVigilance between 1 January 2001 and 31 December 2016, 41 patients (including four patients aged between 3 months and 3.5 years; sexes not stated; not all ages stated) were described, who exhibited medication errors and died due to disseminated infections, vaccine-associated paralytic poliomyelitis, allergic reaction, intussusception, systemic lupus erythematosus, yellow fever vaccine-associated viscerotropic disease, vaccine-associated mumps encephalitis, anaphylactic reaction or unspecified cause of death following vaccination with BCG vaccine, diphtheria and tetanus vaccine, diphtheria-tetanus vaccine, hepatitis-B vaccine, Hib vaccine, influenza virus vaccine, measles mumps and rubella virus vaccine, measles vaccine, Pneumococcal vaccine, Poliovirus vaccine inactivated, Rabies vaccine, Rotavirus vaccine, Varicella zoster virus vaccine, Human papillomavirus vaccine or yellow fever vaccine.

The patients received vaccination with BCG vaccine, diphtheria and tetanus vaccine, diphtheria-tetanus vaccine, hepatitis-B vaccine, Hib vaccine, influenza virus vaccine, measles mumps and rubella virus vaccine, measles vaccine, Human papillomavirus vaccine, Pneumococcal vaccine, Poliovirus vaccine inactivated, Rabies vaccine, Rotavirus vaccine, Varicella zoster virus vaccine or yellow fever vaccine. However, medication error occurred in the form of poor quality drug administered, unspecified medication error, wrong route of administration, contraindication to vaccination, contraindicated drug administered, labeled drug-disease interaction medication error, vaccine administered at the inappropriate site, inappropriate schedule of vaccination administered, inappropriate age at vaccine administration, inappropriate schedule of drug administration, inappropriate/incorrect route of vaccination, an expired vaccine used, extra dose administered, incorrect storage of drug, vaccine administered at the inappropriate site, drug dose administration interval too long, wrong technique in drug usage process or wrong solution used in drug reconstitution. Subsequently, all patients died due to disseminated infections, vaccine-associated paralytic poliomyelitis, allergic reaction, intussusception, systemic lupus erythematosus, yellow fever vaccine-associated viscerotropic disease, vaccine-associated mumps encephalitis, anaphylactic reaction or unspecified cause of death. Based on the WHO tool for causality assessment of an Adverse Event Following Immunization (AEFI), the vaccines were considered as consistent, indeterminate or unclassifiable causality with fatal outcomes.

Hoeve CE, et al. Fatal outcomes following immunization errors as reported to the EudraVigilance: A case series. Vaccine 38: 3086-3095, No. 15, 30 Mar 2020. Available from: URL: http://doi.org/10.1016/j.vaccine.2020.02.074