A679

in European countries. In Poland and France the same, highest rate of reimbursed orphan drugs (19.4%) was observed. The lowest rate is in Scotland where only 1.1% of identified orphan drugs is reimbursed. The highest rate of reimbursed drugs is among drugs which obtained positive or conditional recommendation from HTA Agencies. Atypically, in Poland and Germany 45%-60% of drugs with negative recommendation is reimbursed from public funds. **CONCLUSIONS:** More than 75% of approved orphan drugs have been assessed by any of European HTA Agency, but only part of them (36%) are reimbursed from public funds. The reimbursement status not always corresponds with the type of HTA Agency recommendation in case of orphan drugs.

### **PSY115**

# THE FEASIBILITY OF APPLYING DEFINITIONS OF PERSISTENT OPIOID UTILISATION TO QUANTIFY THE PERSISTENCY OF TRAMADOL USERS

Chen T, Chen L, Knaggs RD

University of Nottingham, Nottingham, UK

OBJECTIVES: Persistent opioid exposure is associated with increasing healthcare resource utilization and mortality. In last decade, there has been an increase in  $tramadol\text{-related deaths} \ in \ the \ U.K \ that \ may \ be \ related \ to \ persistent \ use \ of \ tramadol.$ However, there is a lack of consensus on defining the persistency of tramadol utilisation. This study aimed to explore the feasibility of applying definitions of persistent opioid utilisation to quantify the persistency of tramadol utilisation. **METHODS:** This retrospective cohort study used the Clinical Practice Research Datalink. Patients who were prescribed tramadol from 2000 to 2011 were followed from the first tramadol prescription. Patients who were issued at least one tramadol prescription consecutively in each follow-up patient year were defined as persistent users. The annual define daily dose (DDD) and number of supply day were calculated and stratified by persistent and non-persistent users. Descriptive statistic was used to report the proportion of persistent tramadol users consuming more than 180 DDD, 365 DDD and 90 days of supply annually. **RESULTS:** Overall, 526,624 tramadol users were identified, but 5460 (1%) tramadol users were persistently prescribed tramadol annually for 10 years. The median and interquartile range (IQR) of annual DDD and number of supply day are 200 (IQR: 100, 330) DDD and 224 (IQR: 114, 327) days in persistent group, and 45 (IQR: 17, 147) DDD and 51 (IQR: 16, 166) days in non-persistent group, respectively. For patients have been persistently prescribed tramadol annually for 10 years, 81% had annual number of supply day more than 90 days; however, only 45% and 19% had annual DDD more than 180 DDD and 365 DDD. CONCLUSIONS: The definitions of persistent opioid utilisation are not effectively in quantifying persistency of tramadol utilisation. Further study is needed to explore the association between persistent tramadol utilisation and clinical outcome and resource utilisation.

### **PSY116**

### EXPERTS CONSENSUS ON THE FUTURE OF RARE DISEASES CARE AND ORPHAN DRUGS ACCESS IN SPAIN: A DELPHI STUDY

 $Paz\ S^1, Torrent\ J^2, Poveda\ JL^3, Perez\ J^4, Moreno\ JL^5, Martin\ A^5, Gonzalez\ L^6, Cruz\ J^7, Comellas$ M1, Abaitua I8, Urcelay J5

<sup>1</sup>Outcomes 10, Universitat Jaume I, Castellon, Spain, <sup>2</sup>Committee for Orphan Medicinal Products (COMP), London, UK, <sup>3</sup>Hospital Universitario La Fe, Valencia, Spain, <sup>4</sup>Hospital Vall d'Hebron, Barcelona, Spain, 5Shire, Madrid, Spain, 6H. U. Infantil Niño Jesús, Madrid, Spain, 7FEDER, Madrid, Spain, <sup>8</sup>Instituto de Investigación de Enfermedades Raras, Madrid, Spain

