

JEMP

JOURNAL
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CARE ISSUES
AND MEDICATION
REVIEW



COMMUNITY
PHARMACIST
PERCEPTION OF
SUPPLEMENTARY
PRESCRIBING

METHICILLIN
RESISTANT
S. AUREUS
IN AUTOPSY
CASES

GENERIC
MEDICINE PRICES
AND THEIR
DISTRIBUTION
IN MALTA



Picture taken by Jakov Cordina (B.Pharm) at Vittoriosa Pharmacy, Vittoriosa.

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EDITORIAL

EVOLVEMENT OF WARD AND CLINICAL PHARMACY

Anthony Serracino-Inglott

When pharmacists started visiting wards in early days of clinical pharmacy, some 40 years ago, they concerned themselves primarily with organising the supply of non-stock items and with reviewing the medication sheets to prevent misinterpretation and hence administration errors. These tasks are still important and in recent years the role of the pharmacist has evolved with the teaching of clinical pharmacy to all students at the undergraduate and postgraduate level.

At last year's annual pharmacy symposium organised by the Department of Pharmacy at the University of Malta, the Minister of Health Dr Joe Cassar emphasised the need for more pharmacy graduates to take up the practice of clinical pharmacy in earnest. He mentioned the importance of including a Clinical Pharmacist in the team of Health Care Professionals working at Mater Dei Hospital. Dr Cassar also expressed his hope of a near golden future where clinical pharmacists competently carry out their work in collaboration with other trained personnel helping them whilst working by their side.

The Department of Pharmacy has set up and planned a three year undergraduate course leading to a BSc. in Pharmaceutical Technology. This course will serve to bridge the gaps in the separate roles of the pharmacy technician and the pharmacist. Such a course would serve as a means for training professionals in complementing the job of and assisting pharmacists in the various work settings- ranging from the Pharmaceutical Industry to Community Pharmacy. This is especially relevant for the Community Pharmacy sector due to the recently implemented Pharmacy of Your Choice scheme where support for the pharmacist is needed in order for the system to be successful.

On the occasion of the 2011 Annual Pharmacy Symposium, the Department of Pharmacy and the Malta Pharmaceutical Association, organised a commemoration for Professor Steve Hudson. Professor Hudson was truly a leading example as a great innovator and promoter in the field of Clinical Pharmacy. He was a well respected colleague of many Health Care Professionals around Europe.

Steve's distinctive character and the impact which he left on the pharmacy profession was clearly seen at the highly attended Commemoration Seminar held at the Faculty of Medicine and Surgery at the University of Malta. Among the numerous distinguished participants was the key speaker of the event Professor Peter Noyce from the University of Manchester. The past president of the European Association of Faculties of Pharmacy (EAFP), Professor Benito del Castillo from Spain and the EAFP current president, Professor Bart Rambart from Belgium also contributed to the event. Coming from Steve's adopted home in Scotland were Dr John McAnaw and Dr Julienne Johnson who received the Medal of Merit bestowed by the Department of Pharmacy on Professor Steve Hudson in recognition and admiration for his contribution to Clinical Pharmacy.

This issue of the journal was sponsored by Actavis (Malta) an example of collaboration between industry and academia.

Professor Anthony Serracino-Inglott is immediate past Head of Department of Pharmacy at the University of Malta and is an internationally recognised pioneer in the development of Clinical Pharmacy since 1972.



“THE ROLE OF THE PHARMACIST HAS EVOLVED WITH THE TEACHING OF CLINICAL PHARMACY TO ALL STUDENTS AT THE UNDERGRADUATE AND POSTGRADUATE LEVEL”

EVALUATION OF PHARMACIST CLINICAL RECOMMENDATIONS IN A GERIATRIC HOSPITAL

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ABSTRACT

OBJECTIVES This study was undertaken to record the number and type of recommendations made by pharmacists reviewing the drug treatment of older patients, to note acceptance of these recommendations by physicians and to assess clinical significance of pharmacist recommendations.

METHOD Three pharmacists providing inpatient services at Zammit Clapp Hospital were asked to record specific details of all recommendations given using a designed documentation form. The clinical impact of the pharmacists' recommendations was assessed by the pharmacists making the recommendations together with a panel of two independent pharmacists and a medical doctor who had to rate the contribution of each recommendation as major, moderate, minor or of no clinical significance.

KEY FINDINGS A total of 263 valid pharmacist recommendations were documented. The most frequent recommendations, accounting for 20.5% (n=54) of the total number of recommendations were adjustment to dosage, frequency and time of administration followed by discontinuation of a medication. The majority of recommendations were accepted by physicians (80%) and were rated by the panel to be of moderate (60.5%) clinical significance.

CONCLUSION Clinical pharmacists make a number of recommendations of significant clinical benefit to the care of hospitalised elderly patients, the majority of which are accepted by physicians.

KEYWORDS Interventions, Geriatric Pharmacy, Hospital Pharmacy, Clinical Pharmacy

INTRODUCTION

The pharmacist has a knowledge of the optimal use of medications and the ability to influence physician prescribing.¹ Studies have shown that interventions by hospital pharmacists are effective in reducing medication errors, improving patient health outcomes and decreasing both costs and length of stay.²⁻⁴ Significant and clinically important results can be achieved by pharmacists reviewing the drug treatment of older patients who are being hospitalised.⁵

This study aimed to quantify and evaluate the impact of recommendations made by pharmacists at Zammit Clapp Hospital, a 60-bed hospital targeted for the treatment and rehabilitation of patients sixty years of age and older. The objectives of this study were to: record the number and type of recommendations made, note acceptance of the recommendations by physicians and assess the clinical significance of recommendations.

METHOD

DOCUMENTATION FORM

A documentation form was designed to standardise the recording of recommendations. It was created by combining aspects of other data sheets used in previous studies.⁶⁻⁸ The documentation form consisted of two parts: the first section for recording information including patient age and gender, the primary reason for admission and the patient's number of chronic medications. The other section was created for describing the pharmacist recommendation, the drugs involved and to document whether the recommendation was accepted by the physicians.

PILOT STUDY

The documentation form and the study design were piloted in one ward for two weeks. Minor changes in wording and content were made to the form, which was then used throughout the study.

DATA COLLECTION

During the actual study, each of the three pharmacists providing inpatient services at the hospital was asked to record specific details of all recommendations during a specified 12-week period. For the purposes of this study, the definition of a recommendation was "Any proactive or reactive activity made with the intent of improving patient management or therapy, involving the application of the pharmacist's knowledge to a specific patient or physician order".^{7,9-11}

ASSESSMENT OF CLINICAL SIGNIFICANCE

The clinical impact of the pharmacists' recommendations was assessed by the intervening pharmacist and a panel which consisted of two other clinical pharmacists and a medical doctor. All three evaluators were independently provided with the documentation forms. Evaluators had to rate the contribution of each recommendation as either major, moderate, minor or of no clinical significance. At least two of the three evaluators had to agree on the degree of significance of the recommendation. This gave rise to a single panel rating for each recommendation which was termed 'the average significance'.

STATISTICAL ANALYSES

The documentation forms were coded and entered onto a Microsoft Office Excel 2007 spreadsheet to quantify and analyse the data. The data was then transferred to SPSS 15.0 to perform statistical evaluations and cross tabulations. The scores of the pharmacists coding their own recommendations, the physician and the evaluator pharmacists were compared using the paired-sample Student t-test.

RESULTS

A total of 263 valid pharmacist recommendations to 158 different patients were made during the study period. Some patients required more than one recommendation: (a mean of 1.7 recommendations were made per patient). The nature of recommendations is shown in Table 1.

ACCEPTANCE RATES

Of the 263 recommendations, 80 per cent were accepted by physicians (n=211), 16 per cent were not accepted (n=43) and 3 per cent could not be evaluated for acceptance (n=9). Pharmacist recommendations classified as 'Recommendation of monitoring' had the highest percentage of accepted recommendations (93.3%) (n=245). The highest percentage of unaccepted recommendations was for the addition of a new medication (30.4%) (n=80).

SIGNIFICANCE

The majority of recommendations (60.5%) were rated to have provided an average significance in the moderate level (n=159), followed by recommendations of minor significance (35.4%) (n=93). Recommendations that were judged to have made a major contribution to the quality of patient care comprised 3% of recommendations (n=8). A relatively small percentage of recommendations (1.1%) (n=3) were judged to be of no clinical significance.

STATISTICAL ANALYSES

There was no difference in the mean significance ranking scores between the two evaluator pharmacists (P=0.48; paired t-test). When the average significance of both evaluator pharmacists was compared with that attributed by the pharmacists coding their own recommendations, a significant difference resulted, (P<0.001; paired t-test) with the latter attributing higher significance than the evaluator pharmacists. The physician rated the highest percentage of recommendations as minor. This resulted in a poor agreement between the physician and the evaluator pharmacists in their assessment of the significance of recommendations (P<0.001; paired t-test). Overall, both the evaluator pharmacists and pharmacists coding their own recommendations rated the clinical significance of the recommendations higher than the physician.



"CLINICAL PHARMACISTS MAKE A NUMBER OF RECOMMENDATIONS OF SIGNIFICANT CLINICAL BENEFIT TO THE CARE OF HOSPITALISED ELDERLY PATIENTS"

DISCUSSION

Adjustments of dosage, frequency and time of administration were the commonest reasons for pharmacist recommendations, followed by discontinuation of a medication. Thirty seven per cent (n=97) of the recommendations in these two categories featured central nervous system drugs, including benzodiazepines, antipsychotics and tricyclic antidepressants. The risks with these medications, enhanced by their concomitant use, are sedation, increased tendency to falls (and thus risks of fractures) and anticholinergic adverse effects, which are especially relevant in the older patient. The importance of these two categories can be interpreted in the light of polypharmacy, adverse drug reactions and decreased adherence to treatment in the elderly population.

Physicians accepted advice on most of the recommendations proposed by pharmacists (80%), which confirms that pharmacists input is needed for high-quality care and that the pharmacists' approach of therapy matched the practice adopted by the physicians. Of the unaccepted recommendations, reasons for not being accepted might be that a patient's medication would have been commenced by a specialist and the physician would be reluctant to override another specialist's initial prescribing decision,¹² or the physician might not consider the recommendation a priority. Physicians would also sometimes know that patients would object to a change in their medications since they may have previously attempted and failed the strategy recommended by the pharmacist.

The physician generally rated the recommendations as being of lower clinical relevance than the pharmacist did. This is consistent with findings in other studies.^{13, 14} However although there was not an agreement on an individual case basis, both the evaluator pharmacists and pharmacists coding their own recommendations believed that overall, the highest percentage of recommendations were of moderate significance.

CONCLUSION

This study provided several important insights. Clinical pharmacists make a number of recommendations that affect the care of hospitalised elderly patients, the majority of which were accepted by physicians and are of moderate clinical significance. Recommendations are aimed at improving quality of care and were judged to be mostly of moderate significance.

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Category	n	(%)
Drug treatment initiated	23	(8.7)
Drug treatment discontinued	32	(12.2)
Recommendation of alternative therapy	21	(8.0)
Adjustment of dose / frequency / time of dose	54	(20.5)
Alteration of the formulation	17	(6.5)
Duration of therapy	31	(11.8)
Recommendation of monitoring	15	(5.7)
Identification of drug interaction / adverse drug event	6	(2.3)
Clarification of order – prescription sheet unclear / error in prescription sheet	20	(7.6)
Provision of drug information	15	(5.7)
Switch from regular to as-required	21	(8.0)
Investigate reason for a drug	5	(1.9)
Other	3	(1.1)

COMPLIANCE AND MEDICATION PROBLEMS IN CHRONIC CONDITIONS

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ABSTRACT

OBJECTIVES The project aimed to determine the level of medication compliance in patients having a chronic condition and to determine the types and frequency of medication-related problems identified by a pharmacist working in a community pharmacy.

METHOD The study population was identified from the database of patients receiving free medicinals under the 'Pharmacy of your Choice' scheme from a particular community pharmacy. Patients included in the study were older than 60 years of age and taking more than 3 drugs. A Compliance Questionnaire was distributed to these patients. The pharmacist classified medication problems and used a specifically developed data collection tool in order to collate all the relevant patient information.

KEY FINDINGS Of the 75 patients included in the study, 33 (44%) said they never missed a dose whilst the remaining 42 (56%) were non-compliant. Out of the 205 medication-related problems identified, the most common medication-related problems observed were non-compliance (56%) and the occurrence of adverse drug reactions (55%).

CONCLUSION Compliance is a significant medication-related problem encountered by community pharmacists amongst elderly patients receiving multiple drug therapy for their chronic conditions.

KEYWORDS compliance, medication-related problems, chronic conditions, POYC.

INTRODUCTION

Chronic conditions are diseases of long duration and generally slow progression. They are conditions that can only be controlled and not, at present, cured. Chronic conditions, such as cardiac disease, cancer, chronic respiratory diseases, stroke and diabetes, are by far the leading cause of mortality in the world, representing 60% of all deaths. The major risk factors for chronic disease are an unhealthy diet, lack of physical exercise and tobacco use.¹

Living with a chronic disease has a significant impact on a person's quality of life. The incidence of such diseases increases with age. In fact, many older people are living with more than one chronic condition meaning that they face different challenges, both medical and social.² One of the most prominent medical challenges is compliance to medication. Since older people tend to be consuming a number of medications, they keep forgetting when their next medication is due, or which drug they are supposed to be taking at that time.

Medication compliance refers to the degree or extent of conformity to the recommendations about daily treatment by the health care professional with respect to the timing, dosage, and frequency.³ It may be defined as "the extent to which a patient acts in accordance with the prescribed interval, and dose of a dosing regimen".⁴

Another medical challenge faced particularly by the elderly is that of medication errors. A medication-related problem is an event or situation whereby drug therapy is negatively interfering with the patient's health. These problems can cause, contribute or aggravate common geriatric problems. Pharmacists can identify and prevent medication-related problems through careful evaluation and monitoring of patients' drug regimens.⁵

The aims of this study were to determine the level of medication compliance in patients having a chronic condition and to determine the types and frequency of medication-related problems identified by a pharmacist working in a community pharmacy.

METHOD

The study population was identified from the database of patients receiving free medicinals under the 'Pharmacy of your Choice' (POYC) scheme from a particular community pharmacy. Patients included in the study were older than 60 years of age and taking more than 3 different drugs under the scheme. Seventy-five eligible patients participated in this study after signing an informed consent form. Ethics approval for the study was granted by the University of Malta Ethics Committee.

The study was divided into three sections. The first part consisted of proposing a Maltese version of the 'Compliance Questionnaire' which was previously developed by Letizia Zammit in 2005 as part of her undergraduate pharmacy project.⁶ The Maltese version of the questionnaire was validated by an expert panel consisting of a general practitioner, a pharmacist, a head of school, a university lecturer specialising in the Maltese language and a lay person.

The second part of the study saw the implementation of the questionnaire to the 75 patients when they called at the pharmacy to collect their medicine. The third part dealt with the pharmacist identifying medication problems. The pharmacist classified the medication problems and developed a data collection tool in order to collate all the relevant patient information. This included demographic data, drug history, past medical history, current diagnosis, any recent clinical parameters and the potential medication problems, which were classified into: sub-optimal dosing, over-dosing, therapeutic duplication, unnecessary medication, clinically significant interactions and non-compliance.

