spontaneous reporting. In addition, attention will be given on how to raise awareness about the importance of pharmacovigilance and what means of communications can be used for this purpose. To illustrate these aspects, practical experiences from our centre will be shared with the participants.

O 23

Coordinating the WHO Drug Monitoring Programme: The Role of WHO Collaborating Centres

C. Ondari[1]

(1) WHO, Safety and Vigilance, Geneva, Switzerland

The World Health Organization (WHO) is the United Nation's specialist agency for health. Amongst a range of health issues, the organization covers safety and vigilance of medicinal products via the WHO programme for International Drug Monitoring. In advancing its global health priorities and strategies, WHO works with a network of more than 700 Collaborating Centres (WHOCCs) that support implementation of mandated work. WHO works with 4 Collaborating Centres to advance pharmacovigilance (PV) in countries. Thanks to these Centres, the WHO PV programme has expanded in membership and in its scope of work, especially in those regions with weak infrastructures but a high burden of diseases.

The present talk will trace the growth of pharmacovigilance as a global partnership, value added and the roles and responsibilities of each of the partners; and how WHO will continue to exploit the WHO CC model while joining hands with other groups and initiatives to support pharmacovigilance worldwide.

O 24

Knowledge About Adverse Drug Reaction and Reporting Among the Healthcare Professionals in Bhutan

C. Dorji[1,2], P. Tragulpiankit[2], A. Riewpaiboon[2], T. Tobgay[3]

(1) Drug Regulatory Authority, Post marketing, Thimphu, Bhutan, (2) Mahidol university, Faculty of Pharmacy, Bangkok, Thailand, (3) Khesar Gyalpo University of Medical Sciences, Human resource and planning, Thimphu, Bhutan

Introduction: National pharmacovigilance centre (NPC) of Bhutan, under drug regulatory authority (DRA) became official member of WHO programme for international drug monitoring in December 2014.Despite trainings and awareness created by NPC the number of adverse drug reaction (ADR) reports sent to NPC is considerable low. Better understanding about ADR among the healthcare professional could improve the pharmacovigilance system.

Aim: The aim of this study is to investigate knowledge about ADR and ADR reporting among the healthcare professional, both modern and traditional medicine practitioner.

Methods: Cross sectional study was conducted, using validated self-administered questionnaire. The questionnaires were distributed to 670 healthcare professionals including Clinical doctors, Nurse, Pharmacist and Traditional practitioner from four referral hospitals. There are 12 questions on knowledge and 10 questions on knowledge about reporting. The collected response was analysed descriptively by using SPSS version 20.

Results: Overall response rate was 65 %, consisting Clinical doctors 94 (21.6 %), Nurse 257 (59.1 %), Pharmacist 52 (12.0 %) and Traditional practitioner 31 (7.1 %). For each professional Mean score ± SD score are presented in the (Table 1). Overall mean score of the knowledge on ADR among healthcare professional was 6.52 ±2.81 out of the maximum score of 12. Whereas, knowledge on ADR reporting among healthcare professional was 3.94 ± 1.89 out of the maximum score 10.

Table 1 Score and mean ± SD of healthcare professionals on knowledge about adverse drug reaction and adverse drug reaction reporting

	Type of Healthcare professional
(1) Knowledge on ADR	**Clinical doctor Nurse Pharmacist Traditional Practitioner**
Mean ± SD	7.48 ± 2.950 6.15 ± 2.475 8.15 ± 2.428 4.13 ± 3.181
Score	
Excellent (≥10)	25(26.6) 24(9.3) 18(34.6) 1(3.2)
Good (7–9)	42(44.7) 91(35.4) 19(36.5) 9(29.0)
Fair (5–6)	12(12.8) 78(30.4) 12(23.1) 2(6.5)
Poor (≤4)	15(16.0) 64(24.9) 3(5.8) 19(61.3)
(2) Knowledge on ADR reporting	**Clinical doctor Nurse Pharmacist Traditional Practitioner**
Mean ± SD	3.93 ± 1.809 3.75 ± 1.742 1.79 ± 0.750 4.00 ± 1.770
Score	
Excellent (≥8)	1(1.1) 8(3.1) 5(9.6) 0(0.0)
Good (5–7)	35(37.2) 66(25.7) 26(50.0) 13(41.9)
Fair (3–4)	38(40.4) 127(49.4) 15(28.8) 8(25.8)
Poor (≤2)	20(21.3) 56(21.8) 6(11.5) 10(32.3)

Conclusion: Clinical doctor and pharmacist have better knowledge on ADR but nurses and traditional practitioner were relatively low. In addition knowledge on adverse drug reaction reporting is low for the entire healthcare professional. This study indicates that the healthcare professional have good knowledge on adverse drug reaction but the national pharmacovigilance centre need to focus on enhancing the knowledge on reporting adverse drug reaction.

O 25

The Impact of ADRs on Patient's Quality of Life After Packaging Changes of the Drug Thyrax®

L. Rolfes[1], F. van Hunsel[1], E. van Puijenbroek[1]

(1) Netherlands Pharmacovigilance Centre Lareb, 's-Hertogenbosch, The Netherlands

Introduction: Adverse drug reactions (ADRs) may have a great impact on the patient's quality of life (QoL). There are several factors that may interact with QoL, like the severity of the ADR. There is little information

to what extent ADRs influence the patient's QoL and which factors are of influence.

