Pharmacy Education (2020) 20(3) 66 - 76
https://doi.org/10.46542/pe.2020.203.6676

CONFERENCE ABSTRACTS

FIP VIRTUAL 2020

Pharmaceutical Practice: Social and Administrative Pharmacy

Pharmacist-led opioid stewardship in a General Practice - an innovative professional service

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Background: General Practice provides a common setting for all patients. As evidence of opioid-related harm accrues, Australian General Practioners (GPs) are encouraged to restrict prescribing regular opioids for chronic, non-cancer pain and after acute care. A pharmacist integrated into the practice team can help reduce the risk of harm.

Purpose: To assess the impact of a practice-based pharmacist on the management of opioids in people transitioning through care and to describe factors contributing to opioid reduction.

Method: An opioid policy was endorsed and a model for patient-pharmacist-GP consultation iteratively developed. Over nine months, all patients prescribed long-term opioids were reviewed by a second GP, referred to the pharmacist, and then had opioid agreements established and doses tapered if appropriate.

Data collected included demographics, opioid use at baseline, six and nine months and overall reduction. Pharmacist-initiated strategies that enabled tapering of opioid dose (converted to daily oral morphine equivalents (OMEs)) were documented.

Results: Overall, 100 patients aged 36-100 years (mean 67), 62.0% female, had pharmacist consultations; 18 were post-discharge. Prior opioid use was from two weeks to 20 years. Median daily OME was significantly reduced: 43mg (IQR= 30-90) at baseline, 12mg (IQR= 0-40) at six months and 6mg (IQR= 0-30) at nine months. Mean overall OME reduction was 65.0% (range= 0-100%): 41.0% no longer received regular opioids. Pharmacist-initiated strategies included use of alternate formulations, communicating with all prescribers and heeding patient needs.

Conclusion: Interdisciplinary clinical governance and patient engagement contributed to opioid reduction. These key stewardship principles may be transferable to other high-risk medicines.

Promoting community pharmacist's involvement in HIV/AIDS services through educational interventions in Nigeria

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Background: In Nigeria, studies on community pharmacists' involvement in the delivery of HIV testing services (HTS) are scarce and they have little involvement in antiretroviral (ARV) medication therapy management (MTM).

Purpose: This study evaluates the provision of HIV/AIDS services by community pharmacists in the southwest of Nigeria before and after they underwent training on HTS and ARV/ MTM.

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ISSN 1477-2701 online

Method: Semi-structured questionnaires on a 5-point Likert scale were administered to selected community pharmacists in 2019 to assess their involvement in HTS and ARV/ MTM services before and after a training intervention. Participants' opinions about the training was also assessed to determine its adequacy. Data were analysed with both descriptive and inferential statistics.

Results: At baseline survey, 22.0% of the respondents were involved in the services with mean scores of 2.62+2.190 and 2.55+2.179 in HTS and ARV/ MTM respectively while 91.0% were willing to participate in the training to improve services. Barriers to integrating services into practice before the training, among others, were the lack of clinical tools (46.8%), lack of collaboration with other healthcare professionals (39.1%) and lack of information/training on services (36.2%). Participants' opinions based on the indicators measured during the training programme was 4.60+0.518 and all the participants agreed that the training was sufficient for them to provide services. After the training, an average of 60.0% of the respondents are involved in the provision of services as compared with 22.0% before the training (p<0.05).

Conclusion: Community pharmacists' involvement in HIV/AIDS services was low before training. However, training intervention was shown to improve services.

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A modified Delphi method to develop quality indicators for geriatric care by community pharmacists in Japan

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Background: National guidelines on geriatrics were introduced by the Ministry of Health, Labour and Welfare in Japan in 2018 and 2019 to improve the safety of geriatric pharmacotherapy. Currently there are no tools available to evaluate geriatric care in community pharmacy. Therefore, it is important to develop quality indicators (QIs) for geriatric care.

Purpose: To develop quality indicators for geriatric care provided by community pharmacists in Japan.

