Background and importance The management of investigational health products (IHPs) is a major part of conducting clinical trials (CTs). It presents specific risks all along the circuit, with data integrity and patient safety issues. However, few standardised tools are available, and no national inventory has been conducted in hospital pharmacies.

Aim and objectives The aim of this work was to make an inventory of the current situation in our country, and then to prioritise risk reduction standardised tools to develop.

Material and methods A national survey was developed by a regional working group including four clinical research pharmacists (CRPs), a coordinating pharmacist and a pharmacy resident. The 76 questions dealt with the quality approach and the proposal of new tools. The online anonymous survey was emailed to CRPs in health facilities and activated for 2 months.

Results 94 pharmacists participated, allowing a response rate of 70%: 35 non-university hospitals, 25 university hospital centres, 12 private clinics, 11 cancer centres, 10 not-for-profit private hospitals and 1 academic cancer institute. The results regarding the features of quality approach were: documentation system (76/94), adverse drug event reporting system (77/94), prior risk assessment (24/94), training and empowering staff (42/94), using means of evaluation and monitoring (49/94, including 13 conducting internal audits) and ISO 9001 certification (10/94). All of these features were synthesised into an overall score: from I (basic quality approach) to IV (ISO certification). Score II was the most frequent (38/94). The score depends on the type of health facility ($p<0.0005$) and increases with the number of active CTs ($p<0.0005$). 88/94 pharmacists were interested in standardised tools. All nine proposed tools were useful for over two-thirds of pharmacists. Two tools with the highest utility scores were self-assessment ($p<0.001$) and the internal audit grids.

Conclusion and relevance All types of facilities conducting CTs were represented and the response rate suggested an overall interest in this topic of management of IHPs. The quality approach was heterogeneous in hospital pharmacies and depended on the level of activity. The needs identified justify prioritising the self-assessment and traceability audit tools which are being validated for dissemination. Such tools will help to harmonise practices in hospital pharmacies by identifying the specific risks and improving the circuit for IHPs.

References and/or acknowledgements

Conflict of interest No conflict of interest

5PSQ-195 IMPACT OF INTENSIFIED CLINICAL DECISION SUPPORT SYSTEMS ON PRESCRIBING ERRORS: AN INTERRUPTED TIME SERIES ANALYSIS IN TAIWAN

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Background and importance Clinical decision support systems (CDSSs) are frequently adopted in hospitals to increase prescription accuracy in patients with renal impairment, but the alerts from CDSSs are usually overridden in clinical practice. Therefore, an intensified CDSS with more detailed

information should be developed and its effectiveness with regard to prescribing errors determined.

Aim and objectives To evaluate the effectiveness of an intensified CDSS with regard to prescribing errors for inappropriate drugs in cases of renal dysfunction.

Material and methods We conducted a pre- and post-intervention study in an inpatient setting in the largest medical centre in Taiwan in 2019. Previously, the CDSS only reminded clinicians to adjust drugs according to the patient's renal function. After May 2019, we initiated an intensified CDSS directly providing clinicians with the precise drug dosage or alternative drug recommendations for patients with renal impairment. The study outcome was the rate of prescribing errors, as identified by pharmacists after prescribing by clinicians. We used interrupted time series analysis to estimate the trend in prescribing error rate before (January 2019 to May 2019) and after (June 2019 to December 2019) implementing the intensified CDSS. As a control, we conducted similar analyses in another hospital with the same healthcare systems but without an intensified CDSS. We hypothesised there would be a reduction in the rate of prescribing errors for inappropriate drugs in cases of renal dysfunction after the intensification of CDSS in the study hospital, compared with the control hospital.

Results The mean prescribing error rates due to inappropriate drugs in patients with renal dysfunction were 1.70 and 1.59 per 1000 inpatient beds before and after the introduction of the intensified CDSS, respectively, which did not constitute a significant change between the pre- and post-intervention ($\beta=0.01$; 95% CI -0.32 to 0.35). However, we observed a non-significantly increased prescribing error rate between the study hospital and the control hospital ($\beta=0.04$; 95% CI -0.51 to 0.59) after the introduction of the intensified CDSS.

Conclusion and relevance The deployment of an intensified CDSS providing detailed information on how to prescribe drugs for patients with renal impairment may inhibit the increase in prescribing error rate due to inappropriate drugs in patients with renal dysfunction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-196 ASSOCIATION BETWEEN PHOSPHODIESTERASE 5 INHIBITOR USE AND INCIDENT DEMENTIA IN PROSTATE CANCER PATIENTS TREATED WITH ANDROGEN DEPRIVATION THERAPY

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Background and importance Recent studies have indicated that androgen deprivation therapy (ADT) increased the dementia risk in prostate cancer (PCa) patients. Phosphodiesterase 5 inhibitors (PDE5i) with nitric oxide mediated vasodilation can increase blood flow in the brain. However, no current studies have explored the association between PDE5i exposure and dementia in PCa patients treated with ADT.

Aim and objectives To determine the association between PDE5i exposure and incident dementia in PCa patients treated with ADT.

