

## **Pharmacotherapy**

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## Compliance Issues in Hypertension

Charyl Fava

**Background:** Hypertension is a significant condition in many countries. In Malta, in 2007, 40.7% of deaths were due to diseases of the circulatory system.<sup>1</sup>

**Objective:** To evaluate compliance amongst hypertensive patients, to study compliance factors, to monitor blood pressure and Body Mass Index (BMI) and to investigate non-compliance rates.

**Design:** Hypertensive patients of any gender and age were recruited randomly on purchasing their antihypertensive medications. A validated questionnaire was administered, blood pressure monitored and BMI calculated. The chi-square test was used to analyse the data.

**Setting:** Ten community pharmacies

**Main Outcome Measures:** Patient compliance and control of hypertension and identified compliance factors such as age and gender.

**Results:** One hundred and fifty patients, 37% (n=56) males and 63% (n=94) females, with a mean age of 57 years participated. Full pharmacological compliance was found in 78% (n=117) of patients whilst 22% (n=33) of patients were non-compliant. The control of hypertension was good in 59% (n=89) of the patients. There was a statistically significant correlation between pharmacological compliance and gender (better in females), age (better in younger patients) and level of education (better with higher education), with p values of 0.021, 0.000 and 0.034 respectively. Salt, saturated fat, smoking and alcohol were statistically significantly correlated to pharmacological compliance. There was also a statistically significant correlation between pharmacological compliance and the control of hypertension (p = 0.008).

**Conclusion:** Hypertensive patients who buy their medications are more pharmacologically compliant, being female, the younger they are and the higher their level of education. The more the patient is pharmacologically compliant, the higher the chance to have the blood pressure controlled. These results highlight the importance of the healthcare professionals to give weight to both the pharmacological and the non-pharmacological compliance.

### Reference:

1. National Statistics Office (NSO). Demographic Review 2007 [Online]. Malta: Government Printing Press; 2008 [cited 2008 Jan 24]. Available from: URL: [www.nso.gov.mt](http://www.nso.gov.mt).

## Osteoporosis

Judith Fenech

**Background:** Osteoporosis is a bone disease contributing to yearly mortalities and morbidities.

**Objective:** To identify risk factors, assess patients' knowledge and evaluate prescribing trends.<sup>1</sup>

**Design:** A previously validated patient questionnaire was used to identify patients' risk factors, assess knowledge on osteoporosis and the services offered to them.<sup>2</sup> A healthcare professional (HCP) questionnaire was designed and validated to evaluate the prescribing trends. A three gatefold patient leaflet was also designed. Results were analysed using Microsoft<sup>®</sup> Excel 2007 and the Bio-Medical Data Package Software.

**Setting:** Bone Density Unit at St. Luke's Hospital and Mater Dei Hospital.

**Main Outcome Measures:** Assessment of patients' risk factors, knowledge and evaluation of treatment using the patient questionnaire and evaluation of prescribing trends using the HCP questionnaire.

**Results:** Sixty five patients (2 males, 63 females) undergoing routine bone density scanning participated in the study (mean age group > 60 years). The mean lumbar T score was -2.90 while the mean hip T score was -1.93. The most common risk factor was a postmenopausal state (n=54), followed by lack of exercise (n=38) and family history (n=28). Patients obtained an average score of 10.2 (51%) when their knowledge was assessed. Bisphosphonates with calcium supplements (n=22) were the most commonly prescribed drugs followed by bisphosphonates alone (n=9), calcium supplements alone (n=9) and strontium ranelate (n=9). The doctors referred patients for bone density scanning in 75% of the scenarios. Bisphosphonates (33%) and raloxifene (31%) were mostly prescribed.

**Conclusion:** Similarly to foreign studies, patients' knowledge can be improved. Local prescribing trends compare to established guidelines.

### References:

1. National Institute for Clinical Excellence (NICE). Technology Appraisal Guidance 160. NICE [Online] 2008 [cited 2008 Dec 2]. Available from: URL: [www.nice.org.uk](http://www.nice.org.uk).  
2. Fendin S, Jones G, Oldenburg B, Winzenberg T. The design of a valid and reliable questionnaire to measure osteoporosis knowledge in women: the Osteoporosis Knowledge Assessment Tool (OKAT). *BMC Musculoskeletal Disorders* 2003; 4(17): 1-7.

## Vitamin D Inadequacy among Maltese Postmenopausal Women

Erika Griscti

**Background:** Vitamin D is essential for maintaining calcium homeostasis and optimising bone health.<sup>1</sup>

**Objective:** To investigate the prevalence of vitamin D inadequacy among postmenopausal women with and without osteoporosis and to evaluate the factors related to vitamin D inadequacy.

**Design:** The questionnaire was administered to 300 postmenopausal women. Concentrations of 25-hydroxyvitamin D [25(OH)D], 1,25-dihydroxyvitamin D (1,25-(OH)<sub>2</sub>D) and 25-hydroxyvitamin D<sub>3</sub> (25(OH)D<sub>3</sub>) were determined. Statistical analysis was carried out using the Pearson chi-square test on SPSS<sup>®</sup> version 16.0.

**Setting:** Department of Obstetrics and Gynaecology Outpatients and Immunology Lab, St. Luke's Hospital; Zammit Clapp Hospital.

**Main Outcome Measures:** The medical history questionnaire evaluated factors related to vitamin D inadequacy. The *Immundiagnostik* Enzyme-Immuno-Assay kit determined 25(OH)D concentrations. The High Performance Liquid Chromatography determined 1,25-(OH)<sub>2</sub>D and 25(OH)D<sub>3</sub> concentrations.

**Results:** The 25(OH)D concentration was determined from 250 patients; 112 patients (44.8%) had an inadequate concentration. Risk factors related to 25(OH)D inadequacy included exposure to sunlight (p=0.047), vitamin D supplementation (p=0.038). The 1,25-(OH)<sub>2</sub>D and 25(OH)D<sub>3</sub> concentrations were determined from 166 patients; 46 patients (27.7%) had an inadequate concentration. Risk factors related to 1,25-(OH)<sub>2</sub>D and 25(OH)D<sub>3</sub> inadequacy included vitamin D supplementation (p=0.044), activity limitation (p=0.006), climbing stairs (p=0.024) and seasonal (p=0.003). The bone density condition did not reflect the vitamin D results of the patients.

**Conclusions:** A high prevalence of vitamin D inadequacy was found. Pharmacist-initiated discussions regarding the importance of vitamin D for bone health and intake of vitamin D supplements could be implemented to reduce the prevalence of vitamin D inadequacy.

### Reference:

1. Holick MF, Siris ES, Binkley N, Beard MK, Khan A, Katzner JT et al. Prevalence of Vitamin D inadequacy among postmenopausal North American women receiving osteoporosis therapy. *J Clin Endocrinol Metab* 2005; 90(6): 3215-24.

