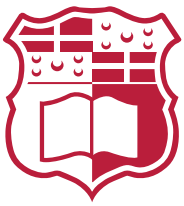

L-Università ta' Malta

DEPARTMENT OF PHARMACY

FACULTY OF MEDICINE AND SURGERY

DISSERTATION ABSTRACTS AND PROJECT DESCRIPTIONS 2021

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Foreword

Lessons learnt from the Pandemic

The COVID-19 pandemic, together with Brexit, presented real challenges for several areas, not least the way all of us participate in educational activities. It is pertinent to note that everyone is preparing for every possible scenario including that of not reaching a conclusion to the situation and instead establish new norms. Malta and the United Kingdom have had very strong ties for a long period. These ties remain even today. During this pandemic period, the fact that the United Kingdom is no longer part of the European Union presented additional challenges. New rules in the relations with the UK apply. In this scenario, the pandemic presents opportunities of how one could stretch contacts with other European partners. How does all this tie with education, especially as related to pharmacy?

The pandemic presents an occasion of days on end enabling us to reflect on profound scientific examination and exploration contributing towards the improvement and progression of science and practice. The virtual experiences challenged us to become immersive in such media while addressing a variety of topics, including basic sciences, translational and clinical aspects retaining at all stages a scientific approach. One has to be aware that while resolving immediate crisis, the need of establishing and even expanding the network must be achieved. It is realised that the pharmaceutical world continues to evolve at all times. The pandemic presented the opportunity to explore and discover new, perhaps neglected, topics such as vaccinology. A lesson learnt from this pandemic, often overlooked, is the distinctive improvement in collaborative research and patients' participation in health-decision making such as the mastering of self-management. Pharmacy education is constantly gearing up to meet these challenges and opportunities presented by the pandemic.

Our pharmacy education system must learn to:

1. Put in place appropriate arrangements to work through IT and communication media with students and colleagues and to find new ways to continue our well established participation in programmes such as the Erasmus programme.
2. Work to ensure the participation in international conventions involving third countries, including now the UK, with particular emphasis on the need to accessibility to medicines. A lesson learnt with the pandemic situation is tackling the shortage of medicines and medical devices, which shortage was brought to the forefront during these times.
3. Step up communications with pharmaceutical stakeholders and expand interprofessional education enhancing collaborative and team practice, breaking barriers between professionals, starting from the educational stages and eliminating barriers between the different facets of pharmacy.
4. Ensure to bridge basic sciences with professional practice always keeping the patient in the centre of all our activities whether one is working in the production of medicines or in a clinical scenario be it in the community or in the hospital. If there was ever a lesson learnt, it was the collaboration needed in making available COVID-19 vaccines starting from basic RNA sciences to the identification of quality, safety and efficacy of the vaccine from the laboratory bench to the person. Application of regulatory sciences exerts vigilance before, during and post-administration of vaccine doses.
5. Keep abreast of developments with regards to the sciences and practice in an era of digitalisation.
6. Re-visit areas of ethics and EU-GDPR in view of their adequacy to be maintained in a pandemic scenario, whether the involvement is at a national level or at a corporate level following principles of equality in pharmaceutical health care.

There is need to take preparatory actions to a post-pandemic scenario by assessing the pros and cons of the current arrangements such as the advantages and limitations of on-line learning, the lines to take in terms of a hybrid model of education, the social and mental implications versus the positive contribution to environmental enhancement directly or indirectly. New ways on how research and innovation have evolved during the pandemic, such as that the dissemination of research findings needs to be quick yet retain robustness. New developments such as the contribution of pre-prints to science and knowledge present fresh opportunities and challenges.

The Pandemic has taught us pharmacy professionals to appreciate the virtues of such attributes in developing and evolving our pharmacy interventions such as attention to detail, careful planning of pharmaceutical care plans, determining factors in accuracy in dosing medicines, composing, presenting and disseminating results from projects - the background, methodology, results and importantly the conclusions and discussion and the rigor required to be followed to ensure the good quality, effectiveness and safety of medicines.

Professor Anthony Serracino-Inglott
Pharmacy Practice Projects Co-ordinator

Introduction
Digital Health, Pharmacy Education and Research

Digital health has immense potential to facilitate and improve access to health services. Opportunities for communication with patients, particularly vulnerable patients, improvements of collaborative and shared care across care settings and healthcare professionals are a few examples of how digitalisation can support pharmaceutical services delivery. At the same time, digitalisation of medical devices is allowing for real-time monitoring of patients and the generation of 'big data' which contributes to health indices and measurement of patient outcomes. Wearable technologies providing health data is a reality. The demarcating line between a medical device and smartphones is becoming blurred. Digital health presents opportunities which come with challenges and require preparedness of the workforce and implementation science to overcome negative perspectives which may tarnish the full potential. Pharmacists are key professionals involved at a broad spectrum from a regulatory aspect in terms of assessing safety, quality and effectiveness of digitalised medical devices, to reinforcing effective use, to supporting interpretation of data by patients. The positive aspect is that harnessing digital technology in the pharmaceutical services domain, provides an infrastructure enabling achievement of the United Nations Sustainable Development Goal of ensuring good health for all.

The COVID-19 pandemic served as a catalyst towards leveraging features of digital technologies in pharmaceutical services. Telepharmacy was useful for pharmacists to communicate with vulnerable patients, to ensure access to chronic medications, to monitor patient outcomes and to address patient pharmaceutical needs. In February 2021, the International Pharmaceutical Federation launched a report on 'Digital health in pharmacy education'.[1] The report provides a snapshot of the readiness, adaptability and responsiveness of pharmacy education institutions and describes skills needs expectations of pharmacy students and the pharmaceutical workforce. It was encouraging to note that pharmacy academic institutions are engaged to develop graduates competent in providing a patient-centred digital health provision.

Playing a strategic role to support digital health in pharmacy settings is an expected contribution by academic pharmacy institutions as part of their social accountability involvement. The strategic role relies on two actions: 1) education of the workforce and 2) practice research to guide evolvement. The impact of Practice Research as an implementation science that serves to push practice transformation has been witnessed in Malta in pharmacy for many years.[2] The Department of Pharmacy at the University of Malta has been a pioneer of embedding the development of research skills in undergraduate pharmaceutical education. Pharmacy and pharmaceutical technology students participate in practice research projects where the focus is to understand measures and quality assurance metrics required to implement innovation in pharmaceutical processes and services. By adopting this approach, students are exposed to develop a research aptitude and to participate in reducing the timeframe of research findings getting close to providing outcomes relevant to society. Academia, whilst ensuring a prepared workforce, is at the same time, contributing to narrowing the gap to get innovations introduced in practice.

At the postgraduate level, graduate students following the Doctorate in Pharmacy degree undertake dissertations in areas that are relevant to direct patient care services at hospital and community pharmacy settings and to models of access to safe, effective and quality medicinal products. Aspects of leveraging on digital technology to develop sustainable and effective pharmaceutical services models are addressed in research presented this year. Such examples include feasibility, quality impact and evaluation of telepharmacy to optimise use of medicines in older persons and for patient monitoring of chronic diseases. Aspects of maximising on digitalisation as a means to ensure harmonised and transparent systems for patient profiling and entitlement to medicinal products are investigated. The results presented in this Abstract Book serve to provide an insight into the Research activity at the Department of Pharmacy.

The Abstract Book serves to transmit the ethos within the Department of Pharmacy of supporting research skills development in students and engaging in Practice Research that serves to provide conceptual frameworks which support innovation in pharmaceutical healthcare systems.

Professor Lilian M. Azzopardi
Head, Department of Pharmacy

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2. Azzopardi LM, Serracino-Inglott A. Clinical pharmacy education and practice evolvement in Malta. J Am Coll Clin Pharm 2020; 3: 973-979.

Doctorate in Pharmacy
Dissertation Abstracts

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A Review of the POYC Medicines Approval System

Charles Mandy Ayran

Background: The Pharmacy of Your Choice (POYC) is the government's pharmaceutical service responsible for approving free medicine entitlements under the Schedule V legislation. According to the 2013 Annual Report,[1] 50,251 applications were processed and 3,184 out of the 21,168 requests for protocol-regulated items were not approved due to failure to follow set protocols as per the Government Formulary List (GFL).

Purpose: To optimise the POYC medicines approval system through pharmacist interventions to ensure efficient service delivery to patients.

Method: A mixed-method development design was utilised. The reasons for non-approvals were characterised through retrospective database review and Pareto analysis. A panel composed of a community pharmacist, a prescribing doctor, and POYC officers evaluated non-approval risks through Failure Mode and Effects Analysis (FMEA) via Delphi technique to develop interventions to streamline access to entitlement approvals. The Risk Priority Number (RPN) of failure modes ranging from one (1) to 125 were calculated by multiplying scores from five-point ordinal scales for severity, occurrence, and detectability. Risks were then stratified by plotting RPNs in a 2x2 matrix.

Results: From January 2012 to July 2020, characterisation of medicines not approved (n=26,220) showed that leading medicines contributing to non-approvals were clopidogrel (8.17%), levothyroxine (4.52%), and omeprazole (3.57%). Process-specific reasons which served as bottlenecks were: medicine not corresponding to the Schedule V condition (48.67%), application not according to government protocol (9.76%), and medicine not available on the GFL (7.29%). Research panelists in FMEA agreed that risks stratified as critical were: lack of permit application for protocol-regulated items (RPN=100), lack of supporting document as required by protocol (RPN=80), and medicine not corresponding to the Schedule V condition (RPN=80). Interventions identified included: orientation manual for applying prescribers and participating pharmacies, review of information technology systems to facilitate access to supporting documents, and monthly feedback system regarding data on non-approvals.

Discussion: Risk assessment and prioritisation of the most common causes of non-approvals through FMEA is important in implementing interventions which can reduce delays in access to entitlement approvals.

Reference:

1. Ministry for Health. Annual Report 2013 [Internet]. Malta: Ministry for Health; 2013 [cited 2021 Jan 06]. Available from: https://www.gov.mt/en/Government/Government%20of%20Malta/Ministries%20and%20Entities/Annual%20Government%20Reports/Documents/Annual%20Reports%202013/Ministry%20for%20Health%20Annual%20Report%202013.pdf

An Innovative Approach to Pharmacovigilance

Elisa Curtolo

Background: Reporting of adverse drug reactions (ADRs) safeguards patient safety and encourages appropriate use of medicines.

Purpose: To assess healthcare professionals (HCPs) knowledge about ADR reporting and to identify tools to empower and motivate them to participate in pharmacovigilance (PhV) activities.

Method: 1) Review of individual case safety reports (ICSRs) received by the Malta Medicines Authority (MMA) from 2004 until 2019. 2) Setting up of three focus groups with HCPs from different settings (academia, hospital, regulatory). 3) Development, validation and dissemination of questionnaire to assess knowledge, attitude, practice, and barriers for reporting of ADRs by HCPs. The questionnaire was disseminated to pharmacists, medical doctors, nurses and dentists. 4) Development and validation of an educational seminar Pharmacovigilance in the time of a pandemic crisis – Adverse Drug Reaction reporting and its evaluation through a second questionnaire.

Results: The total of ICSRs received by the MMA increased from 13 in 2004 to 189 in 2019. The focus groups pointed out the need for quantifying the extent and reasons of underreporting. The questionnaire was completed by 236 respondents – 131 pharmacists, 75 nurses, 16 dentists, 14 medical doctors. The mean knowledge score among all the HCPs was 43.03/50, where nurses got the lowest mean score (39.15/50; $p < 0.001$). HCPs strongly agreed that ADR reporting is important for product safety and patient care (94.5%; n=223) and is part of their duty (87.7%; n=207). Nurses wanted to be sure that it is the medicinal product that causes the ADR before they report it ($p < 0.001$). Out of the HCPs who have encountered ADRs (n=143), 32.2% (n=46) almost never reported the event, claiming difficulty in understanding whether the ADR has occurred (46.2%; n=109) and ADRs being already known and documented (40.3%; n=95). Ninety-three HCPs (39.4%) stated that they require more education on ADR reporting, through continuing professional education seminars (35.3%; n=160) and learning activities online (46.2%; n=109). The educational seminar consisted of 5 sections: Background, Reporting, Case studies, Outcomes and Practice.

Discussion: The study indicates that underreporting of ADRs remains a barrier for ADR monitoring.

Optimisation of Medication in Older Persons

Tiziana Fenech Caruana

Background: Optimisation of medication in older patients is challenging and explicit criteria assist in the identification of pharmaceutical care issues enhancing pharmacist intervention.

Purpose: To assess the feasibility and applicability of clinical tools and to optimise patients' pharmacotherapy in a community pharmacy setting using a collaborative care approach.

Method: The study was carried out on a sample of 80 patients in a community pharmacy setting. Two inclusion criteria were identified: patients ≥65 years and taking ≥3 medications. Patients were selected by convenience sampling from one community pharmacy. The GheOP^{3}S[1] tool was applied to identify pharmaceutical care issues which were assessed by the pharmacist to identify necessary interventions. A tool was developed for the documentation of the pharmacist interventions. Patients were followed up after 2 months. Pharmacist sessions were carried out either face-to-face or through telephone.

Results: The mean number of medications the patients were taking was 7 (range 3-16). The mean interview time was 11 minutes for face-to-face interviews and 12 minutes for telephone interviews. Through the GheOP^{3}S tool, the pharmacist identified 254 pharmaceutical care issues: 61% of the care issues concerned general care-related items, 13% related to potential prescribing omissions and 9% were associated with drug-drug interactions. The pharmacist carried out 193 interventions: 41% of the interventions dealt with checking the medication adherence of patients, 13% concerned patient education about a specific condition or medication and 12% were influenza vaccine recommendations.

Discussion: The application of the GheOP^{3}S tool in conjunction with the developed data documentation tool was feasible and applicable to the community pharmacy context. The tools identified pertinent care issues and facilitated pharmacist intervention. The documentation tool ensures appropriate documentation and follow-up of the proposed interventions.

Reference:

1. Tommelein E, Petrovic M, Somers A, Mehuys E, van der Cammen T, Boussery K. Older patients' prescriptions screening in the community pharmacy: development of the Ghent Older People's Prescriptions community Pharmacy Screening (GheOP^{3}S) tool. J Public Health. 2015 Jun;38(2):e158-70.

