

A Brief Report on Industrial Expert Interaction series – Lecture II

(Enhancing interpersonal and professional skills)

Date: 20.12.2021

Name of the presenter:

Dr. Anand B Harugeri
Director, Service Operations
PV Project Leadership and Strategic Solutions,
Lifecycle Safety, IQVIA
Bangalore
(AnandB.Harugeri@iqvia.com)

Title of the presentation:
Signal detection in Vaccinovigilance



Program Organized by:

Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

& Pharmacy Education Unit
JSS College of Pharmacy, Ooty

With an objective of enhancing interpersonal and professional skills of the students, Department of Pharmacy Practice in association with Pharmacy Education Unit, JSS College of Pharmacy, Ooty has planned to conduct Industrial Expert Interaction series. Industry expert interactions series provides a platform for budding Pharmacists to be aware of the skills required to enter profession and what Industry expects from the young graduates.

Dr Anand B Harugeri has more than 20 years of experience working in pharmaceutical industry. He graduated as a Pharmacist from College of Pharmaceutical Sciences, Manipal, completed the Post-graduation in Pharmacy Practice from JSS College of Pharmacy, Mysore, completed PhD in the area of Pharmacovigilance from Rajiv Gandhi University of Health Sciences, Bangalore. Over the past 20+ years, Dr Anand has worked as Clinical Research Scientist for Ranbaxy Research Laboratories, and Bio-Clinical Project Coordinator for Apotex Research Pvt Ltd. Worked as Senior Research Fellow for an Indian Council of Medical Research. Was a Visiting Faculty for Pharmacovigilance at Clinical Research Education and Management Academy. Served AstraZeneca Pharma India Ltd as Patient Safety and Regulatory Affairs Manager. Presently working as Director in PV Project Leadership and Strategic Solutions unit of Lifecycle Safety at IQVIA.

Dr Anand started on the discussion with Introduction to signals and their importance in Pharmacovigilance industry. He explained about the important terminologies used by WHO, Hauben & Aronson definition and GVP Module IX terminologies of signal. Further, he elaborated about the importance of signal detection for vaccines. Dr Anand explained in detail about the various steps involved in signal detection for vaccines which involves steps like detection, selection, strengthening, assessment, follow-up, action. Further, he details about the favouring situations for signal generation along with sources of signals.