Method: This study involved two steps: 1) preparation of preliminary QIs based on guidelines and a review of literature; (2) evaluation of the appropriateness of QIs using a modified two-round Delphi method with a panel discussion between the rounds. Panellists (five physicians and five pharmacists) assessed the appropriateness of each QI developed in step 1, using a 9-point scale with the opportunity to provide free text comments. QIs with a median score of 7-9, without disagreement (at least three panellists scored 1-3 and at least three panellists 7-9) were considered 'appropriate'.

Results: In step 1, 143 preliminary QIs were prepared. In step 2, 133 QIs met the criteria and were assessed as 'appropriate' (110 process indicators, 23 outcome indicators). These QI were divided into 19 categories by disease state for example dementia (n=15), diabetes (n=11), COPD (n=11) and osteoporosis (n=11). In terms of drug-related problems, 27 QIs pertained to risk of adverse reactions and 23 QIs pertained to risk of drug-drug reactions.

Conclusion: Guideline-based QIs were developed. The use of QIs may be an effective strategy to improve geriatric care and address poly-pharmacy. Field testing is needed to evaluate QI measurement properties (e.g. feasibility, applicability, improvement potential).

Understanding educational needs of pharmaceutical stakeholders: Pharmacy operators

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Background: A capable, flexible, and adaptable workforce is crucial to meet the needs of patients (FIP, 2017). The educational needs of pharmaceutical operators and support personnel who are responsible for pharmacy operations involving the storage, inventory, manufacture, and distribution of medicines requires understanding.

Purpose: To identify the educational needs of operators.

Method: A questionnaire was developed and validated by a panel and disseminated to pharmacy operators and managers/ supervisors in different fields of pharmacy.

Results: The questionnaire has four sections. The first section is dedicated to demographics and the second section lists the course topics. Respondents must identify whether training about the topic has been received and to rate each topic according to its relevance to the operators' practice. In the third section, respondents evaluate perception towards training courses and the last section identifies preferred methods of delivery for the courses.

Conclusion: Understanding pharmaceutical operators' perceptions of having training courses and identification of their educational needs, presents opportunities for operators to perform additional duties and responsibilities, possibly increasing efficiency and best practice in operations.

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Pet owner perception of the role of the pharmacist in animal care

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Background: Pharmacists are uniquely positioned to counsel pet owners and collaborate with veterinary surgeons to provide the best care for animal patients.

Purpose: To identify the pet owners' perception of the role of the pharmacist in animal care.

Method: A questionnaire was developed, validated and disseminated to pet owners using social media platforms. The questionnaire consisted of three sections:

1. Demographic data
2. Challenges and barriers of access to medicines and good animal care
3. Perception of pharmacist interventions and the contribution towards the treatment of animals.

Results: Two hundred and thirty-two (232) pet owners answered the questionnaire. Fifty percent (n=116) agreed that pharmacists have the knowledge to give advice regarding human medicine use in animals. Fifty-three percent (n=122) disagreed that pharmacists can give advice on chronic medical conditions that affect their pets. Ninety-one percent (n=208) prefer to ask the veterinarian for advice rather than the pharmacist. Seventy-five percent (n=172) would be more willing to go to a pharmacist for advice if they can be sure pharmacists are knowledgeable and skilled with respect to animal care. Eighty-three percent (n=193) would like community pharmacies to stock veterinary medicines. Other services suggested by pet owners included urine testing (n=114), compounding medicinal products (n=94) and glucose checks (n=87) for their pets

Conclusion: Considering that 83% of pet owners would like pharmacies to stock veterinary products shows that access to medicines needs to be improved. The lack of trust towards pharmacists perceived by 53% of respondents indicates that pharmacists should strengthen their role with pet owners.

Pharmacy stewardship services - A conceptual framework

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Background: Pharmacists around the world are expanding their role in clinical care through formal and informal means. Pharmacy stewardship services that improve judicious use of medications are one example of role expansion in many different care settings. However, when a best practice in pharmacy stewardship is established, there is little guidance for

adaptation and implementation of innovation in different country sites or care settings. The guidance that does exist is typically narrowly focused, limiting use to specific service types and specific care settings.

Purpose: The aim of this research is to create a framework to guide adaptation and implementation of best practices in pharmacy stewardship. The framework will be used across country borders and care settings to improve judicious use of medicines and improve patient care around the world.

