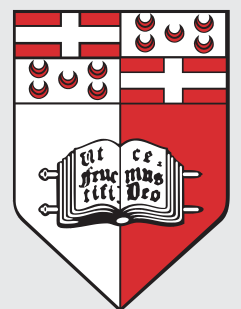


Pharmacy Students' Symposium

2007



Department of Pharmacy
University of Malta



Outstanding Results

The pharmacy graduate is unique in being flexible in the interventions that are required across the different settings. Projects presented cover areas ranging from Pharmacy Administration to Information and Health Promotion, Pharmacotherapy, Pharmaceutical Care, Pharmaceutics and Medical Devices, Industrial Pharmacy and Regulatory Affairs.

The education of the pharmacist has evolved to prepare the graduate to cope smoothly in the transition from the traditional role as drug dispenser to that of a direct patient-centred care. The validation of pharmacy services forms an integral part of research at our pharmacy department and has led to some of the results obtained by us being used for benchmarking of validation processes in the international scenario. Pharmacy students are exposed to a taste of this research through the running of projects in specified areas such as geriatrics. Leadership is essential for every profession. The setting up of a pharmaceutical association which deals only with professional matters and shies away from pure trade union dealings was a good practical exercise in training of leadership. The department prepares its graduates to be flexible and be in a position to adjust to tackle contemporary needs of our islands. Dissemination of information such as correct translation of pharmaceutical terms, publishing the findings of previously submitted projects, health education information in community pharmacies, awareness on use and misuse of alcohol, and first aid in sports were all subjects addressed in student projects.

Pharmacy students are immersed in their course of studies in both the width and depth of a subject. For example, in depth aspects of looking at the treatment of hypertension has led to consideration of specific details such as chronopharmacology in hypertension and hypertension in dialysis patients. Ways of how pharmacist interventions may improve the quality of life of patients has been the subject of projects carried out in the Pharmacy Department over the past years and these included the amplification of the pharmacist intervention in controlling chemotherapy induced nausea and vomiting. Pharmacoeconomics is a chosen area of research specialisation in our department. The use and cost of antibiotics was compared between a hospital in Perugia and two wards at St Luke's Hospital. This was possible through the strong participation of our students in Erasmus-Socrates Exchange programmes. This year 15 fourth year students, out of 28, participated in a semester placement at another European university. The maxim of prevention better than cure is impressed on our students. Some projects feature areas of prevention with the importance stressed on early intervention in several diseases including colorectal cancer, hypertension, diabetes mellitus and hyperlipidaemia and the relevance of the intervention and counselling of patients whether in the community pharmacy or at the pain clinic or during the use of oral anticoagulant therapy. The quality of medical devices and monitoring kits used in monitoring glucose and cholesterol, body temperature and blood pressure were investigated.

The strong ties and cooperation that exist between the Department and the pharmaceutical industry have developed into the preparation of five projects by final year students. These include various experiences in several aspects of research and development being carried out at our pharmaceutical industry such as stability studies, instrument and cleaning validation, LD50 determination and the use of process analytical technology.

Quality Assurance has become a household word in the field of pharmacy and health services. Three of our final year students gained some insight into this relatively new area to the education of pharmacy students by looking at a quality system for a hospital laboratory services, the registration requirements for medicines and the need for statistical evaluation of stability data.

The Pharmacy Department enjoys a close association with other departments at the Faculty of Medicine and Surgery and in other faculties as well as with a number of institutions on the island. Such collaborations have led to three interesting studies which exemplify the robustness and flexibility of pharmacy graduates. These projects involved a study on how the quantification of pancreatic amylase in gastric juice could aid in the detection of hyperamylasemia in the stomach due to duodenogastric reflux, a study to determine whether hospital stay predisposes to nasal colonisation with *Staphylococcus aureus* and MRSA using swabs taken from cadavers undergoing post mortem examination and a project on the use of performance enhancing agents in sports carried out in a number of gyms and health and fitness clubs in Malta and Gozo.

All the projects were carried out with diligence and dedication of the students under the supervision of their tutors who are full time academic staff members at the pharmacy department. However the outstanding results obtained could not be possible without the contribution of over 100 collaborators from several fields both in the clinical and industrial related fields. The department of pharmacy is grateful to all those who have assisted in any manner, whether academic or support staff at the university, or at other institutions including the hospitals and NGOs as well as laboratories and industry especially the pharmaceutical industry.

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Public Perception of the Pharmacist

Francesca Wirth

Background: The pharmacy profession is in the midst of a transition. Pharmacists are moving from a traditional role as drug dispensers, towards a new role as providers of direct, patient-centred care¹.

Objective: To identify to what extent the community pharmacist is focusing on a more patient-oriented service, to determine the perceptions of the Maltese public, and to present suggestions for discussion by the respective authorities for the development of improved pharmacy services.

Design: A psychometrically evaluated questionnaire was distributed to a random sample of 50 community pharmacies, with a response of 46. A second questionnaire was distributed to 500 members of the Maltese public. Statistical analysis was undertaken using Microsoft® Excel® XP and the BMDP. A discussion paper entitled 'A Vision for Community Pharmacy in Malta' was drawn up.

Setting: Community pharmacies

Main Outcome Measures: Pharmacist perception concerning issues such as consultation areas and supplementary prescribing and perception of the public regarding pharmacy services.

Results: Sixty seven percent of pharmacies have some sort of consultation area present in the pharmacy; the chief limitation being lack of space. Fifty one percent of pharmacists agreed that supplementary pharmacist prescribing should be implemented. Sixty seven percent felt they do not possess adequate clinical knowledge to provide such services; however, 91% were willing to participate in continuing education. Eighty percent of the public considered having a private consultation area in the pharmacy as important, 69% considered it important for the pharmacist to help the doctor manage patients with chronic disorders, but only 46% of the participants thought that the pharmacist should be able to prescribe certain medications without the doctor's permission.

Conclusions: Most pharmacists were in favour of performing consultations with patients, however, were less willing to accept the implementation of supplementary pharmacist prescribing. A good response was obtained from the public regarding certain pharmacist extended roles.

Reference

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Validation of Policies in a Geriatric Setting

Melissa Smith

Background: Policies provide consistency and basis for standardizing practice. Development of regularly reviewed policies is recommended.¹

Objective : To develop tools to assess compliance with pharmacy policies at Zammit Clapp Hospital and to amend and implement them if required.

Design: The four pharmacy policies considered for the study were: Dispensing of Medications for Admissions (DMA), Dispensing of Medications for Discharges (DMD), Amendments in Medications (AM) and Checking of the Emergency Trolley (ET). Tools were developed to validate the policies by means of observation of the processes for thirty times for DMA, DMD and AM policies and eighteen times for the ET policy. The pharmacists were interviewed regarding their views on these policies. A questionnaire regarding nurses' knowledge about the ET was developed.

Setting: Zammit Clapp Hospital (ZCH)

Main Outcome Measures: Pharmacists' compliance with the policies, pharmacists' opinions on the policies and nurses' knowledge about ET.

Results: The AM and ET policies were fully compliant. Most steps of the DMA and DMD policies were fully compliant. Three parts of the DMA showed 17% (n=5), 67% (n=20) and 93% (n=28) compliance and one part of the DMD showed 60% (n=18) compliance. The pharmacists agree that only minor changes to DMA and DMD policies are needed. The mean score for the nurses' questionnaire was 72%.

Conclusions: The tools are useful to assess compliance by the pharmacists with the policies. By identifying non-compliance and reviewing pharmacists' opinions, steps that may be amended can be identified. Following background from this study the ET policy has been amended and a similar study should now be carried on the nurses' section.

Reference

1. NHS Connecting for Health. Policies and procedures for clinical coding. [updated 2005 October 7; cited 2005 November 18]. Available from: http://www.connectingforhealth.nhs.uk/clinicalcoding/data_quality/policy/f

The Malta Pharmaceutical Association

Kenneth Ellul

Background: The Maltese pharmacy profession currently lacks an Association whose sole role should be that of promoting the pharmacist among the general public as a health care professional, whilst putting forward innovative methods of practice with the intent of improving the Pharmacy Profession.

Objective: To Set up and run the Malta Pharmaceutical Association and in so doing provide innovative services such as: The Pharmacy Locum Service (a locum list accessible via the association by pharmacies who may need a locum), The Pharmacy Emergency Number (a service which would ensure that the Pharmacy Profession is giving a 24 hour service to patients) and the Association's website (<http://ww.mpha.info>, to be used as a platform for Online Continuous Education.)

Design: A Questionnaire-based survey was undertaken in order to assess the best possible ways by which to implement the locum service and the pharmacy emergency number. The questionnaire was randomly distributed to pharmacy owners, managing pharmacists and pharmacists.

Main Outcome Measures: Number of pharmacists interested in joining the association, to review the willingness of pharmacists and pharmacies to take part in the services offered by the Association.

Results: Out of 180 questionnaires distributed 60% (n=108) were eligible for analysis. The pharmacy locum service was positively perceived by 90% (n=74) of the pharmacy owners and managing pharmacists whose pharmacy would benefit from such a service and by 82% (n = 34) of the locum pharmacists who would be willing to be on this list. The majority of pharmacy owners and managing pharmacists 51.3% (n=74) showed interest in having their pharmacy take part in the Pharmacy Emergency Number Service.

Conclusion: The findings indicate that there is a need for an association such as the Malta Pharmaceutical Association in order to put forward innovative services within the pharmacy profession.

An English-Maltese Dictionary of Medical & Pharmaceutical Terms

Eliza Camilleri

Background: In September 2003, EMEA issued a regulation stating that "certain documents for medicinal products authorized by the Centralized System have to be translated into Maltese".¹

Objective: To gather medical and pharmaceutical terms and validate them with linguistic experts, healthcare professionals and laymen, to produce an English-Maltese Dictionary of Medical and Pharmaceutical Terms.

Setting: The Medicines Authority (MA) and a local pharmaceutical agent were contacted to obtain guidelines and assistance.

Design: Initial entries were mainly based on the MA's 'Glossary of Terms'¹, and Aquilina's 'English-Maltese Dictionary'². Other terms were elicited from 'Mosby's Medical Dictionary'³, translated using Maltese norms, reviewed, and proofread to ensure they followed proper linguistic and syntax conventions. Interview-based questionnaires were carried out in 10 pharmacies to 200 laymen and 30 healthcare professionals to validate the effectiveness of the newly translated terms.

Main Outcome Measures: The entries were compiled into an electronic dictionary containing a search facility.

Results: A total of 5400 terms, commencing with the first 5 letters of the alphabet, were compiled. Terms elicited from the MA's Glossary and Aquilina's Dictionary amounted to 267 and 1433 respectively. Terms coined into the Maltese language amounted to 3700. The dictionary was made available for sale.

Conclusion The value of the dictionary is reflected in its demand by local authorities and local pharmaceutical companies and agents. It will facilitate translation processes of patient inserts and summary of product characteristics into our mother language, thus contributing in improving therapeutic compliance. The validation methods have helped to explore measures of improving translations, to attain terms understandable by everyone.

References

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- 3 Anderson DM, Keith J, Novak PD, Elliot MA. Mosby's Medical Nursing and Allied Health Dictionary. United Kingdom: Mosby, Inc.; 2002.

Preparation of Articles for a Clinical Pharmacy Journal

Karl Sammut

Background: A journal is the medium through which researchers are able to report the result of a particular study to their peer community in a particular discipline such as clinical pharmacy. A clinical pharmacy journal provides a platform for clinical pharmacists to share their work and ideas.¹

Objective: The main objective of the study was to share research projects carried out by past Maltese pharmacy students in the field of clinical pharmacy in a three times a year publication: Clinical Pharmacy Europe (CPE).

Design: Abstracts of undergraduate clinical pharmacy projects carried out over the last five years were read. Three of these projects which were all carried out in 2006 were chosen and a draft paper for each study was prepared for submission to the CPE Journal. Draft papers were prepared in divided sections comprising of an Introduction, Methodology, Results in point form list, Discussion and a summary box summarizing the main points of the study. The papers were then proof read and submitted for publication in the journal.

Setting: Pharmacy Department, University of Malta

Main outcome measures: Articles being published in Clinical Pharmacy Europe

Results: Out of a total of approximately 109 clinical pharmacy related projects carried out by undergraduate pharmacy students over the past five years, two projects carried out in 2006 were chosen and two draft papers prepared. Two draft papers titled: Community Pharmacists' Intervention in Immunisation Programmes in Malta and Quality of Life and Acne Management are being submitted for publication in the CPE.

Conclusion: Through publication in journals such as the CPE such projects were communicated to a larger audience while generating discussion about clinical pharmacy studies amongst interested health professionals.

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Pharmacy Information Programmes for Community Pharmacies

Jessica Ghigo

Background: Diabetes, hypertension and hypercholesterolaemia are common ailments on the Maltese Islands. Therefore health education must be promoted to increase knowledge and to develop skills in order to improve the community's health and environment.

Objective: To make available and create information for customers who visit the pharmacies in order to educate and to increase awareness.

Design: A CD was created and together with information from the Health Promotion Unit were made available in the participating pharmacies. This scheme was analyzed using different questionnaires: for the public and the pharmacists.

Setting: Community pharmacies (n= 13) were selected according to the electoral districts.

Main Outcome Measures: Public and pharmacists' perception of the importance of health education that can be offered in a community pharmacy.

