For this summer edition of our VSQ we have opted to introduce a leading theme: rotavirus vaccination. Prof. Jim Buttery introduces this topic by presenting an update on intussusception. Further in this newsletter you will also find a summary of the discussion on this topic as we had it in the Journal Club. And you may also want to read Dr. Paul Offit’s view and perspective about rotavirus vaccines. But we have also other scientific updates for you: WHO and Brighton Collaboration started a project to harmonise definitions of adverse events and to develop guidance in maternal immunisation and you will learn about VAXSIG, maternal influenza immunization in low and middle-income countries, BCG osteomyelitis in Russian children and much more from contributions from network members. We are also happy to have launched the forum on our website. This new medium will definitely help to increase the interaction among the Brighton Collaboration network. Finally, I would like to point to the Science Board elections that will be organised in the second half of 2014 and for which we accept candidacies. More details can be found in the management update.

FEATURED ARTICLE

INTUSSUSCEPTION AND ROTAVIRUS VACCINES: AN UPDATE

Associate Prof. Jim Buttery
Monash Children’s Hospital, Melbourne, Australia

Jim P. Buttery\textsuperscript{1,2} MBBS MD MSc, Jane Standish\textsuperscript{1,3} MBBS FRACP, Silvia Pérez-Vilar\textsuperscript{4} PharmD MSc, Julie E. Bines\textsuperscript{2,3} MBBS MD FRACP

\textsuperscript{1}Department of Infectious Diseases, Monash Children’s Hospital, Monash Health, Dept of Pediatrics, Monash University, Victoria, Australia; \textsuperscript{2}Murdoch Childrens Research Institute, Victoria, Australia; \textsuperscript{3}Department of Pediatrics, University of Melbourne, Royal Children’s Hospital, Victoria, Australia; \textsuperscript{4}Vaccine Research, FISABIO-Public Health, Valencia, Spain

Two oral live-attenuated rotavirus vaccines, indicated for vaccination of infants aged 6 to 24 or 32 weeks, were licensed in 2006: a monovalent human vaccine, Rotarix\textsuperscript{\textregistered} (GlaxoSmithKline Biologicals, Rixensart, Belgium), and a pentavalent bovine-human reassortant vaccine, RotaTeq\textsuperscript{\textregistered} (Merck & Co., Inc., West Point, PA, USA). Previously, a confirmed association between Rotashield\textsuperscript{\textregistered}, the first licensed rotavirus vaccine, and intussusception was the reason of its withdrawal from the US market in 1999, only 9 months after licensure\textsuperscript{1,2}.

Intussusception is an acute bowel obstruction due to the telescoping of one part of the bowel into an adjacent section, resulting in obstruction and reduced blood flow\textsuperscript{3}.

The Rotashield\textsuperscript{\textregistered} experience informed the clinical development programs of Rotarix\textsuperscript{\textregistered} and RotaTeq\textsuperscript{\textregistered}. Both underwent massive phase III safety trials, with sample sizes able to detect an association with intussusception similar to that observed with Rotashield\textsuperscript{\textregistered}, and found no significant association with intussusception. Over the next 2 years, rotavirus vaccination was implemented in many countries including the US, Mexico, Brazil, Australia and some European nations, with strict guidelines around age at dosing. However, given the limitation of even these studies to detect an association at a lower level than Rotashield\textsuperscript{\textregistered}, post-licensure studies were conducted in multiple settings to ensure early detection of any association, across nations with varying background rates of intussusception.
The first suggestion of an association was reported in Australia, with both RotaTeq® and Rotarix® showing an excess of observed intussusception cases following dose 1 compared with expected number of cases based upon historical rates5. The small numbers and potential bias in the study relating to use of historical rates necessitated further confirmation. Subsequently, case-control and self-controlled case series (SCCS) studies from Mexico and Brazil confirmed an association with Rotarix® dose 1 in Mexico5,6 and with dose 2 in Brazil7. However, despite utilising multiple data sources and methodologies, an association in the US with RotaTeq® was not confirmed until 20137-10 when VAERS reports were examined using the self-controlled risk interval (SCRI) methodology11. The association with RotaTeq® was also confirmed in the US, in a large distributed database system that included three large health plans, using SCRI and cohort designs12. In another US study in a large linked database, using sequential analyses, a significant risk for RotaTeq® was not observed. In the same study, a significant association for dose 1 and 2 combined for Rotarix® was found13. SCCS and case-control methodologies from a larger dataset in Australia have since confirmed the original findings for dose 1 for both vaccines14. An additional study in Australia using SCCS analyses, with and without medical record review, found a significant increased risk after dose 1 of Rotarix®15. (Figures 1-2)