End of 2013 the packaging of the drug Thyrax® (levothyroxine) has been changed from a brown glass bottle to a blister package in the Netherlands. The product has not been changed. The Pharmacovigilance Centre Lareb received about 1800 reports concerning ADRs that occurred after this packaging change, of which more than 90 % from patients.

Aim: This study aims to explore the impact of ADRs on the QoL of patients who reported an ADR in relation to the packaging change of the drug Thyrax® to the pharmacovigilance centre Lareb.

Method: Patients who reported an ADR in relation to the packaging change of Thyrax® until April 2015 were included. QoL before and after the ADR and factors that may influence the QoL were studied using a web-based questionnaire. Domains in QoL that were explored are physical, social, mental, daily activities and overall health status, using an adapted COOP/WONCA tool [1]. QoL was expressed on a 5-point scale: very good (1) to very poor (5). Data were analyzed using a dependent and independent sample *t* tests and one-way ANOVA. Statistical significance was based on $p < 0.05$.

Results: The questionnaire was sent to 1638 patients, the response rate was 71 %. Overall, there was a statistically significant difference for each domain of QoL ($p < 0.001$). Average difference in QoL before and after the ADR was −0.8 for physical, −1.2 for mental, −1.4 for daily activities, −1.3 for social and −1.3 for overall health status. Factors that influenced 1 or more domains in QoL were: severity and seriousness of the ADR, if the patient was still able to go to work, the recovery and duration of the ADR, gender, age and education of the patients.

Conclusion: For patients included in this study the experienced ADRs have a clear negative impact on the patient's QoL. Changes in QoL was seen for each domain. Overall QoL score decreased by 1 point on a 5-point scale. Several factors that influence the QoL were found. Due to the specific setting of this analysis, it is unclear to what extent the results can be generalized to ADRs in general.

O 26

Enforcing the Habit—the Role of Champions in Pharmacovigilance Education

K. Khangura[1], A. Adams[2], C. Anton[1], R. Bracchi[3], E. Carey[2], A. Thomas[2], R. Ferner[1]

(1) Yellow Card Centre West Midlands, West Midlands Centre for Adverse Drug Reactions, Birmingham, United Kingdom, (2) Yellow Card Centre Wales, Cardiff and Vale UHB, Cardiff, United Kingdom, (3) All Wales Therapeutics and Toxicology Centre, University Hospital Llandough, Penarth, United Kingdom

Introduction: Many ADRs go unreported. Ignorance of what and how to report was one of Inman's 'Seven Deadly Sins' [1]. A system of local reporting centres can improve reporting rates and provide a focus for reporters in a locality [2]. In the United Kingdom, five regions have pharmacovigilance (Yellow Card) centres.

Aim: To improve reporting by recruiting a "Yellow Card champion" in hospitals and primary care groups (CCGs).

Method: Yellow Card Centre Wales set up and trained 14 pharmacist champions in Welsh hospitals in November 2012 to provide information and help others to complete Yellow Cards. The reporting rate in Welsh hospitals subsequently increased (Table below). This encouraged the Yellow Card Centre West Midlands to appoint a new pharmacovigilance pharmacist in October 2014 with the role of recruiting champions both in hospitals and CCGs. We offer these champions generic learning materials which they can adapt and use locally; and invite them to educational meetings.

Results: We have recruited 17 pharmacists, 3 nurses and 6 consultants in hospitals and 7 pharmacists in CCGs as champions, and held one regional study day and many local visits.

Reporting rates changed in Wales for the period 2012–13 to 2013–14 and in the West Midlands for (July–September) to (October–December) 2014 (Table 1).

Table 1 Reporting rate changes in Wales and the West Midlands

Wales	Change 2012–13 to 2013–14	
Hospital pharmacists	+189 (+134 %)	
All other reports	+339 (+67 %)	
West Midlands	Change from (July–September) to (October–December) 2014	
	Area with champions N (%)	No champion N (%)
Hospital	+31 (+43 %)	−3 (−12 %)
Primary Care	+5 (+9 %)	+24 (+21 %)

Conclusion: The introduction of the Welsh scheme has been associated with a substantial increase in reporting. Hospital reporting rates have also increased in the West Midlands scheme in the first three months where champions were introduced. Local pharmacovigilance champions appear to help increase the number of reports.

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Parallel Session F—Emerging Sources of PV Data

O 27

Use of Social Media for Data Mining in Pharmacovigilance

N. Dasgupta[1], C. Pierce[1]

(1) Epidemico-Inc., Boston, USA

Introduction: Many patients do not report adverse events to regulatory agencies or manufacturers because they are unaware that they can or should. However, patients often discuss AEs in social media and in online communities, often describing concerns that may be different from what they discuss with their doctors. Data mining tools can be leveraged to derive insights from these unstructured online conversations in real-time, thereby providing safety reviewers with an additional resource for drug