Preparing for pharmacist prescribing in Maltese hospitals

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Abstract

Objectives To develop and evaluate a framework for pharmacist prescribing in a hospital setting, assess differences between pharmacist and physician prescribing and analyse pharmacist perceptions on pharmacist prescribing.

Methods A framework for pharmacist prescribing in hospital based on a collaborative drug therapy management approach was developed. Guidelines on three therapeutic scenarios, namely oral anticoagulation therapy, hypertension and diabetes mellitus, were compiled as part of the framework. The framework was validated by an expert panel consisting of five pharmacists and four physicians. A self-administered questionnaire was developed and distributed to the expert panel to evaluate the framework. A case study relating to each therapeutic scenario identified was designed and given to the expert panel to assess differences between pharmacist and physician prescribing. The framework and the questionnaire were disseminated to all 62 pharmacists practicing in local public hospitals to evaluate the framework and their perceptions on pharmacist prescribing.

Key findings All nine expert panel members strongly agreed or agreed that the proposed framework is well-presented, clear and comprehensive, and seven strongly agreed or agreed upon its practicality for use in the hospital setting. Results of the case studies showed that pharmacists and physicians prescribed similar treatment when the correct diagnosis was established. Of the 31 pharmacists who completed the questionnaire, more pharmacists were willing to prescribe antihypertensive (n = 27) and antidiabetic medications (n = 27) compared to oral anticoagulation therapy (n = 20). Twenty-seven pharmacists recommended further education to a specialised Masters or Doctorate level for pharmacist prescribing.

Conclusions The proposed framework puts forward a well-presented, comprehensive and practical system to prepare pharmacists for pharmacist prescribing in a hospital setting within a multidisciplinary team practice for chronic conditions.

Keywords chronic conditions; collaborative drug therapy management; continuing professional development; hospital setting; Malta; pharmacist prescribing

Introduction

Pharmacists are valued and accessible healthcare professionals positively contributing to the care of patients with chronic diseases. Pharmacists in the United States of America, Canada, the United Kingdom, Australia and New Zealand have been given the authority to prescribe medications for continuity of patient care and medication accessibility. Expanding the prescribing role to pharmacists as part of a multidisciplinary team supports optimisation of medication management, improves continuity of care, increases patient access to medications and reduces healthcare costs.

There are two main types of pharmacist prescribing; dependent and independent prescribing. Dependent pharmacist prescribing involves the delegation of prescribing authority from the physician, or any other independent prescriber, to a pharmacist, where the pharmacist has to follow a pre-defined protocol. Within independent pharmacist prescribing scenarios, the pharmacist initiates, monitors and modifies a patient’s treatment.
Prescribing by pharmacists has been reported in the management of chronic diseases requiring frequent monitoring and dose adjustments, including conditions requiring anticoagulation therapy, hypertension, diabetes mellitus, asthma and dyslipidaemia. Pharmacist prescribing and management interventions in these conditions improved blood pressure, glycaemic, INR and lipid level control, quality of therapy, adherence and cost-effectiveness.\(^{[11]}\)

This study proposes a framework for pharmacist prescribing for chronic conditions in a hospital setting within a multidisciplinary approach. The proposed framework includes specific clinical guidelines developed for three therapeutic scenarios considered in this study, namely conditions requiring oral anticoagulation therapy, hypertension and diabetes mellitus. Hospitalisation presents an opportunity for patients suffering from these chronic conditions to receive medication review which may require new treatments or close monitoring and adjustments. In this context, the intervention of clinical pharmacists to participate in the prescribing process is relevant, as the multidisciplinary team may be focused on looking at reasons for admission that may go beyond medicine needs.

The objectives of the study were to review pharmacist prescribing models, identify hospital scenarios where pharmacists are willing to prescribe, develop and evaluate a framework for pharmacist prescribing in hospital for specific chronic conditions, assess differences between pharmacist and physician prescribing, and analyse pharmacist perceptions on pharmacist prescribing.

