National Vaccine Safety Workshop: summary and draft recommendations

Glenda Lawrence, on behalf of the National Immunisation Committee

Introduction

A National Vaccine Safety Workshop was held at the University of Sydney on 17 November 2005. The workshop was sponsored by the National Centre for Immunisation Research and Surveillance (NCIRS), the Australian Government Department of Health and Ageing (DoHA) and the National Immunisation Committee (NIC). It was attended by 40 invited representatives of federal, state and territory health departments, the Australian Technical Advisory Group on Immunisation, the Therapeutic Goods Administration (TGA), the Adverse Drug Reactions Advisory Committee (ADRAC), the Australian Medical Association, the Royal Australian College of General Practitioners, the Australian Divisions of General Practice (ADGP), clinical immunisation specialists, consumers and industry. The aims of the workshop were to review current post-licensure vaccine safety practices in Australia and to work towards developing a national vaccine safety strategy.

The first part of the workshop consisted of a series of presentations outlining international and current Australian practices. This formed the basis for the second part of the workshop where participants divided into three working groups to discuss issues and formulate draft recommendations in the areas of (i) surveillance; (ii) clinical management and research; and (iii) communication. Final workshop recommendations were reached by consensus.

Presentations

International overview

Mike Gold (Women's and Children's Hospital, Adelaide) outlined initiatives by the World Health Organization in developing a set of indicators for national regulatory authorities to assess vaccine safety practices, including the ability to detect and investigate adverse events following immunisation (AEFI) and ensure transparency and accountability. In the United States of America, the role of vaccine safety was recently separated from the immunisation program to avoid perceived conflicts of interest. Internationally, the focus of vaccine safety programs is moving away from the purely population health focus of AEFI surveillance to one where both the individual and the population are considered. This new paradigm includes surveillance, clinical management and communication.

Vaccine safety in Australia

National overview

Ian Boyd (TGA), David Isaacs (ADRAC) and Glenda Lawrence (NCIRS) described the current national passive AEFI surveillance system from different perspectives, and identified the major strengths and weaknesses of the system. Strengths included the centralised notification, review, analysis and regular publication of summary data. Weaknesses included the significant differences in surveillance practices between the states and territories, and the conflicting priorities of timely reporting at the national level versus complete reporting after case investigations are concluded. The complexity of analysis and interpretation of AEFI surveillance data was highlighted, as well as the need for better communication of available information to providers and consumers.

Paul Roche (DoHA) highlighted parallels between disease surveillance systems and AEFI surveillance at the local, jurisdictional and national levels. Mechanisms implemented in Australia's communicable diseases surveillance processes to improve consistency between states and territories, timeliness of reporting to the national system and case management at the local level could serve as a model for AEFI surveillance.

State and territory perspectives

Each state and territory representative spoke briefly about AEFI surveillance practices, clinical management and communication processes in their jurisdiction. Surveillance practices differ considerably as do the level of resources available for surveillance and clinical management of AEFI. All jurisdictional representatives indicated that systems were in place for individuals to consult clinical specialists regarding AEFI. Many indicated the need to improve

Corresponding author: Dr G Lawrence, NCIRS, Locked Bag 4001, Westmead NSW 2145. Telephone: +61 2 9845 1433. Facsimile: +61 2 9845 1418. Email: glendal@chw.edu.au

education and communication with providers and consumers, and between jurisdictions. All indicated a willingness to address issues of communication and consistency in AEFI surveillance practices at a national level.

Special initiatives

Data linkage

Sarah Dugdale (South Australian Vaccine Safety Data Linkage Project) summarised a pilot data linkage project that is being conducted in South Australia. Like the United States of America and United Kingdom AEFI data linkage programs, the pilot South Australian project aims to link clinical and immunisation records to detect both known and unknown AEFIs, test hypotheses and investigate signals identified through passive AEFI surveillance. Surveys of consumers and providers found a high level of acceptance of data linkage for this specific purpose. Assessment of the feasibility of routine data linkage is in progress.

Special immunisation clinics

Nick Wood (NCIRS) gave an overview of the roles and practices of clinics located in major hospitals in Sydney, Canberra, Melbourne, Adelaide and Perth that specialise in the management of children who may have experienced an AEFI. Staff from each clinic collaborate via regular national teleconferences to discuss specific clinical management issues and have recently conducted a clinical trial on the re-immunisation of children who have had a large local reaction to a diphtheria-tetanus-acellular pertussis vaccine. Future plans include the development of clinical protocols for the management of AEFI and harmonisation of clinic databases to allow a summary report to be produced annually.

