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Review

The role of the pharmacist in low back pain management: a narrative review of practice guidelines on paracetamol vs non-steroidal anti-inflammatory drugs

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Abstract

Low back pain (LBP) is a common and costly condition and a leading cause of disabilities across the globe. In Australia and other countries, there has been changes in LBP management guidelines and evidence in recent years, including the use of pharmacotherapy. Inadequately treated LBP is a burden with significant health and economic impacts. Although there is some variability, non-steroidal anti-inflammatory drugs (NSAIDs) have largely replaced paracetamol as the first-choice analgesic for non-specific LBP in many international clinical guidelines, including the current Australian Therapeutic Guidelines. More recent clinical evidence also supports that targeting LBP with the use of NSAIDs can provide superior and more effective relief of LBP symptoms compared with paracetamol. Community pharmacists are one of the most accessible and frequently visited health professionals that offer vital primary healthcare services aimed to provide enhanced clinical outcomes for patients. The position of a community pharmacist is pivotal in LBP assessment and management, from both a pharmacological and non-pharmacological standpoint, including the use of clinical guidelines, yet their roles are often not fully utilized in LBP therapy. Studies investigating the community pharmacist's views, practices, knowledge, and roles, specifically in LBP management in Australia are variable and limited. This narrative review will briefly cover the impacts of LBP, and to provide a summary on recent evidence, updates and a comparison of the Australian and international low back pain management guidelines on paracetamol vs NSAIDs in LBP, as well as pharmacists' roles and interventions in a primary healthcare setting in this context.

Keywords

Low Back Pain; Pain Management; Guidelines as Topic; Anti-Inflammatory Agents, Non-Steroidal; Acetaminophen; Pharmacies; Pharmacists; Australia

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INTRODUCTION

Low back pain (LBP), defined as pain that is localised below the costal margin and above the inferior gluteal folds, is one of the most commonly presenting complaints encountered in the Australian healthcare system.[1] Approximately 25% of Australians suffer from LBP and this number is set to rise with the aging population.[2,3] Furthermore, it has been identified that around four in five Australian adults lived will experience LBP symptoms at some point in their lives, and approximately 50% of Australians who experience LBP discomfort seek medical care.[2,3]

Many LBP sufferers seeking symptomatic relief will present to community pharmacies, sometimes for large quantities of analgesic medicines.[2] Community pharmacists are an important primary healthcare resource that contributes to patient care, yet their roles in LBP management are often not fully utilized. Although serious pathology is not common in patients with LBP symptoms, it is imperative that health professionals recognize and identify the presence of alerting features which may potentially lead to serious systemic and neuropathic consequences.[4] However, clinical guidelines and evidence are also constantly being updated and evolving, including for LBP, thus reinforcing the importance for pharmacists to manage accordingly based on best practice and best clinical evidence.

This narrative review will first briefly cover the impacts caused by LBP. Additionally, this review will also provide an overview on recent updates and comparisons of the Australian and several international LBP management guidelines on paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) for LBP, including a brief summary of their current clinical evidence, as well as pharmacists' roles and interventions in a primary healthcare setting in this context.

With the aim of providing insights into the assessment and management of LBP and the role of pharmacists in this space, systematic searches of the following electronic databases were carried out: Pubmed, Medline, Science Direct, Proquest and Google Scholar. Results were limited to January 2000 to February 2020. Search items used for each database included: 'low back pain', 'chronic low back pain', 'low back pain management', 'low back pain burden', 'low back pain guidelines, 'low back pain evidence', 'paracetamol', 'acetaminophen', 'non-steroidal anti-inflammatory drugs', 'NSAIDs', and 'community pharmacist'. References from identified journal articles were also screened to identify relevant articles and studies. Studies and books were included if they reviewed the global burden of LBP, as well as the guidelines and evidence on the management and assessment of LBP.

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CONSEQUENCES OF INADEQUATELY TREATED LOW BACK PAIN

Cases of LBP symptoms encountered in primary care settings are often attributed to acute local musculoskeletal injuries and strains. These presentations of LBP (termed non-specific LBP) are typically self-limiting and primarily require non-pharmacological strategies to manage symptoms.[4] However, as is the case with all acute pain in general, inadequate treatment of LBP can potentially lead patients to experience persistent and ongoing symptoms, with 10-15% of cases leading to chronic pain.[5,6] There are reported cases of patients who develop chronic non-specific LBP which can be severe and disabling.[7] It is essential that sufferers of LBP are provided with holistic and evidence-based therapy in order to minimise the risk of symptoms developing into chronic cases.[4,5] Failure to adequately treat LBP symptoms can impact the quality and functionality of life of patients who experience these symptoms.

In a 2010 study that investigated the global burden of LBP, results showed that out of the 291 conditions that were included in the study, LBP was found to cause more global disability than any other condition.[8,9] Further retrospective analysis of this study increasingly heighten these findings by confirming that in 2010, LBP was ranked as the 6th leading contributor to years lived in ill health compared to 1990 in which LBP was ranked 11th.[8] It appears that the rate that individuals experience LBP in their day-to-day lives is unquestionably on the rise. LBP sufferers, and in particular those who experience chronic and persistent symptoms, express the desperate need to pursue assistance from numerous healthcare providers for targeted pain relief.[4,5] Unfortunately, from a therapeutic perspective, pain collectively is often inadequately treated. Poor assessment and treatment give rise to clinical as well as practical health concerns for pain sufferers. Failure to adequately manage pain in general results in significant costs to the healthcare system as well as posing financial strains on sufferers and their families in dealing with the pain management.

The economic consequences

In addition to being common, LBP is also among the most costly conditions encountered in primary care. One study reported that in 2001, there was a AUD 1.02 billion dollar direct cost of treating LBP in Australia.[10] These direct costs included charges for diagnosis, treatment and rehabilitation, and more than 70% of these costs are attributed to physical treatment provided by massage therapists, physiotherapists and chiropractors.[10] A more recent study reported that in 2011, the direct and indirect costs associated with LBP management in Australia had not improved. The estimated direct costs of LBP treatment were still sitting at approximately AUD 1 billion with a further AUD 8 billion on indirect costs.[3]

There are currently limited reports on the exact economic burden associated with inadequate pharmacological LBP management. However, it is suggested that less than optimal management can also result in an increased economic burden. A secondary analysis study published in 2018 reported that there was an increase in healthcare costs associated with inadequate pharmacological management of LBP.[11] It was found that there was a substantially lower healthcare cost to patients who did not receive paracetamol compared to those who did as part of first-line care.[11] This is indicative of the fact that taking paracetamol as part of first-line care for acute LBP increases the economic burden overall, whilst also providing patients with suboptimal LBP relief.[11] It is therefore essential from both a health and economic perspective that primary healthcare professionals can correctly assess, identify and characterise the different aetiologies of LBP as this is often the first step in providing appropriate tailored therapeutic strategies to patients.

ASSESSMENT AND MANAGEMENT: A LOOK AT CLINICAL LOW BACK PAIN GUIDELINES

When healthcare professionals who practice in primary care settings (such as general practitioners and community pharmacists) encounter LBP presentations, one of the initial aims of assessment is to exclude serious pathologies. Examples of cases warranting an immediate clinical response include pyelonephritis, prolonged morning stiffness, pain with recumbency or significant neuropathic pain or numbness.[2,12,13] These warning signs of serious causes of LBP can be uncovered with the use of correct and targeted questions by healthcare professionals, such as pharmacists.[2] In this context, clinical practice guidelines can be essential tools for promoting evidence-based practice, as they integrate clinical expertise and research findings in order to support therapeutic decision-making.[6,14,15]

Australian healthcare professionals such as pharmacists have an advantage in that they can readily access clinical and up-to-date resources that can be used as tools to aid in their assessment, diagnosis and treatment of health conditions. Resources such as the Australian Medicines Handbook and the Australian Therapeutic Guidelines provide pharmacists with therapeutic information in the context of LBP management.[4,16] According to these guidelines, management of LBP is dependent on the aetiology as well as whether the flare up of symptoms is acute or chronic in nature.[4,17] According to the current Australian Therapeutic Guidelines, treatment of LBP begins with the implementation of non-pharmacological strategies where appropriate. This is consistent with many other international guidelines.[15,18-20] Clinical resources are conflicting with regards to the use of passive physical therapies such as acupuncture and transcutaneous electrical nerve stimulation (TENS) in LBP cases.[4,21] However there are cases of patients reporting temporary pain relief from thermotherapy and remedial massage.[4,14,22] Clinical guidelines highlight that health professionals may consider and recommend a trial of these non-pharmacological treatments as part of an overall management approach inclusive of patient education and pharmacological therapy.[4] After non-pharmacological options, a number of current international guidelines suggest the simple analgesic paracetamol to be the first-line treatment for acute and localised non-specific LBP. The mechanism of action is complex and it is suggested that paracetamol reduces the severity of pain symptoms via inhibition of prostaglandin synthesis and modulation of inhibitory descending serotonergic pathways.[16] Despite paracetamol's limitation in analgesia, the aim of pharmacological management according to Australian

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clinical resources is to not only reduce the severity of symptoms but to also minimise the risk of acute cases transforming into chronic cases leading to physical disabilities.[4,5] Guidelines also emphasise that patients ought to be educated on the benefits of regular dosing (as opposed to when required dosing) of paracetamol, given that this dosing regimen increases the analgesic potential of the drug.[4,5] In light of this recommendation, one Australian study published in 2011 found that 82% of LBP patients who were self-managing their symptoms with paracetamol were under-dosing.[23] This highlights the need for primary healthcare professionals, such as community pharmacists to openly engage with patients and provide education around the quality and effective use of analgesic medicines.

In almost all cases, LBP does not have a known pathoanatomical cause and as a result there are no specific LBP treatments.[22] However, LBP often results in inflammation in the surrounding muscle layers which can further exacerbate and worsen the symptoms.[1,13] Therefore, much current clinical evidence suggest that targeting LBP with the use of NSAIDs can provide superior and more effective relief of symptoms, especially in comparison to the analgesic effect paracetamol offers. A number of studies have reported that paracetamol use did not affect recovery time compared with placebo treatment in LBP patient groups.[24-26] Interestingly, further research also showed that patients who experience LBP symptoms typically respond well to the use of NSAIDs such as ibuprofen, aspirin, and diclofenac. Australian clinical resources have recently been updated to reflect the position of NSAIDs as first-line treatment options, however, resources also emphasise the importance of health professionals using their professional judgment and ruling out potential contraindications before recommending NSAIDs. Additionally, in cases where healthcare professionals deem NSAIDs suitable, resources highlight that NSAIDs are to be used in as low dosages as possible and for the shortest time possible in order to minimise potential complications.[4] This in part is due to the fact that NSAIDs carry undesirable adverse effects profiles, potentially causing gastrointestinal ulcerations, renal impairment and cardiovascular complications.[2,4,16] Despite these adverse effects, results from another Australian study reported that around 37% of patients were provided with NSAIDs by their medical professional compared to 17% of patients who were given paracetamol for LBP.[27] This is possibly due to the fact that primary healthcare professionals are aware of NSAIDs' superiority in providing LBP relief, however, clinical guidelines suggest that medical professionals must be mindful of the fact that all patients should be screened to rule out contraindications and drug-drug interactions as a result of using NSAIDs.[4]

Many international clinical resources also reinforce that although NSAIDs are more effective, they are not without harm. Numerous literature investigating clinical pain management guidelines in North America, Asia, Africa and Europe found that many countries actually favour the use of NSAIDs in LBP.[15,18,20,28,29] One study published in 2018 highlighted that of the 15 countries involved in analysis, 14 countries recommended NSAIDs in their clinical guidelines for the management of LBP.[15] Despite there being 8 international clinical guidelines that support the use of paracetamol, Belgium, Denmark, Germany, United Kingdom and the United States of America hold clinical guidelines that advise against the use of paracetamol in LBP casses.[18,20,29-31] A summary of this information is provided in Table 1. New Zealand clinical guidelines on the management of LBP suggest the use of either paracetamol or the NSAID aspirin as a first-line option, however, these clinical guidelines also suggest that from a therapeutic perspective, all NSAIDs are equally effective and health professionals can recommend whichever NSAID they deem suitable.[19] In contrast to this, while the NICE guidelines which are adopted in the United Kingdom strongly advise against the use of paracetamol alone, these guidelines highlight that the choice of NSAID is crucial.[32] Health professionals are advised to profile the patient's risk factors in relation to gastrointestinal, cardiovascular and renal function and recommend the most appropriate NSAID at the lowest dose according to these risk factors.[32] LBP guidelines adopted in the United States (e.g. American College of Physicians) and Canada are also consistent with this argument, emphasising that the use of the most appropriate NSAID for a specific patient is recommended with the core aim of allowing the patient to return to normal activities and work as soon as possible.[33,34] It is interesting to highlight that clinical guidelines have evolved

Table 1. Summary of current international clinical guidelines on the pharmacological management of low back pain[16]

Geographical region	Paracetamol	NSAIDs	Favour NSAIDs over Paracetamol
Africa		✓	✓
Australia	✓	✓	✓
New Zealand	✓	✓	
Brazil	✓	✓	
Belgium		✓	✓
Canada	✓	✓	✓
Denmark		✓	✓
Finland	✓	✓	
Germany		✓	✓
Malaysia	✓		
Mexico	✓	✓	
Netherlands	✓	✓	
Philippines	✓	✓	
Spain	✓	✓	
USA		✓	✓
London/UK		✓	✓

NSAID: Non-steroidal anti-inflammatory drug

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over the past 20 years. As is the case with Australian therapeutic guidelines, many international clinical guidelines historically showed favour in the recommendation of paracetamol as a first-line treatment option, with NSAIDs reserved as second line options.[7,35,36] The negative profile associated with NSAIDs appears to have shifted in light of the fact that NSAIDS seem to be more widely adopted in clinical guidelines in the area of LBP management.

NSAID FOR LBP – A BRIEF SUMMARY OF SOME RECENT EVIDENCE

Disease state management should be holistic and evidence-based, incorporating both pharmacological and non-pharmacological approaches where possible. For acute LBP, the efficacy of analgesics remains unclear, however NSAIDs have largely replaced paracetamol as the first-choice analgesics for non-specific LBP in many guidelines due to the latest evidence.

In a 2014 systematic review and meta-analysis of randomised controlled trials on acute LBP, Abdel Shaheed *et al*. reported very low quality evidence that NSAIDs (ibuprofen and diclofenac "when required" dosing) provides an immediate analgesic effect, however suggested more research is needed.[37] This followed similarly from a 2011 systematic review by Kuijpers *et al*. where they also reported low quality evidence that NSAIDs and opioids produces higher pain relief on the short term, as compared to placebo, in patients with non-specific chronic LBP; however both types of medication showed more adverse effects than placebo.[38]

In a 2016 Cochrane review by Enthoven *et al*., it was concluded that NSAIDs reduced pain and disability in people with chronic LBP compared to placebo, however the differences were small and the quality of evidence was low.[39] Further, the authors added that the number of adverse events was not significantly different between the people receiving NSAIDs and people receiving placebo; that different types of NSAIDs did not show significantly different effects; and that there were no differences found between NSAIDs and paracetamol in either effect or adverse events. However, the authors also did suggest the need for additional larger studies of longer duration.[39]

In 2017, Machado *et al*. published a systematic review and meta-analysis of randomised placebo controlled trials looking at efficacy and safety of NSAIDs for spinal pain (neck or LBP). The authors reported that NSAIDs reduced pain and disability, but only provided clinically unimportant effects over placebo, however NSAID use did increase the risk of gastrointestinal reactions by 2.5 times.[40] Lastly, a recent paper by Yabuki *et al*. in 2019 (following a review of the evidence and expert discussions) provided the general recommendation that oral NSAIDs should be considered as a first-line pharmacological treatment for chronic LBP based on recent evidence in the Asian context.[41] Taken together, these above studies appear to be more supportive of NSAIDs use as a pharmacotherapeutic option in LBP management, however it is clear that more research is needed.

PARACETAMOL FOR LBP - A BRIEF SUMMARY OF SOME RECENT EVIDENCE

As indicated above, the role of paracetamol in LBP management has changed in recent years. Previously, the simple analgesic paracetamol was suggested to be a first-line treatment option for acute and localised non-specific LBP in Australian as well as numerous international guidelines despite its efficacy in LBP being a constant subject of debate.

In a double-blind, randomised controlled trial (the Paracetamol for Low-Back Pain Study (PACE)) looking at paracetamol for acute LBP, it was reported that that regular or as-needed dosing with paracetamol does not improve recovery time compared with placebo in LBP, with the authors further questioning the use of paracetamol in this patient group.[26]

In 2015, Machado *et al*. published a systematic review and meta-analysis of randomised placebo controlled trials looking at efficacy and safety of paracetamol for spinal pain (neck or LBP) and osteoarthritis. The authors concluded from high quality evidence that paracetamol was ineffective in reducing pain intensity or improving Quality of Life in the short term in people with LBP. Similarly, the authors also went on to suggest that the results should further put into question the recommendations to use paracetamol for patients with LBP in clinical practice guidelines.[42]

In a 2016 Cochrane review, it was concluded that paracetamol (4g per day) did not lead to better outcomes than placebo for people with acute LBP (from high-quality evidence), and it is unclear if it has any effect on chronic LBP (low-quality evidence).[43] The authors also reported about one in five people reported side effects, though few were serious; however, they also reported that most of the participants studied were middle-aged.[43] The lack of effectiveness of paracetamol (acetaminophen) for acute LBP was also reported in another systematic review from 2017.[33] Similarly, a recent paper by Yabuki *et al*. in 2019 also suggested that long-term use of paracetamol for chronic LBP is not recommended based on recent evidence and expert discussions for the Asian context.[41] Interestingly, a recent paper in Japan by Miki *et al*. in 2018 reported that acetaminophen has comparable analgesic effects on acute LBP, based on at least a noninferiority margin, compared with loxoprofen (a traditional NSAID in Japan) at 4 weeks.[44]

THE PHARMACIST'S ROLE IN LOW BACK PAIN MANAGEMENT AND FUTURE CONSIDERATIONS

Many Australian adults will experience LBP symptoms at some point in their lives. For many chronic illnesses, medicines remain the major modality of treatment, and LBP is no different in this context. LBP sufferers seeking symptomatic relief will present to community pharmacies, sometimes for large quantities of analgesic medicines.[2] Therefore, it is no surprise that Australian community pharmacies are considered to be one of the most frequently accessed primary healthcare services and is regularly the first point of contact for most patients due to convenience, accessibility and availability of analgesic medicines at reasonable costs.[45-47] The role of an Australian

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community pharmacist is pivotal in the area of LBP management from both a pharmacological and non-pharmacological standpoint, including providing education, counselling, assess the patient condition, assess the appropriateness of interventions, and advice on key therapeutic strategies to patients experiencing LBP symptoms. The important role of pharmacists in the quality use of medicines is further heightened when appreciating the fact that patients who experience chronic back pain symptoms are often on multiple analgesic medicines long term. As primary healthcare professionals, pharmacists can address this health concern by effectively engaging with the patient at each encounter, thereby improving patient knowledge and minimising misuse and overuse of analgesic medicines.[45,48] Additionally, appropriate diagnostic questioning is necessary for pharmacists to select the safest and most appropriate NSAID for each patient, which includes a thorough holistic therapeutic consideration of the suitability, risks and benefits of using medications such as NSAIDs. This once again emphasises the important need for community pharmacists to familiarise themselves with the correct clinical assessment, diagnosis and management of LBP, including staying up-to-date with the latest clinical guidelines and evidence.

The pharmacist's role is also critical given the recent legislative changes to over-the-counter (OTC) analgesics that have occurred in the Australian community. For example, due to ongoing concerns with the misuse of codeine in the Australia, as of February 2018, codeine that was once available in fixed low dose combinations with simple analgesics can no longer be supplied by Australian community pharmacists without a valid prescription from an authorised prescriber.[49] There has been substantial research aimed at investigating the impact this codeine restriction will have on community pharmacists.[50-52] One study published in 2019 reported that there were mixed views of Australian community pharmacists concerning the codeine upscheduling.[52] Pharmacists who opposed the codeine up-scheduling highlighted that community pharmacies are now limited in the pain management area now that fewer OTC analgesics that can be supplied to patients.[52] Results also showed that pharmacists conveyed that patients who are unable to regularly see their medical practitioners are now forced to excessively use simple analgesics such as paracetamol or NSAIDs in order to obtain the same amount of pain relief, and this overuse of medicines may cause further harm.[52] Conversely, there were many pharmacists who were in favour of the codeine restriction, emphasising that the codeine content in the OTC fixed combinations was subtherapeutic and provided inadequate pain relief.[52] Despite the diversity of opinions, the unanimous opinion expressed by community pharmacists in this space is that patient education in the area of pain management is important and necessary.[51,52] Research in patient education has demonstrated that pharmacists who appropriately educate patients (in the area of pain management) enables them to manage their pain more effectively.[53,54] Although codeine is not recommended as a first-line option for LBP, the recent codeine restrictions in Australia has reinforced that pharmacists are in an ideal position to interact with their patients and offer alternative pain management strategies that may provide more effective LBP relief. In a study by Abdel Shaheed *et al*., it was reported that community pharmacists are indeed suitability placed and are receptive to optimising the primary care management of LBP patients.[55] However, it was also identified that adequate remuneration and staff training were critical factors to its implementation.[55] A more recent study published in 2020 also demonstrated that community pharmacists are ideally placed to provide first-line care for LBP, which can be aided by clinical decision support systems that enhances LBP care.[56]

Lastly, in appreciation of the newer evidence regarding effective pharmacological management of LBP, community pharmacists have the opportunity to effectively engage with patients and assess whether pharmacological management of pain symptoms are attuned to the latest clinical evidence and guidelines. The views and opinions of Australian community pharmacists in generalised pain management is well documented, however, there are less studies investigating the community pharmacist's role and knowledge, specifically in the context of LBP management in Australia.[14,52] Australian community pharmacies are routinely the first point of contact for primary healthcare related inquiries, thus understanding and appreciating community pharmacists' opinions with regards to LBP assessment and management can serve to identify inconsistencies from what the Australian clinical guidelines and evidence recommends. Whilst clinical guidelines are important and are critical therapeutic resources, research suggests that they are not always followed by health professionals.[57,58] For example, investigating precisely what Australian community pharmacists recommend as therapeutic strategies in the context of LBP management, and why, is research worth exploring, given the limited published literature in this space.

CONCLUSIONS

LBP is currently one of the leading causes of disability worldwide. It is one of the most commonly presenting conditions seen in the Australian healthcare setting. Failure to adequately assess and manage LBP can give rise to clinical, health and economic consequences. LBP has been shown to respond well to NSAIDs, and as such, current Australian clinical guidelines have demoted the position of paracetamol as a first-line treatment option, replacing it with NSAIDs. Additionally, there is a growing shift towards the adoption of NSAIDs in LBP treatment across the world, with more emerging evidence supporting its use. Since many cases of LBP are treated with the use of OTC analgesics, Australian community pharmacists are ideally placed to engage with patients and identify whether there is room for improvement in the way patients manage their symptoms. However, it is unclear what community pharmacists recommend specifically in the context of LBP. Research in this space can identify whether there are opportunities for pharmacists to promote additional education and evidence-based strategies to further optimise LBP management in the community.

CONFLICT OF INTEREST

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Original Research

Pharmacists' perception of their role during COVID-19: a qualitative content analysis of posts on Facebook pharmacy groups in Jordan

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Abstract

Objective: This study aimed to evaluate the content available on Facebook pharmacy groups in Jordan regarding the perception of the pharmacists' role during the coronavirus pandemic in Jordan.

Methods: Researchers identified Facebook pharmacy groups through the search engine on the Facebook website. The main search keywords were pharmacy, pharmacist, pharmacists, and Jordan using both Arabic and English. Two researchers analyzed the posts and discussion threads on local pharmacy Facebook groups in a period between March 20th and April 3rd. A total of 184 posts and threads were identified for the purpose of the study.

Results: Identified threads and responses resulted in three overarching themes: pharmacists having a positive role during the pandemic, taking additional responsibilities and services, and having passive or negative roles. A positive role was seen in pharmacists acting as first-line healthcare providers, creating public's awareness regarding COVID-19, and being responsible for chronic medication refill during the pandemic. Taking additional responsibilities was summarized in home deliveries and involvement in industrial and corporate efforts to deal with the pandemic. A passive/negative role was seen mostly among hospital pharmacists not being proactive during the pandemic and by pharmacists trying to maximize profits during pandemic time.

Conclusions: Pharmacists perceived their role as a positive role during the coronavirus pandemic. Not only they took responsibilities for their daily services during the crises, but they took additional responsibilities to assure patient safety and satisfaction.

Keywords

Pharmacists; Pharmaceutical Services; Pharmacies; Severe Acute Respiratory Syndrome; Coronavirus; Pandemics; Professional Role; Self Concept; Personal Satisfaction; Social Media; Qualitative Research; Jordan

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INTRODUCTION

Coronavirus Disease 2019 (COVID-19) caused by the novel coronavirus (SARS-CoV-2) is a condition that emerged in Wuhan city and disseminated outstandingly, affecting many countries around the world in a short period of time, in an uncontrollable way.[1-3] As a consequence to this serious outstanding situation, the World Health Organization (WHO) declared this viral outbreak to be a Public Health Emergency of International Concern on the 30th January 2020.[4] Soon after, the WHO classified COVID-19 as a pandemic infectious disease on 11 March 2020.[5,6] As of 2nd April 2020, the total number of confirmed cases exceeded 1,010,000 cases in over 180 countries, resulting in over 52,800 deaths.[7]

There is also strong evidence that this novel virus can be transmitted by people with mild symptoms, pre-symptomatic or even asymptomatic.[8] Most infected SARS-CoV-2 patients reported clinical symptoms ranging from mild symptoms such as fever, dry cough, fatigue, shortness of breath and muscle pain to severe acute respiratory distress syndrome.[9] such as dry cough, sore throat, and fever. Several cases have been resolved spontaneously. Nevertheless, some fatal complications have occurred, including organ failure, septic shock, pulmonary edema, and, extreme pneumonia.[10] Also, patients with COVID-19 are at increased risk of developing cardiovascular complications including venous thromboembolism, dysrhythmias, acute heart failure, and acute myocardial infarction.[11-15]

This requires a collaborative teamwork by all healthcare professionals to support in controlling this scenario.[2] Pharmacists worldwide are integral part within the healthcare system, and since the emergence of this viral outbreak they have experienced a challenging situation and hard time like never before. They are currently working in the frontline with other healthcare providers in fighting the battle of COVID-19 outbreak, and they are undertaking everything they can do to support their patients in all possible areas. This role of pharmacists was supported by the declaration of the updated International Pharmaceutical Federation (FIP) guideline for pharmacists all around the world on the 19th of March 2020.[16] The aim

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of this guideline was to guide pharmacists in community, hospital and clinical biology on COVID-19 pandemic.[16] The guideline documented several recommendations to deal with COVID-19 viral outbreak, among them the interventions and patient counselling that should be provided by pharmacists during this serious situation.[16]

One noticeable question that stands up here is whether pharmacists in Jordan could have responsibilities in counteracting this COVID-19 outbreak efficiently and what are their perception regarding their contributing roles. To assess that, it was difficult for us as researchers to conduct structured interviews with pharmacists because of the quarantine imposed on all citizens in Jordan. Hence, social network content analysis for pharmacists' posts on various local pharmacy groups was performed. This quantitative content analysis aimed to measure frequencies and informative analysis of Jordanian pharmacists' Facebook posts to assess their perception about their role and responsibilities in dealing with this COVID-19 pandemic. It is thought that exploring pharmacists' perception about their role during the pandemic would help facilitate and increase their contribution along with other healthcare professionals and support them to deliver optimal services.

METHODS

Sample

Facebook represents a vast and unbiased source of information, posts on Facebook are believed to be bias free and represent members' honest opinions making them optimal for social and qualitative research.[17,18] Hence, it was adopted for the present study to evaluate the content that is available on Facebook pharmacy groups regarding pharmacists' perception of their role during the COVID-19 pandemic in Jordan.

Researchers identified Facebook pharmacy groups through the search engine on the Facebook website. The main search keywords were pharmacy, pharmacist, pharmacists, and Jordan using both Arabic and English. The inclusion criteria included active groups that clearly stated being pharmacy groups in Jordan, active groups for working pharmacists, active groups with a clear location as Jordan, groups that at least had 100 members. The exclusion criteria were Facebook groups that did not have recent activities during the last 30 days, pharmacy students' groups, and groups that had pharmacists from outside Jordan, and groups that had commercial purposes. Ten groups were identified and a requested to join the selected groups was placed. A list and description of the groups selected for the study purposes are present in Table 1. Both public and private Facebook groups were sought for the study's purpose. Although private groups are visible in Facebook search, only the group's name and member list are visible on the group's main page. Content posted on the group's Timeline is visible on a members-only basis. The opposite is true for public groups.

Threads and post that included a discussion related to pharmacists' role and duties during the COVID-19 pandemic were included in the study. Threads and posts that discussed irrelevant pharmacist duties during the pandemic were excluded. Two independent researchers identified and analyzed relevant threads and posts posted on local pharmacy Facebook groups in a period between March 20th and April 3rd 2020. This resulted in a total of 184 posts and threads identified across all ten Facebook groups.

The research protocol was reviewed and approved by the Institutional Review Board at the King Abdulla University Hospital/ Jordan University of Science and Technology (REF: 2020228).

Analysis

A generic qualitative approach was chosen to get a better understanding of pharmacists' reports of their subjective opinions, attitudes, and beliefs. The majority of posts and comments were in Arabic. For reporting purposes, responses were translated from Arabic to English and back translated from English to Arabic to ensure that the context and meaning has not changed. Posts by respondents were edited on a limited basis to remove content that did not convey meaning (repeated words, stutters, etc.) and to correct for grammar. An ellipsis mark was used to note removal of such extraneous content. Square brackets were used in quotations to supply words omitted by participants or to replace sensitive information. All responses were copied and de-identified prior to analysis and later imported into QSR International's NVivo v11 Software.