Risk of Pharmacist Prescribing with Statins

Milica Jovanovic

Background: Pharmacist prescribing has been shown to have positive clinical outcomes and is cost-effective. When used for primary prevention of atherosclerotic cardiovascular disease in patients with hypercholesterolaemia and/or diabetes mellitus type 2, statins reduce morbidity and mortality.[1] Careful assessment of risks and benefits maximises effectiveness of statin treatment and enhances the advantages of pharmacist prescribing.

Purpose: To determine the risks related to prescribing low- and moderate- intensity statins to patients aged 40-75 years with hypercholesterolaemia and/or diabetes mellitus type 2, both by medical practitioners and pharmacists and to propose factors that could ease the process of implementation of pharmacist prescribing statins in Malta.

Method: Two self-administered questionnaires, one for the medical practitioners and one for the pharmacists, were developed, content validated using modified Delphi method and reliability tested. After ethics approval, questionnaires were distributed both in person and online. Data was analysed using SPSS statistics. A regression model was developed to determine the statistical difference, if any, of risks associated with prescribing of statins by medical practitioners and by pharmacists.

Results: The questionnaires were completed by 62 medical practitioners and 148 pharmacists. Pharmacists were supportive (83%) towards giving statin prescribing rights to pharmacists while medical practitioners opposed this scenario (68%). Fifty-one percent of pharmacists thought they are competent to prescribe statins, 37% had a neutral opinion and 12% thought they are not competent. Medical practitioners have shown statistically significant better awareness than pharmacists with respect to guideline recommendations ($p<0.001$). Factors that could ease the implementation of pharmacist prescribing in Malta, as perceived by both healthcare professionals, were good collaboration of pharmacists and medical practitioners (74%) and patient privacy in a community pharmacy setting (73%). The regression model showed no statistically significant difference ($p=0.139$) in risks associated with prescribing of statins by medical practitioners and by pharmacists.

Discussion: Pharmacists were in favour of expanding their scope of practice to prescribing of statins and the regression model showed there are no increased risks associated with this activity. Efforts should be made to promote and strengthen the collaboration between health care professionals in Malta to help the implementation of pharmacist prescribing.

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1. Chou R, Dana T, Blazina I, Daeges M, Jeanne T; US preventive services task force. Statins for prevention of cardiovascular disease in adults. Evidence report and systematic review for the US preventive services task force. The Journal of the American Medical Association. 2016;316(19):2008-24.

Pharmacist Of Your Choice: Pharmaceutical Service Review

Daryl Magno

Background: In 2007, The Pharmacy of Your Choice (POYC) Scheme was introduced to improve access to free pharmaceutical products and provide direct pharmacist intervention.

Purpose: To review the implementation and service provision of POYC.

Method: A mixed-method approach was adopted. Data was collected via a self-administered questionnaire from 107 community pharmacists and 153 POYC registered-patients, recruited via convenience sampling, accessing medicines from 4 pharmacies. The questionnaire consisted of a five-point Likert scale questions. Semi-structured interviews were carried out with POYC stakeholders and data collected was subjected to content analysis. Fault Tree Analysis (FTA) was conducted with patients' failure to receive the medication as the top-level fault.

Results: Pharmacists agreed that POYC is an opportunity for an extended role in primary health care (n=98, 92%). This finding was supported by the high expression of interest by pharmacists and patients for possible POYC clinical services including new medicines review (pharmacists: n=102, 96%; patients: n=151, 99%) and health screening management on chronic diseases pharmacists: n=102, 95%; patients: n= 142, 93%). Pharmacists also recognized their role in public health during crisis situation by serving as direct point of information on infection prevention and control measures (n= 89, 83%). The key driver identified by pharmacists to POYC activities during the pandemic was their open and good communication with POYC (n=83, 78%) whereas the barrier included the inadequate supply of medicines they received from POYC (n=86, 80%). This identified barrier of lack of supply was addressed and mitigated by the pharmacists and translated to patients' favourable experience during the pandemic. Patients expressed receiving adequate supply of their entitled medicines (n=146, 95%). Data collected from the interview with POYC stakeholder identified issues in medicine management such as in procurement, distribution and utilization monitoring. The FTA revealed 25 events that may lead to patient's failure to receive medication.

Discussion: The study highlighted the unique service provision of POYC and the vital role of community pharmacists in ensuring that patients have consistent access and supply of free medicines especially in crisis situations such as the pandemic.

Pharmaceutical Service Development in Anaesthesia

Deborah Louise Rayner

Background: Pharmacy services in intensive care decrease adverse event and medication costs, improve morbidity, mortality and costs related to infectious disease, aid in enhancing clinical and economic outcomes and enhance compliance with Intensive Therapy Unit (ITU) protocols.[1]

Purpose: To develop and establish a pharmaceutical service in the ITU within the Anaesthesia Department at Mater Dei Hospital specifically tailored to the needs of the particular area.

Method: Phase I focused on developing the pharmaceutical service. The researcher attended ward rounds and observed the current practice delivered nationally. The gap analysis tool by Falzon[2] was adapted and used to compare current national practice to standards of practice for clinical pharmacy services for ITUs. Two questionnaires compiled by Portelli[3] were adapted and distributed to assess the perception of the role of an ITU based pharmacist among ITU nurses and doctors respectively. Phase II targeted the implementation of the pharmaceutical service. Pharmaceutical care issues (PCIs) identified were discussed with the interdisciplinary team and outcomes recorded.

Results: Gap analysis and questionnaire responses highlighted the need for a pharmacist during ward rounds to provide on the spot recommendations with regards to drug selection, associated expected adverse events and monitoring required, including the method of dilution and administration. A total of 116 PCIs were identified during 34 ward rounds attended to-date, with a 95% implementation rate. The most common PCIs were categorised as need for an additional drug to properly manage a condition (n=22); no indication for drug or indication no longer apparent (n=15) and need for guidance on dilution and method of administration (n=14).

Discussion: This study highlights the benefits of the pharmacist as part of the interdisciplinary team in improving the outcomes for patients admitted for intensive care.

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1. Stollings JL, Bloom SL, Wang L, Ely EW, Jackson JC, Sevin CM. Critical care pharmacists and medication management in an ICU recovery center. Annals of Pharmacotherapy. 2018; 52(8):713-723.
2. Falzon S. Development of a Pharmaceutical Care Model within Paediatric Oncology [dissertation]. Msida (Malta): Department of Pharmacy, University of Malta; 2018.
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Training Needs in Quality Systems: A Course on Standards - ISO 17025:2017

Rogelio Rivera

Background: Quality assurance is key to reliable laboratory functions and a fundamental step towards accreditation.

Purpose: To identify the educational needs of laboratory personnel with regards to quality and to develop, implement, and evaluate a training course on quality with a focus on ISO17025:2017 as a case example.

Method: A questionnaire to capture the training needs of laboratory personnel on quality standards was developed, validated by a focus group, and disseminated to laboratory personnel. A course on ISO 17025:2017 "General requirement for the competence of testing and calibration laboratories" was developed, validated and implemented. The training was evaluated by the participants.

Results: The respondents (N=50) of the questionnaire on training needs consisted of laboratory managers, pharmacists, and scientists from pharmaceutical & nutraceutical QC, medical & diagnostic, research & teaching, food & water, plant & veterinary, and forensic laboratories. Courses on ISO 17025:2017 (n=10), quality assurance and instrumentation (n=9), measurement uncertainty (n=5), ISO 9001:2015 (n=3) and Good Laboratory Practices/Good Manufacturing Practice (n=3) were requested by 30 respondents. A two-day interactive training programme on ISO 17025: 2017 "General requirement for the competence of testing and calibration laboratories" was developed for the laboratory professionals of a forensic science service. The programme of the course consists of learning objectives, outcomes and description of the content scheduled over 14 hours delivered in a classroom mode. Out of 25 laboratory personnel working in the forensic field, 22 participated in the course delivered by qualified tutors. The course topics covered the individual requirements of the ISO 17025, the basic understanding of quality management systems and the practical aspect of the quality manager with specific focus on forensic sciences. The training course was evaluated by 17 participants (N=22). The majority of the respondents strongly agreed that the subject (n=10), content (n=12), tutors' knowledge (n=13), and logistics (n=11) met their expectations.

Discussion: Addressing training needs on quality management systems through the development of courses that are tailor made for the end-users helps to sustain the quality requirements whilst providing an academic platform for sharing of the expertise between participants and experts.

Aspects of Cannabis in the Laboratory

Eva Tejada Rodríguez

Background: There is a need for the determination of tetrahydrocannabinol (THC) in cannabidiol (CBD) products as a result of the consideration being taken at the United Nation Narcotic Board in line with the reclassification of CBD as a narcotic.

Purpose: To develop and validate a High-Performance Liquid Chromatography-ultraviolet (UV) analytical method for the determination of THC in CBD oil for medicinal use.

Method: The method was divided in two parts: [1] Determination of conditions for extraction of THC from CBD oil and [2] Development and validation of method of analysis to determine THC in CBD oil. The best conditions for extraction of THC from oil were determined by changing three different ratios of solvent to THC in oil (0.3mL MeOH and 0.3mL 2.5 µg/mL THC in oil, 0.3mL MeOH and 0.6mL 2.5 µg/mL THC in oil and 0.6mL MeOH and 0.3 mL 2.5 µg/mL THC in oil), the sonication times(15 and 20 minutes), the centrifugation force(4500, 6000 and 10000 rpm) and time (15 and 25 minutes) and the temperature (4ºC and -20ºC). The analysis was conducted using an Agilent 1260 Infinity Series® II HPLC unit with UV detection at 220 nm. Separation was carried out on an ACE 5µm C18 Column (250 x 4.6 mm) using a mobile phase composed of acetonitrile and pH 2.5 phosphate buffer (90:10 v/v) at a flow rate of 1 mL/min using ibuprofen as the internal standard. Area under the peak (AUP) and retention time (RT) were compared for each scenario. All the runs were carried out in triplicates.

Results: The best conditions for the extraction of THC from CBD oil were 0.6mL MeOH and 0.3 mL 2.5 µg/mL THC in oil, 20 minutes of sonication, 15 minutes at 6000rpm of centrifugation and two hours at -20ºC. The shortest RT and the largest AUP were 7.880 minutes and 2693751 mAU.

Discussion: The developed method is innovative, quick, and easy to use and can determine THC in oil with good peak shape and resolution. Application of the analytical method will help in the determination of THC in CBD oil for medicinal use.

Interprofessional Education and Assessment

Alessandro Zaccomer

Background: A consequence of interprofessional education (IPE) that is challenging to study is the improvement in the delivery of health care.

Purpose: To assess changes in students' perception of IPE before and after an experiential learning activity, and to design, validate and implement an IPE tool to determine impact of IPE activities in pharmacy practice.

Method: SPICE-R2[(1)] was adopted to assess undergraduate third year pharmacy students' (N=24) and postgraduate doctorate in clinical pharmacy students' (N=36) perception of IPE learning activities. The tool was implemented before (t0) and after (t1) an experiential learning activity. An innovative IPE tool which measures impact of IPE activities on patient services and change in pharmacy organisational practice, was designed and validated through a three-step Delphi technique.

Results: The SPICE-R2 tool was completed for both t0 and t1 by 75% (N=45) of the students: 12 third year pharmacy and 33 doctorate students. A significant change ($p<0.05$) between t0 and t1 was measured in both groups in the following three subscales: 'Interprofessional Teamwork and Team-based Practice' ($p=0.035$, $p=0.005$), 'Roles/ Responsibilities for Collaborative Practice' ($p=0.032$, $p=0.010$) and 'Patient Outcomes from Collaborative Practice' ($p=0.036$, $p=0.013$). The largest improvement was observed in the 'Roles/Responsibilities for Collaborative Practice' subscale for undergraduate (mean=3.72±0.62, $p=0.002$) and first year doctorate students (mean=3.67±0.57, $p=0.030$). The new tool developed and validated titled 'Interprofessional Education on Pharmacy Competencies (IPEPC)' consists of ten items divided into four competency cores: 'Values-Ethics for Interprofessional Practice', 'Roles-Responsibilities', 'Interprofessional Communication' and 'Teams and Teamwork'.

Discussion: The results of this study appear to indicate that positive changes occur in students' perception of IPE for both early learners and postgraduate students exposed to experientials. The change in the Roles/Responsibilities for Collaborative Practice subscale was the lowest across the groups. This subscale does not seem to be particularly correlated with academic exposure. The developed tool, IPEPC, is a valid instrument to explore the impact of IPE learning experience on pharmacy practice, in particular the effect on patients' outcomes and on change in organisational practice for clinical pharmacy interventions.

Reference:

1. Zorek JA, Fike DS, Eickhoff JC, Engle JA, MacLaughlin EJ, Dominguez DG, et al. Refinement and Validation of the Student Perceptions of Physician-Pharmacist Interprofessional Clinical Education Instrument. Am J Pharm Educ. 2016;80 (3):47.

Point-of-Care Testing in Community Pharmacy Practice

Rebecca Zammit

Background: Community pharmacists are accessible health professionals who play a key role in the prevention and management of non-communicable diseases (NCDs). Point-of-care testing (POCT) service provision by community pharmacists facilitates pharmacists' intervention.

Purpose: To assess the feasibility and impact of POCT offered in community pharmacies for NCDs.

Method: A POCT service covering blood glucose, total cholesterol and triglycerides, blood pressure and body composition measurement was planned. A data collection sheet was developed and validated. A document was prepared and used to train a community pharmacist in offering the service, and practicality, feasibility and inter-rater reliability in compiling the data sheet were established. The POCT service was implemented on 80 patients identified by convenience sampling from four community pharmacies. Test results were interpreted and an action plan for each patient was developed (t0). The action plan reflecting test results consisted of: lifestyle advice, referral to general practitioner (GP), referral to emergency department, and retesting at three (t3) and six (t6) months.

