

ANAPHYLAXIS FOLLOWING IMMUNISATION

- Abstract** Anaphylaxis following immunisation is a potentially life threatening adverse event. All primary immunisers are asked to maintain training and facilities in order to be able to recognise and treat anaphylaxis. Despite this investment in training by front line staff, very little is known about this rare condition. It is difficult to study rare adverse events following immunisation, but important for vaccine safety and public confidence. Previous retrospective studies have been hampered by the paucity of information available to passive reporting schemes, and differences in case definitions have also reduced the comparability of these studies. In contrast this study will collect prospective data and use the international consensus case definition created by the Brighton Collaboration. It will also follow up cases reported to the MHRA Yellow Card scheme. The aim is to provide detailed picture of this rare adverse event to inform public health policy.
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- Background** Anaphylaxis following immunisation is estimated at 1 in a million doses of vaccine in the UK.¹ Previous studies have used retrospective data collection from passive reporting systems to estimate incidence.² Case reports in these instances are often scanty and different case definitions have reduced the ability to compare studies. This study will use the Brighton Collaboration case definition for anaphylaxis as an adverse event following immunisation.³ This definition was designed especially for use in this situation and has several advantages over rival case definitions.⁴ It will also collect prospective data front the MHRA Yellow Card scheme.
- Coverage** **United Kingdom and Republic of Ireland**
- Duration** September 2008 – October 2009 (13 months).

Research Questions	<p>Specific aims of the project are:</p> <ul style="list-style-type: none"> • To define the incidence of anaphylaxis as an AEFI and the vaccines implicated in its onset. • To estimate the level of under reporting of anaphylaxis as an AEFI by the 'yellow card' passive reporting system by prospective active surveillance through the BPSU. • To describe the clinical presentation and, in particular, the clinical pathway taken by children experiencing a reaction and the time from immunisation to the onset of symptoms. The clinical management of cases including the initial resuscitation, requirement for adrenaline, use of serum mast cell tryptase as a marker for anaphylaxis, admission to hospital, and subsequent immunisation record of affected children. • To provide further validation of the Brighton Collaboration case definition for anaphylaxis as an AEFI in the context of a prospective reporting scheme. • To contribute national incidence data to a multinational prospective study of anaphylaxis as an AEFI
Case definition	<p>Any child under 16 years old who in the opinion of the notifying paediatrician may have experienced anaphylaxis following the administration of an immunisation.</p>
Reporting instructions	<p>Please report any cases seen within the last month, either acutely or through clinic referral after the event, that meet the case definition. Report cases where the diagnosis of anaphylaxis is only suspected but where you feel that further doses of vaccine are contraindicated. Report any case where the child received an immunisation in the 48 hours prior to the onset of anaphylaxis where no other precipitant has been identified. We will consider cases that occur after this cut off where there is a strong clinical suspicion that a vaccine was implicated in the reaction. Note that BPSU surveillance does not replace other forms of adverse event reporting such as the MHRA <i>yellow card</i> scheme.</p>
Methods	<p>Paediatricians reporting a case through the orange card system will be asked to complete a short paper questionnaire with a limited set of patient identifiers followed by an anonymous online questionnaire on the clinical presentation, management and outcomes.</p>
Ethics approval	<p>This study has been approved by the North Somerset and South Bristol NRES (Ref: 07/H0106/119) and has been granted PIAG Section 60 Support (Ref: PIAG/BPSU 3-05(FT1)/2008).</p>
Funding	<p>Unrestricted educational grant from Sanofi Pasteur MSD</p>
References	<ol style="list-style-type: none"> 1. Salisbury, D. Immunisation Against Infectious Disease. 4 ed. London: TSO,2006. 2. Bohlke, K., et al. "Risk of anaphylaxis after vaccination of children and adolescents." <i>Pediatrics</i> 112.4 (2003): 815-20 3. Ruggeberg, J. U., et al. "Anaphylaxis: case definition and guidelines for data collection, analysis, and presentation of immunization safety data." <i>Vaccine</i> 25.31 (2007): 5675-84 4. Erlewyn-Lajeunesse, M., et al. "Anaphylaxis as an adverse event following immunisation." <i>J.Clin.Pathol.</i> 60.7 (2007): 737-39.