Despite of the significant results from most studies, mainly in the first week following rotavirus vaccination, specially for first dose administration, the benefit-risk ratio stays highly favorable to vaccination5,14. Additional studies from countries at very high risk for both rotavirus disease and intussusception would be useful to further inform decision makers on this issue.

References
We now have data that all three rotavirus vaccines — RotaShield, RotaRix, and RotaTeq — all cause intussusception; in the United States the relative risks were 10, 5.3, and 1.5 cases per 100,000 vaccine recipients above background, respectively. Most interesting is that these vaccines use different strategies to protect against infection. RotaShield was based on simian-human reassortant viruses; RotaTeq on bovine-human reassortant viruses; and RotaRix is an attenuated human strain first isolated from a child with diarrhea in Cincinnati in 1989.

The fact that RotaRix is a rare cause of intussusception begs the question of whether natural rotavirus infection is also a rare cause of intussusception. If so, the question then becomes, Which is rarer, intussusception caused by natural infection or by vaccination? This is an answerable question. Simply examine the number of cases of intussusception observed in various databases before and after vaccine virus lessened the incidence of infection with wild-type virus. In the United States, the answer is that vaccination has not increased the rate of intussusception, suggesting that intussusception following vaccination occurs at roughly the same rate as that following natural infection.

What remains clear is that the benefits of rotavirus vaccine clearly outweigh the risks, which current data suggest are at most negligible.

**SCIENTIFIC NEWS AND UPDATES**

Yolanda Brauchli Pernus  
Scientist  
Brighton Collaboration Foundation, Basel, Switzerland

We are pleased to announce that a forum has been created on the Brighton Collaboration website. For technical information, please see under the section management news and updates. At the moment, we have two active fora, one for the Journal Club discussions and one for the Clinical Advisory Forum of Experts (CAFÉ). The journal club discussion summarized in this issue has already taken place using this new tool. Please send us your feedback to contact@brightoncollaboration.org.

With regards to the CAFÉ forum, the plan is to move discussions having started on the CAFÉ mailing list and appearing to be more extensive to this forum for further discussion among interested participants. Furthermore, the forum shall also serve as archive for all discussions on the mailing list. Since the first update in the VSQ 1/2014, further interesting questions have been posted and discussed on the CAFÉ mailing list (see box):

Another topic we would like to mention here is the joint project between the Brighton Collaboration and
QUESTIONS DISCUSSED SO FAR:

- Experience/Precautions of BCG vaccination in newborn when mother was treated with Adalimumab (Ind. Crohn’s disease) during pregnancy?
- Information on concerns for transfer of aby via breast-milk if mother still on Adalimumab after 4-6 months when maternally derived transplacental aby would have waned?
- How long should disseminated BCG be treated in immunocompromised with 4 drugs and when does it have to be changed to 2 drugs?
- Is there literature about allergic reactions to Saccharomyces cerevisiae (baker’s yeast) and the administration of HPV vaccine? Is this hypersensitivity considered as precaution or real contraindication?
- Pronounced abscesses following vaccinations, allergic work-up concluded hypersensitivity to aluminium: how to handle aluminium-adjuvanted vaccines in the future?
- Is there any experience or are there reference/guidelines on the vaccination of haemophilia patients?
- Point in time for VZV and measles vaccination after stop of Natalizumab, during Methylprednisolone and before Fingolimod treatment
- Is a prolonged latency of 2 weeks sufficient to exclude a causal relation between FSME meningitis vaccinations and continuous muscle pain?
- Potential consequences of too early administration of MMR to a two-month old baby and use of immunoglobulin administration?
- Is there any possible and plausible biological explanation for pseudotumor cerebri related to MMR vaccine within hours of administration?
- Causality assessment for Dermatofibrosarcoma at injection site following 12 months vaccination (MMR and Hib MenC) and procedure for subsequent vaccines?
- Causality assessment for Hypopigmentation at injection site following 12 months vaccination (MMR and Hib MenC).
- Has reactivation of VZV infection post HPV vaccine been seen, and is a latency of 36 hours too short for a potential causal association?
- When to administer live-attenuated vaccines to a patient treated with tocilizumab and methylprednisolone?