### Methods

#### Study setting

Pharmacists in Malta do not presently have prescribing authority and legal reform in the Maltese healthcare system is required to implement the proposed framework. The framework was proposed for Mater Dei Hospital (MDH), the only acute general public hospital in Malta. MDH offers a range of inpatient services including medical, surgical, paediatric, obstetrics and gynaecology, emergency, intensive care and cardiology wards. In addition to general medicine and surgical outpatient ambulatory clinics, the hospital runs specialised ambulatory services, including pain, \textit{in vitro} fertilisation, breast care, diabetes mellitus and oral anticoagulation clinics. Most of the ambulatory care clinics incorporate a multidisciplinary approach, where patients are attended to by physicians and other healthcare professionals, including clinical pharmacists.

The National Health System in Malta is a unique model being a fully non-contributory national health service solely funded and supported by the government. Patients entitled to the service do not pay for hospitalisation and for medicines available on the Government Formulary List for chronic conditions listed in the Social Security Act, such as hypertension and diabetes mellitus. Consultant physicians prescribe medicines for each patient under their care and apply for a yellow card. Normally this takes place during a hospitalisation or in an ambulatory clinic visit. Patients present the yellow card at the community pharmacy of their choice together with a prescription to collect their free entitled medicines. Only medicines which are available on the Government Formulary List may be prescribed to be obtained free-of-charge.

#### Selection of pharmacist prescribing model for proposed framework

The Collaborative Drug Therapy Management (CDTM) approach was selected as a model for the development of the pharmacist prescribing framework in this study. CDTM is a form of dependent pharmacist prescribing which involves developing a treatment plan, where the physician diagnoses the patient’s condition and the pharmacist collaboratively selects, initiates, monitors and modifies the patient’s pharmacotherapy according to treatment response.\(^{[23]}\) The CDTM approach was selected as it supports the prescribing intervention by the clinical pharmacist centred within a multidisciplinary practice. This pharmacist prescribing model was identified as a framework which is easier to be accepted by the other prescribing healthcare professionals as it reduces the possibility of pharmacist prescribing without updating the other members of the team, in the interest of patient safety.

#### Selection of scenarios for pharmacist prescribing in a hospital setting

Scenarios for which clinical pharmacists are willing to prescribe were identified according to results from a previous Maltese study by Vella\(^{[24]}\) which concluded that pharmacists in the hospital setting were most willing to prescribe oral anticoagulation therapy, antihypertensive and antidiabetic medications. These three scenarios were selected for development of the pharmacist prescribing guidelines in this study.

#### Development of pharmacist prescribing guidelines

Guidelines for prescribing of oral anticoagulation therapy, in hypertension and in diabetes mellitus by clinical pharmacists were compiled by the investigators (AA, FW, MAP, LG, LMA). The guidelines were divided into four sections.

- **Section I:** Prescribing by the clinical pharmacist in the hospital consists of steps for the pharmacist prescribing framework using the CDTM model and highlights the clinical pharmacist’s input within the multidisciplinary team. In the proposed framework, clinical pharmacists have to establish the patient’s medical and drug history, evaluate established patient information, formulate a pharmaceutical care plan, communicate information with the patient, relatives/carers and other healthcare professionals, and implement, review and monitor the care plan. A patient profile was developed to document patient information required by the clinical pharmacist during this stage.

- **Section II:** Prescribing of drugs requiring frequent monitoring includes guidelines for pharmacist prescribing of oral anticoagulation therapy, in hypertension and in diabetes therapy.
mellitus. Clinical guidelines were used to compile the clinical content of these guidelines. The guidelines for pharmacist prescribing of oral anticoagulation were compiled according to established guidelines at MDH developed in 2014 by the ‘Anticoagulation Guideline Development Group at MDH’, titled ‘Warfarin Initiation and Maintenance Guideline’[25] and ‘Warfarin Reversal Guideline’. [26]