Method: An initial conceptual framework was drafted after discussion at the Tenth Biennial Monash Pharmacy Education Symposium in July 2019 in Prato, Italy. A systematic literature review was then conducted. Articles detailing conceptual models for pharmacy stewardship service implementation were included for in-depth review.

Results: Of the 152 articles returned in the systematic search, 81 articles were included for in-depth review. These articles were used to modify the domains and subsections of the initial framework.

Conclusion: A conceptual pharmacy stewardship services framework was constructed to help pharmacists adapt and implement international best practices in pharmacy. Further exploration with content experts is needed to increase the validity of this framework.

Implementation and evaluation of ward-based clinical pharmacy services in Malawi

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Background: Clinical pharmacy services have been shown to have a positive impact on patient outcomes, yet the transition from product-focused to patient-focused pharmacy practice has been slow in many low-income countries.

Purpose: To evaluate the implementation and impact of ward-based clinical pharmacy services in a 1000-bed tertiary referral hospital in Malawi.

Method: Clinical pharmacy services were implemented in the female adult medical ward from September 2019 to January 2020 using one-month Plan-Do-Study-Act cycles. Implementation barriers and strategies were documented during monthly meetings. Pharmacy recommendations and physician response were recorded. Changes in prescribing habits across rational prescribing and antimicrobial prescribing were evaluated in the intervention ward and a corresponding control ward. Logistic regression was used to evaluate differences in the probability of outcome attainment over time.

Results: Pharmacy interns made 321 recommendations across care optimisation (60%), antimicrobial stewardship (27%), and patient safety (13%) with 67% of recommendations accepted by physicians. There was a significantly greater increase in probability of rational prescribing in the intervention ward compared to the control ward (p=0.04), but no significant differences in antimicrobial prescribing (p=0.48). Barriers faced during implementation included physician resistance, inter-professional team dynamics, and clinical pharmacy knowledge and confidence.

Conclusion: This study demonstrated the feasibility and impact of implementing new clinical pharmacy services in a limited-resource setting. Barriers and strategies presented can be used to inform implementation of similar services in other settings.

Questionable use of preventive care among older multi-morbid adults: A cohort study protocol

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Background: Providing high value care and avoiding 'care overuse' is a challenge among older multi-morbid adults. Because preventive care has a lag-time to benefit, many guidelines recommend tailoring preventive care according to the estimated life expectancy (LE). However, because LE is difficult to estimate in elderly populations, questionable use of preventive care could be frequent.

Purpose: To assess the practice of cardiovascular diseases (CVD) preventive care and cancer screenings in older multi-morbid patients and to assess the association of preventive care with estimated LE and to identify questionable use.

Method: We conduct a prospective cohort study by extending the follow-up of 822 multi-morbid patients with poly-pharmacy (≥70 years, ≥3 chronic medical conditions, ≥5 drugs for >30 days) in Bern, Switzerland, included in the OPtimising thERapy to

prevent Avoidable hospital admissions in Multi-morbid older people (OPERAM) study over three years. We assess CVD preventive care by collecting information on antihypertensive, antihyper-lipidemic, antidiabetic, and anticoagulant medication. We also assess cancer screening practice. LE will be estimated based on Lee mortality index. Questionable preventive care will be defined based on guidelines and in case of estimated LE shorter than the lag-time to benefit.

Results: Preliminary results will be presented at the Congress.

Conclusion: The hypotheses are that questionable use of preventive care is frequent among older multi-morbid patients. Our study will eventually help physicians and pharmacists to personalise preventive care and optimise poly-pharmaceutical drug regimens of older multi-morbid patients.

Abem: Emergency COVID19 - when everybody must stay at home, Abem programme goes closer

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Background: Coronavirus disease 2019 (COVID-19) was classified by WHO as a global pandemic, and has gone on to affect millions of people worldwide with severe social and economic consequences.

Purpose: Due to the global crisis the international community has been facing, many people leave their homes to have access to the medicines they needed. Moreover, many Portuguese households lost their source of income, being in a very difficult situation. Abem: Emergency COVID-19 aims to help the economic deprived citizens to have access to the medicines, health products and healthcare services they need.