Results: From the 260 questionnaires, 75.38% (n=196) were returned out of which 125 participants (64%) obtained information from the community pharmacies and 95% (n=116) found it beneficial. Participants were both male and female whose age ranged from 16 to 83 years. Moreover, 90% of the participants (n=176) believe that the pharmacist can deliver useful advice. From the 65 questionnaires distributed with the CDs 50.8% were returned, 29 (88%) participants found the CD useful and 46% rated the CD presentation as Good. The pharmacists (n= 13) agreed that the customers were interested in obtaining information thus making this activity viable. However, 4 pharmacists (31%) admitted that this activity slowed the customer flow.

Conclusion: Community pharmacists offer advice and education to customers in several media. The availability of information on CDs is one medium which reaches a variety of age groups.

Use of Alcohol

Maria Rita Agius

Background: Alcohol is related to various social activities and to certain aspects of human behaviour. Most societies feature drinking as part of their culture.

Objective: To evaluate knowledge of health professionals and the public about alcohol; compare systems of support organisations; provide information on harmful effects.

Design: Two questionnaires were developed, validated and reliability tested. 106 health professionals answered one, 481 youngsters answered the other. 100 leaflets were developed and distributed as a pilot to a booklet (4,000 copies) both containing a question section. 4 support organisations were interviewed and their systems compared.

Setting: General practice, local community pharmacies; Secondary, Post-Secondary, EFL schools, e-mail networks; local support organisations

Main Outcome Measures: Knowledge on alcohol, awareness, familiarity with legislation, frequency of drink-driving traffic accidents through questionnaires and leaflet.

Results: An average of 67.8% health professionals would be helpful when a potential alcoholic enters their pharmacy/clinic. 96.0% males and 98.0% hospital pharmacists have met an alcoholic. A spirit with mixer was the preferred drink amongst youngsters (33.4%). 28.3% (highest percentage) would pay 90c for one unit of alcohol. 5.5% had been involved once in a drink-driving traffic accident, 3.4% more than once – an increase since 2000¹.

Conclusions: Health professionals lack education on dealing with potential alcoholics. Knowledge/interest in the subject is scarce, pharmacists' knowledge increased since 1992². Strong alcohol is the youngsters' favourite drink. Most would pay 90c for one unit. Knowledge of effects is high whilst that of legislation is quite low. Peer-pressure determines alcohol intake. The legal drinking age is rarely respected.

References

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2. Sultana A. Alcoholism in Malta: Role of Pharmacists and Doctors. B. Pharm (Hons.) Dissertation, Malta: Pharmacy Department, University of Malta, 1992.

First Aid in Sports

Donnah Calleja

Background: The actions following an injury can strongly influence the result of medical treatment.

Objective: To determine and enhance the knowledge of first aid in the local sports scene and to investigate the standards of first aid facilities available.

Design: A test- retest study was carried out amongst 200 athletes and coaches from 17 sports. A booklet containing concise first aid procedures was compiled and distributed and the participants' knowledge of first aid re- tested by means of a questionnaire. A data sheet was used to assess the standards of first aid facilities of the sport complexes. Guidelines to improve these standards were issued to the people in charge.

Setting: Sport complexes including swimming pools, football courts and hockey pitches.

Main Outcome Measures: Basic first aid knowledge, information and views regarding the subject from the participants.

Results: Response rate for the pre- test study was 100%, whilst that for the post- test study was 90%. 92 participants (46%) never attended a first aid course (n= 200). 100% of the participants agreed with the importance of a first aid course as being an official requirement for coaching and only 5% (n=200) were satisfied with the first aid services offered. 100% (n= 10) of the venues visited had an easily identifiable first aid box or room.

Conclusion: All participants had encountered an injury that hindered their sport and agreed with the advantages of first aid, although many were not familiar with it.

Chronopharmacology in Hypertension

Jeanelle C. Portelli

Adequacy of Blood Pressure Control in Maltese Dialysis Patients

Alison Ferriggi

Control of Nausea and Vomiting in Cancer Chemotherapy

Nathalie Fenech

Surveillance of Antibiotic Use and Cost

Francesca Zammit

Correlating Risk Factors in Hereditary Non-Polyposis Colorectal Cancer Patients

Angelique Pace

Chronopharmacology in Hypertension

Jeanelle C. Portelli

Background: The blood pressure (BP) of both normotensives and hypertensives has a particular pattern associated with the body's inherent clock set according to a circadian rhythm, thus the timing of antihypertensive drug administration is important.

Objectives: To compare the effects of morning and evening dosing of the antihypertensive drugs atenolol and perindopril on both circadian BP and heart rate (HR) in essential hypertensive patients.

Design: Patients on once daily perindopril (n = 12, age 55 ± 13.1 years, dose 4.5 ± 1.2 mg/day) (mean \pm S.D.) and once daily atenolol (n = 9, age 49.9 ± 11.2 years, dose 72.2 ± 24.9 mg/day) participated in the study. The patients suffered from essential hypertension, were on no other antihypertensive medications or medications that affect BP. Each patient was instructed to take the antihypertensive drug in the morning at 0800h for 5 days, and then cross over to evening administration (2000h) for another 5 days. The BP and HR were monitored for 24 hours after each treatment period using an ambulatory blood pressure monitor (ABPM)¹.

Setting: Medical Out-Patients at St Luke's Hospital (SLH), Mosta Health Centre, Cardiac Laboratory (SLH).

Main Outcome Measures: ABPM (A&D TM-2340 and Schiller BR-102 models) to monitor daily systolic/diastolic and heart rate values.

Results: Evening administration of atenolol reduced HR significantly during early morning period (0600h-1000h) when compared to morning atenolol administration and evening perindopril administration ($p < 0.05$). Morning vs evening atenolol and perindopril administration did not result in similar circadian SBP ($p = 0.6$ and $p = 0.3$, respectively) and DBP ($p = 0.6$ and $p = 0.5$, respectively) values. Daytime DBP after evening administration of atenolol was significantly lower than evening perindopril administration ($p = 0.04$).

Conclusions: Atenolol administered in the evening produced a significantly lower HR during the early morning period, which may be advantageous in reducing early morning cardiovascular risk.

Reference

1. Neutel JM. The importance of 24-h blood pressure control. *Blood Press Monit* 2001;6:9-16.

Adequacy of Blood Pressure Control in Maltese Dialysis Patients

Alison Ferriggi

Background: High blood pressure (BP) is present in up to 85% of chronic renal failure patients starting dialysis¹.

Objective: To determine the prevalence of hypertension and adequacy of BP control in dialysis patients, to examine Quality of Life (QoL) issues, compliance to antihypertensive medications and to evaluate ambulatory BP data in a subset of patients.

Design: Two hundred subjects were recruited in the study. One hundred were dialysis patients (Haemodialysis (HD) = 60, Continuous Ambulatory Peritoneal Dialysis (CAPD) = 40) and another 100 were healthy controls chosen from a GP's database. The Chi - squared test, t - test, backward - stepwise multivariate regression and Fischer's exact test were used. The QoL was measured by the KDQOL - SFTM questionnaire and the SF - 36 in the dialysis and non - dialysis patients respectively. In dialysis patients, compliance to antihypertensive medications was assessed using a standard validated questionnaire.

Setting: Renal Unit, St. Luke's Hospital.

Main Outcome Measures: Prevalence of high BP; patients QoL and compliance to antihypertensive medications.

Results: The prevalence of hypertension in patients was 47% (n = 100). The most commonly used antihypertensive medications were calcium channel blockers (35%). Significant differences in the QoL scores were found when comparing the following five groups: dialysis vs. non - dialysis patients, HD vs. CAPD, hypertensive vs. normotensive non - dialysis patients, hypertensive dialysis vs. hypertensive non - dialysis and normotensive dialysis vs. normotensive non - dialysis patients ($p < 0.05$). Compliance rate was 34% (n = 47). ABPM results showed an overall adequate BP control in the dialysis population.

Conclusions: Nearly half of the dialysis population has hypertension. BP was adequately controlled in the majority of patients. The inferior QoL in dialysis patients was attributed to the dialysis itself rather than the high BP.

Reference:

1. Dhakal MP, Sloand JA, Schiff MJ. Prevalence of hypertension and adequacy of BP control in haemodialysis patients. *Dialysis and Transplantation* 2000; 29, 628 - 637.

Control of Nausea and Vomiting in Cancer Chemotherapy

Nathalie Fenech

Background: Chemotherapy-induced nausea and vomiting (CINV) are significant side effects of cancer treatment, and only the poor disease prognosis makes CINV acceptable. Together with the use of appropriate and rational antiemetic therapy, pharmacists' intervention can be amplified to the patients' benefit.

Objective: To assess occurrence of CINV, to compare and revise local antiemetic guidelines with international guidelines.

Design: Chemotherapy protocols and antiemetic protocols at Sir Paul Boffa Hospital (SPBH) were obtained. Twenty oncology patients or relapsed patients starting a new chemotherapy regimen were selected. Patients were interviewed before chemotherapy administration where emetogenic level was quantified and baseline QoL collected, and after the first and third chemotherapy cycle to assess CINV pattern.

Setting: Sir Paul Boffa Hospital, Malta.

Main Outcome Measures: 'Emetic Effect of Chemotherapeutic Agents'¹ was used to quantify emetogenic level. Baseline QoL was collected using 'European Organisation for Research and Treatment of Cancer' core questionnaire². Occurrence of CINV was measured using 'Morrow's Assessment of Nausea and Emesis'³, and 'Functional Living Index Emesis'⁴.

Results: Comparison of CINV during the various stages of chemotherapy yielded no statistical significance ($p > 0.05$, $v = 19$). Antiemetics given were rated as very effective by 14 (70%) patients on both cycles. Severe-intolerable nausea and vomiting symptoms were experienced by 4 (20%) patients in cycle 1, and 2 (10%) patients in cycle 3.

Conclusion: Low symptom occurrence and high patient QoL with highly emetogenic chemotherapy indicates the effectiveness of antiemetic therapy being used by the healthcare team at SPBH. Evaluation of compliance with current antiemetic guidelines at SPBH was done.

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Surveillance of Antibiotic Use and Cost

Francesca Zammit

Background: Antibiotic resistance has been growing at an alarming rate, such that "there is an urgency to improve physician prescribing practices"¹ when an antibiotic is indicated.

Objective: To identify quantitatively the conditions which most commonly warrant antibiotic use in a medical ward. To assess the appropriateness of Antibiotics prescribed according to local guidelines¹ and to compare the cost per defined daily dose (DDD) of antibiotics available at St. Luke's hospital to that at an Italian hospital.

Design: Cases of antibiotic use by patients in two medical wards at St. Luke's Hospital were recorded following approval by the Research Ethics Committee, as patients were identified from their medical history files. The cost of all antibiotics which may be prescribed at St. Luke's hospital and Monteluce hospital in Perugia Italy was collected from the respective pharmacy departments.

Setting: Medical wards M5 and M6 at St. Luke's Hospital and Monteluce Hospital in Perugia, Italy.

Main Outcome Measures: Cost of antibiotics, the difference, variance and standard deviation of cost between Malta and Italy per DDD and dosage form.

Results: Antibiotics were most commonly prescribed to treat respiratory infections ($n = 11$, 55%). The most significant difference in cost of antibiotic therapy worked out to be Cefepime at a DDD of 2g via the parenteral route; locally this therapy costs €9.62 compared to €6.64 in Italy, with a cost difference of €1.92.

Conclusion: All antibiotics prescribed ($n = 20$) adhered to local antibiotic prescribing guidelines¹. Co-amoxiclav remains the most commonly prescribed antibiotic ($n = 8$, 40%). Most of the drugs prescribed (in the public sector) are relatively more expensive locally when compared to Italy.

Reference

1. Borg M, Cuschieri P, Mallia Azzopardi C, Zarb P. Antimicrobial Prescribing Guidelines 2004. G'Mangia (Malta): St. Luke's Hospital

Correlating Risk Factors in Hereditary Non-Polyposis Colorectal Cancer Patients

Angelique Pace

Introduction: Hereditary Non-Polyposis Colorectal Cancer accounts for 15% of all large bowel adenocarcinomas¹. In 2004, two million eight hundred eighty six thousand eight hundred persons were diagnosed with colorectal cancer in Europe², with 160 cases being Maltese (1 in every 2500 persons).

Objective: To identify risk factors for developing colorectal cancer and how they correlate with the age at which colorectal cancer develops.

Design: A questionnaire was adapted from Harvard University³ and an additional data sheet devised. Patients diagnosed with colorectal cancer were identified and eligible ones chosen and interviewed (n=14). An information booklet was designed and printed.

Setting: Histology Department, St. Luke's Hospital.

Main Outcome Measures: Harvard University Disease Risk Questionnaire

Results: Eight developed cancer before the age of 50, six after the age of 50; four are overweight; three smoke over 20 cigarettes daily; eight do not consume five portions of fruits and vegetables daily; five have a family history of cardiac problems; seven have a family history of hypercholesterolaemia; ten have a personal history of bowel disorder/s; eight do not exercise; one consumes alcohol and red meat daily. None have taken aspirin daily for at least 15 years. One patient did not attend regular check-ups, and one patient is unaware of being diagnosed with colorectal cancer.

Conclusions: Those patients, who exercised regularly, ate healthily and did not smoke developed cancer at a later age. The fact that most of them suffered from bowel disorders is an indication for further monitoring, screening and education.