**OBJECTIVES:** This study aims to determine the level of consensus that exits amongst experts on the most likely actions to be implemented to enable equal access to Orphan Drugs (OD) and specialized care to Rare Disease (RD) patients' in the public health sector in Spain. **METHODS:** Two-round Delphi survey; RD experts identified by the study scientific committee. The questionnaire [32 statements related to OD price and reimbursement (n=5); access to OD and specialized health care (n=19); RD registry (n=7); care model for RD (n=1)] was based on a literature review and 2 focus groups. Agreement was sought on the desire (D) and prognosis (P) for each statement to occur over the next 5 year. Consensus was reached when 75% participants, or more, choose the totally or partially agreed options (agreement), or the totally or partially disagreed alternatives (disagreement). Descriptive statistics were applied. RESULTS: 82 experts (50.9% response rate) participated [clinicians (n=41); hospital pharmacists (n=16); health care managers (n=13); patients (n=9) and pharmaceuticals representatives (n=3)]. Agreement on D and P of occurrence was reached in 66.07% (n=37) assertions: reference teams will define referral protocols, treatment criteria and practice guidelines (D: 97.56%; P: 89.74%); a unified, etiology based RD registry will support clinical decision making (D: 97.56%; P: 84.62%). Divergence between D and P existed in 32.14% (n=18) statements: OD reimbursement conditions will be reviewed every 5 years based on clinical evidence (D: 90.24%; P: 74.36%); medical teams will network to coordinate RD patients' care (D: 99%; P: 62%); home care teams will enable a more efficient care support to RD patients (D: 91%; P: 56%). CONCLUSIONS: Consensus was mostly reached on practical issues. RD experts are less optimistic about the immediate future of endeavors that require health care processes review to succeed in easing access to OD and specialized care for RD in Spain.

# PSY117

## ANAESTHESIA IN DEVELOPING COUNTRIES

Epiu I<sup>1</sup>, Tindimwebwa JV<sup>2</sup>, Mijimbi C<sup>3</sup>, Chokwe T<sup>4</sup>, Lugazia E<sup>5</sup>, Ndarugirire F<sup>6</sup>, Twagirumugabe T7, Dubowitz G8

<sup>1</sup>Infectious Disease Institute, Kampala, Uganda, <sup>2</sup>Makerere University, KAMPALA, Uganda, <sup>3</sup>Mulago Hospital, Kampala, Uganda, <sup>4</sup>University of Nairobi, Nairobi, Kenya, <sup>5</sup>Muhimbili

 $University\ of\ Health\ and\ Allied\ Sciences,\ Dar\ es\ salaam,\ Tanzania,\ ^6Centre\ Hospitalo-Universitaire$ de Kamenge, Bujumbura, Burundi, <sup>7</sup>National University of Rwanda, Kigali, Rwanda, <sup>8</sup>University of California, San Francisco, San Francisco, CA, USA

**OBJECTIVES:** The United Nations 2015 Millennium Development Goals targeted 75% reduction in maternal mortality. However in spite of this goal, the number of deaths per 100 000 live births remains unacceptably high across Sub-Saharan Africa. As many of these deaths could be averted with safe access to surgery including cesarean sections, the objective of this study was to assess the capacity to provide safe anaesthetic care for mothers in the main referral hospitals in East Africa. METHODS: The

cross-sectional survey was conducted at the main referral hospitals in East Africa - ${\bf Mulago, Uganda; Kenya; Muhimbili, Tanzania; Center Hospitalier Universite}$ de Kigali (CHUK), Rwanda; and CHUK, Burundi. Using a questionnaire based on the World Federation of the Societies of Anaesthesiologists (WFSA) guidelines for safe anaesthesia, we assessed demographic, administrative, peri-operative variables by interviewing anaesthetists in these hospitals, key informants from the Ministry of Health and National Anaesthesia Society of each country. RESULTS: Using the WFSA checklist as a guide, only four percent of respondents were able to provide safe obstetric anaesthesia, and only seven percent reported adequate anaesthesia staffing. There were only 30 anaesthesiologists in Uganda, 168 in Kenya, 22 in Tanzania, 15 in Rwanda, and 2 in Burundi. Hospitals were barely equipped with monitors that some-times were not functional. The paucity of local protocols, the failed referral system and lack of intensive care unit services was also reported to contribute significantly to poor maternal outcomes. **CONCLUSIONS:** We identified significant shortages of both personnel and equipment needed to provide safe anaesthetic care for obstetric surgical cases across East Africa. There is need to develop policies and strengthen the health systems in order to improve surgical outcomes in developing countries.

# HOSPITALIZATIONS IN HYPERCHYLOMICRONEMIA PATIENTS IN QUEBEC, CANADA; RESULTS FROM A REAL-WORLD OBSERVATIONAL STUDY

Lachaine J1, Gaudet D2, Miron A1, Tremblay K2

<sup>1</sup>University of Montreal, Montreal, QC, Canada, <sup>2</sup>Centre de médecine génique communautaire de l'Université de Montréal; ECOGENE-21, Chicoutimi, QC, Canada