Results: Of the 80 patients, 43 were female, mean age 60 years (range 19-85 years) and taking a mean of 2 medications daily (range 1-6 different medications daily).
At t0, patients were referred to a GP due to out-of-range blood pressure (n=19) or due to elevated fasting blood glucose levels (n=6), of whom 2 patients were started on antidiabetic treatment by the GP. Patients (n=30) with an elevated total cholesterol level (moderate risk) were asked to retest after three months. All 80 patients were offered lifestyle advice. Fifty-six patients were asked to retest at t3 and 24 patients at t6.
At t3, 23 patients were tested and an improvement was observed through reduction in the level of blood pressure (n=11), total cholesterol (n=9) and fasting blood glucose (n=6). At t6, 10 patients were tested, maintaining all parameters within range.

Discussion: The results indicate that provision of blood pressure, blood glucose and lipid profile POCT in community pharmacies is feasible and effective since improvement in test parameters at follow-up were observed.

The Effect of Brexit On Accessibility to Medicine

Doubara Jessica Zuofa

Background: According to article 12 of the International Covenant on Economic, Social and Cultural Rights ''Health is a basic human right and access to medicine is a fundamental means to ensure health. It recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health".[1] According to WHO ''Nearly 2 billion people have no access to basic medicines'' .[2]

Purpose: To gather information and data using a scientific approach to enhance the accessibility to medicines, through application of knowledge assembled by critically analysing the demand and supply of medicines in Malta with relation to Brexit.

Method: A pragmatic approach was adopted for the comprehensive extraction and systematic classification of data on challenges with accessing medicines. Explorative analysis of alternative routes was undertaken using Micromedex® and international regulatory authorities.

Results: On reviewing the Government Formulary list (GFL) and private list of medicines the issues raised leading to lack of access in Malta was identified:
1. Due to Brexit and the UK ban on export of medicines.
Lack of cooperation in the regulation of medicines between the EU and the UK post Brexit. A list of best options for medicines was duly compiled and the following are examples:
a. GFL: verapamil 2.5mg/mL injection was suggested instead of adenosine 3mg/mL injection.
b. Private market list: Acetylsalicylic acid 75mg – Different brand of generic in other country not the UK.

Discussion: The lack of cooperation in the regulation of medicines between the EU and the UK post Brexit has proven to be more difficult to address because it requires co-operation between other countries. Partnership, consultation, collaboration between the Health system and pharmaceutical industry is important to avoid and control medicines accessibility challenges.

References:

1. United Nation Human Rights Office of the High Commissioner (OHCHR). International Covenant on Economic, Social and Cultural Rights. OHCHR; 1996-2020 [cited 2020 Nov 30] Available from URL: http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx
2. World Health Organization (WHO). Ten Years in Public Health, 2007-2017—Access to Medicines: Making Market Forces Serve the Poor. Geneva: WHO; 2017 [cited 2020 Nov 08] Available from URL: https://www.who.int/publications/10-year-review/chapter-medicines.pdf.

M.Pharm. Students
Dissertation Abstracts

Pharmaceutical Care

Pharmaceutical Interventions in the Use of Antibacterial Drugs in Obstetrics and Gynaecology
Naomi Fiteni

Pharmacist-led Monitoring of Patients with Respiratory Disease
Christy Caruana

Pharmacist-led Diabetic Patients Monitoring in Community Pharmacy
Mathea Montebello

Pharmacist Contribution in Post-Hospitalisation Cardiac Rehabilitation
Gabrielle Scicluna

Pharmaceutical Interventions in the Management of Febrile Neutropenia in Paediatric Oncology
Sarah Marie Falzon

Pharmaceutical Interventions in the Use of Antibacterial Drugs in Obstetrics and Gynaecology

Naomi Fiteni

Background: Surgical antibiotic prophylaxis is considered as a key strategy for the prevention of surgical site infections following obstetric and gynaecologic interventions.

Objectives: To audit the use of antibacterial drugs within the field of obstetric and gynaecologic surgery, and to assess the degree of adherence with the local protocols and international guidelines.

Design: A retrospective study was undertaken, whereby post-operative obstetric and gynaecologic interventions performed during the period of study were identified. Patient medical records and drug treatment charts were reviewed with regard to five parameters; indication for antibiotic use, choice of antibiotic(s), dose, route of administration and duration of antibiotic prophylaxis. A copy of the local protocol was obtained, and extensive literature search was performed to identify international guidelines.

Setting: Obstetrics 1, Obstetrics 3, and Gynae Ward, Mater Dei Hospital.

Main outcome measures: Compliance with the local protocols; identification of weaknesses in antibiotic use.

Result: A total of 100 cases were collected; 72 related to obstetric surgery and 28 related to gynaecologic interventions. For each parameter, adherence with the local protocol was evaluated, as for relevant cases. For indication and selection of antibiotic(s), adherence obtained was 93% and 89.2%, respectively. For dose and route of administration, adherence was 100%. However, for duration of antibiotic use, adherence was solely 8.4%. Out of 83 patients, 37 were given 3 doses of antibiotic, 23 were given antibiotics for 2 to 3 days, and 16 were given antibiotics at a stretch of 7 days. Intravenous-to-oral switch was observed with extended duration of use.

Conclusion: This study has contributed to identifying weaknesses associated with surgical antibiotic prophylaxis, namely extended duration of antibiotic use.

Pharmacist-led Monitoring of Patients with Respiratory Disease

Christy Caruana

Background: Community pharmacists play a crucial role as educators in the management of inhalation therapy through medication use reviews.[1]

Objectives: To develop and evaluate the impact of a pharmacist-led medication use review in patients with chronic respiratory conditions.

Design: Sixty patients with asthma or Chronic Obstructive Pulmonary Disease (COPD) were recruited from a community pharmacy. A questionnaire for a semi-structured interview was developed and a one-to-one consultation was conducted at baseline and after one month. The correct technique was demonstrated by the researcher at baseline. The inhalation technique of the patients was assessed during both consultations using an Aerosol Inhalation Monitor. A Peak Flow Meter (PFM) was used to keep a record of peak flow rate.

Setting: A community pharmacy.

Main outcome measures: Improvement in inhalation technique to optimise treatment and evaluation of intervention of inhalation technique.

Result: Out of the 60 patients who participated in the first consultation, only 7 (12%) patients had good control when performing inhalation technique. In the second consultation, 42 out of the 60 patients participated and 15 (36%) of these 42 patients demonstrated a good technique. The number of patients with poor control decreased from 26 (43%) to 3 patients (7%). The PFM readings obtained from both consultations were similar.

Conclusion: Preliminary findings indicate an improved inhalation technique during follow up. This study includes patients with asthma or COPD and proposes a pharmacist-led consultation within a community pharmacy setting, contributing towards safe and effective use of medications.

Reference:

1. Barefield KL, DeBellis HF. A review of health-related outcomes from community pharmacist interventions in patients with chronic obstructive pulmonary disease. J Am Coll Clin Pharm. 2019;2(4):433-443.

Pharmacist-led Diabetic Patients Monitoring in Community Pharmacy

Mathea Montebello

Background: It is estimated that a diabetic patient visits the pharmacy more frequently than other patients and this provides an opportunity for pharmacists to contribute to the management of diabetes mellitus.[1]

Objectives: To assess the impact of a pharmacist-led monitoring plan for diabetic patients in a community pharmacy setting, and improve patient knowledge, adherence to medications and condition monitoring.

Design: Diabetic patients were recruited from one community pharmacy to participate in the study. The study was divided into 3 sessions carried out at baseline, after 6 months and 12 months. Patient interviews were carried out using a developed questionnaire in which data relating to patient knowledge, treatment, views on treatment and condition, and management of condition was collected. The glycosylated haemoglobin (HbA1c) and random blood glucose (RBG) tests were performed during each session and the patient Body Mass Index (BMI) was calculated. IBM SPSS® software was used to analyse data.

Setting: Community Pharmacy.

Main outcome measures: Improvement in HbA1c result, patient knowledge on condition and monitoring.

Result: At the start of the study 32 patients were recruited (16 females, 16 males, mean age 59 years). Out of the study population 6 were Type 1 diabetics and 26 were Type 2 diabetics. Patient knowledge on diabetes is reasonable with 58% of the participants choosing the right answers. Metformin was the most prescribed medication for the management of diabetes. The mean reading for HbA1c was 7.03% at (T1), 6.72% at (T2) and 6.68% at (T3).

Conclusion: This study has demonstrated a feasible and effective pharmacist-led process of following-up diabetic patients in a community setting.

Reference:

1. Ali M, Schifano F, Robinson P, Phillips G, Doherty L, Melnick P, et al. Impact of community pharmacy diabetes monitoring and education programme on diabetes management: a randomized controlled study. Diabetic Medicine. 2012; 29(9): 326-333.

Pharmacist Contribution in Post-Hospitalisation Cardiac Rehabilitation

Gabrielle Scicluna

Background: Continued smoking after a cardiac event significantly increases morbidity and mortality, thus smoking cessation should be prioritised in cardiac rehabilitation (CR).[1] In the local scenario, there is no focus on smoking cessation interventions and no pharmacist contribution in CR.

Objectives: To develop a pharmacist contribution in post-hospitalisation CR and to evaluate outcomes

Design: An educational smoking cessation intervention was developed and implemented during the initial assessment session of the current CR programme for active smokers and those who quit post-cardiac event. Patients were counselled on posology of smoking cessation pharmacotherapy suggested by CR nurses and provided with pamphlets developed by the 'Health Promotion & Disease Prevention Directorate'. Telephone follow-up was undertaken after 3 and 6 months. Descriptive statistics were undertaken.

Setting: CR Unit, Mater Dei Hospital

Main outcome measures: Pharmacist intervention in CR regarding smoking cessation; smoking abstinence at 3 and 6 months

Result: Twenty-four patients (13 active smokers, 11 quit post-cardiac event, 19 male, mean age 56 years, 16 referred post-percutaneous coronary intervention) were enrolled. Eight of the 13 smokers accepted to receive smoking cessation pharmacotherapy (NRT n=6, varenicline n=2). Between 3 and 6 months, of the 14 active smokers, 8 increased, 4 decreased and 2 maintained same daily cigarette consumption. All 9 patients who were abstinent remained abstinent, and 1 patient did not respond.

Conclusion: Most patients were still smoking after 6 months, suggesting that a more aggressive approach in CR to improve smoking cessation outcomes is required.

Reference:

1.Pipe AL, Reid RD. Smoking Cessation and Cardiac Rehabilitation: A Priority! Can J Cardiol. 2018; 34: 247–51.

Pharmaceutical Interventions in the Management of Febrile Neutropenia in Paediatric Oncology

Sarah Marie Falzon

Background: Febrile neutropenia is a common complication in patients undergoing anti-cancer treatments It refers to the occurrence of a fever during a period of major neutropenia (<500 neutrophils/mm^3).[1] This results in an increased risk for infections, and in most cases, an increase in the severity of a given infection.[2]

Objectives: To identify and gap analyse local and foreign guidelines for the management of febrile neutropenia, and to evaluate practice in the local scenario.

Design: An electronic search strategy was developed to examine databases for available guidelines in the management of febrile neutropenia. Pro Quest Central, MEDLINE, MEDLINE Complete, Web of Science and Cochrane, databases were accessed through the University of Malta portal, Hy-di. An advanced search in Google Scholar was also performed. The terms ("fever" or "febrile"), ("neutropenia" or "neutropenic"), ("child" or "children"), ("pediatric"), ("cancer"), ("oncology") and ("management"), were used as search terms. The reference lists of identified protocols were in turn screened for relevance, and any articles identified were included in the study.

Setting: Rainbow Ward, Mater Dei Hospital

Main outcome measures: Gap analysis of available guidelines and analysis of local practice in the management of this complication.

Result: Seven guidelines were identified including the one used locally. Four were specifically compiled for use in the paediatric community.

Conclusion: In general, there was no great variation in the definition of febrile neutropenia. Risk stratification is recommended by all except for one, whilst empiric broad-spectrum antibiotic treatment is recommended by three.

References:

1. Hakim H, Gaur AH. Initial Management of Fever and Neutropenia in a Child With Cancer—The Past, the Present, and the Future. Clin Pediatr Emerg Med 2011;12(3):174-84.
2. Phillips B, Selwood K, Lane SM, Skinner R, Gibson F, Chisholm JC. Variation in policies for the management of febrile neutropenia in United Kingdom Children's Cancer Study Group centres. Arch Dis Child. 2007;1;92(6):495-8.

Pharmacotherapy

Optimisation of Oxytocin Use during Labour
Rebecca Marie Falzon

Use of Warfarin and Novel Oral Anticoagulants
Grazielle Camilleri

Assessment of Pain Management in Anaesthesia
Julia Micallef

Optimisation of Oxytocin Use During Labour

Rebecca Marie Falzon

Background: A concern of a suspected overuse of Oxytocin (OT) led to a particular interest in this field. Endogenous OT plays a key role in labour. OT misuse can lead to uterine hyper-stimulation, which can in turn lead to several other repercussions on both mother and baby, including potential fatality in either or both.

Objectives: To investigate the relationship of the duration of labour with and without the use of OT as well as the effect of OT on neonates expressed as Apgar scores at 1 and 5 minutes.

Design: A cohort prospective observational approach was adopted. Data was collected prospectively from patient files against inclusion criteria which includes cases from July 2019 to September 2019 and all cases except Elective Low Segment Caesarean Section, that is, excluding multifoetal and breech pregnancies. Women with missing or incomplete information were also excluded from the study. Data was then inputted in IBM SPSS Version 26 to allow for statistical tests, the One-Way Anova, Pearson Correlation and Chi-Squared Test.

Setting: Obstetrics wards 1 and 3- the two postnatal wards at the Obstetrics and Gynaecology Department, Mater Dei Hospital.

Main outcome measures: Maternal and foetal outcomes following OT use.

Result: 359 cases were consulted in all, 283 of which met the inclusion criteria. Results obtained show that there is no statistically significant difference between the duration of labour when using OT and when not. The Apgar scores at 1 minute of new-borns whose mother was administered OT has been found to be less than when OT was not used. This difference was found to be statistically significant. This is not the case with the Apgar scores at 5 minutes. The occurrence of instrumental deliveries was significantly higher when OT was used.

Conclusion: OT does not decrease the duration of labour significantly. The lower Apgar score at 1 minute of the OT group resolves at 5 minutes, indicating that OT does not have a significant effect on foetal well-being.