RESULTS

Out of the 75 patients involved in the study, 46 (61%) were female and 29 (39%), were male. The average age of the patients was 74, whilst the median age was 72. The patients age ranged between 60 and 88 years of age, with 30 (40%) being within the 60-69 age bracket and 45 (60%) being over 70 years of age. Sixty-eight (91%) of the patients were married, 36 (48%) patients were living with other members of their family, 23 (31%) were living alone and 16 (21%) were retired in an institution. Patients' educational level ranged from 28 (37%) having completed 5-9 years of full-time education, 26 (35%) patients completed up to 4 years of education, whilst the remaining 21 (28%) accomplished more than 10 years of education. All patients but six (8%) were born in Malta. The majority (88%) of patients said they visit the same doctor each time. For those living in an institution (21%), this would happen automatically since one doctor would be responsible for that home.

COMPLIANCE ISSUES

Sixty-six patients (88%) said they usually visit the same doctor. Regarding compliance to medications, 33 patients (44%) said they never missed a dose, 24 (32%) would rarely miss their medication, 15 (20%) missed a dose once a week whilst the remaining 3 (4%) patients always missed a dose. Reasons for non-compliance were various. From the non-compliant group, 19 (25%) claimed to be asymptomatic, 13 (17%) experienced side-effects related to their chronic disease medication, 3 (4%) showed lack of concern whilst 7 (9%) did not comply since they forgot to take their medication.

When asked what action patients take upon realizing they had missed a dose, 24 (32%) admitted to skipping the dose altogether, 15 (20%) said they took the dose when they remembered and 3 (4%) said they took double the dose at the next dose.

Compliance with the prescribed times of medications is also an important factor in determining patient compliance. Patients were asked whether they were compliant with the prescribed times of their medications. The majority of patients (64%) took their medications at the prescribed times.

MEDICATION-RELATED PROBLEMS

The pharmacist identified 205 medication-related problems in the drug treatment of the 75 patients. The most common were non-compliance (42), the occurrence of adverse drug reactions (41), subtherapeutic dose (26) and risk of drug interactions (25) (Figure 1).

DISCUSSION

The majority of patients in this study 56% (n=42) were non-compliant and the reasons given correlate well with results reported by Corlett in 1996 where non-compliance was reported to result from patients not knowing how to take the medication, not understanding the importance of drugs in managing the symptoms, polypharmacy, anticipation or experience of side-effects, forgetfulness or impaired physical function.⁷ In the scenario of this study a reason for non-compliance was inaccess to free medicines.

When the medicine is out of stock from government stocks the risk of non-compliance is higher since patients are either too old to go to collect their supply from the Government pharmacy, are not eager to wait long hours in the queue at the Government pharmacy or have no relatives to send to pick up their medications. Most patients are unwilling to buy the out-of-stock medications resulting in the patients not taking their medications, increasing the problem of non-compliance.

Pharmacists have a pivotal role in optimizing compliance to pharmacotherapy and therefore improve health outcomes by assessing each patient individually. This will result in assessing each patient's own compliance problem, recommending targeted interventions that are responsive to the patients' risk factors and needs, identifying predisposing factors and providing comprehensive counseling.⁸

The pharmacist spends time educating the patients in order to increase the level of drug compliance and after identifying individual drug related problems the pharmacist can focus the counselling to address this area or contact the prescriber to follow-up patient care. Such interventions by the community pharmacist add value to the level of care provided to patients receiving their medicines through the POYC scheme and contribute to improving patient safety and patient outcomes.

The most prominent medication-related problem as identified by the pharmacist in this study was non-compliance in 56% (n=42) of patients, followed by the incidence of adverse drug reactions or side effects in 55% (n=41) of patients. This finding coincides well with results from other studies.^{9,10,11} In the case of older adults, adverse drug reactions may contribute to already existing geriatric problems such as increasing risk of falls, urinary incontinence, constipation and weight loss.

CONCLUSION

Results indicated the importance of educating patients regarding compliance since only 44% claimed to be compliant at all times. The elderly may tend to be more non-compliant since they would not understand the dosage regimen and would be unaware of the consequences of poor compliance.⁶ Elderly qualify as a patient group to undergo regular treatment review sessions by the community pharmacist when collecting the medications for chronic diseases. This review will reinforce information about the drugs, identify medication-related problems and reduce non-compliance due to confusion or misinformation about drug dosages.

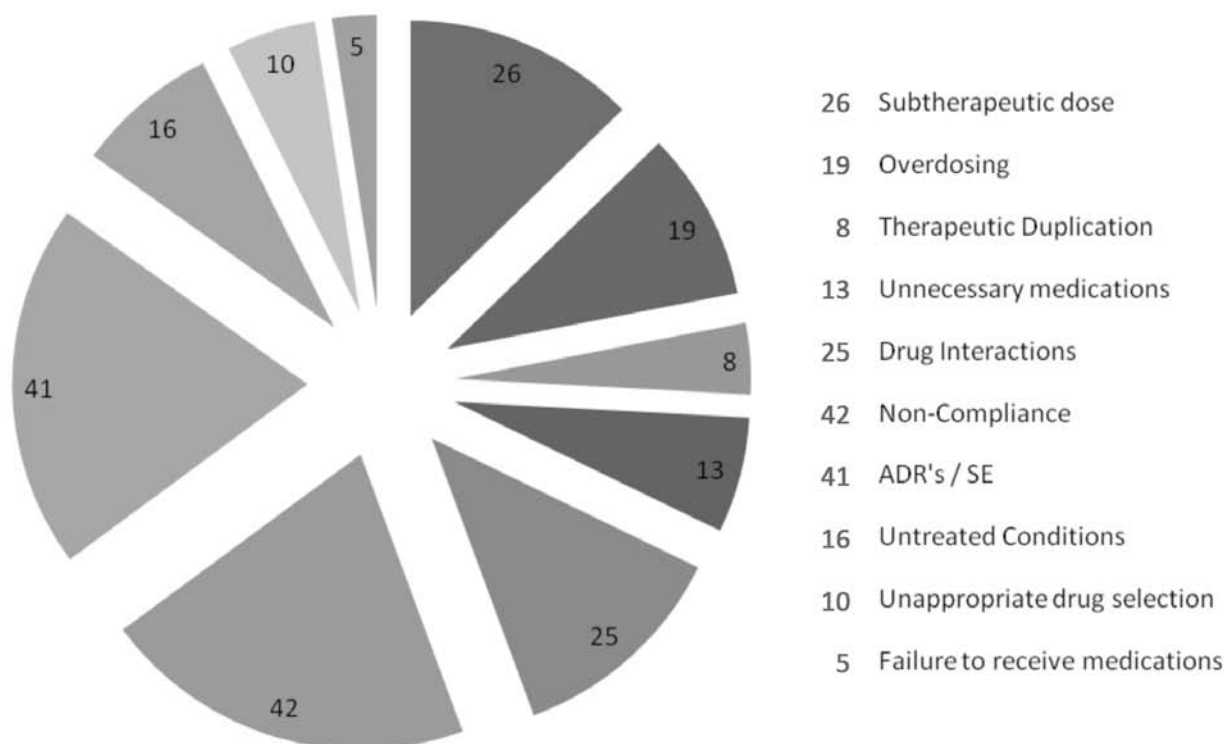


“RESULTS INDICATED
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Figure 1: Classification and frequency of medication-related problems (n=205).



CARE ISSUES AND MEDICATION REVIEW

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ABSTRACT

OBJECTIVE To undertake a pharmacist medication review for patients receiving chronic medication in a community pharmacy setting.

METHOD Patients collecting their free medication from a specific community pharmacy through the 'Pharmacy of Your Choice' (POYC) scheme had their medication records reviewed by a pharmacist to identify any drug-related problems. A questionnaire regarding the use of their medication, patient check-ups and medication compliance to their prescribed regimen was performed for each individual patient.

KEY FINDINGS Eighty patients were studied. The average number of medications per patient was 6 medications. Forty-two patients (52.5%) claimed to pick up their repeat prescription when they visit their doctor. Thirty-one patients (39%) stated that they experienced medication side effects. From the pharmacist medication review it transpired that 19 patients (24%) were at a risk of clinically significant drug interactions.

CONCLUSION Community pharmacists can help patients use their medication more effectively. They can support prescribers in the selection of the most appropriate therapy for the individual patient. In chronic disease management, pharmacist-led medication reviews can help optimize pharmacological therapy reducing medication-related problems. This can help achieve treatment goals and improve patients' quality of life.

KEY WORDS Medication review, medication regimen, community pharmacist, patient monitoring.

INTRODUCTION

The 'Pharmacy of Your Choice' (POYC) scheme was introduced in Malta in 2007. This is a scheme whereby people suffering from chronic diseases obtain their medicines for free through the public national health system from a private pharmacy of their choice.

Regimens, pertaining to patients who intend to make use of their medication chronically, might need certain periodic adjustments. Common amendments which can be made include the removal of unnecessary medication or the addition of another drug. In chronic treatment patients may need medication review especially when receiving treatment from different health care professionals. Some patients might not be compliant to the medication prescribed to them or they might have difficulties when it comes to managing their own medicines.

In the local scenario, these issues could be addressed during a medication review undertaken by the community pharmacist prior to dispensing the chronic medications through the POYC scheme. When a medication review is conducted, maximum benefit of particular medication is sought and negative effects caused by one or more medication's side effects or interactions eliminated.¹ Application of therapeutic guidelines to decide what action is needed and the implementation and monitoring of this action is of utmost importance.^{2,3}

The aims of this study consisted of performing a detailed examination of the patient's medication regimen through a medication review exercise. Also, identification of any significant problem present in the medication regimen and amendment of these problems through discussions with the patient's GP or specialist and the patient were undertaken.



“REGIMENS, PERTAINING TO PATIENTS WHO INTEND TO MAKE USE OF THEIR MEDICATION CHRONICALLY, MIGHT NEED CERTAIN PERIODIC ADJUSTMENTS”

METHOD

Patients visiting the pharmacy to collect their medication through the POYC scheme had their medication regimen observed and recorded. This was done by looking through the patient's medication record held at the community pharmacy where the study was carried out. Approval was granted from the managers of the community pharmacy and from the University of Malta Research and Ethics committee.

The patients which were selected had to be either; taking 4 or more different types of medication, older than 60 years of age, with special psychiatric needs, taking high risk medication (eg; drugs with a narrow therapeutic index) or patients experiencing particular undesirable effects through routine monitoring.

A patient profile was set up which included the name, gender and history of medical conditions that the patient was suffering from. This profile also included a list of all the medications that the patient was taking, prescription and non- prescription medicines.

When patients visited the pharmacy to collect their medicines each patient participating in the study was asked to answer a questionnaire. The questionnaire assessed through patients' self- reporting, adherence to the prescribed medication regimen. Questions consisted of whether patients usually visited the same doctor or not and information about and frequency of medical check- ups. Patients were asked whether they received a full medical check- up when they collected their repeat prescription for their 'free medicines' or whether they just collected their repeat prescription with no further discussion. Also, patients were asked questions about taking medication regularly at the prescribed time, missing doses and reasons for poor compliance. Patients were asked to report any experienced side effects.

Following collection of this data, a check- list was set up by the pharmacist conducting the review. By using this tool, the pharmacist evaluated appropriateness of drug therapy and dosage regimen given to the patient, if there were any untreated or unnecessary indications, if duration of therapy was appropriate, if there were any interactions or side effects which could be avoided, if the regimen could be simplified and if the regimen was cost effective. All the information attained was recorded in the check- list.

RESULTS

Eighty patients participated in the study. Forty (50%) were male and 40 (50%) were female. All patients were Maltese. The average age for this population of patients was 69 years (range: 37-91 years).

The most common types of conditions which these patients were suffering from were hypertension, hyperglycaemia and hypercholesterolaemia with 51 (64%), 22 (28%) and 30 (38%) patients suffering from them respectively. The average number of medications per patient was 6 different types of medication (range: 1- 34 types of medication). Seventy patients (88%) claimed to usually visit the same doctor. The average frequency of medical check- ups was every 6 months (range: every week – every 3 years).

Thirty-seven patients (46%) claimed to receive a medical check-up and discuss their medication when they collect their repeat prescription from their doctor whilst the remaining 43 patients (54%) claimed to collect the repeat prescription with no thorough discussion.

When assessing patient compliance to their medication, 55 patients (69%), claimed to never miss a dose of their medication. The remaining 25 patients (31%) claimed to miss their dose of medication either rarely or more often. The majority of patients (77 patients; 96%) said that they usually took their medication at their prescribed time. Thirty-one patients (39%) reported that they experienced side effects which they knew were caused by their medication.

From the check-list completed by the pharmacist, it was observed that 69 patients (86%) were receiving appropriate treatment for their condition. No patients had any untreated indications and no patients were being treated for unnecessary indications. Seventy- five patients (94%) had a constant need for the drugs being provided to them whilst the remaining 5 patients (6%) were taking medication which should have been stopped previously. Seventy out of the eighty patients (88%) were being administered an appropriate dosage regimen. A One Way ANOVA test indicated that patients being administered a relatively lower number of medications were those most likely to be receiving the most appropriate treatment ($p= 0$; Figure 1). Nineteen patients (24%) were at risk of significant drug interactions which could be minimized. For 72 patients (90%) there was duplication of treatment.

DISCUSSION

Results of this study show that most patients were receiving a considerable amount of poly-pharmacy. This could indicate the presence of various co-morbidities but could also indicate the fact that duplication of treatment prevails in this population. This could be due to the fact that although most patients usually visited the same doctor, a considerable amount of them visited different specialists and co-ordination of treatment was lacking. This reflects the need for medication review by the community pharmacist from where the patient is collecting the medicines through the POYC. In this scenario the pharmacist has a complete view of all medications being taken by the patient irrespective of disease, condition or specialist visited.

Also such a process will reduce the risk that patients experience side effects caused by their medication. The community pharmacist can indeed help their patients use their medication more effectively and can support prescribers to select the most appropriate clinical or most cost effective treatment for the individual patient. Pharmacist-based medication review reduces the potential for drug-related problems.⁴ Continuity of care is of utmost importance when it comes to the delivery of health care of high quality.⁵ The community pharmacist is in a position to follow up on patients' drug therapy in the primary care setting particularly in a scenario where patients may not be receiving a detailed medical check-up when getting the repeat prescriptions.

CONCLUSION

In chronic disease management the presence of multiple prescribers and the lack of frequent reviews could present potential problems to the individual patient. Health-care professionals should collaborate to provide optimal therapy to all patients. Good education should be given to all patients regarding their treatment. Pharmacist-led medication reviews for patients on the POYC scheme should be proposed as this will lead to better patient monitoring, care and use of medicines.