Method: Citizens in an unexpected situation of economic shortage due to the COVID-19 pandemic could be referred by local entities (Municipalities and Institutions of Social Solidarity) to be given access to their medications from local pharmacies. The beneficiaries belonging to risk groups received the medicines at their homes, through an articulation between our partners: pharmacies and local referral entities. Its transportation, articulated by pharmacies, was paid for by this initiative. The medicines and healthcare services were paid for by a Solidary Fund, to which many companies and citizens have contributed.

Results: The Abem: Emergency COVID-19 are putting efforts in place to present effective results by the time we present the poster at the FIP Virtual 2020.

Conclusion: This support shows the importance of pharmacies in their communities, as well as their synergic involvement with other partners, such as referral entities (Municipalities and Institutions of Social Solidarity), ANF, AFP, APIFARMA, ADIFA, Plataforma Saúde em Diálogo and other local entities helping citizens in need.

Health system and the appraisal of medicines for rare diseases in England and Brazil: A comparative analysis

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Background: Universal health systems have struggled to ensure access to expensive medicines. Technological and scientific practices pose a constant challenge for managers, in order to determine which technologies should be incorporated into health systems, and predicting all factors involved for incorporation. However, in many scenarios, decisions can differ in terms of the evidence presented and social and political interferences.

Purpose: The study aims to analyse recommendation reports for medicines for rare diseases (DR) performed by the National Commission for Incorporation of Technologies in Health (CONITEC) and the National Institute for Health and Clinical Excellence (NICE).

Method: Use the model of the European HTA network (EUnetHTA).

Results: The analysis of three selected medicines, sapropterin, nusinersen and elosulfase alfa, allowed researchers to identify that the reports from both agencies did not contemplate all the domains proposed in the analysis model, and, the decision making did not only involve scientific and technical judgments, but involved value judgments that, in many cases, overlap with technical-scientific and economic domains. Multiple layers of uncertainties can be observed in the reports, including clinical results, cost-effectiveness, well-being benefits, economy for health system and social pressure.

Conclusion: New mechanisms for evaluating DR medicines need to be developed and applied, proposing transparency and legitimacy of decisions, guaranteeing the preservation of the legality and legitimacy of HTA agencies.

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Health-related quality of life for patients with hypothyroidism

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Background: Hypothyroidism is a disorder where the thyroid gland does not produce enough thyroid hormones. The standard treatment for hypothyroidism is levothyroxine T4. In Denmark, some patients with hypothyroidism are treated with combination therapy with a supplement of T3. But still some patients with hypothyroidism continue to experience symptoms of hypothyroidism, despite receiving T4-hormone or combination therapy. There is a lack of knowledge about the health-related quality of life (HRQoL) for patients with hypothyroidism.

Purpose: To map the HRQoL for patients with hypothyroidism. The following two research questions were addressed: Do patients being treated for hypothyroidism have a deteriorated HRQoL? What influence does the choice of medical treatment have on the HRQoL for the patients, including patients with and without gene polymorphism in the deiodinase (DIO) enzymes?

Method: A thyroid-specific quality of life measurement tool (ThyPRO) based on patient-reported outcomes was used for structuring the online questionnaire used.

Results: Two Hundred and eighty-eight (288) questionnaire responses were collected. Hypothyroidism patients show a lower HRQoL compared to the general population, and patients treated with either T4 monotherapy or with combination therapy (T4 + T3) have a significantly lower HRQoL than patients treated with thyroid. For patients with a presumed gene polymorphism in DIO1/2, treated with T4 showed significantly lower HRQoL than patients treated with thyroid.

Conclusion: Patients with hypothyroidism have a significantly lower HRQoL compared to the general population in Denmark and the choice of medical treatment has an impact on the HRQoL for patient with hypothyroidism.

Pandemic modelling: The impact of social distancing in Nordic countries

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Background: Without pharmacologic interventions, the preferred strategy to combat COVID-19 is to slow the virus' spread via social distancing measures. The components of social distancing include: school closure, restrictions on gatherings, non-essential business closure, stay at home orders and limitations on travel. Most countries have implemented many of these restrictions. Conversely, Sweden has not initiated these restrictions and instead has recommended that citizens avoid mass gatherings, which presents an opportunity to examine the effects of the components of social distancing on mortality in Nordic countries.

Purpose: Investigate the impact of social distancing measures on fatalities associated with COVID-19.

