



VSQ

VACCINE SAFETY QUARTERLY

ISSUE 4 2015

FOCUS: VASCULITIS

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Prof. Dr. Ulrich Heininger
VSQ, Editor in Chief
Head, Paediatric Infectious Diseases and Vaccinology.
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Dear colleagues, here is probably the longest first sentence of an editorial ever written as I would like to tell you that amongst a variety of other topics, you will read about **a call for volunteers to contribute to the development of several new case definitions for adverse events following immunisation (AEFI)** in this issue. This is one of our core activities at the Brighton Collaboration and if you wonder how it works, here is a short introduction.

Brighton case definitions and associated guidelines are intended to enhance data comparability within and across clinical trials, surveillance systems, and post-licensure clinical studies. They are designed to define different levels of diagnostic certainty of an AEFI and thereby can be used globally irrespective of the access to diagnostic tools. Working groups are composed of usually 5 to 20 volunteers with relevant experience and various professional backgrounds (patient care, public health, clinical trials, safety surveillance and assessment etc.). We specifically encourage volunteers from all over the world including developed and developing countries. Being involved in a working group does not involve travelling – it is all done by teleconferences (usually 1 hour once a month) and e-mail exchange following a standardized procedure based on systematic review of current evidence, consensus formation, structured peer review and finally a scientific publication with all active working group members as co-authors. Our case definitions are well accepted and endorsed by respectable authorities such as the World Health Organization (WHO) and the Council for International Organizations of Medical Sciences (CIOMS). Further, they are recommended for use by the US Food and Drug Administration (FDA), the European medicines Agency (EMA), the US Centers for Disease Control and Prevention (CDC), the European Centre for Disease Prevention and Control (ECDC). For more information visit <https://brightoncollaboration.org/public/what-we-do/setting-standards/case-definitions/process.html>.

We look forward to your mails if you are interested to join a working group (see page 3).

I would like to thank Jorgen Bauwens for his excellent support for our newsletter and wish you peaceful days as we get closer to the end of the year 2015.



FEATURED ARTICLE

Five Brighton Collaboration Case Definitions for Vasculitis



Caterina Bonetto and Patrizia Felicetti,
Italian Medicines Agency (AIFA)

Several types of vasculitis have been observed and reported in temporal association with the administration of various vaccines. Therefore, the Italian Medicines Agency (AIFA) requested the Brighton Collaboration to develop case definitions for vasculitis. Over the past months, several working groups have been working towards: A systematic literature review concerning vasculitis as an adverse event following immunization; A descriptive analysis about spontaneous reports of vasculitis as an adverse event following immunisation; development of five case definitions including Kawasaki disease, Henoch-Schönlein Purpura, systemic lupus erythematosus, cutaneous vasculitis, vasculitic peripheral neuropathy.

The systematic literature review has been published and concluded that existing evidence does not support a causative link between vaccination and vasculitis.¹ Most of the larger, higher quality studies found no association between vaccination and subsequent development of vasculitis, including several studies on Kawasaki disease and Henoch-Schönlein purpura (IgA Vasculitis). Smaller case series reported a few cases of vasculitis following BCG and vaccines against influenza and hepatitis. Only 24% of the articles reported using a case definition of vasculitis. Further investigations will be strengthened by the development of standardised

case definitions and methods for data collection, analysis and presentation to improve comparability and interpretation of vasculitis cases following immunisation(s).

The systematic search of available evidence in the literature was complemented by an analysis of vasculitis reports in spontaneous reporting systems to guide prioritization of case definition development. The published descriptive analysis of spontaneous reporting revealed that similar reporting trends of vasculitides were observed in different databases. We retrieved 1,797 cases of vasculitis in EV, 1,171 cases in VAERS, and 2,606 cases in VigiBase®. Vasculitis was predominantly reported in children aged 1-17 years, and less frequently in the elderly. The criteria adopted to select vasculitis subtypes for in-depth analysis were based on frequency and severity of each subtype.