## Management of Rheumatoid Arthritis

Suzanne Griscti

**Background:** Rheumatoid arthritis (RA) is a chronic disease which warrants education about the disease and its management.<sup>1</sup>

**Objective:** To evaluate the impact of a pharmacist intervention using the Health Assessment Questionnaire<sup>2</sup> and questionnaires regarding desire for information<sup>3</sup>, beliefs about medications<sup>4</sup> and satisfaction on government pharmacy service.<sup>5</sup>

**Design:** Eighty patients with RA were interviewed and divided into Group A (control n=20), Group B (n=40) and Group C (patients on hydroxychloroquine n=20). A pharmacist intervention was then offered to Group B and Group C. An information leaflet on hydroxychloroquine was given to Group C as part of the intervention. Patients were re-assessed after 12 weeks.

**Setting:** Rheumatology Clinic, Mater Dei Hospital.

**Main Outcome Measure:** Impact of the pharmacist intervention on the quality of life (QOL) of patients with RA.

**Results:** A statistically significant improvement in the QOL of patients was registered following the pharmacist intervention (p<0.05). A decrease in the concern (p<0.05) and an increase in the necessity for medications (p<0.05) were registered, when compared to baseline.

**Conclusion:** The pharmacist intervention resulted in improved patients' lifestyle, resolved concerns and increased necessity of patient compliance.

### References:

1. Wood J. Rheumatoid arthritis: management with DMARDs. *Pharm J* 1999; 263: 162-7.
2. Fries JF, Spitz P, Kraines RG, Holman HR. Measurement of patient outcomes in arthritis. *Arthritis Rheum* 1980; 23: 137-45.
3. Duggan C, Bates I, Struman S, Andersson E, Astrom K, Carlsson J. Validation of a "desire for information" scale. *Int J Pharm Pract* 2002; 10: 31-7.
4. Horne R, Weinman J, Hankins M. The beliefs about medicines questionnaire: the development and evaluation of a new method for assessing the cognitive representation of medication. *Psychol & Health* 1999; 14: 1-24.
5. Whitehead P, Atkin P, Krass I, Benrimoj SI. Patient drug information and consumer choice of pharmacy. *Int J Pharm Pract* 1999; 7: 71-9.

## Preconception Care in Type 1 Diabetics

*Karen Sapiano*

**Background:** Pregestational diabetes complicates 1 in 200 pregnancies. Although preconception glycemic control directly impacts perinatal outcome for type 1 diabetic women, these women still frequently enter pregnancy with suboptimal control of glycemia.<sup>1</sup>

**Objective:** To assess the level of knowledge and awareness related to preconception care among Maltese women with type 1 Diabetes Mellitus (DM) during the reproductive age.

**Design:** Thirty seven women, aged 12-30 years with type 1 DM, who presented at the state managed diabetes clinic, were administered a brief questionnaire pertaining to diabetes self-management and preconception care. The participants were exposed to an education intervention, and the responses of the patients before and after the intervention were measured. SPSS<sup>®</sup> version 16.0 was used to analyse the effects of the intervention statistically.

**Setting:** Diabetes Outpatient Clinic at St. Luke's Hospital and Mater Dei Hospital.

**Main Outcome Measures:** Determination of knowledge of patients and evaluation of the impact of the intervention.

**Results:** Out of the thirty seven patients recruited by convenience sampling, twenty two patients agreed to take part in the second part of the study. Sixteen participants (72.7%) claimed they had no knowledge about the value of diabetes care before planning a pregnancy. However, after the intervention, this number was reduced to 9 respondents (40.9%). Seven patients (31.8%), who initially specified they had no knowledge before the intervention, later on, changed their views. Since the p value (0.016) is less the 0.05 level of significance, this change was significant.

**Conclusions:** The respondents lacked awareness of pregnancy-related complications with diabetes. It is imperative for health professionals to raise these issues with their adolescent patients during routine visits.

### Reference:

1. Casele HL, Laifer SA. Factors influencing preconception control of glycemia in diabetic women. *Arch Intern Med* 1998; 15(12): 1321-4.

## Drugs Used in Ophthalmology

*Jasmine Vella*

**Background:** Refractive surgery is a popular procedure used to decrease spectacle or contact lens dependency. Various drugs are used in this surgery; intra- and/or post-operatively.<sup>1</sup>

**Objective:** To assess visual outcome after undergoing photorefractive keratectomy (PRK), to observe the effect of drugs used on the final outcome, and to assess patient satisfaction following surgery.

**Design:** Self-reporting was carried out on PRK patients using a questionnaire entitled 'Patient assessment throughout excimer laser surgery for refractive error'. Data was entered in a spreadsheet using SPSS<sup>®</sup> version 16.0. Statistical tests included the two-way ANOVA and the chi-square test.

**Setting:** Ophthalmic Department, Capua St. James' Hospital.

**Main Outcome Measures:** Information including visual acuity and refraction was obtained from patient files. Drugs used at all stages were noted.

**Results:** Sixty five patients were studied: 95% of patients were treated for myopia; the rest were treated for hyperopia. Visual acuity improved over time in all patients. Mitomycin-C was used in 12.3% of patients. Postoperatively, all patients were treated with the same drug regimen, however, in 35.4% of patients, fluorometholone was replaced with dexamethasone, after 4 or 10 weeks. Of the patients using dexamethasone, 8 patients needed spectacles, 3 patients required re-treatment, while 12 patients did not need spectacles nor re-treatment. Many patients still experienced some irritation or dryness after 6 months; hence lubricating drops were still in use. The most common visual symptoms were multiple images and halos. Most patients were satisfied after 6 months.

**Conclusion:** Visual acuity improved over time in all patients. Mitomycin-C use was necessary in patients having a refractive error higher than -8. Dexamethasone use was due to regression and corneal haze. Most patients were satisfied with the outcome. Less satisfied patients were those with prolonged steroid use, patients needing spectacles or re-treatment.

### Reference:

1. Titcomb L. Laser surgery for refractive errors. *Pharm J* 2006; 29: 511-514.

# Use of Interferon alpha-2b, Temozolomide and Pegylated Liposomal Doxorubicin

*Ambra Cauchi*

**Background:** IFN-alpha2b (IntronA) was introduced on the Government Formulary List (GFL). The introduction of temozolomide (TMZ) and pegylated liposomal doxorubicin (PLD) in the national formulary is controversial.

**Objectives:** To investigate use and market potential of IFN-alpha2b, TMZ and PLD and to study the rational introduction on the GFL of TMZ and PLD.

**Design:** Five oncologists practising in Malta were interviewed using three validated questionnaires. The Toronto Side-Effect Scale (TSES)<sup>1</sup> was adapted to record IFN-alpha2b side-effect incidence.

**Setting:** Oncology Department, Sir Paul Boffa Hospital.

**Main Outcome Measures:** Factors influencing oncologists' prescribing and their opinions on introduction of PLD and TMZ in GFL, incidence and management of interferon-related toxicities.