The thematic analysis was preformed following a generic qualitative approach and the thematic analysis steps described by Braun and Clarke.[19,20] Two researchers independently read through the previously identified threads to get a general sense of the data and become familiar with it. The two researchers independently labeled

Table 1. Facebook pharmacy groups analyzed

Group	Active since	Number of members	Status	link
Jordanian Pharmacists Association - JPA	Jun 2018	1,119	Private	https://www.facebook.com/groups/404805126665582
JUST Pharmacy Alumni	May 2017	4,218	Private	https://www.facebook.com/groups/1369068866473005/
Pharmacy Group	May 2016	1,023	Public	https://www.facebook.com/groups/1753891778182245/
Pharmacy Activities	Nov 2009	1,399	Public	https://www.facebook.com/groups/190711086836/
Pharmacist and proud	Jul 2013	1,559	Public	https://www.facebook.com/groups/1393511454196634/
Pharmacy	Feb 2015	31,478	Private	https://www.facebook.com/groups/933170873373269
Irbid PharmacoFamily	Feb 2019	1,470	Private	https://www.facebook.com/groups/1968190656636999/
Jordan Pharmacist*	May 2018	13,892	Private	https://www.facebook.com/groups/2142688405959087/
Pharmacists of the Hashemite Kingdom of Jordan*	May 2018	4,882	Public	https://www.facebook.com/groups/2067851230153445/
Jordan Pharmacist*	May 2013	2,549	Private	https://www.facebook.com/groups/138056589713165/

* Group name translated from Arabic

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phrases in the entire threads related to the research questions and assigned codes to theses labels and described them. These codes were collated into themes and subthemes through an interactive process between the two researchers and discrepancies were resolved by consensus.

RESULTS

Ten Facebook pharmacy groups were identified for the purpose of the present study. Those included a total of 63,589 participants and were a mix of private (6) and public (4) groups visible to all Facebook users. Further details are present in Table 1. A total of 184 posts and threads were identified across all ten Facebook groups and were analyzed for the purpose of this study.

Qualitative analysis revealed three overarching themes with regards to the perception of pharmacists regarding their role during the COVID-19 virus outbreak in Jordan. The emerging themes were: playing positive roles, taking additional responsibilities and services, and playing passive/negative roles. Emerging themes are summarized and in Table 2.

The first theme was playing a positive role. Many posts and threads discussed the positive role the pharmacists played before and during the COVID-19 outbreak. Three sub themes emerged from this theme and those were: Pharmacists acted as first-line health providers, role in creating public awareness role, and continuing chronic medication refills. It was discussed that pharmacists acted as first line health care provides along with other healthcare professionals who worked effectively during COVID-19 outbreak. Post also discussed that the pharmacists' role during the outbreak reduced the pressure on hospitals and allowed them to focus on more critical cases that needed serious medical attention. Pharmacists highly valued this role and were proud of their contribution during this period. Another important role perceived by pharmacists in their Facebook posts was their role in creating and spreading public awareness regarding COVID-19 risk factors and prevention. Pharmacist encouraged each other to use social media outlets to spread awareness and to fight wrong beliefs. It was also mentioned that they did face-to-face counselling to customers. It was also reported that pharmacists worked on preparing chronic medications refills as they felt obliged to supply patients

Table 2. Summary of themes generating from the analysis of posts

Overarching themes	Sub-themes	Selected posts
Positive perceived roles (n=126)	First-line health provider (n=109)	• "We have relieved part of the burden on hospitals and emergency departments, and this has allowed hospitals to focus on the serious cases that need critical care." • "Pharmacists are still working during the outbreak and dealing with patients. We deal with less serious cases and give patients the necessary medications without them needing to go to hospital, which has helped relieve part of the burden on hospitals in circumstances like these."
	Public awareness role (n=97)	• "a small number of pharmacists have shown initiative or created videos and social media campaigns to spread awareness." • "We are constantly spreading awareness about the virus and how important it is for people with symptoms to get tested. We are continuously educating people on the ways of prevention and trying to prevent patients from panic buying medications and hand sanitizer. We also have to deal with patients taking preventive medications that they've heard about on the T.V. but which are still under research or even medications which could lead to several complications."
	Chronic medication refills (n=83)	• "Pharmacists are refilling medications for chronic conditions, and working to deliver medications to patients where possible." • "pharmacists in medical centers and community pharmacies are going through patients' profiles and making refills for chronic conditions"
Additional responsibilities and services (n=117)	Medicine Home delivery (n=103)	• "During the outbreak, pharmacists have been personally delivering medication to people's homes without charging for delivery, even though the profit made from selling medication is very limited."
	Involvement in industrial and corporate (n=71)	• Let's not forget the main role of pharmacists during this pandemic, which has been to manufacture medications. I would particularly like to mention the role of pharmacists working in pharmaceuticals, who have worked hard and conducted much research with doctors in order to supply the market with medication to treat Covid-19.
Passive/Negative perceived roles (n=79)	Insufficient role in hospitals (n=63)	• The role of pharmacists during the outbreak has been significant but also limited. Clinical pharmacists should be in hospitals providing treatment because that is their field of expertise. This pandemic has revealed just how unfair the medical sector is towards the role of clinical pharmacists. • "In circumstances like these, we should be seeing clinical pharmacists in hospitals, providing treatment to patients. The fact that our role has been limited to working in community pharmacies has been very demotivating. "
	Practice aiming for more profit (n=54)	• "In my opinion, pharmacists should be doing a lot more, as the role of many of them has been solely commercial and has been aimed at serving the financial interests of the pharmacists themselves. This explains why many of them have been calling for permits to allow them to open their pharmacies under the curfew" • "community pharmacists on Facebook groups have been acting selfishly and serving their own interests only." • "It really is disheartening for me to have to say this, but unfortunately, the role of a large number of pharmacists has been solely commercial. I've heard pharmacists' multiple times saying things like "I'm not a delivery person" or "do you expect me to go out just to deliver some baby milk?".

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with their medications regardless of the expected risk during the viral outbreak. Pharmacists reported that they have taken all the possible precautions and that they could not withhold treatment from people at need and guarantee its supply. One pharmacist had written that offering their services at this time is part of their obligation to the oath they took after graduation.

The second theme was taking additional responsibilities and services. Many threads posted by pharmacists focused on taking additional responsibilities that they do not normally do during normal practice days. Two sub themes emerged from this theme and those were: Medicine Home delivery and involvement in industrial and corporate work. Many pharmacists wrote about personally delivering medicines to patients. This point particularly received a lot of discussion and pharmacists reported positive perceptions of this service as home delivery of medicines is not allowed in Jordan usually. However, some pharmacists thought that it was not the pharmacists' role to deliver medicines in person and using a courier service would have been more suitable. This was responded to by many posts that the courier would not be able to counsel patients and assure optimal use of treatment. Further roles were being active in the drug industry business. Pharmacists discussed that many of those working in pharmaceutical industry had to work extra hours to make sure that the strategic inventory of medicines was not depleted, especially that the imports were affected with travel ban and flight restrictions internationally. Those working in drug stores discussed that they had to supply the market with more products such as Vitamin C, gloves, hand sanitizer, antiseptics, facemasks, and many other products needed during the pandemic. In general pharmacists perceived those roles as a health obligation and were satisfied to play this role in such a hard time.

The third theme was playing passive/negative roles. Some pharmacists were not satisfied with their roles during the pandemic and thought that their role was not enough if compared to other healthcare professionals fighting the spread of the disease on frontlines. Sub themes emerging from this theme were: Insufficient role in hospitals and practice aiming for more profit. Pharmacists perceived their role in hospitals as insufficient. It was discussed that the majority of pharmacists working in hospitals did not have direct contact with patients and their role was only to dispense medicines, check prescriptions, and prepare refills for delivery. Pharmacists' posts on Facebook groups indicated that pharmacists had aimed for a greater role, especially clinical pharmacists who would have an effective role in managing the treatments of patients with COVID-19, specifically those with multiple morbidities. Pharmacists believed that their role was limited in hospitals and hoped for more effective roles in the future. It was also discussed that a minority of pharmacy owners took advantage of the pandemic and patients in need to make extra profit and charge more for drugs and products. Though it was reported that such practices were limited, it was thought that they will reflect a negative image on all the pharmacy sector in the country.

DISCUSSION

The present study sheds light on pharmacists' perception of their role during the coronavirus pandemic in Jordan. Since the beginning of the pandemic internationally researchers started investigating different aspects of this novel disease. As the available peer reviewed literature regarding the role of healthcare professionals during this pandemic is scarce, the role of pharmacist has not been studied yet. Understanding how pharmacist contributed during the pandemic would highlight their achievements and would also expose any gap in their practice giving ample opportunity for future enhancement.

Internationally, pharmacists are in the frontline in the fight against the novel coronavirus disease (COVID-19) and they are doing everything in their power to support their patients, including in areas currently in lockdown.[21] In the present study pharmacists perceived their role as a positive role and integral along with other healthcare professionals. Regardless of the risk pharmacists could face they continued offering their services during the pandemic.[22] In Jordan pharmacists act as first line healthcare professionals and due their accessible nature patients tend to refer to the pharmacy before any other healthcare professional.[23,24] It is obvious from this study that pharmacists maintained their practices to serve the community. Important roles, along with their ability to create public awareness about COVID-19, were prevention procedures, risk factors, and signs and symptoms. This role depends on pharmacists having the sufficient knowledge and information regarding the emerging disease. This could be done through online courses managed by the Ministry of Health, Jordan Food and Drug Administration, and the Jordan Pharmacists' Association, which will help the pharmacist to fulfil this role. The Jordan Pharmacists' Associated has launched "Hello Pharmacist" app and a hotline during the COVID-19 pandemic. This service aimed to connect patients with pharmacists to answer their questions and to increase their accessibility to medicine. Moreover, pharmacists in Jordan have launched several campaigns over the social to increase awareness about COVID-19 prevention. Similarly, a multicultural project initiative led by PharmD students translated coronavirus guidelines for America into 23 languages. This initiative was a clear example of the global impact pharmacists can make to provide timely and high-quality information to patients.[25] This altogether, sets an example for the ability of pharmacists in spreading public awareness during the pandemic resulting in better adherence to social distancing and sanitization guidelines, hence slowing the infection rate among citizens.

In addition to their daily responsibilities, pharmacists had been involved in home delivery of medicines.[26] Though this service is not allowed in Jordan, pharmacies have been allowed to deliver medicines to customers during the curfew period.[24] Pharmacist who volunteered to work during the crises were issued daily permits to open their pharmacies and personally deliver medicines. This was to allow pharmacists deliver their full services of dispensing and counselling; hence no courier service was adopted. Home delivery of medicines has been proven to be a valuable service and it helps reducing treatment related problems especially in elderly and patients and those

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suffering from chronic ailments.[27] This was specifically important in patients who were prescribed chronic medications and were dispensed monthly refills. Pharmacists had prepared and delivered those refills to ensure the supply of medications to those patients and guarantee treatment outcomes.[28]

On the other hand, pharmacists were not satisfied with their role in the hospital. It has been discussed that hospital pharmacists did not have any additional role to offer and did not have any contact with COVID-19 patients. This could be due to safety issues, reducing the number of healthcare professional at the risk of infection to the minimum. Furthermore, no roles for clinical pharmacists existed which could be also for similar reasons. According to FIP, hospital pharmacists need to provide several health and pharmaceutical services in collaborations with other health care providers to COVID-19 patients. Such service may have a significance effect in improving the selection of patients' drug therapy, and improving patient's overall health and outcomes.[29] However, details about such pharmaceutical care is still lacking, and need to be urgently established. A recent study suggests that pharmaceutical care provided by hospital pharmacists for hospitalized COVID-19 patients in China was exceptional. The presence of hospital pharmacists in the healthcare team improve COVID-19 patients' outcome and reduce mortality.[30] Still, the role of clinical pharmacists in hospitals is still not clear in the health system in Jordan and is restricted to education rather than intervention.[31]

Unfortunately, it was reported that some pharmacy owners took advantage of the situation and tried to make extra profits. This would be illegal as medicine prices in Jordan are regulated and the same in all pharmacies around the country.[32] Medicines are priced before being granted a marketing authorization by the pricing committee at the Jordan Food and drug Administration.[33] Any change of this price has legal consequences and a financial fine. Pharmacy owners are obliged to abide by the rules and the delivery of their service during the pandemic is considered a national obligation. No healthcare professional should take advantage of citizen whatever the circumstances were. As pharmacist could be facing more risks working during the pandemic, a reduction in licensing fees or taxes could be offered by the government after the pandemic as an incentive.[34] It is however important to deliver pharmaceutical services during the pandemic insuring patient welfare and optimal outcomes. This interest should be the main driver for pharmacy owners and pharmacists regardless of the circumstances.

CONCLUSIONS

Overall, Jordanian pharmacists perceived to have positive role during the coronavirus pandemic. Pharmacists' role was not limited to their routine daily services during the crises, but they took additional responsibilities to assure patient safety, satisfaction, and accessibility to medicine. There is, however, a clear opportunity to engage hospital pharmacists in hospitals to provide pharmaceutical care services to COVID-19 hospitalized patients.

CONFLICT OF INTEREST

None.

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CPPI Practice Forum

Student pharmacists' role in enhancing ambulatory care pharmacy practice

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Abstract

With a primary care physician shortage, utilization of pharmacists in the ambulatory care setting has proven to have positive economic and clinical outcomes for the practice and for patients. To extend the reach of the pharmacists, students may assist with patient care activities, such as medication reconciliation, point-of-care testing, and counseling. Evidence has shown that students benefit in building confidence, as well as improved perceptions of interprofessional care, while positive patient outcomes are maintained. There are many methods for schools to integrate these experiences early into their curriculum, as well as for students to explore opportunities on their own.

Keywords

Students, Pharmacy; Pharmacists; Ambulatory Care; Education, Pharmacy; Problem-Based Learning; Interprofessional Relations; United States

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Introduction

A growing and aging population is contributing to an insufficient supply of physicians to meet the primary care provider demand.[1,2] A report from the Association of American Medical Colleges found that by 2033, there will be a primary care shortage of between 21,400 and 55,200 physicians. This sixth-annual report highlighted that population health goals can be achieved through collaboration with non-physician clinicians.[2] The increase in the number of advanced practice registered nurses and physician assistants has helped address some of the gaps in care by making more chronic and acute visits available for patients; however, pharmacists with an in-depth knowledge of pharmacotherapy can also play an important role in improving medication use to optimize chronic disease state management, thus further increasing access to care.[2-4]

The provision of pharmacy services in the ambulatory setting results in improved clinical and economic outcomes.[5,6] For the purpose of this article, ambulatory care addresses the delivery of care to patients who are able to ambulate, whether they are in a clinic, transitioning from a hospital to home, or in their home receiving services, through means such as telehealth.[7] Pharmacy services are often provided under collaborative practice agreements (CPAs), which allow pharmacists to initiate, modify, and discontinue therapy based on an agreement between a provider and a pharmacist.[8-10]

The combination of pharmacist value recognized in the ambulatory setting, along with a changing health care environment, has resulted in the need for more ambulatory care pharmacists.[6] To account for this demand, post-graduate year 2 (PGY-2) specialty residency offerings in ambulatory care have grown by 85% since 2015, and as of 2019, there were 4,342 board certified ambulatory care pharmacists.[11,12] While the need for and impact of pharmacists on the health care team have been established, the staffing ratio of physician to pharmacist has not been well defined. Estimates vary from 0.20 pharmacist full-time equivalent (FTE) to 1.0 pharmacist FTE matched to a wide range and complexity of physician panels.[13]

Budget constraints often restrict optimal staffing ratios, thus the utilization of student pharmacists in the ambulatory care setting may offset these needs. The purposeful integration of students into the ambulatory setting may also positively impact clinical care and student education, as has been suggested with medical students.[14]

Evidence to support the role of student pharmacists

In the ambulatory setting, there are many technical tasks, such as patient scheduling, obtaining vitals, calling pharmacies to obtain up-to-date medication lists, and investigating patient prescription benefits that take away time from more complex aspects of disease-state management, such as implementing medication adjustments, ordering laboratory tests, and documenting clinical services provided.[15] To better utilize clinical pharmacists' time, the University of Wisconsin used primary care pharmacy technicians to fulfill technical tasks, which enabled pharmacists to focus on clinical tasks.[15] However, a limitation of this model is the need to hire more staff (e.g., pharmacy technicians) to fulfill this role. An alternative solution would be to utilize student pharmacists to perform technical and low-level clinical tasks, which would also have a minimal budget impact. Table 1 provides examples of such tasks, which align with the American Association of Colleges of Pharmacy entrustable professional activities (essential activities and tasks that new pharmacy graduates should be able to perform without direct supervision upon entering practice).[16]

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Table 1. Select examples of non-clinical, low-level, and high-level tasks that student pharmacists may perform in an ambulatory setting

Non-Clinical	Low-Level	High-Level
- Room patients - Schedule patients - Research patient assistance programs - Obtain medications lists from pharmacies	- Obtain vitals - Perform point-of-care testing - Conduct medication reconciliations - Administer immunizations - Screen patients for pharmacy consults - Counsel patients on medications or medical devices - Assess a patient's health literacy utilizing a validated screening tool	- Assist a patient with behavior change through motivational interviewing - Interpret laboratory data and recommend therapeutic changes or additional monitoring - Interpret patient provided health information to develop an evidence-based therapeutic plan

Several studies have demonstrated the positive contribution of student pharmacists collecting medication histories, completing medication reconciliation, conducting patient interviews, performing point-of-care testing, and providing immunizations.[17-23] In an interprofessional setting, the use of fourth-year student pharmacists to obtain medication histories has been employed in a variety of clinics (e.g., internal medicine, cardiology, and pediatrics).[17] In this model, students spent an average of 10 minutes (range 2-30 minutes) collecting medication histories before reporting their findings back to the attending physician.[17] Based on the time spent to obtain a full medication history, this model suggested that medical providers saved time by collaborating with student pharmacists, and students benefited by working in an interprofessional, real-word setting.[17] Dalal *et al*. demonstrated that student pharmacists independently performing subjective interviews and obtaining fingerstick international normalized ratios before making therapeutic recommendations under pharmacist oversight provided comparable clinical care to pharmacist-only visits in an outpatient anticoagulation setting.[18] Furthermore, there was no difference between third-year and fourth-year precepted students.[18] This study suggests that the utilization of student pharmacists to reach more patients does not compromise patient care.

Complementary findings regarding students' abilities to practice in an ambulatory setting have been illustrated when students perform medication reconciliation.[19,20] In a depression clinic, students identified at least one medication list discrepancy in more than 50% of patients and an insufficient antidepressant trial in approximately 32% of patients through a pilot telephonic medication reconciliation and antidepressant treatment history program.[19] Considering each call completed by the students required, on average, 18 minutes, students were able to optimize the pharmacists' time.[19] A retrospective review of this service found there were no differences among student educational level (e.g., all four professional years) for identifying medication discrepancies, suggesting that incorporation of students into ambulatory care practices can occur regardless of the professional year.[20]

Provision of immunizations is another task that student pharmacists can assist with, as many would have been trained at their institution.[21-23] Training can be costly, due to the supplies needed to ensure hands-on experience; however, Woelfel and colleagues compensated for this cost by utilizing immunization-trained student pharmacists to provide vaccinations to Medicare beneficiaries in mobile clinics.[21] Between 2015 and 2016, the net income generated by student pharmacists administering 1,777 vaccinations was USD 19,937, with the greatest return on investment from the influenza vaccine, followed by Tdap and pneumococcal vaccine.[21] This program enabled students to practice their skills and gain experience with immunization coverage and billing while generating revenue for the school.[21] Regarding humanistic outcomes, Hannings et al. showed that 98% of the individuals who received a vaccine through a student-led immunization clinic were satisfied. Furthermore, this clinic was able to capture approximately 68 individuals who would not have been vaccinated otherwise.[22] The availability of pharmacists and student pharmacists to provide immunizations has increased vaccine awareness and access, especially among low-income patients, thus resulting in a positive public health impact.[23,24]

Strategies for incorporating student pharmacists in ambulatory settings

To ensure that student pharmacists have the appropriate skills to practice in an ambulatory care setting, experiences should begin early and be sustained throughout their education.

One way for student pharmacists to build skills prior to rotations is through purposeful and innovative didactic education. Sando et al. demonstrated that use of a game-like educational tool to teach medication history skills increased students' confidence levels and skills.[25] However, ambulatory care is more than just the clinical skill set, as it also entails practice management skills. For student pharmacists to obtain more from their experiential opportunities, education embedded into the pharmacy curriculum regarding the business model of ambulatory care is important.[26] Students should be able to complete a market analysis, perform a needs assessment, accurately describe the service to be provided, and define how the service will be operated and sustained.[27] Colleges and schools of pharmacy should promote classes from both the clinical and the business standpoints so that students stay abreast of the changing health care landscape and are prepared to perform the next generation of pharmacist roles.[28] To build upon the didactic content, students can work on a business plan for implementation of a new service or evaluation of an existing one as part of their fourth-year experiential ambulatory care rotations.

Since the onset of the coronavirus disease 2019 (COVID-19) pandemic, some institutions have found unique ways to engage students in ambulatory care practice by providing patient care via telehealth visits, answering drug information inquiries, and providing educational opportunities for staff.[29,30] The incorporation of student pharmacists into telehealth ensures their experiential training continues during the pandemic, while introducing

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them to a new approach to care that could remain post-pandemic. Evidence is limited regarding patient outcomes when students are involved in telehealth; however, a previous study suggested that students who were involved in telehealth medication therapy management (MTM) programs were more confident in the provision of comprehensive medication reviews compared to students who provided MTM in the community and hospital settings.[31] As telehealth continues to expand, the utilization of students and their impact on patient outcomes will be an area to explore.

Population health initiatives can also be completed via telephone and introduced into experiential education or offered for volunteer students. Kaiser Permanente Colorado incorporated population health management activities for rotation students that entailed students reviewing patient records and identifying interventions that could be made by the student or a clinical pharmacist.[32] Of the 1,406 actionable interventions documented by approximately 46 students, 52% pertained to patient education (e.g., student contacts the patient via telephone or letter for sole purpose of education), 23% to verification (e.g., calling a pharmacy to verify a patient refill history), and 10.5% to medication therapy adjustment (e.g., any dose or medication change within the same medication class).[32] The chart reviews, and subsequent completed interventions, when applicable, conducted by pharmacy students accounted for approximately 765 hours of clinical pharmacist time that would have been required over the four-year study period.[32] These innovative ways for engaging students allow student pharmacists to be exposed to ambulatory care practice, while offsetting pharmacist time.[29-32]

Unique opportunities for students in ambulatory care

Student pharmacists interested in ambulatory care should take it upon themselves to seek out experiences to engage in real-world experience. Some opportunities may be facilitated through their school or college, but some may require the student to apply on their own.

Within the commonwealth of Virginia, there are many opportunities for students to gain early, hands-on, exposure to ambulatory care. For example, in partnership with VCU School of Pharmacy, free clinics in Richmond that provide primary care and chronic disease management for the uninsured population offer ambulatory care electives for third-year student pharmacists, along with numerous volunteer hours.[4,33] Throughout the elective or volunteer hours, student pharmacists work as part of an interprofessional team, conducting patient interviews, addressing medication-related concerns, counseling patients on lifestyle changes and, if needed, providing smoking cessation services under the supervision of the attending clinical pharmacist or physician. In this practice model, student pharmacists not only gain experience with direct patient care and enhance their critical thinking and cultural competence and problem-solving skills, but the clinics benefit from increasing the number of patients that they care for by utilizing student pharmacists as pharmacist extenders.[4]

Not all students will have the opportunity to partake in a formal internship or have an ambulatory care practice-based elective offered. Therefore, students could engage in domestic or international medical outreach events that focus on chronic disease state management (e.g., diabetes and hypertension), or preventive medicine (e.g., cardiovascular disease prevention).[34,35] On these outreach trips, students engage in direct patient care through physical assessments, medication and disease state counseling, and interprofessional collaboration regarding medication choices or therapeutic interchanges.[34,35] While these opportunities do not offer longitudinal ambulatory care experiences, they enable student pharmacists to have a glimpse of what ambulatory care practice entails.

At the national level, externships are available with the Indian Health Service (IHS) and the Junior Commissioned Officer Student Training and Extern Program during the summer months.[36,37] With a large emphasis on ambulatory care at many IHS facilities, students are immersed in ambulatory care practices with pharmacists to manage diabetes, anticoagulation, asthma, smoking cessation, HIV, and other chronic diseases.[37] Beyond participating in patient visits, student pharmacists conduct research projects, create educational handouts for patients, and complete projects that advance clinical services. These opportunities are also available during IHS ambulatory care rotations for schools that have agreements with IHS facilities.[37] Further opportunities for internships can be found with local ambulatory clinics or federally qualified health centers, as well as Veterans Affairs medical centers via the VA Learning Opportunities Residency.

On an international level, there are opportunities for students to experience pharmacy in other countries through the student exchange program of the International Pharmaceutical Students' Federation.[38] Additionally, the VCU School of Pharmacy offers an interprofessional international outreach opportunity, which enables students from any professional year to travel to South American countries and work with other health professions for an intensive two-week direct patient care experience.[33] Furthermore, some schools of pharmacy may offer international fourth-year rotations. These experiences increase student pharmacists' cultural awareness, self-awareness, and knowledge of public health, while providing an environment for them to gain confidence in providing clinical care and making recommendations.[39-41] For students interested in a career with a public health emphasis, engaging in domestic and international outreach events is a way to gain a deeper appreciation for disparities in health.

Barriers to incorporating student pharmacists in ambulatory settings

Despite the many benefits to incorporating student pharmacists into the ambulatory setting, it does not come without barriers. The biggest barrier identified in studies is time.[20,42,43] This can include the time spent training students or planning events for students, such as medical missions or diabetes self-management courses.[42,43] A suggestion to minimize this burden includes planning far enough in advance to overcome any legal barriers or site restrictions for student-led initiatives (e.g., immunization

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clinic).[42] Involving more individuals in the planning is recommended, especially if engaging in an interprofessional activity.[43] Lastly, ensuring there is enough time to train students, especially depending on the level of tasks the student will be performing, is a necessary consideration.[20] Preceptor time may need to be invested up front to ensure students are properly trained; however, as described throughout, when the experiences are well-planned, there is a potential for a large impact on student growth, patient care, revenue generation, and time-savings later on.[17-23,32,42,43]

Conclusion

With numerous opportunities for engagement early on in their careers, student pharmacists can actively contribute to the advancement of ambulatory care practice by functioning as pharmacist extenders. With the opportunity to utilize their clinical and business skills, student pharmacists may enhance patient care services, leading to improvements in quality of care and patient access.

CONFLICT OF INTEREST

None to declare.

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Original Research

A survey on feasibility of telehealth services among young Italian pharmacists

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Abstract

Background: Telemedicine is defined as "the use of medical information exchanged from one site to another via electronic communications to improve a patient's health status". This relatively new concept of healthcare is based on the fusion between medical assistance and Information and Communication Technology (ICT) to provide support to people located in remote and underserved areas. It can be found not only in hospitals, but also in other healthcare facilities such as pharmacies. Starting from 2010, telemedicine or telehealth was formally introduced in the Italian pharmaceutical context with the "Pharmacy of Services Decree". In spite of this regulatory framework, the implementation of this technology was very slow and there are no data about the spreading and use of these services in Italian pharmacies.

Objective: The present study has therefore developed a survey to collect information on the diffusion of telemedicine/telehealth services within Italian pharmacies.

Methods: A two-part questionnaire in Italian was developed using SurveyMonkey, setting a mechanism aimed to have different outcomes according to the answers given. Six hundred eighty-three respondents returned the questionnaire. The results were then analysed statistically.

Results: The questionnaire results have shown a limited diffusion of telemedicine/telehealth services among Italian pharmacies and an apparently limited interest of health authorities in supporting the integration of this technology.

Conclusions: More efforts should be spent by national public health stakeholders to better analyse the contribution of telemedicine services available in public pharmacies and to find the best solutions to implement this innovative technology as an established service.

