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Sustainability of drug use: equity and innovation

ABSTRACT BOOK

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EVALUATION OF METHODS MEASURING MEDICATION ADHERENCE IN PATIENTS WITH POLYPHARMACY: A LONGITUDINAL AND PATIENT PERSPECTIVE

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ABSTRACT

Aim

To explore patients' willingness to have medication adherence measured using different methods and evaluate the feasibility and validity of their combination (i.e., pill counts, a medication diary and a questionnaire assessing adherence two months post-discharge).

Methods

A cross-sectional evaluation of the willingness of patients with polypharmacy to have their medication adherence measured post-discharge. Furthermore, medication adherence was monitored during two months using pill counts based on preserved medication packages and a diary in which patients registered their adherence-related problems. During a home visit, the Probabilistic Medication Adherence Scale (ProMAS) and a questionnaire on feasibility were administered.

Results

A total of 144 participants completed the questionnaire at discharge. The majority was willing to communicate truthfully about their adherence (97%) and to share adherence-related information with healthcare providers (99%). More participants were willing to preserve medication packages (76%) than to complete a medication diary (67%) during two months. Most participants reported that preserving medication packages (91%), completing the diary (99%) and the ProMAS (99%) were no effort to them. According to the majority of participants (60%), pill counts most accurately reflected medication adherence, followed by the diary (39%) and ProMAS (1%). Medication adherence measured by pill counts correlated significantly with ProMAS scores, but not with the number of diary-reported problems. However, adherence measured by the diary and ProMAS correlated significantly.

Conclusion

Combining tools for measuring adherence seems feasible and can provide insight into the accordance of patients' actual medication use with their prescribed regimen, but also into problems contributing to non-adherence.

DIGITAL ADHERENCE MONITORING OF CONTROLLER THERAPY AMONG PATIENTS WITH SEVERE ASTHMA ENROLLED IN A 6-MONTH SERVICE EVALUATION

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ABSTRACT

Rationale

Inadequate adherence in severe asthma may lead to worsening control, poor quality of life, and costly escalation of treatment. Therefore, determining if uncontrolled asthma is a result of poor controller adherence is important.

Methods

Patients (>16yrs) with severe asthma were invited to enroll in a service evaluation at two severe asthma centers in the United Kingdom. Patients were provided with a digital inhaler monitor, and a mobile application (Propeller Health) providing medication reminders, feedback and education. Controller adherence was assessed at 1 and 6 months, by calculating recorded compared to prescribed actuations as a percentage. Clinical outcomes including asthma control questionnaire (ACQ), quality of life (mAQLQ) scores and FeNO, a marker of airway inflammation, were assessed for the same time periods.

Results

99 patients were enrolled (mean age:44(15) years; 77% (70/91) female). During month 1, mean (SD) daily adherence was 84.2 (25.0)%. At six months, mean (SD) daily adherence was 77.2 (30.0)%, with 60.6% of patients having a mean daily adherence >80%. Clinically significant improvements in median (IQR) ACQ (3.2 (2.3,4.0) (n=93) to 2.3 (1.7, 3.1) (n=43) and mAQLQ (3.1(2.3,4.2) (n=91) to 4.2 (3.1, 5.2) (n=42) were seen at 6 months. FeNo was reduced from 31 (13,77) (n=88) to 22 (15,10) (n=44) ppb.

Conclusion

Two-thirds of patients achieved adherence greater than 80%. Electronic monitoring provides objective evidence of treatment adherence in patients with severe asthma. In addition, enhanced adherence with application reminders and education may lead to improvement in asthma control, quality of life and airway inflammation.

SOCIOECONOMIC FACTORS ASSOCIATED WITH LOW INITIATION RATES OF TREATMENT FOR PATIENTS WITH TYPE 2 DIABETES

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ABSTRACT

Aim

This study assessed socioeconomic differences for not previously treated patients with diabetes type II (T2DM) claiming their first prescription of an antidiabetic drug.

Methods

A cohort of 8515 patients over 18 years with T2DM prescribed their first antidiabetic agent (ATC code A10) between 2012-2019 in Uppsala, Sweden, were followed for one year. Medical records data was linked to national registers on dispensed drugs and socioeconomic data. Baseline data was collected two years prior to the first prescription. Initiation of treatment was defined as a dispensation of an antidiabetic drug within day 30 (I_{30}) and a second dispensation within day 150 (I_{150}). Associations with age, sex and socioeconomic factors, including income, country of birth and marital status were determined with multivariate logistic regression.

Results

Within seven days, 84.8% claimed their prescription and 91.9% did it within 30 days. About 71.4% claimed their second prescription (I_{150}). Factors associated with low initiation rates for I_{30} and I_{150} was younger age, being born outside of Europe, unemployment, low income, not being married and low HbA1c. Patients born outside of Sweden had lower initiation rates for I_{150} . Metformin monotherapy was associated with higher initiation rates than all other groups for I_{30} (insulins, other monotherapy and polytherapy) and higher than insulins and polytherapy for I_{150} .

Conclusion

Most patients claim their first antidiabetic agent during the first days after prescription, but fewer claim the second dispensing and 8% do not start therapy. Healthcare professionals might need to encourage patients with risk factors of low initiation rates.

MEDICATION ADHERENCE TRAJECTORIES TO ORAL ANTIDIABETICS AND CLINICAL OUTCOMES IN TYPE2 DIABETIC PATIENTS

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ABSTRACT

Background

Studying adherence dynamics over-time in real-world populations reflects patient behavior more accurately than summarizing adherence as a single average measure. The aim was to investigate relation between adherence trajectories of type-2-diabetes mellitus (T2DM) patients and changes in clinical outcomes.

Methods

Incident T2DM subjects starting oral antidiabetics (OADs) treatment in the Nivel Primary Care Database (2015-2019) were included. We used R (v4.0.1) to estimate patients' Continuous Medication Availability (CMA9;AdhereR) during 1-year follow-up. We selected groups with similar CMA9 trajectories (Calinski-Harabasz criterion). We performed linear mixed-effect models to assess the relationship between T2DM clinical outcomes (HbA1c, LDL levels) and adherence trajectory groups.

Results

Four longitudinal adherence trajectories were identified: 1. Perfect Adherence n=2,386 (70.1%) CMA mean 1.0 ± 0.1 ; 2. Slow decline in adherence n=453 (13.3%), CMA mean 0.6 ± 0.1 ; 3. Low Adherence n=362 (10.6%), CMA mean 0.3 ± 0.1 ; 4. Slow increase in adherence n=203 (6.0%), CMA mean 0.7 ± 0.1 . Patients within the low adherence (17.4%) and slow decline (12.1%) group added insulin treatment 2½ months after OADs treatment started. HbA1c target levels (≤ 53 mmol/mol) were reached for the groups with perfect adherence, slow decline and slow increase in adherence, but not for the low adherence group (53.7mmol/mol). Target LDL levels (< 2.8 mmol/L) were not reached for patients in the slow decline and low adherence group (2.9mmol/L).

Conclusion

Significant differences in clinical outcomes were found for the four adherence groups. Investigating adherence trajectories is opening up new avenues for improving clinical outcomes through targeted interventions and the resulting reduction in healthcare costs and utilization.

COMMUNITY REPURPOSED DRUG USE BEFORE AND DURING COVID-19 PANDEMIC IN THE NETHERLANDS: A DRUG-UTILIZATION STUDY

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ABSTRACT

Repurposing existing drugs may help to reduce coronavirus disease (COVID-19) burden before novel drugs are authorized. Little is known about how the pandemic and imposed restrictions changed dispensing rates. We aimed to investigate the impact of COVID-19 pandemic on repurposed drugs dispensing in the Netherlands.

This drug-utilization study with an interrupted time-series analysis used the University Groningen prescription database IADB.nl to evaluate trends in dispensing of 24 medications that were repurposed for COVID-19. Study period was from 2017 to 2021, with March 1st 2020 as the start of pandemic. Primary outcomes were monthly prevalence and incidence dispensing rates. Autoregressive integrated moving average model was used to assess the effect of pandemic and stringency index that measures the strictness of government's policies during the pandemic.

Annual number of users ranged from 456,700 to 503,936. Compared with expected prevalence forecasted from pre-pandemic data, the observed prevalence of prednisolone and antibacterial use decreased by 0.10% ($\beta_{\text{pandemic}} = 0.121$, $p = 0.104$; $\beta_{\text{stringency-index}} = -0.004$, $p < 0.001$) and 0.31% ($\beta_{\text{pandemic}} = 0.643$, $p < 0.001$; $\beta_{\text{stringency-index}} = -0.015$, $p < 0.001$), respectively. The incidence of prednisolone and antibacterial decreased by 0.05% ($\beta_{\text{pandemic}} = 0.096$, $p = 0.005$; $\beta_{\text{stringency-index}} = -0.003$, $p < 0.001$) and 0.09% ($\beta_{\text{pandemic}} = 0.214$, $p = 0.007$; $\beta_{\text{stringency-index}} = -0.005$, $p < 0.001$), respectively. No such statistically significant correlations were found for hydroxychloroquine, ivermectin, and chronically used drugs statins, antihypertensives, and antidiabetics.

Except for prednisolone and antibacterial, dispensing of most medications was not significantly correlated with pandemic and government's response to it.

IMPACT OF COVID-19 PANDEMIC ON MEDICATION ADHERENCE AND MANAGEMENT IN CHRONIC PATIENTS: A CROSS SECTIONAL ONLINE SURVEY IN GENEVA, SWITZERLAND

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ABSTRACT

Background

The COVID-19 pandemic has been associated with lifestyle changes, reduced access to care and potential impact on medication self-management. Our main objective is to evaluate the impact of the pandemic on patients' access to, adherence to and management of their chronic medications, as well as assessing potential associations with socio-demographic and clinical factors.

Methods

Our study population is part of the Specchio-COVID19 population-based longitudinal study, conducted in Geneva. This online questionnaire included adults with at least 1 chronic condition and investigated the impact of pandemic on 2 main dimensions: a. adherence to medication, diet and exercise; and b. access to medications, medical appointments and exams. Sociodemographic and clinical data were collected at baseline. Statistical analyses were performed in R using logistic regressions.

Results

Our response rate was 56%. 8%(64/827) of participants stockpiled their medication for longer than 3 months, while 1%(9/827) had problems accessing medication. Among participants taking at least 1 medication regularly, motivation to take medications was decreased in 11%(93/827). 47%(24/51) of interruptions and delays in medication intake were not advised by physicians. Taking a medication for the respiratory system was associated with greater odds of a regular medication intake($p<0.01$) while increasing in age was associated with smaller odds of impact on motivation to take medications($p<0.05$).

Conclusion

The COVID-19 pandemics had a minor impact on chronic patients' access and adherence to medication and general healthcare among the Geneva's population, especially for older patients. This information is useful for future pandemics preparedness.

IMPACT OF COVID-19 PANDEMIC ON INITIATION OF ANTIHYPERTENSIVES IN SWEDEN- AN INTERRUPTED TIME SERIES STUDY

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ABSTRACT

Background

Hypertension is a risk factor for Covid-19, and adequate antihypertensive treatment is of importance. Restrictions during the pandemic limited access to healthcare, which may have had a negative impact on drug prescribing.

Aims

Assessing the effect of the COVID-19 pandemic on initiation of antihypertensive drugs in Sweden.

Methods

Data on dispensed prescriptions of diuretics, beta-blockers (BB), calcium channel blockers (CCB), angiotensin converting enzyme inhibitors (ACEi) and angiotensin receptor blockers (ARB) were extracted from the SCIFI-PEARL database linking national registers on drugs and diseases for the entire Swedish population March 2018-November 2021. Interrupted time series analysis was conducted using an autoregressive (ARIMA) model. Monthly cumulative incidence was calculated based on number of patients initiating each drug class after a one-year washout period.

Results

The analysis included 720300 patients. The start of the pandemic was associated with an immediate statistically significant level decrease in initiation of any antihypertensive, followed by a 0.02-0.06% monthly increase, in both sexes. A significant level decrease was observed for ACEi in both sexes and for all classes except diuretics in patients >65 years. A significant post intervention trend change was observed for initiation of diuretics overall (0.013%), driven mainly by a significant increase in patients >65 years. Similar trend differences were also observed for diuretics in females (0.02%) and ACEi (0.03%) in patients >65 years.

Conclusions

The pandemic had an immediate short-term effect, but we found no major adverse influence of the COVID-19 pandemic on initiation with antihypertensive drugs.

IMPACT ON COVID19 PANDEMIC ON NATIONAL OUTPATIENT ANTIBIOTIC USE

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ABSTRACT

Background

The COVID-19 pandemic had impact on the epidemiology of other infectious diseases. We aimed to assess the antibiotic utilisation trends/patterns in outpatients care in Hungary during the pandemic period and to compare it with preCOVID levels.

Methods

Data was obtained from National Health Insurance Fund. Antibiotic (J01) use was analysed according to WHO ATC-DDD index and expressed as DDD per 1000 inhabitants per day (DID). We defined two main periods: preCOVID (from 2015 to 2019) and COVID (from January 2020 to March 2022). Antibiotic utilisation was compared between the two periods and then further analysed monthly in comparison to 5-years average value of preCOVID period.

Results

The national level - antibiotic use was 12.1 DID in preCOVID period and during the COVID period this decreased to 9.3 DID. A notable decline in use was observed for all antibiotic subgroups except the tetracyclines (J01A). The pattern of antibiotic use also changed. The relative use of macrolides, lincosamides increased from 20.6% to 25.3%, while there was a slight decline in the use of quinolones (J01M) from 18.4% to 15.2%. The monthly antibiotic use fluctuate largely (min: 4.7 DID, max: 13.6 DID) during the COVID period. In general, almost in every pandemic month the antibiotic use was lower compared to the pre-COVID periods average.

Conclusions

A notable decrease in outpatient antibiotic use was observed during the pandemic period with high monthly fluctuations and lower monthly values compared to averages of the preCOVID period.

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UTILIZATION OF OPIOIDS IN SWEDEN AND LITHUANIA – A CROSS-NATIONAL COMPARISON

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ABSTRACT

Background

Opioids have an important role in the treatment of pain. However, there is a risk of dependence when using them. The utilization of opioids differs around the world, and studies have shown high utilization in Western Europe, and low utilization in Eastern Europe.

Aim

To compare the opioid utilization between Sweden and Lithuania during 2014–2021, and investigate potential explanations for the presumed differences.

Methods

A cross-sectional study on opioid sales data combined with a qualitative review of Swedish legal documents regarding the regulation of opioids, and three semi-structured interviews with persons with knowledge about the policies, prescribing, and dispensing of opioids in Lithuania was conducted. Sales data between 2014 and 2021 were obtained from the Swedish eHealth Agency and the State Medicines Control Agency of Lithuania.

Results

The opioid utilization, measured in DDD/1000 inhabitants/day, decreased from 17.8 to 10.8 in Sweden, and increased from 2.0 to 2.7 in Lithuania. The most utilized agents in Sweden were codeine/paracetamol, tramadol, and oxycodone, and in Lithuania tramadol, paracetamol/codeine/caffeine, and fentanyl. The reimbursement system is more extensive and inclusive in Sweden and includes most opioids. The regulation of opioids is stricter in Lithuania, and Lithuanian legal documents include more specified requirements in these matters compared to Swedish, e.g. quantity restrictions when prescribing opioids.

Conclusion

Since the utilization in Sweden – with more liberal regulation – decreased, and the utilization in Lithuania – with more strict regulation – increased, we suggest that legislation and policy are not the only aspects that affect opioid utilization.

ESSENTIAL TREMOR AND MEDICATIONS USE: A RETROSPECTIVE COHORT STUDY BY USING UK AND FRANCE PRIMARY CARE DATA.

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ABSTRACT

Introduction

Evidence on Essential tremor (ET) treatment strategies are still scarce. Therefore, this study aimed at describing the treatment pattern in patients diagnosed with ET.

Methods

A retrospective cohort study was conducted by using the Health Improvements Network (THIN) database. Incident ET patients, with ≥ 2 years of follow-up, in UK and France between 1 st January 2014 and 31 st December 2019 were selected. Daily prevalence and treatment pattern of first- (propranolol, primidone, topiramate), second- (gabapentin, alprazolam, zonisamide, olanzapine, clozapine) and other-line (clonazepam, nimodipine) of treatment was assessed within 1-year before and 2-years after index date (ID).

Results

A total of 2,957 and 3,249 patients were selected in UK and France, respectively. Findings were similar in both countries. Specifically, 39% (35% first line and 4% other ones) of patients received at least 1 drug prescription at ID. Before the ID, the prevalence of ET medication use, slightly increased as the timeline approached the ID (from 5% 12-months-, to 10% 1-months-before). After ID, ET medications use reached a peak during the first month of follow-up (41%) and then slightly decreased with $<20\%$ of patients under treatment at the end of follow-up. During follow-up the majority of patients switch to other line of treatment or discontinued the treatment. Propranolol and primidone were the most prescribed substances.

Conclusion

In this study, a minority of ET patients started a frontline medication and most of them discontinue the treatment during follow-up. These data corroborate the medical need for improvement of ET management in clinical practice.

AUDITING ANTIBIOTIC DISPENSING PRACTICES IN COMMUNITY PHARMACIES IN 5 EU COUNTRIES

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ABSTRACT

Background

Pharmacists are considered gatekeepers to antibiotic use by the European Centre for Disease Prevention and Control, but little is known about daily practice in community pharmacies.

Aim

To describe antibiotic dispensing practices of community pharmacists in France, Greece, Lithuania, Poland, and Spain.

Methods

The Audit Project Odense methodology was used for self-registration of antibiotic dispensing practices. Community pharmacists registered all dispenses of oral antibiotics for humans for five days in February 2022.

Results

In total, 104 pharmacists registered 2498 dispensings. Amoxicillin (24.9%) and amoxicillin + clavulanic acid (18.7%) were dispensed most often. In 24% of the dispenses, the location of infection was unknown, most often in Poland (41.8%) and least often in Spain (12.0%). For 31.6% of the dispenses none of three safety checks (interactions, contraindications, allergies) were performed. Not performing safety checks happened most often in Lithuania, Poland, and Spain (41.6%, 41.6% and 40.3% respectively) and least in France and Greece (13.1% and 10.7% respectively). Pharmacists advised on treatment duration and dose in more than 80% of cases. Other advice was given rarely. Although pharmacists did not agree or did not have sufficient information to agree with antibiotic prescriptions in 24.4% of cases, there was only contact with prescribers in 2.4%.

Conclusions

Community pharmacists in the five EU countries do not seem to meet European guidelines regarding antibiotic dispensing and minimum requirements to fulfil their gatekeeper role are not met. Although stronger collaboration between pharmacist and prescriber is essential, many improvements can come from the community pharmacy level.

PREVALENCE OF ANTIDEPRESSANT DRUGS UTILIZATION AMONG ADULTS AND OLDER ADULTS: RESULTS FROM A SYSTEMATIC REVIEW AND META-ANALYSIS

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ABSTRACT

Background

In recent decades, antidepressant use has increased. This study aimed to summarize the evidence on antidepressant utilization prevalence among community-dwelling adults.

Methods

We conducted a systematic review of observational studies reporting data on the prevalence of antidepressant utilization in the adult population and published from January 2010 to April 2021 in the Embase and MEDLINE databases. Studies focusing on specific conditions or on hospitalized or nursing home patients were excluded. Pairs of reviewers conducted the study selection and data extraction. Random effects models were used to estimate the aggregated point prevalence of antidepressant use with 95% confidence intervals (CIs). Subgroup analyses were performed according to sex and age.

Results

Of the 22,425 studies retrieved, 32 were included in the review and 14 in the meta-analysis. Prevalence rates were from various countries, mainly European (22) or North American (8). Among adults (29 studies) and older adults (12 studies), prevalence rates of antidepressant use varied from 3.7% in the Netherlands to 25.2% in Australia. Among older adults, prevalence rates ranged from 8.8% in Greenland to 23.1% in the USA. In studies reporting sex-specific prevalence rates, women had higher rates than men (5.1%-23.3% vs. 2.2%-12.1%). Random effects models estimated the global prevalence of antidepressant use at 9.97% (95%CI: 7.73-12.46) in adults and 15.12% (11.93-18.62) in older adults.

Conclusions

Antidepressant drug utilization prevalence varies widely across countries and between sexes. Some differences may be explained by epidemiological differences in mental health prevalence rates and local guidelines, but inappropriate prescribing may also occur.

THE ANTIBIOTICS CONSUMPTION IN ITALY ACCORDING TO THE AWARE CLASSIFICATION

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ABSTRACT

Background

The WHO AWaRe Classification categorizes antibiotics into three groups: Access, Watch and Reserve, according to the impact on antimicrobial resistance. The Access group includes antibiotics with lower resistance potential and are recommended as first or second choice treatment options. Aim of this study was to assess the share of each group on the total consumption of reimbursed antibiotics in Italy in the period 2016-2021.

Methods

The consumption data for reimbursed antibiotics dispensed both in the community and hospital setting were considered using the OsMed database and Traceability of medicines dataflow, respectively. Drug consumption was measured as number of Defined Daily Dose. The 2021 AWaRe Classification was used to calculate the percentage incidence of each group.

Results

In 2021 the greater share of consumption was represented by Watch Group (48.7%), followed by Access (47.0%) whilst the Reserve group was residual (4.3%). In the period 2016-2019, the percentage distribution of each group remained almost unchanged, while in 2020 peaks were found in the use of Watch group, due to the higher use of azithromycin. In 2021, there was a reduction in the use of Watch category, although this group remained the most used.

Conclusion

The Access group consumption in Italy is far from the target identified by WHO, being at least 60% of total antibiotic consumption and from the mean value observed in Europe in 2021 (60.7%). Moreover, no substantial improvements were registered in the analyzed time period, despite the overall reduction in the overall antibiotic consumption.

ENVIRONMENTAL BURDEN AND UTILIZATION OF ANALGESICS AROUND LAKE MÄLAREN, SWEDEN'S LARGEST DRINKING WATER SOURCE

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ABSTRACT

The high and increasing use of pharmaceuticals, in combination with their persistence, bioaccumulating properties, and potential toxicity for water-living organisms, has led to pharmaceutical residues becoming an increasing environmental problem worldwide. The aim of this study was to present use of analgesic pharmaceuticals in relation to environmental hazard in the geographic region surrounding the Swedish Lake Mälaren, Sweden's largest drinking water source. This was examined using sales data on pharmaceuticals from the Swedish E-health Agency. The total sales of analgesics (NSAIDs, paracetamol and other non-opioid analgesics and opioids) for both human and animal use were analyzed for the years 2016 to 2020 in relation to the environmental hazard for each active pharmaceutical ingredient (API). We found that a total of 454 tons of analgesics were sold during these years. Paracetamol, ibuprofen and ASA were the most sold APIs and were all classified as low hazard compounds. Diclofenac, the only pharmaceutical classified as high hazard, was the fifth most sold API with a total of 2321 kg. Veterinary use was small compared to human use, only contributing with a total of 1023 kg. The choice of API seemed to be rather "environmentally friendly" since the most commonly prescribed drugs were the least harmful. Still, the overall level of use may be discussed to reduce over consumption and inappropriate use. By identifying environmental risk, the study can provide a valuable knowledge base for stakeholders such as prescribers and policy makers in mitigating efforts for reducing environmental effects of pharmaceuticals.

ASSESSING ENVIRONMENTAL RISKS OF PHARMACEUTICALS INCLUDED IN THE EUROPEAN WATCH LIST USING DRUG UTILIZATION DATA.

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ABSTRACT

Background

The role of drug utilization as environmental pollutant has only recently been acknowledged. Pharmaceuticals excreted through urines and faeces can reach surface water levels harmful to animals and plants. To address this, the European Commission introduced the Watch List (WL) in 2015, which requires, for the first time, Member States to monitor pharmaceuticals in surface waters. We combined drug utilization and eco-toxicological measures aiming to propose an estimation method that can support eco-toxicological samplings.

Methods

We estimated Predicted Environmental Concentrations (PEC) on surface waters of pharmaceuticals included or candidate for the WL. We adapted the method proposed by the European Medicines Agency to 2020 Italian drug utilization data and default disposal levels set by the European Chemical Agency. We extracted Predicted No-Effect Concentrations (PNEC) from Watch List documents or eco-toxicological databases, and we derived the environmental risks as PEC/PNEC ratio. We classified them as high if ≥ 10 , moderate if ≥ 1 , low if ≥ 0.1 , insignificant otherwise.

Results

High or moderate environmental risk in surface waters was found for three contraceptives (levonorgestrel, estradiol, ethinylestradiol), one antidepressant (venlafaxine), six antibiotics (amoxicillin, azithromycin, clindamycin, ciprofloxacin, clarithromycin, sulfamethoxazole), one NSAID (diclofenac), one antifungal (clotrimazole), and one PPI (lansoprazole). All the other pharmaceuticals in the WL were estimated at low or insignificant risk.

Conclusion

Estimating environmental risk with drug utilization data can be a way to prioritize eco-toxicological monitoring and optimize resources. Nevertheless, the reliability of this estimation method should be verified, for example through the comparison of risk estimates with surface water samplings.

TO WHICH EXTENT ARE FUTURE DOCTORS AND PHARMACISTS IN SWEDEN EDUCATED ABOUT THE ENVIRONMENTAL IMPACT OF PHARMACEUTICALS?

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ABSTRACT

Background

A negative outcome of consuming and manufacturing pharmaceuticals is that these substances reach the environment through different pathways. This can lead to severe consequences such as antibiotic resistance, but also disturbances in entire ecosystems. Educating health care professionals such as doctors and pharmacists about the subject could contribute to more environmentally friendly, pharmaceutical-related decisions to be taken in the future, resulting in less negative environmental impacts.

Aim

To describe Swedish universities' educations of medical and pharmacy programs regarding the impact of pharmaceuticals on the environment, as well as how the students in their future professional role can contribute to reduce this impact.

Method

A survey study consisting of two parts. One questionnaire-based part, and one part reviewing educational plans for pharmacy and medical programs. One questionnaire was sent to course managers for courses within pharmacy programs, and one to program managers for the medical programs.

Results

In total, 47 out of 100 course managers and 6 out of 7 program managers participated in the questionnaires. 19 course managers indicated that their courses within pharmacy programs contain education about the environmental impacts of pharmaceuticals. All 6 program managers indicated that their program contains education about this. The most common areas educated about were sustainable drug use, sustainable drug manufacturing and development. All education plans contained learning objectives related to the environmental impacts of pharmaceuticals.

Conclusion

Sweden's pharmacy and medical programs do contain some education about the environmental impacts of pharmaceuticals. However, more education is needed, especially regarding knowledge databases.

ADHERENCE TO RILUZOLE THERAPY IN PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS IN THREE ITALIAN REGIONS - THE CAESAR STUDY

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ABSTRACT

Background

Amyotrophic Lateral Sclerosis (ALS) is a rare neurodegenerative disease. Riluzole can increase survival and postpone the need for mechanical ventilation. The CAESAR project ('Comparative evaluation of the efficacy and safety of drugs used in rare neuromuscular and neurodegenerative diseases', call AIFA-FV-2012-13-14) involves the evaluation of prescribing patterns, including adherence to riluzole, in ALS.

Methods

A retrospective cohort study was conducted on administrative data from Latium, Tuscany, and Umbria. Newly diagnosed ALS cases with first riluzole dispensing within 180 days of diagnosis were identified in 2014-2019. A look-back period of three years and a follow-up period of one year were considered. We computed 12 measures of monthly adherence through the Medication Possession Ratio using the Defined Daily Dose. Adherence trajectories were identified using cluster analysis based on a three-steps method. Patient characteristics at baseline and during follow-up were described and compared between groups.

Results

We included in the cohort 264 ALS new users of riluzole in Latium, 344 in Tuscany and 63 in Umbria. We identified two clusters in all regions: a larger one including adherent patients (60%, 74%, 71% in Latium, Tuscany, and Umbria, respectively) and another one including patients discontinuing therapy (40%, 26%, 29%, respectively). Compared to adherent patients, discontinuers were more frequently female, used more drugs at baseline, were more frequently affected by comorbidities, and showed higher mortality.

Conclusion

The vast majority of ALS patients starting treatment with riluzole are adherent to therapy in the first year. Patients who discontinue therapy early demonstrate greater frailty and show higher mortality.

IMPLEMENTATION OF A NOVEL APPROACH TO MONITOR EXPOSURE TO LIFELONG THERAPIES: THE USE OF STATE SEQUENCE ANALYSIS (SSA) TO ASSESS MAINTENANCE IMMUNOSUPPRESSIVE THERAPIES AFTER SOLID ORGAN TRANSPLANTATION

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ABSTRACT

Background

Transplant recipients are chronically ill patients, who require lifelong drug therapies to prevent reject and graft loss. Maintenance therapy usually involves calcineurin inhibitors, tacrolimus (TAC) or cyclosporine (CsA), combined with antimetabolites (AntiM) or mechanistic target of rapamycin (mTOR). The long-term management of maintenance immunosuppression involves switching between agents and dose reduction. SSA can help investigators unravel latent information within dispensation data, facilitating the individuation of specific drug patterns

Methods

An observational study, involving 4 Italian regions, was conducted in 2009-19. We identified drug therapy administered in the 2 years following transplantation using pharmacy claims database. Specifically, monthly drug regimens were detected taking into account, for each drug, the days' supply in the 30-day window. A sequence of 24 states for each subject was obtained. We explored variations in treatment patterns over time by graphical visualization and clustering methods.

Results

We retrieved 3,183 kidney, 1,627 liver, 336 heart and 130 lung recipients. Main therapeutic patterns over time were: TAC+AntiM in kidney, TAC-monotherapy in liver, CsA+AntiM in heart, TAC-monotherapy in lung. We found a general continuity of therapies over time. The main changes in drug regimens were: from TAC monotherapy to TAC+antiM for kidney; in the liver, the switch from untreated to TAC might subtend a change in dosage.

Conclusions

Our contribution shows the potential of the SSA method, it may help researchers on exploring complex therapeutic patterns.

COMPARISON OF BIOLOGICAL DRUG USE FOR THE TREATMENT OF IMMUNE-MEDIATED INFLAMMATORY DISEASES IN PIVOTAL CLINICAL TRIALS VS. REAL-WORLD SETTING: AN ITALIAN POPULATION-BASED STUDY FROM THE VALORE PROJECT

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ABSTRACT

Patients enrolled into pivotal RCTs typically differ from those treated in real-world (RW). The study aims to: compare demographic characteristics of patients enrolled in pivotal RCT of biologics approved for immune-mediated inflammatory diseases (IMIDs) with those of RW setting using the Italian VALORE distributed database network; measure the extent of RW users that would have been ineligible for inclusion into RCT.

All indication of use-specific pivotal phase III RCTs of biologics approved for IMIDs up to 2020 were collected. Incident RW users of biologics approved for IMIDs were identified from claims databases of eight regions (2010-2020). Demographic characteristics of RCTs patients were compared with those of RW population. The proportion of biologic users who would have been ineligible for inclusion into RCT was calculated.

37,807 and 66,639 incident users of biologics approved for IMIDs were identified from pivotal RCTs and RW setting, respectively. No statistically significant differences of sex distribution between RCTs and RW population were observed, except for certolizumab pegol, more commonly used by RW (>60%) than RCT (<45%) females. RCT patients were slightly younger (45±15years) than RW patients (48±16years), especially ustekinumab/vedolizumab users with inflammatory bowel diseases. High proportion of RW biologic users would have been ineligible for inclusion in pivotal RCTs (22-81%).

Demographic characteristics of RW biologic users with IMIDs are different of those enrolled in pivotal RCTs. Significant proportion of RW users would have been ineligible for inclusion in pivotal RCTs and as such post-marketing surveillance of biologics should be prioritized in those patients.

ADHERENCE TRAJECTORIES TO BIOLOGICAL TREATMENTS IN PATIENTS WITH INFLAMMATORY BOWEL DISEASES: A PILOT STUDY FROM SICILY REGION

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ABSTRACT

Inflammatory bowel diseases (IBD) are disorders characterized by a chronic or remitting/relapsing inflammation of the gastrointestinal tract. Non-adherence to treatment, especially to biologics, is an obstacle to the achievement of patient's health. This study aims to describe trajectories of adherence to biologics in IBDs patients during the first year of treatment in the context of the VALORE project.

Incident users of infliximab-adalimumab-golimumab-ustekinumab-vedolizumab with a diagnosis of IBD were identified from Sicily claims databases during the years 2010-2020. The study cohort was characterized at baseline and the adherence was evaluated monthly through the Medication Possession Ratio in the first year. Trajectories of adherence to biologics were identified by k-means algorithm.

Overall, 1,713 incident users of biologics, mainly adalimumab (50%) and infliximab (32%), with IBD were identified. The male-female ratio was 1.3 and the median age was 43 (IQR: 28-55). The most frequent comorbidity was hypertension (23%). Antibacterials (83%) and glucocorticoids (68%) were the most frequently used concomitant drugs. Three adherence trajectories to biologic were identified: more than two-thirds (71%) of incident biologic users were identified with 'high' adherence trajectory (C1) followed by 'medium' (C2: 25%) and 'low' (C3: 4%) adherence. Compared to C1 and C2, C3 included patients with less comorbidities.

Three adherence trajectories to biologics approved for IBD were identified. Compared to patients with 'medium'/'high' adherence trajectories, those with 'low' adherence had less comorbidities. Adherence trajectories could be a reliable methodology to identify patient profiles in the use of biologics with a view to personalized medicine.

A PHARMACOLOGICALLY STRATIFIED MODEL OF MULTIPLE DRUG TREATMENTS IN POLYPHARMACY

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ABSTRACT

The prevalence of polypharmacy is increasing worldwide. Evidence of the association between polypharmacy and clinical outcomes is conflicting. Current definitions of polypharmacy are loosely defined and are typically based on the total number of treatments. Such methods assume an equal contribution of each treatment to the clinical effects of polypharmacy, however different treatments may differentially affect patient outcomes.

A combination of published literature, prescribing guidelines and clinical expertise were used to propose a conceptual framework to define treatments relative to the index condition of heart failure, which may be applied to other older multimorbid populations. We have developed a framework to consider the component effects of index, index-linked and non-index treatments on outcomes in a heart failure population.

Pharmacological treatments are categorised based on the reasons for which they may be prescribed, relative to the index condition; those likely prescribed to treat the heart failure (index treatments), other conditions within the cardiovascular system (index-linked treatments), and conditions in other body systems (non-index treatments). Preliminary results indicate differential effects on all-cause mortality between treatment categories.

Each component treatment category may be considered differently, allowing for the identification of the contributions of different treatment types to the overall effects of polypharmacy on patient outcomes. This pharmacologically stratified model is compatible with large studies, and can be used to provide context to complex treatment profiles. By stratifying treatments, we are able to challenge the assumption that all treatments contribute equally to polypharmacy, and instead consider treatments within a relative context.

TEN-YEAR TRAJECTORIES OF MULTIMORBIDITY AND IMPACT ON HEALTH SERVICES AND POLYPHARMACY IN OLDER PEOPLE

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ABSTRACT

The impact of the speed of onset of chronic conditions (CC) remains unclear in older adults. We aimed to identify trajectories of multimorbidity and investigate their value to predict health outcomes.

We used a random sample (5%) of the 1.5 million adults ages >65 in Quebec, Canada, on April 1st, 2019. Number of CC was assessed yearly from 2009-2018 using 31 conditions from Charlson/Elixhauser indices. We identified multimorbidity trajectories using latent class growth modeling. We compared risks of hospitalizations, emergency visits, polypharmacy (≥ 10 medications/year) and death among trajectories using robust Poisson models adjusted for age, sex, deprivation.

We identified 8 trajectories: 3 "stable" with few CC (0,1,2,5); 1 "decreasing" with declining number of CC (0 at end of follow-up); 2 "progressive" with gradual increment in morbidity (6&10CC at end); and 2 "high/recent increase" with abrupt increase in last years (2&6CC at end). The risk of each outcome increased globally with the number of CC at end of follow-up (e.g., death: "progressive" 10CC vs "stable" 0CC, RR=10.63;95%CI:8.62-13.11). The trajectory pattern only impacted the polypharmacy outcome. Compared with "stable" 0CC, polypharmacy risk was higher among the "stable" or "progressive" trajectories than the "high/recent increase" even with similar number of CC at end of follow-up (e.g., "progressive" 6CC [RR=9.90;9.30-10.54]; "high/recent increase" 6CC [RR=7.91;7.41-8.45]).

The speed of onset of CC had a large impact on the polypharmacy risk but little on other outcomes, for which the number of CC at end of follow-up seemed to be a better predictor.

A CROSS-SECTIONAL STUDY ON POLYPHARMACY AND CO-MEDICATIONS IN ALZHEIMER'S DISEASE

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ABSTRACT

Background

The most common form of dementia is Alzheimer's disease (AD). It is an age-associated neurodegenerative disorder, which causes memory impairment and cognitive decline. Older people commonly have more than one chronic condition that requires chronic medications, sometimes polypharmacy. Potential inappropriate medications (PIM) can cause cognitive decline and may be more frequent in AD.

Objectives

We aimed to determine to what extent AD patients have more frequent polypharmacy compared to a reference population. Further, we assessed which potentially inappropriate medications were more frequent in AD.

Method

A case-referent study was conducted with the University of Groningen IADB.nl community pharmacy database. We included people older than 65 years at the initiation of AD treatment with age-matched referents. For measurement of polypharmacy, only chronic medications were included. Logistic regression analysis was applied to estimate odds ratio's and 95% confidence interval.

Results

Preliminary analyses included 4,150 AD patients and 37,350 referents. 59% of AD patients and 49% of referents were on polypharmacy. Several drug classes as PPIs, statins, anti-depressants, anti-epileptics, calcium supplements were significantly more prescribed in AD patients than referents. Gout and COPD/ Asthma medications were significantly less prescribed in AD patients. Frequent PIMs for AD patients were anticholinergics, benzodiazepines, PPIs, antipsychotics, and antidepressants.

Conclusion

The preliminary results showed an association between AD and polypharmacy. Medications like anticholinergics that may interfere with cognition were frequent in AD. This research is ongoing and more in-depth results are expected by April 2023.

POLYPHARMACY'S ASSOCIATION TO MORTALITY: A METHODOLOGICAL CASE STUDY

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ABSTRACT

Background

Studies consistently associate polypharmacy to mortality. However, such studies are highly prone to confounding from indication from the underlying disease(s) the medications are used to treat.

Objective

We investigated the association between the use of multiple medications and mortality, to illustrate the inherent challenges in studying this association, by describing aspects that point to a non-causal interpretation.

Method

We used data on a 20% random sample of all Danish residents moving into care homes 2015-2021 (n=16,649). We illustrated the 1-year mortality, stratifying by number of drugs filled prior to nursing home admissions and performed logistic regression associating the 20 most common drugs to 1-year mortality.

Results

The 1-year mortality was 31% (n=5,082) and highly dependent on the number of drugs used at baseline, with 17% 1-year mortality increasing to 46% among those using 0-1 drug and ≥ 16 drugs, respectively. In sex- and age adjusted analyses, the odds ratio (OR) of 1-year mortality increased almost linearly to more than 5.0 with use of >20 drugs. Upon additional adjustment for use of furosemide and Nordic Comorbidity Index, this dropped to 4.0 and 2.2, respectively. Strong protective effects were seen with use of e.g. thiazide diuretics (OR:0.64) and simvastatin (OR:0.66), while increased risk of death was observed with use of morphine (OR:1.59) and zopiclone (OR:1.13).

Conclusions

While strong associations are observed between the use of multiple drugs and 1-year mortality, associations were markedly attenuated by adjusting for comorbidity and there are numerous paradoxical relationships with use of individual drugs and mortality.

ASSESSING THE NEEDS OF CLINICIANS WORKING IN ADULT CRITICAL CARE IN SCOTLAND FOR A SEPSIS FLUID MANAGEMENT ARTIFICIAL INTELLIGENCE TOOL

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ABSTRACT

Background

The introduction of Artificial intelligence (AI) technology into healthcare is complex. The application of human factors approaches can assist in developing this technology. Research has indicated that patients with sepsis should receive an individualised volume of fluid guided by their own characteristics, which may be calculated using AI technology. Therefore, the aim of this study was to understand clinicians' needs for a sepsis fluid management AI tool in adult critical care using a human factors approach.

Methods

A vignette was created demonstrating how a proposed AI tool could be applied in sepsis fluid management, and an interview schedule was developed using the extended Work System Model (WSM). Clinicians working in adult critical care in Scotland were invited to participate through social media, existing contacts, and snowball sampling. Using the vignette as an aid, interviews were conducted on MS Teams between Dec 2022 – Feb 2023. Interviews were transcribed and a framework analysis was conducted using the extended WSM.

Results

To date 20 clinicians have participated (55% female) including, four consultants, six trainee doctors, five advanced critical care practitioners/nurses, and five pharmacists. There is representation from across Scottish critical care, with a mix of urban and rural locations. Only one participant had experience of working with AI technology previously. Full results will be available at the conference.

Conclusions

NHS Scotland has set out a five-year strategy for the adoption of healthcare AI technology. Human factors approaches can be applied to facilitate the benefit realisation of this type of technology.

EXTRACTING PREGNANCIES FROM HETEROGENEOUS DATA SOURCES IN EUROPE: A NOVEL ALGORITHM IN THE CONCEPTION PROJECT

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ABSTRACT

Background

The IMI-ConcePTION project aims to build an ecosystem to generate Real World Evidence to address the information gap of medication safety in pregnancy. Pregnancies were traditionally identified based on birth outcome information; but this strategy is prone to miss pregnancies that end early, which may occur more frequently with medicines of teratogenic potential. A novel algorithm to detect pregnancy episodes was designed and tested in heterogenous data sources participating in two EMA-funded studies using the ConcePTION Common Data Model: COVID in pregnancy and valproate/retinoids risk-minimization study.

Methods

Six partners accessed the following data sources: ARS, CASERTA (Italian region); BIFAP (Spain), VID (Valencia region); PHARMO (the Netherlands) and UOSL (Norway). Records, spanning time period between 2005 and 2021 were retrieved from all available provenances, including birth registries, primary care medical records, hospital discharge records, and others, as allowed locally. UOSL only accessed the birth registry, including pregnancies ended after 12 weeks. To retrieve records from coded diagnoses indicative of pregnancy, existing algorithm codes were harmonised across vocabularies.

Results

All data sources except UOSL could retrieve pregnancies with unrecorded end: these constituted 13.2%, 4.5%, 35.2%, 27.5%, and 1.0% of pregnancies identified in in ARS, CASERTA, BIFAP, VID and PHARMO, respectively.

Conclusion

A substantial share of pregnancies could be retrieved that would have gone unnoticed if querying only information recorded at the end of pregnancy. Studies based on these cohorts may provide a more complete representation of drug utilization in pregnancy, particularly for medicines with teratogenic potential resulting in early conclusion.

THE PREGVAL COHORT. A DYNAMIC POPULATION-BASED COHORT OF OVER 600,000 PREGNANCIES FROM ELECTRONIC HEALTH RECORDS IN THE VALENCIA REGION

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ABSTRACT

Background

Clinical trials exclude pregnant women for ethical and safety reasons. Therefore, observational studies are recommended to assess the in-utero safety of drugs.

Methods

The cohort was conformed using a unique identifier that allows linking information from the different VID databases: the metabolic disease registry, the perinatal mortality registry, hospital, primary and specialized care databases, and population information system databases containing accurate socio-economic information. PREGVAL obtains information on all live births and is also capable of detecting pregnancies that have ended in stillbirth (≥ 21 weeks) or abortion (≤ 20 weeks). In addition, there is information on the gestational age at the time of contact, which makes possible to determine the gestation periods and the exposure windows with precision, as well as to link mothers with their newborns. We preliminarily assessed the prevalence/frequency of drug use in this cohort.

Results

More than 600,000 pregnancies have been detected from 2009 to 2021. Of these, 40.4% have at least one dispensed medicine, being the most prevalent groups: J01-Antibacterials (17.2% of all pregnancies), N02-Analgesics (8.4%), B01-Antithrombotic agents (6.4%), J06-Immune sera and globulins (6.4%) and M01-Anti-inflammatory drugs (5.1%).

Conclusion

The population-based nature of PREGVAL, the ability to detect also pregnancy losses and that of linking mothers with their offspring, as well as the availability of a large amount of covariates and outcomes makes it one of the largest cohorts of pregnant women with the great potential at the international level, for the generation of evidence on the use, safety and effectiveness of medications during pregnancy.

USING RECORD LINKAGE OF ROUTINELY COLLECTED ELECTRONIC HEALTH CARE DATA TO DESCRIBE AND EVALUATE SYSTEMIC ANTI-CANCER TREATMENT: EXPERIENCES FROM THE CANCER MEDICINES OUTCOMES PROGRAMME IN SCOTLAND

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ABSTRACT

Background

Post-marketing studies are useful to address limitations of clinical trials such as external validity. The Cancer Medicines Outcomes Programme (CMOP) aimed to utilise electronic health records held in Scotland to develop a methodology for describing and evaluating the use of systemic anti-cancer treatment (SACT) in clinical practice.

Methods

National SACT prescribing data was obtained from the Chemotherapy Electronic Prescribing and Administration System (CEPAS), collated through Public Health Scotland, and linked to other data sources including the Cancer Registry to provide further details. For validation purposes, data was cross-checked against regional CEPAS extracts, and with local clinicians, if required. Initial projects focused on mesothelioma, and immunotherapy use.

Results

Across Scotland, 370 patients started treatment for mesothelioma and 3979 patients initiated immunotherapy for any cancer between 01.2014 and 12.2020. Through record linkage and validation using local data, indication for treatment could be confirmed for most patients (99% for mesothelioma, 92.5% for patients on immunotherapy); demographic information and data relating to hospitalisations were available for >99% and 98% of all patients across the two cohorts, respectively. Death records, enabling the estimation of survival, were complete. Some missing data was observed for variables such as tumour staging and Eastern Cooperative Oncology Group performance status.

Conclusion

Linkage of routinely collected healthcare data offers the opportunity to describe and evaluate SACT use in clinical practice. Nevertheless, complexity of systems – both relating to data capture as well as nuances of cancer treatment – require close collaboration between data providers, analysts, and clinicians working in the studied setting.

THE MANAGEMENT OF ADULT ASTHMA: AN OBSERVATIONAL STUDY INTO REAL-WORLD PRESCRIPTION PATTERNS OF INHALATION MEDICATION

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ABSTRACT

Background

The Global Initiative for Asthma (GINA) suggests a step-wise approach for managing asthma. Studying real-world treatment trajectories using prescription databases is challenging. We aimed to explore how a time-varying proportion of days covered (tPDC)-based algorithm can be used to gain insight into asthma treatment trajectories.