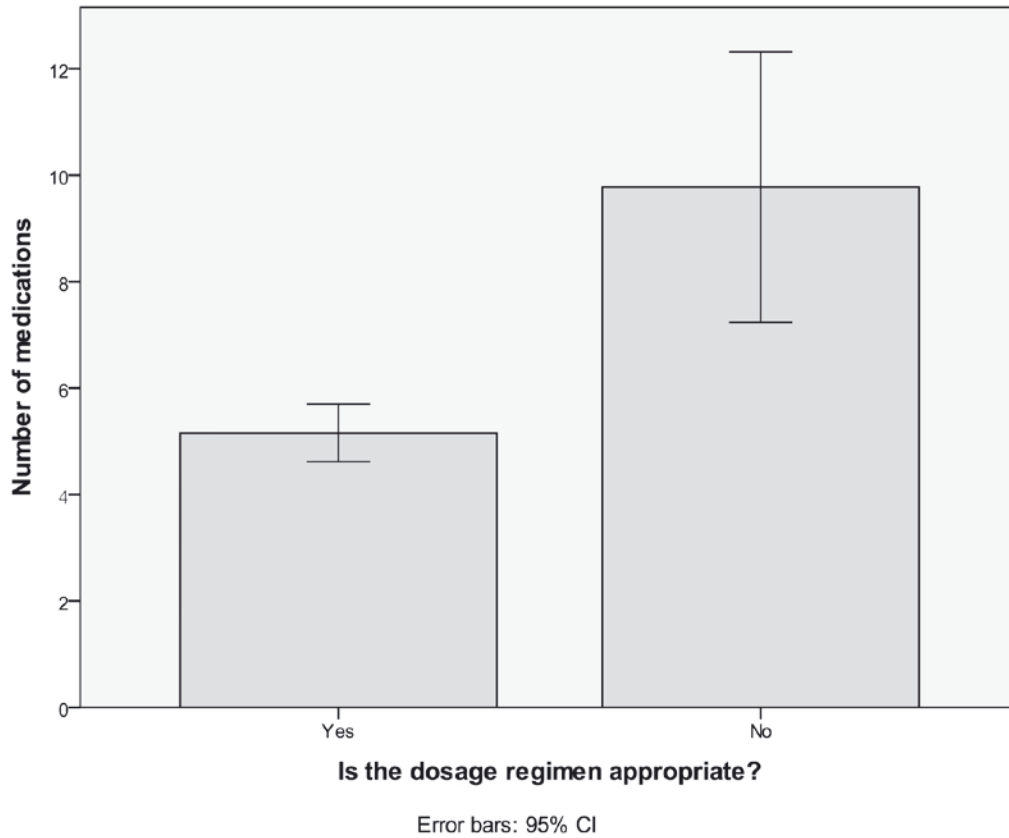
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“RESULTS OF THIS STUDY SHOW
THAT MOST PATIENTS WERE
RECEIVING A CONSIDERABLE
AMOUNT OF POLY-PHARMACY”

Figure 1: Comparison of the number of medications with whether or not patients are receiving the most appropriate dosage regimen (n=80)



“IN CHRONIC DISEASE MANAGEMENT THE PRESENCE OF MULTIPLE PRESCRIBERS AND THE LACK OF FREQUENT REVIEWS COULD PRESENT POTENTIAL PROBLEMS TO THE INDIVIDUAL PATIENT”

COMMUNITY PHARMACIST PERCEPTION OF SUPPLEMENTARY PRESCRIBING

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ABSTRACT

OBJECTIVE To determine the perception of Maltese community pharmacists regarding supplementary prescribing.

METHOD A self-administered questionnaire was developed, tested for validity and reliability and distributed to 50 community pharmacists selected by stratified random sampling. Statistical analysis was undertaken using Microsoft® Excel® XP and the BioMedical Data Package (BMDP) software.

KEY FINDINGS Cronbach's alpha correlation coefficient for the questionnaire was 0.8191. Forty-six pharmacists responded to the questionnaire. Twenty-three pharmacists were in favour of supplementary prescribing for a variety of conditions predominantly gastro-oesophageal reflux disease and asthma (both 19 pharmacists). Pharmacists (20) envisaged the introduction of supplementary prescribing by forming liaisons with general practitioners.

CONCLUSION The initial response to the concept of pharmacist prescribing is encouraging. Community pharmacy in Malta will need to make changes in order to provide such services to patients.

KEY WORDS supplementary prescribing, pharmacist perception, community pharmacy practice

INTRODUCTION

Granting prescribing rights to pharmacists is likely to reduce fragmentation within the health care system, optimise medication management, improve continuity of patient care and improve patient access to medication. Knowledge and clinical significance of adverse effects, dosing, optimal routes, drug-drug and drug-food interactions, pharmacokinetics, pharmacodynamics and patient monitoring is required for prescribing.^{1,2}

Eight models for pharmacist prescribing (Figure 1) have been implemented internationally (in the United Kingdom, the United States of America, Canada and New Zealand), varying in their dependency on protocols, formularies and collaboration with physicians.^{1,2} Supplementary prescribing involves a partnership between an independent prescriber, who establishes the diagnosis and starts treatment, and a supplementary prescriber, who monitors the patient and prescribes further medication, to implement a patient-specific clinical management plan with the patient's agreement. In this scenario, independent prescribers are doctors or dentists and supplementary prescribers are pharmacists or nurses.^{1,2,3}

In the United Kingdom, supplementary prescribing was introduced in the Health and Social Care Act 2001⁴ and there is no restriction on the medical conditions to which this model applies. However supplementary prescribing is unlikely to be used for acute conditions. All medicines, excluding controlled drugs and unlicensed medicines may be prescribed. Supplementary prescribing is not restricted to one-to-one prescriber partnerships. The independent prescriber undertakes the initial assessment and the supplementary prescriber writes prescriptions, working towards a care management strategy agreed by the physician. The roles of the supplementary prescriber include contributing to clinical management plan monitoring, changing the medication and referring to the independent prescriber where appropriate, and recording clinically relevant facts.^{1,2,3}

The aim of this study was to determine the perception of Maltese community pharmacists regarding supplementary prescribing.

METHOD

A self-administered questionnaire was devised. It was divided into two sections with a total of 28 sub-divided questions; Section A was called 'Pharmacy Data', whilst Section B was called 'Patient Consultation'.

The main concept addressed was supplementary prescribing together with other issues including; the use of computer technology in the pharmacy, maintaining of patient medication records, setting up of consultation areas, remuneration for pharmacists' services, and continuing professional development.

After designing the questionnaire, psychometric evaluation of the tool was carried out to assess its validity and reliability. All data was inputted into Microsoft® Excel® XP and statistical analysis was carried out using the BioMedical Data Package (BMDP) software, where internal consistency was measured using Cronbach's alpha correlation coefficient.

The sampling frame consisted of 211 community pharmacies (subdivided into 5 districts according to the National Statistics Office demographic data) from which 10 pharmacies were selected from each district by stratified random sampling. A total of 50 copies of the questionnaire were personally distributed by the investigator (FW) to community pharmacists practising in the 50 identified pharmacies.

RESULTS

RELIABILITY OF THE QUESTIONNAIRE

Cronbach's alpha correlation coefficient was 0.8191 indicating high reliability of the questionnaire.

DESCRIBING THE SAMPLE

Forty-six pharmacists responded to the questionnaire giving a response rate of 92%. Thirty-four were managing pharmacists, 20 were aged between 30 and 39 year and 30 were females. Twenty-eight pharmacists were owners of the pharmacy.

PHARMACIST PERCEPTION

Twenty-three pharmacists were in favour of supplementary prescribing. Pharmacists accepted supplementary prescribing, predominantly for chronic conditions namely gastro-oesophageal reflux disease and asthma (both 19 pharmacists), hypertension (18 pharmacists) and diabetes (14 pharmacists). Pharmacists were most reluctant to accept supplementary prescribing for long-term anticoagulant therapy (2 pharmacists). 'Other' conditions included minor infections such as upper respiratory tract infections and skin conditions (Figure 2).

Pharmacists envisaged the development of supplementary prescribing locally mainly by forming liaisons with general practitioners (20 pharmacists) and by keeping records of interventions (12 pharmacists) (Figure 3).

BARRIERS

Many barriers for the implementation of supplementary prescribing were identified, principally the lack of specialised training and continuing professional development (16 pharmacists), the fact that patients would still refer back to his or the general practitioner (15 pharmacists) and no access to patient medication records (11 pharmacists) (Figure 4).

CONTINUING PROFESSIONAL DEVELOPMENT (CPD)

Thirty one out of the 46 pharmacists interviewed felt that they did not possess sufficient knowledge to carry out consultations such as supplementary prescribing and 42 out of the 46 pharmacists were willing to participate in programmes for professional development in the area.

COMPUTERISATION AND PATIENT MEDICATION RECORDS (PMRS)

A majority of 44 out of 46 pharmacists did not maintain patient medication records (PMRs). Thirty seven pharmacists stated that the main reason for not keeping PMRs is that patients did not always buy medications from the same pharmacy, resulting in incomplete records. Other limitations were that many patients collected free medications from government-owned pharmacies (26 pharmacists), time constraints (28 pharmacists), increased workload for the pharmacist (24 pharmacists), and the cost of installing the computer system and the PMR program (6 pharmacists).

A computer system was installed in 18 out of the 46 pharmacies. Pharmacists used the computer for pharmacy management (14 pharmacists), for point-of-sale purposes (12 pharmacists), for labelling (3 pharmacists) and to aid pharmaceutical advice (1 pharmacist). One pharmacy used the computer to maintain PMRs. Ten pharmacists from the 28 pharmacies without a computer system considered lack of space as the main limitation. Nine pharmacists felt that a computer was unnecessary, 7 pharmacists perceived cost issues to be a limitation and 4 pharmacists were computer illiterate.

CONSULTATION AREAS

Only twelve out of the 46 pharmacists had an area available for consultations. The main limitation for setting up a consultation area was lack of space (32 pharmacists). The need to employ another pharmacist and/or additional pharmacy personnel to cover for the pharmacist whilst s/he is carrying out a consultation was perceived to be another important limitation by 18 pharmacists. Forty one out of the 46 pharmacies had one pharmacist on duty in the pharmacy at any time and only 11 of these were willing to employ other personnel. Twenty two pharmacies out of the 46 had no salespersons employed in the pharmacy.

CONSULTATION FEES

Thirty nine out of the 46 pharmacists would consider charging a fee for carrying out consultations. Nineteen of these pharmacists would charge 1.16 or 2.33 euro per consultation, whilst 1 pharmacist would charge 4.66 euro. None of the pharmacists interviewed would charge more than 4.66 euro.

DISCUSSION

The initial response from community pharmacists towards pharmacist prescribing is encouraging. Half (11 out of 22) of the pharmacists who were against the introduction of supplementary prescribing perceived the lack of patient medication records as a barrier. Fifty-four percent (12 out of 23) of the pharmacists envisaged the local implementation of supplementary prescribing only if the pharmacist keeps records of interventions carried out, together with other information that may be used for that patient if the need arises in the future.

Computer technology will make the recording of pharmacist interventions and prescriptions less time-consuming and the storage and access of patient histories more reliable. Maintenance of patient records is also required for pharmacist prescribing. The system should be effective and may require transfer of information back to the medical practitioner. For pharmacists to be able to prescribe any medication and to provide the best possible care, all medical information concerning the patient must be collected.^{5,6}

Pharmacies are now installing a computer system due to the introduction of the Pharmacy Of Your Choice (POYC) scheme. This computer system should be able to be adapted to facilitate the maintenance of patient records which are essential for supplementary prescribing.

A consultation area is described as a clearly designated area for confidential consultations. It must be an area where the pharmacist and patient can talk at normal speaking volumes without being overheard by other clients or by staff.⁷ Consultation areas are a prerequisite for pharmacist prescribing. Community pharmacies in Malta are small, therefore the main difficulty with setting up consultation areas is lack of space. Areas within the pharmacy which provide privacy could be created.

Securing remuneration for professional responsibility is another step in the adoption of prescribing rights. Changes to the roles of the current workforce may be needed as a result of offering pharmacist prescribing. If a pharmacist is engaged in a private conversation with a patient, mechanisms need to be put in place to ensure the rest of the work continues. This may involve employing another pharmacist.

Training is also necessary. Pharmacists who wish to become prescribers may be offered optional life-long learning programmes which they could follow. There may be resistance to change from within the pharmacy profession, and other professions may feel that prescribing pharmacists intrude on their area of professional responsibility. The development of collegial working relationships is essential in the acceptance of new prescribers. The success of pharmacist prescribing will be determined by the ability of pharmacists and doctors to work as a team.

CONCLUSION

The barriers for the implementation of supplementary prescribing include computerisation, lack of access to patient records, lack of space for consultation, and lack of pharmacist motivation. The implementation of a fee for professional services provided could be an incentive to promote supplementary prescribing. The success of pharmacist prescribing is determined by the ability of pharmacists and other prescribers to work as a team.

In the United Kingdom the issue of pharmacist prescribing has moved a step further. In November 2005 it was announced that pharmacists in the United Kingdom will have powers to independently prescribe medicines. This means that pharmacists were given the right to prescribe any licensed medicine for any condition within their competence, with the exception of Controlled Drugs.⁸

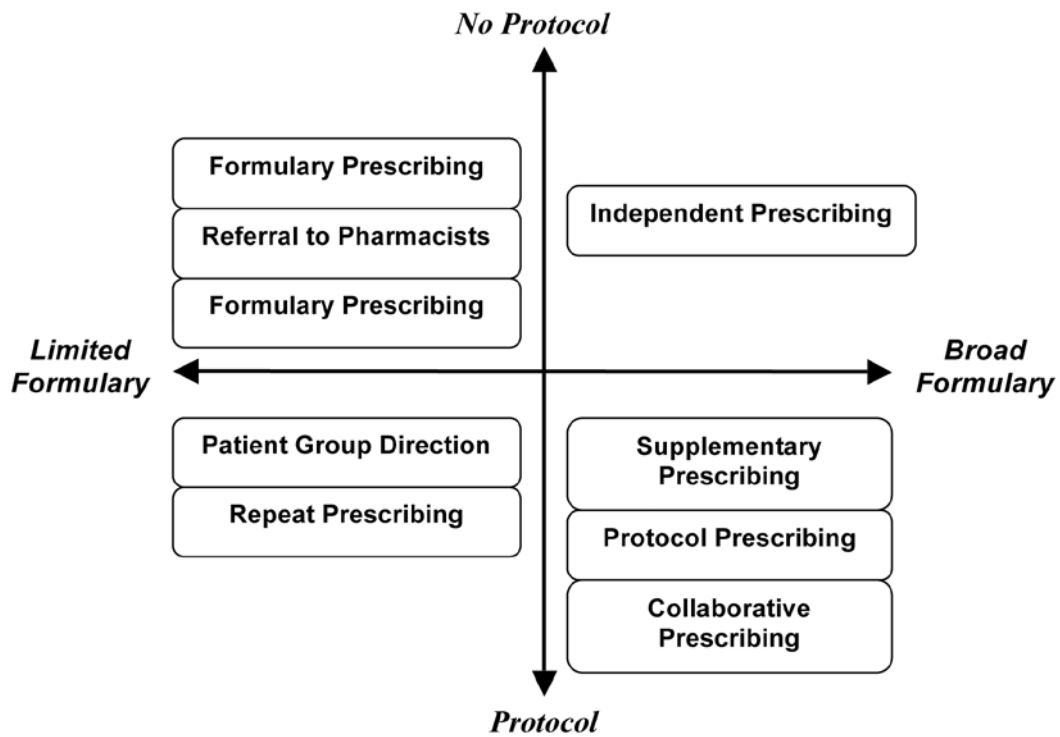
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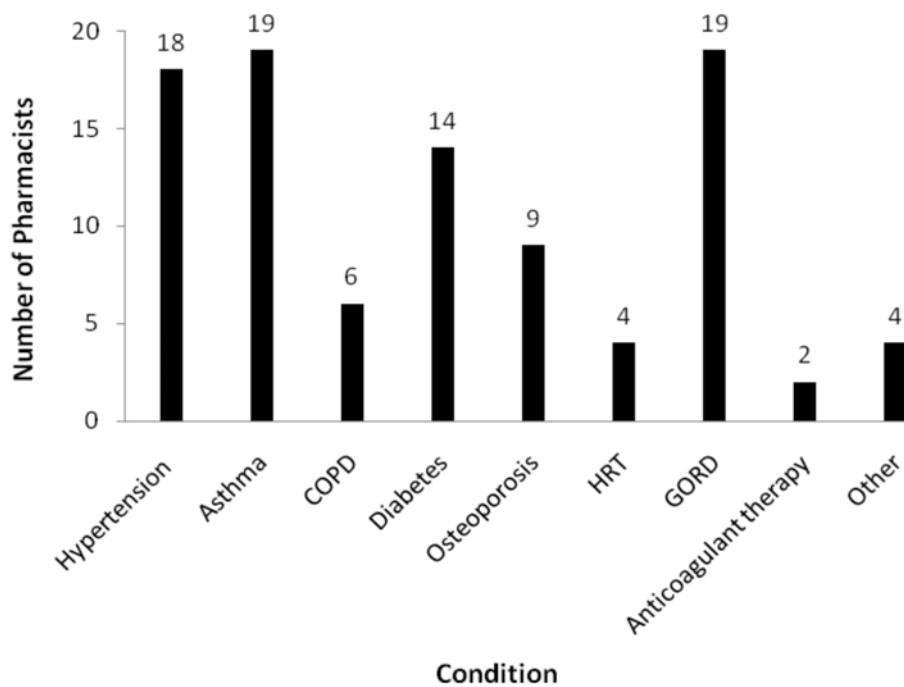
“THE BARRIERS FOR THE IMPLEMENTATION OF SUPPLEMENTARY PRESCRIBING INCLUDE COMPUTERISATION, LACK OF ACCESS TO PATIENT RECORDS, LACK OF SPACE FOR CONSULTATION, AND LACK OF PHARMACIST MOTIVATION”