WHO to harmonize definitions of adverse events in pregnant women and neonates and to develop guidance for data collection. In this context, we were collecting pertinent guidance documents and available definitions of pregnancy/birth or neonatal events among you, the Brighton Collaboration network. We are pleased to say that we had a great response rate and thank all who have shared documents with us. You can still send us documents to contact@brightoncollaboration.org. The project is still in its starting phase. Specific calls for participation in working or reference groups will be sent out in the near future. And this is what you may expect to read in this issue’s scientific news from the network:

Did you hear about the new International Society for Pharmacoepidemiology Vaccine Special Interest Group (VAXSIG)?
- Read about new ways to address obstacles for implementing maternal influenza immunization programs in low and middle-income countries
- Learn about BCG osteomyelitis in children in Russia
- Do you know the Spanish Vaccinology Association and its communication strategy?
- Learn about Training activities offered by the Department of Essential Medicines and other Health Technologies (EMP)
- Read about the suggestions of a meta-analysis on the association between vaccines and autism
- What is the reporting rate of military healthcare providers to the Vaccine Adverse Event Reporting System (VAERS)
- Read about the results of a postlicensure study on the risk of intussusception following rotavirus vaccine
- What is the risk for preterm or small for gestational age birth following maternal influenza vaccine following a retrospective cohort study?
- Read about the influence of timely versus delayed early childhood vaccination and seizures
- Learn about the performance of a Brighton-based algorithm of anaphylaxis for determining diagnostic certainty

With regards to the last contribution, we would like to draw your attention to a follow up project initiated by
the Vanderbilt University with a planned launch in September this year. You can expect a call to the network asking for your interest in comparing the performance of Brighton case definitions for Guillain Barré Syndrome and acute disseminated encephalomyelitis based on clinical cases in comparison to the algorithms developed by Vanderbilt University and the ABC tool developed by the Brighton Collaboration Foundation. Are you also interested in sharing your current activities with the Brighton Collaboration global network? Then please send us YOUR contribution for the next issue by September 2014 to: contact@brightoncollaboration.org

**VACCINE SAFETY PROJECTS**

**ISPE-VAXSIG: INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMIOLOGY VACCINE SPECIAL INTEREST GROUP**

Bob Chen
Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention, Atlanta, USA

Huifeng Yun
Department of Epidemiology, School of Public Health, University of Alabama at Birmingham, USA

In February 2014 the International Society for Pharmacoepidemiology (ISPE; www.pharmacoepi.org) executive committee approved formation of a vaccine special interest group (VAXSIG) following a petition to create the new group from 19 ISPE members led by Bob Chen.

The VAXSIG has established four working groups for each of the following 4 objectives led by Andrea Sutherland, Patricia Saddier, Mendel Haag and Daniel Weibel, respectively:

- Foster development and adoption of methods for the accurate and efficient collection of vaccine information on individual person exposure and product level
- Foster development and sharing of methods for vaccine safety, effectiveness, usage, cost-benefit, risk-management/mitigation
- Provide a forum for interaction between regulatory authorities and public health agencies for regulations and regulatory templates.
- Assist low and middle-income countries in vaccine pharmacoepidemiology.

Progress on these objectives is being made via current monthly VAXSIG conference calls.