Method: COVID-19 fatalities, as reported by the World Health Organisation, were recorded for each of the Nordic countries from 6th February 2020 to 30th April 2020. The fatalities were compared using a Cox proportional hazard regression analysis.

Results: The normalised fatalities ranged significantly (1.87 to 129 deaths/population/km2) in the Nordic countries. Sweden was found to have a significantly higher risk of COVID-19 related mortality at the α=0.05 level as compared to Finland (HR=0.15; p<0.001) and Norway and Denmark (HR=0.23; p=0.002).

Conclusion: The population-density normalised mortality in Sweden was significantly greater than other Nordic countries, possibly due to differences in the implementation of social distancing policies.

Exploring the effect of ethnic diversity on COVID-19-related mortality in the United States of America

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Background: In the setting of COVID-19, hypertension, diabetes, and obesity are postulated to contribute to adverse outcomes. Among different ethnic groups in the United States of America, African Americans have a higher incidence of the above conditions. It is hypothesised that the African American population in the United States may bear a disproportionate burden of COVID-19-related mortality.

Purpose: Evaluate the correlation between African American ethnicity and incidence of COVID-19-related mortality.

Method: COVID-19-related fatalities reported for Oregon, Missouri, and Georgia between the 6th February and 30th April 2020 were obtained from state health departments. These

states were selected due to similarities in the social distancing measures implemented but differences in their African American population (32.4% Georgia, 11.8% Missouri, 2.2% Oregon). Fatalities in each state were analysed using the Cox proportional hazard regression analysis.

Results: Of the reported fatalities in Georgia, Missouri, and Oregon, 51.0%, 38.0%, and 4.0% were in African Americans, respectively. This corresponds to a 2.1 to 2.8-fold increase in the risk of COVID-19-related mortality in African Americans as compared to all other ethnicities. The incidence of African American fatalities for the total population of each state ranged from 0.12 to 3.22 deaths/population/mile2. As compared to Oregon, the risk of COVID-19-related mortality was significantly higher in Georgia (hazard ratio (HR)=4.4; p<0.001) and Missouri (HR=2.2; p=0.001) at the α=0.05 level, proportional to the increased population of African Americans.

Conclusion: Initial results show that African American ethnicity may significantly contribute to an overall incidence of COVID-19-related mortality.

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The impact of pharmacy engagement with human resources on contract negotiations for prescription benefits

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Background: Historically, the PBM contract was negotiated by Human Resources. Pharmacy leadership rarely participates in this process. However, pharmacy has expertise in clinical and economic implications and can provide significant value to PBM contract negotiation.

Purpose: To describe the role that pharmacy leadership has in PBM contract negotiations and consider factors that determine PBM selection, especially those that involve economic savings.

Method: Pharmacy leadership and Human Resources prepared a Request for Proposal (RFP) for competitive analysis during contract renewal. The incumbent PBM agreed to accommodate client needs and contract re-negotiation was initiated. There were seven general contract topics and 56 Contract Review Findings identified for re-negotiation. The top three factors involved in PBM selection included the willingness to reduce administrative fees, customise pharmacy reimbursement formulas, and the client's pharmacy exclusivity to providing specialty pharmacy services.

Results: 'Pass through Retail Pricing' changed to a 'Pay as Submit' reimbursement model, reducing ingredient cost payments by the hospital. Eligible hospital employees had a 50.0% co-pay reduction and a 90-day fill option to utilise the hospital's outpatient pharmacy. The pharmacy also processed all specialty pharmacy prescriptions, eliminating leakage to external sources. The organisation saved 8.0-12.0% on ingredient costs, administrative costs and increased realised gross margin from 11.9% to 15.7% over three-years.

Conclusion: Hospitals should integrate pharmacy clinical and financial expertise into PBM contract negotiation to optimise the organisation's employee prescription benefit plan.

Paediatric major depression: An international comparison of the summary of product characteristics

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Background: There are few psychotropic medicines approved for the treatment of paediatric (<18 years) major depression (P-MD), and little research comparing their approval across countries.

Purpose: To compare the approval of psychotropic medicines for the treatment of P-MD across five developed countries.