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Disease Management in Community Pharmacy
Sarah Aquilina

Pharmacist Intervention and Counselling of Patients
at the Pain Clinic
Ann-Marie Flores

Management of Diabetes Mellitus using HbA1c Testing
Justine May Callus

Patient Education on Hypercholesterolemia and the
Use of Statins
Annelise Sapiano

Pharmacists' Intervention in the Management of Patients
on Anti-Coagulation Therapy
Kristen Buhagiar

The Use of Cholesterol Monitoring Kits and Devices
Kirsty Young

Medical Devices used in Community Pharmacies
Francesca Farrugia

Extemporaneous Preparations
Tara Azzopardi

Disease Management in Community Pharmacy

Sarah Aquilina

Background: Hypertension, diabetes mellitus and hyperlipidaemia, which are major risk factors for cardiovascular disease, are candidates for disease management programmes due to their high incidence, high cost of treatment and consequences of non-compliance.¹

Objective: To evaluate the impact of the community pharmacist's intervention in chronic disease conditions through a prospective intervention study.

Design: Thirty-two patients, chosen by convenience sampling, were monitored for blood pressure, blood glucose, blood cholesterol and body mass index (BMI) at three visits over 9 months. Patient details including relevant medical history, medications taken, and lifestyle habits were documented in a data collection sheet.

Setting: Two community pharmacies in the harbour area.

Main Outcome Measures: Identified drug related problems (DRPs), documented pharmacist's interventions: patient medication counselling, health advice given and referral to the general practitioner, development of guidelines to assist community pharmacists in the management of hypertension, diabetes and hyperlipidaemia, physiological parameters monitored and assessment of patient compliance.

Results: The most common pharmacist's intervention at each visit was health advice (n=32) with special emphasis to patients with high blood pressure, high blood glucose and high blood cholesterol levels. A statistically significant reduction was achieved in the mean blood glucose levels for each visit ($p < 0.05$) and in the mean BMI readings between first and second visits ($p < 0.05$) and first and last visits ($p < 0.05$). There were statistically significant changes in the mean diastolic blood pressure levels between first and second follow-up visits ($p = 0.054$). Missed doses was the most common DRP at the initial and first follow-up visits (n=8 and n=6 respectively) while experiencing a side effect was the most common DRP at the last visit (n=5).

Conclusion: This study highlights the broadening of the community pharmacists' role in preventing and managing chronic diseases. It further proves that the pharmacist is in a suitable position to provide patient education regarding medication and lifestyle changes.

Reference

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Pharmacist Intervention and Counselling of Patients at the Pain Clinic

Ann-Marie Flores

Background: As the importance, complexity and costs of pain have become increasingly clear, pain is now taken more seriously in the medical management of patients and is recognized as an important medical issue in its own right, rather than the inconvenient symptom it was once regarded to be.

Objective: To introduce the pharmacist's role at the Pain Clinic, to assess compliance and improvement in drug efficacy with the use of treatment charts.

Design: Two questionnaires were designed: 'Knowledge of Pain Medication Questionnaire' and 'Assessment of Patient Compliance and Perception of Pain Management Questionnaire'. The study was completed on three different occasions and 31 patients were recruited for the study. During the first visit, the consultant examined each patient and prescribed the necessary medication. The patients met with the pharmacist who explained drug therapy. Patients were seen 4-6 weeks later on their second visit and 4-6 weeks later on their third visit. Results were analysed using the McNemar Test of Symmetry and the Wilcoxon Test.

Setting: Pain Clinic, at the Medical Outpatients, St. Luke's Hospital.

Main Outcome Measures: Patient's sources of knowledge about their condition and medications, patient compliance.

Results: With pharmacist intervention, the number of patients who never missed a dose increased by 19%. Patients' sources of information are mainly the physician (46%) and the pharmacist (23%). A 24% increase was observed in the number of patients who never stopped their medication despite predictable side-effects. After the pharmacist intervention, the percentage of patients who felt excruciating or unbearable pain decreased by 9%. Fifty-eight percent often found the Treatment Chart prepared by the pharmacist useful and 81% think that the pharmacist should have a role in this setting.

Conclusion: Patients feel that a pharmacist at the Pain Clinic would be important in providing beneficial advice, help and support in superseding difficulties encountered during therapy.

Management of *Diabetes Mellitus* using HbA1c Testing

Justine May Callus

Background: “*Diabetes is the most frequently targeted chronic condition because of its high and increasing prevalence, its complexity and proven high costs*”.

Objectives: To assess the level of diabetes management in Malta, using data capture techniques complemented by HbA1c testing. To measure the progress achieved through patient education and to identify key parameters which affect %HbA1c levels.

Design: A randomly selected group of diabetic patients ($n=81$) were interviewed and subjected to HbA1c testing. Statistical analyses were used to provide a picture about the level of management. A sub-group of patients ($n=41$) were followed through for 12 months, supported by education. These had to fill in a follow-up questionnaire and a second HbA1c reading taken. Disease specific indices were developed.

Setting: Diabetes Clinic at SLH

Main Outcome Measures: HbA1c tests and questionnaires score before and after educational intervention.

Results: 81 patients and 4 controls, (aged 26-79 years), mean duration in years with diabetes = 9.69 ± 10.24 years. Mean age when diabetes first diagnosed was 50.31 ± 15.07 years. Mean %HbA1c of population was $7.916 \pm 2.05\%$ with 23.5% within limits, 27.1% borderline and 49% above 7% limit. %HbA1c was higher in insulin-dependents. Mean BMI ($28.93 \pm 5.7\text{kgm}$) showing high +ve correlation with %HbA1c ($r=+0.2642, P<0.0001$). 81.5% report family history of diabetes and 35% had followed an unhealthy lifestyle. Health-monitoring: SMBG (35%) showing -ve correlation ($r=-0.4185, P<0.001$). 26% knew about importance of HbA1c testing. Positive correlations reported for %HbA1c with Relative Health Status Index ($r=-0.3085, P<0.0001$), Health Monitoring Index ($r=-0.3080, P<0.0001$) and Health Awareness Index. ($r=-0.4549, P<0.0001$). Follow-up: Mean %HbA1c of sub-population ($n=41$ DIYD•'3d5yrs) was reduced from $8.651 \pm 2.128\%$ to $7.961 \pm 1.542\%$, c.12 months later.

Conclusion: The use of HbA1c for monitoring diabetes management has shown significant utility.

Reference

Selby J.B et al. Determining the Value of Disease Management Programmes. *Joint Commission on Quality and Safety*, September 2003; 29 (9)

Patient Education on Hypercholesterolemia and the Use of Statins

Annelise Sapiano

Background: Pharmacists' individualized counselling of patients has positive impacts on the management of hyperlipidemia, including improved compliance and better treatment endpoints.¹ The healthcare team at the Lipid Clinic within St. Luke's Hospital (SLH) does not include pharmacists.

Objective: To evaluate patient awareness on hypercholesterolemia and its treatment and assess whether an educational intervention provided by a pharmacist within the Lipid Clinic increases patient knowledge.

Design: One hundred and fifty statin-treated hypercholesterolemics were recruited by convenience sampling. Following completion of a scored pre-intervention questionnaire, education on hypercholesterolemia and its treatment was provided together with an education leaflet to supplement verbal advice. This intervention was evaluated by means of a scored post-intervention questionnaire. Any difference in the knowledge scores obtained pre- and post-intervention was statistically analysed.

Setting: Outpatients Lipid Clinic, SLH.

Main Outcome Measures: The pre-intervention questionnaire indicated patients' baseline knowledge. The post-intervention questionnaire assessed the impact of the educational intervention on patient knowledge.

Results: Forty-two percent ($n=63$) of the subjects were males and the mean age was 59 years (range 32-76 years). Ninety-eight respondents completed both questionnaires thus achieving a response rate of 71%. Following the educational intervention, knowledge regarding the correct action to be taken if muscle pain or tenderness occur during statin therapy increased by 34% ($p=0.0000$). The awareness regarding the ideal total cholesterol level increased by 22% ($p=0.0001$) as did knowledge regarding the need for low-fat diet consumption during statin therapy (by 27%; $p=0.0000$). The mean knowledge score increased by 24% ($p=0.0000$) following the educational intervention.

Conclusion: A health education programme conducted by a pharmacy student improved patient knowledge on hypercholesterolemia and its treatment.

Reference

1. Lee SS, Cheung PY, Chow MS. Benefits of individualized counselling by the pharmacist on the treatment outcomes of hyperlipidemia in Hong Kong. 2004; 44:632-639.

Pharmacists' Intervention in the Management of Patients on Anti-Coagulation Therapy

Kristen Buhagiar

Background: Pharmacists' knowledge of drug interactions, pharmacokinetics and drug counseling skills make them well suited to the role of anticoagulation practitioners¹.

Objective: To investigate patients' knowledge about anticoagulation therapy and implement INR monitoring service in community pharmacies.

Design: Two hundred patients on oral anticoagulants were recruited randomly and interviewed using close-ended questions. Sixty had their INR checked with the point of care monitoring device, CoaguChek S. Results were compared with those from the Anti-Coagulation Lab using correlation and regression analysis. A cost evaluation study comparing the cost of both methods of testing was carried out. Twenty-three patients had their INR tested in pharmacies. Forty managing pharmacists filled a close-ended questionnaire which investigated their perception on implementing this service in their pharmacy.

Setting: Anti-Coagulation Clinic, Outpatients Department St. Luke's Hospital, community pharmacies

Main Outcome Measures: Patients' knowledge of warfarin therapy, pharmacists' and patients' perception about implementing INR monitoring service in pharmacies, reliability of the CoaguChek S device and the running costs of this service.

Results: Eighty percent (n=160) of the patients understood the benefits of this medication. Ninety percent (n= 180) wanted to have their INR tested with CoaguChek S. Only twenty three patients had their INR tested in community pharmacies. These were all very satisfied with the service provided. Seventy five percent (n=30) of the managing pharmacists who would not provide this service since it's too expensive. A reliability test yielded a 98% success rate. The concordance study gave 0.9. Cost of 1 CoaguChek S test is 3.75MTL. Cost of 1 INR test laboratory standard is 0.10MTL.

Conclusion: Incentives such as subsidies need to be given to encourage community pharmacists to provide this service.

Reference

1. Coleman B. Quality standards for a community pharmacist-led anticoagulation clinic. *The Pharmaceutical Journal* 2003; Vol. 270: 308-11

The Use of Cholesterol Monitoring Kits and Devices

Kirsty Young

Background: The development of cholesterol monitoring devices resulted in an inexpensive and convenient way of providing a blood-cholesterol result comparable to that obtained from a diagnostic laboratory.

Objective: To determine whether there is a correlation between the blood-cholesterol results obtained using Accutrend and Reflotron and the standard-blood cholesterol test results obtained from a recognized diagnostic laboratory.

Design: Twenty volunteers were recruited. Two capillary and 2 venous samples of blood were collected from each patient. Capillary samples were analysed using Accutrend. One venous sample was sent to a diagnostic laboratory where the standard blood-cholesterol concentration was determined, the other was analysed twice, using Reflotron. The results obtained were statistically analysed using regression analysis and Wilcoxon two-tailed t-test. A pilot study was carried out to determine the perception of the local community on the use of cholesterol monitoring devices: questionnaires were handed out to 150 consumers, 100 community pharmacists, and 20 physicians.

Setting: St. Luke's Hospital, Community Pharmacies and Shopping localities in Malta

Main Outcome Measures: Reliability of the cholesterol monitoring devices: Reflotron and Accutrend in comparison to the standard laboratory blood-cholesterol test.

Results: A correlation result of 0.99 was obtained in the regression analysis carried out for each device and when these results were compared to the diagnostic laboratory test results. A P value of less than 0.05 was obtained on comparing the results from Accutrend and when comparing the results obtained from Accutrend and Reflotron to the standard blood-cholesterol concentration results.

Conclusions: Accutrend and Reflotron provide a reliable blood-cholesterol result, comparable to that provided by the diagnostic laboratory. A low p value indicates that there is a significant statistical difference in the results obtained, not due to coincidence, but due to other factors.

Reference

1. Sammut A. Cholesterol – Awareness and Monitoring in a Community Pharmacy (dissertation). Msida (Malta): University of Malta.; 1998

Medical Devices used in Community Pharmacies

Francesca Farrugia

Objectives: To determine what diagnostic kits are currently available in community pharmacies, and to determine the accuracy of selected blood pressure and body temperature instruments.

Design: In the first phase of the study, a questionnaire was sent to 100 community pharmacies selected by random sampling, and the overall usage and demand of these diagnostic kits available in each pharmacy, was obtained. In the second phase of the study, 50 randomly selected volunteers were asked to have their blood pressure, body temperature and BMI measured free of charge. A questionnaire was also handed to each patient. Results of the diagnostic tests were analysed using the Wilcoxon test and the Pairwise t-test, whereas the questionnaires were analysed using Microsoft Excel.

Results: Out of the 69 managing pharmacists who returned the questionnaire, 65 (94%) said they offer diagnostic tests to patients. 68 (99%) pharmacists also agreed that blood pressure, blood glucose and blood cholesterol should be monitored on a regular basis, and they believe that anyone over the age of 40 would benefit from having an annual diagnostic test. Out of the 50 volunteers, 31 (62%) said that they had never had a diagnostic test carried out by a pharmacist. 29 (94%) of these said that they were willing to have the tests carried out in a pharmacy in the future. As for blood pressure monitoring, statistics showed that there is a significant difference in the average systolic and diastolic readings of the automatic wrist monitor when compared to both the sphygmomanometer (taken to be a gold standard) and the semi-automatic device. As for body temperature data, results showed no significant difference between using the normal glass thermometer (axillary) and IR thermometer (forehead).

Conclusion: Pharmacy has got great opportunity to make use of diagnostic testing to monitor patients' diseases¹. However, from this study, one concludes that some instruments used and sold in pharmacies are unreliable, and should be withdrawn.