Methods

This retrospective inception cohort study used the University of Groningen IADB.nl community pharmacy prescription database. We included 19184 adult patients initiating asthma medication in the Netherlands between 1994 and 2021. Treatment steps were defined as: 1 - SABA / ICS-formoterol as needed, 2 - low dose ICS, 3 - low dose ICS + LABA or LAMA, or intermediate dose ICS, 4 - intermediate to high dose ICS + LABA or LAMA, or high dose ICS, 5 - prescribed by a specialist. Treatment steps and switches were determined using a tPDC-based algorithm. Individual treatment trajectories were visualized over time using a lasagna plot.

Results

Of the 19 184 included individuals, 52%, 7%, 15%, 16% and 10% started treatment in steps 1 to 5, respectively. The median(IQR) follow-up time was 3(1-7) and the median(IQR) number of switches 1(0-3). 37% never switched between treatment steps. Comparing starting step to last observed step, 20% of individuals stepped down and 22% stepped up.

Conclusion

The tPDC-based algorithm functions well in translating prescription data into continuous data, to study treatment patterns among asthma patients. The low number of switches between steps indicates that tailoring of treatment to patients' needs might be increased.

PREVALENCE OF PAIN-RELATED AND MENTAL HEALTH DIAGNOSES AMONG PERSISTENT OPIOID USERS: A POPULATION-BASED REGISTRY-LINKAGE STUDY

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ABSTRACT

Background

Persistent opioid use carries significant risk, but the characteristics of these patients are not well known. We aimed to analyze the prevalence of pain-related and mental health diagnoses among persistent opioid users.

Methods

Population-based registry-linkage study. All persons 18 years and above with persistent opioid use (ATC N02A) in 2019 were identified from the Norwegian Prescription Database. Persistent opioid use was defined as being dispensed >180 defined daily doses or >4,500 mg oral morphine equivalents and having filled prescriptions in at least three quarters of the year. Patients receiving opioids in palliative care were excluded. Information on diagnoses from primary care (ICPC-2) and specialist care (ICD-10) recorded in 2019 were linked to the study population.

Results

There were 52,404 persistent opioid users in 2019. Around 80% had at least one recorded musculoskeletal diagnosis in primary or secondary care. The most frequent musculoskeletal diagnosis was back pain (35.9%). Among women aged 18-44 years, migraine/headaches (21.5%) and abdominal pain (24.6%) were also frequently recorded. Mental health diagnoses were common (38.7% in the full cohort). The most frequent mental health diagnoses were depression (12.8%) and anxiety (9.7%). Sleep disturbance and substance use disorders were recorded among 17.6% and 5.6%, respectively. Age and gender differences will be further explored.

Conclusion

Persistent opioid users were frequently diagnosed with pain-related conditions for which opioids are not recommended. Prescribers should take into account the high prevalence of mental disorders among persistent opioid users.

EFFECTIVENESS OF ANTIDEPRESSANT USE IN PERSONS WITH SCHIZOPHRENIA IN REAL-WORLD SETTING

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ABSTRACT

Background

Antidepressants are often used by patients with schizophrenia, for instance to treat depressive and negative symptoms. The aim of this study was to investigate real-world effectiveness of antidepressant use in persons with schizophrenia.

Methods

All 61,889 persons treated in inpatient care due to schizophrenia during 1972-2014 in Finland, identified from nationwide registers, were included in the study. Follow-up lasted 1996-2017. Drug purchase data were obtained from the national Prescription register and modelled with PRE2DUP method. Main outcome was hospitalization due to psychosis, and secondary outcomes were non-psychiatric hospitalization and mortality. Within-individual design was used to compare the risk of hospitalization-based outcomes between the time periods of antidepressant use and non-use within the same person, and between-individual design was used with mortality.

Results

The mean age of the study cohort was 46.2 (SD 16.0) years at cohort entry, and 50.3% were men. Altogether 49.3% (N=30,508) of the study cohort used antidepressants during the follow-up (median 14.8 years, IQR 7.5-22.0). The risk of psychosis hospitalization was lower during antidepressant use as compared to non-use of antidepressants (aHR 0.93, 95% CI 0.92-0.95). Use of sertraline (0.87, 0.83-0.91), fluoxetine (0.88, 0.83-0.91), citalopram (0.92, 0.90-0.95), venlafaxine (0.93, 0.88-0.97), and escitalopram (0.93, 0.88-0.99) were associated with the lower risk of hospitalization due to psychosis. Even though certain antidepressants showed minor increased risk of non-psychiatric hospitalization, most antidepressants were associated with a decreased risk of mortality.

Conclusion

Antidepressant use was common in the study cohort, and it was associated with a decreased risk of psychiatric rehospitalization.

A PILOT FIELD STUDY ON ANTIBACTERIAL USE AT AN EMERGENCY DEPARTMENT

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ABSTRACT

Background

Antimicrobial resistance (AMR) is a global threat. Rationalising antibiotic use is an efficient tool to restrain AMR. Antibiotic use data from Emergency Departments (ED) are scarce. We aimed to assess the characteristics of antibiotic initiation, the documentation rate of the indication, and rate of microbiological sampling.

Methods

This retrospective observational field study was conducted at the ED of a tertiary care medical centre. We included all adult ED presentations (N=2140) from the randomly selected 24 study days. All medical documentations were retrieved and scanned to identify patients who were initiated antibiotics and to record patient and therapy related variables.

Results

Overall antibiotic was initiated in 231 patients, that corresponds to 10.8 % (95 % CI: 9.55%-12.18%) of all ED presentations. The majority of patients (N=114) were initiated antibiotic treatment at the ED, 100 patients were only prescribed oral antibiotic course, while in 17 patient ED antibiotic therapy was continued as outpatient (prescription). The most common indications were urinary tract infections and intraabdominal infections, the top one antibiotics were ceftriaxone (ED unit) and co-amoxiclav (prescriptions). The 62% of study patients were above the age of 65 years and 52% had Charlson-Comorbidity index score above 5 or more. In 23.4 % neither the reason, nor a related indication of antibiotic use was documented, while documentation was suboptimal in further 20%. Microbiological sampling was performed in 48 %.

Conclusion

Antibiotic initiation is frequent in the ED. The audit revealed quality problems.

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IMMUNOTHERAPY PRESCRIBING PATTERNS IN CANCER PATIENTS ACROSS SCOTLAND 2014 – 2020

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ABSTRACT

Background

Within the last decade, immune checkpoint inhibitors (ICIs) have emerged as a novel class of cancer medicines. This study aimed to ascertain patterns in ICI prescribing over time across Scotland and describe patient demographics.

Methods

This was a retrospective, observational cohort study of Scottish patients commencing ICI treatment for any cancer between 1/1/2014 and 31/12/2020, followed up until either death or the censor date (30/6/2021). Electronic chemotherapy prescribing records were linked with other data sources, providing additional information, using a unique patient identifier.

Results

Overall, 3,979 patients started ICI treatment during the study period: for lung (49.5%), skin (28.8%), urological (13.9%), head and neck (4.3%), and other cancers (3.5%). The total number of patients initiating treatment with ICIs increased each year, from 95 patients in 2014 to 1,242 patients in 2020; the variety of cancers treated also increased over time. Pembrolizumab and nivolumab, either as single agent or in combination, were most commonly prescribed. Across all ICI types, the median age ranged from 63 – 73 years; patients who were prescribed combination ipilimumab/nivolumab were younger (median 58 years) than patients on other treatments. Patients who received ipilimumab/nivolumab therapy were also more likely to have a better performance status (PS) (65% Eastern Cooperative Oncology Group PS 0).

Conclusions

The results highlight an upward trend in prescribing of ICIs in Scotland throughout the study period, with an increasing variety of cancers treated in line with an ever-expanding range of indications.

PRESCRIBING OF ANTIHYPERTENSIVES FOR DIFFERENT DIAGNOSES – A CROSS SECTIONAL STUDY IN STOCKHOLM, SWEDEN

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ABSTRACT

Background

Many drug utilization studies use dispensed antihypertensives as a proxy for hypertension diagnosis or analyse utilization of antihypertensive drugs without indication/diagnosis. The aim of this study was to assess which diagnoses antihypertensive drug classes are prescribed for.

Methods

This cross-sectional study included all inhabitants of 18 years and older in the region of Stockholm, Sweden, dispensed at least one antihypertensive drug (ATC C02, C03, C07-09) during 2019. Data was collected from Swedish Prescribed Drug Register and the regional healthcare data warehouse of the region. Recorded diagnoses were assessed from years 2015-2019 to match dispensed antihypertensive with the selected diagnoses. R commander was used for analysis and Upset plots were used to present associated data.

Results

A total of 386860 patients (49% male) had at least one antihypertensive dispensed in 2019. Of those, 47692 (12%) were treatment naïve patients (started antihypertensive treatment for the first time); 62% had at least one of the selected diagnoses recorded, most commonly hypertension, followed by hypertension plus diabetes and migraine, but 38% had none of the selected diagnoses recorded in year 2015-2019. Of 339168 (88%) patients with repeated prescriptions of antihypertensives, 81% had at least one of the selected diagnoses recorded, most commonly hypertension, followed by hypertension plus diabetes and hypertension plus atrial fibrillation. Beta blockers were the most frequently used ATC class in both groups.

Conclusion

Most common diagnose for antihypertensive prescribing was primary hypertension. The patterns of diagnoses differed between treatment naïve and prevalent users.

EFFECTS OF THE JULY 2018 WORLDWIDE VALSARTAN RECALL AND SHORTAGE ON GLOBAL TRENDS IN ANTIHYPERTENSIVE MEDICATION USE: A TIME-SERIES ANALYSIS IN 83 COUNTRIES

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ABSTRACT

Objectives

This study aims to examine the effects of the July 2018 worldwide valsartan recall and shortage on global trends of antihypertensive medication use in 83 countries.

Methods

A time-series analysis of monthly purchases of valsartan, other ARBs, and angiotensin-converting enzyme inhibitors (ACEIs) across 83 countries from January 2017 to July 2020 was conducted using the IQVIA MIDAS database. Trends in outcomes were investigated globally and by economic level (developed vs. developing economies). The valsartan recall's impact on antihypertensive use was assessed with interventional ARIMA modelling.

Results

Global valsartan utilization trends decreased significantly ($p < 0.0001$), while global purchases of other ARBs ($p = 0.8523$) and ACEIs ($p = 0.1102$) increased. Of the 32 developed countries, 20 (62.5%) showed a decline in 1-month percentage change in valsartan purchases, whereas only 10 out of 33 developing countries (30.3%) experienced a decrease in valsartan purchases. Mean 1-, 3-, and 6-month percentage changes for developed countries were -1.2%, -9.3%, and -12.2%, respectively, while the changes for developing countries were 25.0%, 7.3%, and -1.2%.

Conclusions

Global valsartan purchases substantially decreased post-recall, highlighting the far-reaching impacts of drug shortages. Opposing utilization trends by economic level raise concerns of potential distribution of contaminated medications from developed countries to developing countries. Concerted actions for equitable global access to quality medications and mitigation of drug shortages are needed.

THE IMPACT OF REGULATORY RESTRICTIONS ON THE USE OF VALPROIC ACID IN WOMEN OF CHILDBEARING AGE: AN ITALIAN STUDY

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ABSTRACT

Background

Due to significant risks to the offspring after intrauterine exposure, the European Medicines Agency (EMA) issued recommendations in 2014 and 2018, restricting the use of valproate (VPA) in women of childbearing age (WOCA). We aimed to evaluate their impact in the Emilia-Romagna Region (ERR), Northern Italy.

Methods

Using administrative databases, we identified all the ERR residents who received antiseizure medications (ASMs) prescriptions from 2010 to 2020. Time series of incidence rates by sex and age groups were evaluated. Focusing on VPA, an interrupted time-series (ITS) analysis was applied to assess the impact of the restrictions on WOCA with epilepsy (WOCA-E) and WOCA with psychiatric disorders (WOCA-P). We then evaluated the chronological order of ASMs prescriptions with regard to the position of VPA.

Results

Incidence rates of VPA prescriptions overall decreased over time. A significant decrease was observed only for females. The effect was stronger for WOCA, both after the first (IRR=0.85; 95%CI=[0.75;0.96]) and the second restriction (IRR=0.67; 95%CI=[0.55;0.82]). The decrease was significant after the second restriction both for WOCA-E (IRR=0.43; 95%CI=[0.27;0.68]) and for WOCA-P (IRR=0.49; 95%CI=[0.35;0.70]), as well as VPA as a first prescription in both populations. VPA prescriptions as further choice did not show the same trend.

Conclusions

After the regulatory restrictions, an overall significant decline in the use of VPA in WOCA was observed in ERR. The second restriction has been effective in consolidating the prescription trend. However, VPA appears to be still a commonly used drug in WOCA when other ASMs fail.

THE UTILIZATION OF RUXOLITINIB IN PATIENTS WITH MYELOFIBROSIS THROUGH A LARGE ITALIAN ADMINISTRATIVE HEALTHCARE DATABASE

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ABSTRACT

Background

Myelofibrosis (MF) is a rare disorder principally treated with the Janus Associated Kinases inhibitor ruxolitinib, until May 2022. This study aimed to identify patients with MF and describe the ruxolitinib utilization, from the perspective of the Italian National Health Service (INHS).

Methods

From the Fondazione ReS (Ricerca e Salute) database (~ 5 million inhabitants/year), patients with a new in-hospital diagnosis of MF (ICD9 codes: 238.76/289.83/238.4/238.71), and ≥ 1 supply of ruxolitinib (ATC code: L01EJ01) in 2017 were identified. Within a variable follow-up (up to 3 years), the ruxolitinib utilization is described in terms of treatment coverage (i.e., the dispensed boxes covered ≥ 28 days/month, according to the Summary of Product Characteristics), discontinuation (i.e., gap of ≥ 30 days between two dispensations), interruption (i.e., dispensations absent until the end of follow-up), and dosage change.

Results

In 2017, 66 new cases of MF were identified (M: 54.5%; mean age 67 ± 10). A proportion of 40.9% of patients (27/66) took ruxolitinib continuously; the remaining people discontinued it for ≥ 1 month (19/66; 28.8%) or definitely interrupted it (20/66; 20.3%). The starting dosage of ruxolitinib was 20 mg in 43.9% patients (29/66), 15 mg in 30.3% (20/66), and 5mg in 21.2% (14/66). At least one dosage change occurred for 42.8% (6/14) of people starting with ruxolitinib 5 mg, 50.0% (10/20) of patients receiving ruxolitinib 15 mg, and 69.0% (20/29) among those starting with 20 mg.

Conclusion

Italian administrative healthcare data can reliably describe the MF-specific treatment, to support regulatory and clinical decisions.

IS INDUSTRY INFLUENCE ON PHARMACOEPIDEMOLOGY 'MUDDYING THE WATERS'? A SYNTHESIS OF CURRENT RESEARCH EVIDENCE

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ABSTRACT

Background

A growing body of evidence indicates an association between pharmaceutical industry funding of clinical research and outcomes. Author conflicts of interest (COI) are also associated with the direction of recommendations in guidelines, opinion pieces and narrative reviews. In this presentation, I synthesise current evidence on the influence of industry funding and COI in pharmacoepidemiology and policies to address influence.

Methods

Evidence synthesis and commentary.

Results

Industry financing is widespread in pharmacoepidemiology: 82% of 1227 observational studies registered in the EU post-authorisation register from 2010 to 2018 were industry-funded. However, a Cochrane systematic review identified only 3 analyses (of 561 primary studies) of research in pharmacoepidemiology, with a relative risk of 1.87 (95% CI 1.54-2.27) for favourable results with industry funding. Case studies of opinion pieces on rare, serious harms leading to regulatory warnings have also found associations between authors' opinions and COI, with frequent methodological critiques of research unfavourable to sponsors. There are several recent policy initiatives to address funding biases, such as the ENCePP code of conduct and INEP policy statement.

Conclusions

Limited research has examined the influence of industry funding and author COI in pharmacoepidemiology. However, results to date suggest a similar direction of effect as in clinical trials. Pharmacoepidemiology also faces unique challenges, including difficulties faced by non-specialists in distinguishing legitimate from spurious methodological critiques, and limited pre-registration of statistical analytical plans. I conclude with recommendations based on the experience in environmental and clinical research, as well as the unique challenges within pharmacoepidemiology.

STRATEGIES TO IMPROVE THE PRESCRIBING APPROPRIATENESS IN PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) IN VENETO REGION: THE IMPACT OF THE ITALIAN MEDICINES AGENCY'S NOTE 100

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ABSTRACT

Type 2 diabetes mellitus (T2DM) is a chronic disease with a significant impact in terms of morbidity and mortality. Since January 2022, the Italian Medicines Agency has extended the prescription of sodium glucose-cotransporter-2 inhibitors (SGLT2i)/glucagon-like peptide-1-receptor-agonists (GLP1-RA) to General Practitioners (Note 100), based on cumulated evidence of positive benefit-risk profile of these drugs, especially in patients with cardiovascular-renal diseases. This study aims to monitor the first-line treatment appropriateness and the impact of the Note 100 on the use of new antidiabetic drugs (ADs) in T2DM patients from Veneto region.

T2DM cohort, identified using outpatient pharmacy claims/hospital discharges/healthcare service payment exemptions codes from Veneto claims database (2017-2021), was characterized on 1st January 2021. The first-line treatments among incident AD users were explored. The proportion of GLP1-RA/SGLT2i users among patients with heart failure (HF)/chronic kidney disease (CKD)/atherosclerotic cardiovascular disease (ASCVD) was calculated (January 2021-June 2022), stratifying by calendar semester.

Overall, 254,796 (5.2% of total population from Veneto region) were affected by T2DM in 2021; male-female ratio was 1.3 and the mean age was 70.4±12.6 years. Among incident AD users, more than one-third started AD treatment other than metformin. The proportion of T2DM patients with HF-CKD-ASCVD receiving GLP1-RA/SGLT2i, as recommended by national-international guidelines/Note 100, significantly raised from 17.6% to 28.0% in the first semester 2021 and 2022, respectively.

Real-world data show a treatment gap between guidelines recommendations and clinical practice, although an increasing use of GLP1-RA/SGLT2i in eligible T2DM patients, as recommended by treatment-guidelines, is observed.

ANTIDEPRESSANTS TO TEENAGE GIRLS IN SWEDEN 2007–2022 – INCIDENCE AND PREVALENCE AS PUBLIC NATIONAL DRUG CONSUMPTION STATISTICS

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ABSTRACT

Background

Drug consumption statistics focus traditionally on volume measurements such as defined daily dose (DDD), packages, number of dispensed prescriptions or annual prevalence. In 2023 annual incidence for prescription drugs will be introduced as public statistics in Sweden, and incidence for other periods and length of run-in can be ordered as statistics.

Methods

Quarterly prevalence and incidence proportion with 18 months run-in for antidepressants (N06A) for young adults 2007–2022 were extracted as statistics from the Swedish Prescribed Drug Register at the National Board of Health and Welfare.

Results

For girls 13-17 years, the amount measured in DDD/1,000 individuals per day (DDD/TID) increased by a factor of 7.3 to 74.5 DDD/1,000 (DDD/TID); the quarterly prevalence proportion with a factor of 5.1 to 40.9 treated girls per 1,000 individuals per quarter; and the quarterly incidence proportion with a factor of 3.3 to 7.1 treated girls per 1,000 individuals per quarter.

The predictive value of 18 months run-in was >98% for first-ever use in this age group.

Conclusion

The increase in the total amount of antidepressants to teenage girls is a consequence of both incidence, prescribed dose, and duration of treatment. The increase in prevalence is significantly higher than the increase in incidence and is thus partly explained by an increase in average treatment duration. Providing national statistics on incidence allows for more dynamic evaluation of drug utilization.

VALIDITY OF THE ISMP MEDICATION SAFETY SELF-ASSESSMENT® FOR LONG-TERM CARE TOOL IN AUSTRALIAN NURSING HOMES

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ABSTRACT

Background

Medication safety is a fundamental part of quality use of medicines. Multiple tools exist for assessing medication safety processes in the hospital setting but few exist for use in nursing homes. The Medication Safety Self-Assessment for long term care (MSSA-LTC) is routinely used to assess medication safety processes in Canadian nursing homes, yet the validity of this tool for use outside Canada is unknown. This study aimed to determine the validity of the MSSA-LTC for assessing medication safety processes in Australian nursing homes.

Methods

A modified 2-round RAND/UCLA Appropriateness Method was used to assess the validity of 133 criteria of MSSA-LTC. The expert panel consisted of 9 registered nurses and pharmacists with expertise in medication management in the nursing home setting. The panel rated each criterion separately for two attributes: importance for medication safety and applicability to the Australian context. For validity, criteria needed to be considered both important for medication safety and applicable to the Australian context.

Results

108 of the 133 criteria were considered valid for use in the Australian nursing homes. Of those not considered valid, one criterion (using barcoding to identify residents) was not considered important for medication safety, and 25 criteria were not considered applicable to the Australian setting.

Conclusion

In general, the MSSA-LTC appears valid for assessing medication safety in Australian nursing homes. Future work to examine the feasibility and impact of the tool in improving the quality use of medicines and medication safety in the Australian context is needed.

FACTORS ASSOCIATED WITH UNRESOLVED POTENTIAL MEDICATION ERRORS – AN EVALUATION OF PRESCRIPTIONS TO PATIENTS RECEIVING SURGERIES AT A TERTIARY MEDICAL CENTRE IN SHANXI PROVINCE IN CHINA

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ABSTRACT

Background

This study explored factors associated with whether pharmacists resolved potential medication errors (PMEs) identified from prescriptions issued to inpatients receiving surgeries in a hospital.

Method

This study used electronic prescription records in a tertiary medical centre in China from 2019 to 2022. Prescriptions issued to patients on surgical wards with PMEs were identified by computerised algorithms and intervened by pharmacists before dispensing. Prescriptions with unresolved PMEs were identified. The multilevel mixed-effect logistic regression was used to associate prescriptions with unresolved PMEs and factors, including patient's gender, age, number of comorbidities, type of surgery, level of surgery complexity, number of concurrent medicines, route of drug administration, prescriber and pharmacist's seniority. The results were presented in odds ratio (OR) and 95% confidence interval (95%CI).

Results

Only 0.51% of the 2,049,499 prescriptions were identified with PMEs, of which 62.38% of prescriptions (n=6537, with 8707 PMEs) were unresolved. The most common PMEs were related to administration routes (42.68%) and dosage regimens (37.71%). The larger number of comorbidities, concurrent medicines, and higher surgical complexity were significantly associated with increasing unresolved PMEs. Besides, PMEs were less likely in prescriptions issued for males than females (OR=0.90; 95%CI: 0.83-0.98) and those issued by senior than junior prescribers (OR=0.89; 95%CI: 0.80-0.98), but more likely in prescriptions reviewed by senior than junior pharmacists (OR=1.48; 95%CI: 1.29-1.70).

Conclusion

The unresolve of PMEs was complex and multifaceted, which may also be associated with types of PMEs and system-related factors. Further qualitative studies are needed to explore the determinant factors.

ADVERSE DRUG REACTIONS IN AN AGEING POPULATION (ADAPT) STUDY: PREVALENCE AND RISK FACTORS ASSOCIATED WITH ADVERSE DRUG REACTION-RELATED HOSPITAL ADMISSIONS IN OLDER PATIENTS

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ABSTRACT

Objectives

The aim of this study was to; (i) determine the prevalence and characteristics of ADR-related hospital admissions among older patients (≥ 65 years) in Ireland; and (ii) identify the risk factors associated with ADR-related hospital admissions.

Methods

A cross-sectional study of ADR prevalence in patients aged ≥ 65 years admitted acutely to hospital in Ireland over 8 months (November 2016- June 2017). A multifaceted review of each admission was undertaken to assess the likelihood of an ADR being causal or contributing to admission in the context of the patient's medication, clinical conditions, comorbidities and investigations. Two independent reviewers applied decision aids to assess ADR causality, avoidability and severity. Multivariable logistic regression was used to assess the association between potential risk factors for ADR-related admissions and non-ADR-related admissions.

Results

In total, 3,760 hospital admissions (in 3091 patients) were screened and 377 were considered ADR-related (10.0%, 95% CI 9.1%,11.0%). 219 (58.1%) ADR-related admissions were caused by an ADR, while ADRs contributed to 158 (41.9%) admissions. 268 (71.1%) of all ADR-related admissions were deemed definitely or possibly preventable/avoidable. 350 (92.8%) ADRs were classified as moderate severity and 27 (7.2%) as severe. Antithrombotic agents, mainly aspirin and warfarin, were the drugs most frequently associated with ADR-related admissions. In multivariate analysis, immobility, frailty, having delirium or ulcer disease and taking anticoagulants and antiplatelets on admission were significantly associated with ADR-related admissions.

Conclusions

One in ten hospital admissions were considered ADR-related. Reliable and validated ADR detection and prediction tools are needed to develop prevention strategies.

DRUG POISONINGS WITH EMERGENCY DEPARTMENT PRESENTATIONS

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ABSTRACT

Background

Poisoning is a major public health concern worldwide and intoxicated patients are often managed in the Emergency Care Departments (ED). Elderly patients might be more vulnerable to the negative consequences of intoxications.

Methods

A local retrospective observational study was conducted in a tertiary care medical center' ED. During the 3 year of analysis we included all elderly patients (aged 65 years or more) who were presented to the ED with an ICD code referring to acute drug intoxication. Data was retrieved from the electronic patient documentations. Frequency and types of intoxications (as number and as %) were determined.

Results

During the study period, overall 251 drug intoxications were recorded. The majority of elderly patient with acute intoxications were women (63 %). In almost every second case, the intoxication was due to a suicide attempt. Unintended intoxications were also prevalent, we recorded 107 cases (43 %). The most frequent active agent in suicide attempts were alprazolam and clonazepam, while in the case of unintended intoxications 95 out of the 107 cases (89 %) were with Vitamin K antagonists (most frequently acenocoumarol). The average length of stay in the ED was 13.5 ± 9.3 hours. Two third of all patients were transferred to other clinical units, including 16 patients to the intensive care unit.

Conclusion

Elderly patients were presented at the ED with various types of intoxications that puts substantial burden on health care. Measures are needed to avoid preventable intoxications.

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MORTALITY AND HEALTH CARE SYSTEM COSTS ASSOCIATED WITH OPIOID USE AND POTENTIALLY INAPPROPRIATE OPIOID USE IN COMMUNITY-DWELLING OLDER ADULTS

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ABSTRACT

Objectives

To evaluate the impact of opioid/inappropriate opioid use on health system costs and mortality.

Methods

Secondary analyses were performed using health survey and administrative data from community-dwelling older adults. Generalized linear models were employed to study health system costs associated with opioid and potentially inappropriate opioid use (defined using Beers criteria) over three years in n=1201. We studied the risk of all-cause mortality among those with at least one incident opioid claim (n=472) using nested case-control analyses. Four controls were matched on age (+/- 5 years) while still at risk of death when their matched case died. Mortality risk associated with opioid use in various exposure windows (0-30 days, 31-90 days, or >90 days before death) was estimated by conditional logistic regression analyses controlled for the number of hospitalizations, presence of malignancies and other potential confounders.

Results

Opioid use and potentially inappropriate opioid use were associated with adjusted three-year costs of \$21,358 and \$26,218, respectively. Adjusted three-year costs were significantly higher in those with inappropriate use compared to no use (Δ \$10,108) and opioid use (Δ \$4,860). Effect modification was found for sex, but not for income or education. Stratified results showed that men incurred higher costs than women during opioid use. Exposure to opioid use in the 30 days before death was associated with an increased risk of mortality (adjusted OR=4.36, 95%CI: 1.13-16.82), whereas other exposure windows were not significant.

Conclusion

These findings can help improve health resource allocation for pain management and encourage safer opioid use in older adults.

PATIENTS' PERSPECTIVES ON THE DEVELOPMENT OF PRESCRIPTION OPIOID USE DISORDER IN PATIENTS WITH CHRONIC NON-CANCER PAIN

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ABSTRACT

Background

Prescription opioid use has increased exponentially in the past decade and concurrently opioid use disorders (OUD) are becoming more common. Several risk factors have been associated with developing OUD, but little is known regarding the patients' perspective on developing a prescription OUD.

Methods

Qualitative study using in-depth, semi-structured remote interviews with 25 adults undergoing treatment for prescription OUD. Utrecht University Institutional Review Board reviewed and approved all study procedures (UPF 2018). Interviews focussed on experiences with starting opioid treatment, long-term opioid use, guidance by health care professionals, and access to opioids. A directed content analysis was conducted on the transcribed interviews using Nvivo.

Results

Participants showed that the development of an OUD is influenced by various internal and external factors, which were grouped into three themes: 1) experiences driving initiation, 2) experiences driving continuation, and 3) experiences with prescription OUD. Poor pain management and subjective stress, as well as, a lack of guidance, both at the start of use and long-term use, easy access to repeat prescriptions, and a lack of medication evaluations were considered main drivers for continued improper use.

Conclusion

Patients' experiences illustrate a clear need for realistic expectations for pain management, repeat benefit-risk counselling sessions, and regular evaluations of the effectiveness and appropriateness of opioid therapy. Increasing patient involvement regarding their opioid intake. In the light of the pressing need for solutions to slow down an opioid epidemic, this research highlights important intervention points, based on patient needs, for health care professionals and policy makers.

ASSOCIATION BETWEEN DOSES OF LEVONORGESTREL INTRAUTERINE SYSTEMS AND SUBSEQUENT USE OF PSYCHOTROPIC DRUGS IN FRANCE.

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ABSTRACT

Levonorgestrel Intra-Uterine Systems (LNG-IUS) have systemic adverse events such as mood disturbances. We hypothesized that the dose of LNG could influence outcomes of mood changes. We conducted a nationwide matched-cohort study using data from the French National Health Insurance database (SNDS). We identified women aged 13-40 years old who got a 52 mg LNG-IUS in 2019 and a control group who got a 19.5 mg LNG-IUS, matched (1:1) on age (± 3 years), gravidity in the 10 years before, month of dispensation in 2019 (± 3) and type of physician. Conditional logistic regression was used to calculate adjusted odds ratios (aOR) and 95% confidence intervals to study the associations between the type of LNG-IUSs and the use of anxiolytics, hypnotics and antidepressants within two years after dispensing. A total of 45,736 women with a LNG 52 mg IUS (user's mean age: 32.3 [5.4]) and 45,736 women with a LNG 19.5 mg IUS (mean age: 31.8 [5.4]) were matched. After adjustment, having a 52 mg LNG-IUS dispensation rather than a 19.5 mg dispensation was associated with the use of antidepressant within two years after dispensation (aOR=1.13 [1.05-1.22]) but not significantly with the use of anxiolytics (aOR=1.05 [0.99-1.12]) and hypnotics (aOR=1.08 [0.99-1.19]). Only women under 25 years old had an increased risk of using hypnotics (aOR= 1.65 [1.15-2.37]). In conclusion, this nationwide French study found a low but statistically significant increased risk of antidepressant use associated with a 52 mg LNG-IUS vs a 19.5 mg LNG-IUS.

COMPARATIVE EFFECTIVENESS OF INSULIN DEGLUDEC (TRESIBA®) AND INSULIN GLARGINE 300 U/ML (TOUJEO®) IN PATIENTS WITH TYPE2 DIABETES MELLITUS TAIWAN: A POPULATION-BASED COHORT STUDY

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ABSTRACT

Background

Tresiba® (insulin degludec) and Toujeo® (insulin glargine 300 U/ml) are second generation long-acting insulin. However, there is still lack of head-to-head long-term studies in Asia population. This study aimed to compare the effectiveness of Tresiba® and Toujeo® in Taiwan.

Method

This retrospective cohort study utilized a multi-institutional electronic medical records database in Taiwan. We included adults with type 2 diabetes newly initiating Tresiba® and Toujeo® during 2020-2022. We followed these patients from initiation of the two agents to outcome events, loss of follow-up, or December 31, 2022. The study outcomes included myocardial infarction (MI), stroke, heart failure (HF), and major adverse cardiovascular events (MACE), the composite of those events. Propensity score methods were applied to enhance between-group comparability. Subgroup and sensitivity analyses were performed to examine the robustness of primary analysis results.

Result

We included a total of 4,264 Tresiba® users and 4,626 Toujeo® users with a mean age of 59.0 (SD 19.1) years, of whom 45.4% were women. After propensity score matching, Tresiba® and Toujeo® had similar risk of MACE (HR:1.00 [95% CI: 0.82-1.21]). Moreover, in subgroup analysis, Toujeo® was associated with higher risk of MI in elder population compared to Tresiba® (HR: 1.84 [95% CI: 1.09-3.11]).

Conclusion

In real-world T2D patients, Tresiba® and Toujeo® had similar cardiovascular risk. However, among elderly patients, Toujeo® users had higher risk of MI than Tresiba® users.

EFFECTIVENESS AND SAFETY OF DIRECT ORAL ANTICOAGULANTS IN NON-VALVULAR ATRIAL FIBRILLATION: A COHORT STUDY IN PRIMARY CARE IN CATALONIA, SPAIN.

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ABSTRACT

Background

We aimed to assess effectiveness and safety of direct oral anticoagulants (DOAC) according to initial dose, adherence and switching during follow-up in non-valvular atrial fibrillation (NVAf) patients initiating stroke prevention treatment.

Methods

Cohort study including NVAf patients initiating DOAC in 2011-2020.

Data source: SIDIAP (Information system for research in Primary Care), capturing information of 5.8 million people from Catalonia, Spain, from the electronic health records in Primary Care and the database of diagnoses at hospital discharge.

We estimated incidence rate ratios (IRR) and 95% confidence intervals (CI) by fitting a negative binomial regression for stroke, cerebral and gastrointestinal haemorrhage for DOAC initiators.

Results

36,458 people initiated DOAC. Receiving a correct vs incorrect dose resulted in no differences in the stroke risk (IRR 0.94, 95%CI 0.85-1.05), cerebral (0.90, 0.63-1.29) or gastrointestinal bleeding (0.99, 0.55-1.80).

DOAC adherence had a protective effect on stroke (0.75, 0.66-0.85) and cerebral haemorrhage (0.44, 0.29-0.67) risks, but no impact on gastrointestinal bleeding risk (0.85, 0.36-2.00).

Switching DOAC during follow-up resulted in higher risk of stroke (1.99, 1.74-2.27), cerebral (2.32, 1.53-3.52) and gastrointestinal bleeding (2.26, 1.16-4.42).

Conclusions

Receiving an adequate dose did not show better outcomes, although we only analysed the first dose prescribed, so further analyses are needed.

Adherents showed lower risk of stroke and cerebral bleeding, highlighting the importance of compliance to prevent negative outcomes.

People switching DOAC showed higher incidence of all outcomes. As we do not know the reasons of switch, we cannot rule out a prior higher risk, independent of DOAC prescribed.

A PROPENSITY SCORE-MATCHED LONGITUDINAL STUDY ON THE ASSOCIATION BETWEEN MEDICAL CANNABIS AUTHORIZATION AND PSYCHOTIC DISORDER-RELATED EMERGENCY DEPARTMENT VISITS OR HOSPITALIZATIONS

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ABSTRACT

Background

Recreational cannabis use is associated with an increased risk for psychotic disorders. However, this risk is not well characterized for patients using cannabis for medical purposes. We aimed to assess the risk of emergency department (ED) visits or hospitalizations for psychotic disorders among adults authorized to use medical cannabis for a health condition in Ontario from 2014 to 2020.

Methods

We performed a retrospective cohort study, using clinical and health administrative data, on patients with a healthcare provider authorization to use medical cannabis and followed in Ontarian cannabis clinics. High dimensional propensity scores matched each patient to up to 3 population-based controls. The primary outcome was an ED visit or hospitalization with an ICD-10 primary diagnosis related to psychotic disorders. We used conditional Cox proportional hazards regressions accounting for matching to assess the association.

Results

A total of 60,414 cannabis patients were matched to 180,397 controls. Less than half of the patients (42%) were aged ≤ 50 , and 54% were women. Incidence rates of psychotic disorders were 2.25/1000 person-years (95%CI: 2.02-2.51) in the medical cannabis group and 1.56/1000 person-years (1.45-1.68) in the control group. In the conditional Cox model, further adjusted for age, sex, and history of psychotic disorders, the hazard ratio (HR) was 1.25 (1.05-1.36). A similar result (HR:1.25; 1.07-1.46) was found among patients without a history of psychotic disorders.

Conclusions

Medical cannabis authorization was associated with an increased risk of ED visits or hospitalizations for psychotic disorders. A careful benefit-risk assessment is needed before authorizing medical cannabis use.

OVERDOSE RISK-INCREASING MEDICATION IS MORE OFTEN DISPENSED TO INDIVIDUALS DYING OF OVERDOSES RELATED TO PHARMACEUTICAL AVAILABLE OPIOIDS COMPARED TO INDIVIDUALS DYING OF OVERDOSES RELATED TO OTHER SUBSTANCES: A POPULATION-BASED REGISTER STUDY.

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ABSTRACT

Background

Previous research indicates that those dying from pharmaceutical available opioid (PO) overdoses differ from those dying from other substances. We investigated differences in overdose risk-increasing medication (ORM) dispensed to persons dying from PO overdoses compared to those dying from other types of overdoses.

Methods

Using the nationwide Norwegian Cause of Death Registry (NCDR), we retrieved information on all overdoses (ICD-10) in 2015-2019, identifying PO overdoses (T40.2; T40.4) and all other overdoses. With data from the Norwegian Prescription Database, we analysed data on ORM (benzodiazepines, benzodiazepine-related drugs and pregabalin) dispensed one month before death.

Results

A total of 605 persons (intentional death: 29.4%, women: 243 (40.2%)) were registered with PO overdoses and 780 persons (intentional death: 6.5%, women: 163 (20.9%)) with other overdoses. During one month before death, we observed the following differences in dispensed medication: benzodiazepines 40.2% in the PO group compared to 29.2% in the other overdose group; benzodiazepine-related drugs 21.8% versus 10.4%; pregabalin 12.2% versus 5.6%. Two or three different medications were dispensed to 19.7% in the PO group versus 8.3% in the other overdose group. Among women, a higher proportion was dispensed ORM in both overdose groups.

Conclusion

The results suggest that the use and concurrent use of ORM is common, especially in people dying of PO overdoses. Clinicians need to be aware of the risk of overdose with these medications and carefully evaluate this risk before prescribing ORM.

LONGITUDINAL TREATMENT PATTERNS IN PATIENTS RECENTLY DIAGNOSED WITH TYPE 2 DIABETES MELLITUS IN CATALONIA

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ABSTRACT

Background

To investigate treatments prescribed to newly diagnosed type 2 diabetes mellitus (T2DM) patients, and how these evolve throughout time.

Methods

Observational study in T2DM incident patients in Catalonia between 2015 and 2020. The data were obtained from SIDIAP (Information System for Research in Primary Care) which includes electronic health records of 5.8 million people in primary care.

Using data processing and algorithms, we captured the first to third-line longitudinal treatment patterns, either alone or in combination, in patients who had at least a year of follow-up.

Descriptive statistics and graphical representation were used to analyse how and when the patterns change.

Results

A total of 121,929 patients were included. 56% of the patients began treatment with a single metformin medication, while 31.4% began with a combination therapy. Glycosylated hemoglobin was 6.70 [6.20-7.40] and 7.50 [6.60-8.70], median[IQR], in patients with monotherapy and polytherapy, respectively.

45.3% of the patients received second-line therapy after a median[IQR] of 15 [6-32] months in first-line. Of these, 26% on metformin monotherapy had an addition of DPP4i or Sulfonylurea.

After 12 [4-25] months, 26.5% of patients switched to third-line therapy, mostly to resume metformin monotherapy following the previous polytherapy.

Conclusions

Patients starting with combination therapy had high glycosylated hemoglobin.

The most common pattern is to start with metformin, add a second antidiabetic in the second-line, and as a third-line therapy retire it to continue with metformin monotherapy.

Future research will examine the association between these patterns and clinical characteristics or negative outcomes.

EXPLORING CURRENT APPROACHES TOWARDS PATIENT PRIORITISATION FOR CLINICAL PHARMACY SERVICES IN INPATIENT MENTAL HEALTH CARE IN THE UK: A MULTI-METHOD RESEARCH STUDY.

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ABSTRACT

Background

Despite evidence suggesting prioritisation is a promising approach to optimise deployment of limited resources to patients in most need in acute hospitals, this remains unexplored in mental health settings. Therefore, this study aims to explore the development, implementation, and impact of current approaches for prioritising inpatient pharmacy services in mental health trusts and boards in the UK.

Method

The study consisted of a national survey followed by semi-structured interviews and document analysis. The survey was electronically distributed to senior pharmacy team members across UK mental health organisations to identify those using prioritisation systems (tools or processes). Those using systems were invited to take part in an online semi-structured interview and to share relevant documents. Interview transcripts were thematically analysed.

Results

A total of 55 survey responses were received from 73 mental health trusts/boards leading to a 75.3% (n=55/73) response rate. Of these, 38.2% (n=21/55) used a prioritisation system within clinical pharmacy. Fifteen semi-structured interviews were conducted and 11 tools received. Systems varied greatly from simple, informally developed tools to complex, systematically developed tools. Systems were perceived to be useful to manage limited resources, optimise services, and record and benchmark current performance. However, reported challenges of systems included balancing professional judgment with standardisation, risks of missing patients who may need pharmacy intervention, and pharmacy staff uptake.

Conclusion

This study has revealed variability in current patient prioritisation approaches in UK mental health organisations, highlighting a need for future development and evaluation of an evidence- and consensus-based prioritisation tool.

COMMUNITY PHARMACISTS' CHALLENGES REGARDING ADVERSE DRUG REACTION REPORTING: AN EXAMPLE FROM SERBIA

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ABSTRACT

Background

The effectiveness of the national drug safety monitoring program directly depends on the active participation of healthcare professionals in reporting suspected adverse drug reactions (ADRs). The aim of the study was to explore community pharmacists' comprehension of pharmacovigilance, their perspectives toward reporting ADRs, and their current practice of ADR reporting.

Methods

This descriptive cross-sectional study was performed on a sample of pharmacists in Serbia between November 2019 and March 2020 using a pre-tested questionnaire distributed online. Non-parametric statistical tests were performed in the analysis of knowledge, perspectives, and ADR reporting. The validity and reliability of the survey were measured by exploratory factor analysis.

Results

The median knowledge score was 6 out of 10 (interquartile range 5–7, range 2–10). No significant differences in the knowledge scores of pharmacists were found based on weekly working hours ($U = 24,805$, $p = .374$), working experience ($\chi^2 = 4.011$, $DF = 2$, $p = .135$), being a member of a professional organization ($U = 24,312$, $p = .209$), or highest level of pharmacy qualification obtained ($\chi^2 = 3.233$, $DF = 3$, $p = .506$). Only 28.8% of pharmacists reported ADR at least once a year, while the majority of them have never reported any ADRs.

Conclusion

Despite the community pharmacists' positive attitude toward adverse drug reporting and their role in the process, they show limited knowledge regarding the issue and highly prevalent under-reporting of ADRs. Educational programs are necessary to increase ADR reporting.

SAFETY MONITORING OF COVID-19 VACCINES BY THE FRENCH PHARMACOVIGILANCE CENTRES NETWORK

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ABSTRACT

Background

Until mid-January 2023, over 155 million of COVID-19 vaccines have been administrated in France. Safety monitoring of these drugs was a major challenge for pharmacovigilance as the particular perception of vaccines, the massive vaccination campaign and the media influence led to an unprecedented volume of reports from health professionals (HP) and patients. To be able to quickly detect safety signals and propose appropriate risk minimisation measures, an enhanced pharmacovigilance system was set up in France.

Methods

All adverse drug reactions (ADR) referred by HP and patients were analyzed by the 31 French Regional Pharmacovigilance Centres network (RPVC). One expert pair per vaccine made a daily analysis of all ADR. These assessments were presented every week to a scientific committee composed of National Agency for the Safety of Medicines (ANSM) and RPVC representatives. Safety signals were discussed and the conclusions of each meeting were shared on the ANSM website.

Results

Until 2023/01/12, 190 968 ADR (25% serious) have been reported. Fifty-three potential safety signals were identified. Of those, 13 have been confirmed (i.e. arterial hypertension, myocarditis, heavy menstrual bleeding), 15 are still under investigation and 25 are considered under surveillance (i.e. Parsonage Turner syndrome, hearing loss,...).

Conclusion

Safety monitoring and transparency are key to the success of a vaccination campaign. The French enhanced pharmacovigilance system has demonstrated its efficiency to detect safety signals and to contribute to a better understanding of the safety of these newly-developed vaccines.

HOSPITAL INITIATION OF OPIOIDS AND LONG-TERM PRESCRIBING AMONG OLDER ADULTS IN PRIMARY CARE - A COHORT STUDY

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ABSTRACT

The upwards trend in opioid prescribing poses concern for older adults given risks associated with prolonged opioid use. This study aims to assess long-term opioid prescribing in opioid-naïve patients initiated on opioid therapy in hospital, and patient and discharge prescription factors associated with long-term opioid prescribing.

This is a retrospective cohort study of approximately 40,000 patients aged ≥ 65 years from 44 GP practices during 2012-2018 in Ireland. Using GP record and hospital discharge data, individuals initiating an opioid at hospital discharge who were opioid naïve (no opioid in the previous 365 days) were identified. Among non-cancer-related hospitalisations, Cox regression analysis assessed associations between patient and discharge prescription factors (opioid drug, duration, tapering instructions, as needed use specified) and the duration of opioid continuation post-discharge.

Overall, 1,069 opioid-naïve patients were initiated on opioids at discharge (48.4% male, mean age 77.9 years). Forty-two percent (n=449) continued opioid therapy following discharge, and 9.4% (n=101) were continually prescribed for >365 days. Of those who discontinued therapy within 365 days, the mean time to discontinuation was 106 days. Initial prescription factors including morphine (HR 0.43, 95%CI 0.23-0.80); duration ≥ 14 days (HR 0.58, 95%CI 0.39-0.86); and no duration stated (HR 0.46, 95%CI 0.32-0.66) had statistically significant associations with long-term opioid therapy among those with non-cancer hospitalisations, adjusting for other factors.