Method: Using the regulatory-approved summary of product characteristics (or equivalent) documents (SmPCs), a cross-comparison document analysis of SmPCs from five countries was performed (Australia, New Zealand (NZ), the United Kingdom (UK), Canada and the United States of America (USA)). Psychotropic medicines were classified according to the Anatomical Therapeutic Chemical (ATC) classification system, comprising the groups 'Psycholeptics' (N05) or 'Psychoanaleptics' (N06). The approval data extracted included the medicine name and ATC code, age and dosage information (initial dose, dose titration, dose range or maintenance dose and maximum dose).

Results: A total of 13 medicines were approved in one or more of the studied countries, across 22 SmPCs. The US had the highest number of approvals (nine), followed by NZ, UK, Canada and Australia (five, four, three and one, respectively). Five of 13 medicines were approved in two or more countries (amitriptyline, doxepin, nortriptyline, fluoxetine conventional oral formulation (COF) and phenelzine), but only fluoxetine COF and phenelzine were consistent for the approved age group. Cross-country discrepancies in dosages were identified among the approved medicines.

Conclusion: There were significant variations in the approval information contained within SmPCs across countries, identifying a need for the harmonisation of regulatory documents. Future research into the reasons for variations may be needed.

Change of Lithuania pharmacy specialists job satisfaction and work-related stress from 2017 to 2020: COVID-19

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Background: During the COVID-19 pandemic, pharmacists were front line healthcare professionals, providing necessary care in a stressful situation. The main stress and job satisfaction driving factors are important, yet they may not have the influence they deserve in specific circumstances.

Purpose: To compare job satisfaction and work-related stress among pharmacy specialists between 2017 and 2020.

Method: Health Professions Stress Inventory (HPSI) questionnaire was translated and adapted to Lithuanian in 2017. In 2020 additional statements regarding COVID-19 were added. Pharmacy specialists completed the questionnaire online both in 2017 and 2020. Data were analysed with SPSS 23 software using independent sample T-criteria, Pearson correlation and Spearman's rank correlation coefficients. Mean comparative analysis and dispersive analysis ANOVA was performed.

Results: Three hundred and thirteen (313) pharmacy specialists completed questionnaire in 2017 and 152 in 2020. In 2017 55.9% of them were satisfied with their job, compared to 40,5% in 2020. The number of specialists feeling work related stress also increased from 25.6% to 46,1%. In 2020, 77.6% pharmacy specialists had been instructed on the use of personal protection at their workplaces within the last three months; 73.0% had attended distanced learning sessions, conferences or seminars on COVID-19. 82.9% of pharmacy specialists had enough personal protective equipment at work. In 2020, 53.3% of pharmacy specialists were worried about their job position in the future.

Conclusion: In 2017 no evidence that work-related stress had a direct impact on job satisfaction was found. Yet, during COVID-19 more pharmacy specialist felt work related stress and less of them were satisfied with their job.

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Pharmacoeconomic surveillance in pharmacovigilance at a tertiary care hospital: An intensive prospective study

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Background: Adverse Drug Reactions (ADRs) is the sixth leading cause of death in the United States of America and 106,000 people die annually because of ADRs. More than 10% of total hospitalisation is due to ADRs and many countries spend 15% to 20% of their hospital budgets specifically on the management of such Drug Related Problems (DRPs).

Purpose: To identify direct and indirect economic burdens associated with the management of ADR. Additionally, to establish the correlation of the cost with ADR assessment parameters.

Method: This was a prospective observational study conducted at a tertiary care hospital for a period of one year (August 2017 to July 2018). Strict definition of ADR by the World Health Organisation was adhered to enrol 201 causalities from medicine and surgery departments. Hospital-In-Patients Billing System (HIPBS) was communicated to receive a final bill and insurance details. Direct cost, indirect cost and average increase in length of prolongation of hospital stay were studied in association.

Results: The average prolongation of length of hospital stay was 3.84 days. The total daily cost for management of reaction was 3869.75 Euros (INR 319997.18). Average cost of each ADR that resulted in hospital admission was 187.60 Euros (INR 15512.95) and for unlisted ADRs the cost was 25.66 Euros (INR 2121.90). Only nine reactions were 'certain' and 27 reactions were 'possible'. Total cost for management of all 201 ADRs was 14775.86 Euros (INR 1228789.2) and the average cost for each ADR on outpatient was out to be 74.08 Euros (INR 6113.37).