We are also delighted to announce that the VAXSIG and the Brighton Collaboration will co-sponsor the first VAXSIG symposium at 30th International Conference on Pharmacoepidemiology (ICPE) annual meeting in Taipei. Topics to be discussed in the symposium include 1) A pilot model of web-based adverse events following immunization tool (Speaker: Ajit Pal Singh); 2) Performance testing of pediatric signal detection methods in surveillance systems (Jan Bonhoeffer); 3) PREVENT: infrastructure for rigorous vaccine safety studies in low and middle income countries (Daniel Weibel) and 4) European Universal Influenza Vaccine (UNISEC) project (Eelko Hak). Miriam Sturkenboom from Erasmus University and Huifeng Yun from University of Alabama at Birmingham will moderate this symposium.

The VAXSIG offers a platform for interested ISPE members to share national and international projects and grant proposals, and joint presentation in form of workshops, symposia or poster walks at annual ICPE meetings. Whenever possible, the VAXSIG will seek to maximize synergy with existing vaccine institutions and stakeholders. For questions about the VAXSIG, please contact Dr. Yun (yunn@uab.edu).
ADDRESSING OBSTACLES FOR IMPLEMENTING MATERNAL INFLUENZA IMMUNIZATION PROGRAMMES IN LOW AND MIDDLE-INCOME COUNTRIES

Dr. Philipp Lambach
World Health Organization, WHO, Geneva, Switzerland

Dr. Joachim Hombach
World Health Organization, WHO, Geneva, Switzerland

In July 2012, the World Health Organization (WHO) stated that pregnant women should have the highest priority for seasonal influenza vaccination in countries initiating or expanding their influenza immunization programs. This prioritization was based on an extensive review of influenza burden of disease, vaccine safety, and vaccine performance by the WHO Strategic Advisory Group of Experts on Immunization (SAGE). Nevertheless, in many low-resource countries maternal influenza immunization has not been incorporated into routine immunization programs despite the WHO recommendation. In 2012, an expert consultation by the Bill & Melinda Gates Foundation identified operational challenges and knowledge gaps hindering implementation of maternal influenza immunization programs.

Based on the scientific evidence base available, WHO aims to reduce maternal and neonatal morbidity and mortality by addressing obstacles to implementing seasonal influenza immunization programs for pregnant women and closing data gaps about their potential impact. Accordingly, WHO’s Maternal and Neonatal Influenza Immunization Group supports the development of evidence-based vaccine policies and introduction of seasonal influenza immunization programs for pregnant women. This includes collating and disseminating information on vaccine supply and demand, safety reviews, support to developing policy recommendations. The group’s work also includes exploring innovative concepts on delivery strategies, developing approaches to monitor program implementation, and expanding maternal immunization programs against other high-burden vaccine preventable diseases.

In July 2014, WHO and the Brighton Collaboration will conduct a global consultation to support harmonization of maternal and neonatal safety monitoring. The consultation will aim to explore opportunities to develop a core list of maternal and neonatal adverse events of special interest following maternal or neonatal immunization and to evaluate how this list can best be standardized and prioritized to support post marketing surveillance in low and middle income countries. The product of this consultation will be used by the Brighton Collaboration for development of a guidance document supporting the monitoring of maternal immunization adverse events of special interest.

References
2. www.who.int/immunization/.../1_Background_Paper_Mar26_v13_cleaned.pdf
The article presents an analysis of 522 cases of complications after BCG vaccination, i.e. post-vaccinal osteomyelitis, based on pharmacovigilance data obtained between 2001 and 2012. All complications developed after primary immunization, 96% of affected children were vaccinated while in maternity hospital. The Russian national immunization schedule calls for revaccination of 6–7 year old children who have no response to tuberculin.

The time interval between vaccination and seeking medical advice varied between 3 months to 5 years, an average period was equal to 17 months. For all cases, the diagnosis of BCG osteomyelitis was made based on clinical, X-ray, bacteriological and pathomorphological findings. All 78 children who were tested by intradermal Diaskintest (genetically engineered product consisting of a complex of two antigens ESAT-6 and CFP-10 present in virulent strains) had negative test responses. In most cases only one bone was affected: femur – 21.2%, tibia and fibula – 20%, sternum – 15.6%, humerus – 11.6%, radius/ulna and hand – 11.6%, foot – 9.3%, ribs – 8.5%. The vertebra was not affected, though it is involved in 80% of “classic” bone tuberculosis cases.