Reference

1. Zarb R. Health promotion in community pharmacy [dissertation]. Msida (Malta): University of Malta; 2004.

Extemporaneous Preparations

Tara Azzopardi

Background: Extemporaneous preparations can be considered as specially made dosage forms that facilitate individualized therapy¹.

Objectives: The aim of this dissertation was to quantify the amount of extemporaneous preparations being prepared and all materials needed in most community pharmacies. The formulary of topical preparations of Sir Paul Boffa hospital was re assessed.

Design: A questionnaire was designed and sent to 150 community pharmacies around Malta and Gozo asking for the name and quantity of extemporaneous preparations carried out during the 2 specified years. The questionnaire also asked whether all materials necessary to produce these preparations were readily available. Another questionnaire was designed to give to the health care team at Boffa Hospital to evaluate the formulary.

Setting: Community pharmacies, Sir Paul Boffa Hospital.

Main Outcome Measures: The popularity of extemporaneous preparations and re-evaluating and compiling a formulary.

Results: The response rate of the first questionnaire was that of 95 out of 150 community pharmacies (63.3%). Results show that pharmacists compound an average of 30 extemporaneous preparations per year which shows a decrease of 61% when compared to 2000. 85 pharmacists (89.4%) replied that space and materials were of no problem inside their community pharmacy. 53 pharmacists (55.8%) agreed that a specialized pharmacy should be opened to cater for more complex extemporaneous preparations. The 'Formulary of Topical Preparations' set up at SPBH was received well by all the health care team that had to assess it (8 people) giving it a grading of good to very good.

Conclusions: Extemporaneous preparations prepared at the local community pharmacies are on the decline however on the rise at SPBH. This comes to show that although numerous preparations are available on the market; extemporaneous preparations offer a greater advantage.

Reference

1. APL [Online]. 2003; Available at: URL:<http://www.apl.apoteket.se/Engelska/extempore/index>

Stability Study on Venlafaxine

Fiona Fenech

Validation of an HPLC Method for Cleaning Validation

Josef Cachia

Cleaning Validation and Cross-Contamination Control

Ian Baldacchino

The Use of Process Analytical Technology

Christian Mangani

Feasibility and Costing of carrying an LD₅₀ Determination in Malta

Christian Saliba

Statistical Evaluation of Stability Data

Anne Marie Spiteri

Registration of Medicines in Malta

Julian De Gabriele

A Quality System at the Gozo General Hospital Laboratory Services

Nicole Zerafa

Stability Study on Venlafaxine

Fiona Fenech

Background: A pharmaceutical product once developed must undergo stability studies to obtain information on the stability of the product. The monograph for venlafaxine first appeared in the 2007 edition of the British Pharmacopoeia.

Objective: To determine the physical and chemical changes in venlafaxine capsules at accelerated and long-term storage conditions, the shelf-life and the packaging that provides the greatest stability.

Design: The study was conducted on venlafaxine 75 mg and 150 mg capsules packaged in blister packs and in amber bottles. During storage under long-term and accelerated conditions, samples were taken at specified time points, and analysed for: visual appearance, assay, identification of active ingredient, impurities, dissolution and moisture. Data was analysed using *Two-way Analysis of Variance* (ANOVA). The shelf-life was determined using the method by Spiteri (2006)¹.

Setting: A local pharmaceutical company

Results: The appropriate specifications for each test attribute, excluding dissolution for accelerated conditions, were met. For the latter, in the initial hours of the 24 hour dissolution profile % venlafaxine released was slightly reduced but > 80% release was always obtained at 24 hours. Effect of time was highly significant on the assay ($p < 0.01$) but not on the impurities ($p > 0.05$). Between 75 mg and 150 mg in blister packs under accelerated conditions, no significant difference ($p > 0.05$) exists in the moisture as opposed to in bottles ($p < 0.001$). A provisional shelf-life of 12 months under long-term storage was obtained.

Conclusions: Venlafaxine is a stable molecule with regards to: no statistical significance being obtained for the impurities over time, and optimal solubility obtained at the end of the 24 hr dissolution profile. Blister packs are the most suitable packaging for both strengths.

Reference:

1. Spiteri A. Statistical Evaluation of Stability Data. Malta, 2006: Personal communication.

Validation of an HPLC Method for Cleaning Validation

Josef Cachia

Background: The objective of cleaning validation is to verify the effectiveness of the cleaning procedure for removal of product residues, so that the analytical monitoring may be reduced in the routine phase¹. Validated analytical methods having sensitivity to detect residues or contaminants should be used in cleaning validation.²

Objective: The objective of this project was to confirm/reject the validity of an HPLC assay, found from the finished goods protocol, thorough laboratory studies, for the cleaning validation of Enalapril Maleate.

Design: A cleaning validation protocol was set up as the preliminary phase in the conducting of the cleaning validation study. The tests which were carried out to validate both the sample preparation process and the analytical method were; specificity, linearity, accuracy and precision, stability.

Setting: Actavis Ltd. Malta.

Main Outcome Measures: HPLC chromatograms

Results: The validation study carried out proved that the HPLC assay is adequate for use during cleaning validation. Test carried out showed that the HPLC assay shows good resolution, column efficiency, and repeatability. Positive results were also obtained in terms of specificity, linearity, accuracy, precision and stability.

Conclusions: Assay methods intended for finished goods are not always able to detect trace quantities, as is expected from assays used for cleaning validation. The project showed that this HPLC assay can be used for cleaning validation without modifications.

References

1. Health Canada. Good Manufacturing Practices - Cleaning Validation Guidelines. May 2001. p. 3-9.
2. European Commission. Final Version of Annex 15 to the EU Guide to Good Manufacturing Practice: Qualification and Validation. 2001. p. 8-9.

Cleaning Validation and Cross-Contamination Control

Ian Baldacchino

Background: Cleaning Validation (CV) procedures are important because they are documented evidence that a cleaning process will consistently produce products free of potentially contaminating residues.

Objective: To perform a retrospective analysis on Cleaning Limits adopted by a generics company, to analyse the application of a Performance Based – Exposure Control Limit (PB-ECL) system, to set-up Cleaning Validation Matrices and to explore the importance of Cleaning Validation in cGMP.

Design: New CV limits were calculated using updated formulas and compared with those in current use. PB-ECLs categories and Cleaning Validation Matrices were obtained from literature and adopted for the company's needs. A full cleaning validation protocol for Sodium Alendronate was followed using swab sample collection and analysis as a practical example.

Setting: Arrow Pharm (Malta) Ltd. Hal Far.

Main Outcome Measures: Recovery & Analyses of Sodium Alendronate using Constix® swabs using Shimadzu & Waters HPLC systems.

Results: As cleaning limits of 5 of the products reviewed had changed, the company's documents were updated accordingly. All original PB-ECL categories for compounds manufactured were confirmed and a literature review link with cGMP was demonstrated. Cleaning Validation Matrices were set up. The total residue collected from production equipment used to manufacture Sodium Alendronate was of ~ 28mg (Limit = 125mg).

Conclusions: Retrospective analysis confirmed that over the past four years Arrow Pharm maintained an excellent standard in controlling cross-contamination as part of cGMP. New matrices developed will be part of the main tools used during the preparation of CV protocols and procedures. Equipment analysed was clean enough to be used for the production of another drug.

The Use of Process Analytical Technology (PAT)

Christian Mangani

Background: PAT is an alternative approach to conventional pharmaceutical manufacturing.

Objective: To apply PAT to an oral solid dose granulation, drying and blending process by means of NIR and to use it for tablet strength identification.

Design: A calibration model with NIR was created with binary mixtures and was tested. Calibration models were developed with NIR with multicomponent mixtures of Alendronate (standards) and were tested by means of a comparison study with HPLC. At pre-determined time points samples from 70mg/10mg batches were taken from granulation & drying and blending. NIR and HPLC analysis was performed on all samples. LOD analysis was performed on granulation & drying samples. By using real batches of Alendronate as standards a library was developed. The library was applied to 100 batches to perform tablet strength identification.

Setting: Arrow Pharm (Malta) Ltd.

Main Outcome Measures: Evaluation of NIR process monitoring technique, development of a fast non destructive model for tablet strength identification.

Results: Highly correlated results were obtained ($r=0.998$), with no significant difference ($p=0.969>0.05$) between the 2 apparatus. Highly correlated results ($r=0.999$) were obtained internally and with HPLC ($r=0.999, 0.991, 0.997$) and no significant difference ($p=0.226>0.05, p=0.809>0.05$) was encountered except for one model ($p=0.030<0.05$). Difference was not significant between the 2 apparatus for every time point for the 70mg ($p=0.244>0.05, p=0.244>0.05, p=0.396>0.05$) but significant for the 10mg ($p<0.05$). Misidentifications were obtained both during the validation process and during the analysis of the 100 batches mainly limiting the utility of this model.

Conclusion: Although very positive and encouraging results were obtained NIR's main utility is not in precision but in providing a fast approximate data cheaply and covering a larger batch proportion. The tablet analysis results indicate that the NIR distinguishes between similar strengths with difficulty.

Feasibility and Costing of carrying an LD₅₀ Determination in Malta

Christian Saliba

Background: To date, no facility exists in Malta that undertakes the Median Lethal Dose (LD₅₀) determination test that must be done on newly discovered pharmaceutical drug substances to classify their respective toxicity. Toxicity classification is a requirement for the transportation of these drug substances¹. Transportation of such substances to other countries for further testing is of significant importance to Malta since local laboratories lack such services.

Objective: To carry out a feasibility study to evaluate the possibility of setting up a LD₅₀ determination programme to be undertaken locally and to determine the cost of carrying such a test.

Design: The study was initiated by reviewing of pharmaceutical legislation with respect to animal experimentation in the European Union. Data was gathered on the requirements and costs in order to obtain a laboratory accreditation and licensing grant to perform such a test. The cost for acquiring the animals together with their housing and feeding requirements was mainly obtained by contacting suppliers. Comparable procedures for attaining the cost for the materials and man labour required to perform this test, were used.

Main Outcome Measures: Indication of the extent and cost of LD₅₀ testing, time taken and efficiency of LD₅₀ testing.

Results: The calculated cost to carry out an individual LD₅₀ determination test sum up to Lm879.56, of which Lm288.96 are costs for acquiring the animals, Lm149.49 are housing and feeding costs, Lm28.60 are costs of materials, Lm390.00 are labour costs and Lm2.51 are other costs. No additional fees are required to obtain the necessary licensing to perform such test.

Conclusion: The implementation of the LD₅₀ determination testing programme would act as an incentive to foreign pharmaceutical entities to conduct research and development for new pharmaceutical drug substances in Malta, since toxicology determination would be available. Consequently, this would spill benefits to the local general economy in terms of revenue generation and foreign direct investments as opposed to the current situation.

Reference

1. United Nations Economic Commission for Europe. Recommendations on the Transport of Dangerous Goods: Model Regulations. 14th ed. Switzerland: The Institute; 2005.

Statistical Evaluation of Stability Data

Anne Marie Spiteri

Background: The recently published ICH Q1E guideline entitled “Note for guidance on the evaluation of stability data” addresses the statistical evaluation of stability data that should be carried out when submitting registration applications for drug products.¹ However, this is addressed rather vaguely.

Objective: To draw up a guideline which explains the process of statistical analysis in a clear and detailed way.

Design: Initially, the steps that must be covered in evaluation of stability data were identified. These were found to be pooling of data, determination of whether data exhibits variability and change-over-time or not, and drawing up of confidence limits for the regression lines obtained. The process for the carrying out of each of these steps was determined, and these were then applied to the stability data of Lidocaine Hydrochloride injection, which was provided by Actavis. The main statistical methods employed were ANCOVA and regression analysis. The guideline was then drawn up.

Setting: Actavis Ltd. (Malta)

Main Outcome Measures: Development of a guideline on the process of statistical analysis.

Results: The main result obtained was a guideline, which covers the process of statistical analysis for drug products which come in a single container size and a single strength, a single container size and multiple strengths, multiple container sizes and a single strength, and multiple container sizes and multiple strengths.

Conclusions: Even though the ICH Q1E document is not yet enforced, this is expected to happen imminently. The guideline drawn up in this study will then be essential to pharmaceutical companies as an aid to the carrying out of statistical analysis in concordance with the current requirements.

Reference

1. EMEA. Note for guidance on evaluation of stability data (CPMP/ICH/420/02). London: The European Agency for the Evaluation of Medicinal Products; 2003.

Registration of Medicines in Malta

Julian De Gabriele

Background: Under European legislation all medicinal products to be placed on the Maltese market must be issued with an authorisation or licence. The Marketing Authorisation Division will set the requirements for the granting of market authorisations. This involves the submission of the required documents (such as Pharmaceutical Dossiers), which comply with E.U. directives and Maltese legislation. The previous Maltese system was based on the WHO certification scheme for pharmaceuticals moving in International Commerce.

Main Outcome Measures: Main issues regarding current registration procedures were determined. A comparison with EU countries with a population below one million was also carried out so as to identify new issues.

Results: There is a drastic decrease in number of medicines (over the last few years) in 2004, 8615 medicines were available to the public whilst in 2006 there were about 2610, that means a decrease of about 70%. This may be due to a number of reasons, a comparison of registration fees between Cyprus, Luxembourg, Malta and England showed that although Malta fares well against England it has remarkably higher registration fees when compared to Cyprus and Luxembourg. With regards to prices of medications, Maltese medicines are on average the most expensive when compared to Cyprus and United Kingdom with the United Kingdom being the least expensive by an average of 24%.