The generic term “vasculitis” was the most frequently reported AEFI across the three databases (range 21.9% to 27.5% of all reported vasculitis for vaccines) For the more specific terms, Henoch-Schönlein Purpura (HSP) was most frequently reported, (19.1% on average), followed by Kawasaki disease (KD) (16.1% on average) and polymyalgia rheumatica (PR) (9.2% on average). Less frequently reported subtypes were cutaneous vasculitis (CuV), vasculitis of the central nervous system (VCe), and Behcet’s syndrome (BS). Influenza vaccines were more frequently reported in association with vasculitis than other vaccines.

Regarding the vasculitis subtypes, HSP, PR and CuV are more frequently reported with influenza vaccines. KD was reported with pneumococcal vaccines in almost one third and with rotavirus vaccines in more than one fifth of the reports of KD. BS was most frequently reported after hepatitis and HPV vaccines and VCe after HPV vaccines.

Given that the generic term vasculitis was most frequently reported and that it comprises a wide spectrum of clinical manifestations, there is a need for more precision and the developments of standard case definitions for specific vasculitides to improve overall data quality and comparability. The first five case definitions are now being finalised by the working groups and will be available for peer-review through the Brighton Collaboration network in the coming weeks.

¹ **Bonetto C**, Trotta F, Felicetti P, et al.. Vasculitis as an adverse event following immunization - Systematic literature review. *Vaccine*. 2015 Sep 21. pii: S0264-410X(15)01292-X. doi: 10.1016/j.vaccine.2015.09.026. [Epub ahead of print]



SCIENTIFIC NEWS AND UPDATES



Jorgen Bauwens, MPH
Programme Manager
Brighton Collaboration
Foundation

In this section we are highlighting vaccine safety projects in which our network members are involved. Our network also shares the following updates:

- Dr. Kevin Pollock reports on HPV vaccine safety monitoring in Scotland.
- Dr. Holla, Mr. Chaitra and Mr. Satyakishore present the challenges and options for cold storage of vaccines.

Also have a look at the following publications:

- Antibodies to influenza nucleoprotein cross-react with human hypocretin receptor 2
- Early estimation of pandemic influenza Antiviral and Vaccine Effectiveness (EAVE): use of a unique community and laboratory national data-linked cohort study.
- Key terms for the assessment of the safety of vaccines in pregnancy: Results of a global consultative process to initiate harmonization of adverse event definitions.
- Two abstracts related to HPV vaccination.

Another current project is the development of vasculitis case definitions including Kawasaki Disease, Henoch-Schönlein purpura, Cutaneous vasculitis, Systemic Lupus Erythematosus, Vasculitic Peripheral Neuropathy. The systematic review is summarised in the featured article on page 2 of this issue. On page 10 of this issue, we are pleased to acknowledge the members of the reference groups who participated in the peer-review of the first vasculitis case definition manuscripts.

In the GAIA (Global Alignment of Immunization safety Assessment in pregnancy) project Brighton Collaboration partners developed the first set of 10

case definitions. On page 11 of this issue, we are pleased to acknowledge the members of the reference groups who participated in this extensive peer-review.

As announced in the editorial of this issue, we are calling for volunteers to join 10 new working groups developing another set of Brighton Collaboration case definitions related to immunisation in pregnancy:

Obstetric terms:

- 1) Abortion
- 2) Antenatal bleeding
- 3) Foetal growth restriction
- 4) Gestational diabetes
- 5) Dysfunctional labour

Neonatal terms:

- 1) Low birth weight
- 2) Small for gestational age
- 3) Neonatal encephalopathy
- 4) Respiratory distress
- 5) Failure to thrive or growth deficiency

Please express your interest to join one or more of these working groups by email to contact@brightoncollaboration.org.

Contributions to the VSQ

We would like to encourage you to share interesting projects with us through the VSQ. This section in our newsletter is reserved for all of you to share any updates about your scientific work that may be of interest for the Brighton Collaboration network.