Conclusion: The average cost for management of each ADR was found to be higher than suggested in previous studies.

Developing a questionnaire to analyse the use of medicinal cannabis for veterinary purposes

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Background: Medicinal cannabis is indicated in the management of loss of appetite, nausea and vomiting and pain. Cannabis is proposed as an alternative medical treatment for a number of conditions in humans such as multiple sclerosis. Research investigating the potential therapeutic value of cannabis in animals is still in its infancy with most studies focusing on pharmacokinetic data.

Purpose: The aim of this study is to design a questionnaire to analyse the use of medicinal cannabis for veterinary purposes.

Method: The method is divided in two phases. The first phase is a systematic literature review from 2010 to 2019 using open-access journal articles. The second phase included the development of a questionnaire validated by three pharmacists working in academia, a regulatory pharmacist and a veterinary surgeon.

Results: The first phase, the systematic literature review resulted in the finding of a total of 20 published studies regarding use of cannabis in animals. An example of a study showed an increased in comfort and activity in dogs suffering from osteoarthritis (Gamble *et al*., 2018). The systematic literature review led to the identification of the domains to be included in the questionnaire. The domains identified were: views about safety, potential indications, barriers and issues related to use of medicinal cannabis for veterinary purposes.

Conclusion: A questionnaire was developed and validated to investigate medicinal cannabis for veterinary use.

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Price and reimbursement policies

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Background: Generic medicines (generics) contribute to health systems' sustainability by its cost-efficiency. Public policies promoting the use of generics have led to significant healthcare-related savings in European countries, but estimated market penetration is not yet achieved.

Purpose: To describe generic medicine pricing and reimbursement (PR) policies of seven European countries which have reported high generics uptake and evaluate the policies which led to high rates of generics use.

Method: Pubmed and Google searches were performed using the following terms: generic medicines, reimbursement, pricing, policies.

Results: Reference pricing is the most common PR system in European countries except for Sweden and the United Kingdom (UK) which rely on value-based pricing and other reimbursement schemes. Germany and the UK reported the highest generics market shares in 2017 (over 80%) and maintained an increasing trend for more than ten years. Germany established generics reference pricing and imposes MAHs rebates for the third payer and substitution of every medicine but OTCs by generics. On the other hand, UK generic prices are determined by market competition forces, substitution is not allowed, and reimbursement is based on actual selling prices obtained by generic manufacturers. Both countries have recently implemented measures to regulate innovative medicines market entry and prices.

Conclusion: Medicines are more expensive in Germany but also more readily accessible, whilst in the UK the wait is longer, but prices are lower. To obtain the most from generics, implemented policies should be tailored to each country specific health care setting. It seems that there is no standard procedure or policy for combination for these measures.

Accessibility to generic medicines

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Background: As the price of innovative and complex therapies increases, availability and access to generic medicines is critical for the sustainability of healthcare systems.

Purpose: To identify generic medicines available on the Maltese market.

Method: Two drug classes were selected for the purpose of this study; drugs for oncology and drugs acting on the nervous system. Innovator drugs for oncology are expensive and nervous system drugs are widely prescribed in Malta and not broadly represented on the national health service scheme, requiring patient out-of-pocket payment. All authorised products as listed by the national competent authority were reviewed, and generic products available for each active ingredient and the corresponding dose and pharmaceutical forms were analysed.

Results: For oncology, 159 generics for 15 originators are available, namely; alkylating agents (n=16), antimetabolites (n=63), plant alkaloids (n=26), cytotoxic antibiotics (n=18), and other antineoplastic agents (n=36). For nervous system drugs, 467 generics for 114 originators are available, namely; antiepileptics (n=104), antipsychotics (n=146), hypnotics, sedatives and anxiolytics (n=65), antidepressants (n=128), central nervous system stimulants (n=8), and drugs used in addictive disorders (n=16). There were nine originators for oncology drugs and 60 for nervous system drugs which did not have generic counterparts.

Conclusion: Results show that for oncology drugs, antimetabolites have the most generics available, while alkylating agents have the least. Drugs for nervous system disorders are generally well-represented, with antipsychotics having the greatest number of generic products available.

