

"baseline" year served as control data. **RESULTS:** There were 1500 intervention and 286 control participants with mean age (sd) 72.75 (7.82) and 73.39 years (7.31), and past year fall rates of 22.8% and 21.8%, respectively. Males comprised 23.1% of the intervention group and 24.8% of the control group. Majority were of Chinese ethnicity (86.7% of intervention and 81.1% of controls). Improvements from baseline to 52 weeks were significantly better ($p < 0.05$) for intervention participants than controls for the Six Minute Walk Test, Step Test, Falls Efficacy Score and Life Space Assessment; Safer Score was significantly better on follow-up for the intervention group. There was no significant difference in the Berg Balance, Timed-Up-And-Go, Chair Rise and EQ-5d. Intervention participants had significantly fewer falls in the third quarter of follow-up (95%CI of the difference=0.00,0.10). Multivariate results revealed that the intervention group had significantly fewer falls for the entire follow-up year (Odds Ratio = 0.75, 95%CI = 0.58,0.97). **CONCLUSIONS:** Results suggest that the program improves physical performance and reduces the incidence of falls in the elderly. Residents may be empowered to take responsibility for preventing falls in their own community.

PHP155

SYSTEMATIC REVIEW OF FDA BREAKTHROUGH THERAPY DESIGNATED PRODUCTS

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OBJECTIVES: In 2012, the United States Food and Drug Administration (FDA) created a new expedited pathway of "Breakthrough Therapy Designation" (BTD) to enable an early approval of therapies which have shown substantial activity in early trials. The objective of this study was to assess the comparative effectiveness and pricing of drugs with BTD. **METHODS:** The data for the number of granted BTDs was obtained from FDA.gov. The data for publically disclosed BTDs was obtained from sponsor's press releases. For all products, the information for their mechanism of action, type of molecule, trial design, clinical efficacy and safety, and pricing and time to approval (for approved products) were obtained from peer-reviewed publications, conference abstracts, FDA and sponsor websites. **RESULTS:** Since the establishment of the BTD pathway, 55 products have been granted breakthrough therapy designations (2012-2015), of which, 42 have been publically disclosed by the manufacturers and 6 have been approved by the FDA. In terms of indications, 43% are for cancer, 18% are for genetic diseases and 14% are for Hepatitis C Genotype 1. The median time to approval for these three drug was ~5 years, significantly shorter than the 2012 median time to approval for priority review applications (6 years). The price premium was 30-50%, compared to other drugs in the same category. The six approved BTDs show 20-30% higher response rates than other products in the same category. The other products in the pipeline with established comparators show 36%-136% improvement in efficacy (based on active controls or previous trials). For approximately half of the products, comparative efficacy cannot be determined because of no previous evidence for a product with efficacy in the targeted indications. **CONCLUSIONS:** BTD is a promising pathway to shorten development time and provides early access, however, the high price could pose challenges for payers and patients.

PHP156

THE USE COMPARATIVE EFFECTIVENESS RESEARCH AND EVIDENCE BASED MEDICINE IN US PAYOR DECISION MAKING

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OBJECTIVES: To understand how comparative effectiveness research (CER) is being used by US managed care plans and pharmaceutical benefit managers (PBMs) to control the growth of healthcare costs and ensure appropriate utilization of products by pharmacy and therapeutics (P&T) committees. **METHODS:** Managed care (MC) medical and pharmacy directors (MDs+PDs) completed an online interactive survey. Topics included: advisor and plan information and current/future coverage of CER. The use of CER and evidence-based medicine (EBM) was evaluated using a 5-point likert scale (5=completely agreeing,1=completely disagreeing). **RESULTS:** Fifty-four percent of respondents were MDs, the remainder mostly pharmacists. Most worked for a health plan (83.6%) and 39.6% of the plans were local; 35.4% national; and 25.0% regional. Public (Medicare and Medicaid) and private (Commercial) plans were represented. When asked to select the area emerging CER is expected to affect: value of care (29.8%), optimization/improvement of clinical guidelines (27.7%), appropriateness of care (14.9%), pharmaceutical research and development (6.4%), medical and pharmacy benefit management (17.0%), and 4.3% uncertain. When asked about their agreement in "progress in obtaining usable information on CER of therapies" the results were slightly negative with 42.5% disagreeing (34%=somewhat,8.5%=completely), 38.3% agreeing (4.3%=completely,34%=somewhat), and 19.1% neutral. When asked if they expect their plan to use CER regularly in formulary decision making by 2015, more than half (53.2%,14.9%=completely,38.3%=somewhat) agreed, 27.7% disagreed (23.4%=somewhat,4.3%=completely), and 19.1% were neutral. When asked to assess how "MC commonly using EBM today in coverage decision making" the results were more favorable with 79.2% agreeing (27.1%=completely,52.1%=somewhat); 14.6% neutral and 6.3% disagreeing (6.3%=somewhat,0%=completely). The most desired change to their plan's/PBM's P&T process was for increased use of CER; and a move toward contractual risk-sharing. **CONCLUSIONS:** Formulary decision making in P&T committees is making progress in the use of comparative effectiveness research. Results suggest that the acceptance of evidence-based medicine is valuable even if not comparative.