Keywords

Telemedicine; Delivery of Health Care; Medically Underserved Area; Public Health; Primary Health Care; Pharmacies; Pharmaceutical Services; Pharmacists; Surveys and Questionnaires; Italy

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INTRODUCTION

Telemedicine, according to the American Telemedicine Association, is "the use of medical information exchanged from one site to another via electronic communications to improve a patient's health status".[1] Telemedicine is found in hospitals, clinics, and pharmacies and also in non-health environments, where it allows various types of diagnostic and therapeutic applications.[2-4] In fact, it has also been described as the use of the most modern and up-to-date medical and information technology (IT), in order to provide "remote" healthcare.[1,5]

In 2016, the US Agency for Healthcare Research & Quality (AHRQ), part of the Department of Health and Human Services, published a report on telemedicine interventions and their impact on patient outcomes. In particular, their data showed positive results in remote monitoring of patients suffering from chronic diseases.[6] A 2017 study on the use of telemedicine to enhance pharmacy services in the nursing facility reported that patients appreciate the benefits of telemedicine, and noted that important economic savings had been achieved.[7] This study estimated that a hospital that uses telemedicine technologies can save around USD 261,109 a year compared to a hospital that does not use teleservice technologies.[7] Furthermore, health professionals, doctors, pharmacists and nurses clearly expressed their comfort in using these technologies and their satisfaction with them.[7]

While telemedicine/telehealth applications can vary, it has proven particularly useful in pharmacies as part of the their healthcare offer.[6-11] For example, pharmacists who offer blood pressure, blood oxygenation or spirometry measurements, blood clotting or blood glucose tests, dermatological tests or electrocardiograms can quickly monitor the patient's health status and report the results directly to patient's physician. Pharmacists can query patients about their compliance with treatment 24 hours a day, report irregularities or adverse drug reactions (ADEs), and collaborate with the general practitioner when problems arise.[12,13]

Pharmaceutical service in Italy is regulated by various sets of legislation that, over time, have ended up overlapping each other.[14] Pharmaceutical service to the population is provided mainly through local pharmacies, classified as

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urban if located in cities with more than 5,000 inhabitants, and rural if located in towns with fewer than 5,000 inhabitants. The density of pharmacies is one pharmacy per an average of 3,000 inhabitants, a value in line with the European standards. Pharmacies in Italy can be owned by private pharmacists or can be government-owned, in which case they are called "municipal pharmacies". In Italy, as of March 2019 there were 19,331 pharmacies, 17,656 of which were privately owned and 1,675 of which were government-owned municipal pharmacies.[15]

In the last 10 years, Italian pharmacies have evolved significantly. Previously they were limited to sales of medicines and health products and to advising customers about medicines or healthcare. Then, with the ministerial decree of 16 December 2010, commonly called the "Pharmacy of Services Decree", pharmacies were given permission to provide services such as "self-diagnostic" tests, that is, those that patients could also perform at home independently, if equipped with suitable equipment and self-sufficiency, or tests that require the participation and help of a healthcare professional, such as electrocardiograms and spirometry measurements.[16] Using appropriate telemedicine devices such as smart phones, tablets or computers through certified connections, it is possible to share the patient's health information with a doctor, who in turn can return to the patient prescriptions and instructions.[17] Moreover, patients can now book specialist examinations directly in the pharmacy, as well as collect medical reports.

European Union institutions have implemented measures to regulate aspects and applications of telemedicine, but laws still differ among the various member states, which have sometimes maintained their own regulations.[18] According to the Italian Ministry of Health guidelines and regulations for telemedicine in Italy, telemonitoring is defined as the performance of clinical examinations and sharing of the results with an off-site physician, so the latter can send prescriptions and instructions for the patient.[19]

Although telemedicine and telepharmacy are gaining in popularity among professionals and patients, the literature provides little information on how telemedicine is actually implemented in pharmacies, or systematic analysis of the actual impact on patient health.[7]

To the best of our knowledge, no governmental or private entity has studied the effects of the 2010 Pharmacy of Services Decree in the area of telemedicine, and there is no information about the impact of this decree in the Italian pharmaceutical context, or the extent to which telemedicine approaches have been adopted.[20]

The present study has therefore investigated how telemedicine/telehealth service are used in Italian pharmacies, by administering a questionnaire to members of the National Federation of Associations of Italian Young Pharmacists (FENAGIFAR). This federation is made up of pharmacists aged under 38.

The results obtained may provide interesting insights into how the telemedicine is being used in Italian pharmacies.

METHODS

The questionnaire

The two-part questionnaire in Italian was designed using SurveyMonkey.[21] The 3 questions in Part 1 asked about the type of pharmacy where the respondent works, its location, and whether or not the pharmacy provides telemedicine service. Respondents who indicated that their pharmacy offers this service were asked to continue to Part II and answer 25 questions about their experience.

The type of questions included were as follow: 27 close-ended questions (that about the type of services provided envisaged more than one answer possible, while the remaining 26 envisaged only one answer); 1 open-ended question about the geographic location of the pharmacy. The English version of the questionnaire is included in the Appendix at the bottom of the article. The mechanism of the survey is depicted in the flowchart in Figure 1.

The questionnaire was developed and the investigation carried out by researchers of the “Telemedicine and Telepharmacy Center” of the University of Camerino. A local community pharmacist whose pharmacy is equipped with telemedicine devices was asked to critique the questionnaire in terms of construction, wording, and content, and once those suggestions were incorporated, the text was sent to the FENAGIFAR president for further assessment. The most glaring problem was the length of the survey. The researchers cooperated to find a suitable solution, and in the end, decided to merge sixteen of the remaining queries into 2 questions about the average number and mean age of patients who took advantage of each telemedicine service cited. Then, each researcher assessed the items using the CVI scale to analyse the appropriateness of the instrument. Once the questionnaire was approved unanimously by the research team and the FENAGIFAR president, it was transcribed into the SurveyMonkey tool.[22] After that, the researchers tested the

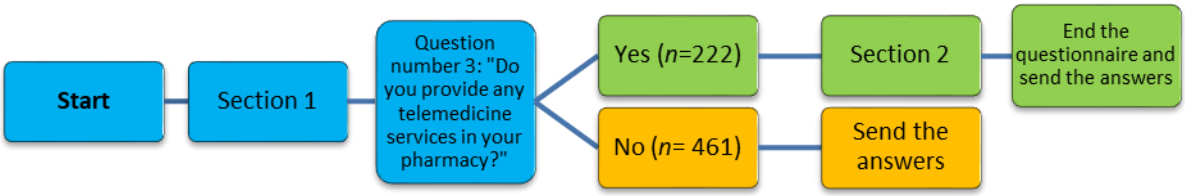

Figure 1. The questionnaire mechanism shows the different outcomes possible, according to the third answer in section 1, the checkpoint of the survey. An affirmative answer to this question allows the respondent to continue to the second section. Otherwise, the respondent stops working on the questionnaire and send the answers given up to that point.
The questionnaire was submitted to 3,400 pharmacists with a response rate of 20%.

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survey to ascertain that the mechanism worked properly, but did not allow the answers to be registered in the system.

The criteria for eligibility to participate in the survey were a degree in pharmacy, board certification, and work in one of the three types of pharmacies (privately owned urban pharmacy, privately owned rural pharmacy, or government-owned municipal pharmacy). The researchers invited 10 eligible pharmacists to complete and critique the questionnaire. Their answers to the questions were not recorded in the system at this point. They reported no problems, and so the questionnaire was emailed to all FENAGIFAR members with a cover letter from the two survey creators explaining the purpose of the study and specifying that data collected would be treated confidentially. No informed consent was requested, as the decision to click on the link to participate in the survey was considered permission. In any case, no personal data were collected and anonymity was maintained, in respect of the European privacy law (GDPR EU 2016/679).[23] No reminders were sent. Data collection was carried out between May and June 2019.

Statistics

Once the questionnaires were completed, the researchers used a SurveyMonkey Excel worksheet as the basis for calculating the frequencies of the answers and producing bar graphs. Frequencies were calculated based on the whole sample of 683 respondents for the first three questions. Question three, which asked whether their pharmacy provided telemedicine services, was the cut-off point. From the fourth question onward, frequencies were calculated for 222 respondents, that is, the number of pharmacists whose workplaces offered telemedicine services.

Data stratification

Further data analysis consisted of data stratification using two variables, namely, the type of pharmacy and its geographic location, to investigate whether these parameters affected the use of telemedicine services.

The types of pharmacy considered were government-owned municipal pharmacies, privately-owned urban pharmacies, and privately-owned rural ones. Geographical partition adopted sectors identified by the Italian National Institute of Statistics, namely North-West (NW), North-East (NE), Centre, South, and main Islands (Sicily and Sardinia).[24] The frequencies for each question were calculated according to these variables. Again, from the fourth question onwards, percentages for each subgroup were calculated in terms of the number of respondents whose workplaces use telemedicine.

Next, these data were transferred into the Origin 9.1 (Origin Lab) software to perform the chi-square test to find any differences, using the total sample data as reference.

RESULTS

In this section, the most outstanding data are presented to give an insight of the phenomenon studied. Information is organized into three subsections, namely general analysis and the two stratifications. This to give first a comprehensive overview of the entity of the diffusion of the telemedicine/telehealth in the Italian pharmaceutical context and implications that lay behind it. Then, our second purpose is to shed the light on possible variables that could affect its distribution within the Italian soil. The results of analysis of the questionnaire input are organized into two sections. The first section provides an overview of the extent to which telemedicine in used in Italian pharmacies, while the second section reports information analysed in terms of the type of pharmacy and its geographic location.

General analysis

The survey had a response rate of 20%: it was sent to 3,400 pharmacists, of whom 683 chose to participate.

It was not possible to ascertain the number of those who did not respond to the questionnaire for the reason that they do not work in pharmacies and thus were ineligible.

Telemedicine in Italy. According to the data collected, telemedicine is not a well-established practice in Italian pharmacies. In fact, only one third of our interviewees (32.5%) offer telemedicine services, and of these, 82.4% have done so for over a year. As noted above, this question was the checkpoint of the questionnaire.

Among all the available services, ECG, BP and BG were the most commonly offered examinations (respectively 86.9%, 67.1%, 56.8%)

Compliance with regulations. In general, good practice regulations were respected, as over 90% of the respondents indicated that they perform the examinations in a separate room, and most require patients to provide informed consent. The patient's right to information, in the context of health treatment, is of crucial importance, the violation of which by healthcare personnel constitutes a hypothesis of medical liability (so-called medical malpractice). The acquisition of consent is in fact different from the health service, and its purpose is to protect the fundamental right to health.

Failure to comply with the obligation to acquire informed consent violates the patient's right to self-determination regarding his / her psycho-physical state, protected by law.

The patient who has not been adequately informed by the doctor before being subjected to a therapy or a diagnostic examination, may institute a judgment against the health care professional to ascertain the latter's responsibility and therefore to obtain compensation for the damage suffered.

Trend of use. Respondents were asked to indicate the average number of clients per month who use the services, their mean age, and whether these clients used the services more than once. Unfortunately, respondents usually indicated “I don’t know” for the first two questions. The most detailed data were provided for ECG and BP. For ECG, “fewer than 20 patients a month” was answer the most commonly indicated, whilst for BP, a slightly higher tendency for the answer “between 20 and 60 patients per month” was registered. Some interesting trends were observed for BP and BG (Table 1).

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Table 1. Patients using telemedicine services per month.				
	< 20 patients	**20 - 60 patients**	**> 60 patients**	**I don't know**
Electrocardiogram	169 (76.1)	25 (11.3)	1 (0.5)	27 (12.2)
Blood oxygenation	44 (19.8)	8 (3.6)	0 (0.0)	170 (76.6)
Spirometry	30 (13.5)	2 (0.9)	0 (0.0)	190 (85.6)
Blood clotting	41 (18.5)	7 (3.2)	4 (1.8)	170 (76.6)
Dermatological test	33 (14.9)	6 (2.7)	2 (0.9)	181 (81.5)
Blood pressure	62 (27.9)	67 (0.2)	48 (21.6)	45 (20.3)
Blood glucose	70 (31.5)	67 (7.9)	17 (7.7)	73 (32.9)
Other	104 (46.8)	27 (12.2)	4 (1.8)	87 (39.2)
Data are expressed as the absolute frequencies (percentage).				

Respondents were asked to indicate for each service the mean age of clients who use it, choosing from a list of 5 age groups (AG): under 30 years (AG1), 30-40 (AG2), 41-50 (AG3), 51-60 (AG4), over 60 years (AG5). The most significant results concerned the ages of clients who use ECG, BP, and BG services (Table 2).

An approximatively homogeneous distribution, from AG1 to AG4, was seen for ECGs, while the rate of use dramatically dropped off for the most elderly patients (AG5). BP and BG were more attractive for the last three groups, with a peak in AG4 (34.7% for BP; 28.4% for BG). Overall, the youngest patients were more interested in ECGs, the oldest ones in BP measurements. Respondents indicated that 59% of their clients use a service more than once.

Physician involvement. These examinations are meant to monitor health parameters, and sometimes can reveal the need for follow-up care, or even a medical emergency. The availability of such services in the pharmacy saves the long waiting list for such services from the public healthcare system, usually conducted in a hospital. Thus we investigated the degree to which medical professionals are involved in follow-up care, asking how many patients (I) turn to a specialist, (II) get a new prescription from their general practitioner (GP), or (III) from a specialist, (IV) have their therapy modified by the GP, or (V) by a specialist. The possible options were "fewer than 10%", "10-20%", "21-40%", "over 40%", and "I don't know" (Table 3). Quite a high percentage answered "I don't know," but even so, the results offered some interesting information.

Relationship between the pharmacy and local health authorities. Fully 97% of the respondents indicated the lack of an agreement with local governmental health authorities to oversee the fruition of services. Similarly, 70.3% responded that authorities do not assess the quality of service or determine whether regulations are being respected. Moreover, the majority of those who answered that there is a periodic inspection stated that they are carried out less than once a year (62.1%). Pharmacies are periodically inspected by competent authorities and police forces (such as the "Nuclei Anti Sofisticazioni", acronym NAS). The purpose of this question is to investigate whether the presence of telemedicine entailed greater involvement of local health authorities. These inspections are intended to verify that the telehealth procedures carried out inside the pharmacies comply with current legislation in terms of health, hygiene and privacy.

Device and computer network quality check. Most of the respondents indicated that quality checks are carried out for devices (82.9%) and computer networks (69.4%), but considering the previous results, one may surmise that they are carried out by the companies that sell the equipment.

Patient's medical report. A considerable percentage of respondents (62.2%) indicated that their pharmacy has an agreement with one or more specialists to analyse the results of the health parameter measurements conducted in their pharmacy. These specialists usually work for a private healthcare company (66.7%) rather than the governmental healthcare service (33.3%).

The efficiency of telemedicine/telehealth services was attested to by the fact that the waiting time to receive the medical report from the specialists is less than 24 hours in slightly more than half of the cases (50.9% of respondents). In addition, 77.9% of respondents said the medical report could be sent directly to the patient.

However, it is crucial that pharmacies establish agreements with companies recognized by the national health system, and operating through certified health care professionals. On the contrary, it may represent an illegal activity that can endanger the patient's health and privacy.

Pharmacist's training and provision of services. Generally, pharmacists received training in how to use the equipment (for example, blood pressure cuffs, blood glucose kits, or ECG sets) from the seller (82.4%). Some respondents indicated they "obtained training independently" (14.4%), "from local health authorities" (2.3%), or "from a university or a hospital" (0.9%).

Table 2. Patients using telemedicine services per month and use of telemedicine services according to the different age groups.						
	<30 years	**30-40 years**	**41-50 years**	**51-60 years**	**60 years**	**I don't know**
Electrocardiogram	32 (14.4)	42 (18.9)	48 (21.6)	43 (19.4)	14 (6.3)	43 (19.4)
Blood oxygenation	3 (1.4)	4 (1.8)	8 (3.6)	13 (5.9)	13 (5.9)	181 (81.5)
Spirometry	4 (1.8)	3 (1.4)	8 (3.6)	6 (2.7)	2 (0.9)	199 (89.6)
Blood clotting	3 (1.4)	4 (1.8)	4 (1.8)	17 (7.7)	19 (8.6)	175 (78.8)
Dermatological test	5 (2.3)	11 (5.0)	16 (7.2)	5 (2.3)	2 (0.9)	183 (82.4)
Blood pressure	1 (0.5)	3 (1.4)	32 (14.4)	77 (34.7)	48 (21.6)	61 (27.5)
Blood glucose	1 (0.5)	2 (0.9)	42 (18.9)	63 (28.4)	33 (14.9)	81 (36.5)
Other	1 (0.5)	13 (5.9)	34 (15.3)	38 (17.1)	14 (6.3)	122 (55.0)
Data are expressed as the absolute frequencies (percentage).						

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Table 3. Physician's involvement after performing a test in the pharmacy.

To how many patients, following a Telemonitoring, …	< 10%	10%-20%	20%-40%	> 40%	I don't know
call on to the medical specialist?	35 (15.8)	37 (16.7)	37 (16.7)	58 (26.1)	55 (24.8)
a drug therapy is prescribed by the general practitioner?	37 (16.7)	40 (18.0)	37 (16.7)	20 (9.0)	88 (39.6)
a drug therapy is prescribed by the medical specialist?	32 (14.4)	32 (14.4)	35 (15.8)	24 (10.8)	99 (44.6)
a previous drug therapy is modified by the general practitioner?	39 (17.6)	41 (18.5)	24 (10.8)	9 (4.1)	109 (49.1)
a previous drug therapy is modified by the medical specialist?	42 (18.9)	36 (16.2)	20 (9.0)	10 (4.5)	114 (51.4)

Data are expressed as the absolute frequencies (percentage).

In terms of provision of services, we asked how many pharmacists are responsible for carrying out the clinical tests, and what hours of the workday the services are provided. The percentage obtained for the different options are as follow: In 31.1% of the cases, "only one pharmacist" handled the tests, while 46.8% answered "more than one", and 22.1% answered "all the pharmacists". Moreover, the vast majority of respondents (87.8%) indicated that services were provided throughout the opening hours of the pharmacy.

Stratification

We looked at the data provided by the questionnaires from the points of view of the type of pharmacy and its geographic location, to assess whether implementation of telemedicine is positively or negatively conditioned by these two variables. This in the hope of identifying issues that Italian health authorities should address in their efforts to foster more widespread use of telemedicine in Italy. The most interesting differences are presented below.

Type of pharmacy

Most respondents (69.5%) work in an urban private pharmacy, 24.6% in a rural private pharmacy and just 5.9% in a municipal one (Table 4). In general, 30% of all the pharmacy types use telemedicine solutions, though urban privately-owned ones have the highest percentage of implementation 33.3% and municipal ones the lowest 27.5%; telemedicine is implemented in the 31.5% of the rural private pharmacies.

No remarkable deviations from the total sample were observed for the average number of patients per month, while the mean age question provided some differences from the general trend. Municipal pharmacies showed the highest number of variations. As a matter of fact, ECGs were more likely to be requested by patients 30-40 years old, while no patients under 30 requested this service. BO and DM were requested only by patients 41-50 years old, while SP and BC only by those 51-60 years old (Table 5). However, given that a very high percentage of respondents indicated "I don't know" for these questions, these results may not be fully representative of the reality.

Table 4. Pharmacy type and geographic location stratification.

Categories	n (%)
Stratification by type of pharmacy	
Municipal pharmacies	40 (5.9)
Urban private pharmacies	475 (69.5)
Rural private pharmacies	168 (24.6)
Stratification by geographic location (according to ISTAT regional classification)	
North-West (NW)	224 (33.3)
North-East (NE)	141 (21.0)
Centre	111 (16.5)
South	121 (18.0)
Islands	75 (11.2)

Follow up to pharmacy telemedicine/telehealth services

(I) Turning to a specialist. Clients of urban private pharmacies were more likely to see a specialist after a telemedicine service. In fact, 25.3% of respondents working in urban private pharmacies indicated that "more than 40%" of clients followed up the in-pharmacy tests by getting an appointment with a specialist. (II) New prescription from a GP. Clients of rural pharmacies were more likely to follow-up their tests or measurements done in the pharmacy by obtaining a new prescription from a GP. (III) New prescription from specialist. For all three types of pharmacies, for under 50% of clients, in-pharmacy results were followed up with a change in prescription from a specialist. (IV) Modification of treatment by a GP. Similarly, for under 50% of clients of all three types of pharmacies, in-pharmacy services were followed up with modification of treatment ordered by a GP. (V) Modification of treatment by a specialist. In contrast, "more than 40%" of clients of urban pharmacies usually got a treatment modification from a specialist.

Relationship between the pharmacy and local health authorities. The quality inspections for the telemedicine services are carried out by the local health authorities in the 54.5% of the municipal pharmacies, in the 25.9% of the urban private pharmacies and in the 35.8% of the rural private pharmacies; these quality checks are significantly higher ($p<0.05$) in the municipal pharmacies, as stands to reason, given that they are pharmacies belonging to public institutions.

In fact, even though 62.1% of respondents working in municipal pharmacies indicated that officials inspected their pharmacy "less than once a year," the answer "every two or three months" was definitely higher among respondents working in municipal pharmacies than among those working in private ones (16.7% municipal pharmacies vs. 5.3% rural and 4.9% urban).

Specialists. Agreements with one or more specialists to analyse the results of the health parameter measurements conducted in the pharmacy and to provide a medical report were most common in municipal pharmacies (81.8%), followed by private rural pharmacies (71.7%) and private urban ones (57.6%).

Device and computer network quality check. All the municipal pharmacists reported that devices were periodically checked, while a small percentage of private rural (11.3%) and private urban (20.3%) ones indicated that no checks were carried out. Hence, considering the scarce commitment of local health authorities, it could be possible that this quality check is carried out by the device supplier.

Provision of services. Some fluctuations were also observed in how service was organized. While respondents working in municipal pharmacies and private urban pharmacies

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Table 5. Use of pharmacy telehealth services in the different type of pharmacies according to patient age groups

	Total	Municipal	Rural	Urban		Total	Municipal	Rural	Urban
Electrocardiogram					Blood oxygenation				
< 30 years	32 (14.4)	0 (0.0)	8 (15.1)	24 (15.2)	< 30 years	3 (1.4)	0 (0.0)	1 (1.9)	2 (1.3)
30-40 years	42 (18.9)	5 (45.5)	9 (17.0)	28 (17.7)	30-40 years	4 (1.8)	0 (0.0)	1 (1.9)	3 (1.9)
41-50 years	48 (21.6)	2 (18.2)	11 (20.8)	35 (22.2)	41-50 years	8 (3.6)	1 (9.1)	1 (1.9)	6 (3.8)
51-60 years	43 (19.4)	1 (9.1)	12 (22.6)	30 (19.0)	51-60 years	13 (5.9)	0 (0.0)	3 (5.7)	10 (6.3)
>60 years	14 (6.3)	1 (9.1)	2 (3.8)	11 (7.0)	>60 years	13 (5.9)	0 (0.0)	5 (9.4)	8 (5.1)
I don't know	43 (19.4)	2 (18.2)	11 (20.8)	30 (19.0)	I don't know	181 (81.5)	10 (90.9)	42 (79.2)	129 (81.6)
Spirometry					Blood clotting				
< 30 years	4 (1.8)	0 (0.0)	1 (1.9)	3 (1.9)	< 30 years	3 (1.4)	0 (0.0)	1 (1.9)	2 (1.3)
30-40 years	3 (1.4)	0 (0.0)	1 (1.9)	2 (1.3)	30-40 years	4 (1.8)	0 (0.0)	1 (1.9)	3 (1.9)
41-50 years	8 (3.6)	0 (0.0)	3 (5.7)	5 (3.2)	41-50 years	4 (1.8)	0 (0.0)	0 (0.0)	4 (2.5)
51-60 years	6 (2.7)	1 (9.1)	1 (1.9)	4 (2.5)	51-60 years	17 (7.7)	1 (9.1)	5 (9.4)	11 (7.0)
>60 years	2 (0.9)	0 (0.0)	1 (1.9)	1 (0.6)	>60 years	19 (8.6)	0 (0.0)	3 (5.7)	16 (10.1)
I don't know	199 (89.6)	10 (90.9)	46 (86.8)	143 (90.5)	I don't know	175 (78.8)	10 (90.9)	43 (81.1)	122 (77.2)
Dermatological test					Blood pressure				
< 30 years	5 (2.3)	0 (0.0)	1 (1.9)	4 (2.5)	< 30 years	1 (0.5)	0 (0.0)	0 (0.0)	1 (0.6)
30-40 years	11 (5.0)	0 (0.0)	5 (9.4)	6 (3.8)	30-40 years	3 (1.4)	0 (0.0)	1 (1.9)	2 (1.3)
41-50 years	16 (7.2)	1 (9.1)	5 (9.4)	10 (6.3)	41-50 years	32 (14.4)	3 (27.3)	8 (15.1)	21 (13.3)
51-60 years	5 (2.3)	0 (0.0)	0 (0.0)	5 (3.2)	51-60 years	77 (34.7)	6 (54.5)	17 (32.1)	54 (34.2)
>60 years	2 (0.9)	0 (0.0)	0 (0.0)	2 (1.3)	>60 years	48 (21.6)	0 (0.0)	15 (28.3)	33 (20.9)
I don't know	183 (82.4)	10 (90.9)	42 (79.2)	131 (82.9)	I don't know	61 (27.5)	2 (18.2)	12 (22.6)	47 (29.7)
Blood glucose					Other				
< 30 years	1 (0.5)	0 (0.0)	0 (0.0)	1 (0.6)	< 30 years	1 (0.5)	0 (0.0)	0 (0.0)	1 (0.6)
30-40 years	2 (0.9)	0 (0.0)	1 (1.9)	1 (0.6)	30-40 years	13 (5.9)	1 (9.1)	2 (3.8)	10 (6.3)
41-50 years	42 (18.9)	4 (36.4)	14 (26.4)	24 (15.2)	41-50 years	34 (15.3)	1 (9.1)	11 (20.8)	22 (13.9)
51-60 years	63 (28.4)	2 (18.2)	14 (26.4)	47 (29.2)	51-60 years	38 (17.1)	0 (0.0)	9 (17.0)	29 (18.4)
>60 years	33 (14.9)	1 (9.1)	9 (17.0)	23 (14.6)	>60 years	14 (6.3)	1 (9.1)	5 (9.4)	8 (5.1)
I don't know	81 (36.5)	4 (36.4)	15 (28.3)	62 (39.2)	I don't know	122 (55.0)	8 (72.7)	26 (49.1)	88 (55.7)

Data are expressed as the absolute frequencies (percentage).

presented a peak in the option "more than one pharmacist is in charge of carrying out the clinical examinations", private rural ones had a homogenous distribution among the answer options of "only one pharmacist" "more than one" and "all the pharmacists". Respondents among all three types of pharmacies indicated that they provide telemedicine services throughout the workday, though limitation to only some time slots was definitely more likely in municipal pharmacies (36.4%) than the other two (urban 9.4%; rural 11.4%).

Geographical location. For this kind of stratification, the sample was reduced to 672 respondents, as 11 were excluded due to incorrect information about geographical location. It should be considered that the percentages were calculated over the number of pharmacies in each area, so as to take into account the relative proportion in each group. Moreover, the importance of data has to be evaluated by comparing them with the overall values, namely those shown in general analysis section.

The geographical distribution of the pharmacies of the respondents is summarized in Table 4. No municipal pharmacies are present in the Islands, while the highest concentration of rural ones is in the NE. The NW had the highest number of pharmacies adopting telemedicine solutions (37.5%) (84/224), followed closely by 37.2% for the South (45/121), 34.2% for the Centre (38/111), 27.7% for the NE (39/141), and 17.3% for the Islands (13/75) (Table 6).

An interesting trend is that the Islands had the lowest number of pharmacies offering telemedicine services, but the highest proportion of pharmacies that have recently adopted these services. The highest value for all the geographic areas was registered for the answer "more than 1 year". Pharmacies in Southern Italy had the highest percentage of clients who use telemedicine services more than once (80% of Southern Italian pharmacies vs a general trend of 59%). On the contrary, the NW showed an inverse trend, as the percentage of clients who are repeat users of telemedicine (43.6%) is lower than those who used it only once (56.4%).

Results on the age distribution of patients highlighted some differences. Patients under 30 demonstrated higher interest in ECG in the NE (28.2%) compared with the results of the whole sample. In the Islands, results for ECG varied from the general trend, as it appeared to be more attractive for older patients (38.5% for those 51-60 years

Table 6. Data about the implementation of telemedicine and relationship with local health authorities distinguished from a geographical point of view

	North-West	North-East	Centre	South	Islands
Degree of telemedicine adoption	84 (37.5)	39 (27.7)	38 (34.2)	45 (37.2)	13 (17.3) *
How long has your pharmacy been using telemedicine solutions? (less than 1 year)	8 (9.5)	1 (2.6)	4 (10.5)	5 (11.1)	3 (23.1) *
Agreement with local health authorities (yes)	4 (4.8)	0 (0.0) *	2 (5.3)	4 (8.9)	3 (23.1) *
Quality check carried out by local health authorities (yes)	26 (30.9)	9 (23.1)	10 (26.3)	15 (33.3)	5 (38.5)

Data are expressed as the absolute frequencies (percentage). The values marked by an asterisk (*) are statistically significant data.