The deadlines to submit your contributions for the next editions are:

- Edition 1/2016: 15 January 2016
- Edition 2/2016: 15 April 2016

More information about how to contribute can be found on our website:

<https://brightoncollaboration.org/public/resources/newsletter/contribute-to-next-edition.html>



HPV vaccine safety monitoring in Scotland



Dr Kevin Pollock, MPH
Senior Epidemiologist
Health Protection Scotland

Human papillomavirus (HPV) vaccines are currently utilised in national immunisation programmes worldwide. The HPV immunisation programme was initiated in Scotland in 2008 targeting 12-13 year old girls, and those ≤ 18 years old for the first three years of the programme. Uptake has consistently remained above 90% in the routine cohort. While evidence from clinical trials and epidemiological studies suggest that the HPV vaccines are both effective and safe, concerns about the safety of the vaccine and scientifically unproven associations with severe adverse events following immunisation (AEFI) have led to dramatic decreases in vaccine uptake in Japan and acceptance issues in other countries (1, 2).

A robust system of AEFI monitoring was initiated by Health Protection Scotland (HPS), to ensure the safety of the HPV vaccine and thus allay potential public concern. To augment this, we utilised linked hospital admissions data to assess the impact of the HPV immunisation programme on the incidence of 60 diagnoses between 2004 and 2014 in boys and girls. Fifty-nine diagnoses were assessed and based on the Medicines and Healthcare Products Regulatory Agency (MHRA) list of conditions that were anticipated to be possibly linked to HPV vaccination (3). The remaining diagnosis assessed was a proxy for postural orthostatic tachycardia syndrome (POTS), as no International Statistical Classification of Disease (ICD-10) code exists for POTS, which has been linked to HPV vaccination in Japan and Denmark. Tabular and graphical outputs of the number of admissions, the incidence and the incidence ratio of 59 diagnoses were created to assess trends, before and after the introduction of the HPV vaccine. Data linkage was utilised to further investigate an increase in Bell's palsy diagnoses.

Fifty-four diagnoses showed no change in incidence following the introduction of the national immunisation programme. Small increases in incidence were observed for Bell's palsy, coeliac disease, ovarian dysfunction, juvenile onset of type 1 diabetes, demyelinating disease and juvenile rheumatoid arthritis in girls. Further analysis was performed on Bell's palsy cases, which showed just under half of the 28 cases were aged 12-13 at time of diagnosis of which four had received the vaccine. The average time between the first dose and diagnosis was 2.5 years. Coeliac disease and juvenile onset of type 1 diabetes also increased in boys in the same time period and as they do not routinely receive the vaccine, this suggests other factors are involved in this increase. Ovarian dysfunction increased in girls and women of all ages between 2004 and 2014, while the numbers of girls diagnosed with demyelinating disease and juvenile rheumatoid arthritis fluctuated so widely during this period that the interpretation of any change in incidence is difficult.

The multi-factorial aetiology of the analysed diseases and the use of hospitalisation data, which suffers from various limitations including changes to coding and clinical practices, mean any changes in incidence of these conditions must be interpreted with caution. Notwithstanding these limitations, we present population-level data from a country with high vaccine uptake, which further reiterates the safety of the HPV vaccines.

References

- (1) Hanley SJB, Yoshioka E, Ito Y, Kishi R, Sakuragi N. The Japanese HPV vaccine crisis. *The Lancet* 2015;385:2571.
- (2) Larson H, Schulz W. The State of Vaccine Confidence. The Vaccine Confidence Project; 2015 [cited 15 September 2015]. Available from: <http://www.vaccineconfidence.org/research/the-state-of-vaccine-confidence/>
- (3) Donegan K, Beau-Lejdstrom R, King B, Seabroke S, Thomson A, Bryan P. Bivalent human papillomavirus vaccine and the risk of fatigue syndromes in girls in the UK. *Vaccine* 2013;31:4961-4967.

Note from the editors: Please also read Science Board member Heidi Larson's column in *Nature* (1 December 2015) *The world must accept that the HPV vaccine is safe*. Available from: <http://www.nature.com/news/the-world-must-accept-that-the-hpv-vaccine-is-safe-1.18918>



A COMMON “COLD” DILEMMA



Narayana Holla V¹, Chaitra T², Satyakishore CH³
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 College & Hospital, Sullia, India

Availability of more and more vaccines against crippling and lethal diseases has made vaccination programs the most cost effective interventions and an important strategy from control to eradication of vaccine preventable diseases. Proper storage and handling is crucial as errors in storage and handling decrease vaccine efficacy, increase wastage, and may lead to loss of client confidence. “It is better not to vaccinate than to administer a dose of vaccine that has been mishandled cold chain”.¹