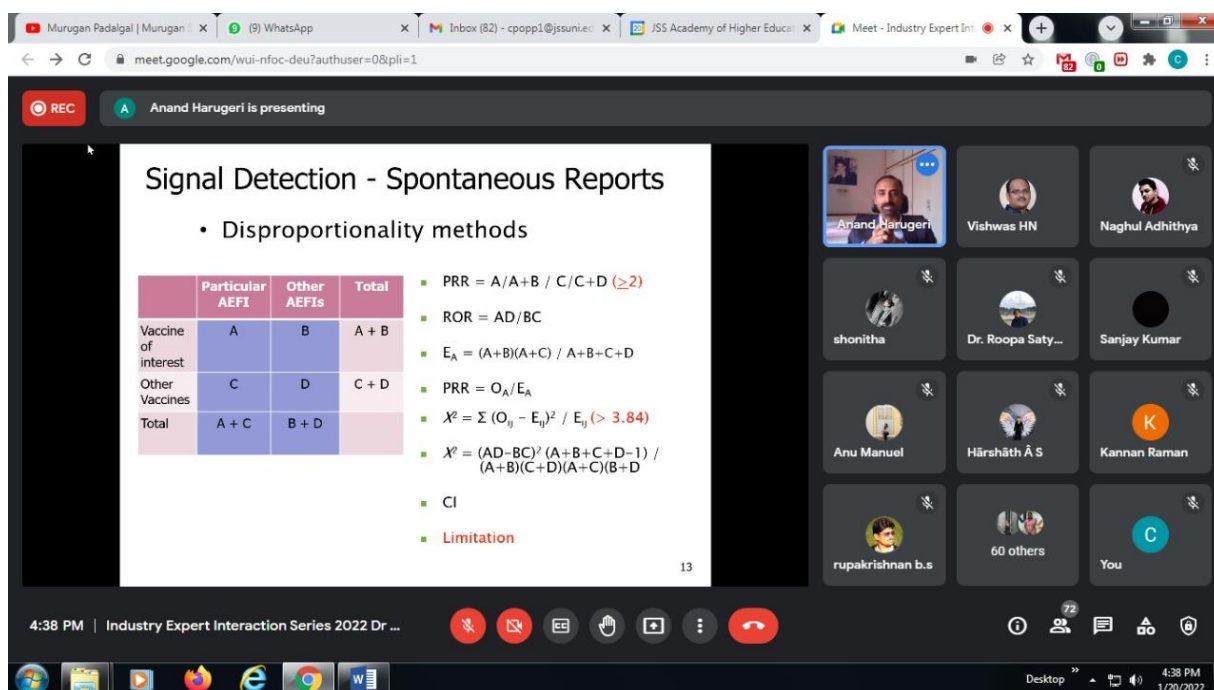
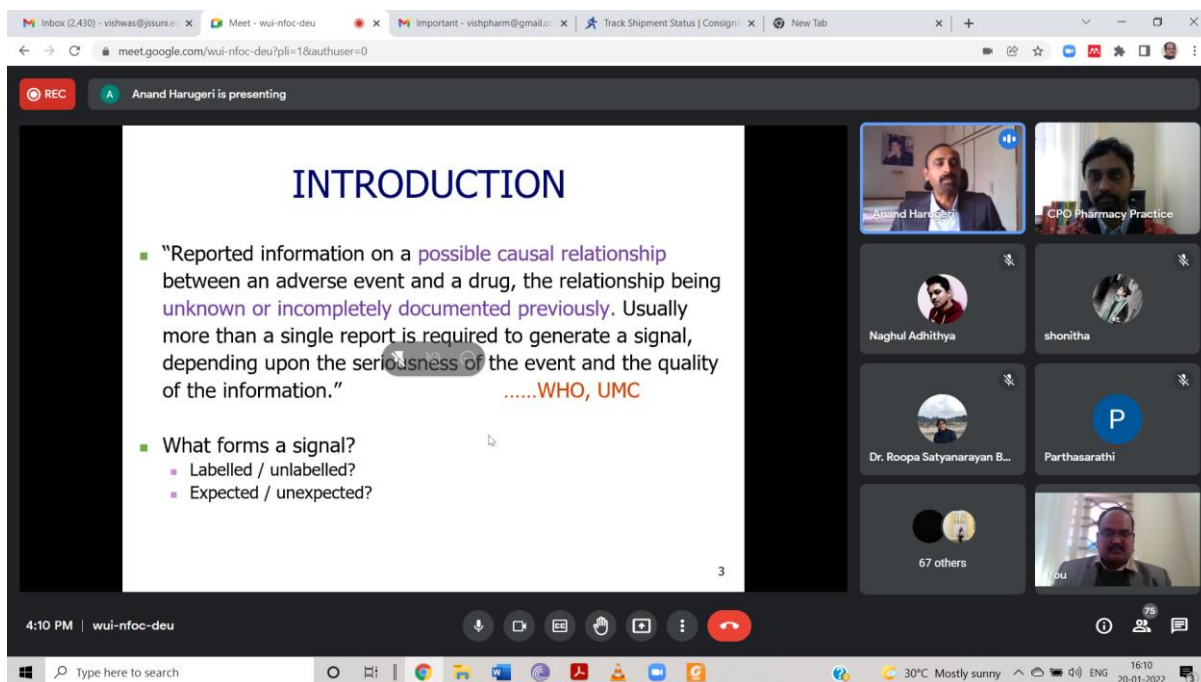
He also elaborated on the various data mining techniques for signal detection along with few methods utilized for analysis. He explained the methods like Bayesian approach, Proportional reporting ratio, Chi-square analysis, Bayesian confidence propagation neural network (BCPNN) and Du Mouchel method (Multiitem Gamma Poisson shrinking). Further, he explained about the stratification of signals and how software help in the process. Further, he explained about the utilization of Log-likelihood ratios in spontaneous reporting data. He further explained about signal strengthening and follow-up.

Finally, Dr Anand summarized the quantitative and qualitative aspects related to signal assessment. He further elaborated about the regulatory actions taken if a signal or a potential signal is identified. He further explained about

the process of signal detection at Uppsala Monitoring Centre, Sweden. He even showed few outputs, sector maps from automated software used for signal identification.

Dr Anand spoke about recent updates in the pharmacovigilance industry like Vigirank, Signal impact assessment tool, Signal detection assessment using change point analysis, Impact of age stratification, GVP-Module IX, Control vocabulary-based ADR signal dictionary, Double fast discovery rate method for signal detection analysis and many other automated tools available with the industry today.

Finally, there was a question-and-answer session where few staff and students clarified their doubts related to pharmacovigilance. Dr S Ponnusankar delivered the welcome address and the importance of the industry expert interaction series, Mr Vishwas H N gave introduction to the speaker and Dr Roopa B S delivered the vote of thanks. A total of 92 participants were present in the session.



Few Screen shots of the Industry Expert Interaction Series-Lecture II

Report submitted by: Mr HN Vishwas, Lecturer, Dept. of Pharmacy Practice