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Table 7. Use of pharmacy telehealth services in the different geographic areas according to patient age groups

	Total	North-west	North-east	Centre	South	Islands
Electrocardiogram						
< 30 years	32 (14.4)	10 (11.9)	11 (28.2)	2 (5.3)	9 (20.0)	0 (0.0)
30-40 years	42 (18.9)	17 (20.2)	8 (20.5)	4 (10.5)	11 (24.4)	1 (7.7)
41-50 years	48 (21.6)	19 (22.6)	9 (23.1)	5 (13.2)	12 (26.7)	3 (23.1)
51-60 years	43 (19.4)	18 (21.4)	4 (10.3)	10 (26.3)	6 (13.3)	5 (38.5)
>60 years	14 (6.3)	9 (10.7)	0 (0.0)	4 (10.5)	1 (2.2)	0 (0.0)
Age not Known	43 (19.4)	11 (13.1)	7 (17.9)	13 (34.2)	6 (13.3)	4 (30.8)
Blood oxygenation						
< 30 years	3 (1.4)	1 (1.2)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)
30-40 years	4 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	1 (7.7)
41-50 years	8 (3.6)	1 (1.2)	1 (2.6)	0 (0.0)	4 (8.9)	2 (15.4)
51-60 years	13 (5.9)	8 (9.5)	0 (0.0)	3 (7.9)	2 (4.4)	0 (0.0)
>60 years	13 (5.9)	8 (9.5)	0 (0.0)	4 (10.5)	1 (2.2)	0 (0.0)
Age not Known	181 (81.5)	66 (78.6)	38 (97.4)	31 (81.6)	34 (75.6)	10 (76.9)
Spirometry						
< 30 years	4 (1.8)	1 (1.2)	0 (0.0)	1 (2.6)	2 (4.4)	0 (0.0)
30-40 years	3 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)
41-50 years	8 (3.6)	2 (2.4)	1 (2.6)	0 (0.0)	3 (6.7)	2 (15.4)
51-60 years	6 (2.7)	3 (3.6)	1 (2.6)	1 (2.6)	1 (2.2)	0 (0.0)
>60 years	2 (0.9)	1 (1.2)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)
Age not Known	199 (89.6)	77 (91.7)	37 (94.9)	36 (94.7)	36 (80.0)	11 (84.6)
Blood clotting						
< 30 years	3 (1.4)	1 (1.2)	0 80.0)	0 (0.0)	2 (4.4)	0 (0.0)
30-40 years	4 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	1 (7.7)
41-50 years	4 (1.8)	1 (1.2)	0 (0.0)	0 (0.0)	1 (2.2)	2 (15.4)
51-60 years	17 (7.7)	8 (9.5)	3 (7.7)	2 (5.3)	4 (8.9)	0 (0.0)
>60 years	19 (8.6)	5 (6.0)	2 (5.1)	8 (21.1)	3 (6.7)	1 (7.7)
Age not Known	175 (78.8)	69 (82.1)	34 (87.2)	28 (73.7)	33 (73.3)	9 (69.2)
Dermatological test						
< 30 years	5 82.3)	0 (0.0)	1 (2.6)	0 (0.0)	3 (6.7)	1 (7.7)
30-40 years	11 (5.0)	5 (6.0)	1 (2.6)	1 (2.6)	3 (6.7)	0 (0.0)
41-50 years	16 (7.2)	5 (6.0)	4 (10.3)	3 (7.9)	3 (6.7)	1 (7.7)
51-60 years	5 (2.3)	1 (1.2)	0 (0.0)	0 (0.0)	3 (6.7)	1 (7.7)
>60 years	2 (0.9)	1 (1.2)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)
Age not Known	183 (82.4)	72 (85.7)	33 (84.6)	33 (86.8)	33 (73.3)	10 (76.9)
Blood Pressure						
< 30 years	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)
30-40 years	3 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	1 (7.7)
41-50 years	32 (14.4)	9 (10.7)	6 (15.4)	5 (13.2)	10 (22.2)	1 (7.7)
51-60 years	77 (34.7)	31 (36.9)	15 (38.5)	12 (31.6)	17 (37.8)	2 (15.4)
>60 years	48 (21.6)	23 (27.4)	6 (15.4)	11 (28.9)	6 (13.3)	2 (15.4)
Age not Known	61 (27.5)	21 (25.0)	12 (30.8)	10 (26.3)	10 (22.2)	7 (53.8)
Blood glucose						
< 30 years	1 (0.5)	0 80.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)
30-40 years	2 (0.9)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
41-50 years	42 (18.9)	13 (15.5)	7 (17.9)	9 (23.7)	12 (26.7)	1 (7.7)
51-60 years	63 (28.4)	25 (29.8)	13 (33.3)	8 (21.1)	15 (33.3)	2 (15.4)
>60 years	33 (14.9)	18 (21.4)	3 (7.7)	5 (13.2)	6 (13.3)	1 (7.7)
Age not Known	81 (36.5)	27 (32.1)	16 (41.0)	16 (42.1)	12 (26.7)	8 (61.5)
Other						
< 30 years	1 (0.5)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
30-40 years	13 (5.9)	2 (2.4)	3 (7.7)	0 (0.0)	6 (13.3)	1 (7.7)
41-50 years	34 (15.3)	16 (19.0)	4 (10.3)	8 (21.1)	5 (11.1)	1 (7.7)
51-60 years	38 (17.1)	14 (16.7)	6 (15.4)	5 (13.2)	10 (22.2)	3 (23.1)
>60 years	14 (6.3)	6 (7.1)	1 (2.6)	2 (5.3)	2 (4.4)	3 (23.1)
Age not Known	122 (55.0)	46 (54.8)	24 (61.5)	23 (60.5)	22 (48.9)	5 (38.5)

Data are expressed as the absolute frequencies (percentage).

old). Patients 30-40 years old in the Islands (7.7%) had more BP examinations than the overall value (1.4%), while those 51-60 years old had the lowest percentage (15.4% vs the general value of 34.7%) (Table 7). Surprisingly, while telemedicine technology is less present in Island pharmacies, as noted previously, this area had the highest number of pharmacies that have established an agreement with local health authorities and receive periodic inspections.

Analysis of in-pharmacy measurements and tests revealed that e NE was the only area where the number of pharmacies with no agreement with specialists to analyse the results of the health parameter measurements conducted in their pharmacy (53.8%) exceeded those that had one (46.2%). The number of pharmacists per pharmacy responsible for conducting tests and measurements, and the hours of the day such services were available fluctuated among the geographic areas. A higher percentage of Island pharmacies assigned all the pharmacy staff responsibility

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for carrying out examinations (30.8% vs 22.1% general trend). In contrast, availability of such services throughout the opening hours was not ensured by 38.5% of Island pharmacies. This is the highest percentage registered, especially compared to the value calculated in the general analysis (12.2%). The question on the providers of training in the use of measurement devices and tests pointed out a deviation from the overall trend for Island pharmacies. In fact, in this area there was a markedly higher percentage of pharmacists trained by a local health authority (15.4% vs 2.3% general trend) or by a university/hospital (7.7% vs 0.9% general trend).

DISCUSSION

As a broad trend, telemedicine offers a new model of medical care to support patients in remote areas or those unable to travel to healthcare service providers, for example, the homebound.[25,26] In addition, even patients able to travel can benefit, as they would be spared the expenditure of time and money for travel to medical appointments.[27] If this technology is used to enable physicians to interact with a greater number of patients, for example, through videoconferencing, it can help in facing the upcoming shortage of physicians and improve the sustainability of health systems worldwide.[28] In Italy, it has been estimated that 56,000 doctors will retire in the next fifteen years, and it is foreseen that the health system will not be able to cope properly with this haemorrhage.[29] In fact, it has been predicted that 1.4 million Italians will remain without a GP.[30] As a consequence of this trend, there will be inequalities in accessing the care provided by doctors and understaffed hospitals. Pharmacies able to offer basic medical tests and measurements and to communicate results to the client's physician could provide a partial solution to this problem. In fact, considering that pharmacies are located throughout the nation, even in small towns or rural areas lacking a physician, their adoption of telemedicine services can help bridge the gap for clients.

A few scientific papers deal with telemedicine/telehealth pharmacy services, but those available indicate promising developments.[31] One US study described a program of telemedicine pharmacy services to support organ transplant patients through such services as medication reconciliation, monitoring of patient compliance in taking medications, and provision of patient education.[31] In Italy, the Templar Project has demonstrated the efficacy of having pharmacies coordinate the distance monitoring of patient blood pressure to manage hypertension.[20] People living in remote and rural areas may not have easy access to pharmacy services and may resort to unnecessary GP consultations, or travel long distances to access a municipal pharmacy.[32]

Telemedicine/telehealth services in Italian pharmacies may have great potential, but the current reality is not exciting. Only one third of our respondents indicated that their pharmacies have implemented telehealth services. Moreover, even though telemonitoring can encompass a variety of clinical examinations, respondents reported that clients relied mostly on ECG, BP, and BG services.

There is a significant increase in the incidence of chronic diseases worldwide, and telemedicine examinations could play an important role in early detection in order to reduce mortality rates and disabilities.[33]

Telepharmacy may offer unique opportunity to improve access to screening and healthcare for cardiovascular patients.[20,34,35]

Studies have highlighted potential applications of telepharmacy in the prevention and treatment of other pathological conditions, such as diabetes, depression, asthma, etc.[7]

As shown by our data, the limited extent of telemedicine/telehealth use in Italian pharmacies probably depends by political reasons. A low commitment of health authorities in supporting the integration of this technology in pharmacies has belied expectations created after the promulgation of the decree introducing telehealth services in pharmacies. Health authorities were expected to act as a guide in helping pharmacists implement telemedicine. Instead, our respondents indicated that local health authorities focused on quality control inspections of state-owned pharmacies devices, and much less so of privately owned ones, even though, according to our results, the municipal pharmacies had the lowest degree of adoption of telemedicine services.

The Italian Local Health Authorities (commonly called in Italian as "Aziende Sanitarie Locali", acronym ASL) are institutions of the Italian public health administration, responsible for the provision of health services. The ASL is part of the National Health Service and is the competence of the Regions. Through the National Accord between the National Health System and the pharmacies, the latter becomes part of the National Health System, as a real healthcare point.[36,37]

Relations between pharmacies and the National Health System are regulated by this National Agreement stipulated between Federfarma and the Regions with renewal every three years.[37]

At the local level, the ASL carries out a Pharmaceutical Service whose activity includes: health education activities about drugs and implementation of scientific information plans prepared by the Ministry of Health; technical and administrative activities in the areas of their competence; control over medicines and the rest of the medical instruments used by hospitals, facilities, and others; control on the proper application of the aforementioned National Agreement, with a technical-pharmacological evaluation of medical prescription and also statistical surveys on the prescriptions of medicines; drafting of the annual report on the trend of pharmaceutical expenditure and the consumption of medicines and the remaining health material at hospitals, facilities, and services of the ASL.[36,37]

Recently, the national and regional governments have increased their involvement in implementing telehealth in the pharmacy setting as witnessed by the recent opening of an experimental project to test the efficacy of some services provided by pharmacies, among them telemedicine services for ECG, spirometry, and Holter measurements for cardiac and blood pressure

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parameters.[38] It is to be augured that 30% rate of adoption of telehealth in pharmacies identified in our study may improve over the next months or years, though we cannot predict its evolution.

To make pharmacists more familiar with telehealth/telemedicine, teaching programs in universities and training activities within the panel of the Continuing Medical Education Program are necessary.[39,40] As noted in section one, over 80% of respondents received training in how to use telemedicine-related equipment such as blood pressure cuffs, blood glucose kits or ECG sets from the seller, about 14% from independent sources, only about 2% "from local health authorities" and a negligible percentage (0.9%) "from a university or a hospital". It would appear that the national or local healthcare authorities are not interested in keeping pace with the innovations of the health domain, at least as far as telemedicine in pharmacies is concerned. This lack of attention is also borne out by respondents who seemed to indicate that quality inspections on devices and computer networks are carried out not by healthcare authorities but by the companies that sell the equipment, and in general, that inspections of pharmacies are generally conducted for government-owned community ones, not privately owned ones. This concern should be addressed by incorporating telehealth/telemedicine training into the obligatory continuing medical education credits that pharmacists are required by law to earn, and by organizing teaching programs on these skills in universities.[39,40]

To sum up, our study has revealed some encouraging results about the use of telemedicine in the pharmacy, the number of pharmacists in each pharmacy who are responsible for providing these services and the number of hours in a workday that they are offered. The opportunity for patients to receive their medical report at home is another positive factor. These services can expand the patient's options for such tests and measurements and thus reduce the workload for hospitals.

Limitations

The study has some limitations. First of all, only 20% of the pharmacists contacted by email chose to participate by filling out the questionnaire; even so, the number was sufficient for a national survey with a confidence level of 95% and a confidence interval of 5%. One reason for the low level of participation could be that few of those contacted were interested in the topic. Another possible but not probable explanation is that few uses the internet and email, and thus did not receive the questionnaires. Probably the most tenable reason is that even though our team made every effort to design the questionnaire for simple and quick response, pharmacists were unwilling or unable to take time out of their very busy days to fill it out and return it. The research team did not collect any personal data in compliance with the Privacy Regulations in force. As a result, there is no way to know which of our respondents are pharmacy owners or employees. In addition, while submitting the questionnaire, we asked to participants to respect a ratio 1:1 between pharmacists and pharmacies. Since this kind of surveys is not carried out in person, it is hard for the investigators to verify whether the respondents stick to the instructions. As a result, the authors cannot ascertain if the ratio required was respected.

CONCLUSIONS

Our study results indicate that, despite its great potential, telemedicine/telehealth has yet to gain a strong foothold in Italian pharmacies. There is a disproportion in the offer of telemedicine services, as 33.3% of respondents in urban pharmacies use it, compared to 27.5% of respondents who work in municipal ones. The main reason could be that local healthcare authorities have failed to support the realization of the telemedicine provisions of the 2010 Pharmacy of Services legislation. This investigation has highlighted some of the most pressing problems limiting the satisfactory incorporation of digitalized patient care services in pharmacies. Future studies should analyse the economic sustainability of such services and evaluate the feasibility of government assistance to pharmacies for the purchase of equipment and to patients for expenditures on these in-pharmacy tests and measurements. In view of this, national health authorities, pharmacy regulatory bodies and academia should cooperate to identify the best possible solutions, starting from the awareness of how this technology could benefit patients and reduce healthcare inequalities. A recent agreement (October 2019) between the National and Regional Governments to which belong the responsibility of delivery locally health services make resources available for the development of large-scale tests on the "pharmacy of services".[36] We hope that this initiative could bring to a relaunch of such a project for the benefit of citizens that are the recipients of health services.

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CONFLICT OF INTEREST

Authors declare that there is no conflict of interests.

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Original Research

The role of the community pharmacist in veterinary patient care: a cross-sectional study of pharmacist and veterinarian viewpoints

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Abstract

Background: The role of the community pharmacist is rapidly expanding to encompass the care of veterinary patients in the United States of America This change makes it imperative for pharmacists and veterinarians who practice in community settings to establish mutual agreement on the roles of pharmacists in the care of these patients.

Objective: To examine community-based pharmacist and veterinarian viewpoints on interprofessional collaboration and the role of the community pharmacist in veterinary patient care.

Methods: Cross-sectional surveys were sent to pharmacists and veterinarians who practice in a community setting in Ohio. Surveys collected demographic information and addressed the following themes: attitudes toward collaboration, perceived roles of the pharmacist, expectations of the pharmacist, and previous collaborative experiences. A chi-square test was used for statistical analysis.

Results: In total, 357 pharmacists and 232 veterinarians participated in the study. Both professions agreed that pharmacist-veterinarian collaboration is important in order to optimize veterinary patient care (chi-square (1, N=589)=7.7, p=0.006). Overall, veterinarians were more likely to identify an important role of the community pharmacist to be compounding medications (chi-square (1, N=589)=26.7, p<0.001) compared to counseling pet owners (chi-square (1, N=589)=171.7, p<0.001). Both groups reported similar levels of agreement regarding the importance for pharmacists to have adequate knowledge of veterinary medicine.

Conclusions: Our study found that while both pharmacists and veterinarians conveyed a positive attitude regarding interprofessional collaboration, they disagreed on what role the pharmacist should play in the care of veterinary patients. Rectifying the discordant perceptions of these health care professionals may be critical to developing collaborative initiatives and optimizing veterinary patient care.

Keywords

Pharmacists; Veterinarians; Professional Role; Intersectoral Collaboration; Pharmacies; Counseling; Drug Compounding; Surveys and Questionnaires; United States

INTRODUCTION

The role of the community pharmacist is rapidly expanding to include the care of veterinary patients in the United States of America (USA).[1] Traditionally, veterinarians were the sole distributors of companion animal medications, otherwise known as pet medications.[2] Following the implementation of The American Veterinary Medical Association's (AVMA) Principles of Medical Ethics, veterinarians are now required to provide prescriptions to pet owners ("clients") upon request, as long as a veterinarian-patient relationship exists.[3] With the freedom to fill prescriptions elsewhere, many clients have chosen to utilize community pharmacies.[2] As a result, a growing number of community pharmacists throughout the county are dispensing prescriptions for common pets such as dogs, cats, and ferrets and interacting more frequently with clients.[2] There not a clear delineation of the percentage of prescriptions filled by community pharmacies compared to veterinary clinics in Ohio. However, it is evident that with the increased demand of medications for companion animals, there is an equal demand for the convenience and competitive pricing of prescriptions obtained at community pharmacies, especially given that a low percentage of clients have pet insurance.[2,4,5]

This change presents both challenges and opportunities and makes it imperative for pharmacists and veterinarians to establish an understanding of and mutual agreement on the roles of pharmacists involved in the care of veterinary patients. Within the practice of human medicine, pharmacists have proven themselves crucial members of the health care team through their integral work and collaboration with other health care providers. Specifically in community settings, pharmacists frequently collaborate with physicians and other providers in order to select appropriate medication therapies, assist with managing chronic conditions, and ensure the safe dispensing of prescriptions for their patients. Pharmacists would be well-suited to engage in similar interactions with veterinarians to further improve patient care. However, numerous limitations, specifically regarding the education pharmacists receive in veterinary pharmacy and veterinary medicine in general, may inhibit optimal collaboration.

A lack of sufficient education in veterinary pharmacy has the potential to greatly influence community pharmacists'

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perceptions concerning their role in the care of veterinary patients. The current Accreditation Council for Pharmacy Education (ACPE) standards do not include a mandate that veterinary pharmacotherapy be included within pharmacy school curricula, and pharmacy programs nationwide lack standardized educational instruction in this area.[6,7] For practicing pharmacists, veterinary pharmacy training is generally limited and may not be prioritized; nine out of ten pharmacists reported no previous training in veterinary pharmacy.[8] Lack of adequate training is a common issue in both the USA and abroad, and insufficient educational experiences could hinder pharmacists from safely dispensing veterinary medications or appropriately counseling clients.[9,10] Additionally, community pharmacists may be unaware of roles in which they are legally prohibited from engaging. Pharmacists have not only reported inadequate knowledge of veterinary pharmacotherapy but also of legal aspects pertinent to compounding for veterinary patients.[8] For example, pharmacists may be unaware they cannot legally recommend over-the-counter (OTC) medications for veterinary patients without the recommendation or a prescription from a veterinarian. Without a clear understanding of their roles, community pharmacists may endanger pet health and place themselves in legal jeopardy.

A related concern is that community pharmacists may have little to no experience interacting with veterinarians upon graduating pharmacy school. ACPE Standard 11 focuses specifically on interprofessional education, with requirements for students to demonstrate competences in interprofessional team dynamics, advancing the quality of patient care, and engage in shared therapeutic decision-making.[7] While pharmacy students often interact with other health care providers in order to hone these skills, these interactions are less likely to involve veterinarians or veterinary students given the dearth of veterinary pharmacy-related education. Consequently, pharmacists may be unsure how to successfully navigate interprofessional relationships with these providers and unaware of specific situations in which referring to or consulting a veterinarian is vital to the care of their patients. Further, pharmacists may request unnecessary information from veterinarians, such as National Provider Identifier (NPI) numbers, or ask common dosage questions that could be referenced elsewhere. These types of interactions could lead to the development of tension within interprofessional relationships. While some veterinary programs are inclusive of an interprofessional education component that incorporates pharmacy students, this alone may be insufficient to ensure a full understanding of the roles community pharmacists can play within veterinary medicine.[11] Ultimately, the potential exists for misunderstandings regarding the role of the pharmacist to occur, which can lead to an environment lacking clear communication or trust.

In a survey of members of the AMVA, pharmacists were ranked among the top health care professionals with whom veterinarians interacted with most frequently.[12] Despite this finding, working relationships between pharmacists and veterinarians have not been established or further developed to the same extent as those with other healthcare providers.[1] Limited data exist regarding pharmacist and veterinarian viewpoints on collaboration and the role of the pharmacist pertinent to veterinary patient care in the community setting. A thorough evaluation of the current working relationship between these professionals could potentially lead to the development of educational and collaborative initiatives and the formation of strong, interprofessional partnerships.

The objective of this study is to examine community-based pharmacist and veterinarian viewpoints on interprofessional collaboration and the role of the community pharmacist in veterinary patient care.

METHODS

Survey design

A literature search was performed in order to determine the extent of available research on the current working relationship between community pharmacists and veterinarians. A search was also performed to assist with the development of survey structure as well as pertinent survey questions.[13] Two electronic, cross-sectional surveys were created: one for pharmacists and one for veterinarians. Each survey collected respondent demographic information. Specifically for the categories of "sex" and "age", respondents had to the option to select "choose not to answer". At the beginning of the survey, respondents were asked whether or not they work in a community practice setting. If they selected "no" the survey ended. The remainder of the survey was organized into four domains. Two of the survey domains, attitudes toward collaboration and expectations of the pharmacist, were comprised of statements that were ranked using a 4-point Likert scale inclusive of strongly agree, agree, disagree, and strongly disagree. For a third domain, perceived roles of the pharmacist, respondents were asked to select any of the listed tasks they felt were important roles of the pharmacist with regard to the care of veterinary patients. For the final domain, previous collaborative experiences, respondents were asked to select the frequency with which they engaged in various collaborative interactions. The terms 'pets' and 'animal patients' were used interchangeably within the survey questions. An open response section was also included, in which respondents could detail any additional thoughts or experiences regarding these themes. Both surveys were piloted, and questions were reviewed for content and structure. Feedback was utilized to make adjustments and clarifications in order to improve the validity of the study. This study was approved by the Northeast Ohio Medical University Institutional Review Board.

Survey distribution

Lists of all pharmacists and veterinarians licensed in the state of Ohio were obtained with permission from the Ohio State Board of Pharmacy (OSBP) and Ohio Veterinary Medical Licensing Board (OVMLB), respectively. Recorded individuals were invited to participate in the study. Participants were sent an email with detailed information regarding the study and a hyperlink to the survey questions. Survey instructions specified that only pharmacists and veterinarians practicing in a community

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Table 1. Respondent characteristics

Characteristic; n (%)	Pharmacists n=357	Veterinarians n=232
Gender		
Male	111 (31)	56 (24)
Female	241 (68)	174 (75)
Choose not to answer	5 (1)	2 (1)
Age (years)		
<25	11 (3)	0 (0)
26-35	118 (33)	84 (36)
36-45	58 (16)	65 (28)
46-55	74 (21)	31 (13)
>55	90 (25)	51 (22)
Choose not to answer	6 (2)	1 (1)
Years since graduation		
<5	79 (22)	44 (19)
5-10	68 (19)	57 (25)
11-20	41 (12)	56 (24)
>20	169 (47)	75 (32)
Number of years in practice		
<5	82 (23)	44 (19)
5-10	66 (18)	58 (25)
11-20	42 (12)	57 (25)
>20	167 (47)	73 (31)

setting should complete the survey. Participants consented to participate in the study by clicking a confirmation link. No identifying information was collected, and all responses were anonymous. Surveys were distributed to potential participants via email on August 7, 2019. A reminder email was sent out every week for three weeks, and the survey closed on September 3, 2019.

Data analysis

Only data for surveys that were fully completed were included in the final analysis. The responses to survey components utilizing the 4-point Likert scale were consolidated into two categories of agree (strongly agree and agree) and disagree (strongly disagree and disagree) and percentages of agreement were reported for each statement. Data related to the perceived roles of the pharmacist section were reported as percentages of pharmacists and veterinarians who selected each option, and responses to the previous collaborative experiences section were also reported as percentages. Responses were compared between the groups using chi-square with alpha set at 0.05. SPSS (version 26.0, SPSS, Inc.) was used to analyze data. Submissions within the open response section were qualitatively assessed for emerging themes.

RESULTS

Surveys were sent to all licensed pharmacists and veterinarians in Ohio and were only intended to be completed by individuals practicing in a community setting. Thus, the response rate for this study cannot be determined, and estimated response rates are reported. In order to achieve adequate power, 372 pharmacists and 347 veterinarians needed to complete the surveys. Of the 19,372 pharmacists invited to participate in the study, 579 began the survey and 357 completed it. Approximately 60% of pharmacists practice in a community setting in the USA, yielding an estimated 3% response rate.[14] Of the 4,196 veterinarians invited to participate in the study, 253 began the survey and 232 completed it, approximately, 85% of veterinarians in Ohio practice in a community setting, yielding an estimated 7% response rate.

Table 2. Attitudes toward collaboration

	Pharmacists	Veterinarians
I am interested in collaborating with local pharmacists/veterinarians*	92%	84%
Collaboration between pharmacists and veterinarians improves patient outcomes*	95%	90%
Collaboration between pharmacists and veterinarians is important in order to provide optimal patient care*	95%	89%
*Statistical significance noted (p<0.05)		

Pharmacist and veterinarian respondents differed significantly with regard to age, number of years since graduation, and number of years in practice. The two groups were similar with regard to gender, with the majority of respondents being female. Sixty-eight percent of pharmacist respondents practice in a chain pharmacy setting and 25% practice in an independent pharmacy setting. Half of all pharmacist respondents have a Doctor of Pharmacy degree. Of the veterinarian respondents, 75% work in a private practice setting and 17% work in a corporate practice setting. The remainder practice in some other community setting, including shelters and nonprofit clinics. All veterinarian respondents have a degree in veterinary medicine. Respondent characteristics are reported in Table 1.

While the majority of pharmacist and veterinarian respondents expressed a positive attitude toward interprofessional collaboration, a significant difference was noted for responses to all three statements related to attitudes toward collaboration (Table 2). A significantly lower percentage of veterinarians felt that collaboration between pharmacists and veterinarians is important to optimize patient care and improve patient outcomes (chi-square (1, N=589)=7.7, p=0.006 and chi-square (3, N=589)=6.8, p=0.009, respectively). Similarly, veterinarians were significantly less likely to have an interest in collaborating with local pharmacists (chi-square (1, N=589)=9.3, p=0.002).

Survey respondents were asked to select any tasks they perceive as important roles of the community pharmacist with regard to the care of veterinary patients (Table 3). While the majority of pharmacists and veterinarians agreed that dispensing prescriptions for veterinary patients is an

Table 3. Perceived roles of the pharmacist

	Pharmacists	Veterinarians
Having a strong, working knowledge of veterinary medications	64%	71%
Referring pet owners to local veterinarians when appropriate	74%	67%
Counseling pet owners (clients)*	77%	22%
Compounding medications for animal patients*	62%	82%
Dispensing prescriptions for animal patients*	97%	87%
* Statistical significance noted (p<0.05)		

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Table 4. Expectations of the pharmacist		
	Pharmacists	**Veterinarians**
It is important that pharmacists are aware of legal and regulatory issues related to pet prescriptions	96%	97%
It is important that pharmacists contact veterinarians with issues regarding pet prescriptions	99%	99%
It is important that pharmacists are aware of toxicities of over-the-counter medication use in animal patients	89%	91%
It is important that pharmacists have adequate veterinary medicine knowledge	85%	83%
Pharmacists do not have a role in veterinary medicine	14%	9%

important role of the pharmacist, a significant difference was noted, with a lower percentage of veterinarians identifying this as an important role (chi-square (1, N=589)=21.1, p<0.001). A significant difference was also found with regard to counseling clients, as approximately 75% of pharmacists selected this as an important role of the pharmacist, while only 22% of veterinarians felt similarly (chi-square (1, N=589)=171.7, p<0.001). Also of note, a significant difference was seen with regard to the role of compounding medications for veterinary patients, with approximately 80% of veterinarians classifying this task as an important role, while only 60% of pharmacists perceived it likewise (chi-square (1, N=589)=26.7, p<0.001).

Survey respondents were asked to rate their level of agreement for five statements related to expectations of the pharmacist with regard to the care of veterinary patients. Agreement was noted for both groups regarding the expectations that pharmacists have adequate veterinary medicine knowledge (chi-square (1, N=589)=0.350, p=0.56) and are aware of toxicities of OTC medications used in animal patients (chi-square (1, N 589)=1.026, p=0.31). No significant differences were noted between the groups for any of the statements (Table 4).

Significant differences were noted between pharmacist and veterinarian respondents with respect to all four scenarios encompassing previous collaborative experiences (Table 5).

Two main themes emerged from the open response section: a desire for improved pharmacist knowledge of veterinary medicine, and the need for better collaboration between practicing community pharmacists and veterinarians. Out of 107 veterinarian respondents who submitted an open response, 50% expressed concern regarding pharmacists' inadequate knowledge pertaining to veterinary medicine. Additionally, 20% of veterinarian respondents specifically mentioned the need for stronger collaboration with local pharmacists in order to improve patient care. Fifty-two pharmacist respondents submitted an open response. Of those, 50% noted concern with the lack of training they received in veterinary patient care, and 25% specifically mentioned wanting additional training in this area.

DISCUSSION

As clients continue to rely more heavily on community pharmacies to fill prescriptions for companion animals, there is a growing need to establish more cooperative relationships between pharmacists and veterinarians in order to better serve the needs of their mutual patients.[1,2] Our study found contact between pharmacists and veterinarians is generally limited, suggesting working relationships are either in progress or not in place. Promisingly, findings highlighted the mutual agreement that collaboration is necessary in order to optimize the care of veterinary patients and revealed a strong interest in collaboration from both pharmacist and veterinarian respondents. With this concurrence, initiatives to enhance collaboration can be piloted, and future studies may assess the effects of such strategies.