Use of Warfarin and Novel Oral Anticoagulants

Grazielle Camilleri

Background: Warfarin is a commonly prescribed oral anticoagulant. It has a narrow therapeutic window and requires frequent International Normalised Ratio (INR) monitoring. Novel Oral Anticoagulants (NOACs) include apixaban, dabigatran and rivaroxaban. In certain cases, NOACs are superior over warfarin, for example labile INR control with the use of warfarin. Not all warfarin patients can be switched to a NOAC, namely those who are stable on warfarin and patients with a mechanical valve or valvular atrial fibrillation.[1]

Objectives: To identify the number of patients on warfarin and NOACs in selected pharmacies, to assess the level of knowledge doctors and pharmacists have on NOACs and to gather feedback from patients on warfarin treatment, medication compliance and willingness to change treatment to NOACs.

Design: Two questionnaires were developed: 1 for doctors and pharmacists and 1 for patients on warfarin. A total of 50 patients from pharmacies from each of the 5 Maltese districts were selected to complete the questionnaire.

Setting: Community pharmacies

Main outcome measures: General feedback on warfarin use and identification of major drawbacks related to the use of oral anticoagulants.

Result: Most warfarin patients reside in the Western District, with the Southern Harbour District having the least patients; 221 and 8 respectively. The pharmacy that dispensed most NOACs in a given 3 month-period was that of the Northern District, with NOACs being dispensed to 24 patients. NOACs were dispensed the least in the Southern Harbour District, with 1 patient being dispensed a NOAC.

Conclusion: The use of NOACs in Malta is limited due to the fact that NOACs are not available on the Outpatients Formulary List. The price of NOACs is considered to be a burden by a number of patients who are entitled to free warfarin and INR testing via the National Health Service.

Reference:

1. Verdecchia P, Angeli F, Aita A, Bartolini C, Reboldi G. Why switch from warfarin to NOACs? Internal and Emergency Medicine 2016;11(3):289-293.

Assessment of Pain Management in Anaesthesia

Julia Micallef

Background: Pharmacotherapy within anaesthesia is related to pain relief and patient comfort in order to provide adequate analgesia and sedation. To control acute pain within intra-operative and post-operative scenarios, paracetamol, NSAIDS and opiates are used. Selective COX-2 inhibitors celecoxib, parecoxib and selective α2-AR agonist dexmedetomidine are currently not available on the local formulary.

Objectives: To collate evidence from literature regarding indications for use and advantages of use of celecoxib, parecoxib and dexmedetomidine, to identify whether these drugs are required for inclusion in the local formulary, to gather scientific data and clinician's perspective regarding the selected drugs, which may serve as a drive for the introduction of the respective agents on the local formulary.

Design: Scientific evidence was gathered from pain management protocols, summary of product characteristics and through a literature review. Feedback from pain specialists including anaesthetists is sought to provide local needs perspective.

Setting: Department of Anaesthesia, Mater Dei Hospital

Main outcome measures: Technology assessment for the potential introduction of celecoxib, parecoxib and dexmedetomidine within the national drug formulary for hospital use.

Result: Both celecoxib and parecoxib are approved for the relief of acute postoperative pain. They have similar pharmacological properties but exhibit lower GI side effects relative to NSAIDs. Celecoxib is highly COX-2 specific but has reduced aqueous solubility, limiting its dosage options. Parecoxib, the water-soluble prodrug of valdecoxib, is the only injectable coxib. No evidence indicates superior degrees of pain relief between the two, but parecoxib offers advantages in the immediate post-operative scenario, when oral administration is not possible.[1]

Conclusion: Evidence from literature favours the introduction of respective agents since they offer advantages in terms of dosage form and safety profiles.

Reference:

1. Gajraj NM. COX-2 inhibitors celecoxib and parecoxib: valuable options for postoperative pain management. Current topics in medicinal chemistry. 2007;7(3):235-49.

Pharmacy Information

Patient Knowledge and Medication Compliance in Osteoporosis
Michaela Vella

Evaluation of Patient Information Leaflet for Stem Cell Transplant Patients
Krysta Cutajar

Characterisation of Patient Advice in Community Pharmacy
Leo Kingsley Osamudiame Omoruyi

Patient Knowledge and Medication Compliance in Osteoporosis

Michaela Vella

Background: For osteoporotic medication to exert their full potential, sufficient levels of compliance with the appropriate regimen is necessary. Poor compliance is associated with a greater risk of osteoporotic fractures which increases healthcare resource utilisation.[1]

Objectives: To evaluate patients' knowledge regarding osteoporosis and to review medication compliance in osteoporotic women.

Design: Questionnaire A was distributed to all patients prior to undergoing a Bone Mineral Density Test. Questionnaire B was distributed to patients taking osteoporotic medication. Data collected was analysed using IBM SPSS®.

Setting: Bone Density Unit within the Gynaecology Outpatient Department at Mater Dei Hospital.

Main outcome measures: To evaluate patients' knowledge regarding risk factors leading to osteoporosis, such as smoking, alcohol abuse and calcium supplementation. Reasons for non-compliance were evaluated.

Result: Out of 215 patients, 94.4% (n=203) were female and 5.58% (n=12) were male. One hundred and twenty-one patients (56.28%) were 66 years or over. One hundred and forty-eight patients (68.84%) do not drink alcohol and 73.49% (n=158) were non-smokers. The majority of the patients (n=154) take calcium as part of their diet and as supplements. Fifty-seven patients (26.51%) suffer from osteoporosis. Twenty-four patients (42.11%) that suffer from osteoporosis have never missed a dose.

Conclusion: Patients are aware regarding the negative effects of smoking, chronic drinking and the importance of calcium supplementation. The main reason for non-compliance is the unavailability of osteoporotic medication from the National Health System (NHS). The process of introducing osteoporotic medication in the Government Formulary has started.

Reference:

1. Yasri S, Wiwanitkit V. Osteoporosis: The present concern on available drugs in view of public health pharmacology. Annals of Tropical Medicine and Public Health. 2017; 10(4):1089-90.

Evaluation of Patient Information Leaflet in Stem Cell Transplant Patients

Krysta Cutajar

Background: Medication regimens prescribed in stem cell transplant (SCT) patients consist of complex medications, with varied timings of administration, that frequently lead to changes in prescriptions depending on the patient's needs. [1]

Objectives: To design a patient information leaflet using a database, trend analysis, and a compliance questionnaire as tools.

Design: Patients diagnosed with haematological disorders in the pre- or post-transplant stage, and aged ≥18 years were recruited by convenience sampling. Methodology consisted of compiling a database consisting of patients' diagnosis, trend analysis of prescribed medications, assessing compliance through a questionnaire entitled "Medication Compliance", and designing and validating patient information leaflets.

Setting: Stem Cell Transplant Clinic, Sir Anthony Mamo Oncology Centre.

Main outcome measures: Robustness of compiled password-protected database, trends of prescribed medications, evaluation of medication compliance, and expert-panel ranking of patient information leaflet.

Result: Between September and March 2019, 25 patients; 13 male, 12 female (range 34–74, mean 58) took part in the study. Eight patients suffered from myeloma and lymphoma respectively, and nine from leukaemia. All patients were compliant to their prescribed medications. Their administered treatment involved three different phases; induction, conditioning and prophylactic treatment. Patient information leaflets on Autologous SCTs, Allogeneic SCTs and Donors for SCTs were developed in both English and Maltese, validated and assessed for their usefulness, readability, and translation.

Conclusion: A developed patient information leaflet was found by the expert panel to show characteristics that it will contribute to answer any questions the patient may have before, at the time of, and after the stem cell transplant.

Reference:

1. Corrêa PM, Zuckermann J, Fischer GB, Castro MS. Immunosuppressive serum levels in allogeneic hematopoietic stem cell transplantation: pharmaceutical care contribution. Pharmacy Practice. 2016;14:683.

Characterisation of Patient Advice in Community Pharmacy

Leo Kingsley Osamudiame Omoruyi

Background: Community pharmacists are key healthcare professionals to provide advice to patients to enhance the rational use of medicines.[1]

Objective: To describe type and frequency of patient advice requests provided in community pharmacy practice

Method: In this observational prospective study, patient encounters (N=1,000) with the community pharmacist for advice over a twelve-week period are observed and recorded in a data collection form developed for the purpose of the study. The time taken to address each patient request is recorded. Descriptive statistics are carried out to assess the type and frequency of patient advice requests. Ethics approval is obtained.

Setting: Community pharmacy

Main Outcome Measures: Characterisation of pharmacist-patient advice

Results: Preliminary data carried out during three days of observation covering 45 patient requests indicate the three most prominent pharmacist-patient advice: Medicine information (n=32), responding to symptoms (n=16) and product recommendation (n=17). The characterisation of patient advice will identify the extent of interventions by the pharmacists in providing advice on medicines, self-care, lifestyle, use of medical devices, signposting, waste disposal, and medical referral.

Discussion: Characterisation of the provided advice to patients contributes to highlight the value of pharmacist interventions in patient care in contributing to enhanced medication effectiveness, adherence and patient safety.

Reference:

1. Ilardo ML, Speciale A. The Community Pharmacist: Perceived Barriers and Patient-Centered Care Communication. Int J Environ Res Public Health. 2020;17(2):536 (16 pages).

Pharmacy Administration

Risk-Based Analysis of the Pharmacy of Your Choice Scheme
Emily Magro

Pharmacist Interventions in POYC Patients
Bright Omoregie

Access To Generic Medicines
Safaa Kador

Risk Identification through Medication Review
Titto Xavy

Risk-Based Analysis of the Pharmacy of Your Choice Scheme

Emily Magro

Background: The dispensing process may be at risk of error if proper guidelines are not adhered to since dispensing is a complex process and not just supplying the medication on the patient's prescription.

Objectives: To identify risk factors in dispensing, evaluate pharmaceutical dispensing processes and establish the best practice for dispensing Pharmacy Of Your Choice (POYC) medicines.

Design: A survey data sheet, pharmacist questionnaire and time-motion study form were developed and validated. POYC prescriptions being dispensed were observed through visits in 40 community pharmacies and recorded via survey data sheets. Pharmacists ranked risks according to their probability of occurrence (PO) and severity of consequences (SC) using a Likert scale from 1 (lowest score) to 5 (highest score) via a questionnaire. Risk was calculated by multiplying PO with SC, giving a risk priority number (RPN) of 1 to 25. A standard operating procedure (SOP) for dispensing POYC medicines was developed and pharmacists' perception recorded after implementation in 10 pharmacies via an evaluation questionnaire.

Setting: Community pharmacies

Main outcome measures: Establishment of risk mitigation strategies and an SOP

Result: The risks with the highest scores were illegible prescription (RPN=13.6) and incorrect prescription (RPN=12.0). All participating pharmacists stated that they deal with customers individually (N=40). All 10 pharmacists participating in the SOP implementation stated that the SOP represents the content clearly and concisely, while 9 agreed that it is useful. Nine pharmacists agreed that the changes made during COVID-19 were effective to limit contamination, 8 stated that they created new risks and 7 agreed to permanently going paperless.

Conclusion: The processes identified as having the highest risk were illegible prescription and incorrect prescription. Individual attention to customers was identified as being the best mitigation factor to risk occurrence.

Pharmacist Interventions in POYC Patients

Bright Omoregie

Background: Pharmacists play an important role in identifying treatment issues and advising patients. Pharmacist interventions when interacting with patients receiving their chronic medications through the Pharmacy of Your Choice (POYC) scheme provide an opportunity to identify inappropriate medicine use and create seamless flow of medication management.

Objectives: To observe and analyse pharmacist interventions in dealing with POYC patients.

Design: Qualitative methodology is undertaken to develop a data collection sheet to capture pharmacist interventions when interacting with patients during POYC medication dispensing. Observation sessions will be undertaken over 8 weeks and interventions studied according to a convenience sample. Study approval from the University and Research Ethics committee is sought.

Setting: Community pharmacy

Main outcome measures: Identification and classification of interventions by community pharmacist

Result: Pharmacist interventions are classified according to contribution towards validation of prescription; entitlement for medication, drug-related problems, patient advice, contact with POYC.

Conclusion: Understanding pharmacist-led interventions in POYC patients contributes to identify professional and administrative duties and to establish value of this intervention towards reducing medicine-related problems.

Access To Generic Medicines

Safaa Kador

Background: Use of generic medicines enables cost saving, generates competition and increases accessibility to medicines.

Objective: To compare prices of generic and originator central nervous system medicinal products.

Design: Access to generic products is identified by identifing availability and range of generic products. Prices of unit doses of originator medicinal products working on the central nervous system , which are available in the community pharmacyse sector in Malta are compared with prices of generic counterpart.

Setting: Community pharmacy

Main outcome measures: Availability and choice of generic products, price comparison between originator and generic products.

Result: Lower prices of generic medicinal products when compared to originator products may indicate higher affordability and access. A unit dose (tablet) of Risperidal (risperidone 1mg) which is the originator medicine costs 0.89 Euro, while a tablet of Nodiril (risperidone 1mg) the generic one costs 0.68 Euro. Indicating a price ratio of 1:0.7 for this example.

Conclusions: Use of generic medicines decreases patient cost of therapy and improves access to therapy.

Risk Identification through Medication Review

Titto Xavy

Background: Conducting a medication review is a relevant intervention by pharmacists in patient-care settings. A medication review is a critical evaluation of a patient's medication list with the intention to optimize therapy in a structured way using available clinical and pharmaceutical resources.

Objectives: To identify and grade risks in patients on multiple medications entitled under the Pharmacy of Your Choice (POYC) as part of a medication review process.

Design: The first 10 prescriptions for chronic medications having at least five medications were considered for this study. A documentation sheet with headers 'Medication and Strength', 'Dose Regimen', 'Interaction' and 'Extent of Interaction' was developed to conduct the medication review. For the header 'Extent of Interaction', a score of 1-5 (low to high) is applied to evaluate the magnitude of the risk. Scores given are validated by an expert panel. 'IBM Micromedex' and 'Medicines.org.uk' were used as resources.

Setting: Community Pharmacy

Main Outcome Measures: Extent of Interactions and weighted risks to patients.

Results: Ten patient cases were reviewed. Seven patient cases have shown major interaction, one patient case has shown moderate interaction and another has displayed a minor interaction. Interactions between calcium channel blockers and statins were observed in 6 out of the 10 cases, whereas interactions between diuretics and bronchodilators were observed in 2 cases.