Opioid type and initial prescription characteristics such as duration were associated with longer duration of use. This study highlights the prescribing factors which can be optimised to reduce their contribution to prolonged opioid therapy post-discharge.

PRESCRIPTION APPROPRIATENESS OF PROTON PUMP INHIBITORS: THE LAPTOP-PPI STUDY

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ABSTRACT

Proton Pump Inhibitors (PPIs) have greatly improved the therapeutic approach to acid-related diseases. Despite the extensive literature regarding the associated adverse events (AEs), PPIs are among the most inappropriately prescribed drugs by General Practitioners (GPs). The LAPTOP-PPI project was aimed at assessing the effectiveness of an informative intervention addressed to GPs to improve the appropriate prescription of PPIs.

The appropriateness of drug prescription among community-dwelling, ≥ 65 years old people was assessed through an algorithm specifically designed and based on national reimbursement criteria. Evaluation was performed on data collected in Bergamo (Northern Italy) and Caserta (Southern Italy) administrative databases, from July 1 to 31 December 2019. In June 2021, GPs were randomly allocated to be informed with summary statistics on their prescribing habits and to receive educational material to be distributed to their patients (intervention group), or to standard practice (control group).

At baseline, among 380,218 older subjects receiving at least one drug prescription, 46.1% and 36.7% received drug prescriptions for acid-related diseases in Bergamo and Caserta, respectively. According to our algorithm, these treatments were not appropriate in 54.0% and in 63.0% of cases. At the time of writing this abstract, we are collecting follow-up data to evaluate the effectiveness of the intervention.

Given the potential risk of AEs, the improvement of PPIs prescription quality is a major concern. Educational interventions for GPs and patients are routine strategies to fight inappropriateness, but it is important to understand whether these low-cost, easy-to-implement interventions are really effective in changing the prescribing practice.

IDENTIFYING POTENTIAL OPIOID-RELATED SAFETY PRESCRIBING INDICATORS: A SYSTEMATIC REVIEW

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ABSTRACT

Background

This systematic review aimed to identify prescribing safety indicators related to opioids in any setting from published literature.

Methods

Literature that reported prescribing indicators from 1990-2019 was retrieved from a published systematic review. A subsequent review was conducted from seven electronic databases to identify any additional studies from 2019 to 2022. Potential opioid safety prescribing indicators (OSPIs) were extracted from the studies that reported prescribing indicators of non-injectable opioids and narcotics prescribed to adults with or without specific conditions, concomitant medications, or laboratory monitoring with concerns about the potential safety risk of harm. Retrieved indicators were split by each opioid and merged for the same drugs. OSPIs were categorised by the type of problem, medication, patient condition/disease, and the risk of the indicators.

Results

Of the 107 indicators retrieved from 48 included articles, 76 OSPIs were included. Half of the OSPIs (n=38, 50.0%) focused on a specific class of opioids, e.g., 'opioids' (n=32, 42.1%) and 'strong opioids' (n=5, 6.6%); tramadol was the most reported drug (n=8, 10.5%). Besides, 27 (35.5%) indicators reported the patient's accompanying conditions, disease or medical history, and 'without using laxatives' was the most common (n=7/27, 26.0%). Drug-drug interaction was the most common prescribing problem (n=24, 31.6%). Central nervous system related adverse effects were most common OSPIs reporting the concerned risk (n=22/50, 44.0%).

Conclusion

This is the first systematic review to identify a comprehensive list of OSPIs, which can be further validated to determine the feasibility of identifying hazardous prescribing in different clinical settings.

RISK OF URINARY TRACT INFECTION WITH DIABETES AND ANTIDIABETIC MEDICATIONS: AN ANALYSIS OF THE CANADIAN LONGITUDINAL STUDY ON AGING

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ABSTRACT

Background

Diabetes mellitus and certain antidiabetic medications have been associated with increased urinary tract infection (UTI) risk. We reviewed the antidiabetic drug utilization and reported its association with UTI using the Canadian Longitudinal Study on Aging (CLSA) Comprehensive cohort data (baseline: 2012-2015 and 3-year follow-up 2015-2018; n=30,097; ages 45-85 years).

Methods

We conducted a retrospective cohort study. We defined diabetes by self-report and/or glycated hemoglobin A1c \geq 6.5%; and UTI by self-report over the prior year.

Results

We included all individuals who provided data at follow-up (n=27,209, mean age 59.4 years, standard-deviation 0.12; 52.6% female). Among these (in a hierarchical decreasing order), 449 were prescribed insulin at baseline, 322 DPP4i (Dipeptidyl peptidase-4 inhibitor), GLP1RA (Glucagon-like peptide-1 receptor agonist) or SGLT2i (Sodium-glucose cotransporter-2 inhibitor) (80%, 17% and 3%, respectively), 380 sulfonylurea, 529 metformin, 3,138 had elevated glucose levels but were not prescribed medications and 20,143 did not have diabetes. Among those without UTI at baseline, logistic regression (odds-ratio, 95% confidence intervals vs. no-diabetes) adjusting for survey weights, age, sex, lifestyle factors and comorbidities revealed higher UTI odds at follow-up in the DPP4i/GLP1RA/SGLT2i (2.17, 1.10-4.28) and no-medication (1.36, 1.08-1.72) groups; while among those with UTI at baseline, UTI odds at follow-up did not differ statistically between treatment groups (DPP4i/GLP1RA/SGLT2i 1.42, 0.48-4.20; insulin 1.77, 0.63-5.00; metformin 1.64, 0.74-3.62, sulfonylurea 1.79, 0.82-3.92 and no-medication 1.53, 0.98-2.41).

Conclusion

Among individuals with diabetes and no UTI history, those prescribed DPP4i/GLP1RA/SGLT2i and those not prescribed medications seemed at higher risk of UTI compared to those without diabetes.

SAFETY AND EFFICACY OF ADD-ON CANNABIDIOL IN PATIENTS WITH LENNOX-GASTAUT SYNDROME: RESULTS OF A RETROSPECTIVE STUDY

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ABSTRACT

Background

An oral solution of highly purified cannabidiol (Epidyolex®) was approved in Italy as adjunctive therapy for preventing seizures associated with specific syndromes, such as Lennox-Gastaut Syndrome (LGS) in young children and adults. This study aims to evaluate the efficacy and safety of Epidyolex® in patients with LGS.

Methods

An observational retrospective study was conducted in the Department of Neurology in collaboration with the Hospital Pharmacy. Three data sets were collected, including demographics (gender, age), drug therapy (failed drugs, daily dosage of Epidyolex®, number of concomitant drugs) and clinical characteristics (seizure frequency, side effects of Epidyolex®). Reduction in seizures between the first and follow-up medical visits was tested.

Results

Seven patients (4 females, mean age: 41.6 ± 12.1 years) were observed for a period of 3.8 ± 1.8 months. They were unresponsive to topiramate and at least to two other anti-epileptic drugs (phenobarbital, $n=5$, and carbamazepine, $n=4$ were the most common). At baseline patients were taking 5 anticonvulsant drugs on average including phenobarbital and lacosamide ($n=3$) and all of them suffered from multi-day seizures. At follow-up the median drug dose was 10mg/Kg/day. Epidyolex® was effective in 42.9% of participants ($n=3$). Seizures halved in one case, and even disappeared in two subjects after 4 and 5 months, respectively. Only one patient presented side effects (diarrhoea, drowsiness), so to discontinue therapy.

Conclusion

As a real-life experience, our findings confirm the safety and efficacy profiles of CBD in the treatment of LGS patients. Future research will help further identify the target population to rise efficacy.

ATYPICAL ANTIPSYCHOTIC DRUGS AND THE RISK OF DIABETIC KETOACIDOSIS: ANALYSIS OF DATA FROM THE US FDA ADVERSE EVENT REPORTING SYSTEM

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ABSTRACT

Objective

Data from the US FDA Adverse Event Reporting System (FAERS) were mined for safety signals of DKA with antipsychotic drugs (APDs).

Methods

Adverse drug reactions (ADRs) of DKA and APDs listed as primary and secondary suspect drugs were compared to ADRs from two reference groups: all other drugs or other psychotropic substances spanning twenty years of spontaneous reporting. Two signal detection techniques, the Proportional Reporting Ratio (PRR) and the Empirical Bayes Geometric Mean (EBGM) were used to search for a possible DKA signal.

Results

Between 2000 and 2020, most DKA ADRs were from submissions originating from within the United States (46.1%), by health care professionals (72.2%) and led to serious hospitalization in over half of the cases (55.7%). Reported ADRs were higher in females (49.3%). The analysis focused on the use of APDs as primary and/or secondary suspect drugs compared to all other drugs or to psychotropic substances alone. As primary suspect drugs, quetiapine and olanzapine, two atypical APDs, were identified as potential drug safety signals when compared to other psychotropic drugs: the PRR for quetiapine and olanzapine were 16.9 (95% CI: 15.7-18.3) and 12.15 (95% CI: 11.2,13.2), respectively. The EBGM values for these two APDs were 9.8 (90% CI: 9.3,10.2) and 8.7 (90% CI: 8.2,9.2), respectively. Comparable results were obtained for the primary and secondary suspect drugs analysis.

Conclusion

This analysis provides additional evidence between the reporting of atypical APDs and DKA.

Keywords

Antipsychotic Drugs, Diabetic Ketoacidosis, FAERS

BARRIERS IN ANALYSING MEDICATION-RELATED INCIDENTS DATA BY MSOS

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ABSTRACT

Background

The risk of incidents has been a concern in healthcare settings. Proposed patient safety programs have focussed on the improvement of learning and sharing rather than on the construction of a technical infrastructure for reporting systems.

Aim

We seek to identify how medication incident report data has been used to meet medication safety learning needs.

Methods

Semi-structured online interviews were undertaken with 14 medicines safety officers (MSOs) in England-NHS trusts to explore how to improve organisational learning from medication-related incidents data. Interviews were audio-recorded, transcribed, and analysed thematically.

Results

Most MSOs independently carry out analysis of incident report data, mostly on medication-caused harm; only a few of them receive wider team input in this process. A standard framework for analysis and quality checking of data is not available to MSOs and analysis is generally descriptive. Themes, trends, and action plans are generated manually. There are barriers to learning from this data such as poor report structure and quality as well as underreporting. Internal investigation of incidents is affected by various factors including lack of resources and staff morale. Analysis is time and labour intensive, which limit going through reports in detail. Free-text is mostly excluded in analysis and used for validation purposes. Some reports require supporting information from other sources of data which are not integrated. We observed the absence of a standard process for sharing and communication.

Conclusion

Further improvements in investigation, analysis and sharing are required to maximise what can be learned from medication incident reports data.

INITIATING PRESCRIPTION OPIOIDS FOR THE TREATMENT OF FIBROMYALGIA: A POPULATION-BASED, REAL-WORLD COHORT STUDY.

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ABSTRACT

Background

The use of opioids for chronic pain has increased significantly in the last years and has translated into the care of many patients with fibromyalgia (FM). Even if there is some evidence that specific opioids such as tramadol can be clinically useful in some patients, there is general concern about the harms in the absence of benefits of opioids in this setting.

Objective

To describe baseline patients and initial therapy characteristics in a real-world cohort of patients initiating opioid treatment for FM.

Methods

Retrospective cohort study combining several population-wide databases from the Valencia Health System Integrated Database, covering a population of five million inhabitants. We included all patients aged 18 years old and over who were initiated opioid treatment from 2014 to 2018 for FM.

Results

We identified 12,977 patients that initiated opioid therapy for FM. Mean age was 56.6 years old, 74,72% were female, 84.87% were Spanish and 73.86% earned less than 18.000 euros a year. Main comorbidities were hypertension (39.46%), depression (30.59%) and diabetes (14.45%), and 15.28% had registered tobacco use. Most patients started tramadol therapy (85.65%), 9.66% started long-acting opioids (with tapentadol the most prescribed, 5,61%) and 4.69 started codeine. Median duration of the initial therapy was 14 (IQR: 6,34), 25.64% started opioids for more then one month, and median daily MME was 11.25 (IQR: 7.50,13.50). More than a third of patients (36.58%) were using benzodiazepines when starting opioids.

Conclusion

The use of opioids in FM should be monitored and potentially inappropriate patterns of use addressed.

AN EXPLORATION OF THE RISK MANAGEMENT OF THALIDOMIDE IN JORDAN: A MIXED METHODS STUDY

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ABSTRACT

Background

Thalidomide, a teratogenic medicine, has been repurposed for the treatment of multiple myeloma after being withdrawn from the market in the 1960s. This study aimed to explore the risk management of thalidomide in Jordan with a view to understanding the relevance of this to the patient population.

Methods

A sequential mixed methods approach, with quantitative data derived from patient questionnaires and extracted from medical records. Qualitative data were obtained from semi-structured patient interviews. Descriptive statistics were used to analyse quantitative data and these were subsequently combined with qualitative data which were analysed thematically to provide a deeper insight of the research question.

Results

Based on medical records, mean age of patients using thalidomide (SD) was 60.6 (11.4) years. Quantitative data from 63 medical records and 29 patient questionnaires showed that contraceptive counselling and contraceptive use were more likely to be reported by patients than documented in medical records. However, while pregnancy testing before starting thalidomide was commonly documented in medical records it was not reported by any female participants. Patients reported how thalidomide was used which highlighted a potential contribution of younger family members in this. Knowledge of the teratogenic risk of thalidomide, and how to avoid foetal exposure, suggests some misconceptions regarding this; however, because of the age of patients risk management was not considered important.

Conclusion

Findings of the study suggest current management of the teratogenic risk of thalidomide is not well aligned to the patient profile or needs.

SAFETY PROFILE OF BIOLOGICS USED IN RHEUMATOLOGY: A MULTICENTER, PROSPECTIVE OBSERVATIONAL PHARMACOVIGILANCE STUDY IN THE CALABRIA REGION

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ABSTRACT

Background

The group of diseases known as inflammatory arthritis are characterized by similar clinical traits, such as those of inflammatory and chronic nature caused by an overactive immune system. In recent years, emerging biological agents have been widely used, although the adverse effects (AEs) have not been thoroughly investigated. The goal of the present study is to describe the preliminary results of a Regional Pharmacovigilance Program (Calabria, Italy) designed to improve reporting of AEs related with biologics use in rheumatology.

Methods

The present work is a multicenter, prospective, observational cohort study based on the Calabria Biologics Pharmacovigilance Program. All consecutive patients treated with one biologic agent from January 2016 to January 2022 and satisfying inclusion criteria were enrolled. Clinical characteristics of patients, type of treatment used, failures, switch/swap to another biologic, and possible onset of AEs were collected.

Results

Overall, 729 (86.3%) of a total of 872 patients did not show AEs or SAEs, whereas 143 (16.4%) patients exhibited at least one AE, of which 16 (1.8%) had at least one SAE. The most common AEs were administration site conditions followed by gastrointestinal, nervous system and skin disorders. We described a total of 173 switches and 156 swaps. Switches mainly occurred for inefficacy (136; 77.7%), whereas only 39 (22.3%) were due to the onset of an AE.

Conclusions

This study confirms the efficacy of our program in monitoring and detecting AEs in the rheumatological area, demonstrating the positive beneficial/risk ratio of biologics.

POTENTIALLY INAPPROPRIATE PRESCRIBING AND ITS ASSOCIATION WITH ADVERSE DRUG REACTION-RELATED HOSPITAL ADMISSIONS

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ABSTRACT

Background

This study aims to examine the prevalence of potentially inappropriate prescribing (PIP) and Potential Prescription Omissions (PPO) among older adults (≥ 65 years) and their associations with adverse drug reaction (ADR)-related hospital admissions.

Methods

This study used the Adverse Drug Reactions in an Ageing Population (ADAPT) cohort (N=361 ADR-related hospital admissions; 437 non-ADR related admissions). Information on patient medications, primary presenting issue and co-morbidities at hospital admission were extracted. All medications were coded using WHO ATC codes. PIPs were assessed using Beers Criteria (2019) and STOPP Version 2. PPOs were assessed using the START criteria. Multivariable logistic regression was used to examine the association between PIP, PPO and where the admission was ADR-related or not, adjusting for covariates (age, gender, comorbidity, polypharmacy).

Results

In total 715 (90%; 95%CI 87%-92%) patients had at least one Beers PIP criteria, 555 (70%; 95%CI 66%-73%) had at least one STOPP PIP criteria and 671 patients (84%; 95%CI 81%-86%) had at least one START PPO criteria. Being prescribed at least one Beers PIP was not significantly associated with the admission being ADR-related, after adjusting for covariates (adjusted OR=1.66, 95%CI=1.00-2.77, $p=0.05$), as was the case for having a STOPP PIP criteria or a START PPO criteria (STOPP OR=1.07, 95%CI=0.79-1.45) and (START OR=0.72; 95%CI=0.50-1.06). Results were similar considering number of PIP/PPO criteria.

Conclusion

Despite a high prevalence of PIP and PPO in this hospital admissions cohort, there was no association with the admission being ADR-related. Predictive factors for ADR-related admissions are still poorly understood.

SEX DISPARITIES IN TREATMENT PATTERNS AFTER METFORMIN INITIATION AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS

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ABSTRACT

Background

Guidelines recommend metformin as first choice treatment for most type 2 diabetes mellitus (T2DM) patients, with the possibility to change doses and add or switch to other drugs when glycated hemoglobin (HbA1c) levels are uncontrolled or metformin is not tolerated. We aimed to assess sex differences in such treatment patterns after metformin initiation among T2DM patients.

Methods

A cohort study was conducted using the Groningen Initiative to ANalyze Type 2 diabetes Treatment (GIANTT) primary care database. Patients aged ≥ 18 years initiating metformin were followed for 2-5 years. Markov modeling was conducted to estimate treatment transition rates and calculate hazard ratios (aHR) comparing men with women adjusted for age, cardiovascular history, and HbA1c level at initiation. Kaplan-Meier analyses and Cox proportional hazards regression models were used to determine the time to and likelihood of getting intensification. HbA1c levels at initiation and intensification were compared using Mann-Whitney U tests.

Results

In total, 11,508 metformin initiators were included (50.1% women). The most common transition after initiation was a dose increase (probability women 0.52, men 0.59, not significantly different). Women were more likely to switch to another oral hypoglycemic drug after initiation (aHR:1.66, 95%CI:1.31-2.12), and after a dose increase (aHR:1.48, 95%CI:1.10-1.98) or decrease (aHR:2.64, 95%CI:1.28-5.46). Time to intensification was longer, time to switching shorter, and HbA1c levels at initiation and intensification were lower for women.

Conclusion

Observed sex disparities in treatment transitions after metformin initiation suggest that prescribers acknowledge more tolerance problems for metformin in women. Underlying factors and impact need further study.

GENERAL PRACTITIONER ADHERENCE TO ANTIBIOTIC PRESCRIBING GUIDELINES FOR EAR AND RESPIRATORY CONDITIONS IN DUTCH GENERAL PRACTICE BEFORE AND DURING COVID-19

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ABSTRACT

Background

Optimising antimicrobial prescribing practices in primary care is essential to improve antibiotic use and prevent antimicrobial resistance.

Aim

To investigate adherence to treatment guidelines of Dutch general practitioners for respiratory tract and ear conditions and the effect of the COVID-19 pandemic hereon.

Methods

A retrospective observational study in which prescription data from the Nivel Primary Care Database from 2018-2021 were used to determine general practitioner adherence to treatment guidelines from the Dutch College of General Practitioners for ear and respiratory tract conditions. Decision to prescribe and choice of antibiotics were investigated. Data were corrected for patient characteristics and analysed using descriptive statistics and multi-level logistic regression analyses.

Results

In 446 general practices, inappropriate antibiotic prescribing occurred most often for acute bronchitis/bronchiolitis (38.7%), acute otitis media (33.0%) and acute sinusitis (31.1%) with several other conditions for which non-indicated prescribing rates are above 10%: tonsils symptoms/complaint, sinus symptoms/complaint, acute upper respiratory tract infections and acute laryngitis/tracheitis. Inappropriate prescription rates decreased for most of the respiratory conditions during the COVID-19 pandemic, such a decrease was not found for ear conditions. There is high interpractice variability for inappropriate antibiotic prescribing.

Conclusions

Inappropriate antibiotic prescribing still occurs, even though on average practice has improved over the past years. High practice variability suggests a more individual practice-based approach could be most effective in improving antibiotic prescribing.

SEX DISPARITIES IN MEDICATION PRESCRIBING AMONGST PATIENTS WITH TYPE 2 DIABETES MELLITUS MANAGED IN PRIMARY CARE

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ABSTRACT

Background

Sex differences in clinical outcomes have been observed for patients with type 2 diabetes mellitus (T2DM). These could be related to sex disparities in treatment. We aimed to determine whether there are sex disparities in medication prescribing amongst patients with T2DM.

Methods

A cohort study was conducted using the Groningen Initiative to ANalyze Type 2 diabetes Treatment (GIANTT) database, which includes data from Dutch primary care patients with T2DM. Data on demographics, physical examinations, laboratory measurements and prescribing were extracted. Validated prescribing quality indicators assessing the prevalence, start, intensification and safety of glucose-, lipid-, blood pressure- and albuminuria-lowering medication were applied for the calendar year 2019. Odds ratios (OR) from logistic regression analyses are presented.

Results

We included 10,456 patients (47% females). Females were less often treated with metformin (81.7% vs. 86.5%; OR:0.70, 95%CI:0.61–0.80), and were less often prescribed a renin-angiotensin-aldosterone inhibitor (RAAS-i) when treated with multiple blood pressure-lowering medicines (81.9% vs. 89.3%; OR:0.55, 95%CI:0.46–0.64) or when having albuminuria (74.7% vs. 82.1%; OR:0.64, 95%CI:0.49–0.85) than males. Statin treatment was less frequently started (19.7% vs. 24.7%; OR:0.75, 95%CI:0.58–0.96) and prescribed (58.7% vs. 63.9%; OR:0.80, 95%CI:0.73–0.89) in females. There were no differences in starting and intensifying glucose-, blood pressure- and albuminuria-lowering medication.

Conclusion

Sex disparities in medication prescribing amongst T2DM patients were seen, including less starting with statins and potential undertreatment with RAAS-i in females. Such disparities may partly explain higher excess risks for cardiovascular and renal complications associated with diabetes observed in females.

ASSESSING DURATION OF ANTIBIOTIC THERAPY ACROSS HOSPITALS IN SCOTLAND INCLUDING THE IMPACT OF COVID-19 PANDEMIC: A SEGMENTED INTERRUPTED TIME SERIES ANALYSIS

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ABSTRACT

Background

Inappropriate antibiotic use, including unnecessary longer duration of therapy, is the key driver for antimicrobial resistance. Yet, evidence on duration of antibiotic use in hospital settings is scarce. This study evaluated duration of hospital antibiotic therapy for four commonly prescribed antibiotics (amoxicillin, co-amoxiclav, doxycycline and flucloxacillin) including the assessment of COVID-19 impact.

Methods

This study was a repeated, cross-sectional study using the Hospital Electronic Prescribing and Medicines Administration system (January/2019-March/2022). Monthly median duration of therapy/duration categories (≤ 3 days, $>3-5$ days, $>5-7$ days, $>7-10$ days and >10 days) were calculated, stratified by routes of administration (oral, IV and "Both"), age and sex. Impact of COVID-19 was assessed using segmented time-series analysis.

Results

There were significant variations in the median duration of therapy across routes of administration ($P < 0.05$), with the highest value among those antibiotic courses comprised of both oral and IV antibiotics ("Both" group) but IV route consistently had the lowest median duration of therapy. Significantly higher proportions of prescriptions within the "Both" group had a duration of > 7 days compared to oral or IV. Duration of therapy overall differed significantly by age. Some small statistically significant changes in the level/trends of duration of therapy were observed in the post- COVID-19 period, albeit clinically insignificant.

Conclusions

No evidence for prolonged duration of therapy were observed, even during COVID-19 pandemic. Duration of IV therapy was relatively short suggesting timely clinical review and consideration of IV to oral switch. Longer duration of therapy was observed among older patients.

BIOLOGICS AND BIOSIMILARS – WHAT PRESCRIBING DATA DOESN'T TELL US – INSIGHTS FROM THE VIP bDMARDS PROGRAM

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ABSTRACT

Introduction

The success of educational or regulatory strategies encouraging the use of biosimilars over bio-originators is usually measured by prescribing rates, providing limited information on reasons for potential variations in their uptake. The evaluation of the Australian Value in Prescribing bDMARDS program provided insights into motivations for clinicians' choices of TNF-inhibitor formulations and brands.

Methods

Clinician feedback obtained during the realist evaluation of the ViP bDMARDS educational visiting program, which encouraged the uptake of biosimilar TNF-inhibitors in the treatment of inflammatory bowel disease (IBD), rheumatoid arthritis (RA), plaque psoriasis (CPP), was analysed thematically.

Results

For the treatment of CPP, TNF-inhibitors are rarely indicated as first- or second-line therapies, currently limiting the scope of dermatologists in prescribing biosimilars. In IBD, many patients need escalated doses to achieve clinical remission (at least temporarily), with necessary extra doses often supplied by manufacturers, which may influence gastroenterologists' and hospitals' choice of biologic brand. Rheumatologists potentially experience the lowest barriers to prescribing a range of biosimilar TNF-inhibitors. Prescribers are concerned about patients' adherence with different injectable devices when changing between brands. Many prescribers and patients access available manufacturer support programs for self-administered medicines.

Conclusion

Across just three specialties and indications the uptake of biosimilars follows different patterns, guided by considerations unique to treated illness, individual clinician and patient needs as well as safety, efficacy and economics. Knowledge of implicit and contextual drivers for choice of biologics and biosimilars can contribute to educational and regulatory efforts to influence their prescribing.

POTENTIALLY INAPPROPRIATE MEDICATIONS IN HUNGARY: CENTRAL NERVOUS SYSTEM MEDICATION USE AMONG THE ELDERLY

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ABSTRACT

Background

Potentially inappropriate medications (PIMs) increase the risk of drug-related problems so their common use among the elderly is worrisome. The aim of this study was to investigate the frequency of PIM use and potential gender differences in this sensitive patient group.

Methods

Aggregated national drug utilisation data of 764 196 elderly patients (≥ 75 years, who redeemed at least 1 prescription in 2019) were obtained from the Hungarian National Healthcare Service Center, covering a period of 1 year. Adapting international PIM lists to identify PIMs in our dataset, a national PIM list was compiled, adjusted to the Hungarian drug spectrum. We focused on WHO's 'N' ATC main group, assessing active ingredients that were used by at least 1% of our study population.

Results

Eleven PIMs were found (alprazolam, carbamazepine, chlordiazepoxide, clonazepam, medazepam, midazolam, paroxetine, piracetam, tramadol, zolpidem, zopiclone). Seven of the eleven PIMs were benzodiazepine receptor agonists. Alprazolam was the most common PIM (used by 30.3% of the study population), accompanied by piracetam (12.2%) and tramadol (8.0%). A gender difference was observed in the use of all eleven PIMs: almost all of them were more frequent among women. The gender difference was the most marked in alprazolam use (35.8% of the women were alprazolam users, while 19.1% of the men were affected). Carbamazepine was the only active ingredient with a greater ratio of male users.

Conclusions

Our results revealed significant benzodiazepine receptor agonist use among the elderly, particularly among women.

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IMPROVING ACCESS TO ESSENTIAL MEDICINES THROUGH A SYNERGIC APPROACH. WHO ESSENTIAL MEDICINES LIST APPLICATION OF TREATMENTS FOR MULTIPLE SCLEROSIS.

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ABSTRACT

Background

The WHO Essential Medicines List (EML) is a reference guide for countries for the development and updating of national lists of essential medicines. Inclusion of a medicine in the EML facilitates its access in limited resource settings, promoting equity in health. The Bologna WHO Collaborating Centre in Evidence-Based Research Synthesis and Guideline Development (BCC), part of the public health system of the Region Emilia-Romagna (Italy), is mandated by the WHO to develop applications for the inclusion of medicines in the EML.

Methods

The BCC in collaboration with the Multiple Sclerosis International Federation, developed an application for the inclusion of disease-modifying therapies (DMTs) for multiple sclerosis (MS) in the EML. Prioritization of medicines was informed by multi-stakeholder panels that developed evidence-based guidelines on the treatment of MS by means of the GRADE methodology. Evidence synthesis on efficacy and safety of DMTs was provided by the Cochrane Review Group on MS and Rare Diseases of the Central Nervous System.

Results

The BCC and MSIF submitted to the WHO an application, developed by means of rigorous, transparent methodology, for the inclusion of the first DMTs for MS in the 23rd Model List of Essential Medicines. Such process was informed by stakeholders from low-resource settings.

Conclusion

Collaboration and synergy among entities involved in health decision-making may avoid resource waste and conflicting decisions. This is particularly important when equitable access to medicines at a global level is at stake, like in the development of WHO EML applications.

THE (IN)APPROPRIATE USE OF ANTIBIOTICS IN PRIMARY CARE IN ITALY

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ABSTRACT

Background

This study aims to estimate the prevalence of inappropriate use of antibiotics when prescribed for acute respiratory tract infections and acute lower urinary tract infections in primary care in Italy.

Methods

Using the Health Search Database the prevalence of inappropriate antibiotics use in outpatients aged ≥ 14 years during the years 2018-2021 was calculated.

Inappropriate prescription was defined as: a) (any) antibiotic being prescribed for flu or flu-like syndromes, common cold or acute laryngotracheitis; b) fluoroquinolones, cephalosporines or macrolides prescribed in patients with pharyngitis or acute tonsillitis; c) injectable cephalosporins and fluoroquinolones in patients with a diagnosis acute bronchitis; d) fluoroquinolones (as fist-line therapy) in women diagnosed with uncomplicated cystitis.

Results

In 2021, the prevalence of inappropriate use of antibiotics was greater than 24% for every examined indication. The highest values were observed in older age groups and in the South of Italy. Overall, after a decrease of inappropriate use observed between 2018 and 2019; the rate newly increased in 2020-2021. In particular, the prevalence of inappropriate use of antibiotics increased in patients diagnosed with pharyngitis or acute tonsillitis and in those with acute bronchitis. As for flu, cold or acute laryngotracheitis, the prevalence decreased in 2020, while it rose in 2021. Finally, uncomplicated cystitis, after the increase in 2020, showed a stability in 2021.

Conclusion

Our findings indicate the need for specific interventions aiming to promote the appropriate use of antibiotics in Italian primary care setting in order to prevent antimicrobial resistance in Italy.

MEDICATIONS USE IN ITALIAN NURSING HOMES: PRELIMINARY RESULTS FROM THE NATIONAL MONITORING SYSTEM

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ABSTRACT

Background

Long-term care nursing homes (NHs) for older people are an important clinical setting showing deep regional heterogeneity and only a few data on medications use are available. This study aimed to describe medications used by older adults in Italian NHs and identify areas of inappropriateness.

Methods

Data on drug consumption and expenditure were extracted from the "Direct and per conto distribution" flow for the years 2018 and 2019. Only information from Regions/Autonomous Provinces showing high data quality were used (Bolzano, Veneto, Friuli Venezia Giulia, Emilia Romagna and Umbria). The characteristics of NHs were extracted from the Italian Health Ministry.

Results

In 2019 total consumption of medications amounted to 797.86 DDDs per 100 days of NH stay, with a reduction, compared to that of 2018, of 5.2%. Drugs for the cardiovascular system accounted for 22.2% of all DDDs, blood drugs had the highest cost per day of NH stay (0.33 euros) and antiparasitic products had the highest cost per DDD (1.11 euros). Furosemide (48.7 DDD/100 days of NH stay), ramipril (36.7 DDD), lansoprazole (34.5 DDD), acetylsalicylic acid (29.4 DDD) and lactulose (28.0 DDD) were the most used substances.

Conclusion

According with the most frequent diseases diagnosed in elderly, treatment of hypertension and heart failure are the most used drugs. Antiulcer drugs and laxatives which showed high consumption represented areas of potential inappropriateness, as well as antibiotics with high resistance potential. Nursing homes are an ideal setting to monitor the older people's pharmacological therapy and to define quality improvement initiatives.

OUTCOMES OF TIGECYCLINE USE IN A TERTIARY CARE HOSPITAL: ROLE OF CLINICAL PHARMACIST

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ABSTRACT

Background

Tigecycline is an antibiotic for treatment of multidrug-resistant bacteria. In Thailand, it is still a restricted drug that requires drug use evaluation. Clinical pharmacist interventions (CPI) are conveyed to physician when drug-related problems occurred. The aim of this study was to evaluate mortality, adverse drug reactions (ADRs) and factors affecting mortality in patients received tigecycline.

Methods

A cross-sectional retrospective study was conducted between January 2017 and June 2020. Electronic medical records of hospitalized patients who received tigecycline at least 3 days and documented CPI were evaluated. Mortality and ADRs were evaluated at the end of treatment. Binary logistic regression was performed to identify factors associated with mortality.

Results

Of 252 patients (67.1% male, average age 65.3±17.3 years old) were included in this study. Tigecycline was used as combination therapy (98.8%) and specific treatment (81.3%) for multidrug-resistant *Acinetobacter baumannii* (54.4%) and Carbapenem-resistant Enterobacteriaceae (19.8%) in hospital-acquired pneumonia (50.3%). Median duration of treatment was 10.0 (IQR 6.0–14.0) days. Mortality rate was 32.1%. Only 43 (17%) patients received CPI, mortality rate in CPI group (20.9%) was lower than non-CPI group (34.4%), ($p=0.084$). No ADR was found. Renal dysfunction (OR 7.7, 95% CI 2.9-20.8, $p<0.001$) and hepatic dysfunction (OR 3.2, 95% CI 1.7-6.0, $p<0.001$) were significantly associated with mortality.

Conclusion

Tigecycline showed favorable treatment outcomes without adverse effects. Renal and hepatic dysfunction were associated with mortality. Our study fail to show benefit in statistically reduced mortality by CPI. However, further studies should be conducted because of a few patients received CPI.

THE REAL-WORLD EFFECTIVENESS OF GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS VS. OTHER GLUCOSE LOWERING AGENTS ON STROKE: A SYSTEMATIC REVIEW AND META-ANALYSIS OF OBSERVATION STUDIES

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ABSTRACT

Background

The real-world effectiveness of Glucagon-like peptide-1 receptor agonists (GLP-1RAs) on stroke disease were still controversial. We aimed to conduct a systematic review of observation studies to evaluate the stroke effectiveness of GLP-1RAs.

Methods

We searched Pubmed and Embase databases from 2006 to October 2022 for observation studies comparing GLP-1RAs with non GLP-1RAs in the patients with type 2 diabetes mellitus (T2DM). The outcomes of interest was any type of stroke (i.e., hemorrhagic and ischemic stroke). We only included cohort designed studies, higher level of evidence in observation study, in our study. Studies were screened independently by two reviewers for eligibility, extracting data, and assessing the risk of bias and certainty of evidence. Pre-defined subgroup analyses, including different glucose lowering agents and subtype of stroke, were performed.

Results

A total of 29 studies were included, including 1,287,927 patients (adjusted population), which mean age was between 49 and 73 years. In primary analysis, use of GLP-1RAs was associated with lower stroke risk (hazard ratio [HR], 0.86; 95% confidence interval [CI], 0.81-0.91) compared to non GLP-1RAs. In the subgroup analyses, GLP-1RAs was consistently associated with a greater reduction in stroke events compared to sodium-glucose co-transporter 2 inhibitors (SGLT-2i) [HR: 0.90 (0.84-0.97); thirteen studies], dipeptidyl peptidase-4 inhibitors (DPP4i) [HR, 0.81 (0.73-0.90); five studies], insulin [HR, 0.52 (0.37-0.74); three studies].

Conclusion

The use of GLP-1RAs were associated with a clinical benefit on stroke events compared to non GLP-1RAs, including SGLT-2i, DPP4i and insulin in T2DM patients.

AN APPROACH TO EVALUATE APPROPRIATENESS IN THE ANTIBACTERIAL THERAPY USING THE WHO AWARE CLASSIFICATION

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ABSTRACT

Background

WHO launched the global AWARe campaign to promote the use of a new tool that classifies WHO EML antibiotics into 3 categories: Access, Watch and Reserve. WHO includes a country-level target of at least 60% of total antibiotic consumption being Access. The study proposes the use of the AWARE indicator also to hospital antibacterial data.

Methods

ATC/DDD methodology was used for the data analysis and has been introduced the AWARe classification for antibacterial drugs. The consumption rates (jan-sept 2022) were calculated in the Surgical Department (which includes intensive care, general and specialist surgical units) and Medical Department (infectious diseases and specialist medicines) in the Ravenna Hospital, Emilia Romagna region (Italy). The indicator was also applied to both hospital and outpatient antibacterial data in the same data range of the region.

Results

Only four units of the Surgical Department achieved the WHO target for the Access class: dermatology (71.50%), ophthalmology (67.52%), vascular surgery (62.70%) and emergency surgery (61.02%). Reserve antibiotics reach significant percentages especially for the Intensive Care Units. In the Medical Department, only gastroenterology achieves the target (66.78%). As regards the regional data, in the outpatient antibiotic data the prevailing consumption is of the Access drugs followed by the Watch; the percentage of Reserve remains limited to hospital consumption.

Conclusion

This tool, shared internationally, allows to monitor the trend in antibiotic consumption and analyze the variability in the use of ACCESS/WATCH/RESERVE drugs also in hospital, allowing to develop ad hoc interventions promptly with a multidisciplinary approach.

UTILIZATION OF ANTIINFECTIVES IN PEDIATRIC WARDS OF FIVE BRAZILIAN HOSPITALS

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ABSTRACT

Introduction

Antiinfectives are among the most prescribed drug classes in pediatrics, mainly for in-patients. This study aims to describe utilization of antiinfectives in hospitalized children in five Brazilian hospitals.

Methods

A descriptive study was carried out in hospital pediatric wards in Ceará (CE), Sergipe (SE), Federal District (DF), Rio de Janeiro (RJ) and Rio Grande do Sul (RS). Prescription data were collected for a six-month period (during 2018 and 2020) and were calculated per patient. Analyses involved patient characteristics and measures of antiinfective use (in days of therapy DOT/1000 patient-days and length of therapy LOT/1000 patient-days). The DU90% was employed to identify most prescribed antiinfectives. The AWaRE classification was used to analyze use of antibacterial agents. The study received approval by the Ethics Committee of the Sergio Arouca National School of Public Health.

Results

Characteristics of 1020 children were described. Age and sex were similar but hospitals differed in relation to comorbidities, history of PICU admissions and length of stay. Most frequent diagnosis was respiratory tract infections. DOT/1000PD and LOT/1000PD showed large variation among hospitals, 278-517, and 265-390 respectively. The hospital in SE presented the most intensive use. Ceftriaxone, followed by penicillins and second-generation cephalosporins were the most used drugs. DU90% showed important antifungal use in RJ. Access group was prevalent in two hospitals, while Reserve use happened in three.

Conclusion

The use of antiinfectives in Brazilian pediatric wards varied in intensity and privileged penicillins and cephalosporins, especially of the Access group.

COMMUNITY CONSUMPTION OF ANTIBIOTICS FOR SYSTEMIC USE IN BRAZIL: A 7-YEAR POPULATION-BASED STUDY

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ABSTRACT

Introduction

Excessive or indiscriminate use of antibiotics has been linked to antimicrobial resistance (AMR) with clinical, economic, social, and environmental impacts. Analyses of hospital and community dispensing help to describe utilization and understand determinants of AMR. This work describes the profile of community consumption of antibiotics for systemic use in Brazil, through a population-based study.

Methods

Retail pharmacy data on dispensing antibiotics to individuals ≥ 15 years, from January 2014 to December 2020, were collected. Annual consumption was expressed according to the number of Defined Daily Doses per 1000 inhab/day (DID), the compound annual growth rate (CAGR), and quality indicators for community consumption of antibiotics, according to ESAC.

Results

Approximately 88% of dispensations originated from a physician's prescription and the rest from dentists. Total consumption in Brazil for the period amounted to 4.590.329.296 DID, with a 4.8% CAGR (non-linear trend, $p=0,357$). 2020 recorded the highest percent variation in consumption (31.2%) with regional variation (93.7% - 23.0%). The ratio between consumption of broad to straight-spectrum antibiotics rose 0.32% and was expressive in 2019 and 2020 (67,9%) possibly due to Covid-19.

Conclusion

A worrisome scenario is presented, due to the rise in community consumption and other factors such as Covid-19. An increase in broad-spectrum use emphasizes favorable conditions for AMR and must be considered a priority in surveillance and stewardship programs focusing on community use.

FIRST USE OF ANTINEOPLASTIC AGENTS AMONG HER-2-POSITIVE WOMEN IN THE STATE OF RIO DE JANEIRO, BRAZIL

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ABSTRACT

Background

Breast cancer is a complex condition, with high clinical, morphological and biological heterogeneity. Women who are HER-2 positive present with worse prognostic, greater chances of recurrence and less global survival. In Brazil, 30% present with HER-2 positive gene, for which trastuzumab is the treatment of choice.

Methods

The Outpatient Information System (SIA/SUS) was used to extract data for chemotherapy procedures from 2013 to 2019 in the state of Rio de Janeiro. The first chemotherapy procedure was selected for each woman, and among these the cases in which a HER-2 positive diagnosis had been made to verify the treatment.

Results

Of 23,232 women, 1,356 (5.84%) were HER-2 positive. Women were predominantly white (39.31%), aged 40-59 years (52.80%), and residing in the capital city (69.21%); with advanced stage 3 (65.41%) and no information on lymphnode involvement (50.44%). Around 60% of all HER-2 positive patients received trastuzumab in their first treatment, in poly or monotherapy. Most common regimens were TAC (docetaxel, doxorubicine, cyclophosphamide) + trastuzumab (24.63%); TAC (17.70%); and trastuzumab alone (14.09%).

Conclusion

Results may reflect challenges faced by SUS (Brazilian Health System) to treat all HER-2-positive women in a timely fashion, as late stage at immuno-histochemical diagnosis shows. Otherwise, treating only a 60% fraction of these patients in need of trastuzumab may show substandard care.

SYNEPHRINE: USEFUL TOOL TO PROMOTE WEIGHT LOSS OR A POSSIBLE SOURCE OF CARDIOVASCULAR RISK?

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ABSTRACT

Background

Obesity has become a pandemic resulting in increased morbidity and mortality. Therefore, health care professionals seek for safe and effective therapeutic agents, and patients wish for products with quick onset of activity and long-lasting effects. Lately, p-synephrine has gained considerable interest as an ingredient of weight loss products. Since synephrine or synephrine-containing extracts (e.g. bitter orange extract) can be legally used in food supplements in several European countries; it is important to clarify its safety profile.

Methods

To confirm the safety and efficacy of p-synephrine, we have performed a meta-analysis based on the available clinical trials. Literature searches were conducted using EMBASE, PubMed, Web of Science and the Cochrane Library. Only human clinical trials examining known doses of synephrine were included. The assessment of weighted mean difference and effect sizes between test and control group values (synephrine vs control) was performed as a post-post analysis. Heterogeneity was assessed by using Chi2 or Tau2 tests.

Results

A total of 18 studies involving 341 patients were included in the final quantitative analysis. The effects of synephrine on the body weight and body composition were non-significant. Taking into account that according to our analysis p-synephrine might increase systolic blood pressure and heart rate and systolic and diastolic blood pressure, the benefit/risk ratio of its use is unfavourable.

Conclusions

The use of synephrine is not without cardiovascular side effects, and its desired effects on body weight and composition falls short of the expectations, i.e. not significant statistically.

COMPARATIVE EFFECTIVENESS OF ANTI-HYPERTENSIVE MONOTHERAPIES IN PRIMARY PREVENTION OF CARDIOVASCULAR EVENTS - A LONGITUDINAL INCEPTION COHORT STUDY

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ABSTRACT

Background

Anti-hypertensive drugs can prevent cardiovascular events. However, real-world comparative drug effectiveness studies taking long-term use and adherence into account are absent. We aim to determine the relative effectiveness of anti-hypertensive monotherapies (ACEIs, ARBs, BBs, CCBs, thiazides) in primary prevention of cardiovascular events in longitudinal cohorts.

Methods

We conducted a retrospective inception cohort study covering a 10-year study period using the University of Groningen IADB.nl database with data from 1996 to 2020. Patients were aged ≥ 18 years free of any cardiovascular drugs prior to initiation of monotherapy. Cohort 1 included adherent patients, cohort 2 included all patients independent of adherence. Sensitivity analysis was done for patients without or only with drug switches or drug add-on. Outcome was the time to first prescription of acute cardiac-drug-therapy as a proxy for cardiovascular events. Effectiveness was estimated using inverse probability of treatment-weighted time-varying Cox regression.

Results

Among cohort 1 (n=15,823), both ARB and thiazide starters had lower hazards than BBs in preventing cardiovascular events (0.80, 95%CI [0.65-0.98]; 0.62, 0.53-0.72). Among cohort 2 (33,427), both ACEI and thiazide starters had lower hazards than BBs (0.87, 0.76-1.00; 0.81, 0.69-0.94), while CCB starters showed higher hazards (1.25, 1.01-1.54). In patients with initial rheumatoid arthritis (RA) and/or initial diabetes drugs, both cohorts showed lower hazards of thiazides compared with BBs than in the total population. Sensitivity analyses showed similar results.

Conclusion

Thiazide monotherapy appeared to be more effective than BBs in the prevention of cardiovascular events, notably among patients on initial RA and/or diabetes drugs.

THE CONSUMPTION OF HUMAN AND VETERINARY ANTIBIOTICS IN ESTONIA, 2013-2022

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ABSTRACT

Background

The use of antibiotics has been quite low and stable in Estonia over the past ten years compared to the other European countries, in both human and veterinary medicine. The aim of this study was to analyse the changes in the consumption of antibiotics during the years of pandemic.

Methods

Estonian State Agency of Medicines collects drug utilization data nationally on wholesale level for human and veterinary medicines, covering 100% of the market. The data is analysed according to the WHO ATC/DDD and ATCvet methodology, as well as mg/PCU-methodology for veterinary medicines.

Results

The total consumption of human antibiotics has remained practically on the same level over the past years, being approximately 12 DDD/1000/day from 2013-2019. During the years of pandemic, 2020 and 2021, the overall use of human antibiotics decreased by 13% and 16%, respectively. In 2022, the consumption of antibiotics increased to the pre-pandemic level. The total consumption of veterinary antibiotics has slightly decreased over the past years from 70mg/PCU in 2013 to 54mg/PCU in 2019. There was a significant increase in 2014 (77mg/PCU). From 2020 (49mg/PCU) to 2021 (47mg/PCU), the overall antimicrobial consumption has decreased.