Conclusions: Major procedural differences between EU countries may not be found in their legislation as this is set by the European Union but in their respective agency operations such as fees charged and organisation.

References

1. Eudralex The rules governing medicinal products in the European union volumes 1 – 10
2. Chapter 456, Medicines Act 2003 (Laws of Malta), section 20
3. Medicines Regulatory Unit (MRU)- Health division Malta
4. Cartwright AC. Matthews BR. Pharmaceutical Product Licensing: Requirements for Europe: Ellis Horwood; 1991

A Quality System at the Gozo General Hospital Laboratory Services

Nicole Zerafa

Background: For a medical laboratory to be in a position to apply for accreditation, it must develop, implement and maintain a quality system in conformity with the international standard ISO 17025 (2005). Accreditation bodies, including the local National Accreditation Body, are assessing medical laboratories seeking accreditation against this standard.

Objective: To provide a basis for identifying the action to be taken by the Gozo General Hospital Laboratory Services to establish and implement a quality system satisfying ISO 17025. The laboratory will then be in a position to apply for accreditation.

Design: To determine the requirements for setting up a quality system, ISO 17025 and supporting literature¹ was obtained. An evaluation of the existing laboratory was undertaken to determine the degree of conformity with ISO 17025, producing a 'Gap Analysis'. Reference solutions were used to produce control charts determining system control.

Setting: Gozo General Hospital Laboratory Services (GGHLS)

Main Outcome Measures: Quality System upgraded according to ISO/IEC 17025 (2005).

Results: GGHLS were evaluated against ISO 17025 requirements producing a gap analysis. Actions to be taken to improve conformity were identified and compiled. The majority of the non-compliances were due to lack of resources and Management Reviews. The quality manual and system control were also upgraded.

Conclusions: A number of actions are to be addressed and implemented for the GGHLS to upgrade the quality system to conform to ISO 17025 (2005), eventually applying for accreditation. System control should be performed daily on each operating machine. The compiled list of recommendations may be used as a basis for a plan of action.

Reference:

1. A2LA Requirements for the accreditation of laboratories Assessor Checklist. USA: 2006. Taken from: www.a2la.org

Determination of Pancreatic Amylase in Gastric Juice

Joanna Vella

MRSA in Autopsy Cases

Marie Claire Camilleri Podestà

The Use of Performance Enhancing Agents in Sports

Andrew Corrieri

Phytochemistry and
Veterinary Pharmacy

The Identification of Plants with Pharmacological
Potential

Nigel Cauchi

Veterinary Pharmaceuticals - A Local Perspective

William Grech

Determination of Pancreatic Amylase in Gastric Juice

Joanna Vella

Background: The quantification of pancreatic α -amylase in gastric juice could aid in the detection of hyperamylasemia in the stomach due to duodenogastric reflux (DGR)¹.

Objective: To compare methods that quantify α -amylase activity and apply them to gastric juice.

Design: The Enzymatic Colorimetric Assay, Reflotron[®] method, Agarose method, Iso-electrofocusing (IEF) and the Phadebas[®] Amylase Test were used to test prepared standards of pancreatic and salivary α -amylase in Artificial Gastric Juice BP. Regression analysis was used to check correlation co-efficients (p 0.05).

Setting: Pharmacy Laboratory, Molecular Genetics Laboratory, University of Malta. Emergency Laboratory, St. Luke's Hospital.

Main Outcome Measures: Pancreatic α -amylase activity in gastric juice.

Results: Total α -amylase activity was observed using the Enzymatic Colorimetric Assay, the Reflotron[®], Agarose method, and the Phadebas[®] Amylase Test, whereas pancreatic α -amylase activity was observed using the Reflotron[®]. A calibration curve with a significant correlation of 0.999 was obtained for pancreatic α -amylase in gastric juice using the Reflotron[®] $y = 0.682x + -1.417$. A standard total α -amylase activity of 71.52 U/L gave a reading of 27 U/L using the Enzymatic Colorimetric Assay. A standard total α -amylase activity of 450 U/L gave a reading of 457 U/L using the Phadebas[®] Amylase Test. Iso-amylase bands were observed by IEF. A pH range for pancreatic α -amylase in gastric juice was obtained between 4 and 10.

Conclusions: Total α -amylase in gastric juice can be quantitatively analysed using the Enzymatic Colorimetric Assay, the Reflotron[®], Agarose method, and the Phadebas[®] Amylase Test. Pancreatic α -amylase can be quantified using the Reflotron[®] and qualitatively analyzed by IEF. Pancreatic α -amylase is irreversibly denatured at a pH of less than 4.

References:

1. Pohle T, Domschke W. Gastric function measurements in drug development. Br J Clin Pharmacol 2003;56:156-64.

MRSA in Autopsy Cases

Marie Claire Camilleri Podestà

Background: MRSA has become a public threat, both in hospitals and more recently in the community¹.

Objective: The aim of the study is to see whether hospital stay predisposes to nasal colonisation with *Staphylococcus aureus* and MRSA when compared to a second cohort that had not been admitted to hospital in the previous six months.

Design and Setting: Nasal swabs were taken from cadavers undergoing post-mortem examinations. The nasal swabs were first cultured on Mannitol Salt Agar (MSA). Yellow colonies from the MSA were sub-cultured on blood agar, nutrient agar and DNase agar and catalase, coagulase and DNase tests were then performed. *Staph. aureus* is catalase, coagulase and DNase positive. A Gram-stain was used to identify Gram positive cocci in clusters. Vitek[®] Gram Positive Susceptibility Cards were used for antibiotic susceptibility. MRSA positive organisms were tested using Penicillin Binding Protein Latex Agglutination, which is a confirmatory test for MRSA.

Setting: Mortuary and Bacteriology Lab, St. Luke's Hospital

Main Outcome Measures: Chi-squared tests were carried out to determine any relationship between the two cohorts.

Results: A total of 93 swabs were taken from cadavers undergoing post-mortem examination. The proportion of *Staph. aureus* nasal carriage was similar in both groups, that is 36% in the hospitalised group and 37% in the non-hospitalised group. However, there are striking differences between the hospitalised and the non-hospitalised group in the incidence of MRSA and MSSA carriage. 53% of the *Staph. aureus* carriers in the hospitalised group were MRSA positive, compared to 21% of the *Staph. aureus* carriers in the non-hospitalised group.

Conclusions: These results show that hospitalisation increases the incidence of MRSA carriage compared to the non-hospitalised population. However, due to the limited number of cases studied the p value of 0.0505 shows that this difference is nearly statistically significant. Although MRSA in the nosocomial setting is significantly higher, Community-Acquired MRSA is on the increase and is associated with both colonisation and infection.

Reference

1. Mandell, Douglas, Bennett. *Staphylococcus aureus (Including Toxic Shock Syndrome)*. In: Mandell G, Bennett J, Dolin R, editors. Principles and Practice of Infectious Diseases. 6th ed. United States of America: Elsevier Churchill Livingstone; 2005. p. 2321-2348.

The Use of Performance Enhancing Agents in Sports

Andrew Corrieri

Background: Athletes in Malta use a variety of substances in attempts to improve sport performance. This represents a special challenge for educators, health professionals, and sport authorities.

Objective: To assess the prevalence of use of presumed performance-enhancing drugs, to find out if users are knowledgeable about what they are doing and whether they are familiar with the reasons for using ancillary drugs and to make athletes aware of the adverse effects of drug use for non-medical purposes in sport.

Design: Interviews were carried out with various local and foreign athletes. A survey was conducted by means of bilingual questionnaires, consisting of opened-ended and closed-ended questions, distributed in the main gyms and health & fitness clubs around Malta and Gozo. Questions were asked more than once with the wording in a different format to ensure more accurate replies.

Setting: gyms, health and fitness clubs in Malta and Gozo

Main Outcome Measures: Number of persons reporting the use performance-enhancing drugs, the extent of knowledge of the abusers, the attitudes underlying the decision to take anabolic-androgenic steroids and the nature of such drug-taking activities.

Results: From the initial study 59% (n=26) were drug users and 41% (n=18) non-drug users. Of the drug users 77% were adequately informed, 4% were insufficiently informed and 19% were dangerously uninformed. Drug users and non-drug users alike said they were willing to learn more about the dangers associated with the drug use.

Conclusion: Although users continue to use these substances despite their knowledge of possible health risks there is an urgent need for the provision of detailed clinical information regarding the dangers of performance enhancing substances to health care professionals.

The Identification of Plants with Pharmacological Potential

Nigel Cauchi

Background: In the past, Maltese medicinal and aromatic plants had important medicinal uses (Lanfranco, 2001).

Objectives: To obtain extracts from 10 plant species of the Asteraceae family namely *Aster squamatus*, *Glebionis coronaria*, *Calendula arvensis*, *Carlina involucreta*, *Dittrichia viscosa*, *Galactites tomentosa*, *Inula crithmoides*, *Leontodon tuberosus*, *Reichardia picroides* and *Sonchus oleraceus*. To identify which constituent classes are present. To determine whether the extracts are pharmacologically active and whether the active extracts possess immunostimulatory properties.

Design: The first step involved extraction from plant material utilising five solvents/solvent systems namely distilled water, absolute ethanol, distilled water/absolute ethanol (1:1 mixture), petroleum ether and chloroform. Phytochemical analysis was then carried out to determine which constituent classes are present. The Brine Shrimp Test (BST) was used as primary screening to determine which extracts are pharmacologically active. Lymphocyte activation tests were then carried out on pharmacologically-active extracts.

Setting: Extractions were carried out at the Agricultural Services Laboratories located at the National Agricultural Research and Development Centre. The rest of the project was carried out at the Pharmacology Tissue Culture Laboratory, University of Malta.

Main Outcome Measures: Determining presence or absence of plant constituents, determining which extracts are pharmacologically active and whether these extracts possess immunostimulatory properties.

Results: Six extracts were found to test positive for the BST. Five of these were chosen for lymphocyte activation assays together with a non-pharmacologically active extract (negative control). Three extracts caused lymphocyte activation. Two of these extracts resulted in cellular apoptosis while the other resulted in lymphocyte proliferation. All six extracts showed a low cytotoxicity.

Conclusion: The pharmacologically active extracts contained predominantly terpenoids and flavonoids. The extract with immunostimulatory properties was the petroleum ether extract of *Calendula arvensis*.

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Veterinary Pharmaceuticals - A Local Perspective

William Grech

Background: On 1st May 2004, the Maltese Islands joined the European Union (EU). With the introduction of Directive 28/2004 a rigorous registration process came into existence and a yearly Lm 25 registration fee per item was incurred by importers (Director Veterinary Diagnostics). It was unclear what effect this had on the availability of veterinary pharmaceuticals and its bearing on the veterinary pharmacist.

Objectives: (i) Investigating the impact Directive 28/2004 had on the availability of veterinary pharmaceuticals locally, (ii) providing an explanation to (i) and (iii) examining the perception of the veterinary pharmacist by veterinarians and role in Animal health.

Design: This research is three pronged. Phase 1 - Data on veterinary pharmaceuticals available before and after EU accession was gathered and recorded in spreadsheets using 'Microsoft Office Excel (2003 Edition)'. Phase 2 - Questionnaires were distributed to all eight veterinary pharmacists. This survey aimed to inform the investigator on current practices in Veterinary pharmacy. Phase 3 - Questionnaires were distributed to all twenty-two practising veterinarians. The latter complemented Phases 1 and 2 apropos the availability of medicines and perception towards veterinary pharmacist.

Setting: Veterinary Pharmacies

Main Outcome Measures: Veterinary registered products, veterinary pharmacy practice.

Results: Phase 1 - Following EU accession, a reduction in registered products from 428 to 173 was observed. Phase 2 - Seven out of eight (87.5%) veterinary pharmacists participated. Five (71.4%, n = 7) reported to be regularly consulted by veterinarians. All agreed that the undergraduate pharmacy course does not provide pharmacists with key competencies in animal health. Phase 3 - Out of twenty-two practicing veterinarians, sixteen (72.7%) participated in the study. Twelve (75.0%, n = 16) participants claimed that there are classes of drugs missing.

Conclusions: The registration fee and a rigorous registration process contributed to the medicines availability problem. Although veterinary pharmacists are trusted professionals, training in veterinary pharmacy is required in the undergraduate pharmacy course.

Pharmacist Intervention in Secondary Care Specialised Settings

Alison Anastasi

The Training Issues and the Introduction of Good Manufacturing Practice
in a New Pharmaceutical Manufacturing Facility

Karl Bartolo

Medical Oxygen

Romina Briffa

Quality-of-Life and Cost-Effectiveness in the Treatment
of Parkinson's Disease

Chantel Ellul

The Study and Evaluation of Wholesale Distribution Systems
in Malta and the Setting Up of a Partial Manufacturing Unit

Owen Farrugia

Validation and Evaluation of Automated Dispensing Systems
in Primary Care

Daniela Sciortino

Pharmacist Intervention in Secondary Care Specialised Settings

Alison Anastasi

Clinical pharmacy services have developed in response to the demand for pharmacy advice at ward level and the need to contribute to the process of collaborative drug therapy management. This project aims in understanding the need for pharmaceutical care in specialities such as general surgery and in the emergency setting, by observing and practising a systematic approach to identify and solve drug-related problems. This proactive use of the pharmacist's skills will improve the quality of patient care and lead to great team working.