**Results:** Payment of treatment by patients emerged as a strong factor determining TMZ and PLD prescription. Their inclusion on the GFL would increase prescribing (4 oncologists agreed). Furthermore, 3 oncologists agreed they would prefer TMZ to current options. Advantages of PLD are not considered sufficient to offset the financial burden of treatment. Low dose IFN-alpha2b (LDI: 6 MIU/m<sup>2</sup> SC TIW pushed to 6 weekly if tolerated) is used instead of high-dose IFN-alpha2b (HDI) to avert high incidence of side effects.<sup>2</sup> Most common side effects (mean rating scores) encountered with low dose IFN-alpha2b were fever (4.4), fatigue-malaise (3.8) and chills (3.6). Sixteen IFN side-effect management interventions were adhered to.

**Conclusions:** TMZ introduction is desired whereas PLD is less supported. Enforcement of side-effect management plans could improve patient quality of life.<sup>3</sup>

## References:

1. Vanderkooy JD, Kennedy SH, Bagby RM. Antidepressant side effects in depression patients treated in a naturalistic setting: A study of bupropion, moclobemide, paroxetine, sertraline and venlafaxine. *Can J Psychiatry* 2002; 47: 174-80.
2. IntronA® (Summary of Product Characteristics). Belgium: Schering Plough Europe; 2005.
3. Hauschild A, Gogas H, Tarhini A, Middleton MR, Testori A, Dreno B et al. Practical guidelines for the management of interferon-alpha2b side effects in patients receiving adjuvant treatment for melanoma. *Cancer* 2008; 112(5): 982-94.

## **Pharmaceutical Care**

### **Diabetic Patient Management**

*Jeffrey Cassar*

### **Monitoring Outcomes in Infant Colic**

*Sonia Bonnici*

### **Denture Hygiene within the Institutionalised Elderly Population**

*Roberta Scalpello*

## Diabetic Patient Management

Jeffrey Cassar

**Background:** Diabetic management centers on self-monitoring of blood glucose (SMBG), patient education programmes and screening of HbA1c levels.

**Objectives:** To identify problems encountered by type I diabetics during SMBG, to evaluate the education programme delivered to type II diabetics and to monitor HbA1c levels of type II patients over a one year trend.

**Design:** A validated questionnaire was distributed to 25 type I diabetic patients. The data was analysed with the chi-square test using MedCalc version 10.0.1.0. The education programme was evaluated according to national standards.<sup>1</sup> The HbA1c levels of 30 type II patients were monitored over one year. Data was analysed via a correlation study using MedCalc version 10.0.1.0.

**Setting:** Diabetes Clinic, Mater Dei Hospital.

**Main Outcome Measures:** Problems of patients during SMBG, issues discussed in the patient education programme, correlation of age and routine HbA1c levels.

**Results:** SMBG more than once daily was performed by 64% (n=16) of patients, with 24% (n=6) and 12% (n=3) monitoring once daily or once weekly respectively. Internal psychological barriers were found to significantly affect SMBG practices (p=0.0018). In the patient education programme delivered, 10% and 2% were allocated to monitoring and psychological issues respectively. The correlation analysis showed no association between age and changes in HbA1c levels (p=0.730).

**Conclusion:** There is a clear indication that internal psychological factors are significant in acting as barriers to SMBG practices. Psychological issues were not emphasised during the education programme. The correlation study showed similar findings to studies showing no changes in HbA1c levels with increasing age.<sup>2</sup>

### References:

1. Funnell MM, Brown TL, Childs BP, Haas LB, Hoseney GM, Jensen B et al. National standards for diabetes self-management education. *Diabetes Care* 2007; 30(6): 1630-7.
2. Wiener K, Roberts NB. Age does not influence levels of HbA1c in normal subjects. *QJM* 1999; 92: 169-73.

## Monitoring Outcomes in Infant Colic

Sonia Bonnici

**Background:** Infant colic is defined as irritability and crying for more than 3 hours a day, occurring for more than 3 days a week and lasting for more than 3 weeks.

**Objective:** To evaluate the use of information material by healthcare professionals and parents in infant colic.

**Design:** A previously, locally prepared leaflet developed in 2004<sup>1</sup> and an infant colic diary prepared in 2001<sup>2</sup>, were amended. Healthcare professionals were provided with the adapted leaflet whilst others were not. An infant colic diary was given to parents whose infants suffered from colic. The diaries collected, were evaluated using the chi-square test and were compared according to the type of intervention.

**Setting:** Five well baby clinics.

**Main Outcome Measures:** Frequency of colic attacks, management of infant colic.

**Results:** Out of 56 diaries, 30 were received and evaluated. There was a significant difference between pharmacological and non-pharmacological methods versus the type of intervention (p = 0.000). The most non-pharmacological intervention used was hot water (25.9%) in patients when the leaflet was not used and movement (16.9%) when the leaflet was used. The most common pharmacological intervention recommended was simethicone before a feed, used in 49.9% of attacks. Diaries completed by parents that had an intervention from healthcare professionals that followed the leaflet used remedies that were not used by parents where the healthcare professionals were not provided with a leaflet.

**Conclusion:** Since parents who were given an intervention by healthcare professionals who had been provided with the leaflet used various other remedies, it was shown that the leaflet was effective and the information provided was utilised by the parents and the healthcare professionals.

### References:

1. Saliba N. Pharmacist intervention in infant colic [dissertation]. Msida (Malta): University of Malta; 2004.
2. Mallia G. Infant colic in Malta [dissertation]. Msida (Malta): University of Malta.; 2001.

# Denture Hygiene within the Institutionalised Elderly Population

Roberta Scalpello

**Background:** Oral health is an important component of overall health, well-being and quality of life for institutionalised elderly patients. Regular and optimal oral hygiene measures together with periodic oral examination will prevent most cases of oral candidiasis in those with dentures.<sup>1</sup>

**Objective:** To investigate the relationship between oral hygiene habits, denture stomatitis, denture cleanliness and the presence and number of yeasts in an elderly denture-wearing population.

**Design:** Ninety nine elderly denture wearers (mean age 83.04) participated in an interview and oral examination and provided an unstimulated saliva sample. The saliva samples were processed to determine the *Candida* cfu/ml of saliva and to identify the yeasts down to their species level.

**Setting:** Government residential homes for the elderly.

**Main Outcome Measures:** *Candida* cfu/ml of saliva, level of denture hygiene, significance of denture hygiene in preventing oral candidiasis.

**Results:** Significant correlations were found between denture cleaning methods and the presence of denture stomatitis ( $p=0.020$ ), yeast prevalence ( $p=0.010$ ) and *Candida* cfu/ml ( $p=0.001$ ) respectively. Denture stomatitis was significantly correlated to yeast prevalence ( $p=0.003$ ), high *Candida* cfu/ml ( $p=0.037$ ) and denture cleanliness ( $p=0.000$ ) but was not associated with denture cleaning frequency ( $p=0.960$ ). Frequency of cleaning was not related to *Candida* cfu/ml ( $p=0.076$ ) or yeast prevalence ( $p=0.226$ ). No relationship was observed between denture cleanliness and yeast prevalence ( $p=0.317$ ) or *Candida* cfu/ml ( $p=0.588$ ). Denture wearing habits were not associated with yeast prevalence ( $p=0.354$ ), mean *Candida* count ( $p=0.140$ ) or incidence of denture stomatitis ( $p=0.301$ ).