Conclusion

The restrictions during pandemics had a clear influence on the need for human antibiotics and the overall consumption decreased remarkably. However, this decrease was temporary, and the consumption of human antibiotics increased in 2022 to the pre-pandemic level. The pandemic has had no significant impact on the consumption of veterinary antibiotics.

DRUG USE PATTERNS IN MYASTHENIA GRAVIS PATIENTS: A REAL-WORLD OBSERVATIONAL STUDY IN ITALY - THE CAESAR STUDY

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ABSTRACT

Background

Myasthenia gravis (MG) is an autoimmune disorder treated with several non-specific drugs. In the context of a comparative study of efficacy and safety of drugs used in rare neuromuscular and neurodegenerative diseases (CAESAR - call AIFA_FV_2012-13-14) we assessed the use patterns of drugs indicated for MG.

Methods

A retrospective cohort study was conducted based on administrative healthcare data. For a cohort of MG patients, prevalent and incident use of pyridostigmine (Py) and other indicated drugs in the first year after case identification was evaluated. Prevalent combined use of major therapies (azathioprine (Az), prednisone (Pr), vitamin d (Vd)) stratifying by PI use was assessed, and a comparison between therapies at MG identification date and during the first year of follow-up was performed.

Results

We included 1,114 MG patients in 2013-2019. In the first year of follow-up, we observed prevalent and incident use of Py in 60% and 3.5% of patients, respectively, 57.1% and 4.4% for Pr, 24.7% and 3.3% for Az, and 42.5% and 8.2% for Vd. Among 668 Py prevalent users, 19.9% also used Az, Pr and Vd, while 13.2% none of these. Among 446 non-Py users, 2.9% used Az, Pr and Vd, 58.3% none of these. An increase of combined therapies was evident in incident Py users, but not in non-Py users.

Conclusion

Most MG patients use Py, often in combination with one of more drugs among Az, Pr, Vd, while most non-Py users are not treated with either of these drugs.

POINT PREVALENCE OF ANTIPSYCHOTIC AND ANTIDEPRESSANT USE IN RELATION TO FIRST DIAGNOSIS OF PSYCHOTIC DEPRESSION

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ABSTRACT

Background

According to guidelines, psychotic depression (PD) should be treated with both antipsychotics and antidepressants, but current practice is largely unknown. We aimed to investigate the prevalence of antidepressant and antipsychotic use among newly diagnosed PD patients.

Methods

We identified persons aged 16-65 with first-time diagnosis of PD (ICD-10 codes F32.3, F33.3) from nationwide data-linkage of Finnish registers during 2000-2018. Point prevalence was measured as 2-week time windows every three months, investigating whether the person had a PRE2DUP-modelled drug use period ongoing during the window or not, censoring to death and end of data linkage (31st Dec 2018).

Results

The final study population included 19,330 persons (57.9% women; mean age 39.8 years, SD 14.7). The point prevalence of use for antidepressants (75.0%), antipsychotics (56.4%), and for both (50.0%) was highest at 3 months after the PD diagnosis. The prevalence declined to 52.0%, 34.4%, and 28.7%, respectively, at 3 years after the diagnosis. In a logistic regression analysis, factors associated with antipsychotic use during first three months after diagnosis (vs. not using) were younger age (adjusted OR for age <25 vs. ≥55, 0.84 [95% confidence interval 0.76-0.93]), diagnosis from inpatient care (1.61 [1.51-1.71]), previous depression (1.20 [1.12-1.27]), and, inversely, substance use disorders (0.80 [0.73-0.87]) and eating disorders (0.80 [0.68-0.94]).

Conclusion

In contrast with treatment guidelines, only half of those with a newly diagnosed PD were treated with both antidepressants and antipsychotics at three months from the diagnosis, and the prevalence declined thereafter. This likely has a negative impact on treatment success.

THE PREVALENCE OF HYPOGLYCEMIA RISK AMONG PATIENTS WITH DIABETES IN THE NETHERLANDS

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ABSTRACT

Background

Hypoglycemia is a complication associated with glucose-lowering treatment. The aim of this study was to describe the prevalence of hypoglycemia risk among patients with diabetes and to explore whether demographic factors were associated with hypoglycemia risk.

Methods

A cross-sectional study was conducted using the IADB.nl prescription database. Patients aged 35 years or older, with at least two antidiabetics dispensing (ATC code: A10) in 2019 and registered between 2014-2021 were included. The risk of hypoglycemia was determined using a validated algorithm based on patient's characteristics and dispensing data at the index date (first A10 drug in 2019). The hypoglycemia score ranged between 0 and 1; 0.6 was the cut-off between low and high hypoglycemia risk. The associations between age, sex, and hypoglycemia risk were explored in univariate analysis, presenting odds ratios (OR).

Results

In total, 36,628 patients were included (53.0% men, mean age 67.8 years). More than half of the patients (52.8%) received monotherapy, and 47.2% combination therapy for diabetes. Common treatments were biguanides (43.6%), a combination of oral antidiabetics (27.0%), or insulin and an oral antidiabetic (17.7%). Twenty-four percent of the patients (8,779) had a high hypoglycemia risk score. Older age (OR: 0.96; 95%CI: 0.92–1.01) and female sex (OR: 1.05; 95%CI: 1.00–1.10) showed no significant association with high hypoglycemia risk.

Conclusions

Overall, 1 in 4 patients had a high hypoglycemia risk score which needs attention in primary care. The risk score was not reduced in older patients, who might be in need of deprescribing.

FDA APPROVED CANCER DRUGS IN BRAZIL: STRENGTH OF EVIDENCE AND TIME TO APPROVAL

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ABSTRACT

Background

Cancer drugs are usually launched first in the US with high prices, not always commensurate with their clinical benefits. We compared the evidence supporting cancer drug approvals in the US and Brazil and examined the association between the strength of evidence and time to approval in Brazil.

Methods

Exploratory cross-sectional study. Document analysis from the United States (US) Food and Drug Administration (FDA) and Brazilian Health Regulatory Agency (Anvisa) websites and Anvisa's information systems. All novel cancer drugs approved in the US from 2010-2019 were matched to approvals for the same indication, with prices approved in Brazil by December 2020. The evidence supporting marketing authorisation (MA) and data on approval pathway, pivotal study design characteristics and outcomes in the US and Brazil, and availability of added therapeutic benefit in Brazil were analysed.

Results

A total of 56 cancer drugs with matching indications were approved in Brazil 522 days (median) after the US (IQR: 932-351). In the US and Brazil, 34 (60.7%) vs 42 (75.0%) of the drugs had pivotal randomised controlled trials (RCTs) and 12 (21.4%) vs 24 (42.9%) had overall survival (OS) benefit, respectively. The time between FDA approval and Anvisa submission was shorter for drugs with pivotal RCTs (49 vs 246 days) and documented evidence of OS benefit (44 vs 155 days) vs those without, with 50% of the drugs without added therapeutic benefit.

Conclusions

Cancer drugs with stronger evidence and more meaningful clinical benefit were approved earlier in Brazil, compared with those without these characteristics.

PHYSICIAN REIMBURSEMENT DATA FROM HEMATOLOGY-ONCOLOGY PRACTICES DEMONSTRATE CONTINUITY OF MEDICATION CARE FOR CANCER PATIENTS IN THE OUTPATIENT SETTING DURING THE SARS-COV-2 PANDEMIC

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ABSTRACT

Background

The analysis of drug prescriptions from health insurance data is dependent on data availability and prone to distortion. Taking cancer treatment as an example, we examined the extent to which the treatment situation during the SARS-CoV-2 pandemic can be described using physician reimbursement data, so-called EBM codes, which are transmitted quarterly to the associations of statutory health insurance physicians (KV).

Methods

From 2017 to 2020, data from every 3rd remuneration quarter and, since Q1/2021, data from every remuneration quarter of office-based hematologist-oncologists from all KV regions in Germany were analyzed. All EBM codes applicable under the Oncology Agreement were included in the analysis, with a focus on the reimbursement codes for oral drug-based tumor therapy (86520) and oral cytostatic chemotherapy (96505).

Results

Up to n=119 hematology-oncology practices were included in the analysis, providing data on the care of up to n=148,243 cancer patients per quarter. The newly introduced billability of drug-related cancer treatments under the Oncology Agreement in 2019 resulted in a tenfold increase in these billing codes in outpatient reimbursement records between 2018 and 2019. In 2020, a plateau was reached, which was maintained during the pandemic in Q1-Q3/2021 (average of 0.13-0.14 billing codes per quarter per patient) and has continued to increase since Q4/2021.

Conclusion

Based on physician reimbursement data, the care situation in hematology-oncology practices can be reliably depicted over time. The German-wide analysis shows a stable medication care situation for cancer patients in the outpatient setting over the observation period, even during the SARS-CoV-2 pandemic.

OVERVIEW OF ANTIDIABETIC CONSUMPTION IN HUNGARY BETWEEN 2015 AND 2021

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ABSTRACT

Background

Diabetes prevalence is growing and several new drug groups have been authorized and used successfully in the treatment while the older drug groups are still in use.

Our aim was to evaluate the utilization trends of antidiabetics in Hungary between 2015 and 2021 and to assess regional differences.

Methods

For the retrospective drug utilization study, yearly wholesale data were provided by IQVIA. This database provides total coverage for antidiabetic drug sales in Hungary including both reimbursed and non-reimbursed medications. Data was expressed in Defined Daily Dose per 1000 inhabitants per day (DDD/TID) and percentage of total use.

Results

Total antidiabetic use emerged from 88.1 DDD/TID in 2015 to 94.8 DDD/TID in 2021 (7.6% increase). Regarding antidiabetic subgroups, metformin and novel antidiabetics' (DPP4Is, GLP1As and SGLT2Is) use showed a dynamically growing tendency. In 2021, 21.45% of the total antidiabetic consumption was novel antidiabetics, 34.3% was metformin and 9.9% was combination products (mainly metformin+novel antidiabetics). Sulfonylurea consumption showed decreasing tendency, but it was still 19.2% of the total antidiabetic use in 2021. Insulin use was relatively stable, the other antidiabetics' use were marginal. In Hungary the regional differences in antidiabetic consumption was considerable mainly in case of sulfonylureas (max/min ratio:2.03) GLP1As (2.85), DPP4Is (2.39) and SGLT2Is (2.87) in 2021.

Conclusions

Although, in Hungary novel antidiabetic drug use was dynamically growing, sulfonylurea use was still remarkable. Antidiabetic drug consumption differences are considerable between regions. Further studies are needed to identify the potential causes of regional differences.

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HIGHLIGHTS OF THE OUTPATIENT'S ORAL ANTICOAGULANTS USE IN HUNGARY FROM 2012 TO 2021

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ABSTRACT

Background

The leading cause of death in Hungary is diseases of the circulatory system; the standardized death rate was 714.8 per 100,000 inhabitants in 2019, which is twice as high as the EU average. Oral anticoagulants play an important role in decreasing cardiovascular mortality rate. This study was aimed to assess the use of oral anticoagulants in Hungary between 2012 – 2021.

Methods

Data was collected from National Health Insurance Fund database including the entire population's reimbursed prescription drug use. Data was collected and analyzed according to WHO's ATC/DDD method and expressed in Defined Daily Dose per 1000 inhabitants per day (DDD/TID).

Results

The use of oral anticoagulants more than doubled from 8.3 DDD/TID in 2012 to 17.4 DDD/TID in 2021. The share of vitamin K antagonists from total oral anticoagulant use was 99.7% in 2012 (with acenocumarol use 6.4 DDD/TID and warfarin 1.9 DDD/TID), which decreased to 31.6% share by 2021 (acenocumarol 2.8 DDD/TID, warfarin 2.6 DDD/TID). The use of novel oral anticoagulants dynamically increased, reaching 68.4% of the total oral anticoagulant use. In 2021 the use of apixaban was 4.7 DDD/TID, rivaroxaban was 3.9 DDD/TID, dabigatran etexilate was 1.9, edoxaban was 1.3 DDD/TID. The total cost of oral anticoagulants showed a ten times increase during the study period.

Conclusion

Over the ten-year study period the use of oral anticoagulant more than doubled. The use of novel anticoagulants greatly increased and became dominant.

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CHANGES IN ANALGESIC PRESCRIBING AMONG OLDER ADULTS HOSPITALISED FOR OSTEOARTHRITIS OR JOINT REPLACEMENTS

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ABSTRACT

Osteoarthritis is a chronic, progressive joint disease, associated with frequent pain, and functional decline. Medications for symptom management may also present risks to older adults. This study aims to evaluate analgesic prescribing patterns before and after an osteoarthritis or joint arthroplasty-related hospital admission in patients aged ≥ 65 years.

This is an observational study of older adults with an osteoarthritis/joint arthroplasty hospitalisation. Data was collected for a larger study from 44 general practices in Ireland during 2012-2018 and included GP records (12 months pre/post-index hospitalisation) and hospital discharge summaries, analysed to identify analgesic prescribing. Multivariable analysis assessed discharge and patient characteristics associated with opioid and oral NSAID use 3-12 months post-discharge.

Overall, 738 individuals were included (52.9% female, mean age 78.1 years). Compared to 12 months pre-hospitalisation, patients were less likely to be prescribed a weak opioid or oral NSAID from discharge to 3 months post-discharge, or in the 3-12 months post-discharge. For strong opioids, prescribing was less likely in the 3-12 months post-discharge (OR 0.54, 95%CI 0.40-0.74). Female sex, and strong opioid or pregabalin discharge prescribing were associated with strong opioid prescribing 3-12 month post-discharge. For oral NSAID prescribing, lower age, female sex, and discharge strong opioids were significantly associated.

Use of opioids and oral NSAIDs typically reduce post-discharge for these patients. Female sex and strong opioids at discharge are associated with prescribing of strong opioids and oral NSAIDs. Further modifiable characteristics will be assessed which could reduce long-term use of these medications where appropriate.

USE OF ANTIBIOTICS FOR URINARY TRACT INFECTIONS UP TO AND AFTER NURSING HOME ADMISSION IN DENMARK

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ABSTRACT

Background

Older people are among the heaviest users of antibiotics for acute and chronic urinary tract infection (UTI), despite diagnostic uncertainty and the growing problem of antibiotic resistance.

Objective

To describe use patterns of UTI-antibiotics and UTI-related hospitalizations prior to and after nursing home admission in Denmark

Methods

This was a register-based national drug utilization study. In a cohort of all Danish residents admitted into nursing homes 2015-2020 and their prescription fills and hospital admissions, we described use of UTI-antibiotics and UTI-related hospitalizations prior to and following nursing home admission. Further, we examined regional and individual nursing home differences in UTI antibiotic use.

Results

The cohort comprised 86,214 residents (61% female; median age 84 years). The most common UTI-antibiotic was pivmecillinam (54%). Fifteen percent of UTI-prescriptions were followed by another UTI-prescription within 15 days. UTI-antibiotic use doubled from 7 to 14 treatments/100 residents/month around two months prior to nursing home admission and remained at 10 treatments/100 residents/month the following two years. UTI-related hospitalizations peaked at three months prior to nursing home admission, with 3 admissions/100 residents/month, subsequently dropping to 1 admission/100 residents/month. We found considerable variation in use of UTI-antibiotics between nursing homes, with ten percent of nursing homes responsible for one third of all UTI-treatments in 2020.

Conclusions

Use of UTI-antibiotics increased prior to and remained at a stable high level during the two-year follow-up after nursing home admission. Use of UTI-antibiotics showed considerable variation at the regional and individual nursing homes levels.

RAPID SURVEILLANCE ON THE USE OF MONOCLONAL ANTIBODIES AND ANTIVIRALS IN PATIENTS WITH COVID-19 IN SCOTLAND

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ABSTRACT

Background

Since December 2021, sotrovimab, molnupiravir, and Paxlovid (nirmatrelvir & ritonavir) have become available to prevent COVID-19 disease progression in vulnerable patients. We aimed to provide information on the use of these drugs across Scotland.

Methods

Exposure data was purposely collected between 21.12.2021 and 13.08.2022 and supplemented with data obtained from the Hospital Electronic Prescribing and Medicines Administration (HEPMA) system to maximise data coverage. Additional data was available through record linkage via a unique patient identifier.

Results

Overall, a total of 11879 patients have been treated with the drugs of interest during the study period. Most patients (5520, 46.5%) received Paxlovid; molnupiravir and sotrovimab were prescribed to 2715 (22.9%) and 3492 (29.4%) patients, respectively, and a small percentage of patients (152, 1.3%) received more than one drug during the study period. The share of each drug amongst all treated patients varied considerably over time.

The majority of patients were female (7031, 59.2%), and the median age was 55 years (IQR 43 – 66); the vast majority had received at least three vaccine doses prior to treatment (11172, 94.0%).

Among the 9969 non-hospitalised patients with sufficient follow-up time receiving treatment in an outpatient setting, 114 (1.1%) were admitted to hospital and 36 (0.4%) died within 28 days of treatment with COVID-19 as the primary reason.

Conclusion

Despite limitations to the data, this study offered valuable insights into COVID-19 treatment patterns in Scotland, highlighting changes over time. No immediate concerns about the use of the three drugs available have been raised.

TRACEABILITY OF BLOOD DERIVATIVES REPORTED TO THE PORTUGUESE NATIONAL PHARMACOVIGILANCE SYSTEM | CAN WE DO IT?

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ABSTRACT

Background

Blood derivatives (BD) are biological medicinal products, so an inherent degree of minor variability can be present within or between batches of the same product. When a biological product is involved in a suspected adverse reaction report, we should be able to clearly identify it through its name and batch number. We propose to assess Individual Case Safety Reports (ICSR) received by the Portuguese National Pharmacovigilance System related to BD in terms of traceability.

Methods

A retrospective search has been performed on Portal RAM between January 1, 2012 and December 31, 2022. Selected reports had at least one medicinal product identified as suspect/interaction classified under the Infomed product group “Derived from human blood and plasma”.

Results

Our search retrieved 383 ICSR, corresponding to 471 BD reported. From these 56.9% can be identified through its name and 40.3% through its batch number. 2012 was the year that had less BD reported (n=12), with 83.3% being able to be identified through its name and 75.0% through its batch number. 2022 had the most BD reported (n=67), with 46.3% being able to be identified through its name and 34.3% through its batch number. The majority of reported BD were from “Physicians” (39.3%), with 70.8% having the name and 55.1% the batch number filled-in.

Conclusion

A high percentage of reported BD didn't have associated information of extreme importance for its unequivocal identification. Strategies to minimize this issue should be studied and implemented, taking into consideration the reality of each reporter category.

A SYSTEMATIC REVIEW OF LONGITUDINAL STUDIES EXAMINING THE DOSAGE OF CANNABINOIDS ASSOCIATED WITH AN OPIOID-SPARING EFFECT

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ABSTRACT

Background

Cannabinoids may reduce opioid use while maintaining similar analgesic effects in patients with pain. We aimed to conduct a systematic review to assess cannabinoid doses associated with reduced opioid use.

Methods

We conducted a systematic review of randomized controlled trials (RCT) and longitudinal observational studies reporting data on the doses of tetrahydrocannabinol (THC), cannabidiol (CBD), or other cannabinoids and opioid use reduction or discontinuation. We searched PubMed, Embase, Web of Science and PsycINFO databases for eligible studies until December 10, 2022. Two reviewers independently assessed the studies through title/abstract and full-text screening and extracted the data from eligible studies.

Results

Out of the 6378 studies retrieved, 15 studies (seven RCTs and eight observational) satisfied the inclusion criteria. Five studies were conducted on chronic non-cancer pain [one RCT], one on not-specified chronic pain, three on cancer pain [two RCTs], and seven on acute pain [five RCTs]. Two observational studies evaluating combined THC/CBD use (17mg/15mg/day) and one assessing a CBD-rich extract (31.4 mg/day) in patients with chronic non-cancer pain showed a significant reduction in opioid use. Among cancer patients, only one observational study on nabilone (1.7 mg/day) showed a significant decrease in opioid use. In patients with acute pain, only two observational studies evaluating dronabinol (5-10 mg/day) showed a significant reduction in opioid use.

Conclusions

The opioid-sparing effect of cannabinoids remains uncertain because of the small number of studies assessing cannabinoid dosage associated with an opioid-sparing effect, contrasting results and the heterogeneity of the included studies.

TRANSLATION AND VALIDATION OF DIABETES KNOWLEDGE QUESTIONNAIRE INSTRUMENT FOR INDONESIAN PATIENTS WITH DIABETES

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ABSTRACT

Background

Knowledge about diabetes is important for people with diabetes to improve their health. The Diabetes Knowledge Questionnaire (DKQ) is an instrument to assess diabetes knowledge. This study aimed to translate and assess the validity of the DKQ in Indonesian patients with diabetes.

Methods

We used forward-backward translation and involved six experts and 39 patients in a pilot to assess the clarity of the Indonesian version of DKQ. Psychometric analysis was carried out in a cross-sectional study among patients with type 2 diabetes in ten primary health care centers in Indonesia, focusing on known-group validity and internal consistency.

Results

Based on pilot testing, three of the 24 items were revised. A total of 215 patients participated in the validation study (69.8% women, mean age 61.45 years, mean DKQ score 13.74±3.6). The DKQ score was higher among younger patients ($p=.000$) and with higher level of education ($p=.000$), showing known-group validity. Cronbach's alpha was higher than 0.7 representing acceptable internal consistency.

Conclusions

The Indonesian version of DKQ is considered a valid and reliable instrument to assess the level of diabetes knowledge in patients with diabetes in Indonesia. The test-retest reliability will be assessed with a second data collection. Further studies are required to evaluate the association between improvement in diabetes knowledge and diabetes-related outcomes.

COMMUNITY PHARMACIST'S ROLE IN THE MANAGEMENT OF NON-CANCER CHRONIC PAIN; A QUANTITATIVE STUDY

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ABSTRACT

Community pharmacists' (CPs) are actively involved in the management of patients with chronic non-cancer pain (CNCPPs) to improve their quality of life. (2)The study aimed to identify the perceptions of CPs regarding their role in the management of CNCPPs in Greece. This quantitative questionnaire consisted of 30 (multiple-choice and Likert-scale) questions after an extensive literature search. The study was conducted in Athens (Ampelokipoi region- RDA) as per the researcher's local knowledge and convenience. The questionnaires were handed out to all 113 pharmacies within the RDA. Implied consent was given by the completion of the questionnaire. The study received ethical approval prior to data collection. Data analysis was conducted using Microsoft Excel. Totally, 92 CPs (females n=55, 59.78%, males n=37, 40.21%) participated (81.41% response rate). Sixty-three (68.4%) agreed/strongly agreed that CNCPPs who visit them are feeling sad and experience chronic stress. Eighty-eight (95.7%) recognised the need for CNCPPs for understanding and empathy. Twenty-five (27.2%) expressed their concerns about opioid use and dependence risk and 30 (32.6%) were concerned about CNCPPs' adherence to their medications. Interestingly, 45 participants (48.9%) mentioned that they rarely/very rarely communicate effectively with prescribers/doctors. Finally, 50 CPs (54.3%) considered that the university education is insufficient regarding CNCP. CPs in Greece have the potential to participate in the care of CNCPPs. As CPs don't receive structured training, CPs' CNCP service provision is currently opportunistic. This is the first study in Greece and could be the basis for a nationwide study exploring this topic further.

THE ASSOCIATION BETWEEN ADHD MEDICATION USE IN CHILDREN, ADOLESCENTS AND YOUNG ADULTS AND THE RISK OF INJURIES LEADING TO EMERGENCY DEPARTMENT ADMISSION OR HOSPITALIZATION

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ABSTRACT

Background

Attention-deficit/hyperactivity disorder (ADHD) patients are at increased risk of injuries and accidents. We thus aimed to estimate the risk of injuries leading to the emergency department (ED) or hospital admissions associated with ADHD medication use.

Methods

We performed a population-based cohort study using medico-administrative data identifying all the individuals aged ≤ 24 years with an ADHD diagnosis or ADHD medication claim between 01-04-2000 and 31-03-2021. Episodes of ADHD medication use were classified as: no ADHD medication use; ADHD medication use, further categorized as psychostimulants only, non-psychostimulants only, and combinations of psychostimulants and non-psychostimulants; not covered under the public drug plan. Injuries leading to ED or hospital admission were the outcome. Individuals were followed until emigration, death, or the end of the study period. The risk of injury was estimated through Prentice-Williams-Peterson gap-time analysis, a Cox model extension allowing for recurrent events, adjusting for potential time-dependent confounders and stratifying by sex. Adjusted hazard ratios (aHRs) and 95% confidence intervals (CIs) were estimated.

Results

Among the 217,192 individuals identified, ADHD medication use episodes were associated with reduced unintentional injuries similarly in males (ED-injury: aHR, 0.75; 95%CI = 0.73-0.76; hospitalization: 0.70; 0.66-0.74) and females (ED-injury: 0.79, 0.76-0.81; hospitalization: 0.80, 0.72-0.89). All ADHD medication classes were associated with reduced risk of ED-leading injuries (psychostimulants: 0.76, 0.75-0.77; non-psychostimulants: 0.77, 0.73-0.81; combinations: 0.66, 0.62-0.70) and hospitalizations (psychostimulants: 0.72, 0.68-0.76; non-psychostimulants: 0.66, 0.57-0.78; combinations: 0.68, 0.57-0.82).

Conclusions

ADHD medication use was associated with reduced risks of injuries in both sexes, independently of the medication classes used.

USE OF DRUGS FOR MENOPAUSAL HORMONE THERAPY IN NORWAY 1987-2022

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ABSTRACT

Background

Menopausal hormone therapy (MHT) use has changed considerably over the last few decades. Since the Women's Health Initiative trial results in 2002 raised concerns about increased risk of breast cancer and cardiovascular disease, accumulating evidence shows that for most symptomatic women, the benefits of MHT outweigh the risks. In this study, we aim to describe the trends of MHT use in Norway during the last 35 years.

Methods

Sales data for MHT in number of defined daily doses/1000 inhabitants/day (DID) were collected from the Norwegian Drug Wholesales Statistics for 1987-2022. Systemic treatment included estrogens (G03C), fixed combinations (G03FA, tibolone G03CX01), and sequential preparations (G03FB). Local MHT included estrogens (G03C) and prasterone (G03XX01). Prevalence of systemic MHT users was collected from the Norwegian Prescription Database for 2004-2021.

Results

Sales of systemic MHT increased more than 7-fold from 1987 to 2001; 5.3-39.1 DID. From 2002 to 2013 sales of systemic MHT were reduced from 35.3-10.2 DID. In the last few years, a small increase in sales and prevalence were observed, and estrogens and fixed combinations accounted for most of the sales. In 2021, approximately 7% of Norwegian women (≥ 45 years) used a drug for systemic MHT. Sales of local MHT increased from 4.0-8.2 DID from 1988 to 1998 but have been relatively stable for the last two decades.

Conclusion

Use of systemic MHT in Norway has remained low after the first concerns about serious adverse effects in 2002 despite accumulating evidence of benefits for most symptomatic women.

UTILISATION TRENDS AND EXPENDITURES OF LIPID-LOWERING THERAPIES IN KUWAIT BETWEEN 2012 AND 2022

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ABSTRACT

Background

Elevated low-density lipoprotein cholesterol (LDL-C) is one of the major risk factors associated with atherosclerotic cardiovascular disease in Kuwait. In addition to using oral lipid-lowering therapies (LLTs) to achieve the desired goal of LDL-C, Kuwait approved proprotein convertase subtilisin/kexin type-9 inhibitors (PCSK9Is) in 2016. These costly medicines have shown to positively impact cardiovascular outcomes. Therefore, it is important to examine utilisation trends of LLTs and how PCSK9Is have affected Kuwaiti healthcare spending when there is lack of data in this regard.

Methods

This retrospective study used an electronic system of the Central Medical Store to extract aggregated data for the consumption and costs of LLTs between 2012 and 2022. Oral LLTs of interest include statins (atorvastatin, rosuvastatin, simvastatin, and pitavastatin), cholesterol absorption inhibitor (ezetimibe), fibrates (fenofibrate, gemfibrozil, bezafibrate), and bile acid sequestrant (cholestyramine). Injectable LLTs include PCSK9Is (evolocumab and alirocumab). Data were analysed using Microsoft Excel.

Results

Among oral LLTs, statins were highly utilised in 2012 (93%) and in 2022 (86%). The overall utilisation of oral LLTs increased by 75% and the total costs increased by 92% over the study period. For PCSK9Is, evolocumab was highly utilised in 2022 (79%) compared to alirocumab. The overall utilisation of PCSK9Is increased by 105 times in 2022, and the total costs increased from £229,635 in 2016 to £11,730,339 in 2022 (+5008%).

Conclusion

The increasing use of LLTs is expected but will eventually lead to more costs. It is imperative to control the pharmaceutical expenditure through assessing rational prescribing.

OPIOID UTILISATION: A RETROSPECTIVE STUDY IN HUNGARY

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ABSTRACT

Background

While opioid use is well-reported in several countries, limited data are available in Europe. To assess the national situation, we analysed Hungarian opioid utilisation in ambulatory care between 2016 and 2020.

Methods

We obtained national drug utilization data on reimbursed opioid analgesics (ATC: N02A) from the Hungarian national health insurance database for a 5-year period (2016-2020). We examined utilisation of opioids using oral morphine equivalent per 1000 inhabitants per day (OME) as a volume-based metric. We analysed our data based on analgesic potency and indication-linked reimbursement categories.

Results

Total opioid utilisation increased during the study period by 30.6% and reached 275.1 OME by 2020. The upward trend was driven by an increase in weak opioid use (33.6%). Throughout the study period, weak opioids represented the majority of opioid utilisation (>93.6%), tramadol being the main active ingredient (157.5 OME in 2020). Tramadol and paracetamol combination products first appeared in the database in 2017; the utilisation of this combination increased threefold by 2020 (105.9 OME). Based on reimbursement categories, opioid use for cancer pain declined during the study period (-20.2% in OME), while musculoskeletal pain became a more common indication (+6.2% in OME).

Conclusions

Our study found a general increase in opioid use between 2016 and 2020. Among the active ingredients, tramadol and tramadol and paracetamol combinations were dominant, most likely because prescribing legislations were less restrictive for these products. We also found that prescribing opioids for musculoskeletal pain became more common during the study period.

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CORRELATION BETWEEN CARBAPENEM CONSUMPTION AND CARBAPENEM-RESISTANT *ACINETOBACTER BAUMANNII* IN A TERTIARY CROATIAN HOSPITAL

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ABSTRACT

Background

Antimicrobial resistance (AMR) represents one of the main global public health threats. The inappropriate use of antimicrobials is one of its main causes. This study aimed to assess carbapenem consumption and determine its correlation with the rate of carbapenem-resistant *Acinetobacter baumannii* (CRAB) in a tertiary Croatian hospital.

Methods

Data collected from February 2015 to December 2021 in Clinical Hospital Centre Rijeka was analyzed. Antimicrobial consumption (AMC) data was obtained from the Hospital pharmacy and data on CRAB from the Clinical department of clinical microbiology. AMC was expressed in DDDs/100 patient days. The rate of CRAB isolates was expressed as the number of CRAB cases/100 patient days. The Shapiro-Wilk test was used to assess the normality of data distribution, the Mann-Kendall trend test was performed to evaluate the trend significance, and the Spearman test was used for correlation determination. Statistical analysis was done in Microsoft Excel and XLSTAT statistical software.

Results

The consumption of carbapenems varied monthly, but an overall significant increasing trend is observed. The overall number of *A. baumannii* and the percentage of CRAB isolates have shown a significant increase. A statistically significant positive correlation between carbapenem consumption and CRAB rate was found.

Conclusion

Our study has shown a significant increase in carbapenem consumption that is correlated with an increase in the proportion of resistant *A. baumannii* isolates. A major increase in carbapenem consumption is observed in the period of high COVID-19 prevalence. There is a need to implement stringent antimicrobial stewardship interventions to reduce inappropriate antimicrobial prescribing.

THE INCORPORATION OF DIRECT-ACTING ANTIVIRALS FOR HEPATITIS C BY THE BRAZILIAN HEALTH SYSTEM, 2012 - 2021

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ABSTRACT

Worldwide, hepatitis C is considered a public health problem, due to its frequency and ability to become chronic. In Brazil, 262.815 confirmed cases of hepatitis C were reported from 1999 to 2020. The public health system (Unified Health System – SUS) is responsible for providing different direct-acting antivirals (DAA), which is the only intervention that can stop disease progression.

The process-making decision to incorporate DAA in SUS was assessed from 2012 to 2021, by qualitative document analysis. The effectiveness of supply of these DAA was also evaluated by quantitative data analysis of health government databases on federal purchases and on outpatient dispensing at primary care level.

The DAA were quickly demanded for incorporation in SUS, as soon as they entered the global market. Analysis was supported by evidence, although financial and political constraints in decision-making were observed. The time taken to complete the administrative process and incorporate DAA was always shorter than the maximum legal deadline. However, the interval between the incorporation of the DAA and its offer in the care network is often delayed and over the legal norm, usually caused by constraints in federal purchases. Overall, DAA reach the patient at expected consumption levels.

The dynamics of incorporation and exclusion of DAA in the Brazilian Health System, although based on scientific criteria, can admit financial or political interferences. Treatment became simpler with pangenotypic treatments and the country was able to dispense DAA in the primary care network, improving universal access to treatment.

PRESCRIPTION OF PSYCHOTROPIC MEDICATIONS IN THE ITALIAN PAEDIATRIC POPULATION

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ABSTRACT

Introduction

There is a global perception that psychotropic drug utilization in children and adolescents is increasing, especially with the onset of COVID-19 pandemic. The aim of this study was to provide updated data on psychotropic medication prescriptions referred to the Italian paediatric population and to evaluate if COVID-19 pandemic had an impact on prescription rates.

Materials and Methods

A descriptive study on psychotropic drug utilization in children and adolescents (<18 years) resident in all Italian regions during 2020 was performed. Patients registered in Pharmaceutical Prescriptions database with at least one prescription of a psychotropic medication (antipsychotics-N05A), (antidepressants-N06A) and (psychostimulants-N06BA) during the study period were considered. The indicators used were the prescription rate (number of prescriptions per 1000 children) and prevalence of use (proportion of paediatric population with at least one prescription in the relevant year).

Results

During 2020 the prevalence of psychotropic drug in the paediatric population was 0.39%, increased of 7.8% compared to 2019. The same trend was observed in prescription rate, which recorded an average of 28.2 per 1000 children with an increase of 11.6% compared to previous year. The data showed a growing trend by age, reaching the peak of prescriptions in adolescents aged 12-17 years old. The highest prevalence was found for antipsychotics, received by the 0.19% of the paediatric population.

Conclusions

Pharmacotherapy of psychiatric illnesses in children and adolescents has grown significantly during 2020, raising alarms from health care clinicians about the increase of burden of mental diseases in paediatric population during the COVID-19 pandemic.

PROFILE OF INDIGENOUS PATIENTS UNDER CHEMOTHERAPY IN THE BRAZILIAN HEALTH SYSTEM

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ABSTRACT

Background

Approximately 900 thousand people are of indigenous ethnicity in Brazil (0.4% of the population), for which epidemiological and clinical data are scarce. There is a countrywide effort to produce quality data for policy decisions. This study aims to produce a profile of indigenous people undergoing chemotherapy in the Brazilian Health System (SUS).

Methods

A retrospective analysis of the publicly available High-Complexity Procedure Authorization (APAC) database was carried out to identify chemotherapy procedures (APAC-quimio) generated between January 2010 and December 2019. Race/color was used to identify indigenous people, and variables year, sex, age, ICD-10, and stage were stratified for indigenous and non-indigenous patients, per Brazilian state.

Results

Of a total of 28,617,400 APAC-quimio records, 18% had missing information on race/color. Mean proportion of valid records in states rose from 7% in 2010 to 13% in 2019. Of the remaining 23,396,524 records, 5,541 were of indigenous patients (0.2%). Median age for indigenous individuals in chemotherapy was 53 yrs, and 62 yrs for non-indigenous. Indigenous women patients were 57% while non-indigenous were 64%. Most frequent diagnoses among indigenous patients were breast and prostate cancers, and lymphoid leukemia. For non-indigenous patients, myeloid leukemia superseded the latter. Among indigenous individuals 32% presented with stage 3 and 25% with stage 4, contrasting with 27% and 22% for non-indigenous, respectively.

Conclusion

Data to support pharmacoepidemiological studies in indigenous populations are lacking in Brazil. Profile of indigenous population undergoing chemotherapy shows marked differences with non-indigenous segments. Future treatment studies will be supported by this data.

GEOGRAPHIC AND SOCIOECONOMIC DIFFERENCES IN POTENTIALLY INAPPROPRIATE MEDICATION AMONG ELDERLY – A REGISTER BASED PROSPECTIVE COHORT STUDY APPLYING ANALYSIS OF INDIVIDUAL HETEROGENEITY AND DISCRIMINATORY ACCURACY (AIHDA) FOR BASIC COMPARISONS OF HEALTHCARE PERFORMANCE

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ABSTRACT

Background

We illustrate the application of the analysis of individual heterogeneity and discriminatory accuracy (AIHDA) for routine evaluations of healthcare performance with focus on equity. Current evaluations could be improved by considering (i) not only geographical differences but also the intersection of socioeconomic axes of inequality like age, sex, income, and country of birth; and (ii) the existence of individual heterogeneity around group averages. Using an established quality indicator (potentially inappropriate medication (PIM)), we apply AIHDA to evaluate both geographical, and socioeconomic inequalities.

Methods

We analyzed 731,339 individuals, >75 years who belonged to 36 socioeconomic strata and resided in the 21 Swedish regions by 31st December 2010. We applied logistic regression models to evaluate the discriminatory accuracy (DA) of the group differences using the area under the ROC curve (AUC).

Results

Overall, the prevalence of PIM in 2011 was 24%. We found conclusive differences in 15 of 21 administrative regions and 33 of 36 socioeconomic strata. All strata including women had higher prevalence of PIM than the strata including men. However, the regional and socioeconomic differences were absent/very small (AUC = 0.550). For instance, in the five socioeconomic strata with the lowest risk there were about 8,000 more cases of PIM than in the five strata with the highest risk of PIM.

Conclusion

Since the DA of the group differences was small, interventions to reduce the prevalence of PIM in Sweden should be universal rather than targeted to the regions and socioeconomic strata with the highest PIM prevalence.

ADVERSE REACTIONS TO ANTIMICROBIALS IN PEDIATRICS

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ABSTRACT

Background

Antimicrobials are widely used in hospitals and are often associated with adverse reactions. Among pediatric inpatients, the use of antimicrobials is especially common. This population is poorly studied mainly due to ethical conflicts, especially in experimental studies.

Objective

The objective was to determine the incidence of adverse drug reactions (ADR) caused by antimicrobials and classify them according to the type of reaction, the class of antimicrobials used and causality.

Methods

A prospective cohort study was carried out with pediatric patients admitted to a tertiary hospital in the south of Brazil, from August 2019 to February 2020. Children hospitalized for more than 48 hours and who used antimicrobials for more than 24 hours, aged between 0 and 17 years and 11 months, were included. Causality was verified using the algorithm of Liverpool (Liverpool Causality Assessment Tool).

Results

303 patients were evaluated, and 18.1% (55/303) of them had one or more ADRs during the hospital stay. In total, 70 ADRs were observed. The most reported type of ADR was gastrointestinal 75.8% (53/70), represented by diarrhoea/watery stools, vomiting and nausea; followed by dermatological 12.9 % (9/70) with unspecified skin reactions, rash and hyperemia. The most used antimicrobials were beta-lactams and second-generation cephalosporins. The most involved antimicrobial with adverse reactions was cefepime. Suspicions of ADR were classified mainly as probable (48.6%).

Conclusion

Adverse reactions were observed in approximately one-fifth of patients and were mostly gastrointestinal and probable.

PRESCRIPTION OF ANTIMICROBIALS FOR RESPIRATORY DISEASES IN PEDIATRICS: ANALYSIS OF AVAILABLE SOURCES OF INFORMATION

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ABSTRACT

Background

The lack of clinical studies and the variability of drug information result in different treatment regimens for pediatric population in clinical practice. This study assessed the agreement of information sources that guide pediatric prescription of antimicrobials in relation to the drug of choice and dosage regimen as well as the types of cited references. Method: Publications from medical associations and healthcare institutions (guidelines and official formularies) as well as package inserts of medicines were selected, totaling 14 different documents. Three common infectious diseases in childhood were considered for analyses (pharyngotonsillitis, acute otitis media and rhinosinusitis).

Results

The penicillin class was prevalent as first-line therapy in the three investigated diseases. The minimum age for the use and the duration of the treatment were presented in 54.3% and 64.4% of the sources, respectively. Body weight was the most used parameter for presenting the dose, followed by age and fixed dose. The simulations carried out in relation to the daily dose show large variation depending on the information source used. For example, a 10 year old child weighing 31 kg may receive doses of amoxicillin ranging from 562 to 1,716mg/day. In general, the analysed sources often cite references classified as review articles followed by clinical trials and official formularies.

Conclusion

The obtained results reinforce the need to encourage clinical trials and/or pharmacometrics studies for establishing dose recommendations of antimicrobials for pediatric patients, as well as to harmonize the provided information to guide prescriptions.

USE OF CENTRAL NERVOUS SYSTEM DRUGS IN PEOPLE WITH AUTISM SPECTRUM DISORDER: PRELIMINARY RESULTS OF A STUDY IN ITALY

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ABSTRACT

Introduction

No pharmacological treatments are available for the core symptoms of Autism Spectrum Disorder (ASD) but the prescription of antidepressant and antipsychotic drugs is frequent since the presence of neurological and psychiatric comorbidities. Aim of the project coordinated by the National Institute of Health was to evaluate use of Central Nervous System (CNS) drugs in Italy.

Methods

The study population consisted of those born in the regions Emilia Romagna, Umbria, Abruzzo and Sardinia in the period 2000-2016 with first hospital admission for autism (cases). A maximum of three controls were matched for each case. Analyses were conducted in terms of prevalence of use and number of prescriptions and packages stratified by age group, therapeutic category and active ingredient.

Results

1,950 cases and 5,827 controls aged 1 to 17 years were included; males accounted for 80% and children aged 1-5 years for 66%. CNS drugs accounted for 38% of the prescribed packs for ASD cases and only 6% in controls. Atypical (risperidone and aripiprazole) and typical antipsychotic are the drugs with the highest prevalence in cases (5.9% and 1.3% respectively), followed with 0.9% by SSRI antidepressants. In controls, the prevalence of these categories is less than 1%. The 0.4% of cases show symptoms attributable to ADHD (Attention Deficit Hyperactivity Disorder) treated with methylphenidate.

Conclusion

This preliminary analysis allowed to evaluate the prescriptive pattern in ASD subjects with particular regard to CNS drugs. However, pharmacological treatment must be considered in a broader framework that also includes non-pharmacological interventions.

DRUG UTILISATION IN PATIENTS STARTING HAEMODIALYSIS, WITH A FOCUS ON CARDIOVASCULAR, AND ANTIDIABETIC DRUGS: AN EPIDEMIOLOGICAL STUDY IN THE LAZIO REGION (ITALY)

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ABSTRACT

Dialytic patients are fragile and often undergo polypharmacy. Within the ETELDIA study, co-funded by the Italian Medicines Agency through the Pharmacovigilance-call 2012-2013-2014, we described drug use in patients entering chronic dialysis.

From the Lazio Dialysis and Transplant Registry, patients initiating dialysis in 2016-2020 were enrolled (day of dialysis initiation = index date), excluding those with prior renal transplantation, stopping dialysis within three months, or dying in the first year. Study drugs were pre-defined by nephrologists. Information on drug use in the two semesters before and after the index date was retrieved from the drug claims register. Proportions of patients with at least two claims of the same drug/drug group by semester, and intensity of treatment (DDDs) of cardiovascular and antidiabetic drugs were compared across semesters.

Among 3,882 patients, high proportions of drug use were observed, with cardiovascular agents at top. Also, proton pump inhibitors and antithrombotics showed continuous high proportions. After initiating dialysis, a general increase in drug therapy was observed respect to the year before (mean number of drugs increased from 5.5 to 6.2). The most evident increases were observed in dialysis specific therapies, namely antianaemic agents (4-fold use of iron, almost 2-fold use of erythropoietins), anti-parathyroid agents (6-fold), and treatment of chelating agents (4-fold). Changes in treatment patterns and intensity were observed for cardiovascular and antidiabetic drugs, with some differences for sex and age groups (18-64 vs 65+).

Starting dialysis is associated with an increase in consumption of specific drugs and often requests adaptations of chronic therapies.

GENDER DIFFERENCES IN PATTERN OF MEDICATION USE IN THE POPULATION OF TUSCANY, ITALY, IN 2021

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ABSTRACT

Background

Gender differences due to biological aspects related to sex and socio-economic and cultural factors can influence the pattern of medication use in the general population.

Methods

The Tuscan administrative healthcare database was used to select all subjects enrolled in the regional healthcare service in 2021. Within each of the first four levels of the ATC classification, the five classes of drugs reimbursed by the National Healthcare Service that showed the greatest absolute value of the difference of prevalence of use between men and women ($|\Delta|$, users/1000 inhabitants) were identified. For such drug classes, the mean number of packages/user during 2021 was also observed by gender.

Results

The greatest differences in prevalence of use were observed for drugs acting on *nervous system* (ATC I°, N=81.4 users/1000 inhabitants), *alimentary tract* (A=79.8), *systemic hormonal preparations* (H=79.7), *genitourinary system* (G=64.4) and *antiinfectives* (J=54.5). Considering the IV° ATC level, the greatest gender differences concerned *vitamin D* (ATC A11CC $|\Delta|$ =97.0), *alpha-adrenoreceptor antagonists* (G04CA $|\Delta|$ =78.9), *thyroid hormones* (H03AA $|\Delta|$ =68.7), *selective serotonin reuptake inhibitors* (N06AB $|\Delta|$ =53.0) and *other antibacterials* (J01XX $|\Delta|$ =39.2). Except for ATC G where both prevalence of use and number of packages/user (G04CA $|\Delta|$ =8.6 packages/user) were higher in men than women, the absolute difference in mean number of packages/user was generally comparable in men and women.

Conclusion

We observed significant gender differences in medication use which should be considered for healthcare resource management and planning as well as in the design of pharmacoepidemiological studies.

PATTERNS OF USE OF ANTIDEPRESSANTS IN CHILDREN AND ADOLESCENTS IN CATALONIA FROM 2008 TO 2017. A COHORT STUDY FROM A PRIMARY CARE DATABASE.