The Training Issues and the Introduction of Good Manufacturing Practice in a New Pharmaceutical Manufacturing Facility

Karl Bartolo

If wrongly prepared, medicines have the potential to cause great harm. A good quality system ensures that drugs are manufactured to adequate levels of quality, safety and efficacy. This project aims at outlining the principal requirements of a quality system, focusing mainly on Good Manufacturing Practice, and the implementation of a training program for employees working within a new pharmaceutical manufacturing facility.

Medical Oxygen

Romina Briffa

This project describes the implementation of the system required for the setting up of a medical oxygen manufacturing plant that operates in accordance with the stipulations of GMP principles. All stages involved in the start-up phase from premises layout planning, to preparation of a quality system, employee training, and operational qualification will be addressed. Validation methodologies together with their results will also be presented.

Quality-of-Life and Cost-Effectiveness in the Treatment of Parkinson's Disease

Chantel Ellul

The difference in the quality of life for patients under medical treatment with dopamine agonists, levodopa and adjunct entacapone in different stages of Parkinson's disease is determined. A protocol on the optimal way to introduce adjunct entacapone when treating Parkinson's Disease will be developed and evaluated. The study also adopts a comparative approach in the effectiveness and costs of adjunct entacapone to standard treatment with levodopa and dopamine agonists in the different stages of Parkinson's Disease.

The Study and Evaluation of Wholesale Distribution Systems in Malta and the Setting Up of a Partial Manufacturing Unit

Owen Farrugia

The Pharmaceutical business from Manufacture to distribution has evolved to a highly regulated business and operates at a high level of quality assurance, achieving its pharmaceutical quality objectives by observing Good Manufacturing Practice (GMP) to manufacture medicinal products which must then be authorised for marketing on the basis of Quality, Safety and Efficacy. This study aims at evaluating the Quality Management Systems involved which would lead to a positive audit by Health Authorities, and setting up a Partial Manufacturing Unit which would be operating under Good Manufacturing Practice, in line with National legislation and EU Directives.

Validation and Evaluation of Automated Dispensing Systems in Primary Care

Daniela Sciortino

An automated dispensing system which allows for communication with the pharmacist via an internet connection allows patients to obtain medications on a 24-hour basis and in areas where retail pharmacies are not viable. Validation of the services provided from the automated dispensing system will be carried out and compared to the same services offered from community pharmacies. Patients' and pharmacists' perception of automated dispensing system will be evaluated.

The Influence of the Formulation on the Release of Doxazosin

Alison Abela

Malta Pharmaceutical Products List

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Reverse Engineering of the Ecstasy Tablet

Edwina Bajada

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Lesley Anne Cini

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Janis Vella

Preparing Liqueurs using Local Medicinal Plants

Matthew Vella

The Influence of the Formulation on the Release of Doxazosin

Alison Abela

Abioequivalence study of a generic form of doxazosin is being carried out. The method involves plasma protein precipitation using methanol. The structurally related compound prazosin is used as an internal standard. Doxazosin is being detected in human plasma using high performance liquid chromatography (HPLC) with fluorescence detection over the concentration range of 1-20ng/ml.

Malta Pharmaceutical Products List

Ilona T. Attard

A list of all pharmaceutical products which are currently being marketed in Malta is being compiled and will be presented in the form of a book. The handbook is currently being designed using the BNF as a model. An evaluating questionnaire is also being produced which will be then given with a sample copy which clearly shows how the list is going to be structured. Pharmaceutical industries, pharmacies, distributors and other large companies are being contacted as possible sponsors for the publication of this book.

Reverse Engineering of the Ecstasy Tablet

Edwina Bajada

Processing methods of drugs of abuse into dosage forms for recreational use are neither known nor documented. Hence, the clubber has no guarantee of quality or efficacy, let alone the content of drug one is consuming. The aims of this study are to determine the quality and content of Ecstasy tablets that are obtained during during police raids by using pharmaceutical tests to determine the quality of manufacture of the tablets. A series of data, that can be used for drug profiling by Maltese forensic intelligence, Toxicology Department and the Law Courts is compiled.

Chronopharmacology and Diabetes

Marisabelle Bonnici

Chronopharmacology deals with circadian rhythms endogenous in the body. A continuous blood glucose monitoring system will be used for diabetic patients receiving insulin therapy in order to evaluate glycaemic control. During the monitoring the patients will be asked to keep a diary recording food intake, insulin administration and physical activities. The relevance of time of insulin dosing and type of insulin used is assessed.

A Concise Overview of the Uses of Oxygen

Dianne Butler

This project aims to compile an overview of the uses of medical oxygen, targeted to a learned audience. Currently used protocols for the management of respiratory, cardiac and traumatic conditions will be presented and discussed. The application of medical oxygen in the management of the aetiological manifestation of a number of clinical conditions widens the scope for the publication of information regarding its uses.

Stoma Care

Paula Cardona

Stoma care patients may encounter problems which may be minimised with the right advice and counselling by stoma nurses and pharmacists. This study will be an evaluation of the pharmacists' intervention in stoma care. A survey will be carried out to analyse the various problems related to stoma care and observe how they are currently handled by patients and pharmacists.

A Concise History of Medical Oxygen

Jana Roberta Chetcuti

The understanding of pharmacological therapies in contemporary use are enhanced through knowledge of their discovery, development and subsequent entrenchment into current pharmacotherapeutic armamentaria. This study intends to follow this course for medical oxygen by outlining the events which subsequent to its discovery as an elemental gas have placed it at the forefront in the management of respiratory, cardiac, and traumatic pharmacotherapy. Landmark clinical trials will be identified and used to illustrate this evolutionary process for medical oxygen.

Training of Operators in a Medical Oxygen Manufacturing Plant

Lesley Anne Cini

Training a cohort of operators in GMP principles requires even greater importance during the start-up phase of manufacture owing to the difficulties inherent in imparting the concepts of self discipline, accountability, and precision which are the

inherent philosophies of GMP. This study aimed to address these issues during the start-up training phase of a local Medical Oxygen manufacturing plant that is currently in the process of acquiring a manufacturing license. Training material was prepared for the operators working at the plant, with emphasis being made on user friendliness, accessibility to the tutor, and the implementation of a hands-on approach for the participants. The effectiveness of this training methodology was evaluated through examination of the participants, which also identified pertinent changes that could improve the quality of future training sessions.

Pharmaceutical Care Aspects in Systemic Lupus Erythematosus

Lucia Conti

A database for patients attending the Rheumatology Clinic was compiled during summer of 2005 and 2006. Out of 254 patients, 12.64% (n = 35) suffer from SLE, in a ratio of females is to males of 10:1. Guidelines on prescribing and monitoring issues of drugs used in SLE were prepared and validated by an expert panel. The SLEQOL and SF-36 questionnaires were administered to the patients at baseline and 14 weeks after the pharmacist's intervention. Results show that there was a significant improvement in the physical function of the patients, following the pharmacist's intervention.

The Pharmacist and Good Drug Distribution Practice

Ariane Darmanin

Monitoring and record-keeping processes are integrated in a pharmacist's role, in sectors spanning from wholesale to community pharmacy. Current and impending legislations, regulations and codes concerning the present distribution of medicinal products assist and guide pharmacists. An integrated database aids in achieving fast, efficient and cost-effective traceability, ensuring product security and patient safety.

Nutrition in Diabetic Patients

Yanika Degiorgio

A questionnaire was distributed to 100 restaurant owners to assess the knowledge of establishment owners on diabetes, and to identify whether a special menu for diabetics is present and if not whether they are willing to introduce a special menu for such patients. Patient compliance with the diet proposed by the Diabetes Clinic and feedback on special menus offered by restaurants is assessed amongst 50 patients attending the Diabetes Clinic at St Luke's Hospital.

The Feasibility of Clinical Trials in Malta

Claudia-Ann Farrugia

The study aims at assessing the need of personnel required to run a clinical trial, and the availability of such professionals possessing the knowledge, training, and possibly experience. Semi-formal, open-ended interviews are being conducted with professionals in the pharmaceutical industry, healthcare sector, regulatory affairs section and trade sector, to obtain information about the current situation of clinical trials locally. The basic features of an adequate facility in which clinical research can be conducted on patients will be designed.

Treatment Protocols in Pregnancy

Roberta Fenech

Protocols, which were developed in a previous local study, were reviewed and modified, and new ones were developed. A focus group consisting of a gynaecologist, two general practitioners and five pharmacists was set up to evaluate the protocols on dyspepsia/nausea and vomiting, headache/migraine, urinary tract infections and vaginal infections in pregnancy. A copy of the protocols together with a questionnaire will be distributed in every pharmacy to assess pharmacist compliance with the protocols.

Herbal Medicine Formulary

Julienne Galea

A compilation of local herbal medicine is prepared. Information includes indications, precautions, contra-indications and side-effects, dosage regimens as well as any known drug interactions for herbal medicines available locally. The formulary is intended for pharmacists and other health care professionals to refer to as a quick reliable reference in the prescribing and dispensing of herbal medicine or in checking for possible interactions with drugs.

Newsletter for Community Pharmacists

Rachel Galea

A newsletter for community pharmacists is produced to provide information to the community pharmacist, to improve communication and to focus on the pharmacist role as a provider of patient health care as opposed to solely a supplier of medication and to promote updates regarding medications and other community pharmacist related issues.

Diuretics in Elderly Patients

Maria Grech

Treatment protocols regarding the use of diuretics in hypertension, congestive heart failure (CHF) and nephrotic syndrome in the elderly have been drawn up. A pilot study has been carried out in order to assess the applicability of the method and to validate the data sheet. The pilot study consisted of a sample of ten patients. At this stage more patients are being recruited for the actual study.

Newsletter for the Pharmacy Department

Yan Grima

The Pharmacy Department Newsletter is produced bimonthly. To date two issues have been printed and distributed. The newsletter's aim is to improve the communication between the Pharmacy Department and the pharmacy working sector as well as the pharmacy students. The newsletter contains a variety of interesting articles and reports all events related to the Department at the time of issue. It also includes several works of students, namely student projects along with their contact addresses which gives an opportunity to readers to contribute to these projects.

Quality Manual for Community Pharmacies in Kenya

Rahima Hamed

A Quality Manual for pharmacies in Kenya has been developed according to the required standards. Observation studies and quality assessment methods were carried out prior to implementation of the Manual. The Quality Manual is now being implemented in 5 community pharmacies in Mombasa and 5 in Nairobi. A final quality assessment method is to be carried out after a year of the implementation so as to assess impact of the quality manual on the professional services provided from community pharmacies.

Packaging Processes in the Pharmaceutical Industry

Mariella Mercieca

The objective of this study is to identify the process variables and parameters that may affect the blister packing and thus ensure a finished product packed to the required client and cGMP specifications. Challenge testing is currently in progress on parts of the line, such as the camera and the thermoformer, which are mainly responsible for compliance.

Chemokine Receptor Transcriptional Regulation: Pharmacogenetic Implications for Asthma Therapeutics

Michael Portelli

The project will study the promoter arrangement of a pharmacogenetically relevant chemokine receptor protein. mRNA was extracted from a relevant receptor expressing cell line and was used as a template for 5'RACE analysis. Cloning of the RACE products, already undertaken, will be followed by sequencing and software-based alignments with the human genome database, in order to map the transcriptional start site(s). The upstream promoter region will then be studied using appropriate bioinformatics platforms and luciferase based reporter assays.

Penetration of Anti-bacterial Agents in the Peripheries

Alfie Palmier

The concentration of three anti-bacterial agents, amoxicillin, metronidazole and imipenem reaching the infection sites of patients with gangrene will be examined in tissue removed during surgical intervention. Correlation between plasma concentration of the mixture of antibacterial agents used and concentration reaching the peripheries will be determined using High Performance Liquid Chromatography.

Palliative Care in Cancer Patients

Maresca Pizzuto

A protocol for pharmacist intervention as a hospice pharmacist is developed and implemented to assess the impact of the pharmacist professional input on patients' care. In this protocol, framework for the development of a pharmaceutical care plan and documentation sheets have been prepared. Four patients were selected at random, visited by the pharmacist who prepared a documentation sheet, which included all the regular medications taken, their strength, the reason for taking them, and the dosing frequency. Patients were interviewed, and were each given a close-ended questionnaire to measure their quality of life.

Advice to Patients on Oxygen Therapy

Analise Scerri

A survey method using pre-test and post-test methodology will be adopted to evaluate the effectiveness of an information

handbook for patients on oxygen therapy. The handbook has been prepared in both Maltese and English, and has been reviewed by a panel of experts in the field of oxygen therapy. A questionnaire designed to test the effectiveness of the handbook has also been prepared and is currently being validated. The questionnaire will assess the impact of the handbook as a means of educating patients regarding all aspects of oxygen therapy, including correct use, equipment handling, and precautions that should be observed.

Pharmacy Technicians in Malta: Roles and Interventions

Judith Sciberras

The aim of the study is to measure out the pharmacy professionals' perception towards pharmacy technician roles and educational needs. A questionnaire was designed and distributed amongst a randomly chosen sample of pharmacists and pharmacy technicians from the different sectors in which they perform. From the questionnaire appropriate suggestions targeting the pharmacy technician in Malta will be proposed to improve the image of the pharmacy technician for a better healthcare service.

Design of Androgen and Oestrogen Receptor-targeted Ligands using 3D computer modelling

Nicole Scicluna

The androgen ligand-receptor complex (PDB ID: 1e3g) was visualized using Sybyl(r). The ligand was separated from the complex and was used as a starting point to create a seed structure. Chemical groups known to exhibit important interactions with the receptor were selected. "Growing sites" were labelled for the GROW module in LigBuilder(r). A pharmacophore model for the receptor active site was derived using the POCKET module in LigBuilder(r). The fitness score of the newly generated ligands will be evaluated by considering chemical viability as well as binding affinity.