**Conclusions:** Denture hygiene plays an important role in the maintenance of good oral health. Therefore there is a pressing need for education of the elderly population in this regard.

## Reference:

1. Apkan A, Morgan R. Oral candidiasis. *Postgrad Med J* 2002; 78: 455-9.

## **Treatment Protocols**

### **Validation of Protocols for the Treatment of the Common Cold**

*Deborah Mercieca*

### **Treatment Protocols for Disorders of the Gastro-Intestinal Tract**

*Steven Ellul*

### **Validation of Protocols for Paediatric Care**

*Stephanie Liane Magro*

### **Guidelines for Antibiotic Use in the Community**

*Ritienne Fenech*

## Validation of Protocols for the Treatment of the Common Cold

*Deborah Mercieca*

**Background:** Protocols for treatment of common cold can assist pharmacists in determining the best course of action for patients presenting with common cold symptoms.

**Objective:** To validate protocols for treatment of common cold developed in a previous local study<sup>1</sup> and implement them in community pharmacies.

**Design:** The protocols, Non-Prescription Protocol (NPP) and Prescription Protocol (PP), were evaluated by a panel of 20 experts, modified accordingly and formulated into a Protocol Booklet. The pilot study indicated that a shorter version would be more practical. Thus, a Protocol Handbook was developed. Fifteen cases were collected from each pharmacy, documenting pharmacist intervention (Time 0). The pharmacists were given the Protocol Booklet and Handbook. After two weeks of pharmacist review of the protocols, another fifteen cases were collected from each pharmacy (Time 1). A total of 206 hours of observation were spent. Statistical analysis was conducted using the Mann-Whitney U-test and Pearson chi-square test.

**Setting:** Twenty community pharmacies identified by stratified random sampling.

**Main Outcome Measures:** Compliance with protocols, use of assessment sheets.

**Results:** The NPP was followed in 74% of cases (n=444). The average percentage compliance with the two protocols was 52% (Time 0) and 74% (Time 1), each ranging between 17 and 100% (p=0.000). The average percentage compliance with NPP was 61% (Time 0) and 79% (Time 1), range 17 to 100% and 38 to 100% respectively (p=0.000). The average percentage compliance with PP was 29% (Time 0) and 57% (Time 1), range 17 to 80% and 17 to 83% respectively (p=0.000).

**Conclusion:** The statistically significant increase in compliance observed after dissemination of the protocols indicates that these protocols have been presented in an effective way to provide information on the management of common cold symptoms.

### Reference:

1. Buttigieg-Scicluna C. Development of protocols for the treatment of common cold [dissertation]. Msida (Malta): University of Malta; 2005.

## Treatment Protocols for Disorders of the Gastro-Intestinal Tract

*Steven Ellul*

**Background:** A treatment protocol is considered to be a set of predetermined criteria that define appropriate diagnosis and guidelines. Protocols describe situations in which the pharmacist makes interventions relative to a course of action for the effective management of common patient care problems such as Gastro Oesophageal Reflux Disease (GORD).<sup>1</sup>

**Objective:** To develop treatment protocols for gastro-intestinal (GI) conditions namely GORD. Design: Treatment protocols consisting of step-by-step guidelines for the management of GORD and Upper GI conditions and definition sheets were developed. These protocols were evaluated by a review team and were distributed to 10 community pharmacists to test their applicability and practicality. SmartDraw 2007<sup>®</sup> was used to design the protocols in a modern, yet practicable way. Microsoft<sup>®</sup> Excel XP and SPSS<sup>®</sup> version 16.0 was used to compile data.

**Setting:** Ten community pharmacies in Malta.

**Main Outcome Measures:** Applicability and practicality of the protocols.

**Results:** Protocol boxes were developed. New boxes compiled were placed according to the criteria presented at a community pharmacy, thus a continuous flow in the flowcharts is assured.

**Conclusions:** Definition sheets are being amended and discussed with the review team. Protocols will be disseminated to the 10 pharmacies around Malta, together with the datasheet and questionnaire to evaluate their practical implementation.

### Reference:

1. Harman RJ, Mason P. Handbook of pharmacy health care, 2<sup>nd</sup> ed. UK: Pharmaceutical Press; 2002: 18.

## Validation of Protocols for Paediatric Care

*Stephanie Liane Magro*

**Background:** Protocol-based care is advantageous as it provides safe and high quality care, specially needed in the paediatric field.

**Objectives:** To modify previously developed protocols<sup>1</sup>, develop new protocols regarding common paediatric diseases, validate them with a group of health professionals and assess pharmacist compliance with the protocols.

**Design:** Protocols on vomiting, diarrhoea and constipation<sup>1</sup> were modified and protocols on fever, cough and abdominal pain were developed. Protocols were validated by a group of professionals consisting of 4 pharmacists, 3 general practitioners and 3 paediatricians. Subsequently, the protocols were modified according to suggestions made during the validation process. Eleven pharmacies where a paediatrician has a clinic were identified, visited on a regular basis and the protocols were implemented. A points system was developed for the protocols. Data was analysed using Microsoft<sup>®</sup> Excel 2003.

**Setting:** Eleven community pharmacies.

**Main Outcome Measures:** Compliance of pharmacists with the protocols.

**Results:** A total of 120 cases were collected during the observation sessions. The majority of patients presenting at the pharmacies were aged between 4 and 6 years (32%) with newborns to 1 year old age group being the least common age group (22%). The most predominant presenting complaint was cough (44%) and the least predominant presenting complaint was abdominal pain (8%). The average compliance for all 6 protocols was 90%: for constipation 93% (range: 77 to 100%), fever 92% (range: 55 to 100%), vomiting 91% (range: 78 to 100%), cough 90% (range: 54 to 100%), abdominal pain 89% (range: 64 to 100%) and diarrhoea 85% (range: 77 to 100%).

**Conclusions:** The average compliance of the pharmacists with the protocols presented is high. This study shows that pharmacist intervention in the management of symptoms in paediatric patients follows very closely evidence-based pharmacy practice that was presented in the protocols.

### Reference:

1. Azzopardi R. Development of protocols of paediatric care [dissertation]. Msida (Malta): University of Malta; 2005.

## Guidelines for Antibiotic Use in the Community

*Ritienne Fenech*

**Background:** A report issued by the National Antibiotic Steering Committee<sup>1</sup> identified the need to develop guidelines and to monitor antibiotic use in the community.

**Objectives:** To develop and validate antibiotic guidelines for the community and to evaluate their applicability and practicality, to assess the knowledge and skills of pharmacists and doctors in the treatment of common infections and to develop and evaluate a monitoring system.

**Design:** Antibiotic guidelines, a monitoring system and case studies for each infection in the guidelines were developed and reviewed by 8 experts. An evaluation form was designed to analyse the guidelines and monitoring system. The data was analysed using Student's paired t-test, Wilcoxon's test and Pearson chi-square test at 95% Confidence Level.