Working groups

At the start of the afternoon session, Mark Ferson (NSW Health), summarised the themes and issues that arose from the presentations and discussion of current international and Australian post-marketing vaccine safety practices. Participants then divided into the three working groups (according to individual interest). Discussion in each working group was lead by a person with relevant expertise in the specific area on which the working group focussed.

The Surveillance Working Group was facilitated by Paul Roche (DoHA). The group discussed the objectives of AEFI surveillance, the events that should be under surveillance, ways to improve the passive surveillance process and options regarding active surveillance.

The Clinical Management and Research Working Group was facilitated by Mike Gold (Women's and Children's Hospital, Adelaide). The group discussion focussed on mechanisms to improve access to specialist advice on the clinical management of children and adults with AEFI, particularly advice about re-immunisation. They also discussed research objectives.

The Communication Working Group was facilitated by Julie Leask (NCIRS). The group identified the major communication players and their information needs. Discussion also focussed on the need for clear communication between all stakeholders about vaccine safety and how best to canvass consumer input.

Workshop recommendations

Final workshop recommendations were reached by consensus and are summarised below.

Surveillance

1. Implement a simple national system for passive AEFI surveillance that retains ADRAC at its core.
2. Clarify the objectives of AEFI surveillance at the local, jurisdictional and national levels.
3. Conduct surveillance for vaccine failures through disease surveillance processes rather than AEFI surveillance processes.
4. Review the AEFI surveillance case definitions for inclusion in the next (9th) edition of the *Australian Immunisation Handbook*.
5. Improve the timeliness and completeness of data submission to ADRAC.
6. Amend the current ADRAC (blue) notification form to collect data relevant to AEFI.
7. Improve feedback between ADRAC and providers and consumers with aggregate reports, or at the individual level where possible.
8. Ensure that the passive surveillance system is functioning appropriately before considering ongoing active surveillance at a national level while recognising that there is the occasional need to conduct active surveillance to investigate specific issues.

Clinical management and research

9. Ensure that providers and consumers have access to expert opinion on the clinical management of AEFI.
10. Standardise and collate data for the individual special AEFI clinics, and report summary data annually using Brighton Collaboration case definitions.

11. Develop uniform national guidelines on the clinical management of AEFI. This process could be assisted by the production of an annual report for all AEFI special clinics.

12. Review the resource requirements to implement recommendations 9 to 11.

Communication

13. Produce AEFI report summaries in an easily digestible format to circulate to Divisions of General Practice, public health units, state and territory health departments, consumers who report AEFI, and other relevant groups. AEFI data should be reported within the broader context of program evaluation and disease prevention.

14. Produce and distribute brochures and online information for providers and consumers about AEFI reporting procedures and the availability of special AEFI clinics.

15. Convene a meeting to assess ways to obtain input from consumers on vaccine safety.

16. Develop mechanisms to enhance communication between states and territories regarding vaccine safety issues.

Conclusion

In March 2006, the recommendations arising from the workshop were considered at a meeting of the National Immunisation Committee. The committee convened the AEFI Working Party to review, prioritise and progress all the recommendations. Members of the AEFI Working Party include representatives of NCIRS (Chair), DoHA, jurisdictions, ADRAC, TGA and ADGP. Linkage has also been established between the AEFI Working Party and the specialist AEFI clinical group to progress recommendations related to the clinical management of AEFIs. The AEFI Working Party meets regularly by teleconference and reports progress to the NIC.

Acknowledgements

The National Vaccine Safety Workshop was sponsored by the National Centre for Immunisation Research and Surveillance, the Australian Government Department of Health and Ageing and the National Immunisation Committee.

The Steering Committee, responsible for planning the National Vaccine Safety Workshop, included Jennie Roe (DoHA), Letitia Toms (DoHA), Sue Campbell-Lloyd (NSW Health), Christine Selvey (Northern Territory Health Department), Mike Gold (Women's and Children's Hospital, Adelaide), Maureen Watson (Department of Human Services, South Australia), Peter McIntyre (NCIRS) and Glenda Lawrence (NCIRS).

The sponsors thank all presenters and participants for their time and valuable contributions to the workshop and to the report. We particularly thank: Mark Ferson (NSW Health) for undertaking the vital role of workshop facilitator; Paul Roche, Mike Gold and Julie Leask for facilitating the small group discussions; and NCIRS staff Kristine Macartney, Nick Wood, Rob Menzies, Helen Quinn and Julie Leask for drafting sections of the report and Jan Michniewicz for organising the workshop.