Figure 1: Models for pharmacist prescribing



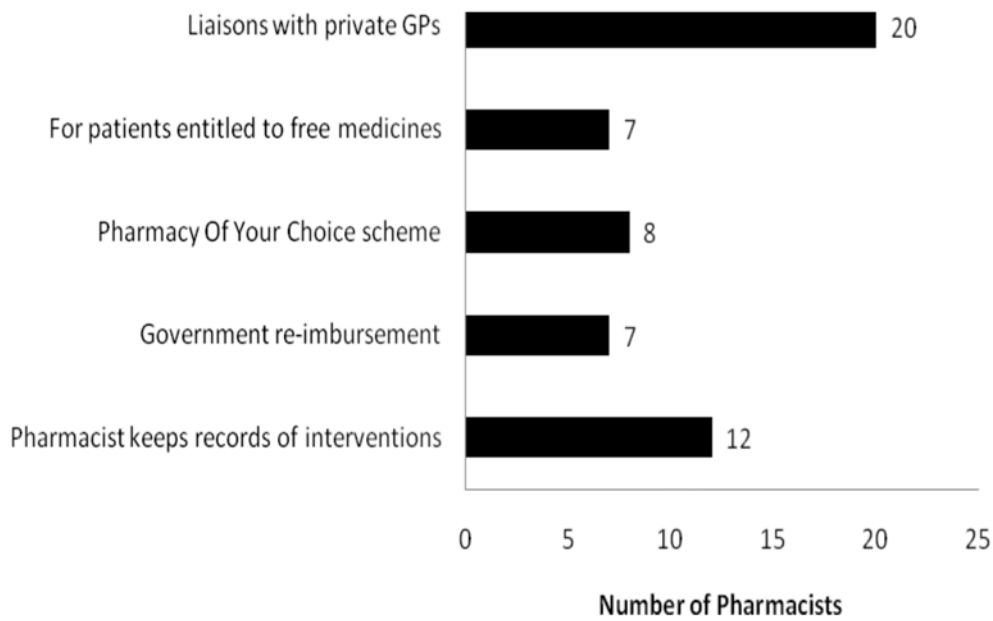
(adopted from Emmerton L, Marriot J, Bessell T, Nissen L, Dean L. Pharmacists and prescribing rights: review of international developments. *J Pharm Pharmaceut Sci* [serial on the Internet]. 2005 Aug [cited 2009 Mar 25];8(2):[9 p.] Available from: [www.ualberta.ca/~csp/JPPS8\(2\)/L.Emmerton/pharmacists.pdf](http://www.ualberta.ca/~csp/JPPS8(2)/L.Emmerton/pharmacists.pdf))

Figure 2: Conditions for which pharmacists accepted supplementary prescribing (n=23)



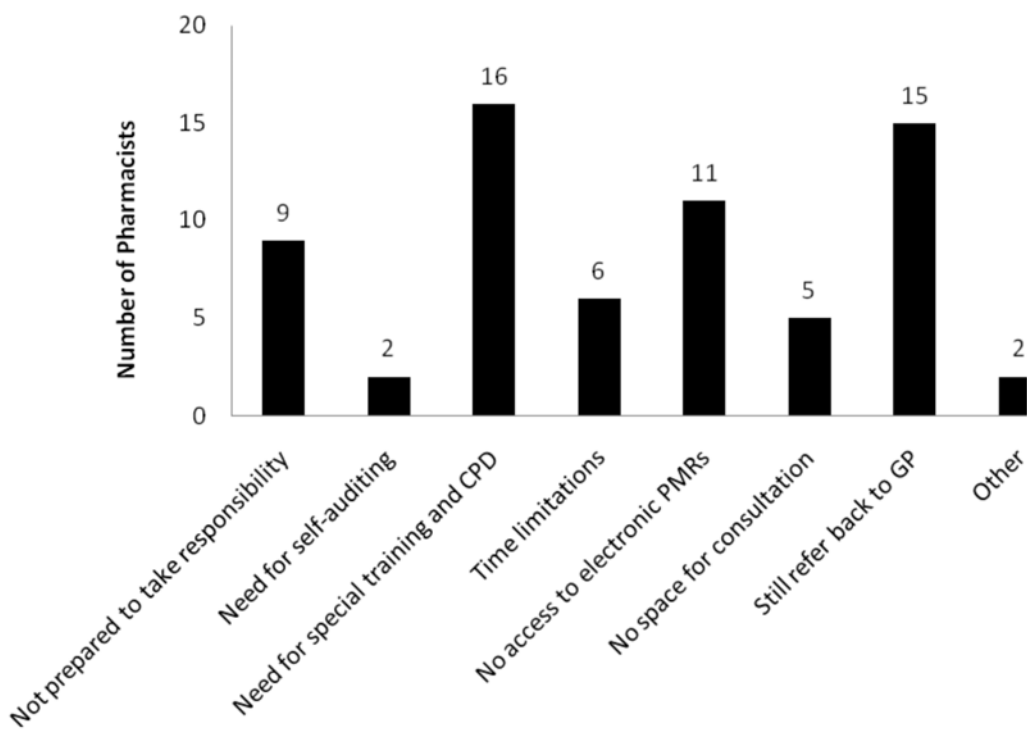
COPD = Chronic Obstructive Pulmonary Disease; HRT = Hormone Replacement Therapy; GORD = Gastro-Oesophageal Reflux Disease

Figure 3: How pharmacists envisage the implementation of supplementary prescribing (n=23)



GP = General Practitioner

Figure 4: Barriers for the introduction of supplementary prescribing (n=22)



CPD = Continuing Professional Development; PMRs = Patient Medication Records; GP = General Practitioner

METHICILLIN RESISTANT *S. AUREUS* IN AUTOPSY CASES

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ABSTRACT

OBJECTIVE To determine whether hospital stay predisposes to nasal colonisation with *Staphylococcus aureus* and Methicillin Resistant *S. aureus* (MRSA).

METHOD Nasal swabs were taken from cadavers undergoing post-mortem examinations at the mortuary of St. Luke's Hospital. The swabs were taken to the Bacteriology Laboratory where attempts were made to culture *S. aureus*. Vitek® Gram Positive Susceptibility Cards were used for antibiotic susceptibility. MRSA positive organisms were tested using Penicillin Binding Protein Latex Agglutination.

KEY FINDINGS Ninety-three swabs were taken. The proportion of *S. aureus* nasal carriage was similar in both hospitalised and non-hospitalised groups. However, 8 out of 15 (53%) *S. aureus* carriers in the hospitalised group were MRSA positive, compared to 4 out of 19 (21%) *S. aureus* carriers in the non-hospitalised group.

CONCLUSION Hospitalisation increases the incidence of MRSA carriage compared to the non-hospitalised population.

KEY WORDS MRSA, *Staphylococcus aureus*, nasal carriage, autopsy

INTRODUCTION

Staphylococcus aureus is an important cause of human disease. Although it is most often associated with skin and soft tissue infections, it has numerous manifestations including conditions with low morbidity and mortality, such as folliculitis and food poisoning, and others which cause fatal systemic illnesses, such as endocarditis and toxic shock syndrome.¹

S. aureus colonises between 30 to 50 percent of the healthy adult population.² The anterior nares are the most consistent site of colonisation.¹ Although the bacteria are normally harmless, they can cause serious infections when the opportunity arises.³ *S. aureus* can develop resistance to a wide variety of antibiotics. Methicillin resistance confers resistance to all penicillinase-resistant penicillins and cephalosporins.² MRSA infections have been associated with increased morbidity and mortality and hospital costs.⁴

Nasal carriage of *S. aureus* has become a means of persistence and spread of multiresistant Staphylococci, especially MRSA. Because MRSA can resist practically all types of antibiotics, they have become a public health threat, in the context of hospital-acquired infections and more recently as community-acquired diseases.⁵ Factors associated with MRSA colonisation include prior antibiotic exposure, particularly incomplete or repeated courses of antibiotics, prolonged hospitalisation, surgery, admission to an intensive care unit, living in a nursing home, and close proximity to a patient colonised or infected with MRSA.⁶

The aim of the study was to determine whether hospital stay predisposes to nasal colonisation with *S. aureus* and MRSA by comparing two cohorts, one which was hospitalised and one that had not been admitted to hospital within the previous six months.

METHOD

Nasal swabs were taken from cadavers undergoing post-mortem examinations. These were divided into 2 categories, those that were hospitalised for at least 24 hours and those that were not hospitalised in the previous 6 months. Individuals who had drowned or who had severe facial injuries were excluded from the study. Approval from the Faculty and University Research Ethics Committee was obtained to carry out this project.

The nasal swabs were taken to the Bacteriology Laboratory at St. Luke's Hospital (SLH) where attempts were made to culture *S. aureus*. In this way *S. aureus* nasal carriers were identified. The nasal swab was first cultured on Mannitol Salt Agar (MSA), which is a selective medium for the isolation of *Staphylococcus* spp. Most other bacteria are inhibited by the high salt concentration. Yellow colonies from the MSA were sub-cultured on blood agar, nutrient agar and DNase agar. Catalase, coagulase and DNase tests were then performed. *S. aureus* is catalase, coagulase and DNase positive. A Gram-stain was also done to verify that the organisms were Gram positive cocci in clusters.

S. aureus organisms were further tested for their antibiotic susceptibility using Vitek® Gram Positive Susceptibility Cards which indicates the range of antibiotics that the organism is sensitive or resistant to. MRSA positive organisms were tested using Penicillin Binding Protein (PBP) Latex Agglutination, which is a confirmatory test for MRSA, since it detects the mutant enzyme PBP2a.

RESULTS

A total of 93 swabs were taken from cadavers undergoing post-mortem examination during the period of study (12 months). The number of cases studied is heavily weighted in favour of the male sex. There were approximately equal numbers of cadavers in each age group with a mean age of 55 years (range 13 to 93 years). Out of the 65 males, 24 were hospitalised and 41 were not hospitalised. From the 28 females, 18 were hospitalised and 10 were not hospitalised.

Figure 1 shows the incidence of *S. aureus* in the nasal swabs studied in both hospitalised and non-hospitalised cases. The proportion of *S. aureus* nasal carriage was similar in both groups, with 36% of the hospitalised population having *S. aureus* nasal carriage compared to 37% of the non-hospitalised population. The incidence of *S. aureus* colonisation appears to be greatest in the 41 to 65 age group with 54% of the cadavers in that age group having *S. aureus* colonisation.

The picture changes radically when one looks at the incidence of Methicillin Resistant *S. aureus* (MRSA) carriage and Methicillin Sensitive *S. aureus* (MSSA) carriage. There are striking differences between the hospitalised and the non-hospitalised group. Eight out of the 15 *S. aureus* carriers (53%) in the hospitalised group, compared to 4 out of the 19 *S. aureus* carriers (21%) in the non-hospitalised group were MRSA positive, with a p value of 0.0505.

There were gender and age differences. MRSA colonisation appears to be relatively more frequent in females, since 5 out of 9 females had MRSA, when compared to 7 out of 25 males. None of the cadavers under 40 years of age had MRSA.

Many of the *S. aureus* nasal carriers exhibited resistance to a range of antibiotics (Figure 2). The resistance was much more common in the hospitalised cases, indicating that MRSA strains are more aggressive in the hospital setting. Most *S. aureus* strains were resistant to penicillin. All the hospitalised cases that were MRSA positive were also resistant to ofloxacin, whereas 2 out of the 4 cases of MRSA nasal carriage that were not hospitalised before death were resistant to ofloxacin. This shows a correlation between methicillin/ oxacillin resistance and ofloxacin resistance.

Most of the MRSA cases were also resistant to erythromycin with 6 out of the 8 MRSA positive nasal carriers that were hospitalised were erythromycin resistant. Two out of the 4 MRSA cases that were not hospitalised were also resistant to erythromycin. There were 2 cases (1 from the hospitalised group and 1 from the non-hospitalised group) which were resistant to erythromycin, but were not methicillin resistant.

Some of the cadavers had *S. aureus* strains which showed intermediate resistance to some antibiotics, namely fusidic acid (4 cases), fosfomycin (3 cases), rifampicin and erythromycin (2 cases each).

DISCUSSION

These results show that hospitalisation increases the incidence of MRSA carriage compared to the non-hospitalised population. Although the incidence of MRSA carriage in the hospitalised group was more than twice the incidence in the non-hospitalised group, a p value of 0.0505 was obtained since a limitation of the study was the small number of cases studied.

The incidence of MRSA carriage in the non-hospitalised cases in this study is similar to that found by Dall' Antonia et al⁷ who report an 8% incidence of MRSA in patients on admission to a United Kingdom healthcare institution. However other studies give a wide range of values; an extensive study carried out in the United States showed an incidence of MRSA of only 0.8%¹ while another study in Lahore (Pakistan) showed that MRSA colonisation was found in 2.89% of the population.⁸ Skov⁹ has shown

that in the Nordic countries (Denmark, Finland, Iceland, Norway and Sweden) the incidence of MRSA infections was successfully kept at low levels (<1%). This is attainable by the conservative use of antimicrobial consumption, prescribing of narrow-spectrum antibiotics, screening patients, treating MRSA positive patients in isolation and the prevention of transmission through appropriate hand hygiene.¹⁰ When preventive measures are strictly enforced, it is possible to keep the incidence of MRSA extremely low.

Between 2008 and 2009, Maltese hospitals reported a 55% incidence of MRSA from invasive *S. aureus* isolates.¹¹ This correlates well with the results in this study which have shown that more than half of the *S. aureus* carriers were methicillin resistant amongst the hospitalised group.

The widespread use of antibiotics in hospitals is universally acknowledged as the critical factor for the development of antimicrobial resistance. It was shown that the level of consumption of broad spectrum penicillins, especially those containing a beta-lactamase inhibitor, cephalosporins, in particular second generation cephalosporins, and macrolides at SLH was significantly greater than the median obtained from a pan-European study entitled 'Development of Strategies for Control and Prevention of Antibiotic Resistance in European Hospitals'.¹²

Until recently, most MRSA cases were found in the nosocomial setting. However, community-acquired MRSA continues to evolve and has been associated with both colonisation and infection. Strains of community-acquired MRSA are normally more sensitive to other antibiotics than hospital-acquired MRSA strains.¹³ The incidence of MRSA in the community is also on the increase due to the widespread and overuse of antibiotics. Since nasal carriage triples the chance of developing bacteraemia with *S. aureus*,³ the incidence of MRSA nasal carriage should not be underestimated.