A detailed study of ill children revealed no clinical manifestations (severe bacterial, viral or fungal infections, repeat bacterial infections of respiratory tract etc) suggesting primary or secondary immunodeficiency. All of the 315 children who were vaccinated with measles, mumps and rubella vaccine and live polio vaccine, respectively had no unusual complications in the post-vaccinal period. Vaccination had been performed before any clinical symptoms of BCG osteomyelitis manifested themselves. Further study will include examination of biological properties of cultures isolated from disease sites, including their residual virulence.

SPANISH VACCINOLOGY ASSOCIATION (AEV) AN EXAMPLE OF SUCCESS ON VACCINES SAFETY AND QUALITY COMMUNICATION ONLINE.

César Velasco Muñoz
On behalf of the Editorial Committee
Vacunas.org
http://www.vacunas.org/es/acerca-aev/comite-editorial

AEV started a leading programme in communication and promotion of vaccines with a web based approach followed by Facebook and Twitter platforms. The impact of the most updated evidence based and trendy online content has been addressed in a recent study published in the national vaccines journal. Information provided by Vacunas.org is focused on healthcare professionals, patients and general population. We will continue assessing the usability and appropriateness of our online strategy in order to provide our users with the best Safety, Quality and general information about vaccines.

Vacunas.org is recognized as a reference in vaccines safety information by the WHO’s Vaccine Safety Net. One of the most consulted areas in the website is the “Ask the Expert” section which is open to the public and to the health professionals and answers more than 700 questions related to travel, schedule updates and vaccine safety coming from Spain and Latin-America every year. The Spanish Association of Vaccinology website team is compound of a multidisciplinary group
of health care professionals: paediatricians, preventive medicine specialists, primary care physicians, nurses, epidemiologists, pharmacists and many others. This year our scientific symposium will be held on November the 13th and 14th in Murcia, Spain.

All topics in the agenda can be found in the brochure in English, this year the theme is the almost forgotten value of prevention and there will be a remarkable international presence.

**TRAINING ACTIVITIES OFFERED BY THE DEPARTMENT OF ESSENTIAL MEDICINES AND OTHER HEALTH TECHNOLOGIES (EMP)**

Dr. Nora Dellepiane  
Regulatory Systems Strengthening, Regulation of Medicines and Other Health Technologies, Department of Essential Medicines and Health Products, WHO, Switzerland

Dr. Ahmed Bellah  
Regulatory Systems Strengthening, Regulation of Medicines and Other Health Technologies, Department of Essential Medicines and Health Products, WHO, Switzerland

EMP carries out a broad range of training activities relating to devices including diagnostics, medicines and vaccines, covering:
- access to medicines and other health technologies, pricing and supply of those technologies, rational drug use, and drugs under international control
- innovation and intellectual property, technology transfer and local production of medicines, vaccines and other technologies
- regulation of diagnostics, medicines and vaccines, including:
  - prequalification of priority health products
  - monitoring of medicines and vaccines safety and quality, including detection and identification of inferior products.

To enable its partners and stakeholders to identify training activities that are of most interest to them, EMP has created a “platform” that collects, displays and updates relevant information.

The Training activities are grouped by area of work and by start date (and also according to the EMP team responsible for the activity). The start date is colour coded:
- red: activity is still to take place
- black: activity is to be confirmed
- grey: activity has already taken place
- blank: activity is not a face-to-face activity i.e. takes the form of e-learning or downloadable resource.