Domestic refrigerators, a combination freezer / refrigerator unit with vertical door opening horizontally and an evaporator plate (cooling coil) which is usually located inside an icemaker compartment (freezer) within the refrigerator, provides frequent temperature excursions (i.e. cumulative time out of recommended temperature range of 2 to 8°C / 35 to 46°F) and is NOT recommended for vaccine storage under any circumstances, even temporarily.¹

To overcome the above, WHO recommends Ice Lined Refrigerator (ILR) having vertically opening horizontal top lid, which can maintain “critically set temperature”. Ice-lining provides sufficient cold-holdover time in case of power outage², provided the lid is not opened often.

Vaccines are supplied in cartons of different dimensions as shown in Figure 1. Cartoon picture in Immunization Handbook for Medical Officers², other books and training materials on cold chain in India, recommend arranging vaccine cartons in tier as per heat / freeze sensitivity gradient which is far from reality (see Figure 2). If this is followed, one basket can accommodate 6 cartons of different antigens = 3050

doses + cartons of respective diluents (see Figure 3). To remove the vials from the bottom carton, either the entire basket has to be removed from the ILR or the upper cartons have to be exposed to room temperature and the vaccines experience repeated “TEs”. This situation is worse than opening the vertical door of a domestic refrigerator.



Figure 1: Dimensions / volumes of vaccines and diluents in the cartons.

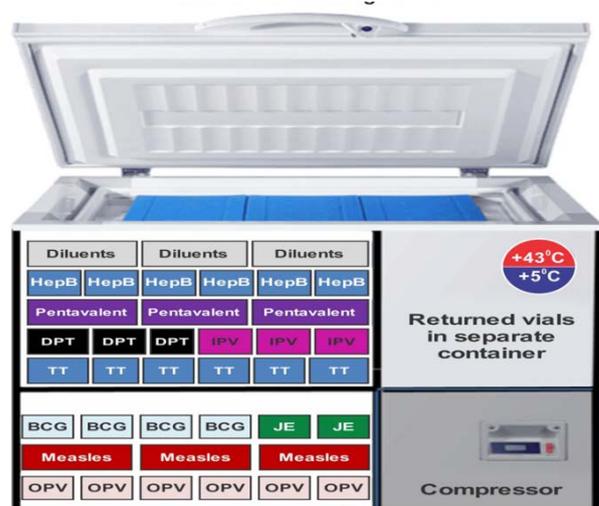


Figure 2: Cartoon showing hypothetical arrangement of vaccines in tiers.



Figure 3: Cartons arranged in tiers in the basket.

The above-mentioned problem can be solved by making use of cylindrical perforated transparent containers, one per vaccine. Live attenuated vaccines such as OPV, Measles and BCG which are not damaged even when frozen are to be placed in the bottom basket. In the upper left basket, diluents which do not have antigen and the returned vials of Open Vial Policy vaccines for immediate distribution to the next session are to be placed. In the upper right basket “T” series vaccines (Tetanus Toxoid, HepB, DPT, Pentavalent) are to be placed. Required number of vials can be easily taken out by the Cold Chain Handler from the wide mouth screw capped container without exposing the basket / container with vials to the room temperature.³ This is used as storage code since 2000 in Karnataka and the Government of Karnataka made A4 size job-aid sticker in regional language and displayed on the Ice Lined Refrigerator since 2012 (see Figure 4).



Figure 4: Holla’s bottle method of keeping vaccines – job-aid.

Practically, keeping vaccines in the cylindrical bottles solves or minimizes the “TE” problem.

References:

1. Centers for Disease Control and Prevention Epidemiology and Prevention of Vaccine-Preventable Diseases, 13th Edition April, 2015, p 63. from <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/vac-storage.pdf>
2. GOI (2008). Immunization Handbook for Medical Officers. Dept of Family Welfare. Ministry of Health and Family Welfare. Government of India.
3. Technet21 Digest: Issue 109, 24 June 2011 Keeping Vaccines in the ILR at PHC/CHCs. from <http://www.technet-21.org/fr/component/acymailing/archive/view/listid-1-weekly-digest/maillid-139-technet21-digest-issue-109-24-june-2011>

LITERATURE POINTERS

Members of the Brighton Collaboration network are sharing the following selection of recent publications.