PHP157

IMPACT OF CLERKSHIP ATTACHMENTS ON STUDENTS' ATTITUDE TOWARDS PHARMACEUTICAL CARE IN ETHIOPIA

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OBJECTIVES: The present study aimed at investigating the impact of mandatory clinical clerkship courses on fifth year pharmacy students' attitudes and perceived barriers toward providing pharmaceutical care (PC). **METHODS:** A cross-sectional survey was conducted among 5th year pharmacy students undertaking mandatory clinical clerkship in the University of Gondar, Ethiopia. A pharmaceutical care attitudes survey (PCAS) questionnaire was used to assess the attitude (14 items), commonly identified drug-related problem/s (1 item) during clerkships, and perceived barriers (12 items) toward the provision of PC. Statistical analysis was conducted on the retrieved data. **RESULTS:** Among the total of 69 clerkship students, 65 participated and completed the survey (94.2% response rate). Overall, 74.45% of participants had positive attitude toward PC provision. Almost all respondents agreed that the primary responsibility of pharmacists in the healthcare setting was to prevent and solve medication-related problems (98.5%), practice of PC was valuable (89.3%), and the PC movement will improve patient health (95.4%), respectively. Unnecessary drug therapy (43%), drug-drug interactions (33%), and non-adherence to medications (33%) were the most common drug-related problems identified in wards. Highly perceived barriers for PC provision included lack of a workplace for counseling in the pharmacy (75.4%), a poor image of pharmacist's role in wards (67.7%), and inadequate technology in the pharmacy (64.6%). Lack of access to a patient's medical record in the pharmacy had significant association ($P < 0.05$) with PC practice, performance of PC during clerkship and provision of PC as clinical pharmacists. **CONCLUSIONS:** Students attending the new clinical pharmacy program in Ethiopia have a good attitude toward pharmaceutical care. However, the barriers to pharmaceutical care need to be addressed by integrating PC provision with pharmacy practice.

PHP158

RELATIONSHIP BETWEEN COMMUNITY PHARMACY ATTRIBUTION AND PATIENT'S OUTCOMES IN HEALTHCARE SERVICE OF HOME-VISITING

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OBJECTIVES: Aim of this research was to investigate ideal attribution with revealing the relevance between pharmacy attribution and patients' outcomes. **METHODS:** A self-completion questionnaire from composed of two forms of "Pharmacy attribute" and "Patients attribute" was delivered to 3321 pharmacies across Japan which agreed to join in January 2013. Pharmacy attribute: a number of pharmacist, prescription/day, home-visiting patients/ month, cooperated medical facilities. Patients attribute: adverse drug event, change in prescription, change in adherence, finding of unused drugs, and change in the amount of unused drugs. We grouped by 2 indexes (a number of prescription/day/pharmacist as 'work load' and cooperated medical facilities as 'positivity to cooperate') to 4 groups. (Used SPSS ver.21) **RESULTS:** Among 1,890 community pharmacies data (collecting rate: 56.9%), we extracted answers to all the question items about community pharmacy attribute necessary for grouping. The 1,327 community pharmacies data was collected as the target (the number of patient data: for 4,947) for the analysis. The data of 1327 pharmacies showed the middle of attribution showed 20 prescriptions filled /day/pharmacist (work load) and 1 medical facility cooperated. The group of 'Prescriptions \leq 20 and Cooperated facility>1' and the groups of 'Prescriptions>20 and Cooperated facility>1' changed in prescription($p < 0.003$), changed in adherence($p < 0.001$), find of unused drugs($p < 0.001$), and decreased the amount of unused drugs ($p < 0.001$) more than others. There is no significant differences in adverse drug event. **CONCLUSIONS:** It was suggested that there was relationship between pharmacy attribution (work load/ positivity to cooperate) and patient's outcomes on healthcare service of home-visiting.