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ABSTRACT

Background

After psychostimulants, antidepressants are the most consumed psychotropic drugs in children and adolescents, varying their pattern according to diagnosis, sex and age.

Methods

Population-based cohort drug study use in Catalonia from 2008 to 2017. Data source: SIDIAP. Cohort: initial users less than 18 years of any antidepressant drug (ATC group N06A) during the study period.

Results

27.760 children initiated an antidepressant treatment: 6% were 0-5 years and consumption was similar in girls and boys (45% vs 55%), 20% were 6-11 years and consumption was higher in boys (63%). 74% were 12-17 years and consumption was higher in girls (58%). Treatment duration varied depending on age (1-2 months in the 0-5 group, 5-6 in the 6-11 and 7-8 in the 12-17 group).

In the 0-5 years group, the consumption was distributed mostly between fluoxetine, escitalopram, paroxetine and citalopram (~15-20% each) and in the rest of groups, fluoxetine was the most consumed (~30-35%) followed by sertraline (20-25%). There were no gender differences. Amitriptyline consumption was higher in girls 12-17 years old (14% vs 8%) and imipramine's higher in boys in the 6-11 years old group, (4% vs 7%). Diagnosis most associated with consumption were anxiety followed by conduct disorders, depression and ADHD (20%, 14%, 10% and 10%). For amitriptyline, 23% of the children were diagnosed with migraine and for imipramine, 23% with urinary incontinence.

Conclusions

Antidepressants are mostly used in teenagers, being fluoxetine and sertraline the most used drugs. Anxiety and conduct disorders are the most frequent diagnosis.

PATIENT PERCEPTION OF CONTINUITY, QUALITY, AND ADEQUACY OF CARE AND THEIR ASSOCIATION WITH OPIOID USE AND POTENTIALLY INAPPROPRIATE OPIOID USE IN OLDER ADULTS WITH AND WITHOUT PSYCHIATRIC COMORBIDITY

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ABSTRACT

Background

Mental health (MH) factors are associated with opioid and potentially inappropriate opioid use (PIOU) in older adults (OA). Others have also shown differences in patient-reported experiences with healthcare between those with and without MH problems. We sought to assess the association between opioid use/PIOU and indicators of continuity, quality, and adequacy of care.

Methods

Secondary analyses were carried out on a cohort of n=945 French-speaking OA without cancer recruited in primary care clinics in Quebec, Canada. Opioid use was captured from pharmaceutical registries in the 3 years following at-home interviews and PIOU was defined according to the 2019 Beers list. Patient-reported experience measures (PREMs) relating to their last medical visit included 9 indicators adapted from the Primary Care Assessment Survey. We conducted adjusted multinomial regression analyses to assess the association between PREMs and opioid use/PIOU. Analyses were stratified for psychiatric comorbidity, defined as the presence of anxiety and/or depression.

Results

In OA with psychiatric comorbidity, poor physician knowledge of their medical history was associated with increased odds of PIOU compared to no use (OR=2.39, 95%CI: 1.08-5.26). In those without psychiatric comorbidity, communication difficulties during patient-provider interactions were associated with increased odds of PIOU compared to no use (OR=3.04, 95%CI: 1.20-7.68). Opioid use was associated with perceived adequacy of care.

Conclusions

Different aspects of patient perception of continuity, quality, and adequacy of care are associated with PIOU and opioid use. Patients' perception of their relationship with physicians is essential for good communication to improve the prescribing process.

EXPOSURE TO PSYCHIATRIC MEDICATIONS BEFORE AND AFTER THE DIAGNOSIS OF CLUSTER B PERSONALITY DISORDER: AGE- AND SEX-STRATIFIED TRENDS FROM 2002 TO 2018

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ABSTRACT

Background

Prescribing psychiatric medications is common among cluster B personality disorder (PD) patients, despite the lack of solid evidence of their efficacy. This study aimed to explore age- and sex-stratified trends in psychiatric medication use before and after the first PD diagnosis.

Methods

We used the Quebec Integrated Chronic Disease Surveillance System database to identify all newly PD-diagnosed individuals (≥ 14 years) between 2002 and 2018 covered by the public drug plan. We calculated yearly and monthly proportions of individuals exposed to psychiatric medications during the year before and after the diagnosis according to sex and age. Using robust Poisson regressions, we tested age- and sex-adjusted trends in medication use changes.

Results

We identified 87,778 individuals with a first cluster B PD diagnosis (mean age: 44.5 years; 57.5% women). For both sexes, the proportion of users increased after PD diagnosis. In general, women were more frequently exposed to psychiatric medications (74.3%-80.5% vs 68.0%-71.0%), especially antidepressants (60.6% vs 46.9%, in 2018-19) and anxiolytics (33.2% vs 27.4%). Men were more likely to use antipsychotics (38.3% vs. 35.2%) and ADHD medications (11.2% vs 10.5%). Younger patients (14-24 years) were more likely to be exposed to ADHD medications, while anxiolytics were mainly used by those aged ≥ 65 . Over the study period, ADHD medication use increased while anxiolytic use decreased.

Conclusions

Psychiatric medication use is high among cluster B PD patients, with differences in medication classes according to diagnosis age and sex. Changes in prescriptions over the last decade are similar for men and women.

RISK OF POLICE INVOLVEMENT AS ACCUSED OR VICTIM/WITNESS OF A CRIME IN ANTIPSYCHOTIC USERS RECENTLY DIAGNOSED WITH A PSYCHOTIC DISORDER.

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ABSTRACT

Introduction

Persons with psychotic disorders have increased risk of justice system involvement. We aimed to estimate the risk of being accused or victim/witness of a crime while taking antipsychotic medications.

Methods

Using linked population-based health, registry and justice data from Manitoba, Canada, we conducted a cohort study (January 2002 - March 2020) in persons diagnosed with psychotic disorders. Between- and within-person analyses using Cox proportional hazards regression were conducted. Secondary-analyses evaluated sex-stratified risk, risk during exposure to individual antipsychotics, and risk of violent crime.

Results

4,215 persons were included, 1,676 (39.8%) were female. During follow-up, 1,007 (23.9%) subjects were accused and 207 (4.9%) were victim/witness of one or more crimes. Risk of being accused of a crime was significantly reduced during antipsychotic exposure in within-person analysis (adjusted hazard ratio [aHR] 0.72, 95% confidence interval [95% CI] 0.61,0.86) but was not statistically significant in between-person analysis (aHR 0.88, 95% CI 0.64,1.20). Risk of being victim/witness of a crime was reduced but not statistically significant (between-person aHR: 0.53, 95% CI 0.27,1.05; within-person aHR: 0.62, 95% CI 0.38, 1.04). In sex-stratified analyses, males had an 18-31% reduced risk of being accused of crime and 26-41% reduced risk of being victim/witness of crime, but findings were not statistically significant.

Conclusion

These findings suggest antipsychotics reduce the risk of being accused of a crime in persons with psychotic disorders. We also observed a trend towards reduced risk of being victim/witness of a crime.

INFLUENCE OF DIVERSITY ON DEALING WITH POLYPHARMACY

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ABSTRACT

Background

The Belgian city of Antwerp is a majority-minority city due to migration. In health care diversity is often related to other determinants of health inequity. Dealing with polypharmacy may also be impacted by diversity. It has been shown that a lower socioeconomic position increases the risk of polypharmacy. It is unclear what challenges diversity brings in the care for patients dealing with polypharmacy. This study aimed to examine experiences of primary health care workers, who almost daily encounter patients with a migration background or ethnic minority, providing care for these patient groups.

Methods

Twenty-three primary health care professionals (HCP), pharmacists, nurses, and physicians were interviewed. An inductive thematic analysis was undertaken.

Results

All HCP perceived low language skills as an important barrier for them to provide adequate support in dealing with polypharmacy. Another concern of HCP, poor health literacy and low educational levels, was sometimes masked by language problems. Most HCP didn't provide proactive care for patients fasting, for example during Ramadan, albeit they found it worrying for the health condition. Financial constraints were noticed most by pharmacists as some patients didn't buy all prescribed medication.

Conclusion

To guide and counsel patients with a diverse background who are dealing with polypharmacy remains difficult for primary health care professionals. Raising the awareness of determinants of health inequity is necessary.

EVIDENCE-BASED DATA FOR THE USE OF NEWLY APPROVED MEDICATIONS IN OLDER ADULTS: A DESCRIPTIVE ANALYSIS FROM CLINICAL TRIALS TO PRODUCT MONOGRAPHS

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ABSTRACT

Background

Older adults have historically been excluded from clinical trials, limiting evidence-based data. It is unclear whether the situation is similar with newly marketed medications. We aimed to describe 1) recommendations specific to older adults in monographs of newly marketed medications; 2) representation of older adults in clinical trials of those medications.

Methods

We listed all medications that received a notice of compliance from Health Canada between 2006-2020, excluding those with indications irrelevant to geriatrics or only used in hospital. We assessed the monograph recommendations' availability and clarity regarding older adults, and renal and hepatic impairment. We identified phase III-IV randomized controlled double-blind trials led in Canada/United States of 30 widely used medications. We extracted information on participants, and efficacy/safety analysis specific to older adults.

Results

We included 195 monographs. A quarter (n=47;24%) reported a lack of data regarding efficacy and/or safety in older adults. More than half reported uncertain/no recommendation for at least one stage of renal (n=101;52%) or hepatic (n=120;62%) impairment. From the 373 trials included, most (n=217;58%) did not limit inclusion based on age, but only 93 (25%) included a proportion of older adults similar or above the proportion found in real-life setting. Two studies (0.5%) reported the number of concomitant medications and 3 (0.8%), the number/score of comorbidities. Most trials (78%) did not provide efficacy or safety data specific to older adults.

Conclusions

Clinical trials still appear to under-represent older adults. The resulting lack of recommendations in monographs compromises evidence-based practice.

AN ANALYSIS OF ANTIPSYCHOTIC PRESCRIBING COSTS AND PATTERNS IN THE IRISH SETTING

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ABSTRACT

Second-generation antipsychotic use is growing as first-generation antipsychotic prescribing decreases. The cost of this shift in prescribing practices to the use of newer, more expensive agents is burdensome on healthcare systems. We aimed to quantify the prevalence and cost of antipsychotic prescribing in the Republic of Ireland, to compare antipsychotic prescribing patterns between funding models and to investigate regional differences in prescribing.

Quantitative analysis of a dataset from the Primary Care Reimbursement Service relating to antipsychotic drugs from April 2020-2022 inclusive was conducted using Microsoft Excel®. Descriptive statistics relating to the prevalence of prescribing of individual drugs, drug ingredient costs per funding scheme and to the State in 2021 were performed.

The prevalence of antipsychotic prescribing increased yearly from 2020-2022, peaking at 90,036 prescriptions in April 2022. Quetiapine, olanzapine, and risperidone were the most prescribed antipsychotics, accounting for 66.58% of antipsychotics on the General Medical Services scheme. Paliperidone was the drug associated with the highest cost. Regional variation in spending on paliperidone was identified between the East and West of Ireland. The total cost of antipsychotics to the State in 2021 was €34,010,700.50.

This study identified the large expenditure on antipsychotics in Ireland, with a higher proportion of the Irish healthcare budget spent on antipsychotics than that of the UK and the USA. Paliperidone prescribing variances led to large differences in spending across the country. To address these findings there is a need for the development of Irish antipsychotic prescribing guidelines to allow for structured, cost-effective prescribing.

ASSESSING THE USE OF POTENTIALLY INAPPROPRIATE MEDICATIONS AS A PREDICTOR OF HOSPITALIZATION IN NURSING HOME RESIDENTS: A COMPARATIVE STUDY OF THE KOREAN MEDICATION REVIEW TOOL AND BEERS CRITERIA

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ABSTRACT

Background

Hospitalizations of nursing home (NH) residents are a significant burden on healthcare system, and previous studies have suggested that inappropriate prescribing increase the risk of hospitalization. In order to implement a medication review (MR) system in Korean nursing home, long-term care-specific MR tool has been developed. We aimed to investigate the nationwide prevalence of potentially inappropriate medications (PIMs) using both the Korean tool and Beers criteria, and to assess their associations with hospitalization.

Methods

We identified 20,306 older adults aged 65 or above who were admitted to NH between 2008 and 2018 from a nationwide senior cohort database. We estimated the prevalence of PIM use on the date of NH admission based on the Korean tool and 2019 Beers criteria. The association between PIM use and hospitalization or emergency department (ED) visits within 30 days of admission was analyzed using Cox proportional hazard model.

Results

The average number of medications per person was 7.5 ± 4.7 . According to the Korean tool and 2019 Beers criteria, 89.3% and 67.9% of NH residents had PIMs, respectively. Having one or more PIMs based on the Korean tool significantly increased the risk of visiting the ED or being hospitalized (1-3: aHR=1.24, 95% CI 1.03-1.49; ≥ 4 : 1.47, 1.20-1.79). Having ≥ 4 PIMs based on Beers criteria increased the risk by 28% (1.28, 1.06-1.53).

Conclusion

Our study highlights that exposure to PIMs based on the Korean tool is a stronger predictor of ED visits or hospitalization in NH residents compared to Beers criteria.

ASSESSING THE IMPLEMENTATION OF CLINICAL DECISION SUPPORT SYSTEMS FOR PATIENTS WITH A HISTORY OF ADVERSE DRUG EVENTS IN KOREAN HOSPITALS: A NATIONWIDE CROSS-SECTIONAL SURVEY

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ABSTRACT

Background

Adverse drug events (ADEs) pose significant risks to patient safety, leading to higher patient morbidity, mortality, and healthcare costs. Identifying a patient's ADE history is essential for preventing recurrences. Clinical decision support systems (CDSS) have been implemented in many medical institutions to alert physicians when prescribing medications with known ADE histories.

This nationwide survey aimed to assess the current implementation status of CDSS for alerting ADE history in Korean hospitals.

Methods

A structured survey was conducted among 487 hospitals affiliated with the Korean Society of Health-System Pharmacists. The survey questionnaire gathered information on basic hospital characteristics, ADE reporting systems, and CDSS implementation for sharing and alerting ADE history.

Results

Of the 126 hospitals that responded, 118 had an ADE report system based on electronic or written form, and 86% of these reported having a CDSS in place for alerting ADE history. CDSS methods included prescription contraindication, limited permission, and information provision. Most hospitals determined the methods and criteria for applying alert for ADE history through internal committee discussions, with severity, causality, and preventability being common criteria.

Conclusion

This study identified that a majority of the participating hospitals had implemented ADR reporting systems and adopted CDSS for ADE history in Korea. Further research is needed to explore the effectiveness of these systems in preventing ADEs and to optimize their integration into clinical practice.

ORIGINAL AND RENEWED PRESCRIPTIONS IN DIFFERENT ATC GROUPS

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ABSTRACT

Background

In long-term pharmacotherapies, renewal of prescriptions is common. Renewing without the prescriber meeting the patient may lead to insufficient pharmacotherapy monitoring. This study aimed to determine the proportion of original prescriptions and prescriptions renewed with or without meeting the patient in different ATC groups.

Methods

A 10% random sample of all prescriptions issued in Finland between 1 January and 31 December 2019 was retrieved from the national Prescription Centre. Data on healthcare visits was retrieved from national registers. Prescriptions were classified as renewed in case of a renewal request or a previous prescription including the same ATC code. Prescriptions were considered renewed without meeting the patient if no healthcare visit on the date of renewal was found in the data. Descriptive analysis was conducted.

Results

The final sample included 2,815,091 prescriptions. Of them, 39.3% were original, 24.0% renewed with meeting the patient, and 36.6% renewed without meeting the patient. Of main ATC groups, the highest proportion of original prescriptions, prescriptions renewed with meeting the patient, and prescriptions renewed without meeting the patient was among dermatologicals (66.7%), antineoplastic and immunomodulating agents (44.7%), and cardiovascular system (52.8%), respectively.

Conclusion

Logically, original prescriptions were more common among ATC groups typically used for acute conditions and renewals among those typically used in chronic diseases. However, there were differences between ATC groups in renewing prescriptions with or without meeting the patient. Further research is needed to explore associations of different characteristics to renewing without meeting the patient and its implications on pharmacotherapy monitoring.

ANTIBIOTIC MEDICATIONS CONSUMPTION IN BRAZIL: PATTERNS AND TRENDS BETWEEN 2014-2019. A TIME-SERIES STUDY

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ABSTRACT

Background

Antimicrobial consumption drives the increase in antimicrobial resistance.

Objective

To analyze variations in antibiotic consumption and its appropriate use in Brazil from 2014-2019.

Methods

We conducted a time series study using the surveillance information system database (SNGPC) from the Brazilian Health Regulatory Agency. Antimicrobials sold in retail pharmacies were evaluated. All antimicrobials recorded for systemic use identified by the active ingredient were eligible. Compounded products and formulations for topic use (dermatological, gynecological, and eye/ear treatments) were excluded. The number of defined daily doses (DDDs)/1,000 inhabitants/day for each antibiotic was attributed. The number of DDDs per 1,000 inhabitants per day (DDIs) was used as a proxy for consumption. Results were stratified by regions and the average annual percentage change in the studied period was estimated. Finally, we categorized antimicrobial drugs into access, watch, and reserve group according to WHO Access, Watch, and Reserve (AWaRe) antibiotic classification framework.

Results

An overall increase of 30% in consumption from 2014 to 2019 was observed in all Brazilian regions. Amoxicillin, azithromycin and cephalexin were the antimicrobials more consumed, with the Southeast region responsible for more than 50% of the antimicrobials utilization. Among all antimicrobials, analyzed 45.0% were classified as watch group in all Brazilian regions.

Conclusion

We observed a significant increase in antibiotics consumption from 2014-2019 in Brazil restricted to the Northeast and Central West regions. Almost half of antibiotics consumed in Brazil were classified as watch group, highlighting the importance of promoting rational use in this country.

ISIMPATHY SHARED LEARNING MODEL

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ABSTRACT

Background

iSIMPATHY was an EU funded project delivering 6,481 person-centred medicine reviews and training to 212 healthcare professionals in Northern Ireland, Scotland and Republic of Ireland. A model for shared learning and peer support was needed to support healthcare professionals throughout the project.

Methods

A shared learning model was developed with 4 components: education (delivered by a clinical expert), case presentation, case-based discussion and addressing project challenges/solutions and was delivered in collaboration with Project ECHO NI at monthly virtual sessions, each of 90 minutes duration. Resources were uploaded on Moodle for access retrospectively. The project team participated in curriculum development to agree topics for the education component. Participants were surveyed at the end of both Years 1 and 2 to evaluate the model.

Results

A total of 13 sessions were delivered over 2 years. The average number of participants in Year 1 was 16 with 71% attending >7 sessions. At the end of Year 2, 86% respondents had applied their learning in practice, 88% had increased confidence delivering reviews and 63% agreed the network created a community of support. All participants responded that case based discussion was an impactful way of learning.

Conclusion

The iSIMPATHY virtual shared learning model was successfully developed and delivered and was well received by participants. The model is suitable for both cross sector and cross-border multidisciplinary healthcare professionals to support virtual shared learning and peer support in the roll out of structured medicine reviews.

PUBLIC'S PERSPECTIVE ON COVID-19 ADENOVIRUS VECTOR VACCINES AFTER THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME (TTS) REPORTS AND ASSOCIATED REGULATORY ACTIONS: A CROSS-SECTIONAL STUDY IN SIX EU MEMBER STATES

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ABSTRACT

Objective

In 2021, thrombocytopenia syndrome (TTS) was confirmed by the European Medicines Agency (EMA) as a rare side effect of the COVID-19 adenovirus vector vaccines from AstraZeneca or Janssen. We aimed to describe the public's knowledge of TTS and how it affected the willingness to be vaccinated with COVID-19 and other vaccines.

Methods

In 2022, a multi-country cross-sectional online survey was conducted in Denmark, Greece, Latvia, Netherlands, Portugal and Slovenia. The minimum target of participants to be recruited was linked to country population size. The results were analysed descriptively.

Results

In total, 3794 respondents were included in the analysis. Many (33.3% to 68.3%) reported being aware about TTS and its association with the vaccines from AstraZeneca and Janssen, though most were not familiar with the exact symptoms. Changes in willingness to be vaccinated with COVID-19 and other vaccines varied by country. The largest change in the willingness to be vaccinated with AstraZeneca and Janssen vaccines was in Denmark (61.2%), while the largest change in the willingness to be vaccinated with other COVID-19 vaccines was in Slovenia (30.4%).

Conclusion

Information about TTS seemed to be considered by the public in the European countries resulting in changed willingness to be vaccinated with the COVID-19 vaccines from AstraZeneca and Janssen. Willingness to be vaccinated against other COVID-19 vaccines and vaccines in general seemed to be determined by the approaches of the national health authorities to react to and communicate about the COVID-19 vaccination risks. Further investigation of risk communication strategies is warranted.

MEDICAL DEVICES GLOSSARY

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ABSTRACT

Background

As medicines, medical devices, which are used in prevention, diagnostics, therapy, and rehabilitation, are also crucial for all areas of healthcare. The World Health Organization (WHO) estimates that there are approximately two million different types of products on the global medical device market. To establish a common understanding in this heterogeneous work of the medical devices, a comprehensive Medical Devices Glossary was developed.

Methods

For the development of the glossary, the content and scope were defined, terms were collected, categories were formed, and the selected terms were assigned to the categories. A draft version was reviewed by 34 Austrian national experts. In addition, the process for ensuring future updates and version management was also determined.

Results

This first version of the glossary includes three glossary sections: the list of abbreviations (Glossary A) contains a total of 219 abbreviations, the list of terms (Glossary B) with 763 terms and their definitions and the list of symbols (Glossary C) which contains 140 graphic symbols and their explanations. All abbreviations, terms, definitions, and symbols are listed and described in German and English.

Conclusion

The Medical Devices Glossary is a very comprehensive and unique document in Europe for practical use in economy, politics, and research.

WHAT ARE THE BARRIERS AND FACILITATORS THAT INFLUENCE THE ADOPTION OF DIGITAL HEALTH-RELATED TOOLS FOR MEDICATION APPROPRIATENESS?

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ABSTRACT

Background

Digital health is described as the use and development of all types of digital technologies to improve health outcomes. It could be used to prevent medication errors which is a priority for health systems worldwide. However, the adoption of such tools remains slow. To improve adherence, an understanding of barriers and facilitators that can influence its adoption and use by healthcare professionals (HCPs) is the first step required. This study aims to identify factors (attitudes, knowledge, and beliefs) acting as barriers and/or facilitators reported by HCPs for the adoption of medication appropriateness digital health-related tools.

Methods

A systematic review was performed by searching the literature in the MEDLINE PubMed, and EMBASE scientific databases for original articles regarding qualitative and quantitative data.

Results

Fifteen articles were included and a total of 125 barriers and 108 facilitators were identified and categorized within technical, organizational, economical, user-related, and patient-related components. The most often reported barriers were the need for additional training (n=6) and the time consumed (n=6), and the facilitators were the easy way of using or learning how to use the tools (n=9).

Conclusions

The barriers and facilitators identified in this study can be used as a starting point for the designing of successful digital health-related tools. Future research includes economic evaluation-focused studies and in-depth case studies of specific barriers and facilitators.

ANALYSIS OF REAL-WORLD DATA FROM THE KOREA ADVERSE EVENT REPORTING SYSTEM DATABASE

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ABSTRACT

Backgrounds

Pediatric patients are not included in clinical trials due to ethical issues. Therefore, many medication labels did not include age-specific indications or dosing information. This has led to off-label medication use, which lacked data on its use in pediatric patients. Therefore, we aimed to analyze the real-world data to evaluate the safety of off-label drugs in pediatric patients.

Methods

Based on a previous study on the pediatric use of off-label medication, we selected 21 medications. Then, we analyzed 574,452 cases with the Korea Adverse Event Reporting (KAERS) Data to assess their adverse drug events as age groups and severity.

Results

We identified a total of 105,102 cases related to medications in KAERS data from 2014 to 2021. ADRs were reported in 7,154 cases (6.80%) in pediatric and adolescent groups; for ADRs that resulted in hospitalization or prolonged hospitalization, high incidence of piperacillin/tazobactam (389 events, 22.9%) and dexamethasone (176 events, 10.4%) were observed across all age groups. In the pediatric group, there were frequent reports of antibiotics such as cefazolin, meropenem, and salbutamol. Enalapril was reported especially in adolescents, and propacetamol was reported particularly in infants.

Conclusions

Despite avoiding off-label medication use, we often face using them for treatments. We verified the medications which need to evaluate more cautiously their usage and to determine their safety by age group.

DETERMINING THE FREQUENCY OF HIGH-ALERT MEDICATION IN GENERAL PAEDIATRIC WARDS TO GUIDE IMPROVEMENT STRATEGIES FOR MEDICATION SAFETY

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ABSTRACT

Background

Paediatric inpatients are at a high risk of drug-related problems. A list of 20 drugs of particular concern (high-alert medications (HAM)) from the perspective of paediatric pharmacists has been published for Germany with recommendations for interventions. Our aim was to analyse the use of HAM on general paediatric wards of a German university hospital to guide improvement strategies for medication safety.

Methods

We explored an established database created from the electronic medical record at our tertiary children's hospital from 2014 to 2019. The outcome was the exposure to HAM in 17059 paediatric admissions, stratified by age.

Results

11.8% of the admissions received at least one HAM. Out of the 20 HAMs, 14 were used in our setting. Phenobarbital and vancomycin accounted for almost half of this use (22.6% and 20.5% respectively). Potassium salts, midazolam, tacrolimus, cyclosporine, amphotericin and epinephrine were also frequently administered. More than 17% of the HAM were given to infants. The distribution of the different drugs used was age-dependent. Polypharmacy (median: 8 drugs/admission) and prolonged hospital stays (median: 7 days) were common among the affected admissions.

Conclusions

HAMs are widely used in the treatment of our inpatients, although few neonates, cardiac and complex oncology patients and no intensive care patients were treated in the selected wards. Therefore, interventions to improve medication safety, e.g., involvement of the hospital pharmacy, standardisation, or training, are expected to have a high potential benefit in general paediatric care, too. Drug utilisation studies are valuable to rationally prioritise medication safety initiatives.

A PILOT STUDY OF ADHERENCE TO ANTIHYPERTENSIVE TREATMENT IN GREECE

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ABSTRACT

Background

Medication adherence is a very important factor of successful antihypertensive therapy that has not been studied adequately. The aim of this pilot study was to check medication adherence to antihypertensives by using a modified MARS-5 questionnaire.

Methods

A six-item/5-scale modified version of the MARS-5 adherence questionnaire was used to evaluate adherence to antihypertensives in outpatients of the General Hospital of Katerini, in Northern Greece. The participants of the study were outpatients of the Department of Microbiology and the Department of Cardiology, who received antihypertensive therapy and visited the Hospital from February 1st, 2023 to April 30th, 2023. All participants gave their informed consent to participate in the study that checked adherence to antihypertensive therapy by using a subjective and an objective method: the modified adherence questionnaire and blood pressure measurement.

Results

82 patients that received antihypertensive therapy were enrolled in the study. 38 of them (46%) were male and 44 (54%) were female; their mean age was 63 years. According to the answers to the questionnaire, adherence to antihypertensives was very good in the study group (mean score 28.3 out of 30). This score of high adherence was in accordance to the good control of the measured blood pressure (mean systolic pressure 137mmHg, mean diastolic pressure 82mmHg, heart rate 74 beats per minute). Surprisingly, men had higher scores of adherence in all items checked.

Conclusion

Adherence to antihypertensive treatment was very good in the studied group in Greece, and was higher in men than women.

LINKING MEDICINAL PRODUCTS FROM ALL OVER EUROPE TO PHARMACOTHERAPEUTIC CLASSIFICATIONS WITH IDMP TO ENABLE THE SMOOTH CONNECTION OF DECISION SUPPORT SYSTEMS FOR MEDICATION MANAGEMENT IN MULTINAITIONAL AND MULTILINGUAL EUROPE

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ABSTRACT

Background

Europe has more than 5 medicinal drug dictionaries and databases per country, with an estimated 400,000 authorized medicinal product packs across the 27 member states. For developers of decision support systems, breaking out of the country of origin and accessing different national markets with varying languages and medicinal products is a challenge. The ATC classification is often used for medicinal products, but its granularity is insufficient for decision support. The implementation of ISO/CEN standards for identification of medicinal products (IDMP) could provide a universal language and code system to describe national medicinal products.

Methods

Reliable links could be established between the ATC classification Level V and the Pharmaceutical Product Concept in UNICOM, with instances of the Pharmaceutical Product Concept and their PhPIDs kept in a repository managed by WHO-UMC. An intermediary concept, the Virtual Medicinal Product Group (VMPGROUP), could be introduced to facilitate aggregation and guide cross-border services in prescribing and dispensing. A simple ontology of substance and dose form was used to create the VMPGROUP.

Results

A prototype of the approach was developed for four substances, with linkage to medicinal product dictionaries and drug labeling information in national languages.

Conclusion

The ATC and IDMP have many use cases, including drug information, drug utilization research, pharmaco-epidemiology, and decision support. As standardization in national agencies is slow, this proposal could be considered on an international scale. This could be an interesting work package for UNICOM follow-up projects.

DEVELOPING A METHODOLOGY FOR CROSSNATIONAL COMPARISON OF PHARMACOTHERAPEUTIC ARSENALS IN THE COUNTRIES OF EUROPE BY USING ISO/CEN STANDARDS FOR IDENTIFICATION OF MEDICINAL PRODUCTS (IDMP).

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ABSTRACT

Background

The variability in the number and nature of medicinal products across European countries and the US is not well understood, and there is no accepted method for comparing pharmacotherapeutic arsenals. The implementation of IDMP holds the promise of providing deeper insights into this variability.

Methods

Data were collected from five countries - Belgium, Greece, Norway, Italy, and the US - on authorized and marketed medicinal product packs for four substances. The data were standardized to IDMP, and a common format Excel sheet was used to check consistency across countries.

Results

The number of medicinal product packages and products varied widely across the countries, with Belgium having the fewest and the US having the most. 124 unique pharmaceutical products were identified across the four substances, which were further aggregated to create 65 unique VirtualMedicinalProductGroups.

Conclusion

IDMP implementation provides new insights into the variability in medicinal products across countries, and harmonizing concepts provides a trustworthy basis for comparison. Further exploration is needed to understand the relationship between national identifiers and IDMP concepts.

A TIME SERIES ANALYSIS OF IMMUNE CHECKPOINT INHIBITORS USE IN ITALIAN POPULATION: 2017-2022

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ABSTRACT

Background

The advent of immunotherapy significantly changed the therapeutic scenario of cancer patients. The adoption of immune checkpoint inhibitors (ICIs) represented the new weapon for cancer treatment in different settings. The aim of this study was to describe trends in ICI utilization and corresponding healthcare expenditures within the Italian population.

Methods

We analyzed IMS-Health National data to describe trends in total number of claims, total annual expenditures, and expenditures per claim for ICIs from January 2017 to December 2022 among Italian population (~60 million inhabitants) (PRIN2017 Prot.2017NR7W5K). Seven market approved ICIs in Italy were analysed (Ipilimumab, Nivolumab, Pembrolizumab, Durvalumab, Avelumab, Atezolizumab, Cemiplimab). A time-series modeling was used for analysis.

Results

From 2017 to 2022, utilization rates for each of the seven market approved ICIs in Italy increased 15.1%, from 215,441 to 614,510 unit-per-year, also overall expenditure on ICIs increased 16.3%, from €236,322,360 to €778,745,480. In the first three-year period analyzed, Nivolumab recorded higher rates of consumption and spending than the other ICIs with a sharp decrease in the following years (-57.1% consumption and -46.6% spending). Opposite trend was recorded for Pembrolizumab with a slow increase in consumption (+38.9%) and spending (+29.0%) over the whole time period.

Conclusion

The rapid increase in the use of ICIs has accounted for a disproportionate share of the growth in public pharmaceutical consumption and spending in Italy. Future research should relate patient outcomes to overall spending to justify the long-term investment in the use of these therapies for the Italian health service.

DRUG UTILIZATION PROFILES OF IMMUNE CHECKPOINT INHIBITORS FOR THE TREATMENT OF SOLID TUMOURS

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ABSTRACT

Background

Immune checkpoint inhibitors (ICI) are increasingly used across multiple cancer types and stages and little is known about real-world outcomes. The study aim was to assess drug utilization patterns of patients diagnosed with solid tumours treated with ICIs in Italy.

Materials and methods

A retrospective study (PRIN2017 Prot.2017NR7W5K) was conducted in Campania Region during 2017-2021. Data were retrieved from the Monitoring Registries of the Italian Medicine Agency, i.e. the Drug-product Registry (DPR), consisting of dispensed treatments and clinical info on patients with a cancer diagnosis using ICI in Italy. Outcomes were end of drug-treatments, frequent immune-related adverse events (irAEs), mortality rates and all-cause mortality.

Results

In total, 7,456 patients started an ICI treatment between 2017 and 2012. Overall, the 66.4% of these interrupted the immunotherapy treatment cycle within about 8 months (264.9 mean days; SD 325.2 days). Majority of patients were treated with Nivolumab (41.2%) and Pembrolizumab (40.5%). The overall IrAEs rates recorded was very low (0.1%), the highest addressed for pembrolizumab and atezolizumab treatments (0.2%). Same trend was recorded for mortality rates and causes. The overall mortality rate was 4.3%, highest rates were recorded for avelumab (9.1%) and ipilimumab (8.2%). Altogether, all-causes mortality were rarely related to disease progression (8.1%) or to drug toxicity (0.6%) for all seven ICIs.

Conclusions

Low rates of irAEs, mortality, and drug toxicity occur with immunotherapy for solid tumors. Findings highlights benefits of immunotherapy in a real-world scenario candidate as a new frontier for solid tumors treatment.

BIOSIMILARS PRICING IN ARGENTINA, BRAZIL AND ITALY

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ABSTRACT

Biosimilar medicines are biologicals highly similar to an already licensed reference product (RP). The market entry of these products is expected to reduce the costs of biological therapies. Thus, this study aims to evaluate the differences between the prices of biosimilars and the corresponding RP in Argentina, Brazil, and Italy.

This is a cross-sectional study investigating the differences in list prices between biosimilars and RP in Argentina, Brazil and Italy. For each dosage form, the price per milligram or international unit was calculated. Biosimilar price difference (BPD) was calculated by dividing the unit price of the biosimilar by the unit price of the corresponding RP and the results were presented as percentage, indicating the proportion of difference between the price of biosimilar in relation to the RP.

The analysis covered 15 biosimilars approved in Argentina, 36 in Brazil, and 44 in Italy. Brazil had the highest median price reduction (-22.1%) in biosimilars price in relation to RP, followed by Italy (-20.0%) and Argentina (-18.9%). The BPD in Brazil varied from -70.7% to 206.0%, while in Argentina and in Italy they ranged from -32.7% to 40.7% and -61.0% to -6.3%, respectively. All the biosimilars prices in Italy were below the price of the RP, conversely, there were one and six products priced above the RP in Argentina and Brazil, respectively.

The study revealed a marked dispersion in BPD across the studied countries. Governments should evaluate the effectiveness of the pricing policies in achieving the expected savings with market entry of biosimilars.

EXTENT OF THE RANITIDINE SHORTAGE AND ITS IMPACT ON ACID SUPPRESSION DRUG UTILIZATION IN CANADA AND THE UNITED STATES: AN INTERRUPTED TIME SERIES ANALYSIS

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ABSTRACT

Drug shortages are a complex global challenge, and few studies have analyzed quantitative data on their impacts. In September 2019, detection of a nitrosamine impurity in ranitidine led to recalls and shortages. We investigated the extent of the ranitidine shortage and its impacts on acid suppression drug utilization in Canada and the United States (US).

We conducted an interrupted time series analysis of acid suppression drug purchases in Canada and the US from 2016 through 2021 using IQVIA's MIDAS database. We used autoregressive integrated moving average models to determine the impact of the shortage on purchasing rates for ranitidine, other histamine-2 receptor antagonists (H2RAs), and proton pump inhibitors (PPIs).

Prior to the recalls, 20,439,915 ranitidine units were purchased monthly in Canada and 189,038,496 in the US on average. After the recalls started in September 2019, purchasing rates decreased for ranitidine (Canada $p = 0.0048$, US $p < 0.0001$) and increased for non-ranitidine H2RAs (Canada $p = 0.0192$, US $p = 0.0534$). One month into the recalls, purchasing rates dropped by 99% (Canada) and 53% (US) for ranitidine and increased by 128.3% (Canada) and 37.3% (US) for non-ranitidine H2RAs. PPI purchasing rates did not change significantly in either country.

The ranitidine shortage led to immediate and sustained shifts in H2RA utilization in both countries, potentially affecting hundreds of thousands of patients. Our results emphasize the need for future studies of the clinical and financial implications of the shortage, and the importance of ongoing work to mitigate and prevent drug shortages.

CROSS-SECTIONAL SURVEY TO DESCRIBE MEDICINE USE AMONG SYRIAN ASYLUM SEEKERS AND REFUGEES IN GERMANY

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ABSTRACT

Objectives

The aim of our study was to describe medicine use and document self-reported diseases or conditions for which medicines were used among Syrian asylum seekers and refugees (AS&Rs) in the German state of North Rhine-Westphalia (NRW). We examined in this study differences in the use of medicines among different age and sex groups of the study participants.

Methods

Fifteen different refugee shared accommodation centres in the greater Cologne area, a community centre with a language school and consultation office, and other places frequented by the Syrian community.

Results

Of the 1641 Syrian AS&Rs who took part in our study, the overall 7-day prevalence of medicine use was 34.9%. Among adults, headache and hypertension were the most common indications that led to medicine use. By dose, hypertension (954 doses) and diabetes (595 doses) were the first and second most frequent indication. Among children, fever and cough were the most common indication; ibuprofen and hederæ heliæ folium preparations were the most used medicines. Low prevalence was found of medicine use for the treatment of either infectious diseases or mental disorders.

Conclusion

Among the Syrian AS&Rs in NRW who participated in the study, non-communicable diseases (NCDs) were common presumed causes of use of medication among adults. We encourage future studies to pay more attention to NCDs medicine use among AS&Rs. Researchers should also consider reaching AS&Rs who live in private housing and not limit studies only to newly arrived AS&Rs who live in shared accommodation centres.

DISINVESTMENT PROFILE OF DRUGS IN THE BRAZILIAN UNIFIED HEALTH SYSTEM BETWEEN 2012-2022

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ABSTRACT

Background

Divestment refers to withdrawing resources from interventions that offer little or no health gain compared to their cost, seeking to reinforce practices proven to be safe, effective or more cost-effective and to optimize health outcomes and the economic sustainability of health systems. The study characterized the drug divestment process conducted by the National Commission for Incorporation of Technologies (CONITEC) in the Brazilian Unified Health System (SUS) between 2012 and 2022.

Methods

We analyzed the technical recommendations reports produced by CONITEC. Drug name and ATC classification, clinical indication, proponents, occurrence of Public Consultation, recommended divestment modality and justifications for divestment were evaluated.

Results

We evaluated 25 reports corresponding to 80 technologies. All requests were from the Brazilian Ministry of Health. The disinvested drugs mainly belonged to the ATC classes L (29.3%), J (21.3%) and A (20%). The main related clinical indications were rheumatoid arthritis, HIV, hepatitis C, and Crohn's disease. The main justifications were absence of market approval for the drug in Brazil (24.1%) and problems related to safety (20.6%) and effectiveness (19.9%). Public Consultation was carried out in 36% of the situations. There were recommendations to exclude the drug for a specific indication in 31.3% of the cases, total exclusion from the SUS in 30%, exclusion of a particular pharmaceutical presentation and exclusion of presentation for a specific indication in 27.5% and 10%, respectively.

Conclusions

Although divestment initiatives have advanced in recent years, this theme still needs to improve in establishing a solid agenda in Brazil.

THE INCORPORATION OF RIFAPENTINE FOR THE PREVENTIVE TREATMENT OF TUBERCULOSIS IN THE BRAZILIAN HEALTH SYSTEM

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ABSTRACT

Introduction

Rifapentin was incorporated into the Brazilian Health System in 2021, aiming to improve the effectiveness of Latent tuberculosis infection (LTBI) treatment, and , to be used in association with isoniazid, in weekly doses for a period of 3 months (3HP). This study analyzes the incorporation of this new treatment in different macro-regions of the country.

Methods

This is a descriptive quantitative study, using secondary data from the latent tuberculosis database (IL-TB) managed by the Brazilian Ministry of Health (MoH). The IL-TB records non-compulsory notifications of latent tuberculosis cases treated in the country. Treatment variables and regional uptake of regimens were analyzed. The study was approved by the ENSP/Fiocruz Ethics in Research Committee.

Results

Among the total number of latent TB case records in 2021, 93% were treated with isoniazid, 6% with rifampicin and only 1% with rifapentine + isoniazid. By 2022, these percentages had risen to 62%, 6% and 31%, respectively, showing rapid adherence to the new combined treatment instead of INH alone. We also observed consistent use of rifampicin. The regional dispersion shows that most treatments were administered in health units in the Southeast, followed by the North, data consistent with the higher incidence of tuberculosis in these two macro-regions.

Conclusion

The MoH in Brazil centralizes TB treatment and care. From the point of view of pharmaceutical logistics , such information is extremely important to ensure medicines availability. This research will support adequate forecasting and distribution, and contribute with future analyses of treatment effectiveness.

USE OF NON-SPECIFIC HUMAN IMMUNOGLOBULINS IN AMBULATORY PATIENTS: A DESCRIPTIVE ANALYSIS FROM A HOSPITAL'S REGISTRY

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ABSTRACT

Introduction

The use of non-specific immunoglobulins (NSI) has increased in recent years, especially in unauthorized indications. Due to their high cost and complicated manufacture, the study of their use in real-world practice is of great relevance.

Objectives

Describe the use, indications, and costs of the NSI.

Methods

We conducted a retrospective observational cohort study on incident users of NSI between Sep-2019 and Dec-2021. Data was obtained from Hospital Vall d'Hebron's Patients and Treatment Registry. Evidence of use was classified following national guidelines (authorized, unauthorized with or without scientific evidence or unknown evidence). A descriptive analysis was performed with RStudio.

Results

There were 224 incident users of NSI with a follow-up of 207.7 person-year. Population included 111 (49.6%) females with a median age of 42 years. Use for authorized indications (64.7%) included transplanted organ and tissue status (20%), common variable immunodeficiency replacement therapy (11.6%) and inflammatory polyneuropathy (7.4%). Unauthorized indications included immunodeficiency associated with other major defects (12.6%), dermatopolymyositis (3.3%) and encephalomyelitis (1.9%). A 42% of patients discontinued the use of NSI mainly for remission (29%) or lack of response (18%). Mean cost of NSI per patient-month was 2,213.39€ and was higher (3,213.9€) in indications with unknown evidence. The total cost of NSI treatments was 4,246,655.89€.

Conclusions

NSI were prescribed for heterogeneous indications focused on primary or secondary immunodeficiencies and inflammatory or autoimmune diseases. A third of NSI were used in unauthorized indications with higher costs. NSI use should be prioritized in authorized diagnosis indications with proven efficacy.

REAL WORLD EVIDENCE ON ANTIBIOTICS USED FOR URINARY TRACT INFECTIONS IN AUSTRALIAN NURSING HOMES FROM 2016 – 2019

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ABSTRACT

Background

Nursing homes (NHs) are known to be a reservoir for antimicrobial resistance (AMR) development due to high infection burden and antibiotic use. Urinary tract infection (UTI) is the most common reason for antibiotic use. Real life data on antibiotic use is lacking in this setting. Aim is to investigate the utilization trends of antibiotics commonly used to treat UTIs in NHs.

Methods

Pharmacy medication data of NH residents in the Illawarra region (Australia) was used for repeated cross-sectional analysis, between May 2016 to May 2019. Primary outcome was monthly prevalence of systemic antibiotics commonly used for UTIs. Secondary outcomes included antibiotic type and duration of use determined as the number of antibiotic days per 100 residents' days. Trends were analyzed using descriptive statistics.

Results

This study included 3459 unique residents from 20 different NHs. Antibiotic use decreased slightly over time with a mean of 168/1000 (95% CI 146 -177) residents on one or more antibiotic per month in June 2016 and 148/1000 (95% CI 127-156) in May 2019. Amongst the UTI antibiotics, cefalexin, amoxicillin and amoxicillin/clavulanic acid were most frequently used. The average duration of antibiotic use was 8 days per 100 residents' days, with a small proportion (< 2%) used for ≥ 3 months (261 days on average).

Conclusion

We found high prevalence of UTI antibiotics in Australian NHs between 2016 and 2019. A small proportion of residents were on prolonged durations of antibiotic use. Both high use and prolonged durations are known determinants for accelerating AMR development.

ANNUAL COVERAGE OF TREATMENT FOR INTRAOCULAR PRESSURE IN PATIENTS WITH GLAUCOMA THROUGH ITALIAN ADMINISTRATIVE HEALTHCARE DATA

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ABSTRACT

Background

Glaucoma is preventable by reducing intraocular pressure (IOP) through medications, for most adults. This study aimed at analyzing IOP-treatment coverage from the perspective of the Italian National Health Service (INHS).

Methods

From the Fondazione Ricerca e Salute (ReS) database (~5 million inhabitants/year), patients with glaucoma/IOP are identified by in-hospital diagnosis (ICD-9-CM codes) and/or disease waiver claim and/or IOP-drug supplies (ATC codes) in 2018, and split into new and old (until 2013) IOP-drug users. The IOP-drug supply is the index date. Among patients who did not change the therapy within the follow-up year, treatment coverage (DDD) is assessed, also related to comorbidities potentially interfering with the drug administration.

Results

In 2018, 96,700 (2.0%) patients with glaucoma/IOP and treated with IOP-drugs are identified. Within the follow-up year, among old users (81,220/96,700; 84.0%): 73.9% (60,050/81,220) did not change therapy; timolol (plain and combinations) was the most dispensed (59.2%); 54.6% are treated continuously (>75% of follow-up year); ~30% are covered for ≤50% of the year. Among new users (15,480/96,700; 16.0%): 82.1% (12,715/15,480) did not change therapy; timolol (plain and combinations) was the most dispensed (62.8%); 17.3% are treated continuously (>75%); 65.0% are covered for <25% of the year. Following the comorbidity analysis, depression (~10%), cerebrovascular diseases (~5%) and psychosis (3%) are the most frequent in both cohorts. Treatment coverage reduced with increasing comorbidity number.