Title	Antibodies to influenza nucleoprotein cross-react with human hypocretin receptor 2
Reference	Ahmed SS et al., Science Translational Medicine. 2015 Jul 1;7(294) p. 105
What this paper adds	A fascinating study with results suggesting a new possible molecular mechanism for a causal link between Pandemrix vaccination and narcolepsy. However, the findings and new hypothesis as presented in this publication clearly need confirmation by further investigational work.
News item by	Valeriu Toma (Swissmedic, Switzerland)



Title	Early estimation of pandemic influenza Antiviral and Vaccine Effectiveness (EAVE): use of a unique community and laboratory national data-linked cohort study
Reference	Simpson CR, Lone N, McMenamin J, Gunson R, Robertson C, Ritchie LD, Sheikh A. Health Technol Assess. 2015 Oct;19(79) pp. 1-32
What this paper adds	A new sentinel system has been created in Scotland and the reporting platform is ready to be activated in the event of any pandemic of influenza. This will allow rapid extraction of data to determine vaccine effectiveness of any new pandemic vaccine (if) available, to analyse protective effect conferred by antiviral drugs as well as the clinical attack rate of pandemic influenza in general practice.
News item by	Pawandeep Kaur Dhawan (Clinical Development Services Agency, India)

Title	Key terms for the assessment of the safety of vaccines in pregnancy: Results of a global consultative process to initiate harmonization of adverse event definitions
Reference	Munoz FM, Eckert LO, Katz MA, Lambach P, Ortiz JR, Bauwens J, Bonhoeffer J. Vaccine. 2015 Sep 19. pii: S0264-410X(15)01278-5. doi: 10.1016/j.vaccine.2015.07.112
What this paper adds	Two Brighton Collaboration interdisciplinary taskforces prioritised 45 maternal and 62 foetal/neonatal events, and key terms and concept definitions were endorsed. Also recommendations to further improve safety monitoring of immunisation in pregnancy programs were specified, including the elaboration of disease concepts into standardised case definitions and the development of guidance, tools, and datasets in support of a globally concerted approach.
News item by	Jan Bonhoeffer (Brighton Collaboration Foundation, Switzerland)

Titles	<p>1. Human papilloma virus vaccines and gastrointestinal motility disorders</p> <p>2. Characteristics of adverse event reports after HPV vaccination: a global perspective</p>
Reference	<p>1. R. Chandler, S. Hult, P. Caduff-Janosa 1WHO Collaborating Centre for International Drug Monitoring - Uppsala Monitoring Centre, Research, Uppsala, Sweden</p> <p>2. R. Chandler, K. Juhlin, O. Caster, K. Star 1WHO Collaborating Centre for International Drug Monitoring - Uppsala Monitoring Centre, Research, Uppsala, Sweden Poster presentations and personal communications on the occasion of the International Society for Pharmacovigilance (ISoP Meeting) in Prague, from 28th to 30th of October 2015. Drug Safety. 2015; 38(10) pp. 847-1048.</p>



What these papers add Gastrointestinal motility disorders (GID) have been identified as a signal for human papilloma virus (HPV) vaccines using Vigibase. Furthermore, HPV vaccines have been reported in association with autonomic nervous system dysfunction (AD). Although data on a biological mechanism and the incidence of AD in the target population is lacking at this moment, this work opens up avenues for further investigations in the relevant industry databases.

News item by Simona Nistor-Grahl (Simona Grahl Consulting, Germany)



BCF TOOLS & SERVICES

Together with the valuable efforts of the members of the Brighton Collaboration's network, the Brighton Collaboration Foundation provides support and coordinates several products (e.g. tools) and services (e.g. think tanks, working groups). In this section, we want to give visibility to these products and services.

In this last version of the VSQ in 2015, we share with you an overview of our services and tools. From 2016, we will provide regular updates and additional information.

We kindly invite you to reach out to should you wish to learn more or if you would like to be involved in any of our initiatives.