PHP159

A STUDY OF KNOWLEDGE, ATTITUDE AND PRACTICE OF COMMUNITY PHARMACISTS TOWARDS ADVERSE DRUG REACTION REPORTING & MONITORING

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OBJECTIVES: This study was conducted to assess the knowledge, attitude and practice of community pharmacists (CPs) towards ADR reporting and monitoring. **METHODS:** A prospective cross sectional study was conducted at selected community pharmacies. Pharmacists at selected pharmacies were administered a questionnaire by research pharmacist and two weeks' time was given to each pharmacist to complete the survey. Questionnaire was designed with various elements which can evaluate knowledge, attitude and practice of pharmacists towards ADR reporting. **RESULTS:** A total of 256 community pharmacists were approached at selected community pharmacies per study criteria and were administered a questionnaire. Of 256, only 56 CPs (21.8%) responded to the survey. Of 56 respondents, 37.5% were able to define ADR correctly, whereas 35.7% of pharmacists believed ADRs solely as allergic response. Only 46% of pharmacists could correctly identify potential risk factors responsible to cause ADRs and 57% of pharmacists were aware of the consequences of ADRs. Almost 93% of respondents admit that safety reporting is an important responsibility of pharmacist however, surprisingly almost 73.2% pharmacists were not aware of existing pharmacovigilance program in the country. As per 78.5% respondents ADR reporting in the community pharmacies lead to additional workload. Looking at willingness to report, almost 50% of pharmacists expect incentives to get involve in the safety reporting and other 50% feels it as professional responsibilities which do not require incentives. Among respondents only 20% of them had ever reported ADR to nearer national safety reporting centres. However, majority of CPs are interested to contribute for ADR reporting if appropriate training is provided. **CONCLUSIONS:** Majority community pharmacists do not possess required knowledge on ADR reporting, its importance and national safety reporting program. There is a strong need to implement educational and regulatory interventions periodically to improve the understanding of safety reporting among CPs.

PHP160

TAKING MEDICATION SAFELY: IMPLEMENTING AND DEVELOPING A MEDICATION REVIEW PROGRAM IN GERMAN COMMUNITY PHARMACIES OVER 4 YEARS

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OBJECTIVES: The objective of this study was to analyze the implementation process and changes over a 4-year period of medication review services in an older adult population in German community pharmacies. Medication review is a patient-oriented service, designed to identify drug-related problems in a personal consultation. **METHODS:** This study focuses on adults older than 65 years. Medication reviews were conducted in 254 pharmacies in Germany and analyzed over a 4-year period (2011 to 2014). Data extracted from medication reviews included patient demographics, drug-related problems (DRPs) detected by the pharmacy and pharmacy-related data. In addition to descriptive analysis, we performed binary multivariate logistic regression models to identify the main patient-, medication- and pharmacy-related predictors associated with the overall assessment of therapy. **RESULTS:** A total of 2,931 medication reviews were analyzed with patients aged between 66 and 98 years. In the sample, the mean number of medicines taken by individuals was 6.08 with 66.6% of individuals taking five or more medicines. During the 4-year period, in 60.5% of all medication reviews (n = 2,931), DRPs were detected by participating pharmacies; significant differences could be determined between different years (p < 0.001) with scores ranging from 56.7% to 66.7%. In nearly half (47.1%) of the medication reviews, interactions were detected and the interaction potential was classified according to the ABDA database classification system. However, over-supply remains low at 6.9% of all medication reviews. Binary multivariate logistic regression analysis revealed different significant patient- and pharmacy-related predictors associated with overall assessment of therapy. **CONCLUSIONS:** Findings indicate the potential to identify drug-related problems through medication review, based on a disclosure of all drugs taken by the patient. The extent of implementation of medication review in Germany cannot be regarded as satisfying at present. Hence, existing programs should be enhanced to increase the number of participating pharmacies and patients.