OBJECTIVES: Familial Chylomicronemia Syndrome (FCS) is a rare hereditary form of hyperchylomicronemia, a lipoprotein dysfunction leading to high levels of plasma triglycerides and resulting in various complications, including acute pancreatitis and abdominal pain. It affects about 1-2/1,000,000 individuals worldwide. The purpose of this study was to estimate the health care resource utilization, more specifically hospitalizations associated with FCS patients in a real-life setting. METHODS: A retrospective study was conducted using data from patients who were diagnosed with FCS at the Saguenay-Lac-St-Jean hospitals and clinics between January 1958 and April 2015. Patients were included in the database regardless of their age or the time since diagnosis. Data collection was performed from December 2014 to June 2015. Hospitalizations were confirmed by an exhaustive medical chart review. We focused on characteristics associated with FCS pancreatitis-related hospitalizations (PRH) and abdominal pain-related hospitalizations (APRH). RESULTS: The study included 58 FCS patients (mean age of 43.9 years (SD=15.1), 57.0% men). Thirty-one (53.0%) patients suffered from at least one episode of pancreatitis or from other abdominal pain, among which, 30 and 24 of these patients required at least 1 hospitalization because of PRH or APRH respectively. PRH were more frequent (15.7 hospitalizations/patient) than APRH (4.5 hospitalizations/patient). Furthermore, the PRH rate was higher in women than in men (19.9 hospitalizations/women vs. 12.0 hospitalizations/men). Moreover, pancreatitis and abdominal pain were associated with an average of length of hospital stay of 8.1 (SD=8.5) and 6.5 (SD=7.4) days respectively, and was higher in women than men for PRH (9.1 vs. 6.5 days) and for APRH (9.5 vs. 4.6 days). Based on the current average hospital cost per day in Quebec, Canada, estimated costs is CDN\$7,970 per PRH and CDN\$6,396 per APRH. CONCLUSIONS: FCS is associated with increased hospitalization resource utilization and cost. Pancreatitis and abdominal pain represent cost-generating complications.

## PSY119

### REVERSAL OF NEUROMUSCULAR BLOCKADE: A DISCRETE EVENT SIMULATION MODEL OF CLINICAL AND OPERATING ROOM EFFICIENCY OUTCOMES OF SUGAMMADEX VERSUS NEOSTIGMINE IN CANADA

Insinga  $\mathbb{R}^1$ , Joyal  $\mathbb{C}^2$ , Schelfhout  $\mathbb{J}^1$ , Yang  $\mathbb{K}^1$ 

<sup>1</sup>Merck & Co., Inc., Kenilworth, NJ, USA, <sup>2</sup>Merck Canada, Kirkland, QC, Canada

OBJECTIVES: Sugammadex significantly reduces time and variability of recovery from neuromuscular blockade (NMB) compared to neostigmine. We explore potential impact on operating room (OR) efficiency and incidence of residual neuromuscular blockade (RNMB) with use of sugammadex versus neostigmine in Canada. METHODS: A discrete event simulation (DES) model was developed to compare ORs using neostigmine and sugammadex for NMB reversal, for the same simulated schedule of procedures. Selected inputs included OR procedure and turnover times, hospital policies with respect to paid staff overtime and procedural cancellations due to OR time over-run, and reductions in RNMB and associated complications with sugammadex use. Trials have shown that sugammadex's impact on OR time and RNMB varies by whether full neuromuscular recovery (train-of-four [TOF] ratio ≥0.9) is verified prior to extubation in the OR. Two scenarios were therefore evaluated; when full recovery is verified prior to extubation and when it is not. RESULTS: In the modeled scenario where full neuromuscular recovery was verified prior to extubation (92 procedures performed over one month with sugammadex), the use of sugammadex versus neostigmine over one month avoided 5.5 procedural cancellations and 9.3 hours of paid overtime, while saving an average of 61 minutes per OR day. No difference was observed between comparators for these endpoints in the modeled scenario when full neuromuscular recovery was not verified prior to extubation, however, the per procedure risk of RNMB at extubation was reduced from 60% to 4% (reflecting 48 cases prevented over one month), with associated reductions in risks of hypoxemia (12 cases avoided) and upper airway obstruction (21 cases avoided). CONCLUSIONS: The impact of sugammadex was found to vary according to practices for neuromuscular recovery and extubation. Use of sugammadex can improve the current trade-off between OR efficiency and occurrence of RNMB when utilizing neostigmine.

HEALTHCARE RESOURCE UTILIZATION COSTS RELATED TO ANAEMIA MANAGEMENT IN CHRONIC KIDNEY DISEASE NON-DIALYSED PATIENTS: A RETROSPECTIVE CLINICAL AND ADMINISTRATIVE DATABASE ANALYSIS

Pessina E<sup>1</sup>, Degli Esposti L<sup>2</sup>, Buda S<sup>2</sup>, Saragoni S<sup>2</sup>

<sup>1</sup>Amgen S.r.l., Milano, Italy, <sup>2</sup>CliCon S.r.l., Ravenna, Italy