**Setting:** Forty eight local community pharmacies.

**Main Outcome Measures:** Participants' knowledge and skills on a category of infection were assessed using case studies prior and following administration of the antibiotic guidelines.

**Results:** Before administration of the guidelines, the mean scores for pharmacists and general practitioners (GPs) were 62.84% (n=40) and 60.53% (n=33) respectively. No significant difference was observed in most categories for the two professions. After administration of the guidelines, the mean scores increased by 22.17% and 24.07% for pharmacists (n=39) and for GPs (n=33) respectively. Participants agreed with the monitoring system proposed (87%, n=47) and found the guidelines useful (96.43%, n=56) and practical (85.71%, n=42).

**Conclusions:** The guidelines and monitoring system would be a step forward to improve antibiotic use in the community. The mean scores for pharmacists were similar to that for GPs, thus shedding new light on the possibility of pharmacists being able to prescribe antibiotics.

### Reference:

1. Antibiotic use and resistance in Malta: a report of a working group setup by the health department. Malta: Department of Health [Online] 2000. [cited 2007 Aug 10]. Available from: URL: [www.slh.gov.mt/pdf/antibiotic%20resistance%20report.pdf](http://www.slh.gov.mt/pdf/antibiotic%20resistance%20report.pdf)

## **Pharmacy Administration**

### **Devising a Course to Enhance Prescribing Competence**

*Analise Schembri*

### **Computerised Medication Records**

*Daniela Hili*

### **Computerised Records of Medication Errors**

*Mark Magro*

### **The Maltese Directory of Pharmacists: Present Status and Future Predictions**

*Sarah Marie Hili*

## Devising a Course to Enhance Prescribing Competence

*Analise Schembri*

**Background :** The implementation of a prescribing course will enable pharmacists to use their expertise to help patients get the right treatment for their conditions in new, more patient-focused ways.

**Objective:** To design a prescribing course and to evaluate the perception of pharmacists and doctors on its possible implementation.

**Design:** The study was divided into three phases: 1. A literature review assessing the best level of prescribing; 2. A course (7 modules) designed following analysis of the course specifications and development of a course leaflet and supplementary prescribing background; 3. Questionnaire designed to evaluate the course and perception of health professionals on its implementation: Questionnaire, course leaflet and prescribing booklet were distributed to pharmacists and doctors. Statistical analysis was carried out using SPSS<sup>®</sup> version 17.0.

**Setting:** Community, clinical (Mater Dei Hospital, Zammit Clapp Hospital and health centres) and administrative settings.

**Main Outcome Measures:** Rating scales given to the course overview; willingness to participate and possible implementation of course and supplementary prescribing strategy.

**Results:** Out of the 96 questionnaires; 83 (86%) were answered: 89% agreed that all the course content was essential, classifying pharmacogenetics as the least relevant by doctors 40% (16) and pharmacists 63% (27), 60% (24) of doctors and 100% of pharmacists agreed that models of consultation and principles of diagnosis should be included, 63% (25) of doctors agreed to act as mentors during the placement period and 93% (40) of pharmacists would participate, 77% (67) of the respondents believe that the course provides pharmacists with the tools to offer a greater contribution as prescribers.

**Conclusion:** Both physicians and pharmacists agreed that the course is suitable to enhance the pharmacists' prescribing competence, recommending slight changes particularly in oncology, pharmacogenetics and diagnosis. A teamwork approach while maintaining distinctive roles between health professionals is the key to success in such a course.

## Computerised Medication Records

*Daniela Hili*

**Background:** Computerised Medication Records (CMRs) electronically store patient medical data and their medication in a consistent way.<sup>1</sup>

**Objective:** To devise a database to store patient medication records which can be accessed from a website created for the project and to indicate advantages of CMRs over paper-based records.

**Design:** A database was built using SQL manager 2005 Lite for MySQL and was populated with a total of 150 medication records. The software program HAPedit was used to build a website from which a search for a particular patient medication record could be carried out. PHP and MySQL languages were both used. Xara Xtreme was used for the website design. The website contains several features and was evaluated by 30 healthcare professionals and 10 pharmacy students. Microsoft<sup>®</sup> Excel was used to present results.

**Setting:** Medication records were collected from Zammit Clapp Hospital and from patients in the waiting room of the Birkirkara Healthcentre Pharmacy.

**Main Outcome Measures:** Use of computerised records.

**Results:** Seventy percent (21) of the healthcare professionals make use of some form of record keeping; 19% (4) use computerised records, 52% (11) use paper-based records and 29% (6) use both. Ninety eight percent (39) thought that CMRs offer a great advantage over paper-based records. The same number of participants stated that they would use CMRs if a standard system would exist.

**Conclusion:** The advantages of CMRs over paper-based records indicated in the evaluation were: data exchange and sharing, increase legibility of record and reduction of medication errors.

### Reference:

1. Bommel JH, Musen MA, Helder JC. Handbook of medical informatics. Michigan: Springer Verlag [Online] 1997 [cited 2008 Nov 29]. Available from: URL:[www.mieur.nl/mihandbook/r\\_3\\_3/handbook/home.htm](http://www.mieur.nl/mihandbook/r_3_3/handbook/home.htm)

## Computerised Records of Medication Errors

Mark Magro

**Background:** A Medication Error (ME) is any preventable event that may lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional, patient, or consumer.<sup>1</sup>

**Objective:** To develop a website containing records of different MEs with the aim of increasing awareness regarding a major healthcare problem and also providing adequate prevention advice.

**Design:** Two hundred examples of different MEs were collected from various sources such as the *Australian Prescriber* and *Hospital Pharmacy Europe* and inserted into a database purposely created using MySQL. Using PHP programming language, a website was developed with HAPedit and connected to the database to represent the MEs online. Certain features and design enhancements were implemented to ensure that it would be fully functional and professional. Xara Xtreme Pro was used to enhance the website design and Microsoft<sup>®</sup> Excel was used to represent results.

**Setting:** Community setting, St Vincent De Paul Residence.

**Main Outcome Measures:** Evaluation of the website. Results: Evaluation was carried out amongst 40 participants (10 medical doctors, 10 pharmacists, 10 nurses and 10 students) and a 100% response rate was achieved. Thirty three percent (13) of the participants stated that they have been directly involved in the occurrence of a ME. Eighty three percent (33) of the participants strongly agreed that the website had increased their awareness on MEs. All the participants (40) stated that the website had increased their cautious approach whilst handling medications.

**Conclusion:** Results have shown that the website is capable of increasing awareness on MEs and increasing cautiousness whilst handling medications.

### Reference:

1. National coordinating council for medication error reporting and prevention. What is a medication error? [Online] 1998 [cited 2008 December 28]. Available from: URL: [www.nccmerp.org/aboutMedErrors.html](http://www.nccmerp.org/aboutMedErrors.html)

## The Maltese Directory of Pharmacists: Present Status and Future Predictions

Sarah Marie Hili

**Background:** The 6<sup>th</sup> edition of the 'Maltese Directory of Pharmacists' is an updated compilation of contact details of locally registered pharmacists, pharmacies, pharmaceutical agents, importers, wholesalers and companies, and a list of undergraduate pharmacy project titles.