CONCLUSION

The study shows that hospital stay does not increase *S. aureus* nasal colonisation when compared to the non-hospitalised group. However, the incidence of MRSA was much higher in the hospitalised group. The study also shows a relatively high incidence of MRSA cases in the community. The prevalence of MRSA nasal carriage both in the community (8%) and in the hospital environment (19%) should alert our health professionals to the urgent need to embark on a strict preventive regime.

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Figure 1: Flowchart showing summary of findings (n=93)

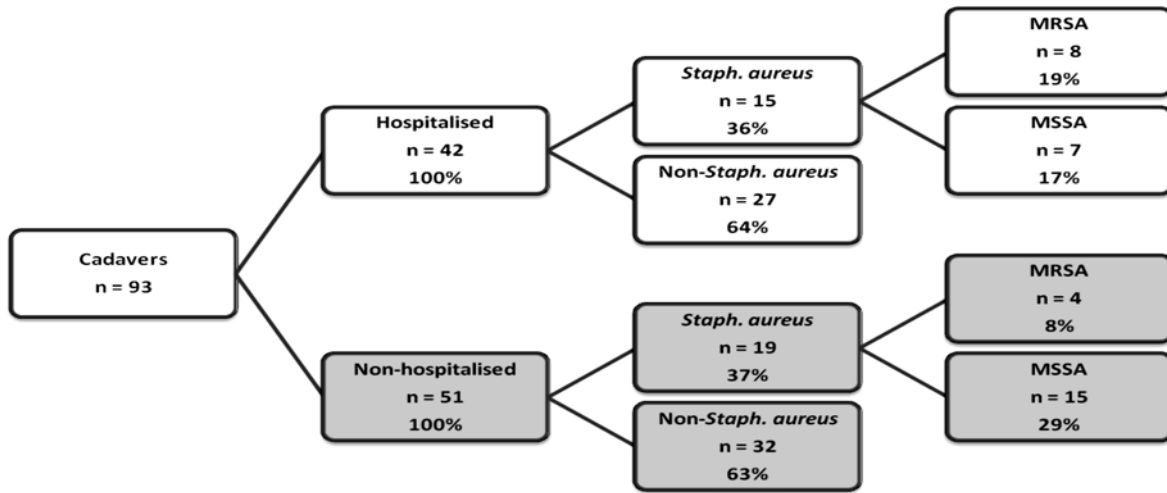
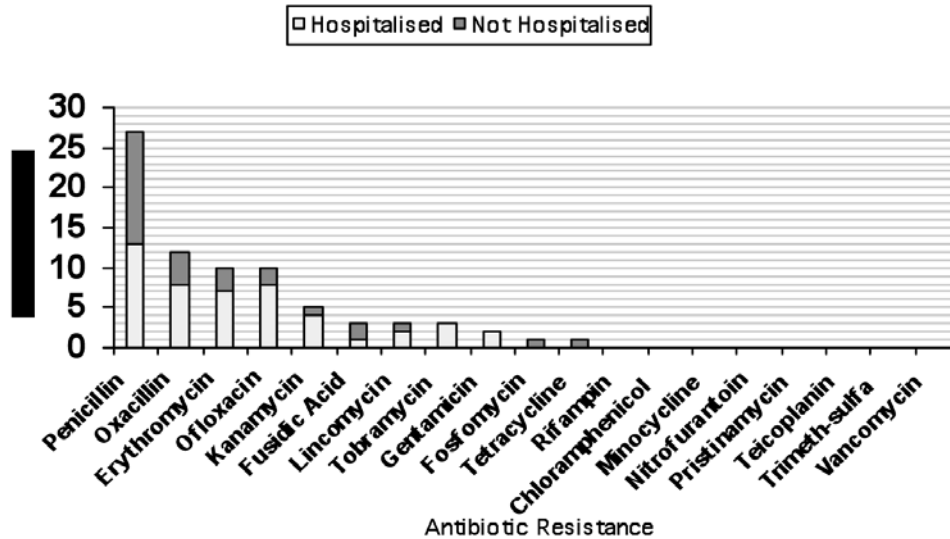


Figure 2: Incidence of resistance to other antibiotics from *S. aureus* isolates (n=34)



A PILOT STUDY TO DETERMINE THE COST OF PHARMACEUTICAL DRUG TREATMENT FOR CHRONIC CONDITIONS PRESCRIBED IN RELATION TO PATIENTS' AGE

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ABSTRACT

OBJECTIVE To determine the age distribution of patients and the total drug cost. To establish the average cost per age group and identify factors that may influence cost.

METHOD A pilot study was conducted by selecting by convenience sampling a number of patients over 18 years who were registered in the Pharmacy of Your Choice scheme with a community pharmacy where the study was carried out. For each patient, type, frequency and cost of medication supplied were identified from treatment cards and from Government Health Procurement Services (GHPS).

KEY FINDINGS Data was collected for 491 patients (aged between 18-98 years) were 272 (55%) were females and 10% (n = 47) were institutionalised. Eight percent (n=395) were prescribed drugs for cardiovascular diseases which constituted 50% of the total drug expenditure. Daily cost per patient was one euro. Pearson correlation value ($p < 0.05$) revealed a significant relationship between the increase in cost, unit doses and number of diseases with increasing age, between gender and different settings. Gender variation between drug categories was not significant ($p > 0.05$).

CONCLUSIONS Cost of drug treatment is vital information that financing providers and policy makers require for the allocation of budgets. Findings suggest that populations are ageing, cost increases with age and that gender and setting influence the treatment being provided.

KEYWORDS Cost, drug utilisation, ageing

INTRODUCTION

The cost of treatment is a prominent topic discussed all over the world. In view of population ageing¹, strategies that sustain health, such as social security funds, total or partial reimbursement and co-payments, adopted in various countries are increasing the pressures on the financing providers which include governments and insurances.

Availability and price of drug together with the age and socio-economic status of the patient influence the drug treatment prescribed and its benefit. The larger proportion of the population are elderly, who in general are dependent on social security funds, requiring long-term treatment for a number of chronic conditions.²

Locally, the state provides drug treatment for chronic conditions free of charge.³ The ever increasing number of eligible patients requiring treatment impacts the healthcare costs and makes review of drug treatment and cost vital. The aim of the study was to determine the cost of chronic drug treatment in relation to increasing age.

METHOD STUDY DESIGN

This was a pilot study performed on a sample of patients (491) aged 18 years and over, selected by convenience sampling, that collect their free medication supplied by the government from a pharmacy in Malta which is part of the POYC scheme. The study was approved by the Research Ethics Committee of the University of Malta.

The age and gender of all the patients who took part in the study were recorded on a data collection sheet. Patients were assigned a code, ensuring confidentiality. Patient treatment cards were reviewed and the four week drug treatments were documented. The patient setting was also noted. The British National Formulary⁴ was used as a guide to the main drug classes. The prices of all tenders procured by the government for each drug identified was supplied by the Director of GHPS of Malta⁵. All prices were quoted in the Euro currency. The average unit price of each item was calculated.

DATA HANDLING AND STATISTICAL ANALYSIS

A data collection sheet was used to extract required data. The patients were ranked in ascending order according to age and were segmented in 5 year intervals. The data was imported into a MySQL database which facilitated the extraction of any required information. The age distribution of the sample population was estimated and was categorised by gender.

Statistical analysis was carried out using SPSS PASW version 17. Descriptive statistics on the population characteristics were performed. ANOVA tests were used to compare the means of cost, unit doses and number of different drug categories between age groups. Chi-squared tests of association were used to compare the prevalence between men and women and between settings.

RESULTS

PATIENT CHARACTERISTICS

A total of 491 patients aged between 18 and 98 years were recruited in the study. The mean age was 65.9 years (SD = ± 14.9), the mode 65 years and median age 66 years. The 60-64 years age group had the highest number of patients (n=75) followed by that of 65-69 years (n=71) (Figure 1). The gender distribution was 45% (n=219) males and 55% (272) females. The setting for the patients was 10% (n=47) were institutionalised and had a mean age of 83 years (range 58-98 years) while those living in the community had a mean age of 64 (range 18-98 years).

DRUG CATEGORIES

Fifteen drug categories were identified. Drugs used for the cardiovascular system (CVS) constituted the largest proportion of prescriptions. Eighty percent of patients (n=395) consumed at least one type of CVS drug which accounted for the observed 50% of the total drug expenditure for the whole sample. Drugs used for the central nervous system (CNS) and the endocrine system (END sys.) constituted 18% and 11% of the total expenditure respectively. The daily cost per patient was 74c for CNS drugs and 64c for CVS drugs (Figure 2).

TREATMENT COST

The daily total cost for the drugs provided to the whole sample population amounted to €491.43c, which is approximately equivalent to €1 per patient.

Figures 3 and 4 show how the average and total cost of drug treatment vary with increasing age by both genders and settings of the patient. The average daily cost and unit doses consumed and the number of diseases suffered by patients over 65 years was higher than for those under 65 years. (€1.18, 11 doses and 10 diseases as opposed to €0.88c, 9 and 5 respectively). Pearson correlation coefficient (0) revealed a significant difference between age, gender and setting ($P < 0.05$). Differences ($P < 0.05$) between the different drug categories prescribed in terms of cost, unit doses and number of patients suffering from a particular disease for patients living in nursing homes were observed to be significantly higher ($p < 0.05$). Differences observed between gender were not significant ($p > 0.05$).

DISCUSSION

The cost of pharmaceutical drug treatment reflects a fraction of the total treatment cost. This study showed that the direct cost posed by the pharmaceutical drug treatment is dependent on the price of the procured drug product, the units consumed by each patient, the duration of treatment, the number of different drugs prescribed, and the total number of patients taking the drug/s. Other factors such as the age and gender of the patient were found to influence the overall cost.

Findings were consistent to data obtained in other studies. In a Dutch study conducted in 2002, the health care costs were observed to increase with increasing age and showed higher values for women both for acute and long term care.⁶ Furthermore, a retrospective case-control study carried out in the UK, revealed that the cost of therapeutic drugs for patients living in nursing homes was more than double when compared with those of the community.⁷ The age distribution of the patients in this study is consistent with population age distribution observed nationally and worldwide.

The observed high cost in the older age groups could be explained by the prescription of more expensive treatment. Studies revealed that social class appears to relate to polypharmacy and use of more CNS drugs.⁸ Higher costs imposed by the female gender could be explained by the fact that they are more in number and have longer life expectancy; they tend to consume higher quantities of drugs and tend to suffer from more conditions such as osteoarthritis. The number of different diseases increases with age.

Review of drug treatment prescribed shows disease prevalence to be similar to that in European countries.⁹ As reported in previous studies the occurrence of certain diseases such as CVS and CNS, is age dependent whereas, conditions such as asthma tend to be more controlled with increasing age.¹⁰ The Eurofamcare report for Malta provides information on the number of institutionalised persons till 2004.¹¹ A large proportion of the elderly are now making use of these facilities due to increased morbidities and demands on care. The higher costs imposed by institutionalised patients could be explained by the fact that, in most instances, medication is provided under supervision while patients living in the community may skip or refuse to take their medication.

The replacement of old drugs with new, more effective, better quality drugs could have contributed to the increased costs observed. Pharmaco-economic studies are important tools that help to select the most economically feasible and medically appropriate drug treatments. The search by governments and health insurers for cheaper therapeutic alternatives underlines the importance of generic medicines.¹²

Results obtained can be extrapolated for the whole population and can help determine the total yearly cost for all the patients and hence allocate the required resources. Knowledge on the number of patients who are eligible for drug treatment and their characteristics is vital and can serve multiple purposes. Documentation of drug treatment helps to spot trends in prescribing, unnecessary drug use and polypharmacy.^{13,14} Drug review might suggest that certain medication is prescribed to overcome adverse effects imposed by other drug treatment taken concurrently. Elderly patients are more likely to experience side effects than their younger counterparts due to age-related changes in pharmacodynamic and pharmacokinetics. Inappropriate prescribing can be the result of restrictive government drug formularies and lack of consultation with pharmacists.

CONCLUSION

In view of population ageing, long-term benefits towards improved quality of life and cost savings in terms of decreased acute episodes and hospitalisation should be the objectives of policy makers when designing protocols and procuring drugs to be included in formularies. Availability of cheaper, good quality generics help minimise the overall cost. The identification of factors influencing the total cost and establishment of the average drug treatment cost per patient are essential tools that enable policy makers to allocate the required resources.



“COST OF DRUG
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“LONG-TERM BENEFITS TOWARDS IMPROVED QUALITY OF LIFE AND COST SAVINGS IN TERMS OF DECREASED ACUTE EPISODES AND HOSPITALISATION SHOULD BE THE OBJECTIVES OF POLICY MAKERS”

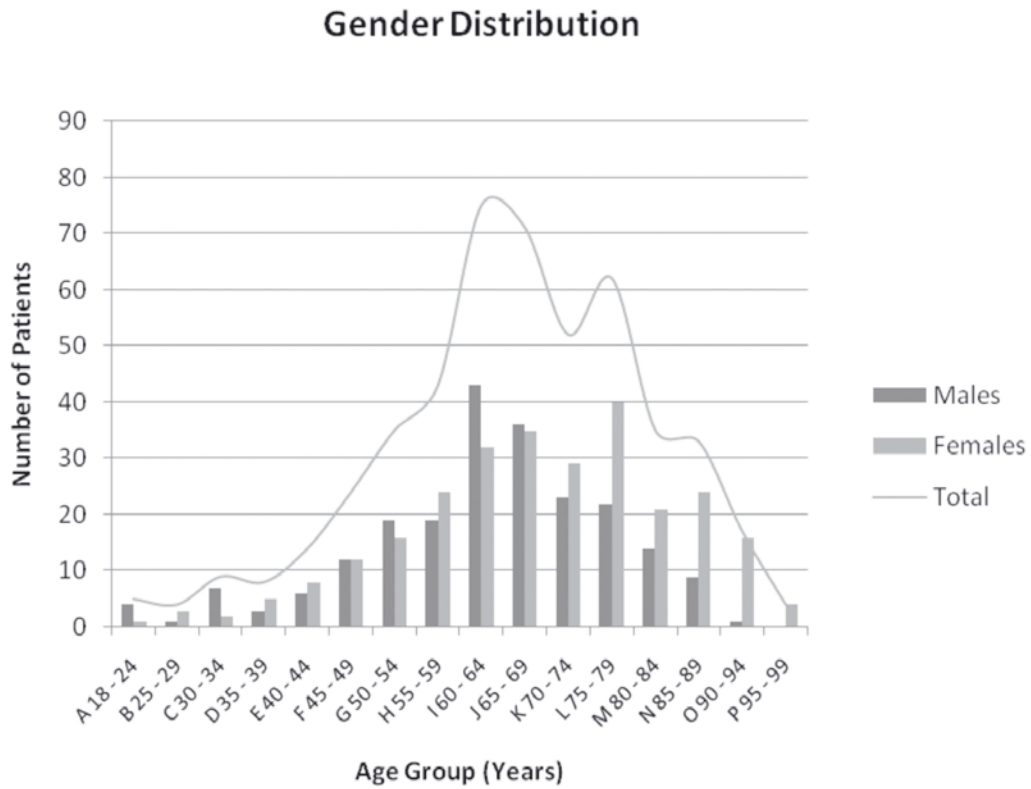


Figure 1: Age distribution of the total population under study categorised by gender