PHP161

CAN GRAPEFRUIT JUICE MAKE SAFE DRUGS UNSAFE OR INEFFECTIVE? AN EVIDENCE-BASED ANSWER

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OBJECTIVES: Grapefruit juice is known for its ability to interact with the pharmacokinetics of many drugs. This work aims at characterising and synthesizing evidence on this interaction via systematic reviews and modelling. **METHODS:** Systematic review was performed to collect data on metabolic interactions between 35 drugs metabolized via the CYP3A4 metabolic pathway and grapefruit juice. Magnitude of interaction was defined as the ratio of areas under the curve with and without grapefruit juice. A Bayesian hierarchical meta-analysis model was used to quantify such interactions and the chemical-specific inter-individual variability. Impact of real-world metabolic interactions on benefit risks on drugs was discussed. **RESULTS:** Data from more than two hundred studies were collected, involving 35 widely used drugs. Grapefruit juice property to inhibit the CYP3A4 elimination translated into up to 20-fold higher internal doses hence raising potential safety concerns. Statistically significant magnitudes of pharmacokinetic effect ranged from 1.09 to 22.07. The mean magnitude of (CYP3A4-specific) interaction was estimated at 3.73 (95%-credibility interval [0.76-23.14]). **CONCLUSIONS:** This work illustrates how real-life food-drug interactions can severely impact real-world benefit/risk of drugs. Such information may be accounted for to inform risk management plans and to optimize early drug development.

PHP162

APPLYING KARNOFSKY PERFORMANCE SCALE IN HOSPITALIZED PATIENTS FOR PROMOTING RATIONAL THERAPY

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OBJECTIVES: Population aging has brought greater demand for admissions of patients with chronic diseases fleeing the routine therapeutic goals. The objective of this study is to evaluate the application of Karnofsky Performance Scale (KPS) to identify patients who need palliative care and avoiding therapeutic futility. **METHODS:** An observational vertical prevalence study made in June 2014 of clinical patients admitted in a public hospital in São Paulo city, by applying a brief and objective questionnaire directly to patient's physicians in order to obtain a diagnosis of the clinical situation aspects, based on KPS. **RESULTS:** According to the analyze of 259 questionnaires/patients (Female: 111 and male: 148) from all adult inpatient sectors in the hospital (medical wards, surgical wards and intensive care unit), we found: a) 62.55% with KPS ≥ 50 (without advanced disease); b) 2.70% with KPS = 40 (disease in progression to advanced); c) 1.16% with KPS = 30 (advanced disease, with no expectation of cure, unless performing organ transplants); d) 15.44% with KPS = 20 (advanced disease without an effective cure or treatment that can modifies the disease); e) 17.76% with KPS = 10 (death prediction in the present admission). Only one patient could not be classified. About 57% of patients were older than 50 years. **CONCLUSIONS:** The KPS analysis showed 37.45% of the patients were with advanced disease condition and without possibility of cure who should be better treated in palliative care environments with more specific conditions for them, without using numerous and expensive drugs and procedures which only cause more suffering to these group of patients. To disseminate and applying the knowledge in palliative care will certainly contribute to a more rational use of therapeutic resources.

PHP163

SURVEY ON ROMANIAN HOSPITALS FINANCING REVEALS MAJOR DYSFUNCTIONS IN COVERING DRUG TREATMENT DURING HOSPITALIZATION

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OBJECTIVES: To investigate the perception of Romanian hospital managers towards under financing of the health sector and to identify the major drawbacks on different aspects of hospital activity. The Romanian hospitals are paid using DRG system since 2009. This is the first attempt to obtain an empiric imagine of the opinion of the hospital's managers regarding the effect of inadequate financing and its consequences. **METHODS:** In the last trimester of 2014, we have sent a questionnaire with 25 questions to the top management of every Romanian hospital. The quiz was based on the results of a focus group held in September 2014 which included 7 managers from different hospitals in Romania. **RESULTS:** In 2013 in Romania there were 435 hospitals contracting services with the social insurance system. The questionnaires were sent by mail and we received 82 answers, which were sent back by mail or completed anonymously in a special online application. 85% (70 of 82) of the managers indicated that the budget negotiated with the social insurance system is insufficient and causes some to major difficulties, some of them saying that is impossible to cover their expenses. As a result, 34,3% of the underfinanced hospitals had difficulties in acquiring the medication for their patients! 22,8% of those said that they faced difficulties in buying the drugs that cost more than 22 Euro per day of treatment. 94% of the managers believed that the official tariffs do not cover the expenses required by the services. **CONCLUSIONS:** Under financing of the Romanian hospitals is due to the inadequate tariffs established unilateral by the National Insurance House. As a result, many of the hospitals are generating debts. As the wages are paid with priority, the main effect of under financing is an inadequate amount of money spent on drugs.

