

distributed in the middle of the second semester, from 16 to 19 April 2018 at the end of the sessions of interactive work groups concentrating, for the first time, on pharmacovigilance. **Results** Of the 122 students in the class, the response rate was 95.90% (n=117). The work group helped to better explain to the students the reporting circuit, however 28 participants reported their inability to report ADR in their future practice (25.92%). Regarding the obligation to report ADRs, 99.4% of students (n=116) thought that it should be made legally valid for all health professionals. The same number (n=116) found the role of pharmacovigilance to be important. In addition, almost all of the comments collected after the tutorials reflected students' appreciation of this initiative and their desire to receive more sessions.

**Conclusion** In this study, students expressed the desire to learn more about pharmacovigilance during their university education. This result led to the introduction of a system of pharmacovigilance work groups for third- and fourth-year pharmacy students for the 2018–2019 academic year.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to all participants.  
No conflict of interest.

#### 6ER-024 ASPIRIN COMPARED TO ENOXAPARIN OR RIVAROXABAN FOR THE PREVENTION OF VTE FOLLOWING HIP AND KNEE REPLACEMENT – A RETROSPECTIVE COHORT STUDY IN IRELAND

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10.1136/ejhp-2019-eahpconf.621

**Background** The risk of venous VTE following major orthopaedic surgery is among the highest for all surgical specialties, and can result in significant morbidity and mortality. Guidelines for thromboprophylaxis following elective primary total hip or knee replacement (THR or TKR) in the Cappagh National Orthopaedic Hospital (CNOH) are based on American College of Chest Physicians (ACCP) guidance. The most recent change to local guidelines was the introduction of the extended aspirin regimen as standard thromboprophylaxis.

**Purpose** The aim of this study was to establish the effectiveness of this regimen by comparing VTE rates in patients receiving extended aspirin to those receiving inpatient enoxaparin or modified rivaroxaban regimens.

**Methods** This was a retrospective cohort study. Data were collected from the CNOH patient record software. All eligible patients who underwent primary TKR or THR between 1 January 2010 and 30 June 2016 were included (n=6,548).

**Results** The overall VTE rate was 0.99%. The VTE rate in both the inpatient enoxaparin group (n=961) and extended aspirin group (n=3,460) was 1.04%. The VTE rate in the modified rivaroxaban group (n=1,212) was lower at 0.66%, but the difference was not statistically significant (p=0.154). A history of VTE was the only significant demographic risk factor for post-operative VTE (0.87% vs. 3.54%, p=0.0002).

**Conclusion** These findings confirm the effectiveness of our current standard thromboprophylaxis regimen. The results are generalisable to patients undergoing elective primary THR or TKR nationally and internationally. This study adds to the

growing evidence supporting the use of aspirin thromboprophylaxis in the orthopaedic setting.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

#### 6ER-025 IMPACT OF THE NEW EUROPEAN REGULATION ON CLINICAL TRIALS IN THE ACTIVITY AND DYNAMICS OF RESEARCH ETHICS COMMITTEES FROM CATALONIA

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10.1136/ejhp-2019-eahpconf.622

**Background** Clinical research proposals on humans as clinical trials (CT), post-authorisation studies or any project must be submitted to an independent research ethics committee (REC). Different legislation has regulated CT in Spain, the last two European transpositions significantly modified the dynamics of REC, especially the most recent one, currently in force. Spain was the first European country to apply Regulation (EU) No 536/2014 with publication in December 2015 of Royal Decree 1090/2015.

**Purpose** The objective was to analyse and quantify the impact of Regulation (EU) No 536/2014 on the dynamics and activity of RECs from Catalonia regarding CT evaluation.

**Material and methods** Through an official request to the Catalan Health Service, annual activity reports that RECs from Catalonia have to present to competent government agency, were analysed.

Two periods were established: period 2007–2015 (under Directive 2001/20/CE) and period 2016 (under Regulation No 536/2014).

RECs were classified into three groups: high (Group 1), medium (Group 2) and low (Group 3), according to their annual evaluation activity.