Bioequivalence Study of Doxazosin; A Cost-Effectiveness Analysis

Amy Tanti

The cost evaluation is calculated in the context of two possible scenarios; (1) carrying out the study within an existent laboratory and factoring in only equipment maintenance and running costs of the study; (2) actually setting up a dedicated bioequivalence laboratory, taking equipment capital expenditures into account. These estimations shall be used to determine the feasibility of setting up such a laboratory locally by comparing the costs incurred with those charged by contract research organizations using the bioequivalence study on doxazosin as a case study

Hospital Pharmacist's Intervention: The Parkinson's Disease Sleep Scale

Janis Vella

A movement disorders clinic is being attended, in order to observe elderly patients suffering from Parkinson's disease. Demographic data is being collected (including mental test score, Hoehn and Yahr status, current medication being taken by the patient as well as any co morbidities present). The Parkinson's disease sleep scale and a questionnaire related with compliance to medications is completed by each patient. Also, a sheet giving advice in sleep hygiene is being handed out to each patient.

Preparing Liqueurs using Local Medicinal Plants

Matthew Vella

The study deals with the extraction of active principles from the plant *Rosmarinus officinalis*. Solvent extraction methods were employed on plants picked from wild and cultivated areas. A mixture of the plant extracts, with alcohol, sugar and glycerin; together with fermentation and distillation will yield a palatable liqueur of medicinal value.

The Pharmacy Practice Resource Unit (PPRU)

Simone Bartolo

Monitoring Outcomes in Infant Colic

Sonia Bonnici

Formulary for Non-BNF Cited Items

Doriella Cassar

Diabetic Patient Management

Jeffrey Cassar

The Development of a Protocol for the Treatment of Cancer Pain

Ambra Cauchi

Validation of Protocols for Skin Conditions

Trevor Darmanin

Formulary for the Management of Mental Disorders

Corinne Elbourne

Treatment Protocols in the Gastro-Intestinal Tract

Steven Ellul

Progressional Development for Pharmaceutical Industry

Stephanie Farrugia

Compliance Issues in Hypertensive Care

Charyl Fava

Osteoporosis

Judith Fenech

Prescribing of Antibiotics

Ritienne Fenech

Standard Operating Procedures for Bioequivalence Studies

Claire Galea

Use of Intravenous Infusion Fluids in Hospital

Ruth Gatt

Vitamin D Inadequacy among Post-Menopausal Women

Erika Griscti

Management of Rheumatoid Arthritis

Suzanne Griscti

Computerised Medication Records

Daniela Hili

Directory of Pharmacists: Present Status and Future Predictions

Sarah Marie Hili

Computerized Records of Medication Errors

Mark Magro

Validation of Protocols for Paediatric Care

Stephanie Liane Magro

Quality of Medical Devices

Stephanie Mallia

Validation of Protocols for the Treatment of the Common Cold

Deborah Mercieca

Drugs and Art

Clint Pace

Development of Patient Leaflets

Fabienne Sant Portanier

Attitudes Towards Pre-Conceptional Care in Women with Diabetes Mellitus

Karen Sapiano

Denture Hygiene within the Elderly Population

Roberta Scalpello

Development of Information Leaflets on Anxiety and Depression

Maria Scerri

Devising a Course to enhance Prescribing Competence

Analise Schembri

Structure Based Drug Design: HIV Proteases as a Case Study

Clinton Schembri

Drugs used in Ophthalmology

Jasmine Vella

The Pharmacy Practice Resource Unit (PPRU)

Simone Bartolo

The PPRU is being developed as a source of drug information to help pharmacy students, post-graduates and tutors. It demonstrates the range of drug information sources that are available and enhances the student's learning experience in the use of medical devices. Pharmacy students can practice the dispensing of pharmaceuticals. It is the ideal setting for tutorials.

Monitoring Outcomes in Infant Colic

Sonia Bonnici

Health care professionals in 4 well baby clinics and 10 pharmacies are presented with an adapted leaflet which presents information on infant colic. Parents will be given an infant colic diary card before and after the health care professional intervention. One well baby clinic and pharmacy respectively will be used as a control, where there will not be any intervention by the health care professional. The infant colic diary card is used so as to document frequency of colic attacks and management.

Formulary for Non-BNF Cited Items

Doriella Cassar

Updating and maintenance of the publication, which presents information on medication and medical devices, not listed in the British National Formulary, is undertaken. This is being carried out by using the list of the medicinal products available from the Medicines Authority (MA), and, by contacting local importers. An evaluation of the updates frequency is undertaken by taking account of the medical products added and removed. The publication, which presented 388 entries, is being updated with information for 998 products.

Diabetic Patient Management

Jeffrey Cassar

This project aims to identify the various problems encountered by diabetic patients when carrying out self-monitoring of blood glucose levels. The education programme currently available at St. Luke's Diabetic Clinic is assessed and an evaluation sheet is prepared. Patient outcomes through HbA1c levels are monitored over a one year trend so as to determine the effectiveness of the education programme.

The Development of a Protocol for the Treatment of Cancer Pain

Ambra Cauchi

The Brief Pain Questionnaire (BPI) will be used to evaluate the frequency and extent of pain of 50 oncology patients. The effect of pain on their QOL will be determined by the FACT-G questionnaire (taken before and after treatment). A comparison of drugs administered, will be used to devise a protocol for Cancer pain treatment.

Validation of Protocols for Skin Conditions

Trevor Darmanin

Protocols on insect bites and stings, athlete's foot and eczema are being reviewed and will be validated amongst a focus group consisting of three general practitioners, ten pharmacists and a dermatologist. The protocols will be published in both hard copy and electronic formats and will be accompanied by a drug database for relevant drugs. The protocols will be implemented in pharmacies to evaluate their practical implementation.

Formulary for the Management of Mental Disorders

Corinne Elbourne

A questionnaire was developed and validated. It was then distributed amongst healthcare workers at Mount Carmel Hospital (MCH). The questionnaire was used to identify what information healthcare professionals require in the formulary. The formulary has been compiled and contains information about the products available at MCH, including pharmacokinetics of drugs such as half-life and protein binding. The first draft of the formulary will be printed and distributed at MCH for evaluation by healthcare professionals.

Treatment Protocols in the Gastro-Intestinal Tract

Steven Ellul

Gastro-Intestinal (GI) disorders such as gastro-esophageal reflux disease (GERD) are commonly present in a pharmacy. Treatment protocols consisting of step-by-step guidelines for GERD and Upper GI treatments, and definition sheets are being developed. The protocols will then be distributed to 10 community pharmacies to test their applicability and practicality in community pharmacies. Subsequently the protocols will be evaluated by a specialist

Professional Development for Pharmaceutical Industry

Stephanie Farrugia

Job requirements for different positions in the pharmaceutical industry, then seeing how much and what type of training was given to each employee and how much money was spent is assessed. Employees will be questioned as to whether they feel more confident in their position after they were trained, if they feel they need more or less training or if the training should be done in a different manner.

Compliance Issues in Hypertensive Care

Charyl Fava

An evaluation on compliance amongst patients suffering from hypertension is undertaken in community pharmacies. Ten community pharmacies distributed around Malta have been chosen. A questionnaire including factors such as gender, age, level of education and medications has been designed and validated by physicians and pharmacists. A pilot study is being carried out where 10 patients are being interviewed and their blood pressure monitored.

Osteoporosis

Judith Fenech

An evaluation of the knowledge, risk factors and the services available for patients suffering from osteoporosis will be carried out by means of a validated questionnaire distributed to 100 patients at the Bone Density Clinic. A comparison between local treatment and that of the NICE guidelines will also be carried out by interviewing 30 health care professionals including rheumatologists, general practitioners and gynaecologists. The patient questionnaire was also translated in maltese and Ethics Committee approval has been obtained.

Prescribing of Antibiotics

Ritienne Fenech

A system for pharmacist prescribing of antibiotics was suggested. Protocols are being written to describe the issue and dispensing of the prescriptions by the pharmacist, preservation of records and internal control of this system. A pharmacist antibiotic prescribing form and a patient antibiotic control card were drafted in accordance to local legislation. The role of an Antibiotic Society to promote and control the rational use of antibiotics is being investigated.

Standard Operating Procedures for Bioequivalence Studies

Claire Galea

This study focuses on the documentation required to carry out bioequivalence studies in conformity with principles of Good Laboratory Practice (GLP). General Policy Statements, a Quality Manual, and Standard Operating Procedures (SOPs) will be prepared for a bioequivalence study that seeks to compare the in vivo characteristics of a generic preparation of doxazosin and its originator counterpart Cardura® which will be taken as a case study. The prepared SOPs will be critically evaluated in the context of the actual carrying out of the study, such that required modifications will be implemented. The resulting set of SOPs will then serve as templates for future bioequivalence studies.

Use of Intravenous Infusion Fluids in Hospital

Ruth Gatt

The aim of this project is to examine the service operation employed at St. Luke's Hospital as regards the preparation of intravenous infusions. The main types of drugs that are given through infusions are recorded. The

storage procedures and the aseptic techniques employed in the preparation areas, are looked into to assess the most crucial points of contamination and intravenous medication errors.

Vitamin D Inadequacy among Post-Menopausal Women

Erika Griscti

The prevalence of vitamin D inadequacy among Maltese postmenopausal women is investigated. Women will be assessed by means of a medical history questionnaire which is prepared and validated. 500 women will be taking part in this study. Research Ethics Committee approval has been obtained. The serum 25-hydroxy vitamin D levels will be evaluated by means of ELISA kits.

Management of Rheumatoid Arthritis

Suzanne Griscti

A leaflet is prepared for patients taking hydroxychloroquine, as part of their treatment for rheumatoid arthritis. Furthermore, the Horne et al Patient Knowledge Questionnaire will be distributed to the patients. In another questionnaire the patients' functional ability will be assessed using the Stanford HAQ 20-Item Disability Scale. This study will be carried out on 100 patients.

Computerised Medication Records

Daniela Hili

A database will be created containing information about the patients such as I.D. number, name and surname, telephone number and their medication. A Medication record from St Luke's hospital will be used as a reference. The database is being created by using the programme MySQL. Once the database is completed with all the information it will be placed on a website by using PhP.

Directory of Pharmacists: Present Status and Future Predictions

Sarah Marie Hili

An update and publication of a new edition of the Maltese Directory of Pharmacists is being carried out and will be available both as a hard copy and online. This data will also be analysed to discover trends to draw up the future predictions of the pharmacists' workforce requirements in Malta.

Computerized Records of Medication Errors

Mark Magro

With the aid of PhP (a hypertext processing language) a website will be designed and implemented. Besides PhP another program, MySQL, will be used to build up a database inside the website. The Database will include commonly occurring medication errors, and it will also include ways and means by which some of these medication errors are reduced and eliminated.

Validation of Protocols for Paediatric Care

Stephanie Liane Magro

The project consists of evaluating and updating three locally previously set up protocols about symptoms in paediatric patients of vomiting, diarrhoea and constipation, together with the development of two protocols about the symptoms of fever and cough. The protocols will be validated by a group of professionals consisting of 4 community pharmacists, 3 paediatricians and 3 general practitioners. The protocols will be tested for their applicability and practicality in 10 community pharmacies. To date the previously developed protocols were updated and the other two protocols were devised.

Quality of Medical Devices

Stephanie Mallia

Four different blood glucose meters and four different blood pressure monitors are used on volunteers in the pharmacy and the hospital setting. Volunteers are tested with all of the four blood glucose meters or blood pressure monitors and the values are recorded and analysed. 50 volunteers will be used for the blood glucose meters test

and another 50 volunteers will be used for the blood pressure monitor test.

Validation of Protocols for the Treatment of the Common Cold

Deborah Mercieca

The protocols established in a previous local study for the management of common colds were modified and reviewed to incorporate current trends in pharmacist prescribing. They will now be validated amongst a panel of experts, consisting of 10 pharmacists, and 10 doctors and medical specialists. Once validated, any further modifications necessary will be made, and subsequently they will be tested in 20 community pharmacies around Malta and Gozo.

Drugs and Art

Clint Pace

The project incorporates evaluating compiled data to examine whether the use of drugs brings about greater achievements for the artists. Achievements will be considered in different ways by evaluating the socio-economic circumstances during the artist's lifetime and later successes. As part of the project a timeline has been developed on the artists, drugs available and whether there is reason to believe the artist made use of it. Together with available data on the subject, the general attitude of local and international art scene towards this subject will also be taken into consideration.

Development of Patient Leaflets

Fabienne Sant Portanier

The design factors of Patient Information Leaflets (PILs) for 229 non-prescription medications were analysed to determine reading ease and comprehension. One PIL from each pharmacological class (n=17) will be edited to improve on the readability. Each newly edited PIL will be distributed to 20 patients to evaluate the benefits of the changes made. To date four PILs (23.5%) have been edited.

Attitudes Towards Pre-Conceptional Care in Women with Diabetes Mellitus

Karen Sapiano

Diabetic women aged 15-30 years will be invited to fill an anonymous self-administered questionnaire during a routine visit to the diabetes clinic and the information obtained will be used to design intervention protocols. The study will help identify the ideal means of reaching out to diabetic patients. Methods to be investigated include a well designed information leaflet, a website and the use of regular counselling groups within the Malta Diabetes Association and the Health Education Unit of the Diabetes Clinic framework.