PHP164

ISOLATION, IDENTIFICATION AND ANTIMICROBIAL SUSCEPTIBILITY TESTING OF SALMONELLA FROM SELECTED POULTRY FARMS IN DEBRE ZEIT

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OBJECTIVES: Isolate, Identify and Determine the Antimicrobial Resistance Pattern of Salmonella Species from Selected Poultry Farms in Debre Zeit, Ethiopia. **METHODS:** Cross sectional study was conducted to isolate, identify and determine antimicrobial susceptibility testing of salmonella organisms from four selected poultry farms in Debre Zeit, Ethiopia. A total of 196 chickens were sampled from four purposively selected commercial poultry farms. Cloacal swab samples were collected from live chickens using sterile cotton tipped swabs moistened with buffered peptone water. The swabs were kept in properly plugged sterile test tubes. Then Isolation and Identification of Salmonella, Biochemical Confirmation, Polymerase Chain Reaction (PCR) and Antimicrobial susceptibility testing were conducted. **RESULTS:** From a total of 196 cloacal swabs collected 50 (25.5%) were found to be positive for Salmonella organisms using culture method, and 15 (7.6%) Salmonella isolates were confirmed using biochemical tests. All culture and biochemical positive samples were further confirmed by Polymerase Chain Reaction (PCR) through amplification of histidine transport operon as a target gene for the presence of salmonella isolates. From culture and biochemical positive samples, gel electrophoresis of the PCR product revealed the presence of 496bp segments in 13 (6.7%) Salmonella isolates. The statistical analysis has revealed a significantly association between different age groups of chickens (X² = 10.56; P = 0.005) and farms (X² = 10.74; P = 0.013) with the percentage of Salmonella isolates. Most of the Salmonella isolates were found to be resistant against commonly used antimicrobials such as Sulfisoxazole, Chloramphenicol and Ampicillin followed by Tetracycline, Amoxicillin/Clavulanic acid and Cephalotin and more than half (69.3%) of the isolates were found to be multi-drug resistant. **CONCLUSIONS:** The high prevalence of resistance to antimicrobial agents found in this study might be attributed to uncontrolled use of antimicrobial agents as growth promoters in poultry farms. Therefore, proper treatment of chickens using appropriate antibiotics is then quite essential.

PHP165

OBSERVATIONAL (OBS), PRAGMATIC (PRA), AND INDIRECT (IND) METHODOLOGIES FOR COMPARATIVE RELATIVE EFFECTIVENESS (RE) AND BENEFIT-RISK (BR) ANALYSES

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OBJECTIVES: Regulators and Health Technology Assessment (HTA)/Payer stakeholders are increasingly looking into Real World Evidence (RWE) for RE and BR. Demonstrating quality, efficacy and safety plus cost effectiveness ('4th hurdle') is no longer sufficient to ensure market authorization and reimbursement. While some RWE stakeholders require randomized study approaches, e.g. to avoid allocation bias, typically in the form of 'pragmatic' trials, others consider observational studies or accept indirect comparisons in the absence of head-to-head comparison results. However, it is unknown how frequently respective comparative approaches are actually used. **METHODS:** To assess relative importance of observational, pragmatic and indirect methodologies for comparative RE and BR, we surveyed Medline using purpose related terms 'relative/comparative effectiveness' or 'benefit/risk' in combination with methodology terms 'observational/non-interventional', 'pragmatic study/trial', and 'indirect comparison/network analysis'. Resulting publication numbers were analyzed, and selected abstracts were assessed qualitatively. **RESULTS:** We focused on publication title analysis as all field searches yielded heterogeneous results. Publication title hits were by far highest for OBS methodologies, followed by PRA and lowest for IND (13,247; 201, 141), and higher for BR than for CE (3,017; 1,152). RE publications continuously increased over time with not more than 50 annual hits before 2005, but consistently above 250 hits after 2013. Similarly, annual CE hits were below 20 before 2006, increased to 250 as of 2010, but tended to decrease after a peak in 2013. For RE, OBS