Conclusion: The medication review exercise provides an opportunity to identify patient risk due to drug interactions.

Pharmaceutical Analysis and Regulatory Sciences

Extraction and Determination of Tetrahydrocannabinol in Oil
Miriana Cachia

The Effect of Covid-19 and Brexit on Compliance of the Falsified Medicines Directive
Mireille Debono

Quality in Medical Devices
Daniel Odibei

An Analysis of the Outcomes of a Quality Management System
Elmery Gem G. Estorque

Management of Quality Improvement Records
Janelle Bianca Mary

Analysis of the Perceived Risk of Cannabis for Medicinal Use
Michael Cini

Extraction and Determination of Tetrahydrocannabinol in Oil

Miriana Cachia

Background: Tetrahydrocannabinol (THC) is responsible for the psychoactive effects of cannabis. As interest in medicinal cannabis increased, extraction and determination of THC gained importance.[1]

Objectives: To develop an effective, efficient and reproducible procedure for the extraction and determination of THC from oil.

Design: Reversed-Phase High Performance Liquid Chromatography (HPLC) is performed on an Agilent® 1260 infinity system with an ACE® 5 C18 column (250 x 4.6mm id). LGC® standard solution of THC 0.1mg/ml in methanol and Natures aid® MCT oil is used. Methods of physical extraction are tested at different velocities and times using Vortex-Genie® 2, Langford Sonomatic® 1400 Ultrasonic Bath and Eppendorf® Minispin centrifuge. HPLC parameters are tested for the analysis and determination of THC.

Setting: Department of Pharmacy Research Laboratory, University of Malta

Main outcome measures: Chromatogram peak size and shape, retention time and area under the peak was measured.

Result: Following the development of a rapid HPLC method for analysis and determination of THC, CBD and CBN in methanol, it was concluded that the optimal HPLC parameters are mobile phase: phosphate buffer (pH2.5) and acetonitrile (80:20, v/v) at flow rate of 2ml/min and UV detector wavelength of 220nm. Best extraction conditions for THC from oil were: vortex for 30sec, sonication for 15min followed by centrifugation for 15min at 6000rpm. Two immiscible layers are yielded. The top layer, methanol and THC is extracted using a micropipette, refrigerated for 12 hours and centrifuged for 15min. Analyte is passed through a syringe filter and HPLC analysis is conducted.

Conclusion: The method for extraction that resulted in the best chromatogram resolution, baseline and retention time was determined.

Reference:

1. ElSohly AM, Murohy PT, Khan I, Walker WL and Gul W. Analysis of Cannabidiol, Δ9-Tetrahydrocannabinol, and Their Acids in CBD Oil/Hemp Oil Products. Medical Cannabis and Cannabinoids. 2020;3(1):1-13.

The Effect of Covid-19 and Brexit on Compliance of the Falsified Medicines Directive

Mireille Debono

Background: The Falsified Medicines Directive (FMD) was ratified in July 2011. The motivation behind the FMD is to stop falsified drugs from reaching patients.

Objectives: To evaluate the impact of Brexit and Covid-19 on compliance with the FMD.

Design: Three questionnaires were disseminated to pharmacists, two in Malta pre- and post- unique identifier (UI) implementation and one in Bonn post-UI implementation. A focus group discussing the consequences of Brexit and Covid-19 with respect to the FMD is conducted and SWOT analysis will be carried out using the results.

Setting: Registered pharmacists in Malta and Bonn.

Main outcome measures: The strengths, weaknesses, threats and opportunities associated with Brexit and Covid-19 with respect to compliance with the FMD.

Result: Eighty-five participants answered the pre-implementation questionnaire in Malta. Participants never encountered a case of falsified drugs (n=78), agree that the UI will increase their workload (n=56), cause drug prices to increase (n=46), will decrease entry of falsified medicines in the legal supply chain (n=69), and is worth its financial impact (n=34). Seventeen participants answered the post-implementation questionnaire in Bonn and eighty participants answered the post-implementation questionnaire in Malta. Participants never encountered a case of falsified drugs (Bonn: n=15; Malta: n=66), agree that that the UI caused an increase in their workload (Bonn: n=12; Malta: n=47), caused drug prices to increase (Bonn: n=0; Malta: n=23), has decreased entry of falsified drugs in the legal supply chain (Bonn: n=9; Malta: n= 47) and is worth its financial impact (Bonn: n=3; Malta: n=28).

Conclusion: The UI is seen as effectively preventing falsified drugs but most participants did not agree that it is worth its financial impact. Increase in workload was envisaged and experienced by pharmacists surveyed.

Quality in Medical Devices

Daniel Odibei

Background: Medical devices play the role of a major determinant of clinical outcomes in healthcare systems. Increased incidences of diagnostic errors gave rise to the need to further regulate and standardize diagnostic equipment. In a bid to further regulate the quality of medical devices placed in the European market, the European parliament replaced previously existing Directives (93/42/EEC, 98/79/EC and 90/385/EEC) for medical devices with new Regulations (EU) 2017/745 (Medical Devices Regulation) and Regulation (EU) 2017/746 (In-vitro Diagnostic Regulation).

Objective: To determine the quality of medical devices in the market and the impact of non-compliance with Medical Device Regulations on the end users or consumer.

Design:
1. Using data from applications received between April, 2020 and February, 2021, devices are categorized into compliant and non-compliant devices. Comparison is carried out on the data collected, the time taken for non-compliant devices to comply, and observing if there is a non-compliance pattern to categories of medical devices.
2. Analyse the complaints received and classify them according to the relevance of the safety challenges to the patient.
3. Develop and evaluate a course for the medical device responsible person.

Setting: The Malta medicines authority medical device unit and the Malta laboratory network

Main outcome measures:
1.Number of compliant and non-compliant devices, non-compliance patterns.
2.Complaints and their classification
3.Course structure and results of evaluation

Results: Settling down in an environment of the competent authority where the regulation of medical devices is taking place. Discussing and running of a number of items classifying them into compliant and non-compliant both with the present directives and the regulations coming into enforcement in May 2021. A plan for the course and the method of the evaluation is established and validated through a focus group.

Conclusion: The planned course reflects the needs of responsible persons to lead regulatory science quality aspects for medical devices.

An Analysis of the Outcomes of a Quality Management System

Elmery Gem G. Estorque

Background: A quality management system (QMS) is implemented in organisations to help coordinate and direct activities to ensure uniform and high-quality operations. It involves detailed documentation of a quality manual, standard operating procedures (SOPs), guidelines, policies, and quality improvement records. These documents are constantly revised and updated based on internal and external audits to ensure that stakeholder requirements are met.

Objective: To analyse the outcomes of implementing a quality management system to foster continuous improvement.

Design: A questionnaire with a five-point Likert rate scale, ranging from 1 to 5 (1 denoting the lowest score) is disseminated and data analysis is done based on descriptive statistics.

Setting: Malta Medicines Authority

Main Outcome Measures: Evaluation of the effectiveness of implementing a quality management system.

Results: The questionnaire includes questions that focus on i.) Customer satisfaction, ii.) Leadership, iii.) Engagement of people, iv.) Process approach, v.) Improvement, vi.) Evidence-based decision making, and vii.) Relationship management aligned with the seven quality management principles to evaluate the effectiveness of the implementation of a QMS.

Conclusions: Analysis of the outcomes of a quality management system is needed to continuously improve and drive a change in an organisation.

Management of Quality Improvement Records

Janelle Bianca Mary

Background: Quality management system (QMS) has been developed and adopted by organisations to achieve excellence in overall performance and customer satisfaction and one of its important goals is continuous improvement. Quality improvement (QI) is an initiative to systematically improve the organisational systems and operations through the use of quality improvement forms (QIFs) and databases to meet customer expectations and applicable statutory and regulatory requirements.

Objective: To investigate (i) how to manage the improvement of QMS, (ii) the relevance of documenting and maintaining all the QI findings through the use of QIFs and databases, and (iii) why quality improvement records are vital to improve QMS.

Design: A gap analysis between the actual and a model system is analysed through a focus group and suggestions to improve these are proposed. An observation data collection is conducted to evaluate how the quality system is being maintained and to assess how QIFs and databases are contributing to its maintenance. A questionnaire is developed and validated to examine and investigate how quality improvement records improved QMS.

Setting: Quality, Continuous Improvement and Internal Audit Unit, Malta Medicines Authority

Main Outcome Measures:
1. Differences between the actual and model system
2. Results of the gap analysis
3. Number of findings that contributed to the maintenance of the quality system
4. Results of the Likert scale used in assessing the improvement of QMS

Results: Differences between the actual quality system and model of improvement through the Plan-Do-Check-Act (PDCA) cycle include (i) criteria for limitations of improvement, (ii) change implementation strategy, (iii) achievement of QI goals and (iv) time and resource consumption. QMS maintenance framework provides information on technical and non-technical approach, in which the former comprises quality improvement records, internal quality audit, corrective and preventive action, data analysis and feedback, training, document control and management review. The questionnaire includes questions on the implementation, effects and importance of the technical approach that focuses mainly on quality improvement records.

Conclusion: Appropriate use of improvement models through the implementation of QMS maintenance framework infers effective management of QMS.

Analysis of the Perceived Risk of Cannabis for Medicinal Use

Michael Cini

Background: The Drug Dependence Act was amended in 2018, authorising the prescription of cannabis products for medicinal use (CM). The risk of using CM in Malta needs to be assessed.

Objectives: To analyse risk of use of CM as perceived by pharmacists (PHR) and physicians (GPs).

Design: Two questionnaires were developed, one for PHR and one for GPs selected by convenient sampling. Five-point Likert scale questions, one being the lowest score and five the highest score, were used to analyse perception of severity and frequency of CM side-effects and to compare the perceived frequency of side-effects and effectiveness of CM to conventional medications for 4 disorders. Two risk matrices were used to analyse the data. Two average Perceived Risk (PR) scores (1 low risk for CM to 25 high risk for CM) were obtained, one by multiplying the average scores for severity and frequency of each side-effect and one by multiplying the average scores of effectiveness and frequency of side-effects for each disorder.

Setting: Pharmacies and GP clinics.

Main outcome measures: Analysis of perceived risk of CM by GPs and PHR in Malta.

Result: Eight family GPs (4 from community pharmacy clinics and 4 through email) and 35 community PHR (12 through email and 23 in community pharmacies) answered the questionnaire.
The average PR scores of both pharmacists and GPs for side effects of CM were: fever:2, convulsions:3, diarrhoea and altered appetite:4, feelings of euphoria, hallucinations, psychosis, fatigue, confusion, vertigo and nausea:6. The PR score is proportional to the perceived risk of the side-effect. A PR score of 2 to 4 indicates low risk, whilst a PR score of 6 indicates moderate risk.
The average PR score for comparing CM to conventional medication was: chronic non-cancer pain, multiple sclerosis, nausea and vomiting, and epilepsy:6. Participants showed nearly equal preference for CM and conventional medication.

Conclusion: This study indicates that CM is perceived to be low risk and may be preferred to be used at the same rate of conventional medications.

Medicinal Chemistry

Validation of the Repurposing of the Methotrexate Scaffold for the Design of Janus Kinase Modulators with Potential Inhibitory Activity
Francesca Borg

Validation of the Repurposing of the Niclosamide Scaffold for the Design of pten-induced Putative Kinase 1 Modulators with Potential Agonist Activity
Abigail Buttigieg

Identification and Preliminary Validation of Potential Endogenous Targets for Maltanedienol
Ella Coppini

Rational Design and Preliminary Validation of Phosphoinositide 3-Kinase Modulators
Hannah Coppini

Rational Design and Preliminary Validation of BRD9 Receptor Antagonists Based on the BI-7273 Scaffold
Paula Gambin

A Preliminary Validation of the utility of the Capsaicin Molecule as a Lead for the Design of Androgen Receptor Modulators with Potential Inhibitory Activity
Johan Grech

Rational Design and Preliminary Validation of Novel BU10119 Analogs for the Management of SSRI Refractory Depression
Matthew Grech

Rational Design and Preliminary Validation of Novel 6-Phosphogluconate Dehydrogenase (6PGD) Inhibitors Using Parietin as a Lead
Daniel Sinagra

Validation of the Computational Simplification of the Experimental Molecule FR900359
Brandon Sultana

Rational Design and Preliminary Validation of Novel Glutaminase C Modulators
Lara Zammit

Validation of the Repurposing of the Methotrexate Scaffold for the Design of Janus Kinase Modulators with Potential Inhibitory Activity

Francesca Borg

Background: Literature shows that mutations in the JAK2V617F gene lead to the activation of the JAK/STAT signalling pathway, and to myeloproliferative neoplasms (MPNs). Methotrexate (MTX) has JAK suppressor activity when administered at low doses, indicating that there is potential for its repurposing.[1]

Objectives: Antagonism of the JAK/STAT signalling pathway can reverse underlying marrow pathology, disrupting erythrocytosis and other inflammatory responses. It is therefore a target in the identification of molecules that target MPNs.[1] The MTX scaffold was used as a lead for the *in silico* identification of high affinity JAK2 modulators.

Design: Tetracyclic pyridone was extracted from the JAK2 ligand binding pocket as described in pdb crystallographic deposition 2B7A.[2] The MTX scaffold was docked into the apo JAK receptor, conformational analysis performed, the optimal conformer identified, and an average pharmacophore created. A protomol representing the energetically unstable amino acids at the interior of JAK2 was generated, and the hits obtained on ZincPharmer® were docked into this protomol and ranked according to affinity.

Setting: Department of Pharmacy, University of Malta.

Main outcome measures: Identification of hit molecules based on the MTX scaffold.

Result: 991 rule of 3 compliant molecules were identified and obtained from virtual screening.

Conclusion: This study was a first step in the identification of novel JAK2 modulators. The virtual screening process included filters that selected exclusively for lead-like structures. The optimal ones will be further validated and optimized.

References:

1. Chinnaiya K, Lawson MA, Thomas S, Haider MT, Down J, Chantry AD, et al. Low-dose methotrexate in myeloproliferative neoplasm models. Haematologica. 2017;102(9):336–339.
2. Lucet IS, Fantino E, Styles M, Bamert R, Patel O, Broughton SE, et al. The structural basis of Janus kinase 2 inhibition by a potent and specific pan-Janus kinase inhibitor. Blood. 2006; 107(1):176-183.