Conclusion

Administrative healthcare data of the universal-coverage INHS allow to capture the burden of glaucoma from a patient-centered view.

DO'S AND DON'TS FOR THE EUROPEAN COMMUNITY PHARMACIST WHEN DISPENSING ANTIBIOTICS: A DELPHI STUDY

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ABSTRACT

Background

Community pharmacists influence the quality of antibiotic use, but specific tasks for community pharmacists to enhance quality of use when dispensing antibiotics have not been defined.

Aim

To define tasks of the community pharmacist in antibiotic dispensing in the European Economic Area.

Methods

A Delphi study with community pharmacist experts in the European Economic Area. Statements on potential tasks during the antibiotic dispensing process were based on a systematic literature review. Participants rated the statements in three rounds from 1 (not important) to 9 (very important). Consensus was defined as $\geq 80\%$ of experts rating a statement between 7 – 9. An online expert meeting was conducted between rounds one and two. Scores for all statements were analysed descriptively.

Results

The first round of the Delphi study was completed by 38 experts from 22 countries. Ninety-seven statements were rated within five themes: 1) collaboration with prescribers, 2) checking prescriptions and dispensing, 3) counselling, 4) education and 5) pharmacy services. Consensus of importance was reached for 71 out of 97 statements. Potential tasks included advising and collaborating with prescribers, guarding safety items, and having access to specific prescription information. Additionally, pharmacists should counsel patients related to the dispensed antibiotic and on antimicrobial resistance and infectious diseases. Pharmacists should not dispense antibiotics without prescriptions or prescribe antibiotics.

Conclusion

Community pharmacists have an extensive role in antibiotic use. Our recommendations should be taken up by policy makers, educators, and community pharmacists to enhance the quality of antibiotic use.

CLOTTING FACTORS AND CONCOMITANT DRUGS UTILIZATION IN PATIENTS WITH HAEMOPHILIA A AND B THROUGH A LARGE ITALIAN ADMINISTRATIVE DATABASE

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ABSTRACT

Background

The replacement therapies of haemophilia A – HA (clotting factor VIII - FVIII) and HB (FIX) are administered on-demand or lifelong (prophylaxis). This study aimed to assess the supply of FVIII, FIX and concomitant drugs, reimbursed by the Italian National Health Service (INHS).

Methods

From the Fondazione Ricerca e Salute (ReS) database (~5 million inhabitants/year), males with one in-hospital diagnosis of haemophilia and/or ≥ 1 supply of FVIII/FIX, from 2017 to 2019 are categorized by prophylaxis (≥ 5 dispensations/ ≥ 1750 UI/kg, annually) or on-demand (remaining patients) therapy. Within one-year after the less recent diagnosis/FVIII-FIX supply, consumptions of clotting factors, and concomitant drugs are assessed.

Results

Three-hundred-forty-two inhabitants with HA (mean age 47 ± 24) and 63 with HB (36 ± 22 y.o.) are identified; 93% are treated with FVIII (318/342) and FIX (59/63), respectively. Within follow-up, 33.6% of patients with HA (107/318) and 45.8% with HB (27/59) are treated for prophylaxis, respectively; the rest is supposed to be on-demand. On average: people with HA received $5969 \pm 10,800$ UI/Kg/year of FVIII for prophylaxis and 363 ± 428 UI/Kg/year on-demand; patients with HB received 3479 ± 1953 UI/Kg/year of FIX for prophylaxis and 612 ± 589 UI/Kg/year on-demand. Within one-year follow-up, ≥ 1 concomitant drug is dispensed to: 73.8% (79/107) of prophylaxis HA-patients and 95.3% (201/211) of on-demand HA-people; 92.6% (25/27) of prophylaxis HB-patients, and 78.1% (25/32) of on-demand HB-people.

Conclusion

Despite the rarity of haemophilia, administrative data can reflect the current clinical practices through the INHS perspective.

TRENDS OF PRESCRIBING AND DISPENSING METFORMIN UNDER THE IMPACT OF WAR AND COVID-19 IN UKRAINE

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ABSTRACT

Background

During major crises (pandemic, war), patients with chronic diseases such as diabetes are among the most unprotected. Today, more than 1.3 million Ukrainians have diabetes. Metformin is the most commonly prescribed oral antidiabetic drug within the national program for reimbursement of medicines in Ukraine. The aim of this study was to analyse trends in prescribing and dispensing metformin under the impact of war and COVID-19 pandemic in Ukraine.

Methods

Data on the monthly prescribing and dispensing of the oral antidiabetic drug metformin covered by the Ukrainian national drug reimbursement program were collected from public data of the National Healthcare Service of Ukraine. Data were expressed as the ratio of prescribed and dispensed prescriptions and Defined Daily Doses per 1,000 inhabitants per day (DDD/TID) among all population of Ukraine and in each region during 2019-2022.

Results

Total DDD/TID of metformin increased from 2.74 in April 2019 to 5.85 in December 2021 (before the war). By starting the war in March 2022, it decreased to 2.86 DDD/TID but increased to 5.20 in December 2022, primarily due to increasing consumption in regions not influenced by military operations. The worst situation of metformin consumption was observed in the provinces of Luhansk, Donetsk, and Kherson, involved in the war. The ratio between dispensed and prescribed drugs with metformin was 92.4% (87.2-95.7%) and 87.8% (70-94.4%) before and after starting the war respectively.

Conclusion

War in Ukraine greatly influenced the utilization of metformin among Ukrainians much more significantly than the pandemic of COVID-19.

PREVALENCE AND INCIDENCE OF USE OF ORAL ANTICOAGULANT DRUGS IN THE UMBRIA REGION IN THE PERIOD BEFORE AND AFTER THE APPLICATION OF THE AIFA NOTE 97

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ABSTRACT

Background

In Italy, the reimbursement of oral anticoagulants by the National Health Service (NHS) is ruled by AIFA Note 97 that, in October 2020, extended the possibility of prescription also to general practitioners, exclusively for patients with Non-Valvular Atrial Fibrillation, one of the most relevant chronic diseases of elderly patient. The objective of the study is to describe the characteristics of oral anticoagulant users in the period before and after the application of the Note 97.

Methods

The prevalence and incidence of use, stratified by age group and sex, were calculated for New Oral Anticoagulants (NOACs) and Vitamin K Antagonists (VKA) based on the pharmaceutical prescriptions charged to the NHS of the Umbria Region.

Results

Umbria is the region with the highest use of NOACs in Italy, also preferred for new treatments (incidence of use), increasing with age and a peak of users between 90-94 years of age (from 340 per 10.000 inhabitants in 2019 to 374 in 2021). In 2021, exposure to NOACs in the adult population increase with age for both genders, especially among the elderly, with a higher prevalence of use in men (around 25%) than in women (around 20%).

Conclusions

The results showed that the Note 97 did not result in a meaningful change in the consumption of oral anticoagulants. The NOACs are the category with the highest prevalence and incidence of use, especially in the elderly population because they have a better safety profile and manageability than the VKA.

NURSES' ROLE IN INTERPROFESSIONAL PHARMACEUTICAL CARE

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ABSTRACT

Background

To prevent missed care and promote interprofessional collaboration, healthcare workers should clearly know what to expect from each other in different settings/situations.

We aimed to investigate nurses' role in delivering pharmaceutical care, to develop a consensual framework about this role, and finally, to examine competences student nurses need to fulfill this role.

Methods

A mixed method study in nurses, physicians, pharmacists and nurse students of 14 European countries was performed between 2018 and 2021.

Results

The NUPHAC-EU framework was developed based on the results of a cross-sectional study in 6719 healthcare workers, followed by 340 in-depth interviews and a scoping review of the literature. The framework, evaluated by 1362 healthcare workers, consisted of the patient and his network, seven main nurse responsibilities, 26 tasks within these responsibilities, varying autonomy levels, and 20 contextual factors.

Based on the NUPHAC-EU framework, a competence framework with 60 competences was developed through 5 Delphi rounds and cross-sectionally evaluated in 1807 nurse students. This evaluation showed the embedding of pharmaceutical care should be extended: 77% of the students perceived an insufficient preparation to achieve pharmaceutical care competences in practice. Mean knowledge scores of nurse students were 56/100 (level 5 students), 68/100 (level 6), 72/100 (level 7).

Conclusion

The future of the NUPHAC-EU framework and the competence framework will depend on its evidence-based implementation in nurse education, interprofessional education and clinical practice. Our study offered healthcare workers, nurse educators, researchers and policy-makers the opportunities to move towards more interprofessional and integrated pharmaceutical care.

HIGHER SOCIOECONOMIC LEVEL IS ASSOCIATED WITH PRESCRIPTION OF CGRP (CALCITONIN GENE-RELATED PEPTIDE) INHIBITORS TO MIGRAINE PATIENTS

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ABSTRACT

Background

Triptan use has been associated with higher level of education, higher income and health insurance in migraine patients. To our knowledge, evaluation of socioeconomic differences regarding the prescription of CGRP (calcitonin gene-related peptide) monoclonal antibody inhibitors as prophylactic treatment of chronic migraine has not been studied.

Methods

This was a register-based cohort study of patients with migraine diagnosis in Region Stockholm. The socioeconomic variable (exposure) was categorized according to three levels: high, middle and low socioeconomic level. The outcome was defined as at least one dispensed prescription of CGRP inhibitors and possible associations were analyzed with chi-square tests and odds ratios with 95% confidence intervals.

Results

Of the 85 829 patients in Region Stockholm with migraine diagnosis and available socioeconomic data (from January 1993 to June 2022), 2 269 (2.6%) had received a CGRP inhibitor while the majority had not (N=83 560; 97.4%). We found an association between socioeconomic level and having received CGRP inhibitors, $p < 0.0001$. Patients with high and middle socioeconomic level were more likely than those with low socioeconomic level to have received CGRP inhibitors (OR 1.52; 95% CI 1.38-1.68; $p < 0.0001$).

Conclusions

This study showed a significant positive association between higher socioeconomic level and having received CGRP inhibitors, which could be an indication of unequal healthcare. To address this issue, directed information should be provided to prescribers. Furthermore, information should be given to the public both about migraine in general and the possibility of prophylactic treatment for chronic migraine.

UNDERSTANDING PEOPLES' VIEWS AND USE OF ANTIBIOTICS IN JORDAN

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ABSTRACT

Background

The misuse of antibiotics contributes to the emergence of antimicrobial resistance. Antimicrobial stewardship programmes (ASP) can help here, and successful ASP interventions need to be grounded in a good contextual understanding.

Aim

To understand people's beliefs about and use of antibiotics in Jordan, a low-middle income country.

Method

Members of the general public were recruited via social media and in person at community groups to take part in a focus group. The socio-ecological model guided exploration of factors relating to individual experiences, relationships, community, healthcare, and regulation. Focus groups were audio-recorded, transcribed verbatim, and analysed inductively and deductively using thematic analysis.

Results

Eighteen males and 25 females participated in six focus groups. Seriousness of symptoms impacted health care choices, participants described 'self-medication' as a common first act, buying medicines particularly from community pharmacies. Respondents viewed antibiotics as similar to other medicines available over-the-counter (OTC), which they bought in response to symptoms, and shared amongst family members. Participants appeared to have little awareness of the prescription-only status of antibiotics, or indeed the emergence of antibiotic resistance. Contextual and cultural factors influenced decision-making, including affordability, difficulty accessing health services and medicines. Weak regulatory enforcement in access to was perceived as another influencing factor in health decisions and antibiotic use.

Conclusion

This study offers insights into how antibiotics are used by the general public in Jordan at the individual and health system levels. Understanding how antibiotics are used can inform decision-makers when identifying areas for possible ASP interventions.

INSULIN ANALOGS IN TYPE 1 DIABETES TREATMENT: AN INCORPORATION PROCESS STUDY IN BRAZILIAN UNIFIED HEALTH SYSTEM (SUS)

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ABSTRACT

Objectives

Despite insulin analogs registration being dated since 1997 in Brazil, availability in Brazilian Unified Health System (SUS) came twenty years later. One way to understand this delay in submission and incorporation is analyzing SUS' Health Technology Assessment Committee (CONITEC) technical recommendation reports. This study aims to scan and examine insulin analogues for type 1 diabetes mellitus (T1DM) submissions to CONITEC and its reports.

Methods

This descriptive and retrospective research collected demands and recommendation reports of insulin analogs from CONITEC's website between 2011 and 2022. Data related to evaluation process, evidence on safety, efficacy, cost-effectiveness, and budgetary impact available in reports and arguments to justify CONITEC's recommendations were defined as variables.

Results

Five requests for insulin analogues to T1DM evaluation were identified until 2022, first of which in 2013. Four reports were considered, two with an incorporation recommendation, one for non-incorporation and another for conditional price maintenance. Evidence of safety and efficacy was based on systematic reviews, meta-analyses and observational studies. All reports have in common high budgetary impact as the main obstacle to incorporation, ranging from 2,7 million to 3,7 billion BRL in five years. Long-acting insulin analogs positive recommendation with cost conditional equal or lower than NPH made in 2019 was revisited in 2022, own to trading session failure after the incorporation.

Conclusion

The main difference between insulin analogs and NPH is still related to adherence increase and post-prandial glycemic control. It is important to follow up actively CONITEC's decisions to maintain SUS sustainability.

EFFECTIVENESS AND SAFETY OF ALIROCUMAB AND EVOLOCUMAB FOR HYPERCHOLESTEROLEMIA IN A POPULATION WITH HIGH CARDIOVASCULAR RISK.

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ABSTRACT

Background

Criteria for use of PCSK9 inhibitors more restricted than those approved were established in Catalonia by CatSalut to improve their efficiency, with different LDL-C targets according to risk factors. Patient's data are included in the Registry of Patients and Treatments (RPT). The aim of the study is to analyse adherence to these criteria and results.

Methods

A retrospective study of patients treated with PCSK9 inhibitors at Vall d'Hebron University Hospital between 2016-2021 was performed using data from the RPT and medical records. Degree of agreement with CatSalut criteria, LDL-C-responders (decrease $\geq 30\%$), cardiovascular events and discontinuations were analysed.

Results

A total of 193 patients treated with alirocumab (106) or evolocumab (87) were followed for a median of 27 months (IQR 23). Median age was 57 years (IQR 25); 63% were men. Most patients (70%) had non-familial hypercholesterolemia (NFH). In 82% of cases treatment was for cardiovascular secondary prevention. The main risk factor was previous ischemic heart disease (66.8%). Median LDL-C decreased from 139 (IQR 52) to 62 (IQR 48) mg/dl. In 72% of patients, all CatSalut criteria were met; the principal reason for not-fulfilling criteria was baseline levels of LDL-C below those required. Rate of response was 80%. During follow-up, 19 patients (9.8%) had a cardiovascular event, and 15 (7.7%) discontinued treatment, in two cases due to toxicity.

Conclusion

PCSK inhibitors were used according to CatSalut criteria in three out of four cases. In this high-risk population, incidence of cardiovascular events was similar than in clinical trials.

UTILISATION AND PRESCRIBING PATTERN OF DISEASE-MODIFYING ANTIRHEUMATIC DRUGS (DMARDs) IN SCOTLAND SUPPLIED THROUGH HOMECARE SERVICES: A POPULATION-BASED STUDY

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ABSTRACT

Background

Disease-modifying antirheumatic drugs (DMARDs) are the key in treating inflammatory rheumatological disorders; these include biological DMARD (bDMARDs), targeted-synthetic DMARDs (tsDMARDs) and conventional DMARDs (cDMARDs). In Scotland, these complex medications are mostly prescribed in hospitals but delivered via Homecare services. We evaluated the utilisation and prescribing patterns of these medications because there is lack of such data, to quantify and assess their quality of use.

Methods

A retrospective cohort study of all patients with an inflammatory rheumatological disorder prescribed one of these DMARDs between January-2019 and September-2022, using data from two Homecare companies (~90% of Scottish homecare prescribing coverage). Prescribing patterns were quantified using monthly number of prescriptions, stratified by DMARDs class, patient's characteristics (age, sex, deprivation) and indication. Data were analysed using descriptive statistics.

Results

Overall, 241,323 prescriptions were included for 17,761 patients (mean age 52.0 [\pm 16.5], 63% female, 87% received a single drug, equally distributed by deprivation). Rheumatoid arthritis (RA) was the most common treated indication (53.4%) [treated mostly with adalimumab (29.8%) and etanercept (29%)], followed by psoriatic arthritis (27.5%) [treated mainly with adalimumab (38%) and secukinumab (25.5%)]. Overall, bDMARDs accounted for ~90% of the 19 homecare DMARD prescribing; principally adalimumab (37%) followed by etanercept (25.7%). There was a consistent pattern in utilisation trends over time across age groups, sex, DMARD class.

Conclusions

RA was the most common rheumatological indication for DMARDs and bDMARDs accounted for the majority of prescribing. No significant variations in the utilisation pattern overtime were observed across patients demographics and types of DMARDs.

ALIGNMENT IN THE REGISTRATION, SELECTION, PROCUREMENT AND REIMBURSEMENT OF ESSENTIAL MEDICINES FOR PEDIATRIC ONCOLOGY IN SOUTH AFRICA

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ABSTRACT

Background

Access to medicines is in part determined by the alignment of core pharmaceutical processes. For South Africa's (SA) public health sector these include the registration of medicines, selection and subsequent procurement through national tenders. Registration, selection and reimbursement are key processes in the private sector. This study assessed the alignment of forementioned processes for essential oncology medicines in SA.

Methods

A selection of priority chemotherapeutics, anti-emetics and analgesics was compared to those listed in 1) the World Health Organization Essential Medicines List for Children (WHO EMLc) 2021, 2) the registered health products database of SA, 3) the relevant South African National Essential Medicines Lists (NEML), 4) bid packs and awarded tenders for oncology medicines for 2020 and 2022, and 5) oncology formularies from the leading Independent Clinical Oncology Network (ICON) and two private sector medical aid schemes.

Results

There was full alignment for 25 priority chemotherapeutics between the NEML, the products registered and those included on tender. Due to unsuccessful procurement, access to seven chemotherapeutics was potentially constrained. For anti-emetics and analgesics 8/9 medicines included on the WHO EMLc were also registered and on the NEML. An exploratory assessment of private sector formularies showed many gaps in ICON's formulary and two medical scheme formularies (listing 33% and 24% of the chemotherapeutics, respectively).

Conclusions

Despite good alignment in public sector pharmaceutical processes, access constraints to essential chemotherapeutics may stem from unsuccessful tenders. Private sector formularies show major gaps, however it is unclear how this translates to access.

A HEALTH SYSTEM ANALYSIS OF ACCESS TO ONCOLOGY MEDICINES FOR CHILDREN IN SOUTH AFRICA

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ABSTRACT

Background

Understanding challenges in access to childhood cancer medicines is key in improving outcomes for these children in South Africa (SA). We sought to identify what barriers and facilitators determine current perceived access to pediatric oncology medicines in SA through in-depth interviews with stakeholders in SA's public and private sectors.

Methods

Qualitative semi-structured interviews were conducted with 30 key health system stakeholders (September – November 2022), including policy makers and regulators, medical insurance scheme informants, medicine suppliers, health care providers and civil society stakeholders. Interviews were recorded and transcribed verbatim. Transcripts were theme coded through an inductive-deductive approach by the first author and verified by a second author.

Results

Major barriers to drug access included 1) the lack of political priority afforded childhood cancer (medicines), 2) delayed or no registration of novel drugs and discontinuation of traditional chemotherapeutics, 3) incomplete insurance coverage and 4) stock-outs of essential medicines. Other fundamental determinants of access to cancer care identified were the low awareness of childhood cancers among primary healthcare (PHC) staff and the general public, and the ability to access care including travel to healthcare facilities. The need for flexibilities in current pricing policies, transparency in decision-making and healthcare spending, and training of PHC staff, nurses and pharmacists emerged as priority interventions to improve pediatric cancer medicine access in SA.

Conclusion

This is the first comprehensive study of determinants of access to childhood cancer medicines in SA, providing context-specific evidence to enable appropriate policy development for improved access to childhood cancer medicines.

HOW FREQUENTLY HAVE ANTI-SPIKE PROTEIN MONOCLONAL ANTIBODIES AND OTHER ANTIVIRAL THERAPIES BEEN USED FOR EARLY TREATMENT OF COVID-19 OUTPATIENTS IN REAL-WORLD SETTING? A NATIONWIDE STUDY FROM THE UNITED KINGDOM AND ITALY FROM DECEMBER 2021 TO OCTOBER 2022

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ABSTRACT

Real-world data on early treatment of COVID-19 outpatients is sparse. Public national dashboards on mAb/antiviral use and SARS-CoV-2 infection diagnoses from the UK NHS, AIFA and WHO were searched to explore the pattern of mAb/antiviral use for early treatment of COVID-19 outpatients from UK and Italy from December 2021 to October 2022. Prevalence of antiviral use in outpatients during the entire study period and every two weeks was calculated. An ITS analysis was carried out to assess the impact of predominant SARS-CoV-2 variants over time on the prevalence of use of mAbs/antivirals. Overall, 77,469 and 195,604 doses of mAbs/antivirals were respectively administered to a total of 12,771,353 and 17,790,912 SARS-CoV-2 infection diagnosed patients in UK and Italy. Prevalence of use every two weeks increased in the UK (0.07-2.9%) and Italy (0.8-2.3%) during the study period. Sotrovimab (1.4%) and nirmatrelvir/ritonavir (1.5%) in UK, nirmatrelvir/ritonavir (1.8%) and molnupiravir (0.5%) in Italy, reported the highest prevalence during a two-week period. The ITS analysis showed a significant increase in the use of sotrovimab, molnupiravir, remdesivir and nirmatrelvir/ritonavir in both countries during the transition from Delta to Omicron predominance, with a reduction of other marketed mAbs. The prevalence of mAb/antiviral use for early treatment of COVID-19 outpatients increased slowly in UK and Italy during the study period and the trend of use varied in relation to predominant SARS-CoV-2 variants. In the most recent period nirmatrelvir-ritonavir was the most frequently prescribed antiviral in both countries.

REIMBURSEMENT POLICY CHANGE IMPACT ON UTILIZATION OF REIMBURSED ANTIHYPERTENSIVE MEDICINES

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ABSTRACT

Background

Pharmaceutical expenditure is increasing in all European countries. As a consequence, third-party payers have introduced reforms to reduce medicine costs. Aim of this study was to evaluate the impact of drug policy amendments on the utilization of antihypertensive drugs.

Method

In this longitudinal observational study trends of antihypertensive medicines utilization from 2017 to 2019 were studied. 11 antihypertensive medicines were selected, because those were medicines where both an original and at least one generic medicine were included in the Price List of Reimbursed Medicinal Products. Utilization data was obtained from Lithuanian National Health Insurance Fund (dispensations of reimbursed medicines) and State Medicines Control Agency of Lithuania (aggregated data of medicines distributed to pharmacies). Trends were analysed using jointpoint models.

Results

Utilization of reimbursed medicines decreased in 10 of the 11 medicines: two to five jointpoints were observed in 7 medicines, in 3 medicines, the utilization decreased without a jointpoint. Only use of reimbursed metoprolol 50 mg increased. For ramipril 5mg and telmisartan 80 mg overall utilization increased while utilization of reimbursed medicines decreased. The timing of the jointpoints suggested that the amendment of Government Resolution No.994 had the most impact on drug utilization. This policy introduced maximum premiums to reimbursed medicines.

Conclusion

We observed a great number of changes in the utilization of different antihypertensives which coincided with a major change in the policy affecting reimbursement. The possible impact of this great number of changes on quality of care needs to be considered.

OUT-OF-POCKET EXPENDITURE ON PRESCRIPTION MEDICINES IN COMMUNITY-DWELLING ADULTS: FINDINGS FROM THE IRISH LONGITUDINAL STUDY ON AGEING (TILDA)

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ABSTRACT

Ireland has a mixed public-private health system, where approximately 70% of people pay out-of-pocket for medicines. This can place a significant burden on patients, particularly those with multiple health conditions. This study aims to characterise out-of-pocket payments for medicines (OOPm) and factors associated with OOPm.

This is a cross-sectional analysis of TILDA wave 4, a nationally representative cohort. Data were collected via face-to-face interviews (2016). Participants reported their typical monthly spend (€) on prescription medicines. A two-part regression model evaluated factors associated with 1) having any OOPm, and 2) the amount of OOPm, including age, sex, numbers of medicines and chronic conditions, and public health cover.

Overall, 5,813 individuals were included (mean age 68 years, 55.5% female), 33.7% reported one chronic condition, and 37.6% reported two or more. Median monthly OOPm was €20 (IQR: €10-40). The median percentage of equivalised household income spent on OOPm was 2.3%, though this varied (1.7%-4.3%) between health cover groups. Controlling for other factors, greater number of chronic conditions was associated with reporting any OOPm (odds ratio 1.31, 95%CI 1.11-1.55), and OOPm amount (rate ratio 1.05, 95%CI 1.01-1.10). Lack of public health cover was associated with the OOPm amount (rate ratio 4.76, 95%CI 4.43-5.21), as were age and number of medicines.

An increasing number of chronic conditions was significantly associated with OOPm, despite health cover entitlements and independent of number of medicines and age. Cost may present a barrier to medicines access and adherence, therefore, strategies should be considered to minimise barriers to both.

ADHD-DRUGS TO TEENAGERS IN SWEDEN 2007–2022 – INCIDENCE AND PREVALENCE AS PUBLIC NATIONAL DRUG CONSUMPTION STATISTICS

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ABSTRACT

Background

Drug consumption statistics traditionally use aggregated volume such as defined daily dose (DDD), packages, number of dispensed prescriptions or annual prevalence. In 2023 annual incidence for prescription drugs will be introduced as public statistics in Sweden. Since sales of ADHD-drugs has increased substantially during the last years, this opens up for more in-depth analyses of treatment patterns.

Methods

Quarterly prevalence and incidence proportion with 18 months run-in for ADHD-drugs (N06BA centrally acting sympathomimetics, excluding N06BA07 modafinil, and including C02AC02 guanfacine) for young adults 2007–2022 extracted as statistics from the Swedish Prescribed Drug Register.

Results

For boys 13-17 years, both the quarterly prevalence and the incidence increased with a factor of 5.4 to 60.9 treated boys per 1,000 individuals (TIN) per quarter and an incidence of 3.2 per TIN per quarter.

For girls, the quarterly prevalence increased by a factor of 11.4 to 38.1 treated girls per TIN per quarter. The quarterly incidence increased by a factor of 19.5 to an incidence of 3.0 per TIN per quarter.

Conclusion

For boys, both the prevalence and incidence increased with the same factor during the period. For girls, the incidence has increased significantly faster than the prevalence and is now on par with the incidence for boys, while the prevalence is still less than two-thirds of the one for boys. Based on this it can be expected that the difference in prevalence between girls and boys in this age-group will decrease the next few years, everything else being equal.

POTENTIAL COST-SAVINGS FROM A MORE EFFICIENT OFF-PATENT BIOLOGICALS PURCHASING IN ITALY

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ABSTRACT

Background

Biosimilars represent a real opportunity for national healthcare systems, ensuring important cost savings and guaranteeing the same efficacy, safety and quality of biological originators. In Italy, a great variability was found across regions in terms of average cost per pack of biologicals. The aim of this study was to estimate the potential savings resulting from more efficient purchasings.

Methods

Based on data from the "Traceability of medicines" dataflow for year 2021 and 2022, the average cost per pack stratified by active ingredient, originator and biosimilar and region was calculated. The potential savings were estimated comparing the actual regional expenditure and the theoretical one calculated applying to each molecule 1) the mean national pack cost; 2) the regional minimum value between the average cost of the originator and the biosimilar one; 3) the minimum regional cost and 4) the minimum value observed at national level.

Results

The results showed potential savings for all regions, albeit in varying degrees. For 2021 the national savings varied from a minimum of 77.5 million euro to a maximum of 370.0 million euro, depending on the considered scenario. Similar results were obtained also for first half of 2022 with savings ranging from 38.8 million euro of scenario 1 to 167.7 million euro of scenario 4.

Conclusion

This study showed that there are still room for improvements in off-patent biologicals purchasing, also promoting multi-regional tenders, in order to reduce the regional price variability and to ensure the highest savings for Italian National healthcare system.

USE OF ANALGESIC OPIOIDS IN PORTUGAL

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ABSTRACT

Background

Opioids are frequently used in the treatment of both cancer and non-cancer chronic pain. Nevertheless, these medicines carry significant risk of misuse, tolerance and dependence, with possible negative outcomes particularly common among patients receiving high-dose opioids. The aim of the present study was to analyse opioid use in Portugal.

Methods

Data were retrieved from the National Health Service reimbursement database on prescribed opioid analgesics dispensed between 2018 and 2021 in community pharmacies of Portugal mainland. We performed a demographic and geographic data analysis by INN, and use was measured by global number of users and DDD, with public spending also studied.

Results

Global use and public spending increased from 2018 to 2021: 20% in use (28.0 M DDD to 33.6 M DDD) and 23% in spending (29.2 M€ to 35.9 M€), the association tramadol + paracetamol accounting for 46% of total consumption. However, no persistent increase was noted in the number of users. A higher use of medicines was observed in women (70%) and in older individuals (>70 years - 53%). Weak opioids, 60% prescribed in primary care, clearly prevail (69% of total DDDs dispensed) over strong opioids. Geographic analysis shows that the central region of Portugal leads consumption, with 11.5 DDD/1,000 inhabitants/day (9.3 at national level).

Conclusion

The increase in opioid consumption during the last years points to the need of close monitoring, given the associated possible risks. The current analysis should be further developed in order to characterise the pattern of prescription opioid use in Portugal.

NATIONAL ASSESSMENT OF PRESCRIBING PRACTICE OF ANTIBIOTIC PROPHYLAXIS AMONG OBSTETRICS AND GYNAECOLOGICAL SURGERIES IN KUWAIT

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ABSTRACT

Antimicrobial resistance has become a significant global health concern, primarily resulting from excessive and inappropriate use of antimicrobials. A significant portion of antibiotics prescribed within hospitals is for surgical patients as prophylaxis (AP) to prevent surgical site infections. Thus, AP must be used judiciously to reduce antibiotic resistance. Proper infection control and judicious use of antibiotics are crucial. This research aims to explore and assess the appropriateness of AP prescribing practice for all obstetrics and gynaecological surgeries in Kuwait.

Methods

A national multicentre point prevalence survey (PPS) based on the Global PPS and WHO PPS methodology. The PPS was conducted in all Kuwait governmental and some private hospitals. The PPS was conducted once in every OBS/GYN ward after the day of the most surgical interventions. All patient files were reviewed for AP usage from the past 24 hours to assess the appropriateness of AP against local and international AP guidelines.

Results

Preliminary results included 208 patients. Antibiotic usage among them was 98%. Only 53% of the patients received antibiotics before surgery, and only 11% were fully appropriate in terms of timing and selection. 85% of the patient received antibiotics for more than 24 hours. This research is still ongoing and requires further analysis.

Conclusion

This study is a benchmark for AP utilisation in Kuwait, which helps in the establishment of antibiotic surveillance for surgical prevention as well as the development of ASP and recommendations for national guidelines tailored for the Kuwaiti healthcare system.

HOW DOES DEPRESCRIBING (NOT) REDUCE MORTALITY? AN ANALYSIS OF RANDOMIZED CONTROLLED TRIALS IN COMMUNITY-DWELLING OLDER ADULTS CASTS UNCERTAINTY OVER CLAIMED BENEFITS OF DEPRESCRIBING

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ABSTRACT

Background

Some recent systematic reviews have suggested that deprescribing may reduce mortality. We aimed to determine whether the observed reduction results from the deprescription of specific medications or rather from the methodological limitations of the trials.

Methods

We extracted information from twelve randomized controlled trials that were included in the latest meta-analysis on deprescribing in community-dwelling older adults. We retrieved data on study population, interventions performed, and statistical methods used. We summarized information on deprescribed medications and potential methodological issues.

Results

Only a third (4/12) of the trials aimed to study mortality. The number of medications was reduced in three trials, did not change in five, and was not reported in four. A wide range of medication classes was deprescribed in the seven studies reporting the information, such as antihypertensive, sedative, gastro-intestinal, and potentially inappropriate medications. Many methodological issues were identified. Six trials did not explicitly report the deprescribing intervention. Five trials included less than 150 participants. Small sample sizes often resulted in unbalanced groups for potentially significant confounding factors (e.g., comorbidities, number of potentially inappropriate medications); yet none of the trials presented multivariate analyses. In addition, many deaths occurred before the intervention in the two trials that had the most weight in the meta-analysis, making inference about the impact of the deprescribing intervention hazardous.

Conclusion

Contrary to the conclusion of the meta-analysis, methodological issues cast great uncertainty on the benefits of deprescribing on mortality. Large, well-designed trials are needed to adequately address the issue.

DRUG-DRUG INTERACTIONS AND ADVERSE DRUG REACTION HOSPITAL ADMISSIONS IN THE OLDER POPULATION: A PROSPECTIVE COHORT STUDY

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ABSTRACT

Background

Drug-drug interactions (DDIs) can lead to medication-related harm, and the older population is at greatest risk. We estimate DDI prevalence and the average causal effect of potential DDI exposure on an adverse drug reaction (ADR) in an older population admitted acutely to a large academic teaching hospital in Ireland.

Methods

Prospectively collected (2016-17) data from the Adverse Drug Reactions in an Ageing PopulaTion (ADAPT) cohort were used (N=862). Medication data (current/recently discontinued/over-the-counter), and objective clinical data (e.g., renal function) were available. 'Severe' DDIs (i.e., may result in a life-threatening event/permanent detrimental effect) were identified using the BNF and Stockley's drug interactions. Directed Acyclic Graphs were used to reduce bias and guide causal inference between DDI exposure and ADR-related hospital admission. Multivariable logistic regression was used. DDI prevalence, odds ratios (OR), and 95% confidence intervals (CIs) are reported. Analysis was performed using SAS(v9.4).

Results

N=782 patients using ≥ 2 drugs were included for analysis, mean age=80.9(± 7.5); 52.2% female (n=408); 92.2% (n=721) with polypharmacy (≥ 5 drugs); 45.1% (n=353) had an ADR-related hospital admission. Overall, n=218 (27.9% [95%CI: 24.8-31.1]) were potentially exposed to at least one 'severe' DDI; DDIs per patient ranged from 1-12. Frequent DDIs included: amiodarone-furosemide (n=20 patients); amiodarone-bisoprolol (n=17); esomeprazole-escitalopram (n=14); amiodarone-warfarin (n=13); allopurinol-ramipril (n=10). After controlling for confounding, the average causal effect of DDI exposure on ADR-related hospitalisation was OR=1.07 [95%CI 0.75-1.53].

Conclusion

'Severe' DDIs are prevalent among older adults on admission to hospital, and carry an increased (non-significant) risk of ADR-related hospitalisation.

DRUG THERAPY PROBLEMS ASSESSMENT AMONG GENERAL AMBULATORY PATIENTS WITH HYPERTENSION AT THE HEALTH CENTRE ZAGREB - CENTRE

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ABSTRACT

Background

Drug therapy problems (DTPs) represent the core of the pharmaceutical care practice and their identification, resolution and prevention are crucial for ensuring patients' optimal medication use and favourable clinical outcomes. The aim of this study was to identify DTPs and determine their occurrence among general ambulatory patients with hypertension following Comprehensive Medication Management (CMM) services provision.

Methods

This prospective, observational study was conducted from June 2020 to February 2022 at the Health centre Zagreb- Centre and included patients with hypertension, older than 18 years of age. Drug therapy problems were determined according to Cipolle et al. and categorized into seven categories related to indication, effectiveness, safety, or adherence. Data were analysed by employing the statistical program SPSS, version 25.0.

Results

Overall, 100 patients with a median age of 73.5 (41 - 86) years were included in the study. On average (SD) they used 10.2 (3.8) medications and had 7.8 (4.0) comorbidities. During the initial two visits, 353 DTPs were identified with an average of 3.5 ± 1.8 DTPs per patient. At least one DTP was identified in 98 % of patients, of which 26 % had 5 or more DTPs. The most prevalent DTPs were "Dosage too low" (32.6 %) and "Needs additional therapy" (30.9 %).

Conclusion

The study results provided preliminary results and for the first time determined the frequency and type of DTPs in hypertensive patients at the primary care level in Croatia, emphasising the need for the CMM services implementation as to address the irrational drug use and medication mismanagement.

A COMPARISON OF THE TOOLS USED TO EVALUATE THE PHARMACOTHERAPY OF ELDERLY PATIENTS, WHO HAVE FALLEN AND RECEIVED EMERGENCY PATIENT CARE

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ABSTRACT

Background and objective

Falls in the elderly can lead to serious injuries, which results in an enormous burden for the individual and the society. ; The risk of falls might be linked to pharmacotherapy. Certain pharmacons can increase the risk of falling, and there are different tools available to evaluate elderly patients pharmacotherapy. Our objective was to compare the tools used to identify drugs that might increase falling risk (EU(7)PIM , START/STOPP, and FORTA lists).

Method

Retrospective data analysis was done on patients >65 years who had fallen and had visited the ER between March-April 2022. Pharmacons were classified by the mentioned PIM lists. Binary logistic regression was performed to calculate the association between risk of falls and pharmacotherapy.

Results

548 medical records were analyzed, 50% of which was the matched control group. In case of FORTA listed drugs, the risk of falls was decreased (OR: 0.911; CI: 0,645-1,287; $p>0.05$), in case of STOPP no effect was observed (OR:1.000; CI: 0,688-1,454). Risk for a fall was 3.263 times higher (CI. 2,264-4,702; $p<0.05$), if an EU(7)PIM drug was used.

Conclusion

Using the EU(7)PIM list, the danger of falling could be recognized, in contrast to STOPP and FORTA lists. With the latter two, more information is needed to evaluate medications properly (e.g. comorbidities), however, EU(7)PIM list is a better tool to analyze insensitive data. STOPP and FORTA are more practical for clinical use, and EU(7)PIM list is better for studies.

EVALUATING A TRAINING FOR HEALTHCARE PROVIDERS ON DEPRESCRIBING IN OLDER PEOPLE: LESSONS LEARNED FROM THE PILOT STUDY

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ABSTRACT

Background

Deprescribing of cardiometabolic medication is recommended for older and frail patients but implementation is challenging. We will conduct a trial to evaluate a training for primary care staff to involve older patients in deprescribing. In a pilot study we evaluated the procedures for patient recruitment and questionnaire administration.

Methods

Staff from three pharmacies was asked to invite patients for “a study involving a clinical medication review (CMR) focusing on deprescribing of cardiometabolic medication”. Patients consenting to participate received the CMR and received questionnaires at five timepoints via telephone, e-mail or mail. We documented issues resulting in loss of patients, missing data and time needed for data collection.

Results

Eight eligible patients were personally invited by their pharmacists, two of whom were not interested, two perceived participating as too burdensome and one dropped out at a later stage, because her treating nurse practitioner had not been informed about the study. Due to time constraints, one of the three pharmacists asked six eligible patients via mail to contact the researcher, which only one did. Overall, four patients were included (median age=79.5 years) and all completed the questionnaires. The average time needed for administration via telephone was 26 minutes per timepoint, which did not result in loss of patients.

Conclusion

To maximize patient inclusion, pharmacists need support to invite patients and all primary care staff must be informed about patient’s participation. Administration of the questionnaires at multiple timepoints was feasible but can scare participants thus resulting in non-response.

WHAT IS THE ADDED BENEFIT OF A COMMUNICATION TRAINING ON DEPRESCRIBING CARDIOMETABOLIC MEDICATION IN DUTCH PRIMARY CARE? PROTOCOL OF A CLUSTER-RANDOMIZED CONTROLLED TRIAL.

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ABSTRACT

Background

Deprescribing of cardiometabolic medication is recommended for older and frail patients but healthcare providers perceive difficulties to implement this in patients without drug-related problems. We developed a communication training for teams of pharmacists, general practitioners and-or nurse practitioners, consisting of e-learning, live meetings and feedback on video-taped patient consultation, to support deprescribing of cardiometabolic medication. We aim to assess the effects of the communication training on deprescribing cardiometabolic medication in older patients.

Methods

A cluster-randomized controlled trial, where 20 intervention teams receive the training, focusing on involving patients and healthcare providers in the deprescribing process. Twenty control teams receive the training after trial completion. All teams will conduct clinical medication reviews in ten patients per team. Patients ≥ 75 years of age who use cardiometabolic medication and qualify for a clinical medication review according to guidelines are included.

Results

Results will focus on a groupwise comparison of the proportion of patients in which cardiometabolic medication is deprescribed as primary outcome. Secondary outcomes include changes in a) patients' attitudes towards deprescribing, b) health-related quality of life, c) health-related complaints with impact and d) medication regimen complexity. Also, patient's involvement in decision making will be assessed. Finally, a cost effectiveness analysis and a process evaluation will be conducted in parallel to the randomized controlled trial.

Conclusions

We expect that the training increases patient involvement in cardiometabolic treatment and deprescribing in older people, resulting in more personalized cardiometabolic medication management. We expect that our approach is feasible and cost effective in routine care.

HEALTH PROFESSIONALS VIEWS ON DISCONTINUATION OF LONG-TERM ANTIDEPRESSANTS: A SYSTEMATIC REVIEW AND THEMATIC SYNTHESIS

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ABSTRACT

Background

Long-term antidepressant use, much longer than recommended by guidelines, may cause harmful effects and generate unnecessary costs.

Objective

To investigate health professionals (HP) views of long-term antidepressant discontinuation and their barriers and facilitators.

Methods

Systematic review and meta-synthesis. We included primary studies that used qualitative data collection and had data on any HP's attitudes, beliefs, feelings, and perceptions on continuing or discontinuing AD use. The review searched nine database sources from inception until May 2022. Study quality was assessed using the Critical Appraisal Skills Programme (CASP) checklist. A thematic synthesis was performed.

Results

Thirteen studies were included in the review. Nine studies were of general practitioners' (GPs) perspectives, one study of GPs and nurses working in nursing homes, one study of psychiatrists, and two of a mix of health professionals. Barriers and facilitators to discontinuing long-term AD emerged within six major themes: 'perception of long-term AD use', 'intrinsic motivation for deprescribing', 'fears', 'patient readiness', 'HP role and responsibility and 'process related and structural factors that support the deprescribing process'.

Conclusions

Barriers and facilitators for HP are numerous and complex. More emphasis on the futility of the actual effect and potential harms related to long-term use is needed to improve HPs' motivation to discontinue long-term AD. The review shows a need to support for GPs around their fear of patient relapse and to initiate discussion around discontinuation. Future studies should assess under-researched HP perspectives (such as pharmacist, psychotherapist, or nursing home staff).

A SYSTEMATIC REVIEW OF THE ASSOCIATION BETWEEN POLYPHARMACY AND OUTCOMES IN HEART FAILURE

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ABSTRACT

Polypharmacy is a loosely defined term, used to investigate the growing concerns of overly complex treatment regimens. The most commonly accepted definition of polypharmacy is five or more treatments, however, this cut-point threshold may be inappropriate for multimorbid populations such as heart failure patients. Previous evidence has reported many different definitions and methods to measure polypharmacy, but there is little consistent evidence on the association between polypharmacy and outcomes in heart failure.

A systematic review of the association between polypharmacy and clinical outcomes in heart failure patients. Included studies were observational cohort studies published between 01/01/2000 - 12/11/2022 in Medline, Scopus, Web of Science or the Cochrane Library that included both polypharmacy and heart failure terms. Quality was appraised using the Newcastle-Ottawa scale.

2,850 studies were identified, with ten studies included. Of seven different definitions of polypharmacy, the most common was five or more treatments. Methods of exposure measurement also varied including the drug treatments selected, the data resources used (electronic health records/interviews/self-reporting) and the exposure time windows. Seven studies investigated mortality and five investigated hospitalisation outcomes. The low number and high level of heterogeneity of studies prevented meta-analyses. There was inconsistency in the associations between polypharmacy and outcomes, with some evidence of increased risk of hospitalisation but no association with mortality.

The relationship between polypharmacy and clinical outcomes of heart failure patients remains unclear. Future studies may need to consider the effect of methodological decisions when defining polypharmacy on observed outcomes.

TEN-YEAR TRAJECTORIES OF MULTIMORBIDITY AND IMPACT ON HEALTH SERVICES AND POLYPHARMACY IN OLDER PEOPLE

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ABSTRACT

The impact of the speed of onset of chronic conditions (CC) remains unclear in older adults. We aimed to identify trajectories of multimorbidity and investigate their value to predict health outcomes.

We used a random sample (5%) of the 1.5 million adults ages >65 in Quebec, Canada, on April 1st, 2019. Number of CC was assessed yearly from 2009-2018 using 31 conditions from Charlson/Elixhauser indices. We identified multimorbidity trajectories using latent class growth modeling. We compared risks of hospitalizations, emergency visits, polypharmacy (≥ 10 medications/year) and death among trajectories using robust Poisson models adjusted for age, sex, deprivation.

We identified 8 trajectories: 3 “stable” with few CC (0,1,2,5); 1 “decreasing” with declining number of CC (0 at end of follow-up); 2 “progressive” with gradual increment in morbidity (6&10CC at end); and 2 “high/recent increase” with abrupt increase in last years (2&6CC at end). The risk of each outcome increased globally with the number of CC at end of follow-up (e.g., death: “progressive” 10CC vs “stable” 0CC, RR=10.63;95%CI:8.62-13.11). The trajectory pattern only impacted the polypharmacy outcome. Compared with “stable” 0CC, polypharmacy risk was higher among the “stable” or “progressive” trajectories than the “high/recent increase” even with similar number of CC at end of follow-up (e.g., “progressive” 6CC [RR=9.90;9.30-10.54]; “high/recent increase” 6CC [RR=7.91;7.41-8.45]).

The speed of onset of CC had a large impact on the polypharmacy risk but little on other outcomes, for which the number of CC at end of follow-up seemed to be a better predictor.

TOOLS AND GUIDELINES TO ASSESS APPROPRIATENESS OF MEDICATION AND AID DEPRESCRIBING IN DIFFERENT TARGET POPULATIONS: UMBRELLA REVIEW

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ABSTRACT

Background

Several tools and guidelines have been developed to help clinicians deprescribe potentially inappropriate medications (PIM). A systematic overview of those tools and guidelines, the level of evidence for the included PIMs is, however, lacking and is needed to provide guidance for both clinical practice and to studies to aiming to evaluate effects of deprescribing on patient outcomes.