Activities are grouped under:
- access
- product efficacy and product performance
- good practice compliance
- patents
- policy
- quality
- regulatory practice
- safety and vigilance
LITERATURE POINTERS

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
<th>What these paper adds</th>
<th>News item by</th>
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<tr>
<td>Military healthcare providers reporting of adverse events following immunizations to the Vaccine Adverse Event Reporting System (VAERS).</td>
<td>Li R, McNeil MM, Pickering S, Pemberton MR, Duran LL, Collins LC, Nelson MR, Engler RJM, Mil Med. 2014 Apr;179(4):435-41. doi: 10.7205/MILMED-D-13-00391</td>
<td>This is the first report of a systematic evaluation of knowledge, attitudes and practices of U.S. military healthcare providers (HCP) regarding AEFI identification and reporting to VAERS. We found in this sample of military HCP that only 33% of respondents who had identified at least one AEFI had ever reported to VAERS. In addition, although the majority of military HCP were at least somewhat familiar with VAERS, 45% of sampled HCP did not have any knowledge about VAERS. Together, these findings suggest that military HCP knowledge and awareness of the process and the practices regarding reporting of AEFI to VAERS is lacking, contributing to underreporting to VAERS, which may negatively impact the system’s public health function. Although military HCP education on identifying AEFI and reporting to VAERS has been enhanced since our study, ongoing efforts to improve understanding of the barriers to reporting of AEFI are needed. This and other provider populations should be studied and the gaps in knowledge addressed.</td>
<td>Michael McNeil, Centers for Disease Control and Prevention Atlanta</td>
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Title                                                                 | Reference                                                                                                                                                                                                   | What this paper adds                                                                                                                                                                                                 | News item by                                      |
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<tr>
<td>Risk of Intussusception after Monovalent Rotavirus Vaccination</td>
<td>Weintraub ES, Baggs J, Duffy J et al. N Engl J Med. 2014;370(6):513-519.</td>
<td>In this prospective postlicensure study of more than 200,000 doses of monovalent rotavirus vaccine, we observed a significant increase in the rate of intussusception after vaccination, a risk that must be weighed against the benefits of preventing rotavirus-associated illness</td>
<td>Eric S. Weintraub, Centers for Disease Control and Prevention</td>
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### Brighton Collaboration

<table>
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<tr>
<th>Title</th>
<th>Maternal influenza vaccine and risks for preterm or small for gestational age birth.</th>
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<tr>
<td>What this paper adds</td>
<td>This retrospective cohort study did not identify an association between receipt of trivalent inactivated influenza vaccine during pregnancy and increased or decreased risk of preterm or small of gestational age births. These findings support the safety of vaccinating women against influenza during all trimesters of pregnancy</td>
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<td>News item by</td>
<td>Julianne Gee, Centers for Disease Control and Prevention</td>
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<th>Title</th>
<th>Timely versus delayed early childhood vaccination and seizures.</th>
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<td>What these paper adds</td>
<td>In this retrospective cohort study no association was found between timing of vaccination and the occurrence of seizures in the first year of life. Delaying vaccination with measles-containing vaccine past 15 months of age increases the incidence of post-vaccination seizures emphasizing the importance of following the vaccination schedule.</td>
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<td>News item by</td>
<td>Julianne Gee, Centers for Disease Control and Prevention</td>
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<tr>
<th>Title</th>
<th>Brighton Based Algorithm More Efficient for Determining Diagnostic Certainty</th>
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<td>What this paper adds</td>
<td>We have worked on converting Brighton case definitions for adverse events following immunization into an algorithm format. We were able to test one algorithm (anaphylaxis) and found it maintained accuracy of assigning a level of diagnostic certainty while being more efficient. We hope that the algorithms facilitate the application of the case definitions in public health settings.</td>
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<td>News item by</td>
<td>Dr. Kathryn Edwards, M.D., Vanderbilt University School of Medicine, Nashville, Tennessee,</td>
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<th>Title</th>
<th>Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies</th>
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<tr>
<td>What this paper adds</td>
<td>There has been enormous and long lasting debate regarding the possibility of a link between childhood vaccinations and the subsequent development of autism. Findings of this meta-analysis suggest that vaccinations are not associated with the development of autism or autism spectrum disorder. Furthermore, the components of the vaccines (thimerosal or mercury) or multiple vaccines (MMR) are not associated with the development of autism or autism spectrum disorder.</td>
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<tr>
<td>News item by</td>
<td>Valeriu Toma, Clinical Reviewer Pharmacovigilance at Swissmedic - Swiss Agency for Therapeutic Products</td>
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The paper “Intussusception risk and disease prevention associated with rotavirus vaccines in Australia’s National Immunization Program” by Carlin et al. used both self-controlled case series and case-control methods to identify an increased risk of intussusception during days 1-7 and 8-21 following first dose and during days 1-7 following second dose of both currently licensed rotavirus vaccines. In addition, the authors compared intussusception hospitalizations versus gastroenteritis hospitalizations in order to evaluate the balance of benefits and risks.