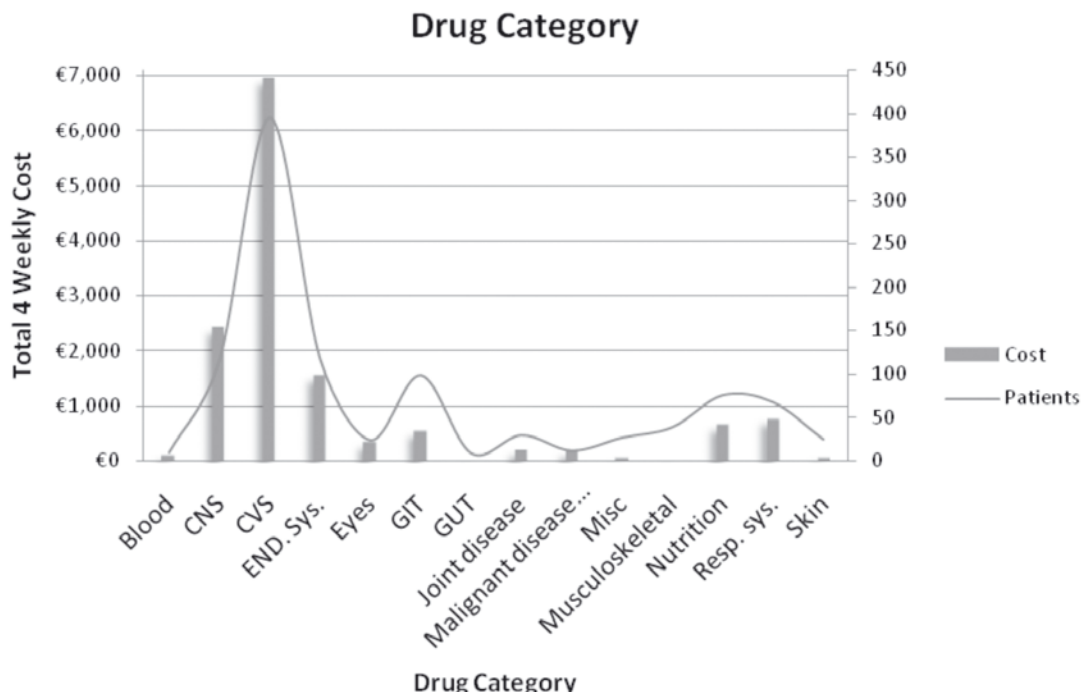


Figure 2: Different drug classes prescribed in the total sample (including four weekly cost and includes the number of patients taking the specified drug classes).

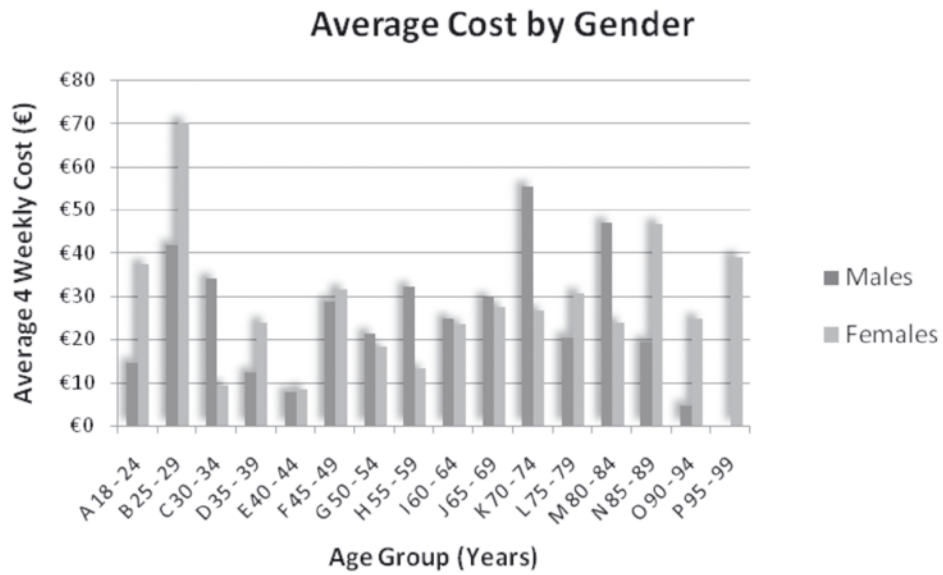


Figure 3: Average 4 weekly cost in euros for male and females according to age

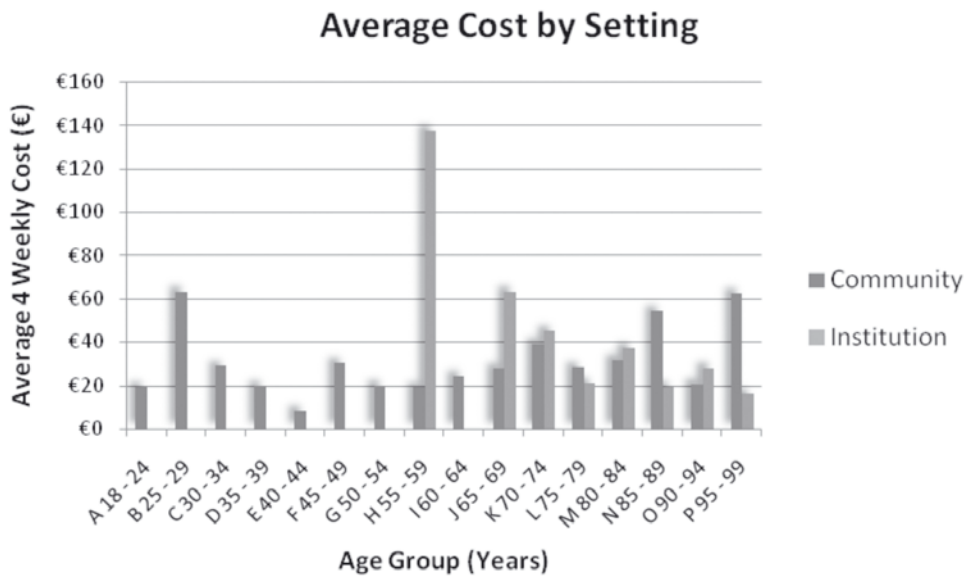


Figure 4: The average 4 weekly drug expenditure on patients living in the community and those living in nursing homes.

GENERIC MEDICINE PRICES AND THEIR DISTRIBUTION IN MALTA

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ABSTRACT

OBJECTIVES To analyse the composition of the private pharmaceutical retail market in Malta on the basis of the originator or generic status of available medicines and to observe the change in prices of generics and originators over time.

METHOD The prices of a sample (n=435) of medicines in Malta were analysed for an eight year period (2002 to 2009). The variation in price in the generic and originator segments was calculated. Thirty-one active ingredients with generics available were identified and the Average Retail Price Per Unit (ARPPU) and the Lowest Retail Price Per Unit (LRPPU) were calculated. The average discount from the originator price was calculated, per compound and also by drug class.

KEY FINDINGS The sample population contained 17.2% generic products. The mean drop in the ARPPU was of 10.87% and for the LRPPU of 21.42% for the LRPU. The average discount was 14.59% in 2002 and 37.19% in 2009.

CONCLUSION The number of generic medicines in Malta has increased in the last eight years, with a consequent decrease in the lowest prices available for the set of medicinal compounds.

KEYWORDS Generic medicines, price discount and originator products

INTRODUCTION

The high cost of medicines for sale at the neighbourhood pharmacy is cause for concern both locally¹ and elsewhere.² Public and private consumers are facing budgetary constraints in dealing with a growing range of medicinal products and an increasing number of patients,³ especially in view of the fact that life expectancy is on the rise and with it the incidence of non-communicable disease.⁴

Generic medicines are seen as the key to ease the financial pressures within healthcare systems worldwide.^{5,6,7} The entry of a generic product onto a market usually has a two-fold downward effect on prices. Firstly, the generic is cheaper, because it costs less to produce, and secondly because it needs to have a competitive edge to impact the end-consumer.⁸

Generics are essential from an economic viewpoint, as they introduce competition to a situation where patent holders have held a manufacturing monopoly for the term of the patent period.^{9,10} This period of monopoly leads to a high price being exacted for a unique product, in this case for innovative drug molecules.

The local market had not been analysed with respect to its relative composition of originator or generic medicines. No specific information was available regarding the prices of generic medicines in relation to their respective originator products. The aims of the study were to analyse the composition of the private pharmaceutical retail market in Malta on the basis of the originator or generic status of available medicines and to observe the change in prices of generics and originators over time.

METHOD

A sample (n=435) of medicines was drawn from the 3100 medicines which had a Marketing Authorisation according to the Malta Medicines Authority in October 2009. The sample was drawn by selecting in descending order on the basis of highest volume of sales in three community pharmacies over an eight year period (2002-2009). Fields included in the data set were the originator or generic status, prescription-only status (POM) or non-prescription (OTC) status and drug class. The latter classification was based on the one used by the British National Formulary (BNF).

Medicine prices were compiled from computerized EPOS data generated by a live system that contained the prices as recommended by the competent authorities. A set of originator drugs which had generic equivalents by the end of 2009 was selected from the sample. This data set consisted of thirty-one active ingredients. The Average Retail Price Per Unit (ARPPU) and the Lowest Retail Price Per Unit (LRPPU) for each active ingredient was calculated for 2002 and 2009. The unit measurements in the ARPPU and LRPPU were calculated by dividing the prices obtained for the medicines by the pack size so as to obtain a comparable variable.

The average percentage discount from the originator price to the generic version was calculated for the thirty-one active ingredients for the years 2002 and 2009, by tabulating the retail prices of originator and generic versions for the two years in question, and including tags for OTC/POM and drug class identifiers.

RESULTS

The sample population contained 17.2% generic products. The mean increase in price for the whole sample was 17.86%. The mean for the originator segment showed an increase of 18.22%, with that for the generic segment rising by 16.2%. When the prices were composited into a retail medicine index the increases were 11.01%, and 11.05% and 10.68% respectively.

Of the 31 active ingredients considered in the second part of the study, 16 had no generic equivalent in 2002, as opposed to the fact that all had at least one in 2009. This is reflected in the mean discount from the originator price for the data set, which rose from 14.59% to 37.19%. The greatest percentage discount observed is that for the Retail Price Per Unit (RPPU) of omeprazole 20mg capsules, and the lowest for paroxetine 20mg tabs, where the price of the originator and generic brands have simply decreased side by side to almost identical levels (Figure 1). The class exhibiting the greatest discount from the originator price was the gastro-intestinal (GIT) segment, with cardiovascular (CVS) medicines in second place. The CVS segment was, however, the most populated, with 13 active ingredients as opposed to the second most popular, the anti-infective drugs (AB & OTH), with 6, out of a total of 31 compounds (Figure 2).

Twenty-seven out of the group of compounds were POM medicines, with the average discount from the originator price to the lowest available rising to 38.41% from 30.88% in this case. No appreciable change was noted for OTC medicines (27.28% to 28.92%).

DISCUSSION

The fact that the prices of medicines exhibited an increase over an eight year period is not anomalous. The prices of both originator and generic drugs showed an upward movement. This statement is somewhat mitigated by the fact that upon further scrutiny it transpires that the prices for the OTC segment (16.22%) increased more than the POM one (7.21%). A greater increase in OTC medicine prices might be explained by the fact that this segment is highly incentivised and results in the cost being passed on to the consumer. The mean drop in the lowest price available for retail for the thirty-one active ingredients studied, 21.42%, is not substantial when considered as a single variable.

Studies in the EU have shown that the price of a generic medicine drops to 80% that of the originator within the first year of launch, leading to savings being passed on to the consumer¹¹. Savings are even greater in the United States where prices drop by 80% after one year.¹² The intense generic competition in the North American market instigates greater investment in the research and development of innovative compounds. Expenditure on R&D exhibited an increase after the publication of the Hatch-Waxman Act, legislation which facilitated the introduction of generic medicines in the United States.¹³

Although the local market has no originator branded manufacturers, all the major companies maintain strong representation, and the presence of generics is vital on two counts. Firstly, to ensure that monopolistic situations are not maintained, thus providing the stimulus to bring newer protected products to the local market and secondly, to provide competition on the basis of price and exert downward pressure.¹³

The great majority of the medicines in the originator/generic pairings are POM medications. Almost half of the pairings surveyed belonged to the cardiovascular group of drugs. The use of this class of drugs increases with age, as the cardiovascular system begins to experience problems of decreasing cardiac output and increased peripheral resistance.¹⁴ It can be deduced that generic drug manufacturers are following the lead of the branded originator companies and launching products targeted at the elderly, so as to take advantage of this increasing demographic shift.

CONCLUSION

The entry of generic products on the market does not have a significant impact on retail prices. Further investigation into the pricing strategy of generic products is required. Measures could be introduced to ensure that generic medicines enter the market at a discount to the originator product. It might be proposed that the granting of a Marketing Authorisation for a generic version of a product that is already present on the market under another brand, would only be undertaken if the Recommended Retail Price would be at a fixed percentage cheaper than the latest mean price for the Defined Daily Dose.

Without an effective education campaign, the further penetration of generic medicines, will be inevitably delayed.^{15, 16} This will prevent immediate savings in spending on pharmaceuticals and thus reduce accessibility to medical care. It is incumbent to enable a balance to be struck between the needs of innovation and branded manufacturers and those of lower-priced, high volume and accessible generic products.