Results also revealed differences between pharmacists and veterinarians with regard to the perceived roles of the

Table 5. Previous collaborative experiences			
Frequency	**Veterinarians n (%)**	**Pharmacists n (%)**	**Chi square test of independence**
A pharmacist contacts you regarding an animal patient/A veterinarian contacts you regarding an animal patient			
Daily	5 (2)	51 (14)	64.9, p<0.001
Weekly	37 (16)	123 (34)	(3, *N*=589)
Monthly	111 (48)	126 (36)	
Never	79 (34)	57 (16)	
You ask a pharmacist to compound a medication for an animal patient/A veterinarian requests you compound a medication for an animal patient			
Daily	15 (60)	22 (6)	222.6, p<0.001
Weekly	83 (36)	9 (3)	(3, *N*=589)
Monthly	99 (43)	66 (18)	
Never	35 (15)	260 (73)	
You ask a pharmacist to counsel a pet owner regarding an animal patient/A veterinarian asks you to counsel a pet owner regarding an animal patient			
Daily	1 (0.5)	17 (5)	55.6, p<0.001
Weekly	2 (1)	21 (6)	(3, *N*=589)
Monthly	9 (4)	71 (20)	
Never	220 (95.5)	248 (69)	
A pharmacist refers a pet owner to you/You refer a pet owner to a veterinarian			
Daily	1 (0.5)	4 (1)	138.2, p<0.001
Weekly	3 (1)	45 (13)	(3, *N*=589)
Monthly	13 (6)	147 (41)	
Never	215 (92.5)	161 (45)	

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community pharmacist involved in the care of veterinary patients. Notably, a relatively low percentage of pharmacist respondents perceive their role as inclusive of compounding for veterinary patients. Even though nonsterile compounding is a common component of pharmacy student training, the translation of these skills for use in veterinary patients may not be made apparent within pharmacy school curricula. Given that a large percentage of veterinarian respondents perceive this as an important role of the pharmacist, this may be an area in which pharmacists can demonstrate a more unique skill set and begin to develop better relationships with local veterinarians through the provision of compounding services. Findings in the literature are encouraging: a recent study found veterinarians and clients agree that pets and clients would benefit from community pharmacies providing compounding services and that pharmacists may be able to fill a need for veterinarians by providing these services.[15]

Given the lack of focus on veterinary medicine within pharmacy programs, it is reasonable that pharmacists have not established agreement on their roles pertaining to veterinary patient care. While The National Association of Boards of Pharmacy (NABP) has encouraged the incorporation of veterinary pharmacotherapy within pharmacy school curricula, other organizations such as ACPE have not made this a priority.[7,16] In the state of Ohio, the pharmacy board describes rules and regulations pertinent to veterinarian prescribing but has yet to place mandates on pharmacist education with regard to dispensing prescriptions for veterinary patients. A lack of uniform recommendations from these organizations creates a potential barrier to not only furthering education within this area but also to encouraging pharmacists to take ownership of these roles. A stronger stance by national and statewide pharmacy organizations may not only help to improve pharmacists' knowledge and abilities but encourage those who work in community settings to put these skills into practice.

There was also noted disagreement regarding counseling clients as an important role of the pharmacist. Our study found pharmacists view counseling clients as an important role, and in the state of Ohio, pharmacists are legally required to offer counseling before dispensing any new or refilled prescription.[17] While pharmacists are extensively trained in counseling within human medicine and this is considered a strength of the community pharmacist, a lack of knowledge and resources may lead to provision of inappropriate or illegal counseling of clients. For example, pharmacists may inadvertently provide dosing information on OTC medications without direct orders from a veterinarian. This further highlights the need for increased training not only in veterinary pharmacotherapy but also of associated legal aspects related to counseling clients for veterinary patients. The majority of veterinarian respondents do not perceive the pharmacist's role as inclusive of counseling clients. This may be due to a lack of confidence in the pharmacist's ability and knowledge to effectively counsel on these medications in multiple, non-human species. These concerns were substantiated by a 2012 survey conducted by the Oregon Veterinary Medical Association, which documented numerous instances of pharmacists inappropriately counseling on veterinary prescriptions.[18] Veterinarian concerns may be rectified through increased pharmacist training in veterinary pharmacy, and veterinarians may encourage this by promoting the advancement of pharmacist education in this area. While more widespread training programs are needed, current opportunities for pharmacists include online continuing education courses and certificate programs such as one offered through the University of Georgia.[19] Pharmacists are able to receive training in veterinary compounding by participating in programs like the Veterinary Compounding Course offered by the Professional Compounding Centers of America.[20] Additionally, pharmacists may choose to join and support professional organizations such as the American College of Veterinary Pharmacists or the Society of Veterinary Hospital Pharmacists in order to participate in additional educational activities. Student pharmacists can consider shadowing veterinary pharmacists, participating in veterinary-focused elective courses or rotation experiences if available, and completing a veterinary pharmacy residency or fellowship.

Finally, our survey reviewed the previous collaborative experiences between veterinarians and pharmacists. The frequencies of the detailed scenarios parallel responses within other sections of the survey. For example, the majority of veterinarians reported they never ask a pharmacist to counsel a pet owner regarding an animal patient. When asked about frequency of requests for compounding, veterinarians reported requesting compounded preparations from pharmacists most frequently on a weekly or monthly basis, but most pharmacist respondents reported they are never asked to compound medications for veterinary patients. This difference could be because only a small number of pharmacies, such as specialty pharmacies, are providing compounding services for numerous veterinarians. Compounded medications for veterinary patients may also be requested from mail order pharmacies, and the structure of our survey did not specifically address this demographic.

Limitations

The authors acknowledge limitations of this research dataset. First, statistical power was not achieved. Despite the use of an incentive to complete the survey, response rates did not reach target levels, though the response rate of pharmacists was close to ideal. Literature has shown physicians have low survey response rates, and while not specifically studied, this trend may translate to veterinarians as well.[21] Due to less-than-ideal response rates, there is the potential for non-responder bias. However, some characteristics of our survey respondents are similar to those of the populations from which they were drawn. Per data obtained from the OSBP and the Ohio Veterinary Medical Association, respectively, 58% of licensed pharmacists and 60% of licensed veterinarians in Ohio are female.[22] These rates are slightly lower than the female respondent rates of our survey. Additionally, the categorization of veterinarian respondents by year since graduation for our sample closely matches that of the practicing veterinarian population in Ohio.

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The population studied only included those pharmacists and veterinarians licensed to practice in the state of Ohio, which could also limit the generalizability of our findings. Future studies may attempt to gather data from a wider selection of pharmacists and veterinarians who practice in community settings. Finally, our survey was not piloted by community-based veterinarians, which may have led to misinterpretation of survey components. Notably, there were no comments suggesting confusion about survey questions or structure within the open response section.

CONCLUSIONS

While both pharmacists and veterinarians expressed a positive attitude regarding interprofessional collaboration, they disagreed on what role the pharmacist should play in the care of veterinary patients. Rectifying the discordant perceptions of these health care professionals may be critical to maximizing veterinary patient care. Educational and interprofessional endeavors should be identified to help clarify roles and develop a synergistic relationship between pharmacists and veterinarians in community practice. Future studies could also examine barriers to effective collaboration and preferred methods of communication between these health care providers.

CONFLICT OF INTEREST

The authors declare no relevant conflicts of interest or financial relationships.

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Original Research

Applicability of American College of Clinical Pharmacy (ACCP) competencies to clinical pharmacy practice in Egypt

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Abstract

Background: The American College of Clinical Pharmacy (ACCP) prepared clinical pharmacist competencies that have specific recommendations. Recently, many efforts to advance clinical pharmacy services in Egypt exist. The literature revealed that no country has assessed the extent of applicability of ACCP competencies in its current pharmacy practice setting. Egyptian pharmacists can provide feedback about applicability of such competencies in clinical pharmacy settings in Egypt.

Objective: The objective of this study was to investigate the extent to which ACCP competencies were implemented by Egyptian clinical pharmacists and therefore evaluate development of clinical pharmacy practice in Egypt. The study also investigated factors affecting the applicability of such competencies in the current clinical pharmacy practice setting in Egypt.

Methods: Four hundred and ninety-five randomly selected clinical pharmacists from several hospitals were invited to participate in a cross sectional survey using a self-administered validated questionnaire composed of 31 questions classified into six domains. This questionnaire was designed to determine the pharmacists' perception about applicability of ACCP competencies to clinical pharmacy practice in Egypt.

Results: The response rate was 64% as 317 out of 495 pharmacists completed the questionnaire. These pharmacists were categorized according to age; gender; qualifications; years of previous work experience, years since BSc. and type of hospitals they are currently working at. Analysis of data revealed the professionalism domain to have the highest percentage of acceptance among pharmacists, while the system-based care & population health domain had the lowest percentage of acceptance. Results also showed that qualifications of participants did not affect their response in three domains; "Direct Patient Care", "Systems-based Care & Population Health" and "Continuing Professional Development" ($p=0.082$, 0.081, 0.060), respectively. Nevertheless, qualifications of participants did affect their response in the other three domains; "Pharmacotherapy Knowledge", "Communication" and "Professionalism" ($p<0.05$). The age of pharmacists, gender, years of previous work experience, and graduation year did not affect their responses in all six domains. The type of hospital they are currently working at, though, affected their responses where, there was a highly statistically significant increase of the mean score of all domains among participants working at the NGOs/private hospitals compared to governmental hospitals ($p<0.001$).

Conclusions: Egyptian pharmacists generally apply high percentage of ACCP competencies but the provided clinical pharmacy services need to be improved through applying the standards of best practice.

Keywords

Clinical Competence; Pharmacists; Professional Practice; Professionalism; Pharmacy Service, Hospital; Education, Pharmacy, Graduate; Cross-Sectional Studies; Egypt

INTRODUCTION

One of the most dramatic changes affecting pharmacy education and the future of pharmacy practice is the emerged concept of clinical pharmacy.[1] The field of "clinical pharmacy" was developed in the early sixties, However, one of the first times this term was used was by Heber W. Youngken Jr. who in 1953 wrote an article titled "The Washington Experiment-Clinical Pharmacy" that was published in the American Journal of Pharmaceutical Education.[2] Expansion of a new role for the pharmacist came gradually with the many socioeconomic changes related to current medical care. The idea of the new role referred to as "Clinical Pharmacist" developed in several parts of America and in 1969 it appeared to emerge as patient-oriented pharmaceutical services.[1] This resulted in more direct contact with other health care team members, especially physicians and nurses.[1] The use of the term "clinical pharmacists" has also been recently criticized as it gives the impression that pharmacists are either clinically trained or not, though in reality all pharmacists are trained to provide maximum patient care. Clinical pharmacists are practitioners who provide medication management and health care for patients.[3] They are licensed pharmacists with advanced education and training who possess the clinical competencies necessary to practice in team-based, direct patient care environments.[4] Clinical pharmacists have many roles such as evaluating of medication therapy; making pharmaceutical care plan; following-up evaluation and medication monitoring; documenting directly in the

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patient's medical record the medication-related assessment and planning of care to optimize patient outcomes.[5]

Competency-based education has been defined in various ways and interpreted differently among academic programs. Spady (1977) defines competency-based education as "a data-based, adaptive, performance-oriented set of integrated processes that facilitate, measure, record and certify within the context of flexible time parameters the demonstration of known, explicitly stated, and agreed upon learning outcomes that reflect successful functioning in life roles.[6] Riesman (1979) defines competency-based education as: A form of education that derives curriculum from an analysis of a prospective or actual role in modern society and that attempts to certify student progress on the basis of demonstrated performance in some or all aspects of that role. Theoretically, such explanations of competence are independent of time served in formal educational settings.[7] The awareness for competency-based pharmacy education is relatively recent compared to other health care professional programs. The American Association of Colleges of Pharmacy has pioneered the implementation of educational outcome-based guidelines since the early 1990s.[8] Descriptions of the entry-into-practice requirements for professional pharmacists are available for Australia, Canada, Europe and the United Kingdom.[9,10] The design of a competency-based curriculum ideally follows a specific sequence from competencies to assessments, to learning outcomes, to teaching-learning activities.[11] Conscious choices and decisions on all organizational levels are needed to achieve consistency between learning tasks, feedback to students, teacher roles, and organization of the curriculum.[12] Development of competences in pharmacy practice is a basic prerequisite for providing pharmacy care and being responsible for patient treatment outcomes.[13] In the United States, medical education has increased its interest in competency-based Education over the past several years.[14] Acquiring new knowledge and skills is essential for professional competency.[15] Competency standards in pharmacy training and education have been formulated by different organizations to focus on various stages in the development of students, residents, and clinical pharmacists.[16] The American Society of Health-System Pharmacists (ASHP) published a book containing competency modules that can be utilized by hospitals as a competency program. The book contains many topics, such as infection control, patient counseling, renal dosing, fire safety and medication safety.[17] The American Pharmacists' Association (APhA) edited code of ethics for Pharmacists which includes the basic principles underlying the roles and responsibilities of pharmacists. These principles are established to guide pharmacists in their relations with patients, healthcare team and society.[18] The fifth principle is "A pharmacist maintains professional competence" which is a key point in the pharmacy career.[18]

The American College of Clinical Pharmacy (ACCP) prepared clinical pharmacist competencies that have specific recommendations. According to ACCP, competency programs should include clinical problem solving, judgment, decision making, communication & education, medical information evaluation & management, management of patient populations and therapeutic knowledge.[19] ACCP is taking the means to improve the health of humans by covering most borders of clinical pharmacy. According to this function and its center principles, ACCP is confirming that any clinical pharmacist must have the knowledge, expertise's, attitudes, and behaviors required to transmit medication management which occur in team-based and direct patient care atmospheres.[20] According to the ACCP competencies, the expectations that clinical pharmacists should be medication experts are present and classified into six essential domains: communication, systems-based care & population health, pharmacotherapy knowledge, professionalism, direct patient care and continuing professional development. In comparison with the physician's competencies, they are especially designed to reflect the clinical pharmacy skillfulness required supplying ACCP requirements in team-based settings and patient-centered approach.[20] Clinical pharmacists must complete the training and education needed to fulfill these competencies. Also, they must carry out big efforts to maintain these competences through continuous professional development. Cooperation between healthcare team will also be needed to guarantee that these competencies drive clinical pharmacists to maintain professional development and assessment by higher educational institutions, professional societies, postgraduate training programs and employers.[20] Although these competencies are similar to the competences of physicians, clinical pharmacist competencies more worthily reflect big focus on pharmacotherapy and guarantee optimal medication-related outcomes and patient needs.[19,21] This similarity based on all these competencies are intended to ensure that a practitioner can provide comprehensive medication management (CMM) as outlined in the ACCP Standards of Practice.[4]

Recently, there are a lot of efforts to advance clinical pharmacy services. In developing countries, the pharmacy practice models significantly vary based on establishing clinical pharmacy and practice.[22] For example, in England, pharmacy practice research was implemented firstly in faculties of pharmacy and conjugated with post-graduation studies in the fields of health promotion programs and wellness and contributed to the development and improvement of pharmacy practice.[23] In United States, There were two evolutions that shaped clinical pharmacy practice including the formation of residencies in clinical pharmacy and doctor of pharmacy degree (PharmD) programs. The Doctor of Pharmacy (PharmD) is a professional doctorate degree, also known as a clinical doctorate - a term only used in the health professions.[24] The list of countries that transitioned from the BPharm to the PharmD degree, as their entry-level qualification are as follows: US, Canada (plan to offer an all-PharmD in 2020), Hungary, Italy, Japan, South Korea, Pakistan, Saudi Arabia, Thailand, Benin, Cameroon, Republic of Congo, Senegal, Tunisia, Nigeria and Ghana.[25] Federal funding assisted with greatly expanding clinical pharmacy education programs in colleges of pharmacy.[26] In African countries like Ethiopia, there seems to be a severe shortage of number of pharmacists. Only 1088 pharmacists are serving 80 million people which is equal to 0.14/10,000 person.[27] The clinical pharmacy plan was implemented in 2007 with an objective

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of training patient centered pharmacy practitioners by extending the undergraduate pharmacy program from 4 to 5 years of clinical pharmacy approach.[28] In Nigeria, a conversion from the traditional pharmacists' role of compounding and dispensing of drugs began in the 1980s with the introduction of unit dose-dispensing systems and drug information services in some hospitals.[29] In Saudi Arabia, the Saudi Council for health specialties developed the clinical pharmacy approach by establishing a residency program, which comprises of a two year accredited training with board certification for clinical pharmacy specialties to the graduates passing the final exam.[30] In Qatar, Hamad Medical Corporation (HMC) incorporated clinical pharmacy services (CPS) at most settings (inpatient, outpatient and community) as of January 2014.[31] In the United Arab Emirates, more clinical pharmacy training programs have been put in place to meet the high demand for pharmacists in the country. In October 2008, Gulf Medical University launched the Doctor of Pharmacy (PharmD) program to meet the high need of clinical pharmacy activities.[32]

Egypt is a developing country, with a population of approximately 100 million people.[33] The healthcare system in Egypt is very complex, with a large number of private and public entities participating in the provision of medical care. Patients can obtain their medical services from university teaching hospitals, public hospitals, private hospitals, medical centers and pharmacies. The Egyptian healthcare system faces many problems including the complexity of medicines; the high cost of drugs and the lack of a sufficient number of healthcare services. There are approximately 230,000 registered pharmacists in Egypt.[34] It is estimated that there is one pharmacist per 2,100 persons (compared to one pharmacist per 5,000 persons internationally) and one pharmacist for every 1.5 physicians (compared with one pharmacist for every three physicians internationally).[34] The clinical pharmacy movement in Egypt was slow. Few publications have addressed the changes in pharmacy education and pharmacy practice in Egypt.[35,36] El Anowr reported that, in 1980, visiting professors from the United States led the efforts to bring clinical pharmacy to Egypt, where they gave lectures at the faculty of pharmacy at Tanta University and trained some lecturers in clinical pharmacy.[36] In 1994, the basic principles of clinical pharmacy were implemented at the faculty of pharmacy at Ain Shams University. After that, many faculties of pharmacy established a clinical pharmacy practice department.

In Egypt, the old model of the dispensing pharmacist is still common. But big efforts are being made to keep speed with the needs of a developed healthcare system. Egyptian pharmacists understand the need to play very important roles in the rational use of medications in safe manner and are willing to accept this important responsibility to guarantee maximum therapeutic benefit and reach the best clinical outcomes.[37] Although there are a lot of challenges to optimize and monitor drug use, there has been a rising interest in extending the role of the pharmacist in Egypt as a clinical pharmacist. The Egyptian Ministry of Health established a decree number 391 for year 2012 to ensure implementing clinical pharmacy services at all governmental hospitals.[37] In Egypt, before September 1997, the role of pharmacists working in Egyptian hospitals was mostly dispensing.[38] All these factors led to the development of clinical pharmacy practice in Egypt. Clinical pharmacy in Egypt was newly developed and needs international competencies like ACCP competencies to develop clinical pharmacy practice. This paper encourages different researchers to study these competencies in different countries. Reviewing the literature revealed that no country has assessed the extent of applicability of ACCP competencies in its current pharmacy practice setting.

The objective of this study was to investigate the extent to which American College of Clinical Pharmacy (ACCP) competencies were implemented by Egyptian clinical pharmacists and therefore evaluate the development of clinical pharmacy practice in Egypt. We used ACCP competencies as a tool for this purpose. It also investigated factors affecting the applicability of such competencies in the current clinical pharmacy practice setting in Egypt.

METHODS

Four hundred and ninety-five randomly selected clinical pharmacists from different hospitals participated in a survey planned to determine their perception about applicability of ACCP competencies to clinical pharmacy practice in Egypt. A multi-stage random sample was used to select participants. The Hospitals were divided into two categories: thirty two Governmental Hospitals and four NGOs/Private Hospitals. The sample was calculated by CDC epi.info online calculator for survey (www.OpenEpi.com) as follows:

The total target population size was 3000 pharmacists. Hypothesized percent of response: 50% +/- 5; we want 95% confidence limit, alpha error: 5% and Design effect:1. Sample size (n) was at least 341 with proportion of 20% from NGOs/Private hospitals and 80% from Governmental hospitals. From governmental hospitals 12 hospitals were chosen randomly by excel and another three hospitals from NGOs/Private hospitals also was chosen randomly. From each hospital (33 pharmacists) were selected randomly by Excel after setting the sample frame from each hospital by their serial number at their work without knowing their identity. The participants were of different age, gender, qualifications, graduation year and years of previous work experience. A validated questionnaire composed of six competency domains which are divided into 31 questions recognized by ACCP was used.[20] The questionnaire was distributed in paper format by random individual interviews to 495 pharmacists for self-completion. All the paper forms were filled on spot. The answers to this questionnaire were evaluated using Likert scoring system which ranged from one to five in ordinal scale: 1 being the lowest and 5 being the highest. Factors investigated to assess their effect on pharmacists' expectations of the applicability of ACCP competencies were age, gender, qualifications, years of previous work experience, years since BSc, and type of hospitals pharmacists where they are currently working at.

First, the study instrument of validated questionnaire was sent to researchers and professionals from pharmaceutical backgrounds (pharmacists and academia) to give their expert opinion with respect to its simplicity (as our native

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Table 1. Pharmacists' expectations about applicability of each ACCP competency domain.

Domains; Mean (SD)	Relative weight of the score % (SD)	Domains' Grades				
		Strongly disagree	Disagree	Partially agree	Agree	Strongly agree
Direct Patient Care: 3.5 (1.0)	69.1% (20.7)	18(5.7%)	54(17.0%)	79(24.9%)	82(25.9%)	84(26.5%)
Pharmacotherapy Knowledge: 3.4 (1.0)	68.1%, (20.0)	18(5.7%)	46(14.5%)	75(23.7%)	96(30.3%)	82(25.9%)
Systems- based Care & Population Health: 3.2 (1.0)	64.0%, (20.5)	30(9.5%)	68(21.5%)	74(23.3%)	92(29.0%)	53(16.7%)
Communication: 3.5±1	70.9%, (20.8)	25(7.9%)	26(8.2%)	64(20.2%)	98(30.9%)	104(32.8%)
Professionalism: 3.6 (1.0)	72.4%, (19.3)	17(5.4%)	36(11.4%)	62(19.6%)	99(31.2%)	103(32.5%)
Continuing Professional Development: 3.5 (1.0)	70.2%, (19.3)	11(3.5%)	43(13.6%)	73(23.0%)	93(29.3%)	97(30.6%)

The values of each domain of ACCP competencies after application of Likert scale analysis to transform the frequency of answers in each domain into scale variables.

language is Arabic).[20] Second, a pilot study was conducted by asking a small sample of pharmacists (N=20) for their opinions on making the questionnaire simpler and shorter. Participants from different hospitals were selected for the pilot study. Reliability was calculated using SPSS v.25 (IBM Corp., Armonk, NY, USA), and Cronbach's alpha was 0.77, 0.87, 0.92, 0.90, 0.81 and 0.92 for the six domains, respectively. The data from the pilot study were not used in the final analysis. Cronbach's alpha as a reliability test was conducted. The study was approved by the Research Ethics Committee of the Faculty of Pharmacy, Beni-Suef University (Rec-H-PhBsu-19002).

Analysis of data was performed using SPSS v.25 for Windows. Likert scale analysis was used to calculate the mean rank of each domain to be used as a numeric scale variable.

Description of quantitative variables was in the form of mean and standard deviation (SD) except for the domains regarding the qualification categories, they were presented as median and IQR (non-normally distribution). Description of qualitative variables was in the form of numbers and percents. Kruskal Wallis test was used to compare between different qualifications regarding the mean of each domain. Independent t-test was used to compare between the mean of the six domains of governmental and non-governmental participants. Pearson correlation was used to correlate between age, years since BSc and years of experience and the six domains (r was considered weak at ≤0.3, moderate at 0.4 to 0.6 and strong at more than 0.6). Significant level was considered when p-value<0.05

RESULTS

A total of 317 out of 495 pharmacists completed the questionnaire with a response rate of 64% with a female dominance (82.3%). The average age of the participants was 29.9 years (SD=6) ranging between 22 and 55 years of age. The participants had a minimum of one year previous work experience and maximum of 32 years of previous work experience with a mean of 6.3, (SD=5) years. The mean years since BSc was 8.3 (SD=6) years. The percentage of participants holding a BSc degree was 199(62.8%), whereas 57 (18%) had a Clinical Pharmacy Diploma, 16 (5%) had a PharmD, 2 (0.6%) had a National Fellowship Certificate, 17 (5.4%) had a Master's degree, 24 (7.6%) had an American Board Certificate, and 2 (0.6%) had a PhD. Results also showed that 246 (77.6%) of the participating pharmacists worked in governmental hospitals while 71 (22.4%) worked in NGOs/private hospitals.

Table 1 illustrates the values of each domain of ACCP competencies after application of Likert scale analysis to transform the frequency of answers in each domain into scale variables. The values of all domains ranged from 3.2 to 3.6 and the relative weights of their scores ranged from 64.0% to 72.4%. Results also showed that 26.5%, 25.9%, 16.7%, 32.8%, 32.5%, and 30.6% of participants strongly agreed with the applicability of "Direct Patient Care"; "Pharmacotherapy Knowledge"; "Systems-based Care & Population Health"; "Communication"; "Professionalism" and "Continuing Professional Development" domains respectively.

Results showed that there was no statistically significant linear correlation between pharmacists' age, years since BSc and years of previous work experience and the mean score of all domains [p>0.05] (Table 2). Similarly, when results were stratified by gender, there was no statistically significant differences between males and females regarding the score of all 6 domains; (p=0.489, 0.680, 0.559, 0.928, 0.861and 0.308, respectively) (Table 3).

Results also showed that qualifications of participating pharmacists did not affect their perception of applicability of "Direct Patient Care"; "Systems-based Care & Population Health" and "Continuing Professional Development" domains (p=0.08, 0.08, and 0.06, respectively). On the other hand, qualifications of participating pharmacists had an effect on their perception of applicability of "Pharmacotherapy Knowledge"; "Communication" and "Professionalism" domains (p<0.05). Regarding the "Pharmacotherapy Knowledge" domain, the median (IQR) of the domain score among pharmacists with BSc, Clinical Pharmacy Diploma, PharmD, National Fellowship Certificate, Master's degree, American Board Certificate

Table 2. Correlation between pharmacists' age, graduation year, and years of previous work experience and different domains

ACCP Competency Domains	Pearson's r (p-value)		
	Age	Graduation Year	Work experience
Direct Patient Care	-0.030 (0.598)	-0.016 (0.776)	-0.034 (0.549)
Pharmacotherapy Knowledge	-0.027 (0.633)	-0.011 (0.847)	-0.037 (0.509)
Systems-based Care & Population Health	-0.007 (0.905)	0.022 (0.702)	0.009 (0.879)
Communication	-0.009 (0.876)	0.011 (0.841)	-0.005 (0.927)
Professionalism	0.032 (0.573)	0.057 (0.308)	0.031 (0.581)
Continuing Professional Development	0.062 (0.270)	0.075 (0.184)	0.039 (0.485)

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Table 3. Effect of gender on applicability of ACCP competencies:

ACCP competency domains	Males (n=56) mean (SD)	Females (n=261) mean (SD)	p-value
Direct patient care	3.5 (1.0)	3.4 (1.1)	0.489
Pharmacotherapy knowledge	3.5 (0.8)	3.4 (1.0)	0.680
Systems-based care and population health	3.3 (0.9)	3.2 (1.1)	0.559
Communication	3.6 (0.9)	3.5 (1.1)	0.928
Professionalism	3.6 (0.9)	3.6 (1.0)	0.861
Continuing professional development	3.4 (1.0)	3.5 (0.9)	0.308

and PhD. was 3.4 (2.6-4.0), 3.2 (2.4-4.0), 3.7 (3.2-4.6), 4.7 (4.4-5.0), 4.0 (3.2-4.2), 4.2 (3.3-4.5), 3.6 (2.4-4.8), respectively. The median score of pharmacists with National Fellowship Certificate as evident was the highest of all qualifications. There was a statistically significant difference between Clinical Pharmacy Diploma and both the American Board Certificate & National Fellowship Certificate ($p<0.05$) among participants with respect to "Pharmacotherapy Knowledge" domain. In the same domain, there was a statistically significant difference between BSc degree and both the American Board Certificate & National Fellowship Certificate ($p<0.05$). Regarding the "Communication" domain, the median (IQR) of the domain score among pharmacists with BSc, Clinical Pharmacy Diploma, PharmD, National Fellowship Certificate, Master's degree, American Board Certificate and PhD was 3.6 (2.8-4.2), 3.6 (3.0-4.2), 4.1 (3.2-4.6), 4.7 (4.4-5.0), 4.0 (3.4-4.4), 4.5 (3.5-4.8), 4.3 (4.0-4.6) respectively. Again, the median score of pharmacists with National Fellowship Certificate as evident was the highest of all qualifications. There was a statistically significant difference between the response of participants with American Board Certificate and participants with both BSc and Clinical Pharmacy Diploma ($p<0.05$). Regarding the "Professionalism" domain, the median (IQR) of the domain among pharmacists with BSc, Clinical Pharmacy Diploma, PharmD, National Fellowship Certificate, Master's degree, American Board Certificate and PhD. was 3.5 (3.0-4.3), 3.4 (3.0-4.3), 3.8 (2.9-4.8), 4.4 (3.8-5.0), 4.0 (3.3-4.5), 4.5 (3.6-5.0), 4.0 (4.0-4.8), respectively. The median score of American Board certified pharmacists as evident was the highest of all qualifications. There was a statistically significant difference between the median score of participants with the American Board Certificate compared to those with BSc degree and Clinical Pharmacy Diploma with respect to the "Professionalism" domain ($p<0.05$). Figure 1 demonstrates the effect of different qualifications of participating pharmacists on the median score of all ACCP competency domains.

Regarding the effect of type of hospitals (governmental versus NGOs/private), that participating pharmacists are working at, on their expectations of the applicability of ACCP competency domains, results showed a highly statistically significant increase of all mean domain scores among pharmacists working in the NGOs/private hospitals compared to governmental hospitals ($p<0.001$) as demonstrated in Table 4.