Among the contributions received, there were some comprehensive comments of particular importance for vaccine safety decision makers. Maybe the most controversial one was whether post-marketing observational studies are appropriate to determine the risk of rare and serious adverse events post-vaccination. Are randomized clinical trials the best solution, or observational studies, despite their limitations, may present advantages? Which is the best way to give a decisive and, at the same time, quick and generalizable answer?

Causality assessment was also discussed. Is case-by-case causality assessment needed, or even feasible, in post-licensure epidemiological observational studies? Or should such studies be limited to their original objective of investigating epidemiological associations?

The hypothesis discussed during the Rotashield® episode regarding rotavirus vaccination as a trigger factor for intussusception was reactivated. The discussion also highlighted the possibility of a recent increase in background rates of intussusception not explained by rotavirus vaccination. Another interesting comment regarded the possibility that intussusception cases associated with rotavirus vaccination could be milder than those unrelated to vaccination. Could this be explained by an increased physician awareness of the risk of intussusception following rotavirus vaccination?

There was a repeated comment regarding the need for caution when extrapolating the findings from the study by Carlin et al. to developing countries. This highlights the ongoing need for more research from low and middle-income countries. We are looking forward to seeing results from the five-year risk-benefit study in Sudan. We hope to discuss these findings soon in one of the Brighton Journal Clubs.

We received 16 comments. We would like to thank the following reviewers and the anonymous ones for their contributions:

- Dr Jacob Puliyel
- Dr George Trimis
- Dr Zobidah Moatasin Hassan
- Dr Emmanuel Grimprel
- Dr Frederik Varrichio
- Dr Nikolai Ozeretskovsky
- Dr Ahmed-Amr Abbassy
- Dr Miljkovic Milena
- Dr Roxana Ghanaie
- Dr Beckie Tagbo
- Dr Y. Madhavi
NEW TOOL ‘FORUM’ AVAILABLE

We are pleased to inform you, that our FORUM is online. As from May, we are hosting a forum space on the Brighton Collaboration website. Currently two forums are available:

JOURNAL CLUB: Here we are hosting the Journal Club discussions. This forum replaces the Journal Club on VaccineOrb and is accessible for all registered users on the Brighton Collaboration website.

CAFÉ: This forum will host an archive of all past CAFÉ discussions. This archive will be gradually completed as from now on. New discussions will be kept in the mailing format and transferred to the forum as soon as the discussion flow has ended. This forum is accessible for all Partners.

The forums can be found here: https://brightoncollaboration.org/public/resources/forum

Using the forum should be self-explanatory. These are the key steps:

> To open the forum: select the appropriate subject.
> To reply to the main post (the abstract) or to anyone’s reaction:
> Click “Reply to this”;
> Write your message and provide a title for your response;
> Click “Post”

SCIENCE BOARD ELECTIONS 2014

We would like to announce that the elections for the Science Board will be organised in the second half of 2014. The Science Board consists of ten members who are elected for a term of three years and can be re-elected for 1 consecutive term. Board members who have served on the Science Board for two consecutive terms may be re-elected again after a minimum period of three years.

The Science Board determines the scientific activities that the Brighton Collaboration engages in. It develops scientific strategies and policies, and decides on new initiatives or re-directing ongoing initiatives. The Science Board supervises activities and provides scientific advice to working groups and committees.

Candidates will be nominated by a Nominating Committee consisting of two Foundation Board and two Science Board members. Candidates will be evaluated based on technical, strategic and policy skills and the Nominating Committee aims to achieve a balance in geographies and professional backgrounds.