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“THE NUMBER OF GENERIC MEDICINES IN MALTA HAS INCREASED IN THE LAST EIGHT YEARS, WITH A CONSEQUENT DECREASE IN THE LOWEST PRICES AVAILABLE FOR THE SET OF MEDICINAL COMPOUNDS”

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“THE GREAT MAJORITY OF THE MEDICINES IN THE ORIGINATOR/GENERIC PAIRINGS ARE PRESCRIPTION-ONLY MEDICATIONS. ALMOST HALF OF THE PAIRINGS SURVEYED BELONGED TO THE CARDIOVASCULAR GROUP OF DRUGS”

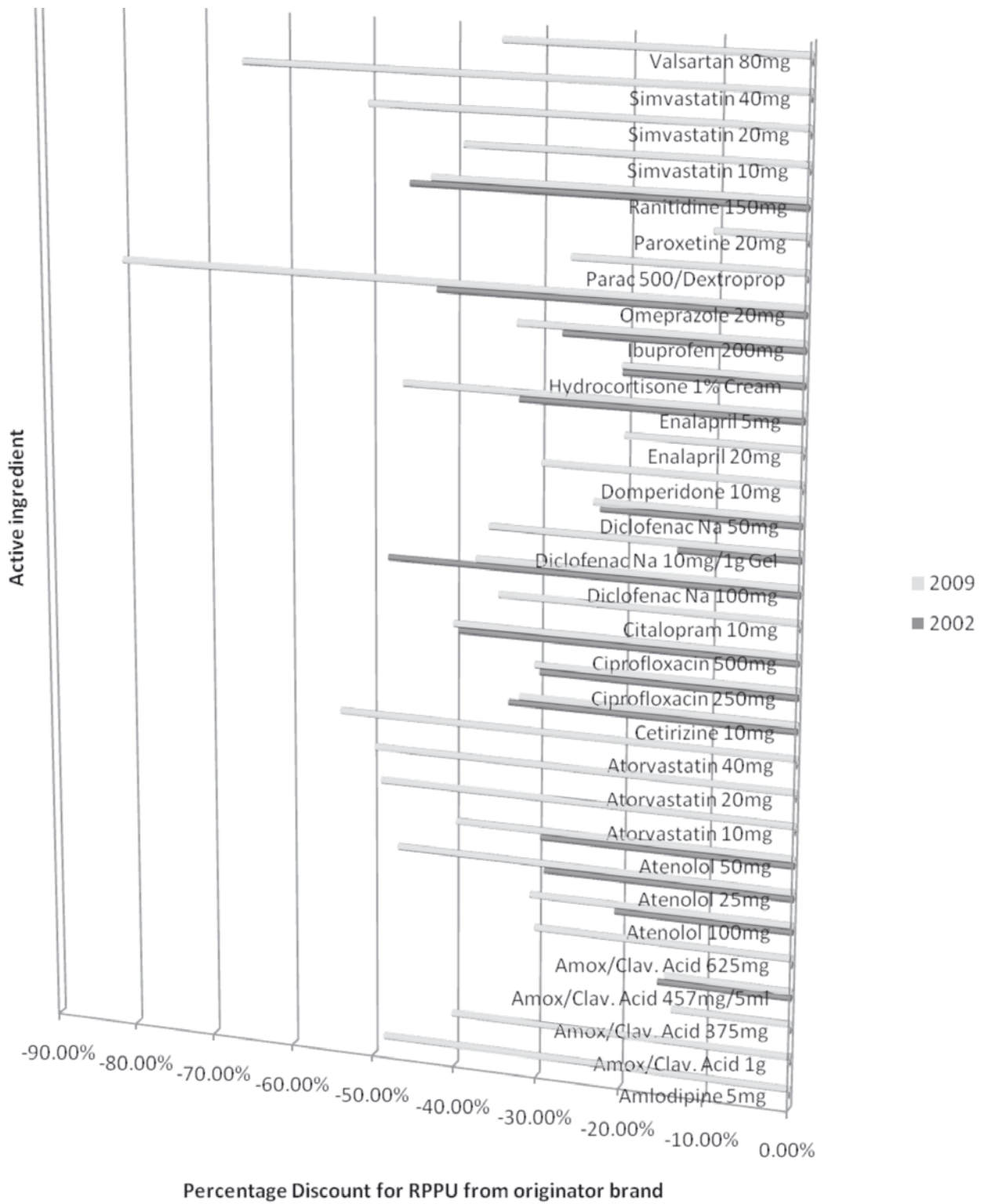


Figure 1 - The percentage discount for the RPPU from the originator product for each active ingredient for 2002 and 2009

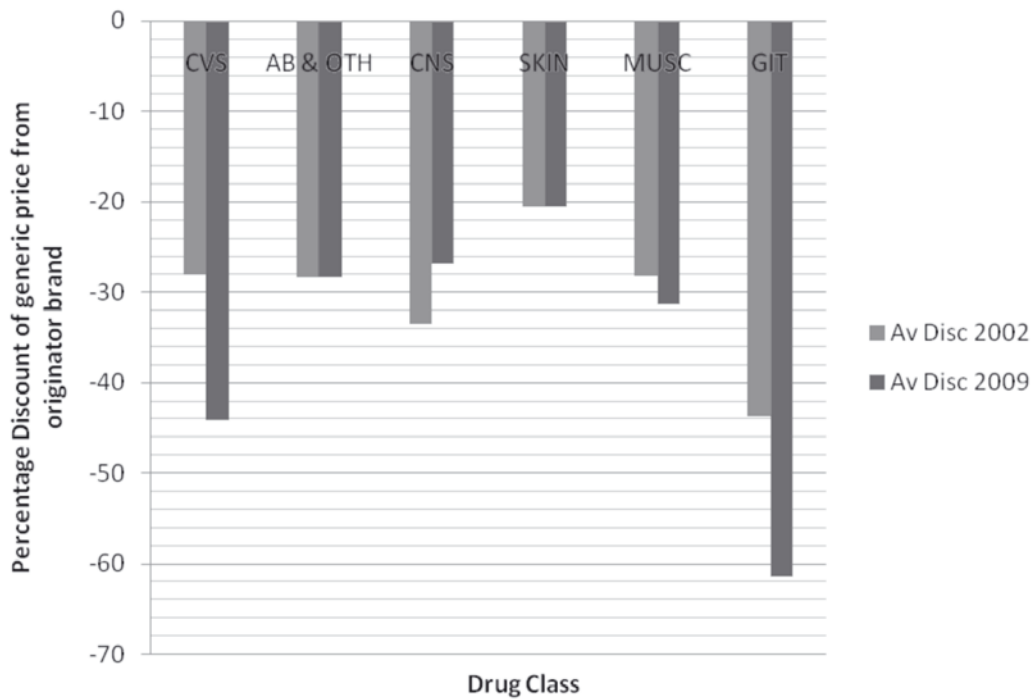


Figure 2 - The percentage discount by drug class in 2002 and 2009



“THE ENTRY OF GENERIC PRODUCTS ON THE MARKET DOES NOT HAVE A SIGNIFICANT IMPACT ON RETAIL PRICES. FURTHER INVESTIGATION INTO THE PRICING STRATEGY OF GENERIC PRODUCTS IS REQUIRED”

HOMEOPATHY AND ALLIED THERAPIES: A REVIEW

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ABSTRACT

Homeopathy is the basis of several forms of therapies that emerged later on throughout Europe. Homeopathy and these related therapies form part of Europe's traditional medical history. Several physicians followed Hahnemann's principles and applied them to their forms of therapies. Such therapies include anthroposophic medicine, gemmotherapy, lithotherapy, organotherapy, Bach's floral remedies, Schüssler's tissue salts. However, in the multicultural and modern Europe, there is still a long way for the official recognition and harmonisation of products within the European Union Member States. Due to popularity of these remedies with EU citizens, the European centralised body and individual Member States medicines authorities are obliged to safeguard the general public through the assessment of safety and quality of these medicinal products.

KEY WORDS Hoemopathy, Anthroposophic medicine, Gemmotherapy, Lithotherapy, Organotherapy, Bach's Floral Remedies, Schüssler's Tissue Salts

INTRODUCTION

Following Dr Hahnemann's evaluation and establishment of homeopathic medicine as an alternative medicine, several other physicians and healthcare professionals applied the principles of homeopathy to different extents in order to develop other forms of therapies, according to their understanding of homeopathy. Homeopathy and allied therapies evolved mainly in Germany, the United Kingdom, France and Belgium. Some of these therapies are not considered as purely homeopathic by the different countries. Such therapies include anthroposophic medicine, gemmotherapy, lithotherapy, organotherapy, Bach's floral remedies and Schüssler's tissue salt therapies. Table 1 represents the different forms of therapies, their originators, the period of establishment and traditional origins.

Table 1: The different forms of therapies, their originators, period of invention and traditional origins.

Therapy	Originator	Period of Establishment	Traditional origins
Homeopathy	Dr Samuel Hahnemann	1792	Germany
Anthroposophic medicine	Dr Rudolph Steiner, Ita Wegman	1921	Austria and Switzerland
Gemmotherapy	Dr Pol Henry, Max Téttau, O.A. Julian	Late 1950's	Belgium and France
Lithotherapy	Dr Max Téttau, Dr Claude Begeret	1970's	Belgium and France
Organotherapy	Dr Frederick Banting, Charles Best, Dr Hans-Heinrich Reckeweg	Mid 1950's	Belgium, France and Germany
Bach's Floral Remedies	Dr Edward Bach	1920-1930	England
Schüssler's Tissue Salts	Dr Wilhelm Schüssler	1873	Germany

ALLIED THERAPIES TO HOMEOPATHY

ANTHROPOSOPHIC MEDICINE

The term 'anthroposophy' is derived from two Greek words, 'anthropos' meaning man and 'sophia' meaning wisdom. Therefore anthroposophy deals with the holistic approach of an individual and towards the knowledge of the self.¹ This means that the patient is in a position to understand health problems with the help of anthroposophic doctors. Although anthroposophic medicine and therapies form an integral part of Europe's traditional medicine, this therapy utilises the vast information and rigorous methodology of allopathic medicine. Anthroposophic medicine is mentioned alongside allopathic and homeopathic medicinal products within Council Directive 2001/83/EC.² Anthroposophic medicines prepared by a homeopathic method are to be treated, with regards to registration and marketing authorisation, in the same way as homeopathic medicinal products. This form of therapy does not solely involve remedies derived from natural sources, but integrates other forms of therapies that affect the moral and psychological components of an ill individual alongside the medical condition. The holistic or integrated image of the whole human being give a better understanding of illness and health. Today, anthroposophic medicine and therapy are practised throughout the world, so much so that there are anthroposophic hospitals dealing with this form of therapy only. In this form of therapy, the human body is compared to a plant and the physiological changes that occur within a plant are transferred to the physiological behaviour of human beings. Commonly used preparations include *Iris germanica* root extract for lymphostasis and oedema, Belladonna herb extract as a spasmolytic and an anti-inflammatory, *Echinacea angustifolia* to strengthen the immune system, *Corallium rubrum* to stimulate haemopoiesis, Cinnabar powder to relieve chronic catarrh.¹

GEMMOTHERAPY

The term 'Gemmotherapy' is derived from the Greek, 'gemma' meaning bud. Remedies used in this type of therapy, are made from the embryonic material of plants. Such plant parts include buds, rootlets, young shoots and seeds. This therapy has been claimed to flush toxins from the body by stimulating the normal elimination pathways. This therapy uses low homeopathic dilutions (1X) of glycerine macerates. At these potencies, some physicians argue that gemmotherapeutic remedies cannot be considered as homeopathic remedies, since they are simply diluted by a factor of ten only. This type of therapy originated in Belgium and France^{3,4,5} and has been recognised as an official form of therapy within the French Pharmacopoeia (CPP, 1965).⁶ The plants' raw material is collected in spring (in the case of seeds in autumn). This form of therapy has been used successfully in the field of rheumatology. Three main remedies are used in the treatment of osteoarthritis. *Pinus Montana*, *Ribes nigrum* and *Vitis vinifera* maintain articular cartilage, reduce inflammation and reduce articular deformations respectively. Other remedies include *Corylus avellana* and *Rosmarinus officinalis* that enhance liver metabolism while *Ficus carica* reduces gastritis by normalising gastric juice secretion.

LITHOTHERAPY

The term 'Lithotherapy' is derived from the Latin, 'lithios meaning stone. It is the use of homeopathic preparations (usually as 8X dilutions) of mineral rocks. The main activity of the rocks is detoxification at the cellular level. These toxins are removed from binding sites hence optimising mineral balance. Although lithotherapy has been used constantly for ages, it has been formalised as a therapy during the late 1970's. The Greeks used marble powder to cure stomach problems or red jasper as a fortifier. In the Middle-Ages, the doctrine of signatures was applied to cure certain diseases. A typical example is the use of emerald in the case of liver disease, as this stone is green resembling bile.⁷ This therapy forms part of the French and Belgian homeopathic tradition. Typical remedies include hematite (iron III oxide) which is used for anaemia, sulphur for arthritis and bursitis, and rhodonite (a manganese inosilicate) used for neurological disorders, amongst others.⁸

ORGANOTHERAPY

The term 'Organotherapy' is derived from the Greek, 'organon' meaning organ. Organotherapeutic remedies are made from homeopathic preparations of healthy tissue of animal origin (bovine cattle, sheep or swine). These remedies, made more potent are used to regulate the function of organs and glands hence normalising their activity. Organotherapy forms part of the French, Belgian and German homeopathic tradition. One of the earliest experiments with organotherapy was with the thyroid in 1912. Children suffering from cretinism and myxoedema were treated with animal thyroid cells. Dramatic improvement was noticed following organotherapy.⁹ Later, in 1922, Frederick Banting and his graduate student Charles Best focused on the pancreas.¹⁰ Banting discovered a range of homeopathic remedies from swine tissues. The remedies are sometimes referred to as suis-preparations and the treatment as homeotoxicology.¹¹

BACH'S FLORAL REMEDIES

Dr Edward Bach was a British homeopath, who like his homeopathic predecessors, was dissatisfied with conventional medicine. Before Dr Bach started experimenting with floral remedies, he developed seven bacterial nosodes.¹² Later, he developed 38 floral remedies, each prepared from the flowers of wild plants, trees and bushes. Initially, he started to collect the dew drops from the surface of flower petals. Later he replaced this method of collection, by taking flower petals and allowing their extraction in 'sun-lit' spring water.¹³ The water obtained was then mixed with an equal volume of brandy to obtain the mother tincture. This was further diluted before use.¹⁴ Although these floral remedies are described in the British Homeopathic Pharmacopoeia (1999)¹⁵, other EU member states argue that these are not prepared according to the common homeopathic manufacturing method. Typical floral remedies include larch for lack of confidence, star of Bethlehem for shock, wild rose for apathy and impatiens for impatience amongst others.¹⁶

SCHÜSSLER'S TISSUE SALTS

Dr Schüssler was a German physician who discovered that when the human cell is reduced to ashes, it exhibits twelve salts.¹⁷ He believed that biochemical imbalances within cells may lead to serial conditions. Restoring salts within cells will reverse or improve the health condition. He called these 'the twelve tissue salts'. Cell salts may be derived from inorganic sources or plants. These are prepared in 6X and 12X homeopathic potencies. Schüssler's salts can be used concurrently with homeopathic medicines, particularly to treat indigestion, recurrent rhinitis and various other conditions. Another twelve salts were added by Schüssler's pupils^{18,19}. These salts are prepared in the form of tablets that can be dissolved either on the tongue or in a glass of warm water. Apart from the tablet form proposed by Schüssler for oral use, his pupils extended their use for topical applications, incorporating these salts into an ointment base. The tissue salts are considered as safe and do not pose any significant side effects. The twelve salts are considered as safe and do not pose any significant side effects. The twelve salts include calcium phosphate as the elasticity salt, calcium fluoride as the nutrition tonic, calcium sulphate as the blood purifier, iron phosphate as the first aid salt, magnesium phosphate as the nerve relaxant, sodium chloride as the water distributor, sodium phosphate as the acid neutraliser, sodium sulphate as the water eliminator, potassium chloride as the blood conditioner, potassium phosphate as the nerve nutrient, potassium sulphate as the skin salt and silica as the toxic eliminator.²⁰

EU DIRECTIVE 2001/83/EC AND HOMEOPATHIC AND ALLIED MEDICINAL PRODUCTS

Due to the fact that these medicinal products contain very low concentrations of active principles and clinical trials are limited, the European Commission has introduced a simplified registration system for these homeopathic medicinal products. However, under such registration system, these products should be placed on the market without medical claims and in dosage forms that do not present a risk to the patient that is orally or externally. Patients are safeguarded by rigorous assessment of quality and safety before the product is placed on the market. Within Council Directive 2001/83, homeopathic medicinal products should be in line with the directive for safety as for allopathic medicines, while they are exempted from proof of efficacy. Therefore, all medicinal products should be assessed and be categorised as either homeopathic medicines, herbal medicines (if derived from plants) or allopathic medicines.

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“SEVERAL PHYSICIANS FOLLOWED HAHNEMANN'S PRINCIPLES AND APPLIED THEM TO THEIR FORMS OF THERAPIES”

STUDENT EXCHANGE PROGRAMME IN MALTA



The Malta Pharmaceutical Students' Association, MPSA was founded in 1966 and was recognized by senate in 1985. It represents pharmaceutical students within the pharmacy department in the Faculty of Medicine and Surgery, within the University of Malta.