Validation of the Repurposing of the Niclosamide Scaffold for the Design of pten-induced Putative Kinase 1 Modulators with Potential Agonist Activity

Abigail Buttigieg

Background: Literature shows that PTEN-induced putative kinase 1 (PINK1) mutation drives early onset Parkinson's disease. There is also evidence that the anthelmintic drug niclosamide, and other molecules bearing its basic scaffold, activate PINK1 through reversible mitochondrial membrane potential[1], resulting in slower disease development.

Objectives: PINK1 is a target for the design of novel anti-parkinsonian drugs.[1] The niclosamide scaffold will be used as a lead molecule for the *in silico* identification and design of high affinity PINK1 modulators.

Design: Small molecule ANP601 was extracted from the PINK1 ligand binding pocket as described in pdb crystallographic deposition 5YJ9.[2] The niclosamide scaffold was docked into apo-PINK1, conformational analysis performed and the optimal conformer identified. An average pharmacophore was constructed in LigandScout® and used for virtual screening using ZINCPharmer®.[3] The identified hits were docked into PINK1 protomol and ranked in order of affinity.

Setting: Department of Pharmacy, University of Malta

Main outcome measures: A molecular cohort with pharmacophoric similarity to niclosamide suitable for further investigation from an atomic perspective.

Result: Two lead-like hits were obtained from virtual screening.

Conclusion: Niclosamide has proven good oral bioavailability and low toxicity1, which makes this scaffold very interesting from a repurposing perspective. The 2 hit structures identified through virtual screening are lead-like making them particularly suitable for further optimisation.

References:

1. Barini E, Miccoli A, Tinarelli F, Mulholland K, Kadri H, Khanim F et al. The Anthelmintic Drug Niclosamide and Its Analogues Activate the Parkinsonss Disease Associated Protein Kinase PINK1. ChemBioChem. 2018;19(5):425-429.
2. Okatsu K, Sato Y, Yamano K, Matsuda N, NegishiL, Takahashi A, et al. Structural insights into ubiquitin phosphorylation by PINK1. Scientific Reports. 2018;8(1).
3. Koes D, Camacho C. ZINCPharmer: pharmacophore search of the ZINC database. Nucleic Acid Research. 2012; 40(W1):W409-W414.

Identification and Preliminary Validation of Potential Endogenous Targets for Maltanedienol

Ella Coppini

Background: Maltanedienol is the active principle of the alga, *Padina pavonica*. It has been shown to mediate *in vivo* calcium deposition through a hitherto unidentified target.[1]

Objectives: To identify potential biological targets for Maltanedienol related to calcium fixation or bone remodelling and to study their interaction with these targets from an atomic perspective.

Design: A previous study utilising a ligand-based approach to identify endogenous targets for Maltanedienol identified potential 59 candidates.[2] The targets were filtered based on their relationship to bone remodelling or calcium fixation, narrowing these to 36, of which only 26 were crystallographically described on the PDB. These 26 targets represented the study cohort. For each target, the small cognate molecule was extracted from its ligand binding pocket (LBP) and mutual affinity calculated in each case. Maltanedienol was subsequently docked into each target *apo* LBP and conformational analysis carried out. The optimal Maltanedienol conformer was consequently identified for each target.

Setting: Computational-based study carried out at the University of Malta.

Main outcome measures: Identification of high affinity endogenous targets of Maltanedienol related to calcium fixation.

Result: Seven of the 26 identified targets bound to Maltanedienol with higher affinity than their co-crystallised ligand.

Conclusion: This study earmarked 7 targets for further investigation. These targets will be used for *de novo* design and to formulate hypotheses regarding the biological activity of Maltanedienol.

References:

1. Galea R. The effect of a marine alga *Padina pavonica* on Maltese menopausal women [dissertation]. Msida (Malta): University of Malta;2009.
2. D'Emanuele J. Discovery of Medicinal Molecules Based on Similarity Networks [dissertation]. Msida (Malta): University of Malta; 2019.

Rational Design and Preliminary Validation of Phosphoinositide 3-Kinase Modulators

Hannah Coppini

Background: Phosphoinositide-3-kinases (PI3K) form part of a pathway that becomes activated in cancer such as spinal chordomas. Therefore, this pathway is both a challenge and an opportunity for the therapeutic intervention in cancer.

Objectives: To use virtual screening and *de novo* design to computationally dock the novel antagonist small molecule into the PI3K ligand binding pocket to determine its optimally bound conformation.

Design: PDB crystallographic deposition 5ITD[1], described the bound co-ordinates of the PI3K receptor bound to the small molecular inhibitor while PDB 6C1S[2] was used as a template to obtain the coordinates of this inhibitor. An apo-PI3K receptor was consequently generated through molecular simplification using SYBYL®-X. Its scaffold was used to create a pharmacophore to use in a virtual screening exercise using the online database ZincPharmer®. The resulting hits were screened for Lipinski Rule compliance and docked into the modelled protomol. These were then ranked in order of affinity.

Setting: Department of Pharmacy, University of Malta.

Main outcome measures: Identification of lead-like molecules.

Result: 7 Lipinski Rule compliant molecules were obtained.

Conclusion: The consensus pharmacophore was modelled to bind the co-ordinates of the antagonists for PI3K. The hit molecules exhibiting the highest affinity for the PI3K ligand binding pocket have been identified and will be recruited for molecular dynamic studies and *in vitro* validation.

References

1. Hoegenauer K, Soldermann N, Stauffer F, Furet P, Graveleau N, Smith A et al. Discovery and Pharmacological Characteristics of Novel Quinazoline-Based PI3K Delta-Selective Inhibitors. ACS Medicinal Chemistry Letters. 2016;7(8):762-767 5
2. Come J, Collier P, Henderson J, Pierce A, Davies R, Le Tiran A et al. Design and Synthesis of a Novel Series of Orally Bioavailable, CNS Penetrant, Isoform Selective Phosphoinositide 3-Kinase y (PI3Ky). Journal of Medicinal Chemistry. 2018;61(12):5245-5256.

Rational Design and Preliminary Validation of BRD9 Receptor Antagonists Based on the BI-7273 Scaffold

Paula Gambin

Background: Literature shows that Bromodomain protein 9 (BRD9) is overexpressed in Acute Myeloid Leukaemia (AML). BRD9 depletion induces myeloid cell apoptosis.[1] BI-7273, a BRD9 antagonist was identified as a novel molecule for AML management.

Objectives: To use the BI-7273 scaffold for the identification of lead-like molecules to probe the BRD9 Ligand Binding Pocket (LBP) via Virtual Screening (VS) and, to design novel molecules capable of its modulation using *de novo* techniques.

Design: Protein Data Bank crystallographic deposition 5EU1 describing the bound co-ordinates of BRD9 and BI-7273 small molecule inhibitor guided this study. The critical interactions between BI-7273 and BRD9 were modelled and the indolizine ligand was identified as a BRD9 antagonist with a similar pharmacophore to BI-7273. A consensus pharmacophore was generated and used for a more thorough VS. The modelled critical interactions between BI-7273 scaffold and BRD9 established the basis of *de novo* approach. Novel fragments were designed and modelled as seeds, with each structure retaining the structural moieties critical to antagonism. Seeds were allotted user-directed growing potential and were planted into BRD9 LBP activating *de novo* growth.

Setting: Computational-based study carried out at the University of Malta.

Main Outcome Measures: Establishment of novel BRD9 modulators using VS and *de novo* approach.

Result: 298 lead-like hit molecules were identified via VS, with the most promising molecule having an affinity of 5.77. The 20 seeds created using the *de novo* technique, sustained molecular growth.

Conclusion: This study established novel BRD9 antagonists to be proposed for further validation and optimization for use in the management of AML.

Reference:

1. Del Gaudio N, Di Costanzo A, Liu NQ, Conte L, Migliaccio A, Vermeulen M, et al. BRD9 binds cell type-specific chromatin regions regulating leukemic cell survival via STAT5 inhibition. Cell Death & Disease. 2019;10(338):1-14.

A Preliminary Validation of the utility of the Capsaicin Molecule as a Lead for the Design of Androgen Receptor Modulators with Potential Inhibitory Activity

Johan Grech

Background: Capsaicin has been shown to have an in vitro apoptotic effect through an anti-proliferative mode of action associated with oxidative stress induction on refractory prostate cell lines.[1]

Objectives: This study used the capsaicin scaffold as a lead molecule for the design of high affinity analogs capable of similar antagonist interactions with the androgen receptor.[2]

Design: DHT was extracted from its binding site as described in PDB crystallographic deposition 2AMA.[3] Capsaicin was docked into the AR ligand binding pocket. Conformational analysis was performed to achieve the best capsaicin conformation. The bioactive conformation of DHT and the best capsaicin conformer were superimposed. A consensus pharmacophore was created and uploaded as a query onto the ZincPharmer® database. Hit structures were identified for Lipinski Rule compliance, docked into a modelled protomol and ranked in order of affinity. The *de novo* approach was fragment based. Capsaicin seed structures were modelled, docked and had molecular lead-like growth. They were grouped depending on pharmacophoric affinity.

Setting: Computational-based study carried out at the University of Malta.

Main outcome measures: Generation of lead-like molecules based on the capsaicin scaffold

Result: Five lead-like cohorts with high affinity for the androgen receptor were generated.

Conclusion: The capsaicin scaffold was suitable for the identification and the design for AR modulators. A balance between structural diversity and bioactivity was obtained by the dual approach adopted. The best structures will be further optimised.

References:

1. Jemal A, Siegel R, Ward E, Hao Y, Xu J, Murray T et al. Cancer Statistics, 2008. CA: A Cancer Journal for Clinicians. 2008; 58(2): 71-96.
2. Díaz-Laviada I. Effect of capsaicin on prostate cancer cells. Future Oncology. 2010; 6(10): 1545-50.
3. Pereira de Jésus-Tran K, Côté PL, Cantin L, Blanchet J, Labrie F, Breton R. Comparison of crystal structures of human androgen receptor ligand-binding domain complexed with various agonists reveals molecular determinants responsible for binding affinity. Protein Science. 2006; 15(5): 987–999.

Rational Design and Preliminary Validation of Novel BU10119 Analogs for the Management of SSRI Refractory Depression

Matthew Grech

Background: Kappa Opioid Receptor (κOR) and Mu Opioid Receptor (μOR) Antagonism has been shown to be of promise in the treatment of SSRI Refractory Depression.

Objectives: BU10119 is a dual κOR/μOR antagonist, used in this study as a lead for potential refractory depression treatment. BU10119 has been designed to incorporate the critical sites of the κOR Antagonist Buprenorphine and μOR Antagonist Naltrexone.[1] The crystallographic structures of the κOR and μOR were obtained from Protein Data Banks 4DKL and 4DJH respectively.

Design: *de novo* Design (Structure based drug design) and Virtual Screening (Ligand based drug design) will be performed in this study.

Setting: Department of Pharmacy, University of Malta.

Main outcome measures: In Virtual Screening, BU10119 will be superimposed on κOR and μOR antagonists to identify the optimal conformers. Consensus Pharmacophores are created and an Overall Consensus Pharmacophore using Ligand Scout®.

Result: Sybyl-X® was used to model the protomol of each receptor. The Consensus Pharmacophores were read into ZINCPharmer® and MONA® to filter down to only Lipinski compliant molecules. These highest affinity hits were then identified by docking each hit into its protomol.

Conclusion: The identification of a dual antagonist has been inbuilt into the methodology of this study. BU10119 is already a dual κ/μ antagonist and thus, the molecular hits identified in this study are capable of interactions with the target receptors. This ensures that the Lipinski compliant molecules obtained through the Virtual Screening exercise could interact in a better way with the Ligand Binding Pocket.

Reference:

1. Almatroudi A, Ostovar M, Bailey CP, Husbands SM, Bailey SJ. Antidepressant-like effects of BU10119, a novel buprenorphine analogue with mixed κ/μ receptor antagonist properties, in mice. Br. J. Pharmacol. 2018; 175(14): 2869-2880.

Rational Design and Preliminary Validation of Novel 6-Phosphogluconate Dehydrogenase (6PGD) Inhibitors Using Parietin as a Lead

Daniel Sinagra

Background: Literature indicates that 6PGD inhibition mitigates tumour growth and that parietin is a 6PGD inhibitor decreasing tumour activity in nude mice with safe toxicity profiles.

Objectives: To use virtual screening and *de novo* design to identify and generate novel structures based on a modelled optimal conformer of parietin capable of 6PGD modulation.

Design: The small molecule PEX was extracted from its complex with 6PGD as described in pdb crystallographic deposition 2IZ1.[1] Parietin was subsequently docked into apo 6PGD, conformational analysis performed, and the optimal conformer identified. Its scaffold was used to create a pharmacophore for use in a virtual screening exercise using the online database ZincPharmer®. The resulting hits were screened for Lipinski Rule compliance, docked into a modelled 6PGD protomol and ranked in order of affinity. The *de novo* approach was fragment based, in which parietin seed structures were modelled, docked into the 6PGD ligand binding pocket and allowed molecular lead-like growth. The resultant molecules were grouped according to pharmacophoric similarity and ranked in order of affinity.

Setting: Department of Pharmacy, University of Malta.

Main outcome measures: Identification of lead-like molecules based on the parietin scaffold.

Result: Two lead like cohorts with high affinity for 6PGD were generated.

Conclusion: The parietin scaffold was suitable for the identification and design of lead-like 6PGD modulators. The dual approach adopted ensured a balance between structural diversity and bioactivity. The highest structures will be further studied with a view to iterative optimisation.

Reference:

1. Sundaramoorthy R, Iulek J, Barret MP, Bidet O, Ruda GF, Gilbert IH et al. Crystal structures of a bacterial 6-phosphogluconate dehydrogenase reveal aspects of specificity, mechanism and mode of inhibition by analogues of high-energy reaction intermediates. FEBS J. 2007;274(1):275-276.

Validation of the Computational Simplification of the Experimental Molecule FR900359

Brandon Sultana

Background: Literature indicates that the experimental molecule FR900359 relieves bronchial spasm through G-alpha inhibition. This molecule however has a large molecular weight, and its magnitude precludes its systemic use.