**Objective:** Updating the 'Maltese Directory of Pharmacists' (2005), evaluating the directory's usefulness among its users and psychographic analysis of local pharmacists.

**Design:** Pharmacists were contacted by telephone or electronic mail to update their contact details. The list and contact details of local pharmacies were updated as well as those of pharmaceutical agents, importers and wholesalers. The directory includes an updated list of undergraduate project titles carried out by pharmacy students along the years. The directory was self-published to reduce costs. Sponsors were required to cover the printing costs of the directory. Various companies were contacted and sponsors were acquired. The study concerning pharmacist analysis was carried out using a separate questionnaire and results were analysed using SPSS<sup>®</sup> 16.0. Following printing, the directory will be distributed to local pharmacies and its usefulness evaluated.

**Setting:** Local Pharmacist Manpower. Main Outcome Measures: Publishing of the 'Maltese Directory of Pharmacists', analysing the role of the pharmacist in the local pharmacy field, identification of new and varying trends within the local pharmacy sector.

**Results:** Results from the socio-demographic questionnaire were formatted for the new edition of the directory.

**Conclusion:** Current workforce patterns are classified showing the various socio-demographic factors which give rise to evolution within the local pharmacy scene. Such factors are invaluable when planning future policies within the pharmacy sector.

## **Pharmacy Information**

### **Formulary for Non-BNF Cited Items**

*Doriella Cassar*

### **Formulary for the Management of Mental Disorders**

*Corinne Elbourne*

### **Development of Patient Information Leaflets**

*Fabienne Sant Portanier*

### **Development of Information Leaflets on Anxiety and Depression**

*Maria Scerri*

### **Newsletter to Community Pharmacists**

*Rachel Galea*

### **The Pharmacy Practice Resource Unit**

*Simone Bartolo*

### **Risk Assessment of the Preparation of Intravenous Infusion Fluids**

*Ruth Gatt*

## Formulary for Non-BNF Cited Items

*Doriella Cassar*

**Background:** The ‘British National Formulary’ (BNF), a publication which provides detailed information about medicinal products available in the United Kingdom, is used as a major reference source by Maltese healthcare professionals since a Maltese national formulary does not exist. In 2006, Micallef<sup>1</sup> developed the ‘Maltese Medicine Handbook’ (MMH) so as to include those drugs found locally that were not present in the BNF, thus making these separate publications ideal to be used together.

**Objective:** To maintain and evaluate the MMH, assess updates and include details of medical devices.

**Design:** A list of medicinal products available in the local market, issued by the Malta Medicines Authority, was used to identify products not listed in the BNF. Details included for all the medicinal products were: trade name, marketing agent holder, active ingredient, PoM/OTC status, dosage form, dosage strength, dosage regimen, consumer price and local distributor. Details included for all the medical devices were: trade name, marketing agent holder, local distributor and consumer price. For drugs not listed in the BNF, the following information was also included: indications, cautions, contraindications, side-effects and dose.

**Setting:** Community pharmacies.

**Main Outcome Measures:** Updating the first edition of the MMH and evaluation of the contents, use and costs.

**Results:** The publication includes 595 items, of which, 566 are medicinal products (and their different dosage forms) and 29 are medical devices. Two hundred seventy eight items of the previous publication were updated, 102 items were removed and 317 items were added.

**Conclusions:** The considerable amount of changes that had to be done to the present edition suggests that this publication should be updated more frequently than every 3 years.

### Reference:

1. Micallef S. Compiling a formulary for non-BNF cited products [dissertation]. Msida (Malta): University of Malta; 2006.

## Formulary for the Management of Mental Disorders

*Corinne Elbourne*

**Background:** To date healthcare professionals (HCPs) at Mount Carmel Hospital make use of a drug list which contains the pharmaceutical products including the dose and the formulation in which they are available at the hospital.

**Objectives:** To develop a formulary for a psychiatric hospital, to identify information requested by HCPs to be included in the formulary and to print and evaluate the final draft of the formulary.

**Design:** The formulary was compiled after giving out 200 questionnaires at the hospital which was aimed to identify information which the HCPs wanted to include in the formulary. HCPs suggested the development of guidelines on the use of medications as part of the formulary. During the development of the formulary, guidelines were developed according to the National Institute for Clinical Excellence (NICE) and Maudsley guidelines, both UK guidelines, and guidelines of the American Psychiatric Association. Both the formulary and the guidelines were evaluated by HCPs. Once compiled, both were submitted for printing and 100 copies were given to HCPs for evaluation.

**Setting:** Mount Carmel Hospital.

**Main Outcome Measures:** Compilation and evaluation of formulary and guidelines.

**Results:** The size of the printed handbook is A5 and consists of 4 main chapters which include: Hypnotics and Anxiolytics, Anti-depressants, Antipsychotics and Anti-Manic drugs. The handbook contains 5 guidelines which include: Depression, Anxiety Disorder, Schizophrenia, Insomnia and Bipolar Disorder. Using SPSS<sup>®</sup> Version 16.0, it is evident that the information within the formulary has been rated well by all the respondents and that all book features were also rated well by all respondents: 98% of the HCPs found the formulary useful and 96% also found the guidelines useful.

**Conclusion:** The developed formulary provides improved information and knowledge about the available medications. It can be carried around, stored easily, is concise and contains tables for better comparison of products.

## Development of Patient Information Leaflets

*Fabienne Sant Portanier*

**Background:** Written drug information, usually in the form of Package Inserts (PIs) or Patient Package Inserts (PPIs), aims to provide brief, concise and comprehensible information to patients. Objective: To analyse design factors contributing to the reading ease of Patient Information Leaflets (PILs) for non-prescription medicines (NPMs) and improve the readability of one PIL from each of 18 pharmacological classes.

**Design:** A sample of 264 NPMs was classified into 18 pharmacological classes. Design factors together with Flesch/Flesch-Kincaid readability scores were evaluated. One NPM from each class was edited and readability values were recalculated. The edited PILs were distributed to patients using the product.

**Setting:** A community pharmacy in Balzan.

**Main Outcome Measures:** Design factors analysed: presence of leaflet, PI or PPI, English version, number of facades, text organisation, text and background colour, date of revision, pictorial representations, active and direct style, boldface and underlining, explanation of medical terminology, number of languages present.

**Results:** Of the 243 NPMs analysed 60 (24.7%) contained a PI, and 119 (49%) contained a PPI. Sixty four (26.3%) lacked a PI, however 59 (92.2%) had sufficient information on the outer packaging. One language was present for 127 (70.9%) of the PIs. English was available for 166 of the PIs (92.7%). Only 52 (29.1%) PIs had two or more languages present. Medical term explanations were available for 65.9% (118) of the PIs. Nearly half of the PIs obtained a Flesch-Kincaid score of 6.1 to 8.0, meaning the text is comprehensible for 6<sup>th</sup> grade students and 60% of PIs obtained a Flesch reading score of more than 48.9.