DISCUSSION

A major problem for clinical pharmacy practice in Egyptian hospitals is that the hospitals do not have enough qualified pharmacists to establish clinical pharmacy services and educate pharmacy students' clinical skills during their training. Other challenges for pharmacists in clinical pharmacy practice are earning the acceptance of other

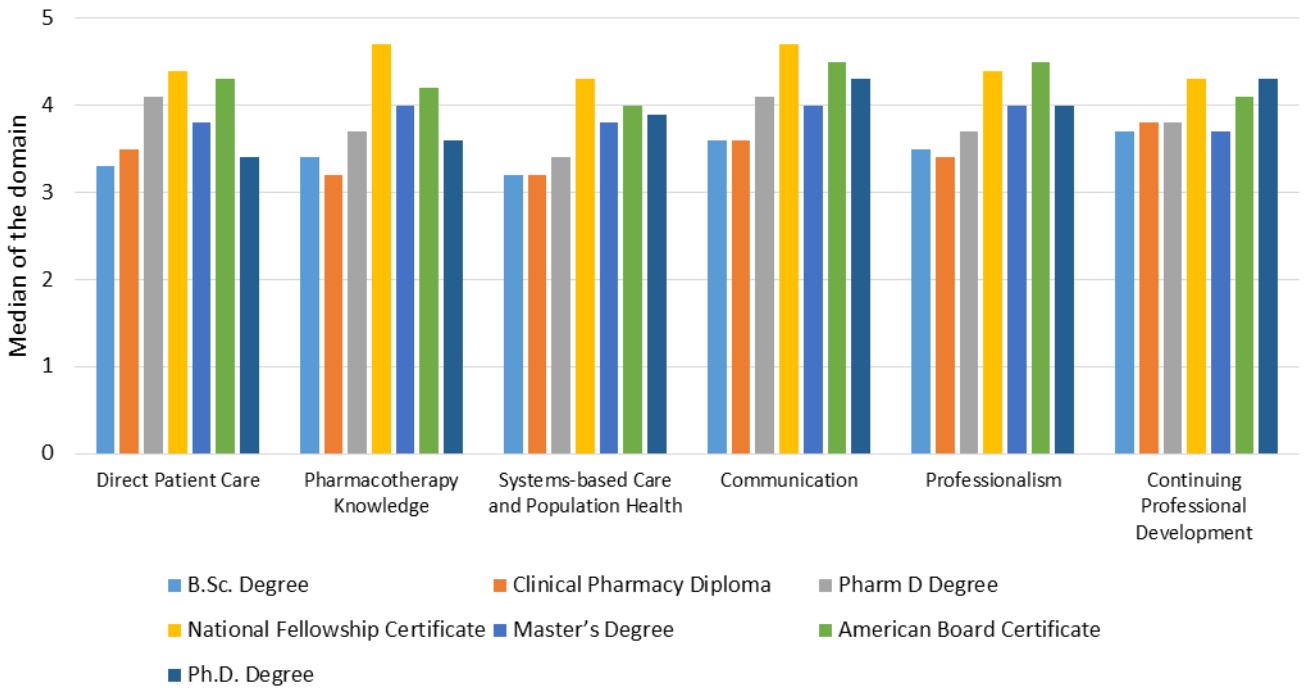

Figure 1. Effect of different qualifications of pharmacists on median scores of ACCP Competency Domains

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Table 4. Effect of type of hospitals (governmental versus NGOs/private) that participating pharmacists are currently working at, on their expectations of the applicability of ACCP competency domains:

ACCP competency domains	Governmental mean (SD)	NGOs/Private mean (SD)	p-value
Direct patient care	3.3 (1.03)	3.9 (0.87)	p<0.001
Pharmacotherapy knowledge	3.3 (1.02)	3.7 (0 .83)	p<0.001
Systems-based care and population health	3.1 (1.03)	3.6 (0 .88)	p<0.001
Communication	3.4 (1.06)	3.9 (0.85)	p<0.001
Professionalism	3.5 (0.99)	4.0 (0.74)	p<0.001
Continuing professional development	3.4 (0.95)	3.8 (0.92)	p<0.001

healthcare team and being recognized as competent to select treatment therapy.[39] The relationship between the pharmacist and physician has been characterized as complex, and some physicians have been annoyed with pharmacists providing direct patient care.[40] Pharmacist-Physician communication is an important factor in the healthcare process to prevent medication errors and ensure medication safety. Many papers have studied the presence of a communication gap between physicians and pharmacists.[41,42] Active communication between pharmacists and physicians in healthcare settings is essential to enhancing patient outcomes. Not only in Egypt but also in other Arabic countries including United Arab Emirates, Kuwait, Jordan, Sudan and Saudi Arabia.[43-47] A ministerial decree was also issued in 2014 to increase the duration of pharmaceutical education of BSc from five to six years. The sixth year will include training in communities, hospitals, and industrial premises to ensure that pharmacy graduates have obtained the competencies required for professional practice as a pharmacist. All these factors encouraged them to study ACCP competencies as standard competencies in Egypt.

In Egypt, and according to the results of this study, pharmacists believe that ACCP competencies are generally being applied in clinical pharmacy practice settings. About one-third of the participants strongly agreed that "Communication", "Professionalism", and "Continuing Professional Development" domains of ACCP competencies are being applied by clinical pharmacists in Egypt. The pharmacists are expected to have good communication skills needed to deliver the best service to their patients, uphold the highest standards of integrity and honesty, serve as a credible role model and leader for students, trainees and colleagues by exhibiting the values and behaviors of a professional with active engagement in professional societies and in training of future clinical pharmacists. Results of this study also showed that about one-fourth of participants agreed that "Direct Patient Care" and "Pharmacotherapy Knowledge" domains are being applied by clinical pharmacists in Egypt, whereas only 16.7% of participants strongly agreed that "Systems-based Care & Population Health" domain of ACCP competency is being applied at the national level. Indeed, as part of the best clinical pharmacy practice, several elements of this domain are yet to be implemented in the majority of clinical pharmacy settings in Egypt. Examples of such elements are the use of health care delivery systems & health informatics to optimize the care of individual patients and patient populations, participation in identifying system-based errors & implementing solutions, resolving medication-related problems to improve patient and population health and quality metrics, applying knowledge of pharmacoeconomics & risk-benefit analysis to patient-specific and population-based care, participation in developing processes to improve transitions of care & design quality improvement processes to improve medication use.

Results showed that there was no statistically significant linear correlation between pharmacists' age, years since BSc. and years of previous work experience and the mean score of all ACCP competency domains which reflects that such factors did not have any effect on pharmacists' response to the survey questions regarding their expectations of the applicability of ACCP competencies. Similarly, gender of participants had no significant effect on their applicability scoring across all six domains.

Qualifications of participating pharmacists exerted a variable effect on different domains where it did not affect the pharmacists' perception of applicability of "Direct Patient Care", "Systems-based Care & Population Health" and "Continuing Professional Development" domains but it had an effect on the pharmacists' perception of applicability of "Pharmacotherapy Knowledge", "Communication" and "Professionalism" domains.

The highest applicability scoring of National Fellowship certificate in many domains may reflect the good standard of this program curriculum dealing with practical/professional direct patient care elements included in ACCP competencies. Nevertheless, this interpretation may not be warranted given that participating pharmacists with National Fellowship Certificate constituted only 2 (0.6%) of the sample.

The pharmacists working at the NGOs/private hospitals responded with higher scores reflecting their beliefs about the applicability of all ACCP competency domains compared to pharmacists working in governmental hospitals and due to difference in services between the governmental and NGO/private hospitals in Egypt. Indeed, in NGOs/Private hospitals, there is great awareness about the importance of applying the best clinical pharmacy practice standards to meet the needs of patients. Also, the better financial resources of private versus governmental hospitals may explain the participants' responses regarding applicability of ACCP standards.

Finally, the present study had several strengths and limitations. The wide range of participants' age, years since BSc, and years of previous work experience (22-55, 1-33, and 1-32 years, respectively) may be considered strengths of this study because it reflects a wide spectrum of opinions. Three limitation of this study are the relatively small sample size of 317 participating pharmacists, the female dominance of the sample (82.3%) and the sample of hospitals seems to be skewed to Cairo and the North of Egypt with limited number of hospitals from the

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South/Upper Egypt. However, it is the first study investigating the applicability of ACCP competencies in clinical pharmacy practice settings in Egypt. The number of participating female pharmacists was higher than male pharmacists probably because most of the men tend to travel outside of Egypt after earning their BSc. Degree seeking higher income to support their families. National Fellowship Certificate & PhD degree programs necessitate acceptance criteria that are difficult to be met and tend to have lengthy course of studies. Greater effort needs to be directed towards increasing studies about applicability of several international competencies on clinical pharmacy practice in Egypt and also in other countries especially competencies concerning with system based care and what benefits can be reflected from this on patients' health-related quality of life. We must focus on weak points in clinical pharmacy practice in Egypt according to results of the study and make continuous follow up in cooperation with the Ministry of Health and Population. Results of the study can encourage other researchers in different countries to use ACCP competencies and other international competencies to evaluate clinical pharmacy practice in their institutions.

CONCLUSIONS

Egyptian pharmacists generally apply high percentage of ACCP competencies but the provided clinical pharmacy services need to be improved through applying the standards of best practice, particularly with respect to "Systems-based Care & Population Health" domain of ACCP competencies, for the purpose of delivering the best patient-care services in all hospitals in Egypt.

CONFLICT OF INTEREST

The authors declare not relevant conflicts of interest or financial relationships.

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Original Research

Pharmacists' practices for non-prescribed antibiotic dispensing in Mozambique

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Abstract

Background: Antibiotics are the most frequently used medicines worldwide with most of the countries defining these as prescription-only medicines. Though, dispensing non-prescribed antibiotics represent one of the chief causal factors to the irrational use of antibiotics that paves the way to the development of antimicrobial resistance.

Objective: We aimed at describing the practices and the enablers for non-prescribed antibiotic dispensing in Maputo city, Mozambique.

Methods: A qualitative study was conducted, between October 2018 and March 2019, in nine private pharmacies randomly selected across Maputo city. Eighteen pharmacists were contacted and seventeen enrolled through snowball sampling. In-depth interviews were conducted, audiotaped, and transcribed verbatim. Transcripts were coded and analysed though thematic analysis with guidelines from Braun and Clark. The Consolidated Criteria for Reporting Qualitative Studies (COREQ) checklist by (Tong, 2007) was performed.

Results: Out of seventeen, fifteen pharmacists admitted non-prescribed dispensing of antibiotics. Common antibiotic dispensing practices included; dispensing without prescription, without asking for a brief clinical history of patients, without clear explanation of the appropriate way of administering, without advising on the side effects. Reasons for non-prescribed antibiotic dispensing are linked to patients' behaviour of demanding for non-prescribed antibiotics, to the patients expectations and beliefs on the healing power of antibiotics, to the physicians' prescribing practices. Other reasons included the pressure for profits from the pharmacy owners, the fragile law enforcement, and absence of accountability mechanisms.

Conclusions: The practices of non-prescribed antibiotic dispensing characterize the 'daily life' of the pharmacists. On the one hand, the patient's demand for antibiotics without valid prescriptions, and pharmacist's wish to assist based on their role in the pharmacy, the pressure for profits and on the understanding of the larger forces driving the practices of self-medication with antibiotics - rock. On the other hand, pharmacists are aware of the legal status of antibiotics and the public health consequences of their inappropriate dispensing practices and their professional and ethical responsibility for upholding the law - hard place. Highlighting the role of pharmacists and their skills as health promotion professionals is needed to optimizing antibiotic dispensing and better conservancy in Mozambique.

Keywords

Anti-Bacterial Agents; Self Medication; Prescriptions; Pharmacists; Professional Practice; Pharmacies; Drug Resistance, Bacterial; Motivation; Law Enforcement; Public Health; Qualitative Research; Mozambique

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INTRODUCTION

The growth of antimicrobial resistance has prompted calls to reduce unnecessary antibiotic use, improving treatment protocols to maximize the lifespan of these drugs.[1,2] In many countries including Mozambique, antibiotics are prescription-only-medicines.[3-6] Though, antibiotics are frequently accessed without prescription mainly in resource-constrained settings, paving the way to the practices of self-medication with antibiotics.[7-9] These practices result from a complex interaction between several factors notably; health care providers' prescribing practices, pharmacists' dispensing practices, health care facilities' conditions, individuals' and communities' beliefs on the healing power of antibiotics, health-seeking behaviours, individual responsibility for one's own health, patients' expectations, previous experience with antibiotics, and individuals' self-care practices.[5,7,8,10-13] Nonetheless, incorrect diagnosis, incorrect therapeutic choice, inappropriate drug and dose selections, and insufficient treatment duration, frequently accompanied the non-prescribed utilization of antibiotics adding risks to individuals' health.[4,5,7,14,15]

The World Health Organization (WHO) recognizes the inappropriate use of antibiotics as an important driving force behind the rise of antimicrobial resistance rates both at hospital and community levels especially within the low and middle-income countries (LMICs), were the burden of infectious disease is high.[9,11] Moreover, evidence of the magnitude of inappropriate use of antibiotics in human health and the subsequent increase in antimicrobial resistance are well documented.[4,18-27] According to the WHO, it has been estimated that more than 50% of the antibiotics worldwide are sold without medical prescription.[9,28] In addition, high resistance rates are noted in communities where antibiotic sales without prescription are common practices.[6]

Pharmacies often serve as the first and the last point of contact for the patients in the healthcare-seeking chain.[26] The expansion of the pharmaceutical industry globally has led to the rapid growth of pharmacies in urban and peri-urban areas of many resource-constrained countries.[25,26,29] While this expansion provides previously underserved populations with access to professional advice and

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medicines, at these pharmacies, medicine sales are largely driven by the aggressive marketing of pharmaceutical companies offering attractive incentive schemes, bonuses, and gifts for increased sales.[29] Pharmacists are ideally positioned as front line health care providers to limit indiscriminate antibiotic use and promote safe and effective administration of these medications.[30] The public practices of self-medication with antibiotics and the pharmacists' practices of non-prescribed antibiotic dispensing has been extensively investigated all over the world.[1,5,6,10,13,16,17,26,31-47] Unfortunately, evidence report that the practices of self-medication and the inappropriate utilization of antibiotics are in the majority of the cases, connected to the pharmacists' frequent and unsuitable antibiotics dispensing practices, to the weak compliance and the fragile law enforcements.[16,17,30,40,48,49]

Published evidence suggests inappropriate dispensing practices with the public frequently acquiring non-prescribed antibiotics from the private pharmacies.[11,50-52] While the pharmacist's compliance and their appropriate dispensing practices are vital to enable the suitable utilization of antibiotics amongst the public, studies documenting antibiotic dispensing practices are to date non-existent in the Mozambican context.

The use of a qualitative analytic approach to describe the practices and reasons for non-prescribed antibiotic dispensing by pharmacists provides a first-hand and frank account of the drivers underlying this practice. An evidence-based understanding of pharmacists' practices and enablers will contribute to the development of appropriate public health interventions. These evidence are also relevant for closing the gap between what pharmacists know they should be doing concerning prescription-only medicines and the non-prescribed antibiotic dispensing practices dynamics and reality. This study thus, aimed at describing the practices and the enablers for non-prescribed antibiotic dispensing by the pharmacists in Maputo city, Mozambique.

METHODS

Study design and setting

A descriptive qualitative study was conducted to develop an understanding of the practices of non-prescribed antibiotic dispensing among pharmacists working in private pharmacies in different socioeconomic areas of Maputo city, the capital of Mozambique. Only private pharmacies in Maputo city were included since the public pharmacies are run by state-related entities that strictly enforce prescription-only dispensing of antibiotics. Private pharmacies are registered within the Ministry of Health, are owned by individuals with a license to run the pharmacy and dispense medicines. The National Direction of Pharmacy at the Ministry of Health provided a list that indicated that by September 2018, there were registered 451 private pharmacies, 150 of which based in Maputo city. Registered private pharmacies were categorized according to the socioeconomic status (high, middle, and low) of their location (area) in the city. Using the Excel random number function three pharmacies were randomly selected from each socioeconomic area (n=9).

Study participants

In this study, we purposively enrolled pharmacists provided they were working in one of the Maputo city private pharmacies for at least twelve months before the study. The room/office was private enough to guarantee a conversation without any interruptions. In Mozambique, pharmacists are entitled to a variety of pharmaceutical activities from the preparation and supply to the distribution of medicines, chemicals, and dietary products. Pharmacists are also entitled to dispense and deliver prescription-only drugs; verify the authenticity of prescriptions and advise patients regarding the safe and storage of medicines, potential drug interactions, the side effects, and management of pharmacies.[57] In this study, we adopted the term pharmacist to refer to the pharmacy professionals, their enrolment was based on the fact that they were working in Maputo city private pharmacies for at least twelve months before the study.

Study sampling and recruitment methods

A modified snowball sampling technique was employed to recruit pharmacists. The first three pharmacists from each socioeconomic area were recruited by telephone based on the information provided by the National Direction of Pharmacy. We then asked each pharmacist to identify at least two other pharmacists working in the identified pharmacies. We contacted eighteen pharmacists in total, seventeen of whom agreed to participate and were enrolled provided they were not the owners of the pharmacies and not member of the pharmacy board. This was to ensure that enrolled pharmacists were working directly with the public directly dispensing various pharmaceutical products and antibiotics with or without prescriptions.

Ethics approval

Written informed consent was read and signed by participants before starting the interview. Participants also signed the informed consent to audio record the interviews. Although we used names to identify and then contact pharmacists, their names, the names and the address of the pharmacies they worked in, were concealed to guarantee confidentiality and anonymity. Pharmacists were assured that no data leading to their identification or place of work would be published in any form. Ethical clearance was sought and obtained both at the University of KwaZulu-Natal and the National Bioethics Health Committee of Mozambique under the numbers HSS/0142/08D and 376/CNBS/18, respectively.

Data collection process and study tools

The primary data collection method used in this study was face-to-face semi-structured interviewing with open-ended questions. Semi-structured interviewing has defined goals and guidelines to enable systematic data collection while offering flexibility to change the sequences of the questions. The interview guide was based on the objectives of the study and consisted on demographic information (e.g. age, gender, years of professional experience). It also included questions regarding dispensing practices and reasons for non-prescribed antibiotic dispensing, the perceptions of pharmacists regarding patients' attitudes

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and behaviours towards antibiotics use, compliance with the regulations and guidelines for antibiotic dispensing and the pharmacists suggestions to improve the current scenario. The interview guide included a definition of self-medication with antibiotics. Self-medication with antibiotics was defined as the circumstances wherein the customer requests, purchases, and administers an antibiotic without prescription to themselves or a child. Two focus group discussion sessions were planned for this study, however of the 17 enrolled, 15 pharmacists refused to participate in the focus group fearing reprisals and losing the job post at the pharmacy. Only two pharmacists consented to participate in the focus groups. Consequently, this data gathering method was dropped off due to the limited number of participants.

Since 11 pharmacists were simultaneously working in public and private pharmacies (performing day shift in public hospital or health care centre pharmacy and night and weekend shifts in the private pharmacy), interviews sessions occurred in private rooms of the public health facilities in a day and time identified by the pharmacists. The remaining six interviews of the pharmacists working exclusively for private pharmacies, occurred in a private room arranged by the researcher (upon agreement with the participant) provided the best time for the pharmacists. None of the interviews sessions occurred at the private pharmacy where the pharmacist worked, since pharmacists feared reprisals from the pharmacy owners. The room/office chosen either by the pharmacists or by the researcher was private, all the interviews settings were calm and appropriated, with interviews occurring between 16.30 p.m. and 18 p.m., after day labour hours (7.30 a.m. - to 15.30 p.m.). A small thank you gift of a USB drive (costing approximately 25 USD) was given to participants at the end of the interview session. Interview lasted between 15 to 38 minutes. Saturation, which was determined by the redundancy of data, occurred after 13 in-depth interviews; nevertheless, we continued with the remaining four interviews due to the already scheduled interviews and participants' availability and willing to participate. These interviews also served to confirm the saturation.

Data management and analysis

The in-depth interviews were audio-recorded in Portuguese, transcribed verbatim, and translated into English. The transcriptions were subsequently checked against the audios by the interviewer. To check the accuracy of the translation, two randomly selected records were translated and then back-translated into Portuguese by a bi-lingual researcher. Data were analysed using thematic analysis, a method of analysis that aims to identify analyse and report repeated patterns of meaning (or "themes") within a data set.[59] A constant comparison approach was used with researchers reviewing and taking notes at the end of each interview session. The first two authors read and familiarised themselves with the transcripts and coded independently and later discussed the codes. Following the discussion of the codes, the first author summarized the first two authors' codes and shared with the second and third author for further discussions and agreements. During coding, a selection of transcripts was read line by line, and initial labels or 'codes' applied to each passage that described the essential meaning of the data within. The coding tree included the main questions, the answers of participants, and the extracted themes and subthemes. This process allowed for the identification of potential themes that the researcher had not yet captured at the same time that tackled the validity of the codes.

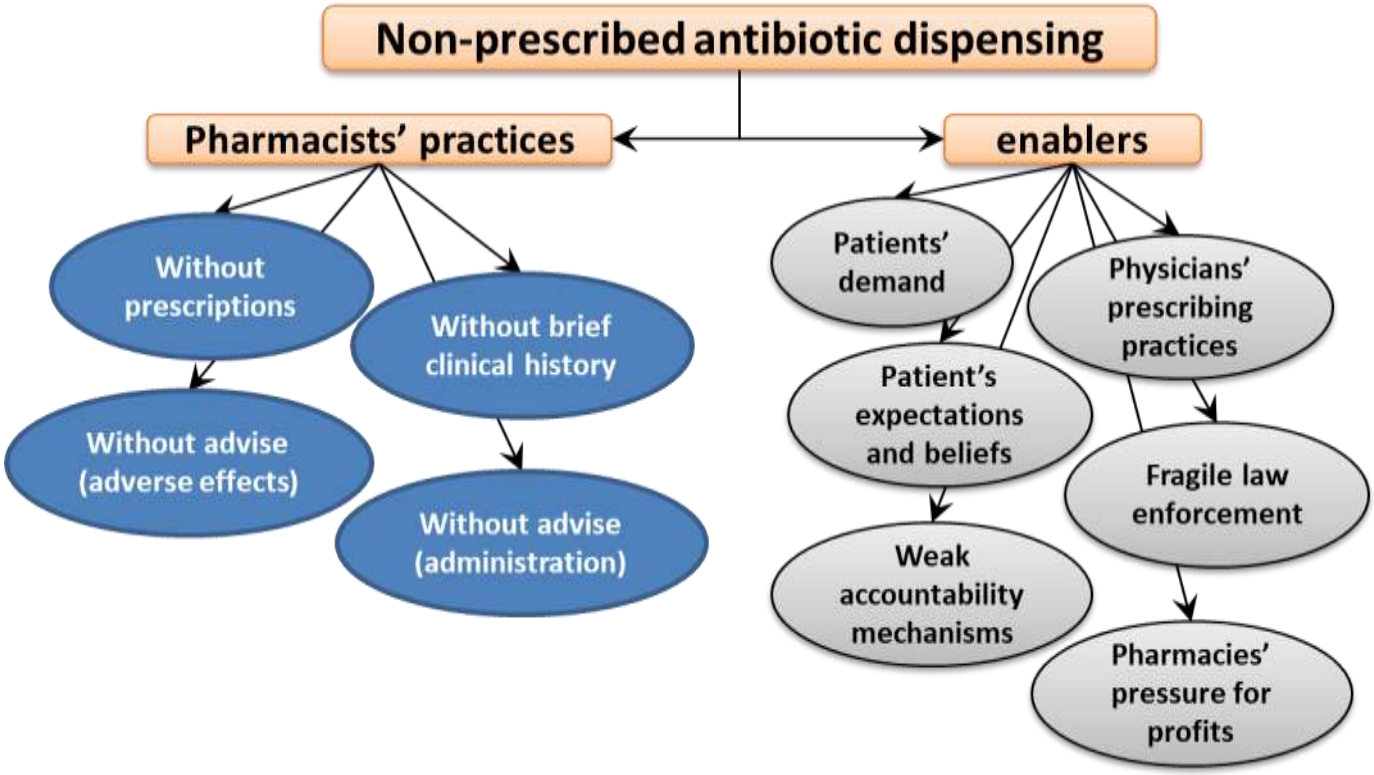

Figure 1. Non-prescribed antibiotic dispensing

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The guidelines outlined by Braun and Clarke were the basis for performing the thematic analyses as a flexible technique that enabled the researcher to determine themes in several ways. Braun and Clarke guidelines follow the steps below; I) familiarising with the data; ii) generating initial codes; iii) searching for themes; iv) reviewing themes; v) defining and naming themes; and vi) producing the report.[59,61] NVivo version 12 was used to store and retrieve the data.

Reflexivity is vital to promote the honesty and transparency of the research process aiming at improving the quality of research, therefore, we used a reflection diary and a constant process of self-awareness and self-reflection. Prior to the data collection sections, the researchers and research assistants undertook refreshing training in qualitative data collection and consulted the study advisor/supervisor before and after each data collection stage and during the analysis of the data. The Consolidated Criteria for Reporting Qualitative Research COREQ-Tong (2007) was performed.

RESULTS

The results of the study are presented below with sociodemographic characteristics of the participants followed by the themes and subthemes emerged, and the most relevant quote from participants. A summarized figure with the practices and reasons for non-prescribed antibiotic dispensing is presented (Figure 1).

Table 1 shows the sociodemographic characteristics of the interviewed pharmacists with variation in age, gender and years of professional experience. The pharmacists' main age was 36 years old, with the majority being male (n=11) and more than half of the pharmacists having between five to fifteen years of professional experience.

Non-prescribed antibiotic dispensing and the practice of self-medication

All pharmacists defined self-medication with antibiotics correctly and considered themselves well informed about the country's legal status of prescription-only medicines. All expressed their dispensing practices were not always optimal and were aware of the risks of dispensing prescription-only medicines without a prescription. However, two pharmacists reported seeing colleagues dispensing without prescription but did not admit themselves endorsing non-prescribed antibiotic dispensing even in the face of potential sanction from pharmacy owners:

> "I don't dispense prescription-only medicines without prescriptions in any circumstances, that's why I'm always changing the pharmacy. Some owners don't appreciate that." (Pharmacist 3).

> " If no prescription is seen, I don't dispense. I'm old school, in a normal situation you and the pharmacy should be fined." (Pharmacist 5).

In contrast, fifteen pharmacists admitted dispensing antibiotics without prescription. These pharmacists stressed self-medication with antibiotic is a common practice with people frequently requesting non-prescribed antibiotics:

> "(…) nowadays it is impressive, in 10 clients, you only find 3 with prescriptions…the pharmacy is like a supermarket at some point (laughs)" (Pharmacist 1).

> "We frequently sell analgesics, antibiotics, and antihistamines, every single day we sell the majority without prescriptions…let me say in four clients only one may handle the prescription." (Pharmacists 2).

One pharmacist mentioned what he called a "never seen before" era of intense antibiotic consumption with patients and physicians, requesting and prescribing a lot of antibiotics respectively:

> "I regret to say this (silence) I'm almost 12 years' experience working with pharmacies and I've never experienced these high levels of self-medication practices. Anti-inflammatory and antibiotics are too much used nowadays, people can buy 5 or 10 tablets for one or 3 days. Doctors are also just prescribing antibiotics, seriously (lower voice)." (Pharmacist 9).

Pharmacist's self-perceived role at the pharmacy

The pharmacists stated their main role is dispensing medicines rationally and responsibly. Dispensing drugs was defined as consistently and responsibly preparing, packaging, labelling, recording, and transferring drugs to a patient or intermediary who is responsible for the administration of the drug.

Pharmacists described their roles primarily as more selling than dispensing drugs suggesting that in most cases, patients know what they want, and they hand over the medicines without asking for a prescription or for health information related to the medicine:

> "Well, I can say I'm more selling than dispensing medicines, the clients come, and request and I just give them what they want." (Pharmacist 11).

> " (…) the person comes to me and says I need cotrimoxazole, 20 tablets, there are no

Table 1. Socio-demographic characteristics of the pharmacists

Participants	Age	Gender	Professional experience
Pharmacist 1	24	Male	2 years
Pharmacist 2	36	Male	3 years
Pharmacist 3	39	Female	5 years
Pharmacist 4	38	Male	6 years
Pharmacist 5	45	Male	15 years
Pharmacist 6	43	Female	11 years
Pharmacist 7	24	Male	2 years
Pharmacist 8	36	Male	8 years
Pharmacist 9	35	Female	11 years
Pharmacist 10	38	Female	4 years
Pharmacist 11	24	Male	2 years
Pharmacist 12	25	Male	2 years
Pharmacist 13	45	Female	3 years
Pharmacist 14	47	Male	9 years
Pharmacist 15	37	Female	5 years
Pharmacist 16	33	Male	7 years
Pharmacist 17	37	Female	10 years

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prescriptions on his hands. Should I ask why or what for? (silent). I don't think so, people come to the pharmacy knowing very well what they want…" (Pharmacist 7).

Practices of non-prescribed antibiotic dispensing

Requesting for a valid prescription: Valid prescription was defined as the original script signed by the prescriber within not more than seven days. To access the practice of requesting valid prescriptions, pharmacists were presented the following probing question: If a customer comes to your pharmacy and requests a certain antibiotic what is the first question you ask and what do you do next? Of the seventeen pharmacists, two responded they would first request the doctor's prescription:

"First thing…clients need to show up the doctor's prescription... if I don't see I would ask for it and nothing else, would do without." (Pharmacist 3).

"Well, I need to ask about the doctors' paper (scripts) otherwise how should I know the type/class, quantity, dosage of that antibiotic?" (Pharmacist 5).

The majority of pharmacist said they would dispense the antibiotic after questioning the customer the following:

"I would ask what health problems the customer intends to deal with?" (Pharmacist 1).

"I would ask what age the patient is (…)" (Pharmacist 6).

"I ask what the antibiotic is for and dispense it " (Pharmacist 4).

"I would ask the quantity of the antibiotics, for how many days" (Pharmacist 8).

Instructing patients on the intake of the antibiotic and safety issues

We assessed non-prescribed antibiotic dispensing practices by questioning if pharmacists ask for a brief clinical history of the patients; if they instruct patients on how they should take the antibiotic; and if they counselled on safety-related information and on the importance of completing the course of antibiotics, two responded:

"…although I should do, I don't ask about allergy when clients come and request, I assume they know the antibiotic and have taken at least once." (Pharmacist 4).