Denture Hygiene within the Elderly Population

Roberta Scalpello

The relationship between denture hygiene and the oral *Candida* spp count in an elderly denture-wearing population is investigated. An expectorated, single, saliva sample in a sterile disposable single-use container will be taken from each participant in the study and the results of each test carried out will be correlated with a questionnaire, regarding denture hygiene, previously completed by the participants. The subjects will be recruited from Government residential homes for the elderly all over Malta.

Development of Information Leaflets on Anxiety and Depression

Maria Scerri

Information leaflets about depression and anxiety are being set up and designed with the help of the Health Care Promotion Department and a review group consisting of psychiatrists, psychologists, pharmacists, general practitioners, pharmacy students and laymen. Pre-leaflet questionnaires will be distributed to assess the knowledge of people on the conditions. The questionnaires will be given to the same participants after they have read the leaflets.

Devising a Course to enhance Prescribing Competence

Analise Schembri

A prescribing course suitable for practising pharmacists is programmed. The course will include the different types of prescribing employed by different countries; the advantages of prescribing in the local situation; the drug categories and disease states that fall under prescribing; the development of a clinical management plan, highlighting the specific roles of pharmacists and doctors; length and cost of programme and learning outcomes. The course will then be evaluated by pharmacists and other healthcare professionals.

Structure Based Drug Design: HIV Proteases as a Case Study

Clinton Schembri

Static models for structure based drug design are recognised as an important tool in the drug discovery process. Software that employs empirical and semi-empirical algorithms for the mathematical elucidation of the binding affinity of receptor for potential cognate ligands is now widely available. This project uses HIV protease 1 (pdb ID 10HR) as a case study to demonstrate the value of the nuvo drug design and binding affinity estimation techniques in the identification of novel structures with potential for development into pharmacologically active agents.

Drugs used in Ophthalmology

Jasmine Vella

The aims of this study are to examine the present use of drugs in ophthalmology, focusing mainly on the role of corticosteroids in the management of ocular conditions such as optical neuritis, to identify any problems associated with their use, and to study their respective efficacy and side-effects, to identify which areas of treatment could be improved with new drugs and technologies developed.

History of Pharmacy*Gerald Abela***Bioequivalence of Doxazosin***Svetlana Agius***Point-of-Care Anticoagulant Monitoring***Melanie Azzopardi***Point-of-Care HbA1c Monitoring***Stephanie Azzopardi***Good Distribution Practice: the Example of a Wholesaler***Vanessa Azzopardi***Computerised Patient Profiles at Zammit Clapp Hospital (ZCH)***Rodianne Bondin***Distribution of Free Medicines in Malta***Gilles Briffa Rizzo***Drug Information Journal***Alison Brincat***Water Quality in the Pharmaceutical Industry***Stephen Ludovic Bugeja***Implementation of Protocols on Allergy Disorders***Kathlene Cassar***New Passenger Regulations: Health and Travel***Maria Cuschieri***The Effect of Treatment on the Quality of Life in Rheumatoid Arthritis***Stephanie Falzon***Microbiological Requirements in the Local Industry***Maria Fenech***Prescribing of Analgesics by the Community Pharmacist***Simone Pace O'Shea***Expiry Dates of Raw Materials***Gayle Papps***Use of Oxygen***Stephanie Rapa***Satisfaction with Pharmacy Services: Areas for Improvement***Annelise Saliba***Protocols for the Introduction of New Drugs in Cancer Care***Francesca Schembri***Production of Modified Release Dosage Forms***Karl Schembri***Feasibility Study of Setting up a Museum for the Medical and Pharmacy Practice***Elaine Seychell***Medicinal Plants***Silvan Spagnol***Dictionary of Medical and Pharmacy Terms (English - Maltese)***Miran Spiteri***Point-of-Care Diagnostics in Infections***Angele Vella***Stock Control at Zammit Clapp Hospital***Antine Vella***Sale of Non-Prescription Medicines from Pharmacies: Price Comparisons***Rebecca Vella***Production of IV fluids : Microbiological Testing Requirements***Thomas Vella***Manufacture of Active Pharmaceutical Ingredients; FDA vs EMEA Requirements***Liu Wei***Determination of Amylase in Gastric Juice***Kirsten Zammit***Pharmaceutical Care of Patients undergoing Heart Surgery***Natalie Zerafa*

History of Pharmacy

Gerald Abela

The aim of this study is to record the major changes in the practice of pharmacy as a profession, both as a supporting profession to medicine and also as a service to the community. The study shall focus on the period from the Second World War to this day, since this era brought considerable changes in different aspects of Maltese society, not excluding the pharmacy profession.

Bioequivalence of Doxazosin

Svetlana Agius

A comparison between a generic and a brand-name formulation of the drug doxazosin will be carried out to show whether the two are bioequivalent. This will be determined by comparing the bioavailabilities of the two drugs after administration of the same molar dose under similar conditions.

Point-of-Care Anticoagulant Monitoring

Melanie Azzopardi

To investigate the feasibility and efficacy of the pharmacist's intervention in monitoring the INR and regulating the anticoagulant dosage of patients on warfarin and to investigate whether the pharmacist's intervention in the community pharmacy setting would offer a substantial advantage in INR monitoring and anticoagulant regulation.

Point-of-Care HbA1c Monitoring

Stephanie Azzopardi

The aims of the study are to identify the potential use of HbA1c tests as a monitoring tool in community pharmacies in assessing the level of diabetes management in a number of type 1 and type 2 diabetic patients. To determine whether HbA1c would improve in patients with poor diabetes control following education carried out by the pharmacist.

Good Distribution Practice: the Example of a Wholesaler

Vanessa Azzopardi

The current state of pharmaceutical distribution for a local wholesaler is reassessed. The GDP at the specified wholesaler will be updated, developed, validated and implemented in line with Maltese regulations and EU directives.

Computerised Patient Profiles at Zammit Clapp Hospital (ZCH)

Rodianne Bondin

A computerised system for handling patient profiles at ZCH will be developed. The system should increase accuracy and reduce error in the recorded patient profiles. The developed computerised system will be tested and compared with the previous system used at ZCH.

Distribution of Free Medicines in Malta

Gilles Briffa Rizzo

The intervention of community pharmacists in the distribution of free medicines to patients who are entitled to such benefits is examined. Its aim is to distribute these medicines all over Malta and ensure that patients obtain this service as close to their homes as possible.

Drug Information Journal

Alison Brincat

A journal will be issued to provide information specific for the local scenario. Information on new medicines released on the market, changes in indications or other details in the product characteristics will be included. The aim of the journal is to provide recent information to healthcare professionals about medicines in Malta.

Water Quality in the Pharmaceutical Industry

Stephen Ludovic Bugeja

Depending on the pharmaceutical use, different grades of water quality are required. The different grades of water quality required will be addressed. The methods used for purification, and the control of water quality with particular emphasis on microbiology will be reviewed.

Implementation of Protocols on Allergy Disorders

Kathlene Cassar

Protocols on allergy disorders that were developed in a previous local study are to be implemented in local community pharmacies. These protocols outline ways in which a pharmacist participates in evidence-based allergy management. Implementation should include credibility, track record keeping, attention to the impact on resources (human and financial), accessibility and an attractive design and tools for application. It should also include involvement of all relevant stakeholders. Compliance of pharmacists with these protocols will be assessed.

New Passenger Regulations: Health and Travel

Maria Cuschieri

Analysis of difficulties encountered by passengers related to health and travel is undertaken. A list of guidelines and regulations will be done after identifying the different cases and circumstances which passengers encounter on their way to Malta and during their stay here.

The Effect of Treatment on the Quality of Life in Rheumatoid Arthritis

Stephanie Falzon

Seventy females will be divided into groups according to their treatment and severity of rheumatoid arthritis. The SF-36 and the Health Assessment Questionnaire (H.A.Q.) will be completed by patients. The scoring will give results on the effects of treatment on the quality of life and will then further be evaluated.

Microbiological Requirements in the Local Industry

Maria Fenech

Food and non-sterile pharmaceutical products provide an excellent medium for bacterial growth due to nutrients which contribute towards making these products such excellent contaminants for humans. Thus products require protection from contamination in the form of Good Manufacturing Practice (GMP) guidelines and adequate preservation. In this study the microbiological requirements for the manufacturing processes as well as the risk of microbial contamination of selected products will be analysed.

Prescribing of Analgesics by the Community Pharmacist

Simone Pace O'Shea

The concept of prescribing of analgesics by the community pharmacists in Malta will be examined. A protocol is developed and implemented in community pharmacies. Documentation systems are prepared and evaluated through focus group discussions and by the assessment of their practicality in the local setting.

Expiry Dates of Raw Materials

Gayle Papps

The stability of raw materials, variations in potency and impact of packaging and storing conditions on the stability is reviewed.

Use of Oxygen

Stephanie Rapa

The use of oxygen as a medical gas requires special handling criteria by health professionals especially during administration. Perception of patients and health care workers about the efficacy of the domiciliary use of the oxygen cylinders will be assessed. Analysis of oxygen where it is used as a piped medical gas is undertaken.

Satisfaction with Pharmacy Services: Areas for Improvement

Annelise Saliba

One method to evaluate quality of services is to measure satisfaction from services provided. This study will evaluate the quality of pharmacy services based on the satisfaction of the general public who require pharmacy services. Results from the study will determine what needs to be improved and appropriate suggestions will be suggested.

Protocols for the Introduction of New Drugs in Cancer Care

Francesca Schembri

Precise and detailed plans that describe criteria on which new drugs for cancer therapy should be introduced are developed.

The plan encompasses the investigation of cancer care, costs and value of life. It is based on the European perspective on the costs and cost-effectiveness of cancer therapies. Ethical considerations and pharmacoeconomic principles, which influence prices of anti-cancer drugs, are discussed.

Production of Modified Release Dosage Forms

Karl Schembri

Different steps involved in the production of modified release tablets and capsules are studied. Good manufacturing practices required are identified by a set of rules and procedures. Liaison with local Pharmaceutical industries which have the capacity of manufacturing such drugs will be undertaken.

Feasibility Study of Setting up a Museum related to the Healthcare Professions

Elaine Seychell

Information by using questionnaires, interviews and other analytical tools will be collected to determine and assess the feasibility of setting up a museum for the healthcare professions. Part of the project is intended to find an adequate location for the museum. Furthermore, a collection of objects of historical value to the healthcare professions will be undertaken. In the meantime objects in hand will be exhibited.

Medicinal Plants

Silvan Spagnol

This study aims to contribute towards the existing knowledge on medicinal plants. One or more plants which are found locally and have a potential for medicinal use will be identified. Plant extracts will be collected and analysed for any pharmacological activity. If positive results are achieved, the inclusion of these extracts in a pharmaceutical preparation will be considered.

Dictionary of Medical and Pharmacy Terms (English - Maltese)

Miran Spiteri

The aim of the project is to continue the compilation of a dictionary of medical and pharmaceutical terms in Maltese and to validate the translated terms with expert opinions acquired from healthcare professionals, linguists and lexicographers together with laymen.

Point-of-Care Diagnostics in Infections

Angele Vella

An evaluation of the use of kits that may be used for the diagnosis of infections in a community pharmacy setting will be carried out. These kits provide a rapid detection of a number of micro-organisms and therefore facilitate prescribing of appropriate therapy. The study will include the feasibility of implementation of these diagnostic kits in our local pharmacies.

Stock Control at Zammit Clapp Hospital

Antine Vella

The current system used for stock control at Zammit Clapp Hospital(ZCH) is evaluated. New procedures, plans to improve the current system will be proposed. Importance would be given to reduce medication errors and to maintain medicinal products in an appropriate environment.

Sale of Non-Prescription Medicines from Pharmacies: Price Comparisons

Rebecca Vella

The aim of this study is to compare prices of non-prescription medicines based on different criteria. Retail prices of non-prescription medicines in Malta, shall be compared with those in the U.K. The retail price of originator products and their generics shall be compared. Patient and pharmacist views about the factors affecting the use of generics, including price and quality, shall be analysed, with the aim of setting up a patient educational leaflet regarding the process involved in the choice of a price.

Production of IV fluids : Microbiological Testing Requirements

Thomas Vella

A number of samples of the same sterile IV fluid will be prepared using different methods of sterilization , namely chemical, thermal, filtration or radiation. The IV fluids will be analysed for the presence of microbes. The expenses involved in the manufacturing process and the different techniques of manufacture will be compared with regards to efficiency and costings.

Manufacture of Active Pharmaceutical Ingredients; FDA vs EMEA Requirements

Liu Wei

The standards required in the production and documentation of active pharmaceutical ingredients (APIs) by the Food and Drug Administration (FDA) and the European Medicines Evaluation Agency (EMA) will be compared. Six areas will be studied, namely - quality, facilities and equipment, material, production, packaging and labelling, and laboratory analysis.

Determination of Amylase in Gastric Juice

Kirsten Zammit

The detection of hyperamylasemia through the quantification of total active amylase present in gastric juice could lead to the understanding of duodenogastric reflux. Relevance of the relationship between gastric pH and the amount of amylase present can be determined. Tests on *in vivo* gastric juice samples are to be performed using the Reflotron® and/or Hitachi analyser. Patients tracing positive to the presence of amylase are to be followed up.

Pharmaceutical Care of Patients undergoing Heart Surgery

Natalie Zerafa

The project deals with the pharmacists' role in managing patients before and after a coronary by-pass surgery (CABG). The pharmacists' intervention in a hospital setting with regards to CABG patients is considered. Pharmaceutical care plans will be developed for CABG patients and evaluated.