Objectives: To use virtual screening and *de novo* design to identify and generate novel structures with a lower molecular weight based on a modelled optimal conformer of FR900359 capable of modulating the G-alpha subunit.

Design: The inhibitor YM254890 was extracted from its complex with the G-alpha subunit as described in pdb crystallographic deposition 3AH8[1] giving rise to an apo G-alpha subunit. FR900359 was subsequently docked into its ligand binding pocket, conformational analysis performed, and the optimal conformer of FR900359 identified. Its scaffold was used to create a consensus pharmacophore using LigandScout. This created a more robust query for use in a virtual screening exercise using the online database ZincPharmer®. Prior to screening, filters were applied so that the identified molecules found would be lead-like. The hits were read into a modelled protomol for affinity ranking.

Setting: Department of Pharmacy, University of Malta

Main outcome measures: Identification of lead-like molecules based on the FR900359 scaffold

Result: With the filters applied no hits were found in any database searched

Conclusion: The FR900359 scaffold was not suitable for the identification and design of lower weight G-alpha modulators. Hence a *de novo* drug design approach will be taken. This is a valid result. FR900359 is a high molecular weight molecule unsuitable for use as a probe for lead-like molecules. The *de novo* approach will consequently be adopted.

Reference:

1. Nishimura, A., Kitano, K., Takasaki, J., Taniguchi, M., Mizuno, N., Tago, K, Structure of heterotrimeric G protein Galpha-q beta gamma in complex with an inhibitor YM-254890. Proc.Natl.Acad.Sci.USA. 2010; 107: 13666-13671

Rational Design and Preliminary Validation of Novel Glutaminase C Modulators

Lara Zammit

Background: Glutaminolysis is a process which drives cell proliferation in tumours. This process is driven by Glutaminase C. (Gc) Literature indicates that Gc is over-expressed in solid tumours mainly those of the lung and that its antagonism could inhibit tumour growth.[1]

Objectives: To design & identify novel Gc modulators through Virtual Screening (VS) & *de novo* design.

Design: The high affinity Gc inhibitor experimental molecule CB-839, was used as a lead for the identification of optimised analogues using VS. A consensus pharmacophore was generated by superimposing pharmacophores of inhibitor molecules obtained from PBD ID 5HL1[2] & 5WJ6[3] using Ligand Scout®. Sybyl-X® was used to model a protomol; followed by docking of hits obtained through VS. The ligand binding affinities of the 2 hit molecular structures were calculated in Sybyl-X®. *de novo* approach was used to design novel modulators, where seed structures derived from CB-839 were modelled and allowed growth within the CB-839 Ligand Binding Pocket (LBP).

Setting: University of Malta

Main outcome measures: Two molecular cohorts of high affinity lead like Gc modulators.

Result: VS yielded 2 high affinity lead-like molecules which were structurally diverse from the lead. CB-839 derived seeds were modelled and will be docked into the Gc LBP in *de novo* phase.

Conclusion: This study was valuable in modelling a unique pharmacophore that explored maximal pharmacophoric space using VS. *de novo* design was used as a complementary approach. The optimal structures will be optimised further.

References:

1. Vogl D, Younes A, Stewart K, et al. Phase 1 Study of CB-839, a First-in-Class, Glutaminase Inhibitor in Patients with Multiple Myeloma and Lymphoma Blood Journal. 2019
2. Huang Q, Cerione R. Crystal structure of glutaminase C in complex with inhibitor CB-839. 2016.
3. Huang Q, Stalnecker C, Zhang C, et al. Characterization of the interactions of potent allosteric inhibitors with glutaminase C, a key enzyme in cancer cell glutamine metabolism. Journal of Biological Chemistry. 2018;293(10):3535-3545.

B.Sc.(Hons) Pharm. Tech.
Project Descriptions

Risk Assessments: A Pandemic Case Scenario
Magdalene Baldacchino

Anti-counterfeiting Measures during the COVID Pandemic
Amber Bonello

Unique Device Identification of Medical Devices
Gretah Borg

Quality Systems in Forensic Science
Fabrienne Catania

3D Printing: Techniques, Materials and Applications
Matthew Conti

Quality Systems on Radiation Safety
Maximilian Johan Evers

Medical Devices in the Management of Diabetes Mellitus
Jeremy Gauci

Effect of Covid-19 on Packaging
Thorin Incorvaia

Vaccinology in the Times of a Pandemic
Nina Petkovic

Analysis of Cannabinoids in Biological Fluids
Fabrizio Testa

Risk Assessments: A Pandemic Case Scenario

Magdalene Baldacchino

This project aims to look into risk assessment as an analytical scientific field and to extrapolate the scientific value of risk assessments when applied to a pandemic scenario. This is achieved by a review of the literature to compare risk assessments in industries whose risk management approaches are robust and well-defined, with risk assessments that have taken place during the COVID-19 pandemic, as well as interviews with stakeholders. The rationale behind the design of risk mitigation measures in a pandemic, according to risk prioritisation and residual risk are put forward.

Anti-counterfeiting Measures during the COVID Pandemic

Amber Bonello

The project focuses on the rise of counterfeit pharmaceutical products during the COVID-19 pandemic. A detailed literature review is carried out explaining the risk of counterfeit drugs in times of the pandemic. The aim of the study is to provide anti-counterfeiting measures taken, including track and trace, block chain, artificial intelligence, unique identifier along with patient awareness. A questionnaire is conducted to obtain the perspective of pharmacists on counterfeiting and measures taken during the covid-19 pandemic.

Unique Device Identification of Medical Devices

Gretah Borg

Medical devices are classified into risk classes defined by their intended purpose. The Unique Device Identification (UDI) system should adequately identify medical devices from manufacturing to patient use. This system is due to take off in 2021 but there are still pending issues regarding its implementation. The study analyses what needs to be done within the Central Procurement and Supplies Unit (CPSU) and the local industry to manage implementation. Focus groups will take place to find out the current knowledge on the UDI system and discuss if Malta is prepared for the implementation.

Quality Systems in Forensic Science

Fabrienne Catania

Quality management systems involving accreditation and certification processes are fundamental to a robust, valid and reliable forensic science operations ensuring compliance to international standards. This project aims at recommending a quality system framework applicable to forensic science. Identification of international standards, certification and accreditation requirements for forensic services are carried out. A scenario analysis of continuous training and education needs required to sustain a quality management systems framework is completed and put forward within a national scenario.

3D Printing: Techniques, Materials and Applications

Matthew Conti

The project aims to assess and evaluate available 3D printing methods and materials used for this technology within the pharmaceutical sector. 3D printing methods used include vat photopolymerization, powder bed fusion, material extrusion, binder jetting and material jetting. The methods are compared and advantages of each technique are evaluated. 3D printing is a versatile technique, which can be applied for the production of medical devices and pharmaceutical drugs. The applications can be conducted using non-costly techniques and environmentally safe materials.

Quality Systems on Radiation Safety

Maximilian Johan Evers

Laser technology has emerged from hospital operating rooms to day clinics and private enterprises for dermocosmetic and health purposes. Due to this wider use, the burden of responsibility for safety is not only on hospital administration but awareness on safety and regulatory aspects is required by operators and users. The aim of the study is to review international, EU and national regulations in terms of non-ionising radiation and laser technology. The results provide a compilation of safety practices to be considered for the development of a quality system to inform use of laser technology.

Medical Devices in the Management of Diabetes Mellitus

Jeremy Gauci

The aim is to review and compare medical devices used in the management of diabetes mellitus available on the local market. The devices selected cover meters for self-monitoring of blood glucose (SMBG), continuous glucose monitoring (CGM) systems, glycated haemoglobin (HbA1c) testing, insulin pens and insulin pumps. Performance and operational characteristics of the devices are reviewed and compared. Of the 24 local suppliers contacted, the following devices were identified from 10 suppliers: SMBG meters (n=9), insulin pens (n=6), HbA1c tests (n=3), insulin pumps (n=2), and CGM systems (n=1).

Effect of Covid-19 on Packaging

Thorin Incorvaia

The aim of this project is to conduct a study on the impact of Covid-19 on the various sectors that handle and deal with pharmaceutical packaging. A literature review evaluates the current trends in packaging, adapted for Covid-19, and the extent to which the supply chain is affected. In this project, the impact of Covid-19 on pharmaceutical packaging is evaluated by means of a questionnaire to observe changes in packaging in the local scenario.

Vaccinology in the Times of a Pandemic

Nina Petkovic

Opinions concerning vaccination are influenced in a multitude of ways. The choice of inoculation depends on cultural background, social values, trust in government bodies, cost and extent of promotion. The proposed methodology assesses the influence historical vaccine development has on tackling vaccine hesitancy. Investigation of factors related to the urgency of vaccine development during devastating pandemic times are performed. Assessment of these aspects are conducted through the use of critical literature search, focus groups, and analysis of patient views expressed in the media.

Analysis of Cannabinoids in Biological Fluids

Fabrizio Testa

Cannabis has been used for centuries for medicinal and recreational purposes. Analytical methods for determination of cannabinoids include the use of gas chromatography and high performance liquid chromatography. Systematic literature review is conducted to compare sample preparation and methods of analysis for the determination of cannabinoids in biological fluids. Knowledge of concentrations of cannabinoids in biological fluids attained from efficient analytical methods can help determine therapeutic and toxic effects.

B.Sc.(Hons) Pharm. Sci. Fourth Year Students

Pharmacy Practice

Project Descriptions

Pharmacy Evolvement and Workforce Development
Nicole Agius Markham

Evolvement of pharmacy systems and impact on workforce is being studied. Questionnaires were developed and directed; to stakeholders (N=292) to understand the professional image of pharmacists, and to pharmacists (N=36) to evaluate self-reflection. Consumers are highly satisfied with the services provided by pharmacists (57%) while 17% feel the need for improvement. Most pharmacists (n= 27) reported to have a very good rapport with patients. Triangulation of data and reflections on evolvement in pharmacy systems is used to put forward proposals for workforce development.

Perception of Green Practices in Community Pharmacies
Michela Baldacchino

There is an increase in awareness about the impact of medications on the environment. Perception of pharmacists and pharmacy technicians towards green practices in community pharmacy was evaluated through a questionnaire. The questionnaire was validated, ethics approval was sought, and dissemination was done online. Out of the 50 participants, 25 have never heard of the term green pharmacy practices. All participants would like more information about the topic through social media (n=33) and webinar/seminars (n=27). Results indicate the need for further education related to green practices.

Evolvement of Systems for the POYC Scheme
Luke Cassar

Quantitative research methodology is applied to assess the Pharmacy of Your Choice system and the perception of pharmacists on the scheme. A questionnaire was compiled in English and Maltese and psychometrically evaluated. This was validated using a panel of advisors consisting of pharmacists and linguistic professionals. Kappa reliability was carried out to analyse the strength of agreement between test and retest. The kappa coefficient is 0.96. The questionnaire will be put forward for ethics approval and disseminated through social media and personal distribution in pharmacies

Facing Brexit: The Impact on Medicines
Andrew Felice

The accessibility of medicines in Malta substantially relied on the UK market supply. By using the Malta Medicines Authority (National Competent Authority) database, it was found that approximately 600 products had been authorised from the UK and are now withdrawn due to Brexit. Prospects of accessibility, pharmacoeconomic impact, stockpiling and packaging are analysed through the dissemination of two questionnaires – one intended for pharmacists and one for patients. Face and content validation and reliability testing are carried out.

Radiopharmaceuticals
Yasmine Fenech

The use and legal framework of radiopharmaceuticals (RP) were reviewed. The inclusion of aspects of radiopharmacy in the curriculum of 82 universities registered with the European Association of Faculties of Pharmacy (EAFP) is being analysed. From the 42 institutions analysed to date, 21 offer study units on RP as part of their pharmacy course. Sixteen of these study units are compulsory. Nineteen study units contain information on the diagnostic use of RP whereas only 8 study units involved RP protection. Three universities offer a post-graduate course on RP.

Development of a Quality System for the Analysis of Medicinal Cannabis
Oksana Friggieri

Instrumentation and consumables used in High Performance Liquid Chromatographic (HPLC) methods of analysis for the determination of cannabinoids, pesticides and mycotoxins were identified by conducting a systematic literature review. A quality system including logbook systems and detailed standard operating procedures (SOPs) of processes involved in the analysis of cannabinoids is set up. Ten SOPs have been set up and 8 logbook systems updated.

Point-of-Care for Infections
Laurent Grech

Implementation, availability and feasibility of point-of-care tests to diagnose *Streptococcus pyogenes* type A infection were undertaken. Locally available test kits (PreventID® Strep A kit and Acro Biotech® Strep A rapid test cassette) were identified. Tests (N=40) were reviewed: 22% of the kits had a sensitivity of more than 95% while 70% had specificity of more than 95% (N=40). The tests' implementation within a community pharmacy could support collaborative pharmacist prescribing. The occurrence of the Covid-19 pandemic has opened a new dimension, prioritising SARS-2 testing.

Direct Acting Oral Anticoagulants in Older Patients
Kevin Kirkop

The study provides a review of the prescribing practices of direct acting oral anticoagulants (DOACs) for older patients in Malta and an evaluation of patient experience. Retrospective data from clinical records of patients prescribed DOACs at Karin Grech Hospital is collected for a two-year period. Quantitative data collected is analysed using IBM SPSS© to establish prescribing trends and assess dose appropriateness in this patient population. A validated questionnaire is applied to a sample of patients to collect qualitative data on patient experience using DOACs.

Biosimilars: Perception and Awareness among Healthcare Professionals
Sephora Scicluna Bugeja

The project aims to gauge the knowledge of Maltese healthcare professionals, namely clinicians and pharmacists, on the use of biosimilars. Data is collected in a quantitative manner through a questionnaire. The ASBM / Europa BioDraft Physician Questionnaire was reviewed as the most adequate research tool and is used as a template for data collection from clinicians and adapted for use with pharmacists. The questionnaire is disseminated electronically to all registered professionals. Data attained is matched to international data for a valid comparison.