"We don't pay attention to the customer, it works like this; the customer arrives and requests, pharmacist dispenses and full stop." (Pharmacist 8).

Why dispensing non-prescribed antibiotics?

Five subthemes emerged under this theme, namely; the customer's behaviour and beliefs on the curative power of antibiotics; the physicians' prescribing practices; the run for pharmacy profits, the law enforcement, and the accountability mechanisms.

Patients' behaviour and beliefs on the curative power of antibiotics: According to pharmacists, patients are increasingly using pharmacies as their first point of contact when seeking health care. This trend influences pharmacists dispensing practices particularly because, many patients believe "antibiotics cure everything". Questioned what they perceive as the main reasons for self-medication with antibiotics, pharmacists responded as illustrated:

"Clients' behaviour is something else, I don't know how to classify, people think they don't need doctors, the person has fever and cough or pain, comes to the pharmacy instead of going to the health care centre, there is a concerning behaviour of self-medication…" (Pharmacist 11).

"(…) for cough, people want antibiotics, for pain somewhere, antibiotics, toothache, antibiotics, they believe antibiotics cure everything!" (Pharmacist 8).

Physicians' prescribing practices: Some pharmacists believe, by frequently prescribing the same or similar antibiotics for different health conditions and for different patients, physicians are influencing patients' decisions to by-pass medical services and indulge in self-medication with antibiotics. Because patients tend to share experiences with others, according to pharmacists, physicians practices may lead patients to make use of the medical information and think they could always use these antibiotics for any other self-diagnosed diseases and directly request these non-prescribed antibiotics from the pharmacies. Additionally, pharmacists believe physicians are over prescribing antibiotics:

"People share information of health experiences, medications and even prescriptions, I think they pay attention to what has been prescribed, what cured this or that and later they make use of that information". (Pharmacist 17).

"Nowadays doctors and nurses just prescribe antibiotics, for anything even viral infections they send patients to by amoxicillin, a sore throat, azithromycin, for a simple cough, cotrimoxazole. It is now trending or fancy prescribing these things. I'm not sure they all need antibiotic treatment and most of the time very potent ones" (Pharmacist 3).

The run for pharmacy profits: The respondents stressed concerns regarding the pharmacy owner's pressure and demand for profits added to their own need for a salary income as an influencing factor for non-prescribed antibiotic dispensing practices. Pharmacists reported some of their employers give attractive incentives to the pharmacist selling the most medicines per month which is contrary to the optimal dispensing practice guidelines:

" Antibiotics are the most sold medicines, so there is no point in working in a pharmacy and not selling antibiotics without prescription, you end up fired. The owner wants profits and I need the salary." (Pharmacist 16).

" If you don't sell antibiotics, analgesics, and anti-inflammatory drugs, you are doing nothing, I have

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> colleagues who earn selling bonus of over their salaries because they made profits. The first thing the owner says when you are offered the job vacancy: here we sell medicines, so make sure you sell…they want profits just that, we need job." (Pharmacist 8).

Law enforcement and accountability mechanisms: Although participants admitted their dispensing practices are suboptimal, they believed the problem would be easily solved if compliance and accountability measures were enforced. This, according to the participants, would educate owners, pharmacists, and clients regarding the optimal use and would slowly eradicate the practices of self-medication with antibiotic and non-prescribed antibiotic dispensing. Two participants suggested:

> "Health authorities should visit pharmacies more often and see what is happening around us, if only one or two owners receive a huge fine by the authorities this would be known by others and would stop. I think authorities must do this." (Pharmacist 10).

> "We, pharmacists, know all the consequences of non-prescribed antibiotic dispensing, we know. But when you get to the position at the pharmacy as a magic trick you tend to forget all in the name of the owner's profits and to protect your month-end and job post." (Pharmacist 6).

Pharmacists suggestions for improving the rational use of antibiotics

Challenge the culture of self-medication, raise awareness and educate patients: Enforcing compliance to the standard guidelines dispensing antibiotics at the pharmacy level is a priority action for changing the culture of self-medication, according to the pharmacists. One stated:

> "People should be told and educated that the pharmacist is not a doctor and a pharmacy is not a health care centre, maybe it would be good to explain to them our roles in the pharmacy, so they stop pressing us and change behaviour." (Pharmacist 7).

One pharmacist also stressed the need to start education at the household level considering the strong influence family members have in the health-seeking behaviour:

> " educating people on what is a pharmacy, how to use medicines properly, when to go to a pharmacy, this should start at home, with the family"(Pharmacist 12).

Strengthen law enforcement and control: Enforcing the law and control the level of guidelines compliance are necessary to ensure medicines are dispensed for health benefits and not exclusively for pharmacy profits. Pharmacists added that consistent and persistent law enforcement and accountability measures would prevent pressure and irrational dispensing. The quote below illustrates:

> " We know the inspection is there, people are there for this work, but I don't see them working properly, they should be consistent to implement the law and sue non-complaints owners with expensive fees." (Pharmacist 10).

Establish a Pharmacy Profession Association: The interviewed pharmacists were not aware of the existence of the Pharmacist's Professional Association in country, which participants regarded as a gap for better address the profession challenges and maximize the skills. For the majority of pharmacists, the establishment of a Pharmacy Professionals Association would be beneficial to organize the collective voice in calling for implementation of standard guidelines addressing the multiple issues regarding medicine use including non-prescribed antibiotic dispensing and indirectly, the profit margin pursuit of some pharmacy owners. Two pharmacists said:

> "We need to be more organized as pharmacy professionals, only this would help us addressing the challenges and barriers we face during activities". (Pharmacist 9).

> "(…) If there was an association among pharmacy professionals, the pharmacy owner would behave better, that would work as a controlling body that protects the professionals." (Pharmacist 12).

Pharmacy and pharmacists awareness activities: As a platform to promote the work, skills and roles of pharmacists and emphasise the role and importance of this service in the health care chain, some pharmacists suggested having an annual pharmacy awareness week. This would demonstrate a variety of activities focused on highlighting the positive role of pharmacists, improving prescribing practices, and promoting the rational use of medicines among prescribers, patients, and pharmacists:

> " If we could just have one month or a week annually for celebrating the pharmacists and having those health fairs to raise awareness and educate more people including doctors to understand the need to prescribe properly, that would be good, people would also get to know our roles…"(Pharmacist 8).

> " I see this situation improving, like if we had a national pharmacy awareness week or one day with a lot of campaigns focused on the community but also the prescribers and the pharmacists themselves. Without an professional association to fight for this, it can be complex, I'm not saying impossible, but this would work better if we put it as an association" (Pharmacist 17).

DISCUSSION

While high-income countries are moving towards a more controlled antibiotic and medicine use, some low-income countries may be moving in the opposite direction. This study sought to describe the practices and reasons for non-prescribed antibiotic dispensing by pharmacists from private pharmacies in Maputo city using a qualitative approach and insight from the pharmacists themselves. Unsuitable dispensing of antibiotics poses an urgent public health threat especially for the resource constrained countries where fragile health care systems are faced with

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high burden of infectious diseases that need antibiotics to be rationally used and available.

Studies have reported the non-prescription sale and utilization of antibiotics as one of the major reasons for increasing irrational antibiotic consumption which paves the way to the emergence of antimicrobial resistance.[26,56,62-64] Mozambican health authorities and partners have emphasized the urgent need for better use of antibiotics at all levels to reduce inappropriate antibiotic consumption and contain antimicrobial resistance.[3] To date, research investigating pharmacists' non-prescribed antibiotic dispensing practices in Mozambique is non-existent. The findings will contribute to generating evidence-based information to help developing appropriate interventions to mitigate the practices of self-medication with antibiotics and of dispensing of prescription-only medicine such as antibiotics, without professional oversight.

Pharmacists' non-prescribed antibiotic dispensing practices

The pharmacists in this study could not deny their non-prescribed antibiotic dispensing as "daily practices". Also the illegality of the practice is well acknowledged, however, these non-prescribed antibiotics dispensing practices are at the same time suggestive of a high-pitched magnitude of self-medication with antibiotics. In other settings, pharmacists that admitted their illegal and irresponsible dispensing practices of antibiotics were noticed.[16,17,25,26,37]

Despite being the first and last point of contact in the health-seeking chain, pharmacists perceived their role as primarily drug sellers than drug dispensers, with a limited health advisory role. To this is added the fact that the advisory role regarding the safety of antibiotics was absent in most of the non-prescribed antibiotic dispensing events, leaving patients purchasing these medicines at their own risks. When not requesting for a valid antibiotic prescription, not explaining the side effects and all the relevant information regarding the antibiotic being purchased, pharmacists' found themselves practicing more as sellers of drugs than as drug dispensers health care professionals. This suggests poor dispensing practices which may determine the underestimation of the pharmacy profession.

According to Fang *et al*., (2013), in high-income countries the status of pharmacists are well established and pharmacy health care services are considered integral to health care chain.[65] On the other hand, Azhar *et al*., (2009), pointed to the emergent status of the pharmacist in LMICs, where their roles are limited to drug manufacturing, procurement, dispensing and storage.[66] In addition, pharmacists in LMICs have a minimal involvement in providing patient care related services and in promoting initiatives related to rational use of medicines, promoting self-testing and monitoring health, such as rapid testing malaria and other non-communicable diseases and quick point of care diagnosis for chronic diseases, for example.[67,68]

As pharmacists regarded themselves as mere drug sellers and dispensers, the opportunity should be grasped to include pharmacists in designing refreshing trainings, health promotion fairs, counselling events, awareness day or week, and campaigns towards emphasizing the need to rationally use the medicines, promote the image of pharmacists and their role in the health care chain. These actions would contribute to retell the pharmacist's roles in promoting the adequate use of antibiotics and influence behaviour change either at the community or at the health care system level. Furthermore, studies have shown positive impact and significant improvement in the quality use of antibiotics with the inclusion of pharmacists in different health promotion activities and health care settings of middle and high- income countries.[69-71]

Pharmacists non-prescribed antibiotic dispensing enablers

Pharmacy clients' behaviour

Rodrigues (2020), has disclosed that self-medication with antibiotics are practices that do not always follow biomedical recommendations of rational use, rather, individuals are actively engaged in therapeutic processes, that emphasises self-reliance and individual responsibility for one's own health.[5] Furthermore, authors have pointed out that self-medication practices are entrenched not only to the individual's previous successful experiences with antibiotics but also to the interplay of the knowledge and expectations of prescribers and patients, and to the individuals and public beliefs on the healing power of antibiotics.[12,13,23,31,32,72-74] However, studies also suggested the behaviour behind the practices of seeking non-prescribed antibiotics are also influenced by the characteristics of the health care system and by the pharmacy regulatory environment.[9,28] These experiences are then part of the process of social construction of the health care centre, the pharmacy, the pharmacists, the medicines and antibiotics in particular, knowledge which are shared with the people from the social group (family members, neighbours, and friends). Previous studies have reported how participants have taken advantage of previous experiences, past prescriptions and leftovers antibiotics to self-treat new sickness events.[5,7,31,47,75] These two factors – the use of medical information and or knowledge gained from past sickness events and the sharing of medical and health information among individuals and groups – pave the way to expand the practices of self-treatment of self-diagnosed diseases which is largely done by approaching the pharmacy and request/purchase antibiotics previously used rather than consulting a physician.

This set of factors affect individual's intention, attitudes and behaviours driving their demand for non-prescribed antibiotics. It is therefore, important to contextually examine the sociocultural, economic and political contingencies that may influence the needs for antibiotics by consider the individual's rationales as integrant part of the solution.[5] Also, engage with all different enablers and actors to tackle the behaviour and the misconceptions about antibiotics by illustrating the disadvantages, the risks and the consequences of self-medication with antibiotics and educate pharmacy clients to improve antibiotic use could be useful.

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Physicians' prescribing practices

Pharmacists in this study believe physicians' prescribing practices influence and contribute to increase self-medication with antibiotics. These prescribing practices include - overprescribing and or frequently prescribing the same antibiotics for different health conditions, quick antibiotic prescribing, blind or needless prescribing, poor communication with patients regarding the prescribed antibiotic and its side effects. Although published evidence regarding antibiotic prescription rates and patterns for outpatients in Mozambique are scarce. One unpublished study by Mamade *et al*., (2019) shows suboptimal oral antibiotics prescription with high proportion of antibiotics such us amoxicillin, cotrimoxazole and metronidazole being prescribed for outpatients in Maputo Central Hospital.[76] While studies have reported inappropriate and high rates of antibiotic prescription in other settings evidence shows that the most prescribed antibiotics are at the same time, the most requested non-prescribed antibiotics, with antibiotics such amoxicillin, amoxicillin with clavulanic acid, metronidazole and cotrimoxazole being in the top of the list.[5,48,79,80] The patients' expectations for antibiotics prescriptions are one of the causes of pressure for physicians to prescribe.[77] Pharmacists, therefore, criticise the physicians for contributing to strengthen the public belief that antibiotics are effective and quick to treat all diseases.[23] Moreover, because medicines are seem as commodities and precious goods, and patients are not active recipients of health care, the individual's adjust, make considerations and use the accumulated and constructed health information gained thanks to their experiences and their interactions with previously prescribed or used medicines, with health care providers and prescribers.[5,31,79] Patients tend to recall the bad or good previous experiences with sickness events, the healing process, the therapeutic itinerary adopted and the prescribed medications and their sources to socially construct the need for antibiotic and or make decision to demand for it. Despite studies reporting the huge pressure physicians receive from patients to prescribe antibiotics, strategies to involve physicians and warn about the patients expectations for antibiotics are needed. Additionally, physicians should be alerted to be more vigilant to their prescribing practices, giving specially attention and explanation to the patients, mainly those in needs for antibiotic prescriptions, explaining and clarifying the utility, the effect on that specific health condition healing process, the side effects and the care patients ought to have while using the prescribed antibiotic. These actions together would be useful to discourage patients to misuse the health information and control their expectations for antibiotic prescriptions.

Pharmacies' run for profits

Consistent with previous studies, our study findings reveal the influence of the proliferation of pharmacies and inter-pharmacy competitiveness on the irrational dispensing of antibiotics.[16,26] The run for profits linked to the aggressive marketing strategies with incentives for pharmacists to increase the sales and the pressure to meet financial targets contributes to the suboptimal and unethical antibiotic dispensing within the pharmacies. To this is added the absence of robust law enforcement and accountability mechanisms to penalize the non-compliant pharmacies and pharmacists. The patients, therefore, have no difficulties accessing and requesting non-prescribed antibiotic. A study conducted in Nigeria reported limited controls on the sales or advertisement of antibiotics that created opportunities for misinformation and misperceptions on the antibiotic utilization and conservancy which exacerbated improper antibiotic use.[54] In Mozambique, the proliferation of pharmacists within the city and suburbs is noticeable, leading to competition and to poor practices of dispensing medicines and antibiotics.[3] Multi-layer robust law enforcement that targets pharmacists and pharmacies by prosecuting, punishing, and finning the non-compliant pharmacists added to the cancellation of the registration and operation license would be useful. Implementing these measures would highly contribute to discourage non-prescribed antibiotic dispensing and enabling good dispensing practices concomitant to discouraging self-medication with antibiotics.

Pharmacists' suggestions to improve the scenario

Towards the improvement of the situation, pharmacists suggested interventions at three levels namely:

1) at the pharmacy profession level

The Pharmacy Professional Association in Mozambique was officially created in December 2014, and the first national conference only happened in November 2018. However, at the time of this study, very little dissemination, awareness and other activities regarding this association had happened so far. This may be the reason interviewed pharmacists were not aware of the existence of the organization, therefore, the participants advocated for the establishment of a Pharmacy Professional Association to champion their collective professional interests and provide a national platform for addressing the multiple challenges and dilemmas pharmacists face in their duties, particularly regarding the dispensing practices. Increasing the professional association visibility and activities among the pharmacists would be helpful to be aware of the dynamics of the profession and effectively address the challenges pharmacists face. Additionally, the study participants are aware of the existence of the world antibiotic awareness week in November every year, where a global campaign aimed at increasing awareness of antibiotic resistance and to encourage best practices among the general public, health workers and policy makers. However, the establishment of a national annual pharmacy awareness week or day, with a variety of activities focused on highlighting the positive role of pharmacists, improving prescribing practices, and promoting the rational use of medicines among prescribers, patients' and pharmacists were suggested as a platform towards appropriate antibiotic use and conservancy. Concordant findings were reported in India, in study where pharmacists considered the institution of an awareness day as a good attempt to improve knowledge.[26]

2) at the policy level

The participants believe health authorities, law enforcement institutions, policy makers and pressure

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groups ought to work together to improve supervision, monitor and publicly apply heavy penalties to non-compliant pharmacies and pharmacists to discourage the practice. In Mozambique prescription-only medicines regulations and guidelines are embedded in the Drug Law number 12/2017. Despite establishing penalties for the non-complaints, to date no strong penalties were publicly applied to pharmacies dispensing prescription-only medicines. This may explain why, no pharmacy has been penalised for non-prescription antibiotic dispensing. Publicly applied penalties would have an impact on decreasing the non-prescription dispensing of antibiotics and other prescription-only medicines. Moreover, studies in other countries have shown that implementation of enforcement measures guided by the existing laws and guidelines for prescribing and dispensing antibiotics has led to a decrease in over consumption of antibiotics.[70,80-82]

3) at community level

Pharmacists advocate for public health and health promotion professionals to constantly raise awareness and intensively highlight the risks and consequences of practicing self-medication by tackling the knowledge gaps and the misapprehensions, while increasing awareness campaigns motivating the community to monitor and report the non-compliant pharmacists/pharmacies. Interventions targeted at enhancing behaviour are more likely to be effective. However, for health policies to be more effective and acceptable, strategies to raise awareness and promote the better use of health care services should consider health-seeking behaviour and its social, economic and political determinants as an integrant parts of the prevention, treatment and healing process.

Finally, this study sheds light on significant issues to be addressed in order to enhance the appropriate utilization of antibiotics. Concordant with Al-Kubaisi *et al*., (2018) the study has revealed that the weak knowledge, the expectations and misapprehensions of antibiotics by the public are enhanced in patients by both the pharmacists who dispense antibiotics without prescriptions and by the physicians who quickly and blindly prescribe antibiotics to their patients.[13] While increasing awareness regarding the appropriate antibiotic use and conservancy among pharmacy clients' and communities is paramount, elevating the advisory role of the pharmacist in delivering patient-centred services of health promotion, infection control, prudent antibiotic utilization, and nutrition are important health education strategies for better antibiotic utilization and conservancy in Mozambique.[65,67]

Limitations

This study presents a comprehensive summary of the phenomena of non-prescribed antibiotic dispensing practices in Maputo city, Mozambique. Notwithstanding the inclusion of pharmacies from the three socio-economic areas of the city, the sample size of pharmacies and pharmacists represents a limitation since the findings of this study are not representative of all pharmacies and pharmacists in the city. Additionally, having some participants giving short answers, feeling embarrassed and skipping questions of the interview guide constituted another study limitation as it reduced the response rate. Moreover, the tools of this study could be improved if focus group discussions with pharmacists could be performed to capture the opinions of pharmacists in a group and compare them to the ones from the individual interviews. Further research involving larger samples, qualitative, ethnographic, observational, and quantitative studies concerning the dispensing practices, the barriers for better compliance and challenges pharmacists face would provide an expanded knowledge base for the development of interventions for a national roll-out.

CONCLUSIONS

This study revealed knowledge regarding the non-prescribed antibiotic dispensing practices and enablers within the private pharmacies in Maputo city. Antibiotic dispensing was widespread with precarious, unsafe, irresponsible, suboptimal, and unethical practices. Pharmacists are troubled by non-prescribed antibiotic and self-medication practices, perceiving themselves as being caught between the rock and a hard place. On the one hand, the patient's requests for antibiotics without valid prescriptions, and pharmacists' desire to assist based on their role in the pharmacy, the pressure for profits and an understanding of the larger forces driving the practices of self-medication with antibiotics - rock. On the other hand, pharmacists' knowledge of the legal status of antibiotics and the public health consequences of their inappropriate dispensing and their professional and ethical responsibility for upholding this law - hard place. Understanding the dynamics and the complex nuances associated with self-medication with antibiotics of patients and the non-prescribed antibiotic dispensing practices of pharmacists is relevant to generate evidence-based information. These would be useful for designing impactful and contextual strategies towards strengthening health promotion and awareness-raising towards antibiotic stewardship and conservancy in-country. Also, a top-down approach from the regulators is needed to ameliorate the run for profits from the pharmacy owners, removing pressure and enhancing good dispensing practices of pharmacists and discouraging non-compliant pharmacists.

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CONFLICT OF INTEREST

The authors declare that they have no competing interests.

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Original Research

Exploring discrimination towards pharmacists in practice settings

Lik De CHUN, Rebecca YE, Kyle J. WILBY.
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Abstract

Background: Discrimination towards pharmacists, as a public-facing health professional group, is reported but not well-studied.
Objectives: The aims of this study were to identify accounts of discrimination in pharmacy practice and to explore the nature and impacts of and discrimination experienced by pharmacists.
Methods: A cross-sectional survey was emailed to practice-based preceptors associated with the School of Pharmacy at the University of Otago. The survey included demographic questions, in addition to questions asking about the frequency and sources of different types of discrimination and abuse encountered in practice. Survey respondents could also provide their contact information for follow-up interviews. Interviews occurred after completion of the survey to better understand the nature of discrimination in pharmacy practice. A thematic analysis of interview transcripts was conducted to identify pertinent themes.
Results: A total of 43 participants completed the survey. A total of 29 (67.4%) respondents reported experiencing discrimination in pharmacy practice. The most common types of discrimination experienced included discrimination based on gender, appearance, or past, present, or expected pregnancy. Verbal abuse and sexual harassment were also frequently reported. Most discrimination was sourced from patients, colleagues, or supervisors/leaders. Discrimination specific to pregnancy was largely sourced from supervisors/leaders. Verbal abuse was sources primarily from patients, patient's family, supervisors/leaders, and other healthcare professionals. Patients were the primary source of sexual harassment. Three themes were identified from the interview phase: Discrimination occurs for a variety of reasons from different sources with different behaviors, the impact on a person is individualized/personal, and preventative strategies can be broad and encompass multiple layers of society.
Conclusions: Findings of this study support the notion that training programs must adjust to adequately train pharmacists with effective coping strategies, prevention mechanisms, and resilience building strategies. Pharmacist employers should also be accountable to creating zero tolerance workplaces and providing route maps for how pharmacists report and navigate situations when faced with discrimination. Doing so may result in a better equipped workforce that is able to navigate the pressures encountered through discrimination in practice.

Keywords

Pharmacists; Pharmacies; Workforce; Workplace; Sexual Harassment; Social Discrimination; Education, Pharmacy; Resilience, Psychological; Surveys and Questionnaires; Qualitative Research; New Zealand

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INTRODUCTION

Discrimination is defined as 'the unjust or prejudicial treatment of different categories of people, especially on the grounds of race, age, or sex'.[1] Discrimination towards health professionals may occur based on these factors but also others, including appearance, religion, sexuality, language, or disability.[2-5] It may also affect any professional group, even those that are not public facing. Pharmacists, as frontline care providers may be at increased risk, due to the unscheduled nature of interactions with patients and caregivers with whom they have no pre-existing relationship.[6,7] Student and training pharmacists may also be exposed during practice-based experiences from patients, other professionals, or even supervising evaluators.[8,9] Whether or not discrimination exists in pharmacy practice, any instance may have poor implications for pharmacist well-being and could consequently negatively impact patient care. Efforts must therefore be made to understand accounts of discrimination in pharmacy practice, in order to provide adequate training to promote development of practitioner resilience and well-being.

Despite the potential detrimental impacts of discrimination within the workplace, there is a paucity of literature attempting to describe the nature and extent of practice-based discrimination in pharmacy. There is also minimal literature describing discrimination within other health disciplines, such as medicine and nursing. Identified reports account for various aspects of discrimination, including told stories of racism, institutional racism, differences in employment opportunities based on cultural and ethnic factors, and discrimination against those actively or planning to become pregnant.[6,10] In pharmacy specifically, it appears that race may be a cause of discrimination that leads to unequal employment opportunities with respect to recruitment, retention, and progression in the UK.[6] There is also evidence of gender discrimination within the pharmacy profession, specifically for recruitment into leadership positions in Australia.[11] Although these are important considerations for the profession, there also needs to be exploration of practice-based discrimination that may occur on a day-to-day basis.

A recent study was published that reported discrimination, abuse, harassment, and burnout in surgical residency training.[12] This study surveyed 7,409 surgical residents in

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the United States and found high rates of discrimination directed towards this population. Greater than 30% reported discrimination based on self-identified gender, over 16% reported racial discrimination, 30% reported verbal and/or physical abuse, and 10% reported sexual harassment. Women reported all accounts at greater frequencies than men. The most common source of discrimination was patients and patients' families for gender and race. Attending physicians (e.g. supervising physician) were the greatest source of sexual harassment and abuse. The authors reported that burnout and resilience depletion was a major concern, with 38% of residents reporting burnout and 4.5% having suicidal thoughts within the past year. Authors call for the establishment of safer, more equitable, and more effective educational environments for these practitioners.[12]

Given the vulnerability of pharmacists as frontline care providers and the recent evidence of prejudice and discrimination within the medical profession, a study exploring instances of perceived discrimination in pharmacy practice is warranted. The aim of the study was therefore to identify accounts of perceived discrimination in pharmacy practice and if identified, to explore the nature and impacts of perceived discrimination experienced by pharmacists.

METHODS

This was an exploratory study that used mixed methods (survey and interviews). The study was based at the School of Pharmacy, University of Otago in Dunedin, New Zealand. In 2018, New Zealand had 3,787 registered practicing pharmacists.[13] The School of Pharmacy hosts a BPharm program that graduates approximately 130 students per year. Students complete a variety of on campus courses, as well as experiential training placements. During placements, students are matched to a practicing pharmacist preceptor who directs and monitors their experiential learning needs and outcomes. Using preceptors as the sampling frame, Phase 1 of this study sought to identify accounts of perceived discrimination experienced by practicing pharmacists and Phase 2 sought to better understand the nature, impact, and implications of these accounts.

Phase 1: Survey of practicing pharmacists

A survey was administered to practicing pharmacists in New Zealand to elicit reports of discrimination in practice. The survey consisted of a questionnaire that was adapted from Hu *et al*. (2019) reporting discrimination towards surgical residents.[11] In addition to the questions addressed from this study, we added questions (based on the literature review) relating to discrimination based on appearance, sexuality, religion, social skills, and English proficiency. We also adapted the sources of discrimination to reflect pharmacy practice. The questionnaire consisted of demographics and two matrices relating to discrimination and behaviors deemed to be associated with discrimination. Participants were informed that discrimination was defined as any perceived mistreatment due to gender, race, sexuality, religion, or other characteristics. The first matrix requested participants to state the frequency (never, a few times a year, a few times a month, a few times a week, every day, or other) of experiencing the type of discrimination or abusive behaviour listed directed towards themselves. Items to be considered included discrimination based on gender, race, sexuality, appearance, religion, English proficiency, social skills, or behaviours of physical abuse, verbal abuse, or sexual harassment. An item was also included for past, present, or expected pregnancy. The second matrix asked participants to select the source of discrimination or abuse for each item given above. Sources included none, patients, patient's family, colleague, other healthcare professional, supervisor/leader, or other. Participants were able to select multiple sources, if applicable. Participants were asked to optionally provide an email address if they were willing to participate in a follow-up interview to better understand their responses. The questionnaire was uploaded to Qualtrics for distribution to potential participants. It was piloted with two individuals who belonged to the target population but no changes were made. These responses were not included in the results.

The survey was administered to a sample of practicing pharmacists in New Zealand using a pharmacist preceptor database maintained by the School of Pharmacy. This database contained 247 email addresses of individuals and/or pharmacies in New Zealand. It was unknown, however, how many active emails were captured in the database. Pharmacists were encouraged to share with other colleagues that may be interested in completing the survey, via the introductory email. The purpose of the survey was to characterize discrimination but to also identify participants willing to be interviewed in Phase 2. The first page of the survey included information about the study, expectations, and informed participants that their participation was voluntary and they could withdraw from participating at any time. A reminder email was sent two weeks after sending the first email. The survey remained open for one month. No specific sample size was targeted due to the exploratory nature of the study (e.g. attempts to capture any report of discrimination in pharmacy practice). Survey responses were extracted to SPSS v. 25 and descriptive statistics were used to summarize results.

Phase 2: Respondent interviews

Participants who provided positive interest and contact information in Phase 1 for a follow-up interview were contacted via email. Interviews were conducted to better understand how participants experience the phenomenon of discrimination in practice. A discussion guide was developed to guide the interview and included questions intended to elicit the participant's narrative about the discrimination they had encountered in pharmacy practice. Investigators asked participants to recall any instance of discrimination they could remember experiencing in pharmacy practice. Then, questions were targeted to better understand the nature of such discrimination by asking questions related to the source of discrimination, how it was delivered (e.g., verbally, written), frequency, emotional impacts, and any actions or reactions provided by participants. All interviews were conducted by members of the investigator team. The lead researcher has extensive training and experience conducting interviews and trained

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the other two investigators himself. In addition to training, three pilot interviews were conducted with practicing pharmacists from the target sample and the full investigator team to receive feedback on the questions asked, as well as for feedback to be provided to all interviewers. Although no changes were made to the process or interview guide upon completion of the pilot, feedback was provided to interviewer with respect to question wording and probing for more information. All interviews (including pilots) were recorded.