**Conclusion:** More than a quarter NPMs did not contain a PI. The English language was not present for 13 (7.3%) NPMs. Based on the Flesch-Kincaid scores obtained, the text can be considered to be difficult in nature for approximately 20% of the PIs analysed.

## Development of Information Leaflets on Anxiety and Depression

*Maria Scerri*

**Background:** The awareness of depression and anxiety is important since their symptoms may be ignored by people suffering from these conditions. Objective: Developing and validating information leaflets regarding depression and anxiety.

**Design:** Information leaflets about depression and anxiety were designed. Questionnaires regarding these two conditions were formulated and the test-retest reliability method with 10 individuals was adopted to test reliability of interpretation of the questionnaires. Both leaflets and questionnaires were reviewed by a review panel. The questionnaires were distributed to 40 participants. Following the distribution of the leaflets, the same questionnaire was re-distributed to the same participants to be able to assess the educational value of the leaflets. Results were entered in a Microsoft<sup>®</sup> Excel sheet and the BMDP package software 2007 was used to compare the responses using correlation coefficient and t-test.

**Setting:** Gan Frangisk Abela Junior Collage; Felice Pharmacy, Zabbar

**Main Outcome Measures:** Reliability of the questionnaire, impact of leaflets on knowledge

**Results:** A Flesch Reading Ease Score of 70 and 75 were obtained for the “Anxiety” and “Depression” leaflets respectively. From the test-retest reliability testing, the correlation coefficients for each questionnaire were 0.7 and 0.8 respectively.

**Conclusion:** The Flesch Reading Ease Scores for both leaflets indicate that the leaflets are fairly easy to read and understandable from an age above 13 years. Since these leaflets are aimed for people older than 16 years this result was very satisfactory. The correlation coefficients for both questionnaires were greater than 0.6 indicating reliability of data generated.

## Newsletter to Community Pharmacists

*Rachel Galea*

**Background:** *The Active Pharmacist* is a newsletter issued on behalf of a local pharmaceutical company, Actavis Malta, in collaboration with the Department of Pharmacy at the University of Malta and directed towards community pharmacists.

**Objective:** To develop and evaluate the newsletter.

**Design:** Four issues of *The Active Pharmacist* were prepared. The newsletter consisted of four A4 size pages designed using FreeHand MX. The articles included news from the pharmaceutical industry, information regarding new drugs available on the local market and information about medical conditions and treatment. Articles discussing chronic conditions were endorsed by medical specialists in the areas concerned. Two hundred and fifty copies of each issue were distributed, together with a questionnaire that was developed to evaluate the newsletter.

**Setting:** Community and hospital pharmacies.

**Results:** Evaluation of the questionnaires resulted in a response rate of 50.3% (n=1000). Two hundred and seventy nine (55.5%) respondents were females. With regards to the design and layout of the newsletter, respondents agreed that the newsletters had an attractive (99%, 497) and professional (96.8%, 487) layout, the font used was clear (97%, 488) and that the illustrations were sufficient to complement the articles (85.7, 431). They agreed that the articles were both interesting (97.4%, 490) and informative (97.3%, 489), useful (93.4%, 470) and well written (91.7%, 461).

**Conclusions:** The newsletter was received well by the pharmacists. Many of the pharmacists suggested that there should be a continuation in the publication of such newsletters as they believed they were interesting, easy to read, practical and were a good method of communication between the pharmaceutical industry and the pharmacist.

## The Pharmacy Practice Resource Unit

*Simone Bartolo*

**Background:** The Pharmacy Practice Resource Unit (PPRU) is a source of drug information and is equipped with medications, diagnostic tests and an extemporaneous area to resemble the appearance of a community pharmacy. Its use helps the future pharmacist develop skills necessary to enable the best and safest use of medicines.<sup>1</sup>

**Objectives:** To collect pharmaceutical preparations, medical devices and recently launched products, to identify discontinued products and display them accordingly, to increase the number of books, journals, drug literature and extemporaneous materials, to provide internet access and to obtain sponsors.

**Design:** New and previously present preparations were listed and arranged according to pharmacological class. The aesthetic appearance and use of space was improved. Drug literature was filed and books were shelved. A computer was installed and a glass show case for displaying diagnostic devices and discontinued medications was provided. Pharmaceutical importers and medical representatives were contacted and asked for any of their products, including their product literature. An appointment was offered to those who wished to view the PPRU. Foreign pharmacy practice laboratories were studied for ideas improve the PPRU. A list of local pharmaceutical importers and manufacturers was compiled.

**Setting:** The PPRU, Pharmacy Department, University of Malta.

**Main Outcome Measures:** Medicines, medical devices and drug information made available at the PPRU.

**Results:** The PPRU now includes 6 books, 809 medicines, a computer tower and a showcase. Conclusion: The PPRU is still in its development and is being used for pharmacy practice tutorials.

### Reference:

1. Colin-Thomé D. Realising the potential of pharmacists. Royal Pharmaceutical Society of Great Britain [Online] 2006 [cited 2008 Nov 8]. Available from: URL: [www.rpsgb.org.uk/pdfs/pharmrolebrief.pdf](http://www.rpsgb.org.uk/pdfs/pharmrolebrief.pdf)

# Risk Assessment of the Preparation of Intravenous Infusion Fluids

Ruth Gatt

**Background:** It is recommended that regular risk assessments of the preparation of aseptic products are carried out to help minimise the risks associated with intravenous (IV) therapy.<sup>1</sup>

**Objective:** To develop a questionnaire that can be used locally to carry out risk assessments of the preparation of IV infusion fluids in medical wards.

**Design:** An extensive literature review was carried out. A first draft was developed, based on 2 validated questionnaires used in recent risk assessment studies in the United Kingdom.<sup>2,3</sup> New questions were added to the drafted questionnaire to include aspects of risks not highlighted in the previously developed questionnaires. The questionnaire was reviewed by 4 healthcare professionals (3 pharmacists and 1 nurse) and the respective recommendations were integrated into a final draft.

**Setting:** Six General Medical Wards, Mater Dei Hospital.

**Main Outcome Measures:** Identification of the hazards present in the ward environment and the current practices used during the preparation of IV infusion fluids.

**Results:** The final draft of the questionnaire entitled 'Questionnaire on the Preparation of Intravenous Infusion Fluids' consists of 6 A4 pages and is divided into 7 distinct sections, namely: (1) General Information, (2) Types of Infusions Prepared, (3) Preparation Environment, (4) Preparation Practice, (5) Training, (6) Policies/Guidelines, (7) Comments and Suggestions.

**Conclusions:** The questionnaire was designed to be user-friendly for nurses in the local general hospital setting as a risk assessment tool for preparation of IV infusion fluids.