Methods

We conducted an umbrella review to summarize tools for identifying PIMs and guidelines to aid in deprescribing PIMs. We searched MEDLINE(Ovid), Embase.com, Cochrane CDSR, CINAHL, Web of Science and guideline databases from date of inception to 7 July 2022. We described and compared different characteristics of these tools/guidelines.

Results

We identified 90 tools (67 explicit, 12 mixed, 11 implicit), and 9 guidelines. The majority were developed to be used for older adults (n=74). Nineteen tools targeted older adults with limited life-expectancy (LLE), 7 targeted pediatrics, and 2 targeted special populations. All guidelines and 61 explicit/mixed tools were validated. In 59 tools, Delphi technique were used for validation. Only 2 tools and 8 guidelines had information on the level of evidence.

Conclusion

Existing tools and guidelines are available in a diversity of populations. The clarity in terms of their development and target group specifications is limited. Discrepancies identified in categorizing medications as appropriate or not can be a result of low quality of evidence. Particularly deprescribing tools and guidelines for patients with LLE are based on a very limited evidence and research to generate this evidence is highly needed.

EQUANU: EQUALITY IN SOCIAL AND PROFESSIONAL RECOGNITION OF NURSES – A EUROPEAN COMPARISON

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ABSTRACT

Background

Healthcare institutions are experiencing increasing difficulties in attracting and retaining qualified nurses. The poor public image of the profession and the professional recognition of nurses themselves may underlie this. This study aimed to identify differences in societal recognition of nurses, as well as their professional recognition by advanced roles in pharmaceutical care (especially prescription management) in European countries, taking into account differentiation in function per country.

Methods

A cross-sectional study design was conducted. Both nurses of different educational levels and the general public were surveyed between November 2022 and February 2023*. The public's recognition of nurses and possible influencing factors, as well as views on nurses' job content were compared across ten countries. Nurses' work environment, job motivation and degree of perceived autonomy in tasks related to prescribing were mapped and correlated with demographics and level of education.

Results

*data collection was still ongoing at the time of abstract submission (n=798 for professional recognition and n=886 for societal recognition), data will be analysed in the period March-May 2023, so that results can be presented at the conference in June. An adjusted abstract can be sent to the organising committee in May.

Conclusion

The benchmark between countries can help nurses in countries with a lower level of recognition to strive for a better recognition, with potential benefits for quality of care. More equality can be supportive for labour mobility for the European nurse.

TIMELINE ANALYSIS OF EPIDEMIOLOGICAL MEASURES AND POLICY IMPLEMENTATION IN THE NORDIC COUNTRIES DURING THE COVID-19 PANDEMIC

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ABSTRACT

Introduction

The Nordic countries used different policy approaches to the Covid-19 pandemic. We aimed to investigate 13 different policy approaches used in the Nordic countries.

Method

We used publicly available data from Our World in Data and the Oxford Covid-19 Government Response Tracker, complemented with national register data, to produce timelines with daily observations from 01/01/2020–30/04/2022 (18/12/2020–01/09/2021 for vaccine roll-out policy). We describe temporal changes in 13 different policies: eight containment and five health system policies. Epidemiological outcomes included the number of new cases, hospitalizations, intensive care unit admissions, Covid related deaths, and excess all-cause mortality in Denmark, Finland, Iceland, Norway, and Sweden.

Result

Covid-19 mortality was initially highest in Sweden with a peak in January 2021 of >250 deaths/million population/month; however, during the omicron wave, Sweden had a peak in February 2022 of 120 deaths/million population/ month. Monthly excess all-cause mortality during the study period was most extreme in Iceland, over 50% in March 2022 and a -20,2% in June 2020. The 13 policies assessed were introduced to some extent in most countries, but the timing and stringency varied. Internal movement restriction was never implemented in Iceland, while masking requirements were only partially implemented in Sweden, and schools kept close for the longest in Finland.

Conclusion

The overview revealed variability between different Nordic countries in their policy approaches; however, more research is needed to understand the extent to which policies and other contextual factors contributed to the different outcomes.

DRUG UTILIZATION RESEARCH DATABASES APPRAISAL OF MATURITY (DURDAM): AN INTERNATIONAL MODIFIED DELPHI CONSENSUS STUDY

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ABSTRACT

Background

Data used in drug utilization research (DUR) is routinely collected data from sales data, reimbursement databases, disease registries or electronic health records. The datasets, their characteristics, content and accessibility varies between countries. The aim of this study is to determine whether maturity of drug utilization (DU) datasets used in DUR could be appraised and, if so, to build a maturity appraisal tool.

Methods

Using web-based software we will conduct a two-phase project. First, using e-Delphi and Qualtrics we will conduct a modified Delphi consensus process of three rounds. A list of statements on the DU dataset maturity dimensions will be collected. The relevance of dimensions on the maturity scales will be ranked and those statements with consensus will be used as the basis for a DU database maturity appraisal tool. In the second phase, the accessibility and usability of this National DU Databases Appraisal Tool will be tested using questionnaires.

Results

Thus far, the recruitment process has started. Participants have been identified from published literature and purposefully sampled so there are 10 per WHO region (60 in total) in so that the maturity appraisal tool would be internationally useful. The questionnaire for the first round of the modified Delphi has been created and piloted.

Conclusion

The project has been launched and is planned to be completed by June 2023. We will present our results to the DURG community this year.

THE EUROPEAN DRUG-DRUG INTERACTION (EURODDI) STUDY PROTOCOL: A CROSS COUNTRY COMPARISON OF THE PREVALENCE OF DRUG-DRUG INTERACTIONS IN THE OLDER COMMUNITY-DWELLING POPULATION

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ABSTRACT

Background

Drug-drug interactions (DDIs), highly prevalent amongst the elderly, can lead to avoidable medication-related harm. The cardiovascular and central nervous system (CNS) are commonly implicated. To date, there is no consensus on how to measure DDIs, making comparisons across countries challenging. By developing a common methodology, we aim to: (i) measure the prevalence of potential DDIs in older populations (aged ≥ 70 years) in three European countries; and (ii) describe differences across the countries.

Methods

This explorative study will apply a harmonised method of DDI identification and analysis using the WHO ATC classification system and national pharmacy claims data from three European countries (Ireland, Italy, Spain). Patients aged ≥ 70 years dispensed ≥ 2 medications during 2016 will be identified from each database. 'Severe' cardiovascular and CNS DDIs (i.e. may result in a life-threatening event or permanent detrimental effect) will be identified using the British National Formulary and Stockley's Drug Interactions. Two separate lists of 'severe' DDIs, per medications reimbursed, will be applied to each database: (i) DDIs relevant to each individual country, and (ii) DDIs relevant to all three countries. DDIs will be defined as co-prescribed (same day) and concomitant (± 7 days).

Results

Descriptive statistics, including DDI prevalence and 95% confidence intervals will be reported for each country. Prevalence will be pooled and compared across countries using random effects models and meta-regression, where feasible.

Conclusion

The EuroDDI study will develop a harmonised method to measure and compare DDI prevalence across health-related databases in Europe.

COMPARING THE PRICE OF MEDICINES AT A GLOBAL LEVEL. THE EXPERIENCE OF AN ITALIAN WHO COLLABORATING CENTRE

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ABSTRACT

Background

The cost of medicines is a key component of access to treatments. Assessing medicines prices, often the main component of treatment cost, is challenging due to lack of transparency (as under non-disclosure agreements) and multi-factorial determinants. Cost assessment is recommended by the WHO when applying for the inclusion of medicines in the Essential Medicines List (EML). The Bologna WHO Collaborating Centre in Evidence-Based Research Synthesis and Guideline Development (BCC), part of the public health system of the Region Emilia-Romagna (Italy), is mandated by the WHO to develop applications for the inclusion of medicines in the EML.

Methods

The BCC, in collaboration with the Multiple Sclerosis International Federation, developed an application for the inclusion in the EML of disease-modifying therapies (DMTs) for multiple sclerosis (MS). Cost was assessed by extracting ex-factory drug prices across countries at a global level from publicly available databases of non commercial governmental agencies and through expert input. Local currencies were converted into US Dollars. Median prices per-patient-per-year and range across countries of the same income level (according to the World Bank classification) were calculated for each DMT.

Results

Prices of DMTs for MS vary greatly across countries, within and between income level groups.

Conclusion

Developing a method for comparing drug prices across countries at a global level may improve the quality of applications for the inclusion of medicines in the EML, also informing health decision makers when addressing affordability. Investigating differences and determinants of the variability of drug prices across countries is warranted.

COVID-19 IMPACT ON MENTAL HEALTH, ADDICTION HABITS, NOVEL PSYCHOACTIVE SUBSTANCES (NPSS) USE AND ASSOCIATED HEALTH RISKS PERCEPTION

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ABSTRACT

Background

Covid-19 pandemic has been a major global public health threat with a great impact on citizens' psychological state and habits. We investigated changes in public's mental health, addictive behaviours and health risk perceptions.

Methods

An online survey was conducted using Jisc Survey tool. It was advertised on drug forums, social media and University sites between 8 August 2020 and 3 March 2021 (248 responses; 55 NPS users).

Results

Respondents were from the UK (64.5%), USA (18.5%) and Greece (17%); with average age 32 years; 43% males. The majority of respondents (83%) were satisfied with their lives prior to Covid-19 whilst following the pandemic 56% were neutral/ dissatisfied; 38% significantly changed their habits. The highest decline in mental health was noticed in Greece. Regarding tobacco use, the majority of respondents reported a high risk (57%) when 20% stated no/low risk or unawareness. In Greece, half of the respondents reported no/low risk or unawareness of tobacco health risks; UK residents were the most well-informed. Regarding alcohol use health risks, over half of the respondents (57%) stated low/no risk or unawareness and only 15% high risk. The majority of NPS users (79%) stated no/low risk or unawareness about NPSs use health risks (69% with underlying health conditions) and only 7% high risk.

Conclusion

Covid-19 pandemic had an impact on public's mental health and addictive behaviours. The low percentages of health risk perception regarding addictive behaviours are concerning and show a need for enhanced health promotion strategies.

COMPARISON OF THE PRESCRIPTIONS FOR PSYCHOTROPIC DRUGS BEFORE AND DURING THE CORONA PANDEMIC IN A GERMAN REGION

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ABSTRACT

We consider the drug prescription covered by the statutory health insurance of all residents in the German region of Schleswig-Holstein in the year 2019 before the Corona Pandemic as compared to the year 2021 during the Corona pandemic.

We consider the total number of patients with drug prescriptions per quarter and per ATC group (ATC: anatomical-therapeutic-chemical) at the four-digit level for psychotropic drugs: Antipsychotics(N05A), Anxiolytics(N05B), Hypnotics and sedatives(N05C), homeopathic and anthroposophic psycholeptics(N05H), Antidepressants(N06A), Psychostimulants, Agents used for ADHD and Nootropics(N06B), anti-dementia drugs(N06D). In the modeling we use Gini coefficients and the Channon entropy.

The comparison of patients with drug prescriptions across quarters starts from an 8.5% decrease in the first quarter to rise to a 6.9% increase in the fourth quarter. Only for N05B (anxiolytics) and N05H (homeopathic and anthroposophic psycholeptics), decrease in the number of patients in a year-to-year comparison before and during the Corona Pandemic can be shown, all other drug groups considered show an increase. The largest patient group N06A (antidepressants) with an increase of 2.9% year-to-year (minimum 2.9% in the first and maximum 4.7% in the fourth quarter), followed by N05A (antipsychotics) with an increase of 5.5% (minimum 4.7% in the second quarter and 7.0% in the third quarter). The highest increase is in the N06B group (ADHD and Nootropics) with 14.9% (minimum 9.9%, maximum 18.5%).

Overall, we see an increase in patients with psychotropic drug prescriptions. A focus on this patient group is of high priority.

ANALYSING THE IMPACT OF COVID-19 LOCKDOWN ON THE UTILIZATION AND PRESCRIBING PATTERNS OF ANTI-DEPRESSANTS IN THE NORTHERN IRELAND PRIMARY CARE SETTING.

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ABSTRACT

Background

Covid-19 has impacted people's mental health and restricted access to health services effecting treatment of depression. This project investigated the impact Covid-19 had on antidepressant prescribing trends across Northern Ireland.

Methods

Trends in antidepressant prescribing patterns across Northern Ireland between March 2019 and September 2022 were measured from publicly available community dispensing data using number of items dispensed/ 1000 inhabitants and defined daily dose (DDD)/ 1000 inhabitants/ day and analysed using segmented regression.

Results

The total number of all antidepressant items dispensed/ 1000 was 6827.9, the majority being SSRIs (51.9%), followed by TCAs (17.2%), SNRIs (16.4%), others (13.8%) and MAOIs (0.0231%). All classes showed a gradual increasing trend except MAOIs.

The total DDD/ 1000 inhabitants/ day for all antidepressants was 8589.5, with SSRIs providing the greatest percentage (65.8%), then SNRIs (17.2%), Others (10.4%), TCAs (6.12%) and MAOIs (0.0293%). All classes displayed an increase except for MAOIs.

Significant changes observed in the number of items during segmented regression analysis were a decrease in MAOIs baseline trend and immediately after the initial lockdown, with an increasing trend post-Covid. Significant changes in DDD/1000 inhabitants/ day were decreasing MAOI baseline and immediate impact trends; post-Covid trends showed an increase in MAOIs. No other significant changes occurred.

Conclusion

Despite overall increases in utilization, segmented regression highlighted there was no significant impact of Covid-19. Further research is needed to understand the effect the pandemic had on management of depression using patient level data to confirm there has been no impact of newly diagnosed patients.

THE IMPACT OF COVID-19 LOCKDOWN ON THE UTILISATION AND PRESCRIBING PATTERNS OF ANTIDEPRESSANTS IN THE WELSH PRIMARY CARE SETTING: A SEGMENTED REGRESSION ANALYSIS

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ABSTRACT

Background

The COVID-19 lockdown impacted accessibility to non-pharmacological and specialist mental health services for the treatment of depression. Subsequently, the safe and effective prescribing of antidepressants are thought to have changed. This study investigates the impact of the COVID-19 lockdown on the utilisation patterns of antidepressants in the primary care setting of Wales.

Methodology

Welsh Prescription Cost Analysis(PCA) data was used to calculate the number of items/1000 inhabitants and Defined Daily Dose(DDD)/1000 inhabitants/day of all antidepressants from March 2019 to August 2022. A segmented regression analysis was applied to understand the significance of the trends.

Results

Total number of all antidepressant items/1000 increased by 14.06% and DDD/1000/day increased by 23.59%. SSRIs, SNRIs, TCAs, and other antidepressants increased in both metrics. SNRIs presented the greatest increase in number of items(25%) and DDD(28.35%). MAOIs showed the greatest change of all antidepressant classes which reduced in number of items(58.40%) and DDD(56.55%). Segmented regression showed a non-significant increase immediately after lockdown began, followed by a non-significant decrease post-lockdown for all antidepressants classes except MAOIs. MAOIs displayed a significant decrease immediately after lockdown initiation, followed by an increasing trend post-lockdown. Similar results were found for DDD of MAOIs; however, these were non-significant ($p>0.05$).

Conclusion

Overall, antidepressant prescribing patterns in Wales does not appear to be significantly affected by the COVID-19 lockdown measures. However, additional studies, using patient-levelled data, are required to, more accurately, estimate the effects the pandemic had on depression management in newly diagnosed patients.

VACCINE RECIPIENTS VERSUS HEALTH PROFESSIONALS IMPLICATED IN THE SAFETY OF COVID-19 VACCINES SURVEILLANCE IN FRANCE

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ABSTRACT

Background

Over 2021-2022, over 80% of the French population received 1 to 4 doses of Covid-19 vaccines. Health professionals (HPs) and vaccine recipients (VRs) requested information from the 31 French pharmacovigilance (PV) centres about the vaccines and reported suspected vaccine adverse events. The PV centres network and ANSM monitored the reports in real time to rapidly generate signals in order to propose risk minimisation measures. The objective was to compare the safety activity of Covid-19 vaccines between VRs and HPs over these 2 years.

Methods

We analysed all questions and ADR reports related to Covid-19 vaccines addressed to the French Pharmacovigilance centres (2021-2022).

Results

The number of questions doubled compared to the pre-pandemic period, 15% were from VRs. VRs wanted reassurance about symptoms and advice on continuing the vaccination program. HPs asked about the risk of allergy (especially at the beginning of the vaccination campaign), the link between unexpected AEs and vaccines, and whether to continue vaccination after AE occurrence. The reporting rate was 125 per 100 000 doses. A quarter of the reports were serious, 48% of the reports were from VRs, 38% physicians and 9% pharmacists. mRNA vaccines were the most involved (82%). High blood pressure, delayed large local reactions, zona, erythema multiforme, menstrual disorders, hearing loss and tinnitus were the main safety signals from questions and reports of VRs.

Conclusion

VRs were an important complementary source of adverse vaccine reactions reporting during the Covid-19 vaccination campaign to generate a safety signal.

MEDICATION USE DURING COVID PANDEMIC IN HUNGARY

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ABSTRACT

Background

COVID pandemic and the lockdowns put an increased pressure on healthcare system and caused disruption in the continuity of usual healthcare services.

Our aim was to assess the effect of COVID pandemic on prescription drug consumption in Hungary from January 2020 to December 2021.

Methods

Data were collected from the National Health Insurance Fund which is the sole, mandatory health insurance provider, and it covers the entire population of the country. All reimbursed drug dispensing was included in the study and was analyzed according to the WHO's ATC/DDD methodology, expressed in DDDs. Monthly utilization changes were compared to the base month of January 2020.

Results

As the first wave started, in March 2020, a peak in the overall drug use occurred with 31.6% increase, followed by a notable decreased utilization during the next months compared to January. Regarding ATC3 subgroups, most groups' use increased in March, and there were some exceptionally high peaks – H03 (thyroid therapy) increased by 46.7%, R06 (antihistamines for systemic use) by 44.3%.

Regarding yearly consumption, in 2020 overall drug use increased by 7.9%, ATC group A (Alimentary tract and metabolism) increased by 28.1%, which included the 61.8% increase of vitamin D (A11CC), while group J (Antiinfectives for systemic use) decreased by 19.7% compared to 2019. The overall medication use decreased by 0,3% in 2021 compared to 2020.

Conclusions

Overall drug consumption showed a considerable increase at the beginning of the first wave of COVID, but not during the following waves.

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PRESCRIBING OF COVID-19 TREATMENTS TO PATIENTS WITH COVID-19 INFECTION AT HIGHEST RISK OF HOSPITALISATION BY PHARMACIST INDEPENDENT PRESCRIBERS (PIPS)

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ABSTRACT

Background

In Scotland nationally commissioned treatment options for ambulatory patients at highest risk of hospitalisation for COVID-19 during 2022 were oral antivirals (nirmatrelvir/ritonavir or molnupiravir) and infused neutralising monoclonal antibodies (sotrovimab). This is a retrospective analysis of prescribing of these treatments by Pharmacist Independent Prescribers (PIPs).

Methods

Setting: NHS Greater Glasgow and Clyde (population 1.3mill) a centrally co-ordinated pharmacy-led service
Data Sources: PIP prescribing decisions record linked to prescription data (community pharmacy and regional cancer centre) and national measures of socioeconomic deprivation.

Results

Between 11/02/2022 and 11/10/2022 PIPs assessed 3,551 patients (average 14.7 per day). Following assessment of need and suitability of treatment PIPs:

- referred 249 patients for sotrovimab;
- prescribed 2,688 courses of oral antivirals (nirmatrelvir/ritonavir=2,099, molnupiravir=589) and in 138 courses prescribed a reduced dose of nirmatrelvir/ritonavir; and
- in 614 cases the PIP decided that no treatment was required (usually because the patient was asymptomatic or symptoms were mild and improving).

For 1,933 patients other drugs interacting with ritonavir had been recently dispensed/supplied and for 889 nirmatrelvir/ritonavir was still prescribed with PIPs provided advice on how to manage the interaction(s).

Conclusion

PIPs provided an important service to reduce hospitalisation from COVID-19. They made referrals and prescribing decisions to ensure an appropriate treatment was provided to patients taking into account drug:drug interactions and renal function.

THE IMPACT OF COVID-19 LOCKDOWN ON UTILISATION AND PRESCRIBING PATTERNS OF ANTIDEPRESSANTS IN THE SCOTTISH PRIMARY CARE SETTING: A SEGMENTED REGRESSION ANALYSIS

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ABSTRACT

Background

The beginning of COVID-19 marked a point of significant change for Scotland's health and wellbeing. The effect of COVID-19 lockdown on antidepressant prescribing within Scotland is not an area with a lot of research. This study aims to evaluate the impact of the COVID-19 lockdown on the utilisation and prescribing patterns of antidepressants in the Scottish primary care setting using a segmented regression analysis.

Methods

Two metrics; monthly number of dispensed items (NOI)/1000inhabitants and defined daily dose (DDD)/1000 population/day were used to analyse prescription cost analysis data for all antidepressants from March 2019-July 2022. Segmented regression analysis was then applied to assess the impact of lockdown on antidepressant prescribing trends.

Results

Baseline NOI/1000inhabitants showed significant decrease for MAOIs and increase for total, SNRI and other antidepressant classes with non-significant increases in SSRI and TCA classes. Immediately following lockdown non-significant increases were observed for all classes except MAOIs which showed significant reduction. Post lockdown there was significant increase for MAOIs and non-significant decrease for all other classes.

Baseline DDD/1000population/day trends show significant decrease in MAOIs, significant increase in SSRI, SNRI, other and total antidepressants and non-significant increase for TCAs. Immediately following lockdown, and post-lockdown, trends were the same as NOI/1000inhabitants.

Conclusion

Out with MAOIs, no significant changes were observed in antidepressant prescribing following lockdown, meaning we cannot determine the effects of COVID-19 on antidepressant prescribing based on this studies results. Further patient specific research is required to accurately determine how lockdown affected antidepressant prescribing in Scotland.

ANTIBIOTIC UTILISATION TRENDS IN THE INPATIENT SECTOR BEFORE AND DURING THE PANDEMIC

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ABSTRACT

Background

The COVID-19 pandemic had major impact on the health care system. The aim of the study was to assess and compare the antibiotic use in the Hungarian hospital care during and before the pandemic.

Methods

Annual systemic antibiotic (J01) utilisation sales data was obtained for the 2010-2021 period. Antibiotics were classified and calculations were performed according to the WHO ATC/DDD index and expressed as DDD per100 patient-days (DHPD). A linear regression (trend analysis) was performed for of the preCOVID years (2010-2019). A prediction interval was set up and antibiotic use during the pandemic years (2020, 2021) was assessed whether fits in.

Results

Antibiotic utilisation was 22.0 DHPD in 2010 and 23.3 in 2019, while we observed sudden increase during the pandemic years (2020: 32.2 DHPD; 2021: 33.7 DHPD), mainly due to decrease in hospital admissions and consequently patient-days. Trend analysis of the preCOVID years confirmed significant increase in the use of parenteral antibiotics and at subgroup level for cephalosporins, carbapenems and imidazol derivatives. Utilisation level of penicillin combinations (J01CR), first, third, and fourth generation cephalosporins, carbapenems, glycopeptides, nitroimidazoles and macrolides exceeded the predicted values in both pandemic years. Before the pandemic, co-amoxiclav headed the toplist of use, while during the pandemic ceftriaxone became the most used antibiotic. Cefazolin disappeared while imipenem-cilastatin appeared on the top 10 list.

Conclusions

The pandemic had major impact on the scale and pattern of hospital antibiotic use

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ANALYSIS OF THE ACCORDANCE OF BRAZILIAN GOVERNMENT PROTOCOLS WITH SCIENTIFIC EVIDENCE IN RELATION TO CHLOROQUINE AND HYDROXYCHLOROQUINE DRUGS: A SCOPE REVIEW

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ABSTRACT

COVID-19 was a recent global health crisis. The severity of the situation has led to a worldwide race to identify treatment for the disease. In vitro studies have shown that chloroquine was effective in blocking infection COVID-19. Clinical studies initially (March-April 2020) had heterogeneous results (observational studies mainly). Then, in April 2020 the Brazilian Ministry of Health released an Official Note, recommending the use of chloroquine to treat COVID-19 in its severe forms; in May, this indication was expanded, including mild forms. A scope review of the scientific literature was carried out; we also searched all recommendations issued by Brazilian government. We compared them to see if there was an agreement between the scientific literature and the official governmental recommendations.

At the end, 35 scientific papers were included in this review.

A large amount of scientific data was produced during a small amount of time about the treatment of COVID-19 with antimalarials. Based on the findings of the scientific literature, antimalarials use in the treatment of COVID-19 was considered non efficacious from May 2020 publications (RCT followed by SRs). Also there were data indicating an increase in serious adverse events, with associated mortality.

The Brazilian Ministry of Health publications, since April 2020, recommend the use of these drugs in the treatment of COVID-19, initially in severe cases, later more generally and early. At no time (from April 2020 to November 2021) the Brazilian government recommendations changed its initial statement and kept issuing antimalarials, in despite of the scientific literature.

THE USE OF HUMAN IMMUNOGLOBULINS - MANAGING IMBALANCE BETWEEN AVAILABILITY AND DEMAND IN PORTUGAL

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ABSTRACT

Introduction

Over the last years problems with the availability of immunoglobulins for human use (IG) due to an imbalance between supply and demand were noticed worldwide.

In Portugal, there has been an increase in the prescription of IG, with this medicine representing the second highest value in total expenditure of the Portuguese National Healthcare Service (NHS) consumptions.

In view of recurrent shortages and the induced price increases a guidance aiming to rationalise the clinical use of IGs was released in 2020.

In the meantime, COVID -19 pandemic, contributed to aggravate the situation. Therefore, it is of utmost importance to characterise the use of IG in Portugal to decide further policy strategies.

Methods

In 2022 a survey was conducted to all national hospitals aiming to assess the level of off-label use and compliance with the guidance published in 2020. National database on consumption and expenditure of IG was also analysed.

Results

32 /41 responses were received. Between 2017 and 2021 an increase of 20% was noticed concerning total amount of units sold at National level. The NHS costs increased 288%. Off label use when reported can achieve 50% of total use. Most hospitals reported that off label use is compliant with the NPTC guidance, although in some situations protocols are not in place for approval and monitoring the use.

Conclusion

Improvement in databases and review in the existing guidance is needed to better monitor and manage the use of IG aiming to reach a cost-effective therapeutic use and to avoid shortage.

PHARMACIST AND PATIENT PERSPECTIVES ON THE USE OF VIDEO CONSULTATIONS IN PRIMARY CARE IN SCOTLAND

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ABSTRACT

Background

Despite access to video consultation (VC) technology being made available nationally across primary care in NHS Scotland, uptake has been limited, both before and during the COVID-19 pandemic. This study aims to better understand the factors influencing the use/non-use of VC by community and general practice (GP) pharmacists and their patients.

Methods

Development of interview schedules were informed by a scoping review identifying studies applying human factors to assess the use of video and telephone consultations in primary care. The schedules were piloted by two patients and two pharmacists. Participants were recruited (November 2022 – ongoing) through cooperation with relevant organisations, conference attendance, social-media, and snowball sampling. All data underwent a framework analysis using the Systems Engineering Initiative for Patient Safety (SEIPS) 2.0 model to highlight where in the current work system the factors influencing use lie.

Results

Recruited to date: 14 patients (57.1% female; five (35.7%) aged between 60-65), and; 18 pharmacists (nine GP pharmacists, six community pharmacists, three working in both settings), qualified <1 – 35 years, from 10 of the 14 Scottish health-boards. The full framework analysis will be available at the conference.

Conclusions

Deployment of VC is a strategic goal for NHS Scotland. Increased understanding of the facilitators and barriers to adoption across the work system is important to increase use of this technology within health care. Noteworthy, there has been strong interest from patients, suggesting this group want their voice heard in health-service research.

UNINTENDED IMPACT OF PHARMACOVIGILANCE REGULATORY INTERVENTIONS: A SYSTEMATIC REVIEW

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ABSTRACT

Background

Studies that assess the impact of pharmacovigilance regulatory interventions often focus on the expected outcomes of those interventions, while the unintended impact may be overlooked. The update of the Good Pharmacovigilance Practice (GVP) guideline in 2017 emphasised the need also to assess possible unintended impact. This systematic literature review investigated how often the unintended impact of regulatory interventions is considered in publications that evaluate pharmacovigilance regulatory interventions in Europe.

Methods

We conducted a systematic literature review from January 1, 2012, to February 28, 2022, on MEDLINE and EMBASE to find studies that evaluated the impact of regulatory interventions in Europe. The primary outcome was the frequency of publications reporting assessments of unintended impact. We studied the characteristics of these publications, including outcomes assessed and analytical methods applied.

Results

The unintended impact of pharmacovigilance regulatory interventions were investigated in 23 of 96 included publications (24%). The drug classes most frequently studied in unintended impact studies were oral glucose-lowering drugs (n=6, 26%), opioids (n=4, 17%), and antidepressants (n=4, 17%). The reported methods to assess the unintended impact were interrupted time series (n=10, 43%), descriptive statistics with (n=2, 9%) or without significance testing (n=9, 39%). The outcomes selected for unintended impact assessments included the use of other drugs (n=16, 52%), health outcomes (n=8, 35%), and behavioural changes (n=4, 17%).

Conclusions

Unintended impact of pharmacovigilance regulatory interventions was reported in only a quarter of identified publications. There was no apparent increase in unintended impact assessments after updating the GVP guidelines.

REVERSING AND PREVENTING PRESCRIBING CASCADES IN PRACTICE: A PILOT STUDY.

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ABSTRACT

Background

Prescribing cascades (PC) occur when adverse drug reactions (ADR) are considered as a new condition and treated with another medication. Reversing and preventing PCs in clinical practice is important. We aimed to assess the feasibility to reverse and prevent PCs and estimate the cost-benefit of pharmacy-led interventions to prevent PCs.

Methods

A pilot study was conducted in two community pharmacies. Retrospectively, dispensing records were evaluated for ten potential PCs. Interventions were proposed to the physician to reverse PCs. Prospectively, patients with first dispensings for medications likely to cause PCs were counselled on ADRs and phoned one month after dispensing to detect ADRs and thus prevent PCs. Time needed for detection and counselling was used to estimate the labour costs of preventing PCs, whereas savings were estimated as one physician visit plus one month medication. Descriptive analysis was performed.

Results

Retrospectively, 22 patients had a potential PC, but 13 needed no interventions after consultation with the pharmacist. For nine patients the prescriber was consulted, which resulted in reversing PCs for three patients. Prospectively, six patients experienced an ADR that could induce a PC. Three patients were advised to monitor their ADR, one patient had already discontinued the medication, and two patients needed interventions (discontinuation or switch). For this, the labour costs were estimated at €70 and the potential PC savings at least €90, resulting in a cost-benefit of €20.

Conclusion

It seems to be feasible to reverse and prevent PC and potentially cost-saving to prevent PCs in community pharmacies.

E-HEALTH TECHNOLOGIES FOR TREATMENT OF DEPRESSION, ANXIETY AND EMOTIONAL DISTRESS IN PEOPLE WITH DIABETES MELLITUS: SYSTEMATIC REVIEW AND META-ANALYSIS

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ABSTRACT

This systematic review of randomized clinical trials (RCT) summarized the available evidence regarding the effectiveness of e-Health technologies for the treatment of depression, anxiety, and emotional distress in people with diabetes mellitus. The databases searched were the Cochrane CENTRAL, MEDLINE, EMBASE, Web of Science, and LILACS; up to January 2023. The primary outcomes were improvement and/or remission of depression, depressive symptoms and/or anxiety, remission of diabetes-related emotional distress, and improvement in quality of life. Reviewers, in pairs and independently, selected the reviews and extracted their data. Meta-analyses were conducted, and the quality of evidence was assessed following the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. Ten RCT and 2,209 participants were analyzed. In general, the studies had high methodological quality. The interventions were web-based programs (n=5) and telehealth (n=5). Meta-analysis showed improvement of depression with the use of Internet-Guided Self-Help or Telephone-Delivered Cognitive Behavioral Therapy (CBT); improvement of anxiety with Internet-Guided Self-Help or Diabetes-Specific CBT interventions; and improvement of emotional distress with the use of Internet-Guided Self-Help, Diabetes-Specific CBT, MyCompass, Internet-Guided Self-Help and Healthy Outcomes through Patient Empowerment. The follow-up ranged from 3 to 12 months and the quality of evidence ranged from very low to moderate. Due to divergences in interventions, populations, follow-up time, and outcome measures, these findings must be confirmed in future clinical trials.

WHAT MAKES IT HAPPEN – A REALIST EVALUATION OF THE VIP BDMARDS EDUCATIONAL VISITING PROGRAM

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ABSTRACT

Introduction

The Value in Prescribing bDMARDs Program was a three year publicly funded Australian collaboration supporting clinicians and consumers managing inflammatory bowel disease, rheumatoid arthritis and chronic plaque psoriasis. It offered educational visits or small group discussions integrating academic detailing to rheumatologists, dermatologists and gastroenterologists to discuss how to maximise the benefits of treatments.

Methods

A realist evaluation developed a theory of why this first of its kind educational program using academic detailing to non-GP specialists works, for whom and under which circumstances. For this realist program evaluation participation data were combined with clinician feedback and interviews, program stakeholder and developer interviews and educational visitor reflections and follow-up.

Results

Initial uptake of educational visits was facilitated through professional networks and organisations, visitors' personal contacts and word of mouth. Clinicians expressed a need for unbiased, evidence-based information about therapeutic options, comparative efficacy and adverse effects, e.g. of biologics, because they found it difficult to access unsponsored information. Program relevance and credibility was ensured by unbiased content, developing clear educational visiting objectives and messaging by an independent organisation with support of expert clinicians. Critical appraisal skills, clinical experience, communication and academic detailing skills of the educational visitors established interest and trust by clinicians who valued the tailoring of discussions to their needs and practice and follow-up to questions.

Conclusion

The realist evaluation points to mechanisms of trust, credibility and service which link independence, skill and depth in program design to meeting individual clinicians' needs for unbiased, evidence-based information through personalised discussions.

GPS STUDY: A PHARMACEUTICAL INTERVENTION TO IMPROVE MEDICATION USE AND WELL-BEING OF OLDER ADULTS WITH NEUROCOGNITIVE DISORDERS IN QUEBEC, CANADA

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ABSTRACT

Background

Pharmacists are now practising in Family Medicine Groups' (FMGs) multidisciplinary teams to support medication optimization in Quebec, Canada. Among populations that could benefit from pharmacists' interventions are older adults with neurocognitive disorders (NCD), due to their increased risk of adverse drug reactions. Our ongoing living-laboratory-type intervention and pragmatic controlled study is evaluating the impact of pharmacists' activities on these older adults' medication and well-being.

Method

We are recruiting older adults with NCD in FMGs in two Quebec regions. In intervention FMGs, pharmacists are systematically involved in these patients' care trajectory. In control FMGs, no FMG pharmacist is involved. Pharmacists report medication-related interventions and use at study beginning and after six months of follow-up. Medication appropriateness patients' medication burden, satisfaction with care, and quality of life are assessed for the same time points. We process descriptive analysis on patients' characteristics and their medication use at their inclusion.

Results

Since September 2021, 136 patients agreed to participate. At inclusion, the median age was 80 years, 58.5% are women and 68.8% have completed 12 years or less of schooling. On average, participants used 10.4 different medications. Therapeutic classes most often used are statins (70.6% of users), vitamin D and analogues (55.1%) and proton pump inhibitors (53.7%). Only 9.6% of patients used an anti-dementia drug.

Discussion

Participant characteristics underline the relevance of involving pharmacists in the care trajectory of older adults with NCD. At the end of the study, the implementation process will be evaluated using the Consolidated Framework for Implementation Research.

ANTIBIOTIC STEWARDSHIP FOR COMMUNITY PHARMACIES IN INDONESIA: DEVELOPMENT AND EVALUATION OF A QUESTIONNAIRE-BASED SURVEY AND E-LEARNING MODULES

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ABSTRACT

Background

Community pharmacists (CP) have an important role in ensuring appropriate use of antibiotics in community settings. The objective of this study was to assess the knowledge of CPs about antimicrobial stewardship (AMS) and evaluate an online learning intervention related to AMS.

Methods

A 31-item questionnaire-based survey was conducted among CPs in Indonesia, comprising sections on AMS practices and perceptions of community pharmacies, and barriers and facilitators to AMS. An online learning module was also developed and tested on CP.

Results

More than 90% of CP agree that AMS in community pharmacies will reduce inappropriate use of antibiotics, and 97.6% agree that collaboration with general practitioners would improve their participation in AMS, as would regulators' clear understanding of CP's role in AMS (94.4%). However, the major barriers limiting CPs' participation in AMS were limited training to participate in the program (48.4%) and limited access to important patient information (74.6%). Online learning using the AMS module for 36 licensed CPs also demonstrated that it was effective in increasing CPs' knowledge of AMS, particularly in the areas of antibiotic classification, identification of special groups of patients who require antibiotic therapy, risk factors for antibiotic resistance, and the core elements of AMS in community pharmacies.

Conclusion

The study highlighted the knowledge and practices of CP toward AMS. A follow-up survey and educational intervention would be necessary to assess long-term improvements in their knowledge and practice of AMS.

INTERVENTIONS TO REDUCE OPIOID USE IN PATIENTS AFTER MAJOR SURGERY - A SYSTEMATIC REVIEW AND BEHAVIOUR CHANGE TECHNIQUE ANALYSIS

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ABSTRACT

Background

Evidence supporting the theoretical basis of effective opioid deprescribing strategies after surgery is lacking. This systematic review aimed to assess the effectiveness and identify the behaviour change techniques (BCTs) associated with effective interventions.

Method

A structured search strategy was applied to Medline, Embase, CINAHL Plus, PsycINFO, and Cochrane Library from inception to February 2022 to identify studies that assessed interventions to reduce opioid use in adults after major surgeries. Individual study's risk of bias was assessed by RoB-2 and ROBINS-I tools, and Cohen's effect size was calculated and classified into small ($d \leq 0.2$), medium ($0.2 < d \leq 0.5$) and large ($d \geq 0.8$) based on the Cohen's term d . A validated taxonomy was used to identify BCTs of interventions, and those associated with interventions of a large effect size were presented.

Results

Twenty studies (6 clinical trials and 14 cohort studies) with heterogeneous risk of bias (mainly medium to high risk) were included. The effect size of educational ($n=10$), guideline-focused ($n=3$), multi-faceted ($n=5$) and pharmacist-led ($n=2$) interventions varied from small ($n=6$), medium ($n=4$) to large ($n=10$). Of the ten studies reporting a large effect size, nine BCTs included information about health consequences, credible sources, social support (unspecified), instructions on how to perform a behaviour, feedback on behaviour, social reward, social comparison, behaviour substitution, and pharmacological support, were identified.

Conclusion

Understanding the dominating BCTs of effective interventions can inform the future implementation of opioid tapering strategies. Further analysis and validation are needed to associate the BCTs with effectiveness considering other influencing factors.

NON-ADHERENCE TO STATIN TREATMENT IN PERSISTENT AND NON-PERSISTENT PATIENTS WITH PERIPHERAL ARTERIAL DISEASE MEASURED USING THE INDEX PROPORTION OF DAYS COVERED

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ABSTRACT

Introduction

Patients' adherence is a requirement for statin treatment to be effective in the secondary prevention of peripheral arterial disease (PAD). The aims of our study were: a) to analyse non-adherence to statin treatment using the index Proportion of Days Covered (PDC); b) to identify factors associated with non-adherence separately among persistent and non-persistent patients.

Methods

Our study cohort consisted of 13,763 statin users aged ≥ 18 years in whom PAD was newly diagnosed between 1 January and 31 December 2012. Non-persistence was defined according to the 6-month treatment gap period without any statin prescription. Non-adherence was identified according to the $PDC < 80\%$. PDC was calculated during the whole follow-up period in persistent patients, whereas only during the period of persistence in non-persistent patients. Patient- and statin-related characteristics associated with non-adherence were identified using logistic regression.

Results

In the study cohort 8,020 patients (58.3%) were defined persistent, and 5,743 patients (41.7%) non-persistent during the 5-year follow-up period. There were more non-adherent patients among the non-persistent patients compared to persistent patients (43.1% vs 30.6%; $p < 0.001$). High intensity statin treatment was associated with non-adherence in both persistent and non-persistent patients, while employment and increasing number of medications were associated with non-adherence only in the group of non-persistent patients.

Conclusions

Poor adherence during the persistent period was observed more often in patients who discontinued their treatment. Different factors were associated with non-adherence in persistent and non-persistent patients.

MANAGEMENT OF MEDICATION ADHERENCE IN EUROPE: A PAN-EUROPEAN SURVEY AMONG HEALTHCARE PROFESSIONALS

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ABSTRACT

Background

The European Network to Advance Best practices & technoLogY on medication adherence (ENABLE) COST action aims to advance the implementation of medication adherence (MA) interventions. To assess current practices and needs, we conducted a survey on how MA is managed across Europe.

Methods

A cross-sectional, online survey was carried out among 40 COST countries using Webropol 3.0 survey and reporting tool. The survey included 19 closed-ended questions. Here, we present the following results: (i) how is MA monitored; (ii) what MA interventions are applied and (iii) unmet needs regarding the management of MA.

Results

2875 healthcare professionals (HCPs) from 37 countries replied to the survey, among them mainly pharmacists (40%), physicians (37%), and nurses (17%). Based on the answers, HCPs monitor MA by asking the patient (86%), and by checking previous prescriptions (57%) and dispensation history (57%). Motivating and counselling the patient was the primary method used to improve MA (93%). Another common strategy was to involve family members/caregivers in the treatment (56%). Unmet needs regarding MA in HCPs' daily work included lack of awareness among patients (66%), lack of time (44%), the need for better electronic solutions (e.g. access to shared databases and better connections between different databases) (42%), and lack of collaboration and communication among HCPs (41%).

Conclusion

Across European countries, MA measurement and interventions were similar as were the gaps. Multidisciplinary MA-enhancing interventions, objective measurements for MA, better digital solutions and databases, and better communication among HCPs are required for further MA optimization.

INTEGRATING PATIENTS' AND HEALTH CARE PROVIDERS' PERSPECTIVES TO ADDRESS MEDICATION NON-ADHERENCE : A QUALITATIVE STUDY AMONG PATIENTS WITH CHRONIC DISEASES IN INDONESIA

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ABSTRACT

Background

Non-adherence to medication is common among people with chronic diseases and is associated with an increased risk of complications and mortality. Therefore, it is important to develop strategies to enhance medication adherence by understanding the integrated patient and healthcare provider perspective. This study aims to explore patients' and healthcare providers' perspectives to address medication non-adherence among patients with chronic diseases in primary health centers (PHCs) in Indonesia.

Method

This study utilized a descriptive qualitative analysis. Face-to-face semi-structured interviews were conducted at five PHCs in Bandung city, Indonesia. The healthcare providers (doctors, pharmacists, and nurses) and patients with chronic diseases were purposively selected. Each interview was audio recorded, verbatim transcribed and subjected to thematic content analysis using software Atlas.ti9.

Results

Twenty-eight interviews (18 patients and 10 healthcare providers) were conducted. Three main medication non-adherence challenges were identified: 1) patient-related factors, which included lack of knowledge, low necessity, high concern regarding common possible side effects, financial issues, difficulty taking medication while travelling, belief about God's power that can only heal, and using traditional medicine; 2) provider-related factors, which included lack of communication and the complexity of health care services; and 3) societal-related factors, which included lack of family support, and social rumors that medication consumption will lead to dependency.

Conclusion

Several factors that have been identified from both patient and healthcare provider perspectives should be integrated to develop tailored interventions to address medication non-adherence among patients with chronic diseases.

PATIENT REPORTED ASSOCIATIONS BETWEEN PEOPLE-CENTERED CARE AND ADHERENCE

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ABSTRACT

Introduction

People centered care (PCC) strategies are believed to improve overall health outcomes. Medicines use is an essential part of treatment for many patients with chronic conditions. Non-adherence rates are high, and result in poor health outcomes, increased healthcare utilization and costs. The aim of this study was to explore the relationship between PCC and adherence to medicines for persons with chronic medicines use.

Methods

Cross-sectional survey design. Adults using at least 3 chronic medicines per day were eligible.

Results

A sample 459 persons participated. The mean score on the Client-Centered Care Questionnaire (CCCQ) (adjusted to pharmacotherapy) was 52.7 (sd=8.83, range [18-70]). The top 20% scored 60 or more. The 20% lowest scores were 46 or less. Adherence levels were high, with a mean score of 22.6 on the MARS-5, and 88% scoring 20 or more. Each point of increase on the adjusted CCCQ corresponded to a 7% higher chance of medicines adherence (≥ 20 on the MARS-5), corrected for age, the burden due to chronic diseases, the impact of side effects on the daily life and participants' beliefs about medicines.

Conclusion

Patients' perceived level of people centeredness of the pharmaceutical care they received is associated with adherence to their medicines. Beliefs about medicines are associated with both PCC and adherence. The people-centeredness of pharmaceutical care showed several shortcomings and can still be improved. It is worth investing in more people centered pharmaceutical care.

PERSISTENCE WITH FIRST-LINE ANTIHYPERTENSIVE THERAPY IN GERMANY

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ABSTRACT

Background

The goal of this retrospective cohort study was to investigate 3-year-persistence with antihypertensive drug therapy and the association between antihypertensive drug classes and therapy discontinuation risk in Germany.

Methods

The present retrospective cohort study was based on the IQVIA longitudinal prescription database (LRx) and included adult outpatients (≥ 18 years) with an initial prescription of antihypertensive monotherapy alone including diuretics (DIU), beta blockers (BB), calcium channel blockers (CCB), ACE inhibitors (ACEi), and angiotensin II receptor blockers (ARB) in Germany between January 2017 and December 2019 (index date). A Cox proportional hazards regression model was also used to assess the relationship between antihypertensive drug classes and non-persistence adjusted for age and sex.

Results

This study included 2,801,469 patients. Patients on ARB monotherapy exhibited the highest persistence within one year (39.4%) and three years (21.7%) after the index date. Patients on DIU monotherapy showed the lowest persistence (16.5% after one year, 6.2% three years after the index date). In the overall population, initial monotherapy with DIU (HR: 1.48) was positively associated with mono-therapy discontinuation, whereas ARB monotherapy was (HR=0.74) negatively associated with mono-therapy discontinuation compared to BB. However, in the age group >80 , there was a slight negative association between DIU intake and mono-therapy discontinuation (HR=0.91).