Negative impacts of the Pharmaceutical Affairs Act - Patent Linkage System

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Background: Patents grant an inventor the right to exclude others from making, using, or selling their invention. In Taiwan (TW), the revision to the Pharmaceutical Affairs Act to accommodate Patent Linkage (PAA-PL) was passed in 2017, and implementation rules went into force on the 20th August 2019.

Purpose: To confirm whether industries benefit from PAA-PL implementation, this study compares the trends of Paragraph IV (P-IV) challenges before and after implementation.

Method: This study analyses P-IV litigation in South Korea (KR) compared to ones in TW. Data on the views of TW officials and industry were collected from the Internet, public opinion, and database searches to analyse obstacles in implementation.

Results: There were 1,957 cases in KR the first year after PAA-PL implementation. Only five P-IV challenges were brought by generic pharmaceutical manufacturers over the past six months in TW. A review of the history of official- industry interaction revealed that there were several obstacles to implementation. The most significant flaw was the lack of prosecution laws in the Patent Act.

Conclusion: Though it is important to respect intellectual property, P-IV challenges may increase generic entry, lower drug prices, and increase quantity. In fact, the success rate of generic drug litigation in TW was 86.0% before PAA-PL implementation. After implementation, less litigation was brought in TW than in KR which may increase the costs for generic pharmaceutical manufacturers to develop a generic product. The observed fewer P-IV challenges can hinder the new drug markets in TW, outweighing the benefits of joining TPP. The new Congress must reconsider the necessity of pursuing PAA-PL revisions.

The overview of orphan drug utilisation in Taiwan In 2018

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Background: The analysis of orphan drug usage is very important for clinicians and rare disease patients.

Purpose: This research analysed the usage of orphan drugs in Taiwan to provide the government with a reference for importing medications, physicians for prescribing medications and pharmacists for providing medications.

Method: In order to let all rare disease patients obtain medication smoothly, the government has created several regulations related to orphan drugs management such as the Ad Hoc Applications for Orphan Drugs Regulation to support the whole administration needs.

For those orphan drugs that already obtain license approval, the PSUR (Periodic Safety Update Reports) is needed to be provided to TFDA every year. For those orphan drugs that without license approval but with special import permit, the hospitals need to provide the utilisation evaluation report to MoHW.

Results: In 2018, the hospitals reported total 91 orphan drugs in utilisation. There are 14 orphan drugs with special import permit and used by 512 patients. In 2018, there are 390 utilisation evaluation reports collected and the recovery rate is 76.2%. Studying those reports, the adverse events happened in 43 patients (incident rate: 11.0%). Those events include flushing, diarrhoea, rash/urticarial, etc.

Conclusion: The efficacy and safety of orphan drugs has been closely monitored in Taiwan. The monitoring and management has started since granting Orphan-Drug Designation, pre-license management, post marketing risk management to efficacy and safety re-evaluation.

Understanding access to pharmacy services: A qualitative exploration of views from marginalised patient groups

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Background: Vulnerable patients from marginalized groups (e.g. people with disabilities, people from black and minority ethnic communities) experience higher rates of ill-health and inequitable access to healthcare. Improving fairness is a priority for many healthcare systems.

Purpose: Using an access conceptual framework (Levesque *et al.*, 2013), this study explored the views of patients from marginalized groups, how they accessed pharmacy and medication review services.

Methods: Semi-structured interviews were conducted to explore patient experiences and how access could be improved (n=10). Interviews of patients who had received a medication review from their pharmacist were also conducted (n=10). Interviews were transcribed and an interpretivist approach was used to analyse the data.

Results: Patient's ability to perceive support, their ability to seek this support, ability to reach, ability to pay and engage were explored. The findings exposed that most patients experienced significant medicine, health and social care challenges affecting their access to medication reviews. Where a medication review was received, these were broadly welcomed. However, the unfamiliarity with this one-to-one support constrained their ability to frame this service as one that could be useful to them.

Conclusion: Pharmacy teams need to be mindful of groups who are marginalised and most vulnerable. Further training is recommended for community pharmacy staff to ensure services are made accessible, inclusive and culturally sensitive. Policy makers should reconfigure services to ensure people from diverse backgrounds can access support from the pharmacy.

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