MPSA is an active member of IPFS, the International Pharmaceutical Students' Federation, which works to bring pharmacy students from all over the world together. The International Pharmaceutical Students' Federation (IPSF) is the leading international advocacy organisation for pharmacy students with the aim to promote improved public health through provision of information, education, networking as well as a range of publications and professional initiatives. Student Exchange Programme (SEP) is one of the main activities in IPSF. It is a mobility programme that gives students from all over the world the opportunity to get to know pharmacy in a different country.

One of the main activities in IPSF is the Student Exchange Programme (SEP). This is a mobility programme that has allowed students from IPSF member organisations and IPSF Individual Members to explore pharmacy in another country since 1953.

Through the Student Exchange Programme, IPSF works to increase opportunities for improvement in pharmacy education through facilitating students and young pharmacists to undertake international professional experiences in community pharmacy, hospital pharmacy, research and industrial fields of pharmacy.

The aim of SEP is to promote understanding and cooperation amongst pharmacy students and all health care professionals. The exchange programme offers a unique educational and cultural experience in addition to the regular pharmaceutical knowledge. It also helps to broaden the students' understanding of pharmaceutical and social conditions in different countries.

The following is the experience of Tijana Rakic, a student who participated in SEP in Malta last Summer:

"Thinking about my SEP in Malta, I can't help missing it badly. Honestly, everything was absolutely perfect. I had professional training at St. Simon's Pharmacy in Bugibba where I had the opportunity to exchange knowledge with colleagues and to learn a lot. I became familiar with the organization of the Maltese Health System. I learned about the way they take care of their patients and also therapeutic choices in the management of common illnesses.



The accommodation at the Student's Residence was really nice. I was happy to be there with people from all over the world who came on SEP as well. We were having fun together and we enjoyed a lot visiting the beautiful historical and cultural treasures of Malta and Gozo. I really have to thank Martina Mifsud who was always there for us, not only as a professionalist dealing with our SEP problems, but also as our friend."

Fabienne Sant Portanier, a pharmacist practising in a community pharmacy reports on her experience in hosting a student through the SEP programme:
"The Student Exchange Programme (SEP) is a mobility program that offers pharmacy students a unique opportunity to gain a wider pharmacy experience from an international perspective. As a Maltese pharmacist who recently had the opportunity to host a Slovenian pharmacy student, I feel that this initiative is one that should be highly encouraged and supported. During the four-week visit the exchange student was acquainted with a variety of community pharmacy-related activities and was given the chance to practice pharmacy in a local setting with different methods and customs. It has been undoubtedly an unforgettable experience. The program serves as an educational tool and has immense personal benefit for all those involved."

Pharmacists who are interested in hosting students can ask for more information by contacting the national Student Exchange Officer (SEO) Charlene Galea by email on char_mt@hotmail.com



Targets bacteria



Levoxa Levofloxacin 500mg tablets Fluoroquinolone

Composition: Levofloxacin 500 mg film coated tablets. **Therapeutic indications:** In adults with infections of mild or moderate severity, Levoxa tablets are indicated for the treatment of the following infections when due to levofloxacin-susceptible microorganisms: Acute sinusitis, Acute exacerbations of chronic bronchitis, Community-acquired pneumonia, Urinary tract infections including pyelonephritis, Chronic bacterial prostatitis and skin and soft tissue infections. Before prescribing Levoxa, consideration should be given to national and/or local guidelines on the appropriate use of fluoroquinolones. **Posology and method of administration:** Duration of treatment - varies according to the course of the disease. As with antibiotic therapy in general, administration of Levoxa tablets should be continued for a minimum of 48 to 72 hours after the patient has become afebrile or evidence of bacterial eradication has been obtained. **Method of administration:** Levoxa tablets should be swallowed without crushing and with sufficient amount of liquid. They may be divided at the score line to adapt the dosage. The tablets may be taken during meals or between meals. Levoxa tablets should be taken at least two hours before or after iron salts, antacids and sucralfate administration since reduction of absorption can occur. The following dose recommendations can be given for Levoxa: **Dose in patients with normal renal function (creatinine clearance > 30 ml/min):** Acute sinusitis: 500mg once daily; 10-14 days. Acute exacerbations of chronic bronchitis: 250-500mg once daily; 7-10 days. Community-acquired pneumonia: 500mg once or twice daily; 7-14 days. Uncomplicated urinary tract infections: 250mg once daily; 3 days. Complicated urinary tract infections including pyelonephritis: 250mg once daily; 7-10 days. Chronic bacterial prostatitis: 500mg once daily; 28 days. Skin and soft tissue infections: 250mg once daily or 500mg once/biweekly for 7-14 days. **Dosage in patients with impaired renal function (creatinine clearance 30ml/min):** 50-30 ml/min: First dose 250mg/24h, then 125mg/24h. First dose 500mg/24h, then 250mg/24h, then 125mg/24h. First dose 500mg/24h, then 125mg/24h. First dose 500mg/12h, then 125mg/12h (<10ml/min including haemodialysis and CAPD): First dose 250mg/24h, then 125mg/48h. First dose 300mg/24h, then 125mg/24h, then 125mg/12h. **Patients with impaired liver function:** have not been examined in clinical studies. However, no adjustment of dosage is expected to be necessary, since levofloxacin is not metabolised to any great extent by the liver and is mainly excreted by the kidneys. **Elderly patients:** No adjustment of dosage is required in the elderly, other than that imposed by consideration of renal function. **Contraindications:** Hypersensitivity to levofloxacin or other quinolones or any of the excipients, epilepsy, history of tendon disorders related to fluoroquinolone administration, children or growing adolescents, pregnancy and breast feeding women. **Special warnings and precautions for use:** Levoxa is not always the optimal therapy in pneumococcal pneumonia, particularly in more severe cases. Nosocomial infections due to *Pseudomonas aeruginosa* may require combination therapy. Tendinitis and tendon rupture: The risk of tendinitis and tendon rupture is increased in the elderly and in patients using corticosteroids. Close monitoring of these patients is therefore necessary if they are prescribed Levoxa. All patients should consult their physician immediately if they experience symptoms of tendinitis. If tendinitis is suspected, treatment with Levoxa must be stopped immediately, and appropriate treatment (e.g. immobilisation) must be initiated for the affected tendon. Clostridium difficile-associated disease: Diarrhoea, particularly if severe, persistent and/or bloody, during or after treatment with Levoxa tablets, may be symptomatic of Clostridium difficile-associated disease, the most severe form of which is pseudomembranous colitis. If pseudomembranous colitis is suspected, Levoxa tablets must be stopped immediately and patients should be treated with supportive measures and specific therapy as appropriate without delay (e.g. oral vancomycin). Products inhibiting the peristalsis are contraindicated in this clinical situation. Patients predisposed to seizures: Levoxa tablets are contraindicated in patients with a history of epilepsy and, as with other quinolones, should be used with extreme caution in patients predisposed to seizures, such as patients with pre-existing central nervous system lesions, concomitant treatment with fenofenib and similar non-steroidal anti-inflammatory drugs or with drugs which lower the seizure threshold, such as theophylline. Patients with G-6-phosphate

dehydrogenase deficiency: Patients with latent or actual defects in glucose-6-phosphate dehydrogenase activity may be prone to haemolytic reactions when treated with quinolone antibiomatic agents, and so levofloxacin should be used with caution. **Patients with renal impairment:** Since levofloxacin is excreted mainly by the kidneys, the dose of Levoxa should be adjusted in patients with renal impairment. Prevention of photosensitisation: Although photosensitisation is very rare with levofloxacin, it is recommended that patients should not expose themselves unnecessarily to strong sunlight or to artificial UV rays (e.g. sunray lamp, solarium), in order to prevent photosensitisation. **Patients treated with Vitamin K antagonists:** Due to possible increase in coagulation tests (PT/INR) and/or bleeding in patients treated with Levoxa in combination with a vitamin K antagonist (e.g. warfarin), coagulation tests should be monitored when these drugs are given concomitantly. **Psychotic reactions:** Psychotic reactions have been reported in patients receiving quinolones, including levofloxacin. In very rare cases, these have progressed to suicidal thoughts and self-endangering behaviour - sometimes after only a single dose of levofloxacin. In the event that the patient develops these reactions, levofloxacin should be discontinued and appropriate measures instituted. Caution is recommended if levofloxacin is to be used in psychotic patients or in patients with history of psychiatric disease. **QT prolongation:** Very rare cases of QT interval prolongation have been reported in patients taking fluoroquinolones, including levofloxacin. Caution should be taken when using fluoroquinolones, including levofloxacin in patients with known risk factor for QT interval prolongation, like for example, elderly, uncorrected electrolyte imbalance (e.g. hypokalaemia, hypomagnesaemia), congenital long QT syndrome, cardiovascular diseases (e.g. cardiac failure, myocardial infarction, bradycardia) concomitant use of drugs known to prolong the QT interval (Ia and II class antiarrhythmics, tricyclic antidepressants, neuroleptics, macrolides). Patients with rare hereditary problem of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interaction with other medicinal products and other forms of interaction:** Iron salts, magnesium-oraluminium-containing antacids, levofloxacin absorption is significantly reduced when iron salts, or magnesium- or aluminium-containing antacids are administered concomitantly with Levoxa tablets. It is recommended that preparations containing divalent or trivalent cations such as iron salts, or magnesium- or aluminium-containing antacids should not be taken 2 hours before or after Levoxa tablet administration. No interaction was found with calcium carbonate. **Sucralfate:** The bioavailability of Levoxa tablets is significantly reduced when administered together with sucralfate. If the patient is to receive both sucralfate and Levoxa, it is best to administer sucralfate 2 hours after the Levoxa tablet administration. **Contraceptive pill:** Some antibiotics can, in rare cases, reduce the efficacy of contraceptive pills by interfering with bacterial hydrolysis of the steroid conjugate in the intestine and thereby the re-absorption of the unconjugated steroid. The plasma levels of the active steroid would by this means be reduced. **Theophylline, Amiodol or similar non-steroidal anti-inflammatory drugs:** No pharmacokinetic interactions of levofloxacin were found with theophylline in a clinical study. However a pronounced lowering of the cerebral set-point threshold may occur when quinolones are given concurrently with theophylline. **Non-steroidal anti-inflammatory drugs or other agents which lower the seizure threshold:** Levofloxacin concentrations were about 13% higher in the presence of fenofenib than when administered alone. **Probenecid and cimetidine:** Probenecid and cimetidine had a statistically significant effect on the elimination of levofloxacin. The renal clearance of levofloxacin was reduced by cimetidine (24%) and probenecid (34%). This is because both drugs are capable of blocking the renal tubular secretion of levofloxacin. However, at the lowest doses in the study, the statistically significant drugs differences are unlikely to be of clinical relevance. **Caution should be exercised when levofloxacin is administered with drugs that affect the tubular renal secretion such as probenecid and cimetidine, especially in renally impaired patients.** **Cyclosporin:** The half life of cyclosporin was increased by 33% when administered with levofloxacin. **Vitamin K antagonists:** Increased coagulation tests (PT/INR) and/or bleeding, which may be severe, have been reported in patients treated with levofloxacin in combination with a vitamin K antagonist (e.g. warfarin). Coagulation tests, therefore, should be monitored in patients treated with vitamin K antagonists. **Meals:** There is no clinically relevant interaction with food. Levoxa tablets may therefore be administered regardless of food intake. **Dosage known to prolong QT interval:** Levofloxacin, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. class Ia and II antiarrhythmics, tricyclic

antidepressants, neuroleptics, macrolides). **Laboratory tests:** In patients treated with levofloxacin, determination of opiates in urine may give false-positive results. It may be necessary to confirm positive opiate screens by more specific methods. **Pregnancy and lactation:** **Pregnancy:** - Reproductive studies in animals did not raise specific concerns. However in the absence of human data and due to the experimental risk of damage by fluoroquinolones to the weight-bearing cartilage of the growing organism, Levoxa tablets must not be used in pregnant women. **Lactation:** - There is no information on whether levofloxacin is excreted in breast milk. Levoxa tablets must therefore not be used during breast-feeding. Other quinolones cross into breast milk in amounts that may affect the child even at therapeutic doses. **Effects on ability to drive and use machines:** Some undesirable effects (e.g. dizziness/vertigo, drowsiness, visual disturbances) may impair the patient's ability to concentrate and react, and therefore may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery). **Undesirable effects:** Very common (>1/10), Common (>1/100 to <1/10), Uncommon (>1/1,000 to <1/100), Rare (>1/10,000 to <1/1,000) and Very rare (<1/10,000), including isolated reports. **Infections and infestations:** Uncommon: fungal overgrowth and proliferation of other resistant microorganisms. **Blood and the lymphatic system disorders:** Uncommon: eosinophilia, leucopenia; Rare: neutropenia, thrombocytopenia; Very rare: agranulocytosis; Isolated cases: haemolytic anaemia, pancytopenia. **Immune system disorders:** Very rare: Allergic reactions (angioedema, hypotension, anaphylactic-like shock), allergic pneumonitis; Isolated cases: severe bullous eruptions such as Stevens-Johnson syndrome, toxic epidermal necrolysis (EpiSt) syndrome and erythema multiforme. **Muco-cutaneous, anaphylactic /-like reactions may sometimes occur even after the first dose.** **Nervous system disorders:** Uncommon: headache, dizziness/vertigo, drowsiness, insomnia; Rare: paraesthesia, tremor, anxiety, depression, psychotic reactions with self-endangering behaviour including suicidal ideation or acts, agitation, confusion, convulsions; Very rare: sensory and sensorimotor peripheral neuropathy, visual and auditory disturbances, disturbances of taste and smell, hallucinations. **Cardiac disorders:** Rare: tachycardia; Very rare: shock (anaphylactic-like); Isolated cases: QT-interval prolongation. **Vascular disorders:** Rare: hypotension. **Respiratory, thoracic and mediastinal disorders:** Rare: bronchospasm /cynpnoea. **Gastrointestinal disorders:** Common: nausea, diarrhoea; Uncommon: anorexia, vomiting, abdominal pain, dyspepsia; Rare: bloody diarrhoea which in very rare cases may be indicative of enterocolitis, including pseudomembranous colitis; Very rare: hypoglycaemia, particularly in diabetic patients. **Metabolic and nutritional disorders:** Common: increase in liver enzymes (e.g. ALT / AST); Uncommon: increase in bilirubin; Very rare: liver reactions such as hepatitis. **Skin and subcutaneous tissue disorders:** Uncommon: pruritus, rash; Rare: urticaria; Very rare: photosensitisation. **Musculoskeletal, connective tissue and bone disorders:** Rare: arthralgia, myalgia, tendon disorders incl. tendinitis; Very rare: tendon rupture - this undesirable effect may occur within 48 hours of starting treatment and may be bilateral. **Muscular weakness,** which may be of special importance in patients with myasthenia gravis; Isolated cases: rhabdomyolysis. **Renal and urinary disorders:** Uncommon: increase in serum Creatinine; Very rare: acute kidney failure (e.g. due to interstitial nephritis). **General disorders and administration site conditions:** Uncommon: asthenia; Very rare: fever. **Other undesirable effects which have been associated with fluoroquinolone administration include:** Vascular disorders: Hypersensitivity vasculitis. **Nervous system disorders:** Extra pyramidal symptoms and other disorders of muscular coordination. **General disorders and administration site conditions:** Attacks of porphyria in patients with porphyria. **Marketing Authorisation Holder:** Actavis Group PTC ehf, Reyjavikurvegur 76-78, 220 Hafnarfjörður, Iceland. **This medicinal product is subject to medical prescription.**

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