Symposium 10: Lessons learned and future challenges in international signal detection

Moderators

Richard Hill, Therapeutic Goods Administration, Australia

Richard is a Senior Medical Officer in the Signal Investigation Unit, Pharmacovigilance and Special Access Branch, at Australia's Therapeutic Goods Administration. His responsibilities include pharmacovigilance activities for medicines, the development of signal detection methodologies, and training in pharmacovigilance.

Richard has worked at the TGA since 1999, in both pre-market evaluation and pharmacovigilance. From 2008-2011 he worked in the Pharmacovigilance Services Department at the WHO Uppsala Monitoring Centre in Sweden, where he was involved in signal detection, pharmacovigilance education and training, and contributed to the UMC's drug safety research program.

Andrew Bate, Pfizer, UK

Andrew oversees the provision of methodological and analytic expertise to the Epidemiology group in support of Worldwide Medical & Safety activities worldwide. Prior to joining Pfizer in 2009, Andrew was at the WHO Collaborating Centre for International Drug Monitoring in Sweden for more than 12 years, where he was responsible for Research. Andrew has over 100 academic publications on the development for methods and tools for safety signal detection and Real World Evidence generation.

Andrew has contributed to several international initiatives and partnerships including membership of the US FDA Science Board Subcommittee on Pharmacovigilance, member of CIOMS Working Group VIII on safety signal detection, Scientific Advisory Board of OMOP and co-PI for the IMEDS Evaluation Pilot, the first evaluative access and use of the FDA's Sentinel Data Network by a non-FDA entity.

Andrew holds a Masters degree in Chemistry from Oxford University, and a PhD in Clinical Pharmacology from Umea University, Sweden. He was a Visiting Professor in Information Systems and Computing, at Brunel University, London, UK and is an Adjunct Associate Professor in Clinical Pharmacology at NYU School of Medicine and was affiliate faculty of the NYU Center for Health Informatics and Bioinformatics.

Speakers

Richard Hill, Therapeutic Goods Administration, Australia

Richard is a Senior Medical Officer in the Signal Investigation Unit, Pharmacovigilance and Special Access Branch, at Australia's Therapeutic Goods Administration. His responsibilities include pharmacovigilance activities for medicines, the development of signal detection methodologies, and training in pharmacovigilance.

Richard has worked at the TGA since 1999, in both pre-market evaluation and pharmacovigilance. From 2008-2011 he worked in the Pharmacovigilance Services Department at the WHO Uppsala Monitoring Centre in Sweden, where he was involved in signal detection, pharmacovigilance education and training, and contributed to the UMC's drug safety research program.

Jeffrey Brown, Harvard Medical School and Harvard Pilgrim Health Care Institute, USA

Jeffrey Brown, PhD is an Associate Professor in the Department of Population Medicine (DPM) at Harvard Medical School and the Harvard Pilgrim Health Care Institute. Within DPM, Dr. Brown serves as a member of the Therapeutics Research and Infectious Disease Epidemiology program Executive Committee. His primary research activities involve new approaches to facilitate large-scale multi-institutional research through the use of distributed health data networks to support a learning health system. This research formed the basis for several established research networks, including the FDA's Sentinel System and PCORnet. He has leadership roles in FDA Sentinel, PCORnet, the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC), and the Innovation in Medical Evidence and Development Surveillance (IMEDS) program. Beyond these distributed data networks, he has led several post-marketing safety studies for various sponsors.Dr. Brown is the inventor of PopMedNet, an open-source software platform that facilitates creation and operation of distributed health data networks. Dr. Brown holds a Master's degree in Economics from Tufts University and a PhD in Social Policy from Brandeis University. He is an 8-time US national champion and 3-time world champion in Ultimate Frisbee and coached the Tufts Men's Ultimate team for 20 years.

Chieko Ishiguro, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Dr. Chieko Ishiguro is a senior epidemiologist in the Office of Medical Epidemiology at the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. She has over 10 years' experience at PMDA. During 2009-2013, she established the team for epidemiological analysis and review for drug safety assessment, through the Medical Information for Risk Assessment Initiative (MIHARI Project). Since 2010, she has been responsible for leading epidemiological studies using healthcare information databases, including the National Claim Database and the electronic medical record database named MID-NET®, and also for reviewing post-marketing study protocols submitted by pharmaceutical industries to PMDA.

She also has experience as a visiting scientist in the Office of Safety and Epidemiology in the Food and Drug Administration and the School of Public Health, at Boston University in Massachusetts in 2010. She is the recipient of the Best Reviewer Award of Pharmacoepidemiology and Drug Safety for 2016. She has been a board member of the International Society for Pharmacoepidemiology (ISPE) since 2018, and also a councilor of the Japanese Society for Pharmacoepidemiology (JSPE) since 2015.

Andrew Bate, Pfizer, UK

Andrew oversees the provision of methodological and analytic expertise to the Epidemiology group in support of Worldwide Medical & Safety activities worldwide. Prior to joining Pfizer in 2009, Andrew was at the WHO Collaborating Centre for International Drug Monitoring in Sweden for more than 12 years, where he was responsible for Research. Andrew has over 100 academic publications on the development for methods and tools for safety signal detection and Real World Evidence generation.

Andrew has contributed to several international initiatives and partnerships including membership of the US FDA Science Board Subcommittee on Pharmacovigilance, member of CIOMS Working Group VIII on safety signal detection, Scientific Advisory Board of OMOP and co-PI for the IMEDS Evaluation Pilot, the first evaluative access and use of the FDA's Sentinel Data Network by a non-FDA entity.

Andrew holds a Masters degree in Chemistry from Oxford University, and a PhD in Clinical Pharmacology from Umea University, Sweden. He was a Visiting Professor in Information Systems and Computing, at Brunel University, London, UK and is an Adjunct Associate Professor in Clinical Pharmacology at NYU School of Medicine and was affiliate faculty of the NYU Center for Health Informatics and Bioinformatics.