Please contact Jorgen Bauwens for further information: j.bauwens@brightoncollaboration.org

SCIENCE BOARD CHAIR/CO-CHAIR ELECTIONS

HECTOR IZURIETA (CHAIR), EPI, WORLD HEALTH ORGANIZATION, Geneva, CH and Heidi Larson (Vice Chair), London School of Hygiene & Tropical Medicine, London, UK were unanimously elected as chair and co-chair of the Brighton Collaboration Science Board.

STRATEGIC PLAN 2015-2016

In April, the Science Board started preparing a new strategic plan covering 2015-2016. This plan will define the major activities and goals for the next two years.

CURRENT SCIENCE BOARD COMPOSITION

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<tr>
<th>Strategic Priority</th>
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<td>Setting Standards</td>
<td>Barbara Law</td>
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<td>Jim Buttery</td>
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<td>Clinical Assessment</td>
<td>Kathryn Edwards</td>
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<td>Michael Gold</td>
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<td>Data Linkage</td>
<td>Miriam Sturkenboom</td>
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<td>Steve Black</td>
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<td>Capacity Building</td>
<td>Egeruan Babatunde Imoukhuede, Hector Izurieta (chair)</td>
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<td>Public Confidence</td>
<td>Heidi Larson (co-chair)</td>
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<td>Daniel Salmon</td>
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VACCINE SAFETY INFORMATION WHEN IT IS MOST NEEDED
  Vaccines are distributed faster and to larger populations than ever. Reliable safety information has to be available
  for decision makers to continue, modify or terminate these new programs. Ideally this information should be
  available to them at a moment’s notice.

  As the number of available vaccines increases and the pace in which they are rolled out quickens, vaccine safety
  research must keep pace. Making the need for timely research ever more crucial, today information on immuniza-
  tion campaigns is broadcast to most households by a 24-hour news cycle that knows no borders. Local safety con-
  cerns are rapidly becoming global. When a concern arises, for each day that it is not thoroughly investigated, public
  trust erodes.

  This may cause more harm than the initial concern intended to prevent. It may even derail an entire immunization
  program, causing untold suffering, which could have been prevented if the research was there on time. However,
  designing and agreeing upon rigorous research protocols takes time. Navigating large organizational bureaucratic
  channels to arrive at actionable research steps takes time. Conducting large studies as well takes time. All activities
  in vaccine safety research take time the researcher does not have if working alone. The BC’s work begins here.

HELP ENHANCE KNOWLEDGE ABOUT VACCINE SAFETY
  Help the Brighton Collaboration with your donation when it is most needed. Your donation will work towards pro-
  tecting people from vaccine preventable diseases. The Brighton Collaboration provides essential vaccine safety re-
  sources that only an independent body of scientists can provide. To maintain the independence and rigorous scien-
  tific safety research, they rely on funds from people and organizations.

WE RELY ON DONATIONS
  We need and accept donations from scientific funding agencies, internationally recognized scientific health and
  particularly vaccine stakeholder organizations, charitable agencies, individual donors and other sources supporting
  vaccine research.

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  Would you like to learn more about the programs of the Brighton Collaboration? Then visit our website or send us
  an Email, we would appreciate getting in contact with you:
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Volunteer professionals form the Brighton Collaboration, sharing invaluable expertise and committing precious time. The network includes professionals from the following sectors:

- Regulatory authorities
- Public health service organizations
- Academic institutions
- Health care providers
- Vaccine manufacturers

DONORS AND CONTRIBUTORS

In addition to our grant support, we receive contributions from Donors including Children’s Hospital Basel, Basel CH, private donors and Brighton members.

PARTNERING ORGANIZATIONS

We have begun to establish organizational partnerships to leverage organizational synergies, by adding a network of organizations to the existing Brighton Collaboration Network. Memoranda of Understandings were established with the following organizations:

- Centers for Disease Control and Prevention (CDC), Atlanta, USA
- Brighton Foundation US, Inc. Boston, USA
- The European Vaccine Initiative (EVI), Heidelberg, GER
- P95 Pharmacovigilance and Outcomes Research, Leuven, BEL
- VACCINE.GRID, Quantifying Vaccine Outcomes, Basel, CH
- International Alliance for Biological Standardization

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