Meetings number and evaluation activity were recorded. Descriptive statistical analysis was performed using SPSS.v.19. No normal distribution was resulted (Kolmogorov–Smirnov test), so the Mann–Whitney *U* test was used, statistical significance p<0.05.

**Results** Three-hundred and seventy-four reports from 47 RECs were reviewed. The median number of meetings per period, analysed by type of REC were:

Abstract 6ER-025 Table 1

	PERIOD 1	PERIOD 2	P
GROUP 1:	22 (IQR=11)	47 (IQR=25)	0.117
GROUP 2:	22 (IQR=10)	16.5 (IQR=14.7)	0.469
GROUP 3:	10 (IQR=12)	8.5 (IQR=11.2)	0.232

p=0.227 (period 1 vs. period 2, globally)

**Abstract 6ER-025 Table 1** Median REC evaluation activity

	PERIOD 1	PERIOD 2	P
GROUP	184	51 (IQR=4)	0.50
1:	(IQR=97)		
GROUP	73	20	0.02
2:	(IQR=66.2)	(IQR=42)	
GROUP	1 (IQR=11)	0 (IQR=3)	0.15
3:			

p=0.011 (period 1 vs. period 2, globally).

**Conclusion** Regulation (EU) No. 536/2014 has not modified the dynamics in RECs, nevertheless activity has been significantly altered, but in a different way depending on its activity. Most affected RECs are low and medium activity because of the drastic decrease in the number of CT evaluated per year because only one REC currently evaluates for all centres involved. Current legislation has caused CT evaluation to focus on RECs of large hospitals.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Regulation (EU) No 536/2014.  
[http://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg\\_2014\\_536/reg\\_2014\\_536\\_en.pdf](http://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf)

No conflict of interest.

**Results** The survey was presented to 43 eligible participants from August to October 2018. Thirty-two students completed the survey (74% response). Seventeen were P2, nine were P3 and six were P4 students. Sixty-one per cent of the responses strongly agreed that the presence of the European students improved their confidence when teaching and counselling Spanish-speaking patients using the peer-to-peer model. There was a strong correlation between confidence and teaching patients ( $r=0.571$ ,  $p=0.01$ ) and confidence and patient counselling ( $r=0.4517$ ,  $p=0.01$ ).

**Conclusion** The presence of the European students in a peer-to-peer mentoring model may improve P2 and P3 students' perception of confidence in medication counselling and teaching of Spanish-speaking patients on how to monitor their medical conditions.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to all our student volunteers.

No conflict of interest.

6ER-027 ABSTRACT WITHDRAWN

#### 6ER-026 PERCEPTION OF A PEER-TO-PEER MENTORING EXPERIENCE WITH EUROPEAN PHARMACY STUDENTS IN A STUDENT-RUN FREE CLINIC

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10.1136/ejhp-pharm-2019-eahpconf.623

**Background** While peer-to-peer mentoring and assessment is encouraged at many academic institutions, very little information exists about the effectiveness of this model in improving learning in student-run free clinics. Moreover, there is no information available about the impact on pharmacy students' perceptions of integrating international pharmacy exchange students into a peer-to-peer programme. Information generated by this study may provide support for the use of European students in peer-to-peer mentoring models.

**Purpose** To investigate students' perceptions of involving European pharmacy students in a peer-to-peer teaching model in a student-run free clinic.

**Material and methods** Data was collected in a student-run free clinic. A model was created where P4 and 5th year European students served as preceptors. The P4 students interacted and counselled English-speaking patients, whereas the European students focused on the Spanish-speaking patients. The teaching method was a modified version of the Hunter Mastery Teaching Model. An electronic survey was given to P2, P3 and P4 students to assess clinical experiences with patients assigned to European peer students. Sixteen survey items were evaluated that included students' perceptions in performing patient counselling, interviewing, writing electronic notes in the medical record, teaching patients how to monitor their medical condition and interacting with the medical team. Participants were asked to rate their perception of confidence from assessment statements on a 5-point rating scale, ranging from 1 – 'Strongly disagree' to 5 – 'Strongly agree.'