For hypertension and diabetes mellitus, the clinical guidelines developed by relevant international entities which are adopted at MDH were used. The guidelines for pharmacist prescribing in hypertension were developed according to the 2013 European Society of Hypertension (ESH)/European Society of Cardiology (ESC) ‘Guidelines for the Management of Arterial Hypertension’[27], the 2011 National Institute for Health and Care Excellence (NICE) Clinical Guideline 127 ‘Hypertension in adults: Diagnosis and management’[28] and ‘Guidelines for the Management of Hypertension’ by Cambridge University Hospitals published in 2010.[29]

The 2015 American Diabetes Association (ADA) Guidelines ‘Standards of Medical Care in Diabetes’[30], the 2015 NICE Clinical Guideline ‘Type 1 Diabetes in Adults: Diagnosis and Management’[31], the 2015 NICE Clinical Guideline ‘Type 2 Diabetes in Adults: Diagnosis and Management’[32] and ‘Type 2 Diabetes National Clinical Guideline for Management in Primary and Secondary Care (update)’[33] published by the National Collaborating Centre for Chronic Conditions in 2008, were used to develop the guidelines for pharmacist prescribing in diabetes mellitus. Monitoring sheets were developed for monitoring and documentation of INR, blood pressure values and blood glucose levels at different daily time intervals.

‘Section III: Reporting adverse drug reactions’ was dedicated to adverse drug reaction reporting by the clinical pharmacist and/or any other healthcare professional. The last section of the developed guidelines, ‘Section IV: Ethical and legal considerations for pharmacists’, incorporated ethical and legal considerations applicable to clinical pharmacists regarding accountability and patient safety.

Validation and evaluation of the framework and guidelines
A nine-member expert panel consisting of five pharmacists (three clinical pharmacists and two community pharmacists) and four physicians (three specialist practitioners and two general practitioners) was set up to validate the guidelines and the proposed framework. The members of the panel were experienced in their professional practice and were identified by convenience sampling. The recommendations put forward by the validation panel were accepted by the investigators and implemented. The updated guidelines and framework were re-distributed to the same panel to seek consensus. Consensus with all nine panel members for the second version was reached as no further amendments were proposed. A self-administered questionnaire consisting of close-ended and Likert-scale questions (from 1 to 5, strongly disagree to strongly agree) was developed to evaluate the final version of the guidelines and the framework by the expert panel.

Assessing differences between pharmacist and physician prescribing
Three case studies, namely ‘hypertensive crisis with congestive heart failure’, ‘diabetic ketoacidosis due to late onset type 1 diabetes mellitus’ and ‘deep vein thrombosis’, were compiled. These case studies were given to the same expert panel used for validation to assess differences between pharmacists and physicians in determining the correct diagnosis and putting forward an appropriate pharmaceutical care plan according to the established diagnosis and the developed guidelines and not as a basis for implementation of pharmacist prescribing.

Dissemination of framework and questionnaire to hospital pharmacists
The questionnaire used by the expert panel to evaluate the framework was updated to incorporate questions to assess the perception of hospital pharmacists on pharmacist prescribing. The proposed framework for pharmacist prescribing in the hospital setting and the questionnaire were disseminated to all 62 pharmacists practising in various areas of pharmacy services in five public hospitals to evaluate the framework and assess pharmacist perceptions on pharmacist prescribing.

Data analysis
Statistical analysis was undertaken using IBM SPSS version 23.0. Descriptive statistics were presented as number of participants who strongly agreed or agreed. The chi-square test was used to assess the association between two categorical variables when analysing pharmacist perceptions of pharmacist prescribing with age, gender and highest academic level of the pharmacist. A P-value <0.05 was considered statistically significant.

Results
Expert panel validation and evaluation of the framework and guidelines
All nine expert panel members strongly agreed or agreed that the proposed framework is well-presented, clear and comprehensive. Eight of the nine panel members strongly agreed or agreed that the information presented in the framework is adequate and that the framework promotes a better multidisciplinary approach to health care. Seven panel members strongly agreed or agreed that the framework is practical for use in the hospital setting. Six panel members strongly agreed or agreed that pharmacists should further their studies to a specialised Masters or Doctorate level degree in clinical pharmacy to have prescribing authority.