## References:

1. National Patient Safety Agency (NPSA). Promoting safer use of injectable medicines. NPSA [Online] 2007 [cited 2008 Feb 6]. Available from: URL: [www.npsa.nhs.uk/EasysiteWeb/getresource.axd?AssetID=2265&type=Full&servicetype=Attachment](http://www.npsa.nhs.uk/EasysiteWeb/getresource.axd?AssetID=2265&type=Full&servicetype=Attachment)
2. Beaney AM, Goode J. A risk assessment of the ward-based preparation of parenteral medicines. *Hospital Pharmacist* 2003; 10:306-8.
3. Munro MJ, Millar BW, Radley S. A risk assessment of the preparation of parenteral medicines in clinical areas. *Hospital Pharmacist* 2003; 10:303-5.

# **Regulatory Affairs, Industrial Pharmacy and Clinical Analysis**

## **Quality of Medical Devices**

*Stephanie Mallia*

## **Standard Operating Procedures for Bioequivalence Studies**

*Claire Galea*

## **Penetration of Antibacterial Agents in the Peripheries**

*Alfie Palmier*

## Quality of Medical Devices

Stephanie Mallia

**Background:** Patients as well as healthcare professionals are increasingly confronted with new devices for blood pressure and blood glucose measurement. However, clinical usefulness of measurements is limited by the accuracy of the device.<sup>1</sup>

**Objective:** To compare medical devices used for point-of-care testing and home monitoring of blood pressure and blood glucose by testing different blood pressure monitors and blood glucose meters.

**Design:** A single-site, single-visit comparison of 4 blood pressure monitors (*ICO Medical* mercury sphygmomanometer, *S+K™ Manuell 50 KC* aneroid sphygmomanometer, *A&D® Medical UA-767 Plus*, and *Hartmann® Digital HG 140*) and 4 blood glucose meters (*Accu-chek® Active*, *Glucometer® Elite*, *OneTouch® Horizon* and *Major® II*). Fifty volunteers were recruited for each study.

**Setting:** A Community Pharmacy.

**Main Outcome Measures:** Comparison of results obtained by the different blood pressure monitors and blood glucose meters using the paired sample t-test and the Pearson correlation coefficient.

**Results:** The blood glucose levels recorded by the different meters had a statistically significant difference ( $p < 0.05$ ). *Glucometer® Elite* and *OneTouch® Horizon* showed the best correlation whilst *Accu-Chek® Active* and *Major® II* showed the least correlation. There was a statistically significant difference between diastolic blood pressure values recorded by *Hartmann Digital* and all the other 3 monitors ( $p < 0.05$ ). The *ICO Medical* and *S+K™ Manuell 50 KC* showed the best correlation whilst *A&D® Medical* and *Hartmann® Digital* showed the least correlation.

**Conclusion:** Different blood glucose meters gave a statistically different result but show a good correlation. The diastolic blood pressure values obtained by *Hartmann® Digital* are statistically significantly different from the values obtained by the other blood pressure monitors. The best correlation was found between the mercury sphygmomanometer and the aneroid sphygmomanometer.

### Reference:

1. O'Brien E, Waeber B, Parati G, Staessen J, Myers MG. Blood pressure measuring devices: recommendations of the European Society of Hypertension. *BMJ* 2001; 322:531-6.

## Standard Operating Procedures for Bioequivalence Studies

Claire Galea

**Background:** Bioequivalence Studies (BS) are financially intensive undertakings requiring significant investment in personnel, facilities and equipment.

**Objectives:** To prepare a set of Standard Operating Procedures (SOPs) for a BS to be used as a template for future BS.

**Design:** SOPs describing a pilot BS were prepared, comparing a generic preparation of doxazosin 8mg (slow-release) with its patented counterpart *Cardura® XL* carried out by *Abela*<sup>1</sup> and *Tanti*.<sup>2</sup>

**Setting:** Department of Pharmacy, University of Malta; Viticulture Laboratory, Ghammieri.

**Main Outcome Measures:** SOP library that can serve as a template for future BS.

**Results:** The created SOPs (n=29) were a result of identification of the processes and sub-processes, both clinical and analytical that were fundamental to the execution of the BS protocol. SOPs were sub-classified into categories general and specific. General SOPs were formulated to ensure their applicability to future BS. All created SOPs were standardised in a format that was laid out in the Master SOP.

**Conclusion:** Although the SOPs produced exhaustively dissected the entire BS, these were not subjected to a validation exercise owing to the fact that the pilot study was terminated prior to SOP completion. Furthermore, the pilot phase of the study has not yet been extended to a fully fledged BS. Once this occurs it will become imperative to challenge the prepared SOPs to the scrutiny of the personnel who will make use of them, and to effect amendments as necessary. This validation process will confer robustness to the procedures and make them suitable for distribution in the laboratory according to GLP principles.

### References:

1. Abela A. Bioequivalence of doxazosin slow release tablets: A pilot study [dissertation]. Msida (Malta): University of Malta; 2008.
2. Tanti A. Bioequivalence studies: A cost effectiveness study [dissertation]. Msida (Malta): University of Malta; 2008.

# Penetration of Antibacterial Agents in the Peripheries

*Alfie Palmier*

**Background:** Diabetes Mellitus patients may present peripheral vascular complications such as ulceration and gangrene.

**Objective:** To determine a method to analyse plasma and tissue concentrations of amoxicillin and metronidazole using High Performance Liquid Chromatography (HPLC) and Solid Phase Extraction (SPE).

**Design:** A HPLC method was developed for the analysis of amoxicillin and metronidazole in plasma and tissue.<sup>1</sup> Swine tissue samples were allowed to soak in a known concentration for 24 hours whilst plasma was spiked with known volumes. SPE was used as a sample preparation technique. Resolution of peaks was achieved with a mobile phase of 30:70 v/v acetonitrile-25mM potassium phosphate buffer containing 0.25% triethylamine, 2% methanol and 2% acetic acid (pH4.5) at a flow rate of 0.5mlmin<sup>-1</sup>. A 5 micrometer phenyl column, equipped with a fluorescent detector pre-set at an emission wavelength of 440nm and 444nm for amoxicillin and metronidazole respectively.

**Setting:** Pharmacy Department Laboratories for the preparation of the mobile phase and SPE; Allied Research Unit for tissue preparation; Ghammieri Laboratory for HPLC analysis.

**Main Outcome Measures:** Development of analytical methods.

**Results:** The analysis of both anti-bacterial agents is possible using a reversed phase HPLC system and SPE extraction techniques. The method yields retention times of 3.8 and 4.3min for amoxicillin and metronidazole respectively. Both agents easily permeate through muscle tissue over a period of 24 hours. Amoxicillin is unstable above a temperature of  $\pm 5.0^{\circ}\text{C}$ , this was evident in repeated analysis. Metronidazole on the other hand shows notable degradation in light over a period of 48 hours.

## Reference:

1. Storms ML, Stewart JT. Development of a reversed-phase liquid chromatographic method for the analysis of amoxicillin, metronidazole and pantoprazole in human plasma using solid phase extraction. *Journal of Liquid Chromatography & Related Technologies* 2002; 25(16):2433-43.