Conclusion

This large cohort study reveals significant differences in 3-year persistence with antihypertensives, which were strongest for ARB and weakest for DIU. However, the differences also depended on age, with much better DIU persistence in the elderly.

PERCEPTIONS AND EXPERIENCE AMONG ICELANDIC CARDIAC CARE PROFESSIONALS OF FACTORS INFLUENCING MEDICATION ADHERENCE IN HEART FAILURE PATIENTS

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ABSTRACT

Background

Heart failure (HF) is a chronic and costly condition with a high mortality rate. Adhering to medication regimens is key to alleviate symptoms and delay disease progress. An efficient and valid tool for assessing medication adherence (MA) specifically for HF-patients is lacking. The aim was to explore perceptions and experience among Icelandic cardiac care professionals on factors influencing MA in HF-patients to start developing a HF-specific MA scale.

Methods

An online survey with closed and open response formats was distributed to cardiac healthcare practitioners (cardiologists and nurses) from October-December 2021.

Results

Of 104 invited, 73 (70%) participated in the study. Patient relationship with healthcare providers (97%), healthcare support at home (95%) and pharmacy multi-dose dispensing (93%) were noted as the most beneficial factors for MA. The youngest and oldest HF-patients, especially males, were considered to have the highest risk of medication non-adherence. Patients with alcohol and/or substance abuse (89%), those lacking knowledge about medication effects (89%), those considering medications useless (88%), and cognitive impairment (86%) were estimated at high risk of non-adherence. Nausea was considered a side effect of highest risk (88%) for non-adherence. Most participants (73%) believed that the healthcare provider should assess and record MA.

Conclusion

Cardiac care professionals consider HF-patients' MA influenced by various patient-, therapy-related, and health system factors. These results feed into item-generation in a HF-specific MA scale and provide valuable input into developing the new scale using both quantitative and qualitative methods.

MEDICATION ADHERENCE AND PERSISTENCE OF PERSONS WITH MULTIPLE SCLEROSIS IN SLOVENIA

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ABSTRACT

Background

New therapies have emerged for multiple sclerosis in the past decade. The aim of this study was to evaluate medication adherence and persistence of patients with multiple sclerosis in Slovenia.

Methods

This retrospective nationwide study was performed using the national Slovenian health claims database. A cohort of new users from 2011 to 2014 was followed for 5 years to evaluate medication adherence and persistence with AdhereR. Adherence was calculated as the proportion of days covered (PDC>80%, CMA5 algorithm). Persistence was defined as the time from first dispensing to discontinuation of treatment (gap length 60 days, Kaplan-Meier survival analysis). Sensitivity analysis was also performed.

Results

A cohort of new users included 316 patients (average 43 years, 70.8% female). The average adherence was 92.3% in the first year and 82.9% in the fifth year of observation and ranged from 62.8% (interferon beta-1a) to 84.8% (glatiramer acetate) over the 5-year period. The share of adherent patients (PDC>80%) in a 5-year observation period was 69.9%. During the 5-year period, 81.3% of patients discontinued their treatment, with half of the patients discontinuing their treatment 581 days (19 months) after the first dispensing. Persistence was higher with glatiramer acetate and interferon beta and lower with teriflunomide, fingolimod and dimethyl fumarate.

Conclusion

The results show an increase of IMM medication use in a 10-year observation period and relatively high adherence. The persistence is relatively low, nevertheless, 95.3% of patients started another treatment with the same or alternative therapy within the observation period.

ADHERENCE TO ADJUVANT ENDOCRINE THERAPY OF PATIENTS WITH EARLY BREAST CANCER IN CROATIA

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ABSTRACT

Background

In women with early breast cancer (BC), adjuvant endocrine therapy (AET) reduces the risk of disease recurrence and mortality if taken for at least five years. Unfortunately, literature reports that about half of BC survivors are non-adherent and discontinue therapy earlier than recommended. This study aimed to investigate adherence to AET in early BC patients in Croatia.

Methods

This cross-sectional study included women with early hormone receptor-positive (HR+) BC treated with AET for more than 3 months. The research was conducted at the University Hospital Centre Zagreb, General Hospital Šibenik and online through collaboration with Croatian BC patient associations. A validated instrument, the Medication Adherence Report Scale (MARS-5), was used. The collected data were analysed using SPSS v. 25, ($p \leq 0.05$).

Results

Overall, 744 eligible BC survivors with a median age of 51 years (21 - 90) and a median duration of the AET treatment of 2 years (3 months - 12 years) responded to MARS-5 and were included in the analysis. Altogether, 54% were non-adherers (not taking all indicated doses), of which 36.6% were unintentional non-adherers, 13.5% intentional/unintentional non-adherers and 3.8% intentional non-adherers. Factors significantly associated with non-adherence were the type of AET (tamoxifen, $p < 0.001$), age (< 62 , $p < 0.001$), BMI ($p = 0.05$) and employment ($p < 0.05$).

Conclusion

The non-adherence rate to AET in Croatia is high, as half of the patients did not take their medicines as indicated. Further research should be focused on exploring targeted measures to address unintentional non-adherence among the patients with the HR+ early BC.

ASSOCIATION BETWEEN BELIEFS ABOUT MEDICATIONS, ATTITUDES TOWARDS VACCINES AND COVID-19 VACCINATION STATUS

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ABSTRACT

Background

Medication beliefs can predict medication adherence. Vaccines may not be perceived as medications, and therefore medication beliefs may not predict vaccination status. The aim was to investigate the association between beliefs about medications, as opposed to attitudes towards vaccines (vaccine hesitancy), and COVID-19 vaccination status in the general public.

Methods

An online questionnaire survey using social media was conducted in Denmark. The validated Beliefs about Medicines Questionnaire (BMQ) was used to measure beliefs about medications. The newly validated Danish translation of the Vaccination Attitudes Examination scale (VAX) was applied to measure vaccine hesitancy. Independent t-test compared medication beliefs and vaccination hesitancy between COVID-19 vaccinated and not vaccinated respondents.

Results

Among in total 211 respondents, 83% were female; mean (SD) age was 49.9 (18.0) years; 83%, 6% and 11%, respectively, were fully, partly and not COVID-19 vaccinated. Fully vaccinated compared to not vaccinated respondents had more positive beliefs about medications and lower hesitancy towards vaccines: respective mean (SD) BMQ scores (scale range 1-5) were 3.7 (0.60) and 2.3 (0.59), $p < 0.001$, while respective mean (SD) VAX scores (scale range 1-6) were 2.4 (0.83) and 4.9 (0.93), $p < 0.001$. The mean total BMQ and VAX scores were negatively correlated ($r = -0.716$, $p < 0.01$).

Conclusion

Even though beliefs about medications and attitudes towards vaccines were correlated, attitudes towards vaccines seem to be more strongly associated with COVID-19 vaccination status than were beliefs about medicines. The findings should be further confirmed in regression analysis.

QUALITY OF LIFE, GLYCEMIC CONTROL AND MEDICATION ADHERENCE OF DIABETES PATIENTS IN PRIMARY HEALTH CENTER IN CENTRAL CITY OF JAKARTA

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ABSTRACT

Jakarta is the city with the highest prevalence of diabetes in Indonesia. A Chronic Disease Management Program (PROLANIS) has been developed for primary care, but little has been done to evaluate the effects of this program. The aim of this study was to assess the quality of life, adherence with medication and glycemic control of patients with type 2 diabetes mellitus enrolled in PROLANIS and explore factors associated with poor glycemic control.

This was a cross-sectional study in patients participating in PROLANIS from one primary health center in Jakarta, Indonesia. Adherence was assessed by the pill count method. For this, patients were instructed to bring in their medication supplies. A pill count of <80% was considered as non-adherent. Quality of life was assessed by the EQ5D5L and EQVAS questionnaires and glycemic control was obtained from the fasting plasma glucose (FPG) test.

Sixty patients (61%) out of the ninety-eight enrolled in the program were included (mean age 53.7 and 48% female). Overall, 80% were adherent; 53% (EQ5D) and 61% (EQ VAS) had a high quality of life, respectively; 53% had uncontrolled blood glucose levels. Multivariate logistic regression analysis showed that low adherence and hypertension comorbidity were associated with poor glycemic control (adjusted OR=0.053, 95%CI 0.005-0.560) and (adjusted OR=5.405, 95% CI 1.008-28.986), respectively.

This first evaluation shows that blood glucose control is a major issue in patients enrolled in PROLANIS. Attention for adherence, especially in patients with comorbidities may be a first step.

Keywords: Quality of life; glycemic control; medication adherence; diabetes

MIXED EFFECT MODELS FOR THE ANALYSIS OF MEDICATION ADHERENCE TO ANTIDIABETIC DRUGS: THE ITALIAN CASE

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ABSTRACT

Background

This study aims to identify, in the Italian population, groups of individuals with diabetes requiring priority health policy interventions, to improve their treatment adherence and health outcomes, through the study of adherence trajectories to antidiabetic drugs.

Methods

This longitudinal cohort study was conducted by the Italian Medicines Agency from pharmaceutical prescriptions for Veneto, Tuscany, and Campania: 24777 incident users, 45 years or older, were followed for a 7-semester follow-up from January 1, 2018 to December 31, 2020. *Medical Possession Ratio* (MPR) and *Proportion of Days Covered* (PDC) were calculated on a semester basis. Adherence trajectories were identified by estimating *Latent Class Linear Mixed Models*, using R software, specifying quadratic functions of time. These are suitable for analysis of longitudinal data because they capture individual extra-variability over time, which is not detectable by traditional static measurements of adherence.

Results

For Campania, Tuscany and Veneto the best classification shows five trajectories, similar in shape but diversified in numerosity and trend by age and number of comorbidities. Specifically, a downward trend in adherence is observed as age increases and more comorbidities occur. Extra temporal variability emerged when using MPR as a measure of adherence, but not PDC. This pilot study also saw the implementation of decision trees based on *Mixed Effects Models* as an efficient alternative approach to pursue the research objective.

Conclusion

This preliminary analysis identified that categories of patients in older age and with two or more comorbidities tended to have poorer adherence, more so for women than for men.

PERSISTENCE WITH ADALIMUMAB TREATMENT IN CROHN'S DISEASE

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ABSTRACT

Background

Adalimumab is the first-line biologic in Crohn's disease (CD). Biosimilars have been on the European market since 2018 (Canada 2020, Australia 2021, US expected late 2023).

Biosimilar prescribing is encouraged for minimising health inequalities, securing supply and/or reducing expenditure. Several studies have dispelled earlier concerns for patient outcomes around safety and efficacy of biosimilar swapping or non-medical switching. Knowledge gaps still exist regarding efficacy and safety when switching between different brands.

To address these questions our cohort study employs persistence with adalimumab treatment as a surrogate marker for efficacy and safety in the absence of clinical outcome data.

Methods:

Complete data on dispensed/reimbursed pharmaceuticals (2004-2022) and ambulatory diagnoses data (2006-2021) for all insurees of the biggest German statutory health insurance group (AOK) were used, covering up to 27 million insured.

We compared treatment persistence with adalimumab as first line biologic for adult patients with a diagnosis of CD, excluding patients with concurrent diagnoses of any other conditions for which adalimumab is licensed in Germany.

We compared persistence over three 5-year time periods:

2004-2008: only TNFI, no alternatives

2010-2014: non-TFNI biologics available (ustekinumab, vedolizumab)

2018-2022: biosimilars available

Results

For 2004-2008, mean persistence was 31.2 months, 2010-2014: 29.0 months, 2018-2022: 25.3 months. In period 3 patients with only one adalimumab brand showed a persistence of 24.3 months; with two, 29.3 months, and with three, 30.2 months.

Conclusions

As treatment alternatives have become available, persistence with adalimumab treatment has reduced noticeably. Switches between biosimilar products correlate with stronger persistence treatment.

LONGITUDINAL TRAJECTORY MODELING TO ASSESS ADHERENCE TO SACUBITRIL/ VALSARTAN AMONG PATIENTS WITH HEART FAILURE

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ABSTRACT

Background

Measuring adherence from electronic healthcare data by single estimates over extended periods does not capture its dynamic nature. Trajectory modeling may provide insights into long-term changes. We estimated distinct Sacubitril/Valsartan (Sac/Val) adherence trajectories and factors associated with each trajectory, focusing on two adherence phases: implementation and persistence.

Methods

Subjects with incident heart failure starting Sac/Val in 2017-2018 were identified from the Campania Regional Database for Medication Consumption, a data warehouse of ~6 million inhabitants. We used R (v4.0.1) to estimate patients' Continuous Medication Availability (CMA9; AdhereR) during 12-month periods over 1 year. We selected groups with similar CMA9 trajectories (Calinski-Harabasz criterion). We performed multinomial regression analysis to assess relationship between demographic and clinical factors and adherence trajectory groups.

Results

The study cohort included 4,455 subjects (mean age: 69.1±12years), 70% male. Group-based trajectory modeling identified 4 distinct adherence trajectories: High Adherence (42.6% subjects; CMA Mean 0.91±0.08), Partial Drop-off (19.6%; CMA Mean 0.63±0.13), Moderate adherence (19.3%; CMA Mean 0.54±0.11), Low adherence (18.4%; CMA Mean 0.17±0.12). Polypharmacy was associated with partial drop-off adherence (OR 1.194, 95%CI 1.175-1.214) while occurrence of HF hospitalizations (OR 1.165, 95%CI 1.151-1.179) or other hospitalisations (OR 1.481, 95%CI 1.459-1.503) were associated with low adherence.

Conclusion

Treatment complexity in terms of polypharmacy and multimorbidity may negatively impact adherence in HF patients. Different determinants were detected for patients belonging to different adherence trajectory groups. These findings may help predict nonadherence risk upstream and guide a patient-tailored approach to supporting adherence.

MEDICATION ADHERENCE TO PSORIASIS TREATMENTS: A REAL WORLD DATA STUDY

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ABSTRACT

Introduction

Medication adherence is essential for disease management and can significantly improve outcomes and quality of life. Levels of adherence to psoriasis treatments, are often inadequate leading to adverse health outcomes and increased costs. The aim was to assess adherence to treatment of patients with psoriasis in a real-world setting.

Methods

Incident subjects with at least one prescription of biologic drug therapy for psoriasis (including apremilast) and/or with a psoriasis diagnosis were identified from the Campania-Regional-Database in 2017-2019 and followed for 1-year from the index-date. The three phases of the adherence process were assessed as per EMERGE guidelines: Initiation, expressed in terms of number of treatment plans prescribed/dispensed; Implementation, in terms of switch and swap rates; Discontinuation, in terms of drug interruption within 6- and 12-months, stratified by biologic drug therapy.

Results

The study included 811 subjects (mean age: 49.2 ± 16.3 years), 60% male. Suboptimal levels of adherence were discovered: 20% of patients did not start the prescribed drug therapy (initiation phase); swap levels were about 13.1% with an average time to swap at 1-month (29 ± 84.8 days) (implementation phase); overall, 51.5% of subjects interrupted biologic drug therapy within 87.5 ± 127.7 days. Subjects treated with anti-IL17 and anti-IL23 resulted in the higher adherence levels.

Conclusions

Findings revealed low levels of medication adherence for patients with psoriasis. Namely, half of them discontinued treatment within 3 months. Higher levels of adherence were detected for patients treated with anti-IL17 and anti-IL23. Further studies are needed to investigate predictors of medication non-adherence focusing on the discontinuation phase.

ADHERENCE TRAJECTORIES TO DIRECT ORAL ANTICOAGULANTS IN ATRIAL FIBRILLATION PATIENTS. A MULTI-REGIONAL STUDY.

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ABSTRACT

Background

Adherence to treatments is a dynamic process that can change over time. Traditional adherence measures, such as the percentage of days covered (PDC), are ineffective in determining differentiated behaviours. This study aims to identify longitudinal trajectories of adherence over time in new users of direct oral anticoagulants (DOACs) with atrial fibrillation (AF) and identify factors associated with poor adherence patterns.

Methods

Population: AF patients naïve to OAC (1-year look-back) over 18 years and with at least 1-year of follow-up were included. Data Sources/Setting: Data came from two regions of Spain: Valencia region and Catalonia (5 and 7.5 million inhabitants respectively). Exposure: initiation with any DOAC prescription in 2012-2018. Outcomes: 1-year PDC and monthly-PDC trajectories were obtained. Statistical analysis: Best model of trajectories was selected based on: best fit (minimum BIC), entropy ≥ 0.75 and minimum size of 5%. Associated factors were evaluated using a multinomial logistic regression model.

Results

Different adherence patterns were identified depending on the region. In the Valencia region (n=19616) three trajectories were obtained: fully adherent (82.7%), highly adherent (12%), and fast decline (5.3%). In Catalonia (n=22632), in addition to these trajectories, representing 62.1%, 14.5%, and 16.6% of the cohort respectively, a slow decline on adherence trajectory was also identified (6.8%). Initiation with dabigatran, hypertension, alcohol, concomitant use of antiplatelets, and coinsurance were associated with poor adherence trajectories. In contrast, hypertension and concomitant antiplatelet use were inversely associated with poor adherence.

Conclusion

Trajectories can add more information and discriminate better individuals with different adherence behaviours.

ATTITUDES TOWARDS VITAMIN D SUPPLEMENTATION IN TURKISH WOMEN OF CHILDBEARING AGE LIVING IN DENMARK – A QUALITATIVE STUDY

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ABSTRACT

Background

Vitamin D deficiency increases the risk of developing several chronic diseases. Sufficient vitamin D levels in reproductive age women are important not only for women's but also for their offspring's health. Vitamin D deficiency in non-western ethnic minorities in Denmark is prevalent, despite specific national recommendations for vitamin D supplementation. This study aimed to explore attitudes towards vitamin D supplementation in Turkish women of childbearing age in Denmark.

Methods

A qualitative interview study was conducted. Women were recruited using the personal network of one of the authors. Interviews were analyzed using inductive content analysis. The interview guide was inspired by the Knowledge - Attitudes - Behaviors model.

Results

Nine telephone interviews, lasting half an hour, were conducted. Age of the women varied from 22 to 37 years; all reported being vitamin D deficient; vitamin D status was obtained from their general practitioners. The analysis revealed two themes: (1) vitamin D supplements were perceived as medication, where the condition for which it was supposed to be used (i.e. vitamin D deficiency) had to be diagnosed and followed-up; (2) vitamin D was preferred to be received naturally, and the concrete information on what to eat and how long to be in the sun to be vitamin D sufficient was desired.

Conclusions

The findings suggest that Turkish women in Denmark may lack trust in vitamin D supplementation. There is a need to raise women's awareness of the benefits of vitamin D supplements, and motivate them to take these supplements regularly.

KNOWLEDGE, ATTITUDES AND PRACTICES OF ANTIBIOTIC DISPENSING AND USE AMONG PHARMACY PERSONNEL AND PATIENTS IN BAGDAD, IRAQ – A QUALITATIVE STUDY

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ABSTRACT

Background

Antimicrobial resistance (AMR) is a growing public health issue. Understanding patients' and health care professionals' motives for antibiotic (AB) use is important to battle AMR. Studies investigating AB-related knowledge, attitudes and behaviors are sparse in the Middle East countries. This study aimed to explore knowledge, attitudes and practices of AB dispensing and use for upper respiratory tract infections (URTI) among pharmacy personnel and patients in Bagdad, Iraq.

Methods

A qualitative interview study was conducted. Pharmacy personnel in community pharmacies and patients, who were, respectively, dispensing and pursuing ABs for URTI, were recruited from community pharmacies situated in three different districts of Bagdad. Interview guides were inspired by a similar study in North Western Russia. Interview transcripts were analyzed using inductive content analysis.

Results

In total, 16 patients (44% females, age 25-51 years, 56% pursuing AB without prescriptions), and 14 community pharmacy personnel (71% pharmacists, 64% female, age 23-32 years) were interviewed. Pharmacy personnel interviews revealed two themes as reasons to dispense an AB without prescription: 1) self-perception of pharmacists as confident and empathic healthcare professionals; 2) non-medical circumstances supporting increased ABs' sales (e.g. economic considerations or practice habits). Patient interviews revealed similar two themes: 1) trust in pharmacists as healthcare professionals; 2) practical reasons for not acquiring an AB prescription (e.g. lack of time and money).

Conclusions

The study showed that the dispensing and use of ABs in Bagdad does not always follow the guidelines. To strengthen appropriate use of ABs, non-medical circumstances around ABs prescribing should be considered.

COVID-19 VACCINATION PERCEPTIONS AMONG ARABIC-SPEAKING MINORITIES IN DENMARK – A QUALITATIVE STUDY

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ABSTRACT

Background

In 2019, the World Health Organization listed vaccine hesitancy as one of the top ten threats to global health. Vaccination hesitancy became especially relevant during the COVID-19 pandemic. Surveys had shown that COVID-19 vaccination hesitancy varied across countries, and across population groups within a country, depending on education, employment, or ethnic minority status. In Denmark, the COVID-19 infection rates and vaccination coverage were lower in areas with many residents having ethnic minority background. However, no qualitative studies have explored the perceptions of COVID-19 vaccination in ethnic minority communities to help understand the reasons behind the low vaccination rates. This study aimed to explore COVID-19 vaccination perceptions in Arabic-speaking minorities in Denmark.

Methods

Sixteen individuals, varying by age, gender, education, employment, health, and vaccination status were interviewed.

Results

Content analysis of the interview transcripts showed that the majority had some knowledge about how vaccines work to prevent infections. Moreover, a wide spectrum of opinions towards COVID-19 vaccines and Danish vaccination policies was expressed. Notably, COVID-19 vaccination issues were intensively discussed in Arabic-speaking gatherings, where agreements were rarely reached, and many people felt confused or took vaccines only for practical considerations. Due to language barriers, some participants experienced difficulties understanding vaccination-related information in electronic invitations and vaccination centers, and usually, it was family members who helped with translations.

Conclusions

Systematic efforts in translating and disseminating COVID-19 vaccine information are needed to support ethnic minority people in making informed decisions about COVID-19 vaccination.

HOW PHARMACY PROFESSIONALS LEARN AND IMPLEMENT SHARED DECISION-MAKING

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ABSTRACT

Introduction

Shared decision-making involves ways for healthcare professionals and people working together on treatment decisions. Grounded in NICE guidance, the Centre for Pharmacy Postgraduate Education (CPPE) developed an NHS England funded learning programme involving a self-directed e-course and two online workshop days, which included peer discussions and role plays with simulated patients.

Aim

To evaluate how well the CPPE learning equipped pharmacy professionals with the knowledge and skills to embed shared decision making into their practice.

Methods

CPPE distributed a survey to all participating learners: 2,242 after day1, 2,181 day2. Simple frequencies were created in Excel, textual comments were analysed thematically. All survey responses were anonymous, ethics committee approval was not required.

Results

Twenty-six percent (n=578) and 21.7% (n=488) of pharmacy learners responded after workshops 1 and 2 respectively. 62.8% and 65.2% of respondents rated workshop 1 and 2 highly (1-low, 4-high) for an increased understanding of shared decision-making. 90.1% and 89.4% expected to change their practice. Participants were asked what they were going to implement in practice; 78% and 59% added narrative. Participants noted being conscious of their own agenda, listening (golden minute), giving person chance to raise their wishes/goals, open questions, empathy, rapport, and thinking holistically (social history). Role plays were perceived as powerful; 89.1% and 83.8% rated the inclusion of simulated patients (actors) as high (4).

Conclusion

Following e-learning and workshops, participating pharmacy professionals felt empowered to reflect on their practice and implement shared decision-making skills. Role plays and actors were important elements to consolidate learning.

WILLINGNESS OF PEOPLE WITH TYPE 2 DIABETES MELLITUS TO ENGAGE IN HEALTHY EATING, PHYSICAL ACTIVITY AND MEDICATION MANAGEMENT

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ABSTRACT

Background

Guidelines recommend medication treatment and lifestyle changes to manage type 2 diabetes mellitus (T2DM). We aimed to assess the willingness of people with T2DM to engage in healthy eating, sufficient physical activity (PA) and medication taking, and explore associated patient factors and considerations.

Methods

A cross-sectional survey study was conducted among people in the Netherlands and United Kingdom who were diagnosed with T2DM in the previous two years. The outcome was patients' willingness to manage T2DM with each of the management options (yes/no based on a VAS score). Logistic regression analyses were used to assess associations of patient factors (including country), and considerations (including perceived capabilities, opportunities and motivation (COM)). Differences in considerations were further explored using Wilcoxon rank sum tests and descriptively using responses to open-ended questions.

Results

Included were 67 patients (mean age 57, 45% females) of whom 73% were willing to manage T2DM with healthy eating, 73% with sufficient PA, 72% with medication and 48% with all three management options. UK participants were less willing to follow the proposed recommendations for healthy eating than Dutch participants (OR:0.05, 95%CI:0.01-0.37). The willingness to engage in PA or medication taking was associated with COM-considerations (OR:7.58, 95%CI:1.50-38.35 and OR:6.05, 95%CI:1.64-22.28, respectively). Those willing to engage in PA perceived less barriers, and those willing to take medication had more positive and less negative outcome perspectives than those not willing.

Conclusion

Most patients had sufficient willingness for either healthy eating, sufficient PA or medication taking, partly associated with country and COM-considerations.

DEVELOPING CORE PRINCIPLES FOR ROUTINE PROMS COLLECTION IN CANCER CARE IN SCOTLAND

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ABSTRACT

Background

Embedding patient reported outcome measures (PROMs) into routine cancer care can help monitor treatment impact on quality of life, inform decisions, and transform care pathways. Although firmly positioned within the Scottish cancer strategy, PROMs are not part of routine care.

The Scottish Government (SG) funded Cancer Medicines Outcomes Programme (CMOP) supported the establishment of the Scottish Cancer PROMs Advisory Group (SC-PROMs AG) to provide strategic leadership in a 'once for Scotland' approach to cancer PROMs in clinical practice. One objective is to have a set of Core Principles; guidelines for clinical teams or digital providers on how to integrate PROMs into care pathways and digital systems.

Core Principles Development

Eight Core Principles were developed by the SC-PROMs AG. Three were presented to an audience for consideration at the SC-PROMs Forum online event focusing on: what PROMs are appropriate; PROMs integration; and accessibility and inclusivity.

Seventy-one people attended, mostly representing healthcare, academia, third sector, digital companies, patients/public and government. Learning included: alongside standardisation is a need for person-centeredness and flexibility; clinical teams need clear and relevant objectives for how/why they will use PROMs; collaboration at all stages is vital; and long-term upfront investment is crucial.

Next Steps

The Core Principles will be refined and presented for agreement and endorsement by SG. Subsequently, they will inform and shape how we progress PROMs as part of routine cancer care in Scotland. The opportunity is for PROMs data to be routinely collected to support cancer medicines intelligence and individual patient care.

TRANSLATIONS AND CULTURAL ADAPTATION OF INDONESIAN VERSION OF TREATMENT SATISFACTION WITH MEDICINES QUESTIONNAIRE (SATMED-Q) FOR HYPERTENSION PATIENTS

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ABSTRACT

Background

Currently, there is no questionnaire available to assess the satisfaction of patients with their medication in Indonesia. The treatment satisfaction with medicines questionnaire (SATMED-Q) is a validated instrument which would be suitable for the Indonesian context. This study aimed to translate and culturally adapt the SATMED-Q as well as to assess the validity and reliability for use in patients in Indonesia.

Methods

We used the five steps cross-cultural adaptation from Beaton et al (2002), including the forward and backward translation to Bahasa, synthesis of the findings, expert review and testing in patients with hypertension. The validity and reliability were statistically investigated.

Result

The translation process provided a version of the SATMED-Q in Bahasa. Three statements (statement 5, 7 and 8) and the answer statements of the Likert scale were difficult to translate and adapt to the Indonesian context. Thirty-six hypertension patients (mean age 53.7 years; 55.6% female, mean duration of hypertension 4.6 years) completed the SATMED-Q. The internal consistency was good (Cronbach's alpha = 0.835). In the range of 0 to 100 points, patient's satisfaction with their treatment ranged from 58.8 to 82.4 (mean 64.9; SD 5.9). A larger sample is needed for further validation.

Conclusion

The Indonesian version of SATMED-Q showed good internal consistency to assess treatment satisfaction of Indonesian patients with hypertension. A larger sample is needed to confirm the validity.

Keywords: SATMED-Q; Indonesian Version; Hypertension; reliability; Validity

CLINICAL BENEFITS OF HERBAL MEDICINES IN GYNECOLOGICAL COMPLAINTS

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ABSTRACT

Background

We aim to generate evidence for the clinical benefits of herbal medicines in menstrual, menopausal, and bladder & urinary tract symptoms.

Methods

Patients were interviewed (questionnaire) about their personal experiences with herbal medicines. PROs were collected in a large pharmacoepidemiological database (PhytoVIS). A data subset on gynecological complaints was extracted and 1,405 data entries from female patients were descriptively analysed. Variance analysis was done by Kruskal-Wallis test. The clinical benefits of herbal preparations were evaluated by CGI-E.

Results

Each of the three gynecological indications were preferentially treated with specific herbal medicines: (i) *cimicifuga racemosa* for menstrual complaints, (ii) *vitex agnus castus* for menstrual complaints (iii) *uva ursi* for bladder & urinary symptoms. The majority of the 228 women applying herbal medicines for menstrual complaints (39.5%) reported a moderate to significant therapeutic effect without any side effects (CGI-E = 3) and about one third (31.6%) had the highest possible clinical benefit (very good to significant therapeutic effect without side effects, CGI-E = 4). Of the 306 women taking herbal medicines for the treatment of menopausal symptoms 31.0% had a CGI-E of 4 and 40.1% a CGI-E of 3. The best treatment results could be observed in 851 female patients taking herbal medicines against bladder & urinary tract symptoms. Here almost half of the women (45.4%) had a CGI-E of 4 and 33.8% a CGI-E of 3.

Conclusions

The therapeutic effect of herbal medicines was very high regardless of whether herbal medicines were applied on a daily basis or upon need.

TOLVAPTAN'S IMPACT ON THE QUALITY OF LIFE: A MONOCENTRIC OBSERVATIONAL STUDY IN THE NEPHROLOGY, DIALYSIS AND RENAL TRANSPLANTATION UNIT OF BOLOGNA

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ABSTRACT

Background

Tolvaptan is an orally selective vasopressin V2 receptor antagonist approved for the treatment of Autosomal Dominant Polycystic Kidney Disease (ADPKD). Despite its positive effect in slowing kidney function decline, the resulting aquaretic adverse events (polyuria, pollakiuria, nicturia) could influence patients' adherence. This study assesses the impact of tolvaptan on health-related quality of life (HrQoL) using the ADPKD Impact Scale (ADPKD-IS).

Methods

The ADPKD-IS questionnaire was administered to 20 ADPKD patients on tolvaptan and an equal-sized comparable control group not on therapy. Differences in the scores were assessed with Student-t and Wilcoxon-Mann-Whitney tests. Multiple regression models were performed to evaluate the effect of tolvaptan and kidney disease progression (Mayo classification) on HrQoL domains. We included, in regression models, an interaction term to test the joint effect of tolvaptan and disease progression on HrQoL.

Results

The ADPKD-IS domain scores (Physical, Fatigue, Emotional) were not significantly different between the groups ($\beta = -0.05, 0.25, -0.55$; $p = 0.862, 0.447, 0.462$, respectively). The analysis of confounders showed that male patients had better HrQoL in all the domains ($-0.78, -0.93, -0.91$; $0.005, 0.005, 0.005$, respectively). The inclusion of an interaction term showed that using tolvaptan in a Mayo class E significantly improved the emotional domain ($\beta = -2.435$; $p = 0.036$).

Conclusion

The study found that tolvaptan, while increasing urination frequency, did not worsen any aspect of HrQoL. Instead, it improved emotional well-being in the case of rapid-progression ADPKD. These results are consistent with other studies and reassure patients and caregivers to initiate tolvaptan.

SNGPC – A WORTHWHILE DATA SOURCE FOR DUR IN BRAZIL

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ABSTRACT

Introduction

Brazil has been held as the largest consumer of antibiotics and the country with the greatest number of data sources for DUR in Latin America. The National Controlled Products Management System (SNGPC) of the Brazilian Health Regulatory Agency (Anvisa) harbors dispensing data of controlled medicines, including antimicrobials, collected from retail pharmacies throughout the country. These data are publicly available since August 2020. The aim of this study was to assess SNGPC data quality for DUR.

Methods

A total of 475,805,207 dispensing data records were collected, covering January 2014 to December 2020. In the first stage, records were grouped, stratified, cleaned, and analyzed mostly through frequency totals for each variable, following a three-step systematic approach (selection, exclusion, insertion of new variables), to warrant preparation for the future analytical phase of DUR.

Results

Antibiotics corresponded to 54.5% of records. Information on prescribers, the legal category of prescription control, and dosing unit were complete. There was < 1% of missing data for the name of the substance. However, missing data were systematically identified for variables: Brazilian Non-Proprietary Names (DCB), sex, age, and ICD-10. Results show that 25% of records extrapolate expected quantities for individual therapy regimens. The system does not critically assess data input to avoid discrepancies in individual regimens or legal restrictions.

Conclusions

In spite of vulnerabilities due to data quality, SNGPC is a potent data source that provides the construction of different analytical plans involving timespan, space, and other categories useful for the investigation of community use of antibiotics.

UNLOCKING THE POTENTIAL OF REAL-WORLD DATA: THE POWER OF OMOP AND CDM IN HEALTH RESEARCH

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ABSTRACT

Background

Real-world healthcare data stored in various formats and databases can present significant challenges in terms of consistency, even when standard terminologies are used. Observational Medical Outcomes Partnership (OMOP) is a platform that provides researchers with access to large electronic health records (EHR) data sets, in order to advance health knowledge. The Common Data Model (CDM) is a standardized data structure used to store and analyze the information obtained from OMOP.

Methods

In this presentation, we investigated the use of the OMOP and CDM platforms in advancing health research. We present mapping of medical ontologies to OMOP, the quality and reliability of the health data conversion to OMOP and review of OMOP in research and regulator decision making.

Results

Our results showed that the OMOP and CDM platforms are a valuable resource for health researchers. The OMOP structure ensures that data are organized consistently, making it easier to perform complex data analysis. Regulatory agencies such as the FDA and EMA, which are increasingly looking to incorporate RWE generated through the analysis of real-world data for regulatory decision-making, have been leveraging OMOP-driven studies for comparative drug utilization, effectiveness, and safety evaluations.

Conclusion

OMOP usage in RWE studies has risen greatly, becoming a crucial tool for EHR data standardization. OMOP standards, methods, tools, processes, study protocols, and results are all Open Source and freely accessible to the public, promoting open discussion and advancing the scientific community.

CONCEPTUAL BASES FOR THE STANDARDIZATION OF CALCULATION APPROACHES FOR ESTABLISHING EXPOSURE DURATION OF SINGLE DRUG UTILIZATION RECORDS IN MULTI-DATABASE STUDIES

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ABSTRACT

Background

In multi-database studies, prescribing, dispensing or administrations records are usually leveraged for exposure assessment. We defined a set of calculation choices (recipes) for standardizing the computation of days of treatment (DOT) for single drug utilization records (DURs) from any observational healthcare datasource.

Methods

Recipes were created based on literature searches, and researchers' experiences. Concepts for recipes implementation were defined using the standard terms of the European Directorate for Quality of Medicine.

Results

Five recipes were identified based on 5 concepts. Concepts: 1)unit of presentations (e.g. tablets), 2)active substance amount (i.e., mass or volume), 3)pharmaceutical product amount (e.g. mass of cream), 4) medicinal product (identified by marketing authorization number), 5)DUR (containing ≥ 1 medicinal product unit). Recipes: Daily Dose (DD)-based (n=3) and Fixed duration-based (n=2). DD-based recipes were further categorized considering the nature of the prescribed/assumed DD: units of presentations/day (recipe 1: $\text{DOT} = \text{number of medicinal products} * \text{number of units of presentation per medicinal product} / \text{DD}$); active substance/day(recipe 2: $\text{DOT} = \text{number of medicinal products} * \text{active substance amount per medicinal product} / \text{DD}$); pharmaceutical product amount/day (recipe 3: $\text{DOT} = \text{number of medicinal products} * \text{pharmaceutical product amount per medicinal product} / \text{DD}$). Fixed-duration recipes calculate DOT assuming fixed duration of the DUR (recipe 4: $\text{DOT} = \text{fixed-duration}$) or assuming fixed duration for each unit of medicinal product (recipe 5: $\text{DOT} = \text{number of medicinal products} * \text{fixed-duration}$).

Conclusion

We provide comprehensive conceptual bases for the standardization of calculation approaches to assign exposure duration to any DUR.

EFFECT OF STATIN USE FOR THE PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE AMONG OLDER ADULTS: AN OBSERVATIONAL ANALYSIS EMULATING A TARGET TRIAL

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ABSTRACT

Background

Evidence concerning the effect of statins in primary prevention of cardiovascular disease (CVD) among older adults is lacking.

Methods

Using Quebec population-wide administrative data, we emulated a hypothetical randomized trial including older adults ≥ 66 years on April 1st, 2013, with no CVD history and no statin use in the previous year. We included individuals who initiated statins and followed them until the occurrence of coronary disease (myocardial infarction, coronary bypass, percutaneous coronary intervention), stroke, all-cause death or until March 31, 2018. Individuals who persisted with statins at least three months after initiation were compared to those non-persistent. Primary outcome was the composite endpoint of coronary disease, stroke, and mortality. The intention-to-treat effect was estimated with adjusted Cox models, and per-protocol effect with inverse probability of censoring weighting. Several sensitivity analyses (e.g., varying definitions of persistent users, excluding or not early events) were conducted.

Results

A total of 61,656 individuals were included (mean age=70.96 \pm 5.54, female=55.4%) and 57,812 (93.8%) were persistent users. There was no association between persistence with statins and the composite outcome (hazard ratio [HR]: 0.99;95% confidence interval[CI]:0.87-1.12). While we observed a 13% reduction in mortality among persistent users (HR:0.87;95%CI:0.76-0.99), coronary disease was higher among persistent users than non-persistent users (HR:1.83;95%CI:1.36-2.47). Results for the per-protocol and sensitivity analyses were consistent with the intention-to-treat analysis.

Conclusion

The results for coronary disease do not seem plausible and suggest residual biases. Emulating a trial may minimize but does not preclude bias and caution is required when interpreting results.

ANTIBIOTIC RELATED KNOWLEDGE OF PHARMACY STUDENTS: QUESTIONNAIRE DEVELOPMENT AND VALIDATION WITH RASCH ANALYSIS

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ABSTRACT

Antimicrobial resistance (AMR) is a global health issue. Proper education of pharmacy students as future healthcare professionals is crucial to combat AMR. However, a valid and reliable instrument to assess their knowledge is scarce. This study aimed to develop and validate an Antibiotic Knowledge Assessment Questionnaire (AKAQ) using Rasch analysis.

Questionnaire was developed by literature review and experts judgement, and had 29 items in three domains. Rasch analysis was used to assess psychometric properties of AKAQ by providing information about the quality and reliability and detecting item-person fit. Validity as acceptable if infit/outfit mean-square (MNSQ): 0.5 to 1.6 and z-standard (ZSTD): 2 to -2), while reliability thresholds were above 0.6 : Person, Item reliability and Cronbach's Alpha. Item-person interaction was assessed by Wright Map which explored distribution of items' difficulty in relation to participants' knowledge levels, Differential item functioning (DIF) was used to check item bias based on the students' semester.

The validity of the questionnaire was proved, except for one item. Person means infit and outfit for MNSQ were 1.02 and 0.95, whereas ZSTD were 0.11 and 0.08, respectively. Items means infit and outfit for MNSQ were 1.01 and 0.96, while ZSTD had 0.11 and -0.23. Item and person reliabilities were 0.99 and 0.68, exceeding the acceptable threshold. Cronbach's alpha reliability was acceptable at 0.71. Two of the 28 AKAQ questions are biased by semester, according to DIF analysis.

The AKAQ has been developed and proved to be a valid and reliable instrument for measuring undergraduate pharmacy students' knowledge

SCIENTIFIC APPLICATION OF THE WEB-BASED HEALTH PORTAL VITERIO FOR THE ACQUISITION AND ANALYSIS OF DIGITAL OUTCOME PARAMETERS

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ABSTRACT

Background

Patient reported outcomes (PROs) are increasingly important for evaluation of efficacy and to overcome challenges associated with long-term tolerability, safety and effectiveness.

Materials and Methods

A web-based health portal named Virtual Tool for Education, Reporting, Information and Outcomes (VITERIO), was established by a consortium of scientists, medical doctors and a foundation. Data quality standards have been considered and a sound data security concept has been established.

Results

A data set of indicators for health screening and self-monitoring of findings, symptoms, health behaviour, and attitudes has been integrated into VITERIO. These indicators can be expanded and customized for any clinical application or for the use in the general practice. The portal has been designed with two independent access opportunities: from the patient side (PROMI - Patient-Reported Outcomes, Measurement and Information) and from the therapist's side (PROFI - Provider Reported Outcomes of Findings and Interventions). Mobile tools for monitoring single patients or groups have been integrated. For patient training and health literacy tutorials and instructions that can be downloaded on demand have been deposited.

Here we show exemplarily some implemented graphical solutions and developed tools and give examples for the daily use.

Conclusions

VITERIO can be applied for digital data acquisition and analysis of outcomes and for quality assurance. The comprehensive data collection through VITERIO guarantees data integrity which offers many opportunities for longitudinal assessments. Furthermore, through active participation of the patients, therapies can be tailored to their specific needs. Thereby patients' adherence and the efficacy of drugs can be enhanced.

EXAMINING THE EFFECT OF MONTELUKAST USE ON DEMENTIA FROM OBSERVATIONAL DATA ON 264,770 OLDER ADULTS IN SWEDEN: A MARGINAL STRUCTURAL MODEL APPROACH

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ABSTRACT

Purpose

Recent studies have suggested a possible association between montelukast, a leukotriene receptor antagonist, and a reduced risk of using dementia medication and improved cognitive and neurological functioning. We aim to investigate whether this finding could be observed among asthmatic older adults in a Swedish context using a record linkage database in an attempt to examine the effect of montelukast use on dementia.

Methods

In this retrospective observational study we identified older adults (65 years or older) with asthma diagnosis and/or asthma or obstructive lung disease medication in 2010. Patients were followed between 2011 and 2014, where the primary outcome was dementia and the primary exposure was the use of montelukast. To measure the average treatment effect and account for time-varying exposure in the presence of time-dependent confounders, we used marginal structural model fitted via pooled logistic regression and applying stabilized inverse probability of treatment weights.

Results

264,770 patients were included and 14,688 were diagnosed with/treated for dementia during follow-up. 10,958 patients used montelukast at any time during that period. The odds ratio (OR) for dementia in relation to montelukast use was 0.628 (95%CI: 0.498-0.792).

Conclusion

Our findings supports the protective association between montelukast and dementia. Further studies are needed to further investigate this potentially causal association.

BUDGET IMPACT OF RISPERIDONE FOR CHILDREN WITH AUTISTIC SPECTRUM DISORDER IN BRAZIL: A REAL-WORLD DATA COMPARATIVE ANALYSIS STUDY

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ABSTRACT

Introduction

Budget Impact Analysis (BIA) of medicines helps managers to promote more sustainable health systems. However, it is not clear whether theoretical data BIA are compatible with actual data. This study aims to compare expenditures with risperidone for children with Autism Spectrum Disorder (ASD) estimated by theoretical and real-world data.

Method

The analyzes were performed based on the Brazilian Clinical Protocol and Therapeutic Guidelines for ASD. The perspective adopted was the Brazilian Unified Public Health System (SUS), considering a time horizon of 5 years (2022-2026). Three possible scenarios were adopted based on the maximum daily dose of risperidone being 2mg/day. Direct and indirect expenses were considered. For the theoretical calculation, prevalence data from the scientific literature were adopted and the population was estimated from the Brazilian demographic census. Actual data on risperidone use were extracted from the SUS database. Descriptive statistics were used to characterize the three scenarios and the estimated population in both methods. A non-parametric test was used to compare the methods.

Results

The population estimated by the theoretical model (n=471,746) was overestimated when compared to real-life data (n=132,004) with statistical significance (p<0.001). Similarly, the 5-year budget impact by the theoretical model (Scenario I: US\$13,055,759.24; Scenario II: US\$15,959,827.62; Scenario III: US\$55,562,715.62) versus the real-life model (Scenario I: US\$ 3,653,263.50; Scenario II: US\$ 4,465,880.12; Scenario III US\$ 15,547,563.12) was overestimated with statistical significance (p<0.001).

Conclusion

The higher estimates of the theoretical BIA suggest that SUS need to consider methodological advances that include real-life values for more assertive calculations.

HOW TO IDENTIFY THE INDICATION OF USE FOR BIOLOGICAL DRUGS APPROVED FOR IMMUNE-MEDIATED INFLAMMATORY DISEASES USING CLAIMS DATA? THE VALORE PROJECT EXPERIENCE

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ABSTRACT

Background

Several algorithms exist for identifying Immune-Mediated Inflammatory Diseases (IMIDs) from claims data. However, biological drugs are usually approved for more than one IMID and an algorithm identifying exact indication of use for biological drugs approved for IMIDs treatment has never been developed. We aimed to develop and validate such algorithm in the context of the VALORE project.

Methods

Incident (no dispensing in the year prior first biological drug dispensing) users of biological drugs approved for the most frequent IMIDs such as rheumatoid arthritis (RA) psoriatic arthritis (PsA), psoriasis (PsO), ulcerative colitis (UC) and Crohn's disease (CD) were identified from Lazio region claims database (2010-2020). An algorithm identifying exact indication was developed using a combination of ICD-9-CM codes, exemption and/or pharmacy claims. Positive predictive value (PPV) and sensitivity (SE) were estimated for each indication using as reference standard subjects with IMIDs as registered in the electronic therapeutic plans of Lazio region filled by the specialist during study period.

Results

Overall, 11,468 incident biological drug users with a single IMIDs indication were identified from Lazio region claims database (4,054 with RA indication, 1,973 with PsA, 2,698 with PsO, 1,562 with UC and 1,199 with CD). Estimated PPV and SE against the reference standard were 0.87 and 0.79 for RA, 0.84 and 0.66 for PsA, 0.45 and 0.87 for PsO, 0.64 and 0.95 for UC and 0.79 and 0.85 for CD, respectively.

Conclusion

The algorithm showed good PPV and SE, but sensitivity analyses are still ongoing to enhance validation estimates.

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