Material and methods We conducted a retrospective cohort study using the Chang Gung Research Database (CGRD) in Taiwan. We included PCa patients newly receiving ADT between 2009 and 2016. We conducted a three step matching and modified landmark approach to identify PDE5i users and non-users after ADT use. The landmark date was defined as 1 year following the start of ADT, and we defined PDE5i users as patients initiating PDE5i before and after the landmark date. We matched PDE5i users to non-users by (1) age, (2) prostatic specific antigen and (3) 1:4 propensity scores for comorbidity and co-medication. We followed the patients from the landmark date until the incident diagnosis of dementia, last date of clinical visit or 31 December 2019. We performed multivariate Cox proportional hazard models to compare the dementia risk between PDE5i users and non-users.

Results We included 4557 PCa patients starting ADT treatment, with a mean age of 69.5 (SD 7.0) years. After matching, we identified 161 PDE5i users and 644 non-PDE5i users. A total of 5.1 person years of PDE5i users and 4.6 person years of PDE5i non-users were included. Compared with non-users of PDE5i, PCa patients treated with ADT initiating PDE5i had a lower risk of dementia (adjusted HR=0.17, 95% CI 0.04 to 0.70) in the modified landmark analyses.

Conclusion and relevance PDE5i use in PCa patients treated with ADT was associated with a decreased risk of subsequent dementia. Future large scale studies are suggested to confirm our findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-197 CONTRAINDICATED DRUG-DRUG INTERACTIONS WITH PAN-GENOTYPIC DIRECT ACTING ANTIVIRAL AGENTS IN CHRONIC HEPATITIS C PATIENTS IN TAIWAN

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Background and importance Treatment of chronic hepatitis C (CHC) has become simpler and more effective since the introduction of pan-genotypic direct acting antiviral agents (DAA), but contraindicated drug-drug interactions (DDI) with DAA should be carefully evaluated to avoid the risk of side effects or loss of treatment efficacy.

Aim and objectives To investigate the patterns of contraindicated DDI with pan-genotypic DAA in real world practice.

Material and methods We conducted a retrospective cohort study by analysing the Chang Gung Research Database, a multi-institutional electronic medical records database which covers 1.3 million individuals (6% of the Taiwan population). We included CHC patients newly receiving pan-genotypic DAA (eg, glecaprevir/pibrentasvir (GLE/PIB) or sofosbuvir/velpatasvir (SOF/VEL)) from 1 August 2018 to 31 September

2019. We identified drugs with contraindicated DDI following the HEP Drug Interaction Checker and pharmaceutical package insert. We calculated the numbers and rates of exposure to contraindicated DDI 3 months prior to initiation of pan-genotypic DAA, and evaluated the changes under pan-genotypic DAA treatment.

Results We included 1311 and 239 CHC patients newly receiving GLE/PIB and SOF/VEL, respectively. Before pan-genotypic DAA treatment, 33 (2.5%) and 3 (1.3%) patients receiving GLE/PIB and SOF/VEL, respectively, received prescriptions involving contraindicated DDI. Among the prescriptions with contraindicated DDI with GLE/PIB, 25 (75.8%) included lipid lowering agents and 6 (18.2%) included anti-convulsants. Among those with contraindicated DDI with SOF/VEL, 2 (66.6%) were for anti-convulsants and 1 (33.3%) involved a nucleoside reverse transcriptase inhibitor. After initiation of pan-genotypic DAA, we found exposure to contraindicated DDI decreased to 14 patients (1.1%) for those receiving GLE/PIB treatment. No change in contraindicated DDI exposure was observed in patients receiving SOF/VEL treatment.

Conclusion and relevance The rate of exposure to contraindicated DDI generally decreased after initiation of pan-genotypic DAA, but some contraindicated drugs remained co-prescribed. Future studies are required to evaluate the outcomes in patients exposed to contraindicated DDI.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-198 VARIATIONS IN EFFECTIVENESS AND SAFETY OF GLECAPREVIR/PIBRENTASVIR AMONG HEPATITIS C PATIENTS WITH DIFFERENT GENOTYPES: A MULTI-INSTITUTIONAL COHORT STUDY IN TAIWAN

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Background and importance Pan-genotypic direct acting antiviral agents (ie, glecaprevir/pibrentasvir (GLE/PIB)), have been proven in clinical trials to be effective and safe in the treatment of chronic hepatitis C (CHC) infection. However, CHC genotypes may vary in different populations and limited evidence is available regarding the effects of GLE/PIB in patients with different genotypes.

Aim and objectives To compare the effectiveness and safety of GLE/PIB in CHC patients with different genotypes in Taiwan.

Material and methods We retrospectively identified a cohort of CHC patients newly initiating GLE/PIB between August 2018 and June 2019 from the Chang Gung Research Database, a multi-institutional electronic medical records database covering approximately 1.3 million individuals (6% of the Taiwan population). We classified patients by genotype who were followed up for 12 weeks from completion of GLE/PIB therapy. Sustained virological response at 12 weeks (SVR12) was observed as the primary outcome. The safety outcome included elevation of alanine aminotransferase (ALT) or total bilirubin by three times the upper limit of normal (ULN), which was taken as an indicator of liver related adverse