Services

1 Setting standards

The BCF establishes and supports Brighton Collaboration Working Groups focusing on creating vaccine safety terminologies and ontologies as well as developing standardised case definitions and guidelines. We support rapid open access publication of these outputs in the Journal Vaccine.

2 Addressing scientific and research gaps

The BCF initiates, forms, supports and coordinates research consortia collaboratively addressing gaps in science and monitoring of vaccine safety. Synapse Research Project Management is our trusted partner for managing larger projects and consortia.

3 Providing expert discussion forum

The BCF provides the Clinical Advisory Forum of Experts (CAFE) as a platform for open scientific exchange about AEFI, their management and related vaccine safety questions. There are currently 578 registered professionals concerned with vaccine safety in five continents.

Help enhance the knowledge about vaccine safety.

Support our VSQ

Although neither the editor-in-chief nor the contributing authors receive payments for their work, the costs for one issue of the newsletter amounts about 5,000 CHF from scratch to production.

This includes steps such as the scientific coordination, the layout and design, as well as revisions and archiving.

Help the Brighton Collaboration now with your donation and support the Brighton Collaboration management team with the coordination and publication of future VSQs.

<https://brightoncollaboration.org/public/donate/donateonline.html>

4 Providing vaccine safety resources

The BCF maintains the Collaboration's website and makes available all standards, tools, guidance, and information to registered users.

5 Network news and updates

The BCF issues the Vaccine Safety Quarterly (VSQ) to provide network partners with news and updates in the field and to give visibility to partner activities. It is intended to serve open interactive scientific exchange.

6 Journal Club

The BCF stimulates critical assessment of scientific studies and research methodologies related to vaccine safety by providing a platform where members of the network can evaluate and discuss recent publications. The Journal Club is typically held quarterly on a recent publication pertinent to vaccine safety assessment.



7 Scientific Consensus meetings

The BCF promotes in-person meetings of scientists and stakeholders in the field by serving as a neutral independent platform for scientific debate and consensus formation.

Tools

8 Online collaboration platform

The BCF provides an online collaboration platform for its projects and for network partners. This includes a global directory of over 3500 professionals in the network, discussion fora, and workspaces for projects.

9 Automated Case Classification Tool (ABC 1)

Brighton Collaboration partners have developed an electronic tool for automated case classification. It supports vaccine safety officers and investigators by facilitating the time- and resource-consuming step of reviewing and classifying AEFI reports. It can be linked to the national AEFI database to identify confirmed cases among the reported events. It can also be integrated in electronic report forms to improve the quality of primary reports. We provide tailored solutions for countries wishing to decrease the burden of thorough case assessment by using this tool.

10 Guided Case Follow-up tool for serious AEFI (ABC 2)

Brighton Collaboration partners have developed an electronic tool for guided case follow-up. It supports country vaccine safety officers and investigators by facilitating follow-up of primary reports of serious AEFI. The tool aims to optimise the quality of data by prompting the user for minimum and critical information for essential case documentation and verification. We provide customisation of the tool to country needs.

11 Viral Vector Profile Database

The Brighton Collaboration is committed to develop and update profiles describing the key characteristics of each major viral vector in use for vaccine development, based on best available scientific evidence. It is almost impossible for the non-expert to stay updated for well informed decision making related to licensure or post-licensure safety concerns. We propose to upscale and maintain this database for the benefit of those reviewing vaccine safety data in GAVI eligible countries, including AEFI committees.

12 Global Unified AEFI Reference database (GUARD)

Brighton Collaboration partners have developed a prototype web-based information source for state of the art knowledge on vaccine-event associations. It aims to reduce the redundant, time and resource-consuming step of country based literature reviews and evidence collection.



ACKNOWLEDGEMENTS

Reference Groups members

In 2015, we finalised a large number of Brighton Collaboration publications.

In addition to the Working Group members, who are listed as authors on each of the publications, we also want to acknowledge the members of the Reference Groups who voluntarily peer-reviewed the manuscripts before publication.

By efforts like these, everyone demonstrates the value of the Brighton Collaboration network!

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- Kristine Shields
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- Huifeng Yun



IMPRESSUM

Volunteer Professionals

Volunteer professionals form the Brighton Collaboration, sharing invaluable expertise and committing precious time.

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