Myths, Science and Realities of Medicines Wastage
Roderick Micallef

Expired or unwanted medicines may be deposited in specialised disposing bins located in pharmacies across Malta. This project studies the nature of disposed drugs and the reasons for wasting medicines. A total of 752 tablets or capsules were deposited within 1 month. Eighty-two percent of disposed medicines are expired and 70% are obtained through the POYC scheme. The most common types of wasted medicines are psychoanaleptics, antidiabetic drugs and antihypertensives. The most frequently cited reasons for wasting medicines are expiry date issues, resolution of condition and changed medication.

Consumer Perception of Risks of Pharmacist Prescribing
Emma Theuma

The public's perceived risks of pharmacists prescribing for selected conditions are evaluated through a validated self-administered online questionnaire to rate probability of occurrence (P) and severity of consequences (S) on a 5-point Likert scale should pharmacists prescribe. Multiplying P by S gives a risk priority number (RPN) ranging from 1 to 25. The condition associated with the highest risk from 146 responses was type 2 diabetes (RPN=12.46) whilst that with the lowest risk was dandruff (RPN=2.32). Findings are used to develop a framework for prescribing in selected conditions.

Clinical Audit of Pharmacotherapy in the Management of Hypertension
Francesca Vassallo

The aim is to assess pharmacotherapy, blood pressure (BP) and therapy adherence in patients with hypertension. Patients (N=100) are recruited from 5 community pharmacies. BP is measured, pharmacotherapy is compared to guidelines, adherence is assessed using a questionnaire, patients are given a BP record card to complete until follow-up after 14 days, and referral to general practitioner (GP) is actioned if necessary. In the pilot study (9 patients), BP in 1 patient was not controlled (192/101 mmHg). Case was discussed with GP, new drug was added and BP decreased in accordance with guidelines.

B.Sc.(Hons) Pharm. Sci.
Third Year Students
Pharmacy Practice
Project Descriptions

Ethical Principles in the Provision of a National Health System for Medicines

Aaron Ryan Bartolo

An analysis of ethical principles governing the National Health System process with respect to selection, sourcing, supply, and patient access for medicines is undertaken. This systematic process is assessing qualitatively via stakeholder focus group discussions the various scenarios involved with the final objective of identifying the gaps in practical ethics.

Clinical Presentation and Impact of Statin-Associated Muscle Symptoms

Jean Claude Calleja

Terminologies, definitions and diagnostic strategies of statin-associated muscle symptoms from literature are reviewed and presented to cardiologists for analysis and standardisation. Patients on statin therapy who had an angiogram and/or revascularisation procedure are identified from the Cardiovascular Information Management System and a telephone survey is conducted to assess adherence.

Educating the Public on the Rational use of Antibiotics

Hannah Caruana

Antibiotics are used for the treatment and prevention of infection. This study aims to evaluate the perceptions of the general public on the use of antibiotics through a questionnaire. Outcomes from international health campaigns on antibiotics are reviewed to determine their effectiveness, and recommendations to encourage the rational use of antibiotics among the local population are put forward.

Time and Motion Studies in Community Pharmacy

Sophie Caruana

An observational time and motion study is carried out in a community pharmacy to compile information on distribution of activities carried out by pharmacists. A time-motion framework is developed and validated by running observational studies in other community pharmacies across different districts. Professional pharmaceutical services provided by the community pharmacists are characterised.

Characterisation of Patients' Requests when Responding to Symptoms

Miriana Cassar

Evaluation of patients presenting with symptoms or requesting a self-care product is undertaken by carrying out non-participant observational studies in community pharmacies. Community pharmacies are selected through stratified random sampling. Requests are categorised by patient groups and organ systems. Pharmacist intervention is characterised.

Pharmacogenetics and Chronopharmacology in Practice

Kimberly May Catania

The knowledge and attitudes of patients and health care professionals (HCPs) on pharmacogenetics (PhG) and chronopharmacology (ChP) are analysed through questionnaires. Drugs that benefit patient outcomes through knowledge on their PhG and ChP characteristics are identified. The sustainability of incorporating characteristics of ChP and PhG in a pharmaceutical care plan is analysed through focus groups.

Maltese Medicines Handbook and Other Drug Information Sources

Luca Farrugia

A quantitative cross-sectional survey analyses what information sources are used within community pharmacies, particularly medicines databases for drug products specifically available in Malta. The survey attempts to identify impact of digitalised drug information and correlations between age, practice settings and information request with the use of drug information sources.

Identifying Needs for Education and Development of the Pharmaceutical Workforce

Martina Fitzgerald

The aim is to identify the educational and professional development needs for the pharmaceutical workforce in Malta. A literature review is conducted to analyse international frameworks targeting the educational and professional aspect. Questionnaires capturing the expectations of students and pharmacists on this development are compiled, validated and distributed. A framework is developed.

Antiplatelet Therapy Prescribing in Patients with High Bleeding Risk Undergoing Coronary Stenting

Raquel Formosa

Patients undergoing percutaneous coronary intervention with stenting are prospectively recruited and bleeding risk is assessed. Patients with high bleeding risk (HBR) are highlighted to the cardiologist and dual antiplatelet therapy prescribing according to ESC guidelines is discussed and documented. Patients with and without HBR are followed up over six months for bleeding and ischaemic outcomes.

Deprescribing Proton Pump Inhibitors in the Older Population

Stephanie Formosa

This study assesses appropriateness of prescribing proton pump inhibitors in the older population to prevent overuse. Data analysis consisting of the indication, dose, duration, concurrent medication, comorbidities and adverse effects of treatment is conducted and appropriateness assessed using evidence-based guidelines.

Risks of Inappropriate Prescribing in a Community Pharmacy Setting

Philippa Galea Salomone

Inappropriate prescribing is a global healthcare concern which results in potential dangers to the patient. The aims are to assess the frequency and nature of medication errors by retrospectively analysing medication errors through prescriptions presented at five randomly selected community pharmacies. Risks of such errors are quantified and a framework for safer prescribing is proposed.

Monitoring Drug Levels in Biological Fluids

Kimberly Grima

The aim is to review and compare screening and confirmatory tests used for the determination of drugs of abuse in biological fluids performed locally and internationally. Needs related to testing for drugs of abuse in biological fluids locally are identified. Questionnaires related to needs for toxicological analysis of drugs in biological fluids are developed and validated.

Quality Control of Cannabis Products

Julian Mifsud

The aim is to compare quality control (QC) tests and Good Manufacturing Practices related to production of medicinal cannabis in different countries. Focus is placed on tests for determination of active cannabinoids, terpenes, mycotoxins, pesticides and heavy metals in cannabis. Interviews related to proposals of QC measures for adoption by local stakeholders are conducted.

Relevance of ISO Standards

Timothy Portelli

Investigations are carried out with pharmaceutical organisations, regulators and competent bodies that award the ISO certification to obtain data about ISO certification. A set of guidelines which informs pharmaceutical organisations to participate in ISO certifications are compiled and validated. The requirements for ISO certification are compared with GMP requirements.

Quality Systems for Community Pharmacy

Alessia Stivala

A community pharmacy quality framework (CPQF) is designed. The framework covers quality with respect to care, safety, services, and improvement whilst incorporating standards and legislation. Standard Operating Procedure (SOP) templates are developed. The CPQF and SOPs are validated via a focus group and tested for practicality and feasibility through feedback from community pharmacists.

Competencies Required for a Responsible Person and for a Qualified Person

Alex Xuereb

The role of a Responsible Person (RP) and a Qualified Person (QP) within pharmaceutical sciences require defined competencies to be carried out effectively. These competencies are deduced by identifying, questioning, and interviewing stakeholders. Data collected is analysed through a focus group. The focus group will also determine the educational needs for RPs and QPs to achieve these competencies.

CE Marking of Products for Medical Use

Nicole Xuereb

The project focuses on defining CE marking of medical devices and the requirements to affix a CE mark. The situation in Malta is evaluated by examining medical devices in terms of the type of device, how the mark was obtained, classification of the device and the perception of the general public. CE marking of in vitro diagnostics (IVDs) is investigated and improvements to CE marking are suggested.

Labelling and Language Requirements for Product Information for Medicinal Products

Tiffany Zammit

A review of labelling and language guidelines is carried out. The advantages and limitations to patient safety afforded by interventions of adjustments to original packs such over-labelling are analysed through product surveillance. A stakeholder meeting would get in touch the user, provider and regulator with an outcome of determining sustainable, patient-centred interventions in improving over-labelling.

B.Sc.(Hons) Pharm. Sci. Second Year Students

Pharmacy Practice

Project Descriptions

Advances in Veterinary Medicines

Zinah Abdaki

Traditionally medicines for veterinary use lack robustness for ensuring safety quality and efficacy. This project investigates how advances in veterinary medicines, including the new EU regulations, optimise the use of medicines in animals for both animal and human benefit.

Pharmacist Empowerment for a Positive Self-care Climate

Surma Ali

Exposing elements of pharmacist interventions in person-centred self-care consolidates the professional input towards a positive self-care climate. The project aims to describe strategies for pharmacist empowerment and evidence of the value of pharmacist-supported self-care.

Vaccinations in Rheumatology

Jonathan Joseph Attard

Patients suffering from Autoimmune Inflammatory Rheumatic Diseases (AIIRD) are subject to increased risk of co-morbidities and infections impacting on the patients' quality of life. The study aims to inform on vaccinations within the immunocompromised AIIRD patients.

Action in the Evolvement of Vaccination in Pharmacy

Tamara Attard

Twenty-six countries have already implemented pharmaceutical vaccination initiatives. The aim is to identify pharmaceutical vaccine strategies, to assess drivers for potential pharmacist-led vaccination services in Malta, and to outline education needs to support pharmacist empowerment.

Determination of Steroidal pKa

Giulia Baluci

The pKa of active pharmaceutical ingredients is an important characteristic for drug absorbance and bioavailability. The aim of this project is to determine the pKa of steroidal compounds using HPLC/UV-Vis and other methods such as titration.

Determination of CBD and THC

Neve Borg

An easy to use analytical method for determination of Cannabidiol (CBD) and Tetrahydrocannabinol (THC) in blood are developed and validated. Method is applied to determine concentrations of THC and CBD in blood of patients taking medicinal cannabis for therapeutic purposes.

Pharmacogenetic Implications of Proton Pump Inhibitors

Leanne Borg Gauci

CYP2C19 genotype is associated with proton pump inhibitor (PPI) exposure, efficacy and adverse effects. This project aims to use CYP2C19 genotype information to guide PPI dosing to optimise therapeutic effectiveness and safety.

Risk Aspects in Off-Label Drug Therapy

Martina Buhagiar

The aim is to analyse the need for off-label drug therapy and evaluate the pros and cons from the perspective of physicians, pharmacists, patients, pharmaceutical companies and regulatory authorities.

Risks in Self Medication

Miguel Camilleri

The aim is to determine the prevalence and factors associated with self-medication practices from the perspective of customers, general practitioners and pharmacists.

Technological Aspects in Drug Delivery

Matthew Cassar

In recent years, the evolution of technology led to an improvement in drug delivery. This study aims to evaluate technologies used in drug delivery and their evolution throughout the years. The use of smart medical devices for drug delivery are also evaluated.

Antithrombotic Therapy after Transcatheter Aortic Valve Implantation

Samuel Cremona

Thromboembolic and bleeding complications negatively impact prognosis after transcatheter aortic valve implantation (TAVI) and selecting the optimal antithrombotic therapy is challenging. This project reviews antithrombotic therapy regimens and assesses complications post-TAVI.

Toxicity of Vaccines

Kristina Filletti

Systematic literature review on toxicity of and technologies used to produce vaccines is conducted. Trends in quality, safety and efficacy of vaccines are identified. Tools to assess toxic effects of vaccines, including the new Covid-19 vaccines, are developed.

Green Pharmaceutical Practices

Christine Gauci

Green pharmaceutical practices seek to minimise the environmental impact of pharmaceutical processes. This study aims to evaluate the application of green practices within the pharmaceutical industry. Their application in manufacturing and waste management is evaluated.

Patient Participation in Pharmaceutical Care Plans

Lianne Melvin

Patient participation in pharmaceutical care plans reduces medication errors and non-compliance which compromise safety and therapeutic management. The project seeks to assess patient medication understanding and to identify modalities that strengthen patient participation.

Digital Health in Cardiology

Elena Mirone

Telecardiology is a modern medical practice for remote diagnosis and management of cardiovascular disease. The project aims to review telecardiology approaches applied in different countries and to develop and implement a framework for remote monitoring of heart failure patients.

Pesticides in Cannabis

Audrey Muscat

Literature review on pesticides used in herbal medicinal products and cannabis for medicinal use is conducted. Regulations and analytical methods used to determine pesticides are compared and guidelines for use of pesticides in medicinal cannabis are proposed.

Science, Myths and Realities Surrounding COVID-19 Vaccine

Joseph Scerri

This project will focus on the different vaccines being produced for COVID-19 undergoing clinical studies. Clinical data supporting the efficacy and safety of the medicines is analysed and used to counteract circulating myths which may lead to vaccination hesitancy.

Pharmacist Intervention in High-risk Medications

Nicole Schembri

High-risk medications have an increased risk of causing significant patient harm when used in error. The aim is to evaluate whether high-risk medications are treated differently to other drugs during dispensing. Guidelines for pharmacists dispensing such products are put forward.

The Cannabis Pharmaceutical Industry

Yasmine Smaoui

This study seeks to outline the pathway of cannabis for medical use from cultivation to production to patient use. An assessment of the regulations surrounding the cannabis industry and an investigation on the sustainability of this industry is carried out.

Deprescribing Benzodiazepines in Older Patients

Keith Joseph Tabone

Long term use of benzodiazepines is associated with several risks, especially in older patients. Overuse is common in this patient population and deprescribing is recommended. Deprescribing tools are available and have been shown to facilitate the withdrawal process.

Market Entry and Competition: Biologicals and Biosimilars

Sarah Xuereb

This project aims to analyse the international and local scenarios with respect to the market entry of biosimilars in relation to prescribed biologicals so as to identify aspects of competition and value-based pricing without compromising the quality and safety of the treatment to the patient.

Developing a Digitally-enabled Pharmaceutical Workforce

Amber Zerafa

Digitalisation in the pharmaceutical field is rapidly evolving and presents opportunities for the profession. The aim is to characterise opportunities of digitalisation in pharmaceutical processes and to identify needs of the pharmaceutical workforce to maximise preparedness.