Eight panel members strongly agreed or agreed with pharmacist prescribing for patients requiring oral anticoagulation therapy and seven strongly agreed or agreed with pharmacist prescribing for patients with hypertension and diabetes mellitus (Figure 1). All nine panel members strongly agreed or agreed that the guidelines for pharmacist prescribing of oral anticoagulation therapy are informative, clear and easy to follow, while eight strongly agreed or
agreed or agreed that the developed pharmacist prescribing guidelines are well-presented, clear, easy to follow, contain adequate information based on recognised international and local guidelines, and that the proposed framework is practical for use in the hospital setting. All 31 pharmacists strongly agreed or agreed that successful implementation of the proposed framework requires employment of more clinical pharmacists in the Maltese health service.

Pharmacists’ perception on pharmacist prescribing

Twenty-seven of the 31 pharmacists who participated were willing to prescribe antihypertensive and antidiabetic medications, while 20 pharmacists were willing to prescribe oral anticoagulants. No statistically significant difference ($P > 0.05$) was observed when willingness to prescribe each of the three medication classes was correlated with age, gender or highest academic level of the pharmacist. Other conditions for which pharmacists were willing to prescribe were hyperlipidaemia ($n = 28$) and asthma ($n = 26$).

According to the pharmacists who participated, the most important benefits of pharmacist prescribing are a reduction in medication errors ($n = 26$), decreased drug–drug interactions ($n = 26$), more comprehensive medication review ($n = 25$) and optimisation of medicines management ($n = 25$). The most common barriers to implementation of pharmacist prescribing identified by the pharmacists are opposition of pharmacist prescribing by physicians ($n = 31$), inadequate human resources ($n = 21$), lack of training or continuing professional development (CPD) for pharmacists ($n = 20$), lack of pharmacist willingness ($n = 17$) and resulting fragmentation of health care due to competition and conflict between pharmacists and physicians ($n = 17$).

Eighteen pharmacists believed that they have adequate knowledge to prescribe. A higher number of pharmacists with a specialised Masters or Doctoral degree ($n = 10$) believed they possess adequate pharmaceutical knowledge to prescribe compared to pharmacists having a first degree in pharmacy ($n = 8$); however this difference was not statistically significant ($P < 0.05$). Twenty-seven pharmacists suggested that pharmacists should further their studies to a specialised Masters or Doctorate level in aspects of clinical pharmacy to be qualified to prescribe. All 31 pharmacists believed that CPD activities should be mandatory for implementation of pharmacist prescribing. Lectures ($n = 22$) and case discussions ($n = 21$) were the most preferred type of CPD activities by the pharmacists who completed the questionnaire (Figure 2). The main limitations to attending CPD activities were the time at which these activities are held ($n = 25$), lack of time to attend CPD activities due to long working hours ($n = 8$) and financial implications ($n = 6$).

Discussion

The proposed framework focuses on preparing clinical pharmacists to prescribe oral anticoagulation therapy, in hypertension and in diabetes mellitus within a multidisciplinary team practice in a hospital setting.
The prevalence of chronic diseases is rising\(^{34}\), resulting in a greater health burden and increased polypharmacy with more risks for patients if therapy management and monitoring are not carried out optimally.\(^{35}\) Pharmacist intervention in the management of chronic conditions, such as cardiovascular disease and diabetes mellitus, has the potential to ease the workload of physicians and allow them to dedicate more time to complicated cases, in the interest of patient safety and well-being.\(^{3,7,35,36}\)

Eight of the nine members of the expert panel agreed with pharmacist prescribing for patients requiring oral anticoagulation therapy. However, the hospital pharmacists who completed the questionnaire were less willing to prescribe oral anticoagulation therapy (20/31) compared to antihypertensive and antidiabetic medications (27/31). Management of oral anticoagulation therapy is an important role of clinical pharmacists in hospital outpatient clinics and in community pharmacy to achieve better INR control and patient outcomes.\(^{16,18}\) With regard to inpatient care, oral anticoagulation management by clinical pharmacists, such as in cardiac patients post-surgery, can result in improved cost-effectiveness and quality of care.\(^{15}\) Pharmacist prescribing for patients with hypertension and diabetes mellitus was agreed upon by seven of the nine expert panel members and by 27 of the 31 hospital pharmacists who participated in the study. Collaborative pharmacist-led management services in hypertension and diabetes mellitus can help to improve monitoring and control of blood pressure and blood glucose, CVD risk factors, medication adherence and optimise therapy.\(^{3,11,36,37}\)

Results of the case studies showed that pharmacists and physicians prescribed similar treatment when the correct diagnosis was established. The case studies were selected as examples to demonstrate the ability of appropriate diagnosis by pharmacists even for ‘atypical’ cases. For the case study on hypertensive crisis with underlying congestive heart failure, experts who established the correct diagnosis prescribed antihypertensive drug therapy, as recommended by the ESH/ESC hypertension guidelines. The remaining four experts who misdiagnosed as hypertensive crisis with unstable angina also prescribed similar antihypertensive treatment, which reflected appropriate therapy recommended by the ESH/ESC guidelines.\(^{27}\) For the case study on diabetes mellitus, the same treatment was prescribed by pharmacists and physicians. Differences in the long-term treatment were noted, where eight experts misdiagnosed the patient as suffering from type 2 diabetes mellitus and only one expert established the diagnosis as diabetic ketoacidosis as a result of undiagnosed late onset type 1 diabetes mellitus. The suggested long-term treatment by pharmacists and physicians was identical when they misdiagnosed the scenario as type 2 diabetes mellitus and complied with the ADA clinical guidelines.\(^{19}\) For the deep vein thrombosis case study, the same initial and long-term treatment was prescribed by pharmacists and physicians according to the warfarin initiation and maintenance guidelines.\(^{25,26}\)

The requirements for pharmacists to be qualified as prescribers are not the same in all countries. Pharmacists in the United Kingdom follow a specific course designed by clinicians and pharmacists leading to qualification as prescribers, and pharmacists in New Zealand and Australia must complete a postgraduate course in clinical pharmacy to be authorised to prescribe.\(^{4,8,9,38,39}\) In the proposed framework, it was recommended that pharmacists should be in possession of a specialised Masters or Doctorate level degree (clinical-oriented PharmD or PhD) in addition to their first degree in pharmacy (MPharm), with a certificate of specialisation in one or more of the three scenarios studied. All pharmacists who participated in the study were willing to participate in CPD activities and believed that these activities should be mandatory for the implementation of pharmacist prescribing. The preferred CPD activities among the participants were lectures, case discussions, conferences and courses.

A limitation of this study was the small size of the expert panel who reviewed the proposed framework and its selection by convenience sampling. Forming the expert panel with a larger size may have added more diversity in terms of their background, experience and opinions.
Conclusions
The proposed framework puts forward a clear, comprehensive and practical system to prepare clinical pharmacists for prescribing in hospital within a multidisciplinary team practice in chronic conditions. All the pharmacists who participated agreed that the developed pharmacist prescribing guidelines for oral anticoagulation therapy, hypertension and diabetes mellitus are easy to follow, practical for use in the hospital setting and contain adequate information based on recognised international and local clinical guidelines. The case studies demonstrated that pharmacists and physicians prescribed similar treatment when the correct diagnosis was established. The participants agreed that pharmacists should further their studies to a specialised Masters or Doctorate level in aspects of clinical pharmacy to be qualified to prescribe.

Launching of the proposed framework in the hospital setting may be approached by adopting hospital practice procedures that allow pharmacists who have undertaken further studies and practiced collaboratively with the medical team to adjust treatment. Further elaboration of this pharmacist prescribing model in other medical areas and consideration of legal changes are suggested to be proposed following a pilot study in the hospital setting. The consensus achieved between pharmacists and physicians in this study gives support to open discussions towards the legal changes required to empower pharmacists to prescribe.

Declarations
Conflict of interest
The Authors declare that they have no conflicts of interest to disclose.

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Authors’ contributions
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