Upon completion of the interviews, recordings were transcribed by one investigator and checked for errors by a second investigator. Full transcripts were provided to the full investigator team for coding. The senior researcher trained the other two investigators to code transcripts. Coding was conducted independently by all three investigators and was conducted via inductive, open-coding. This approach had investigators separate transcripts into words, sentences, or phrases that represented a single thought or idea. Each thought or idea was then given a unique identifying code. Once all coding was complete, investigators met to reconcile discrepancies and produce the final coding framework. Investigators then reviewed all codes collectively and began to categorize closely related codes based on similar meaning. After completion of this stage, investigators met to interpret themes from the categorized data.[14] Transcripts were then reviewed to search for confirming and disconfirming evidence in relation to each theme and representative quotes were extracted. All investigators agreed upon final themes and supporting data.

This study was approved by the University of Otago Human Ethics Committee on January 24, 2020 (D20/005).

Reflexivity

As this study was focused on a sensitive subject nature (e.g. discrimination), it is important to recognize the perspective of the authors interpreting the study results. Two authors are undergraduate pharmacy students and belong to ethnic minorities of Asian descent. Both have encountered discrimination in their respective life experiences, specific to race. One author self-identifies as a member of a sexual minority group and has also encountered discrimination in both work and life experiences, including as a practicing pharmacist. These past experiences may have influenced how investigators interacted with interview participants, the types of probing questions asked, and how results were analyzed. For any instance identified relating to race or sexuality, all investigators had an open discussion regarding the interpretation before coding and development as a theme.

RESULTS

Phase 1: Survey

A total of 43 participants completed the survey. Demographic characteristics of respondents are provided in Table 1. The majority of respondents were experienced (>10 years), worked in urban settings, female (72.1%), heterosexual (90.5%), and identified ethnically as 'New Zealander' (63.3%). A total of 29 (67.4%) respondents reported experiencing prejudice or discrimination in pharmacy practice.

Table 1. Demographics of survey respondents

Characteristic	Number (%)
Experience (n=43)	
Less than a year	0 (0)
1-5 years	7 (16.3)
6-10 years	6 (14.0)
>10 years	30 (70)
Location (n=43)	
Urban	25 (58.1)
Rural	16 (37.2)
Other	2 (4.7)
Age (n=43)	
<30 years	10 (23.3)
31-50 years	22 (51.2)
>50 years	11 (25.6)
Gender (n=43)	
Female	31 (72.1)
Male	12 (27.9)
Sexual Orientation (n=42)	
Heterosexual	38 (90.5)
Gay male	0 (0)
Lesbian female	2 (4.8)
Other	0 (0)
I'd prefer not to say	2 (4.8)
Ethnicity (n=43)	
New Zealand	28 (65.1)
Maori	3 (7.0)
Pasifika	1 (2.3)
European	4 (9.3)
Asian	2 (4.7)
Other	5 (11.6)
Religion (n=43)	
None (Atheism)	12 (27.9)
Christianity	15 (34.9)
Agnosticism	7 (16.3)
I'd prefer not to say	5 (11.6)
Other	2 (4.7)
Hindusim	1 (2.3)
Islam	1 (2.3)
Ever encountered discrimination in pharmacy practice?	
Yes	29 (67.4)
No	11 (25.6)
Unsure	3 (7.0)

Table 2 provides results about the types of discrimination experienced by pharmacists. The most common types of discrimination experienced included discrimination based on gender, appearance, or past, present, or expected pregnancy. The occurrences of these types of discrimination were notably higher than the other types listed. Verbal abuse and sexual harassment were also frequently reported, as compared to the other types of abuse. Table 3 provides results about the sources of discrimination experienced by pharmacists. Most discrimination was sourced from patients, at much greater rates than other potential sources. The exception to this finding was discrimination sourced from supervisors/leaders with respect to expected, actual, or recent pregnancy. Verbal abuse was sourced primarily from patients, patient's family, supervisors/leaders, and other healthcare professionals. Patients were the primary source of sexual harassment.

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Table 2. Frequency of discrimination based on classification or type reported by respondents

Question	Never	A few times a year	A few times a month	A few times a week	Everyday	Other	Total
Discrimination based on gender							
Total	11 (25.6)	19 (44.2)	4 (9.3)	3 (7.0)	0	6 (14.0)	43 total
Female	3 (9.7)	17 (54.8)	4 (12.9)	2 (6.5)	0	5 (16.1)	31 female
Male	8 (66.7)	2 (16.7)	0	1 (8.3)	0	1 (8.3)	12 male
Discrimination based on race							
Total	31 (73.8)	6 (14.3)	2 (4.5)	0	0	3 (7.1)	42 total
Female	21 (70.0)	5 (16.7)	2 (6.7)	0	0	2 (6.7)	30 female
Male	10 (83.3)	1 (8.3)	0	0	0	1 (8.3)	12 male
Discrimination based on sexuality							
Total	40 (95.2)	0	0	0	0	2 (4.8)	42 total
Female	29 (96.7)	0	0	0	0	1 (3.3)	30 female
Male	11 (91.7)	0	0	0	0	1 (8.3)	12 male
Discrimination based on appearance							
Total	18 (42.9)	21 (50.0)	0	0	0	3 (7.1)	42 total
Female	10 (33.3)	18 (60.0)	0	0	0	2 (6.7)	30 female
Male	8 (66.7)	3 (25.0)	0	0	0	1 (8.3)	12 male
Discrimination based on religion							
Total	41 (97.6)	0	1 (2.4)	0	0	0	42 total
Female	29 (96.7)	0	1 (3.3)	0	0	0	30 female
Male	12 (100)	0	0	0	0	0	12 male
Discrimination based on English language proficiency							
Total	40 (95.2)	2 (4.8)	0	0	0	0	42 total
Female	28 (93.3)	2 (6.7)	0	0	0	0	30 female
Male	12 (100)	0	0	0	0	0	12 male
Discrimination based on social skills							
Total	38 (90.5)	3 (7.1)	0	0	0	1 (2.4)	42 total
Female	26 (86.7)	3 (10.0)	0	0	0	1 (3.3)	30 female
Male	12 (100)	0	0	0	0	0	12 male
Physical abuse							
Total	38 (95.0)	1 (2.5)	0	0	0	1 (2.5)	40 total
Female	27 (93.1)	1 (3.4)	0	0	0	1 (3.4)	29 female
Male	11 (100)	0	0	0	0	0	11 male
Verbal or emotional abuse							
Total	12 (28.6)	20 (47.6)	6 (14.3)	2 (4.8)	0	3 (7.1)	42 total
Female	9 (30.0)	15 (50.0)	3 (10.0)	2 (6.7)	0	2 (6.7)	30 female
Male	3 (25.0)	5 (41.7)	3 (25.0)	0	0	1 (8.3)	12 male
Sexual harassment							
Total	33 (78.6)	6 (14.3)	0	0	0	3 (7.1)	42 total
Female	21 (70.0)	6 (20.0)	0	0	0	3 (10.0)	30 female
Male	12 (100)	0	0	0	0	0	12 male
Discrimination based on past, present, or expected pregnancy							
Total	32 (78.6)	8 (18.6)	1 (2.3)	1 (2.3)	0	1 (2.3)	43 total
Female	20 (64.5)	8 (25.8)	1 (3.2)	1 (3.2)	0	1 (3.2)	31 females
Male	12 (100)	0	0	0	0	0	12 males

Phase 2: Respondent interviews

A total of 13 interviews were included for this phase. Ten interviews were solicited from positive survey responses and three were included from the pilot as minimal changes were introduced after pilot completion. Eleven of the participants were female and two were male. Seven identified as European White, two as Indian, two as Chinese, 1 as New Zealand Maori, and 1 as Middle Eastern. Eleven had greater than five years of experience and two had less than five years of experience. Three themes were interpreted from the interview data: discrimination characteristics, impacts, and prevention.

Theme 1: Discrimination occurs for a variety of reasons from different sources with different behaviors

Participants' perceived reasons for the discrimination encountered were broad. These included a patient's own expectations, the participant's own gender (e.g. being female), ethnicity, age (e.g. young/new graduate), English language proficiency, or a lack or rapport with colleagues. With respect to patients' expectations, some expected a specific profile of a pharmacist, 'I would say there are pockets of society that will associate pharmacists with being a white, old man.' A female spoke of gender discrimination against a colleague who recently gave birth, 'She couldn't come back part-time, she could only come back full-time, so she needed to resign.' For ethnicity, an Asian respondent spoke of discrimination that occurred largely from elderly patients, 'And it was primarily with elderly patients, where I would come in and before I say a word, they would say immediately, "I don't want the Asian one."' Participants also revealed many different behaviours associated with discrimination, including racial slurs, bullying, dogmatism, and sexual harassment.

Theme 2: Impacts of discrimination are variable

The main message under the theme of impact was that impacts of discrimination on a person are highly individualized/personal. Affected individuals appear to have a wide range of emotional responses (e.g. no

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Table 3. Sources of discrimination based on classification or type reported by respondents

Question	None	Patient	Patient's family	Colleague	Other HCP	Supervisor /Leader	Other	Total
Discrimination based on gender	10 (26.3)	27 (71.1)	3 (7.9)	5 (13.2)	6 (15.8)	6 (15.8)	0	38
Discrimination based on race	30 (78.9)	8 (21.1)	3 (7.9)	2 (5.3)	2 (5.3)	2 (5.3)	0	38
Discrimination based on sexuality	34 (89.5)	4 (10.5)	0	0	0	0	0	38
Discrimination based on appearance	28 (73.7)	17 (44.7)	2 (5.3)	6 (15.8)	3 (7.9)	3 (7.9)	0	38
Discrimination based on religion	36 (94.7)	0	0	2 (5.3)	0	0	0	38
Discrimination based on English language proficiency	36 (94.7)	1 (2.6)	0	1 (2.6)	0	0	0	38
Discrimination based on social skills	35 (92.1)	0	0	3 (7.9)	0	0	0	38
Physical abuse	36 (97.3)	1 (2.7)	0	0	0	0	0	37
Verbal or emotional abuse	8 (21.1)	28 (73.7)	7 (18.4)	4 (10.5)	6 (15.8)	8 (21.1)	0	38
Sexual harassment	31 (81.6)	8 21.5)	0	0	0	0	0	38
Discrimination based on past, present, or expected pregnancy	27 (71.1)	2 (5.3)	0	3 (7.9)	1 (2.6)	8 (21.5)	0	38

response, frustration, anger, sadness, disheartened). These responses appeared to vary in intensity between individuals but all were noted to reflect negativity and cause distress. Individuals also found discrimination negatively impacted their ability to perform at work (e.g. powerless, under-appreciated, stressful, lack of professional growth). For example, discrimination from patients caused one participant to question 'why they would continue to work so hard' if they were not being appreciated. Alternatively, one participant stated that 'the person who feels potentially discriminated against also has a role in the way they think or perceive discrimination – it could just be that the persons had a bad day.' Impact is therefore likely dependent on the nature of discrimination combined with how one perceives and reacts to it.

Participants discussed coping strategies that also appeared to be largely individualized or situational. Some participants expressed avoidance, 'my way of coping is to try to be as far from him as possible at work.' Others offered support in the context of a colleague experiencing discrimination, 'if anyone says anything even remotely hinting at anything like that [racism], you [the colleague] come to me straight away.' Others were self-assured, 'it is not a reflection of who I am' and this, at times, resulted in ignoring the discriminatory behaviors, 'I am an inclusive person, I don't think I see color, shape…I try to focus on the patient in front of me and focus on them and their needs.'

Theme 3: Preventative strategies can be broad and encompass multiple layers of society

The need to prevent discrimination from occurring in the workplace was addressed by many participants. Strategies discussed by participants ranged from individual efforts to workplace policies to promotion of tolerance and respect within local, national, and global societies. A common thread to participants' responses was that discrimination was not occurring due to being a pharmacist but rather being a pharmacist exposed them to discrimination by some individuals (patients, colleagues, supervisors, other healthcare professionals). As such, prevention efforts need to be addressed at levels higher than simply instituting zero tolerance policies within the workplace. That being said, participants suggested workplace policies are important, as in many cases, there was no clear 'route map' of who to approach or how to deal with discrimination when it occurred. Participants largely agreed that pharmacy curricula should include training on encountering discrimination in practice and coping with depletion of personal and professional resilience. One participant suggested 'revisiting' the topic throughout each year of the pharmacy program.

DISCUSSION

This study aimed to identify and explore perceived discrimination experienced by pharmacists in practice. Findings show discrimination occurs in pharmacy practice and in the sample assessed, primarily based on sexism and appearance. Verbal/emotional abuse was reported as the most common type of abuse encountered by respondents. Sources of discrimination and abuse were largely reported to come from patients, other healthcare professionals, and supervisors. The interviews conducted revealed detrimental impacts on participants but also provided guidance for development of prevention strategies and student training. These finding have numerous implications for education and practice that are discussed below.

A key finding from this study was simply that discrimination against pharmacists is perceived to occur in practice and for a variety of reasons. While some forms of discrimination may reflect greater societal viewpoints that are difficult to control (discrimination from patients, for example), others are specific to the profession and could be prevented (discrimination from supervisors, colleagues, or other healthcare professionals). The findings of this study align with those found with surgical residency training.[12] Both studies suggest that practitioners are facing numerous challenges that may deplete resilience and negatively impact overall well-being. Both studies found a wide range of discrimination and abuse to be reported by participants and from a variety of sources. Despite occurring in different professions and different contexts, the alignment of these results calls for a review of how well programs train graduates for encountering discrimination and abuse in practice.

Findings of this study aligned with other studies conducted in pharmacy and other health professions but also had some key differences. Similarities included the impacts of discrimination encountered by participants, as well as the sources (patients, other healthcare professionals) and type of abuse (verbal).[3,4,6,12] Despite these similarities, the previous literature identified largely focused on race and sexuality as perceived reasons for discrimination.[2-4,6,10] On the other hand, this study found that gender and

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appearance were the most commonly reasons reported by participants. While most respondents were female and this may have biased the sample (as most gender and appearance discrimination was reported by females), it is also possible that females are more likely to respond due to experiencing discrimination or abuse based on their gender or appearance. As pharmacy is a female dominated profession in many countries (including New Zealand), this finding deserves greater attention and further exploration to better understand the pressures female pharmacists face in the workplace and how these can be specifically prevented.

This study has implications for practice, education, and future research. For practice, employers could increase awareness of discrimination within the workplace and collaborate with staff to develop safer working environments. Specifically, developing a route map for reporting such events or promoting zero tolerance policies may be beneficial. For education, it may be beneficial to address coping skills and/or skills for resilience building within pharmacy programs. Pharmacy training programs, as well as continuing professional development, should include these concepts within the curriculum with a goal of better preparing the workforce for encountering and overcoming discrimination in practice. Although coping strategies should not need to be the first line of defense against discrimination encountered within pharmacy practice, it is important for pharmacists to develop these skills to avoid depletion of motivation and resilience, as well as professional accountability. Future research should be conducted to better understand the frequency of this problem in practice, as this study was exploratory in nature. Research should also focus on better understanding pharmacists' coping strategies and ways that professional associations and employers may better support their development. Finally, with the largest source of discrimination identified as being the patient, future studies should assess how occurrences of discrimination may be influenced by the pharmacist-patient relationship and if strengthening these relationships through person-centered care and communication could decrease discrimination encountered in practice.

The results of this study should be interpreted in consideration of some limitations. First, the survey sample size was small. Despite the desire to achieve a greater number of responses, the goal of the survey was largely to identify incidences of discrimination and attain a sample of respondents for the interview phase. Secondly, those responding to the survey may have responded due to interest in the subject or past experiences with discrimination. Results may not therefore be applicable for all practicing pharmacists in New Zealand. It is possible some eligible participants chose not to participate due to the sensitive subject nature or if they did not feel they had anything to contribute. Thirdly, some terms in the questionnaire were purposefully not defined (e.g. abuse, sexual harassment, appearance), in order to not limit responses by participants in the phase for identifying perceived accounts of discrimination. However, these terms may have consequently been interpreted differently across participants. Despite these limitations, the results from this exploratory study are important for design of future studies and education-based interventions targeting discrimination, coping, and resilience.

CONCLUSIONS

This study identified instances of perceived discrimination and abuse occurring towards pharmacists in practice. Findings support the notion that training programs must adjust to adequately train pharmacists with effective coping strategies, prevention mechanisms, and resilience building strategies. Pharmacist employers should also be accountable to creating zero tolerance workplaces and providing route maps for how pharmacists report and navigate situations when faced with discrimination. Doing so may result in a better equipped workforce that is able to navigate the pressures encountered through discrimination in practice.

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CONFLICT OF INTEREST

All authors report no conflicts of interest to declare.

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Original Research

Evaluation of the entrustable professional activities (EPAs) of the population health promoter domain by North Dakota pharmacists

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Abstract

Background: Entrustable Professional Activities (EPAs) are a list of professional tasks that pharmacy educational organizations support, and accreditation organizations encourage, for assessment by colleges and schools of pharmacy.

Objective: This manuscript evaluates the perceived frequency of performing EPAs in the population health promoter (PHP) domain among pharmacists practicing in North Dakota.

Methods: This survey evaluated the self-reported EPA activities of registered pharmacists living and practicing in North Dakota. For EPAs and supporting tasks in the 6 domains (including the PHP domain), respondents were asked to self-report the number of times during the last 30 days that they perform the task, using a 6 point response scale (0, 1, 2, 3, 4, 5 or more times). There were 990 pharmacists surveyed, and 457 (46.1%) of pharmacists responded.

Results: Within the PHP domain, pharmacists reported performing "Minimize adverse drug events and medication errors" most frequently (mean=3.4, SD=2.0), followed by "Ensure that patients have been immunized against vaccine-preventable diseases" (mean=2.3, SD 2.3), "Maximize the appropriate use of medications in a population" (mean=2.2, SD 2.3), and "Identify patients at risk for prevalent diseases in a population" (mean=1.3, SD=1.9). In these Core EPAs PHP domains, the clinical pharmacists reported the highest level, followed by pharmacy managers and staff pharmacists.

Conclusions: Pharmacists in North Dakota currently perform some population health promoter activities, but not at a consistent and high level. Most of the health prevention activities were medication-related and oriented towards individual patients (micro-level), rather than at a community (population-based) macro-level.

Keywords

Pharmacists; Students, Pharmacy; Education, Pharmacy; Schools, Pharmacy; Accreditation; Competency-Based Education; Internship, Nonmedical; Pharmacies; Medication Errors; Population Health; North Dakota

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INTRODUCTION

Ensuring that students successfully transition from didactic education to experiential education, and ultimately into autonomous practice, is a major objective of pharmacy education. To do so, pharmacy educators must link academic outcomes with activities commonly undertaken in practice. They must also ensure that students can undertake these activities with an appropriate (often a minimal) level of supervision when they graduate and pass their board exams.

Medical educators ten Cate and Scheele were the first to investigate the process of integrating practice abilities with academic competencies, which led to the creation of Entrustable Professional Activities (EPAs).[1,2] EPAs are a collection of statements, each of which describes an activity that a pharmacist routinely undertakes with a reasonable degree of autonomy in practice.[3-6] EPAs are written in a manner that allows clinical preceptors to connect the competency statements currently used in didactic education to professional activities undertaken in clinical settings.[5,6] When combined with a rating scale, EPAs with the rating scale represent a competency-based system used to evaluate health care professional training, including pharmacy education.[3-5] In doing so, EPAs attempt to provide a "common language" for both academic and experiential educators to assess the knowledge, skills, and abilities of their students.[3,7]

This manuscript focuses on the development and use of EPAs in pharmacy education. EPAs were introduced into academic pharmacy during the 2015-2016 academic year, when the American Association of Colleges of Pharmacy (AACP) Academic Affairs Committee released its six Core EPA domains for pharmacy: population health promoter, patient care provider, practice manager, information master, interprofessional team member, and self-developer.[8] New Doctor of Pharmacy graduates should be able to perform each and every one of these activities with limited supervision (i.e., "Level 3" performance).[5] Within pharmacy-based EPAs, this manuscript specifically focuses on the population health promoter (PHP) domain.

EPAs also provide a means to characterize the unique contributions of pharmacists to team-based patient care. This is especially true for the PHP domain, which is inherently interdisciplinary in nature.[5,7] Pharmacist preceptors who undertake these activities provide

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pharmacy students with an opportunity to more fully grasp the impact of their practice on the health of patient populations as a whole, as well as a deeper understanding of how their practice integrates with, and supports, the work of other clinicians to ensure healthy populations.

While pharmacists practicing in any setting will undertake each EPA, it is also important to note that specific EPAs will be undertaken more or less frequently in specific pharmacy practice settings (institutional, community, ambulatory care, etc.).[9] The more frequently pharmacists in a given practice setting undertake an EPA, the greater the opportunity for pharmacy students to develop greater levels of entrustability with that activity. Thus, before EPAs can be fully embedded in academic pharmacy, it is vital to assess the frequency with which pharmacists in certain practice settings actually perform specific EPAs in their daily practice. As a corollary, it is useful to determine whether the frequency of use varies by position and preceptor status, in addition to practice setting.

Previous studies have examined the perceived frequency of EPA use (both overall and across practice settings, by preceptor status, and by the type of position/responsibility) in the Patient Care Provider (PCP) and Practice Management (PM) domains.[10,11] Substantial differences were found in the perceived frequency of use across various practice settings. However, little is known about the perceived use of EPAs in the other four domains. This is especially problematic, since the continued evolution of the pharmacy profession is critically linked to its ability to develop an expanded role in population health, information management, and collaborations with other clinicians.

The primary objective of this manuscript is to conduct a pilot study evaluating the perceived frequency of use of EPAs in the PHP domain. As a secondary objective, this manuscript explores whether the perceived frequency of EPAs undertaken in the PHP domain varies across practice settings, across the seniority and responsibilities of the position, or by preceptor status.

METHODS

This study is a part of a larger initiative undertaken by the North Dakota Institute of Pharmaceutical Care to assess the frequency with which pharmacists in North Dakota perform EPAs in all six major domains. The methods utilized in this paper are described by other, previously published studies stemming from this initiative.[10,11] To implement the initiative, a survey was designed, using established criteria in the survey literature.[12-16] The target population consists of all pharmacists who are licensed and currently practicing as a pharmacist (as their primary location of practice) in the state of North Dakota. The research team used its knowledge of survey design, as well as the pharmacy services literature, to create an initial version of the survey.[12-16] Five pharmacists agreed to pilot test the survey and provide feedback for improvement, which was incorporated into the survey. Once those revisions were made, the survey was submitted to the NDSU Institutional Review Board, who approved the survey and its methods of administration in the fall of 2017.

The approved version of the survey was implemented using the Qualtrics Software System (www.qualtrics.com). The survey is comprised of four sections. The first section contains a cover letter (inclusive of explaining all rights and responsibilities of participants, in accordance with Institutional Review Board protocols) and an item designed to identify whether respondents meet the study's inclusion criteria. The second section lists each core EPA, along with supporting tasks.[10,11] Based on the literature and the authors' collective knowledge of pharmacy practice, the authors determined that the vast majority of practicing pharmacists would undertake activities in the practice manager EPA with much greater frequency than activities in other types of domains. This greater frequency of use allows respondents to report their perceptions of these tasks with an extremely high degree of consistency, accuracy and precision. Thus, for the practice manager EPA and all associated supporting tasks, respondents are asked to self-report the number of times during the last 30 days that they perform the task, using an 11 point response scale (0, 1, 2, 3, 4, …, 8, 9, 10 or more times). The authors were less certain that all pharmacists would be able to provide responses with the same degree of consistency, accuracy and precision for activities in other domains, including the PHP domain. Thus, for EPAs and supporting tasks in the other 5 domains (including the PHP domain), respondents are asked to self-report the number of times during the last 30 days that they perform the task, using a 6-point response scale (0, 1, 2, 3, 4, 5 or more times). In the third section, each of the six core EPAs was listed, and respondents were asked to rate (using a 1 "not useful" to 5 "very useful" response scale) the degree to which additional training on the core EPAs would be useful to further the pharmacist's practice. The final section asks respondents to provide some basic demographics, including gender, age, name of the pharmacy school the respondent attended, year of graduation from a pharmacy program, highest degree earned, current primary practice setting, their primary position/level of responsibility, the location of their practice, and whether or not the respondent served as a preceptor for students attending the state's lone school of pharmacy during the past year. The final section of the survey concluded with an open-ended question entitled, "Please add anything else you would like to tell us."

An important consideration in the assessment of EPAs is the location of the practice setting.[10-12,14] Due to differences in patient populations, available staffing, financial resources, and local health services infrastructure, pharmacists practicing in rural areas may not undertake the same combination of EPAs (or with the same frequency) as those practicing in urban areas. North Dakota is an extremely sparsely populated state. More than half of its counties have population densities of less than six people per square mile and are designated by the U.S. Health Resources and Services Administration as "frontier counties".[10,11] Concomitantly, four communities in the state (Fargo, Grand Forks, Bismarck, and Minot) have populations of 25,000 or more residents. The latter are typically categorized as "urban" communities, while all other communities are categorized as "rural".[10,11]

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The North Dakota Board of Pharmacy provided a list of email or physical mailing addresses for all pharmacists currently licensed in the state. Using the physical mailing addresses, the investigators removed the names of pharmacists on the email list who reside well outside of the state's borders (and cannot commute to North Dakota to practice), the research team was left with a set of 990 possible study participants. As an aside, more than half of North Dakota's population resides in the Red River Valley along the Minnesota-North Dakota border. The 990 names likely include pharmacists who are dually licensed in North Dakota and Minnesota, but who primarily practice in Minnesota. Thus, this number likely overstates the eligible study population by a considerable margin.

The final, approved version of the survey was emailed to the 990 possible study participants in late September 2017. Consistent with the survey design literature, email reminders were sent 2, 4, and 6 weeks afterwards. Reminders were sent from the pharmacy program's Senior Associate Dean in week 8, and from the Dean in week 10. A final email reminder was sent by the study's principal investigator in the 12th week of data collection. Data collection concluded in March 2018.

Data analysis

Responses were stored in a secured database, with access limited to the authors responsible for data analysis (3rd and 4th authors, respectively). To be consistent with Institutional Review Board guidelines, all responses were anonymous.

As noted above, respondents were asked to self-assess the number of times in the previous 30 days that they undertook a core EPA or an associated supporting task using an 11 point response scale (0, 1, 2, 3, 4, …, 8, 9, 10 or more times) for the practice manager domain items, and a 6 point response scale (0, 1, 2, 3, 4, 5 or more times) for all other core EPAs and supporting tasks, including those in the PHP domain. The pattern of responses directly impacts the analysis of data and the reporting of any statistical results. If a given EPA or supporting task is performed only rarely each month, then responses should be relatively evenly distributed across the scale. This allows the data collected from this scale to be treated as an approximation of an ordinal variable, which can be appropriately summarized using traditional measures of central tendency (i.e., means) and dispersion (standard deviations). Concomitantly, EPAs and supporting tasks performed regularly (i.e., on a daily basis) will generate responses that are clustered tightly around the upper end of the scale, producing truncation. In those cases, measures of central tendency and dispersion are biased in a downward fashion, and the data are more appropriately summarized using frequencies or proportions of observations that are, and are not, at the upper end of the scale. A priori, the researchers do not have an expectation about which of these two events will occur. Given these considerations, and consistent with the EPA literature, a decision was made to report results in two forms.[10,11] First, for approximately ordinal (i.e., non-truncated) variables, traditional means and standard deviations are reported. For variables that are potentially truncated, the proportion of responses at the truncation point (i.e., the proportion of responses reporting that they perform a task "5 or more times in the last 30 days") is reported. This allows the reader to more clearly grasp the trends in the data and choose the appropriate descriptive statistic to read and interpret, should truncation be present or absent in the data for a given EPA or supporting task.

A corollary to the study's research objective was to assess whether significant differences exist in the self-reported frequency of undertaking PHP EPAs varies across practice settings, across the type of the position, or by preceptor status, among other available demographic groups. Consistent with the academic pharmacy EPA literature, the study adopts a very general null hypothesis of no relationship between the frequency of undertaking a specific PHP EPA or supporting task and the pharmacist characteristic being compared.[10,11] For variables that are not truncated, the Kruskal-Wallis test is an appropriate means to assess the study's null hypothesis.[17] This test operates under the more specific null hypothesis of no mean differences in the self-reported frequency of undertaking a PHP EPA or supporting task across specific groups of pharmacists (based on pharmacist role, community served, practice setting, etc.). For variables that are truncated, the chi-square test of homogeneity can be applied to assess whether or not a significant association exists between respondents who undertake a given PHP EPA or supporting task 5 or more times per month (versus those who undertake the task less than 5 times per month) and a particular set of pharmacist demographics (again, based on pharmacist role, practice setting, etc.).[17] Consistent with the study's general null hypothesis, the chi-square test of homogeneity also operates under a null hypothesis of no association between the frequency of undertaking a given EPA or supporting task and a specific pharmacist characteristic. Since the researchers have no prior expectations about whether specific variables exhibit, or do not exhibit, truncation, both tests are applied to all variables. This allows the interested reader to view both test results and choose the appropriate test to interpret, depending on whether truncation is, or is not, present in the data for a given EPA or supporting task. All tests utilize 5 percent levels of significance. All tests are conducted using the IBM SPSS Version 24 software package.

RESULTS

The survey was distributed to 990 individuals, of which 457 (or 46%) responded to at least one item in the survey. Of the 457 responses, another 102 were eliminated for failing to meet the study's inclusion criterion of actively practicing as a pharmacist in North Dakota. Further analysis of these 102 responses indicates that a plurality were not practicing in North Dakota (n=33) or did not work for an employer that provides direct patient care (n=27). The remaining ineligible respondents were retired (n=28), unemployed (n=7) or employed in a non-pharmacy-related career (n=7). This yields 355 individuals who responded to at least one survey item in the demographic or PHP EPA sections of the survey. Unfortunately, a large number of individuals did not address one or more of these survey items, and many (if not the majority) of these respondents failed to answer many of the survey items.[16] This result makes it infeasible to compare responders and non-responders. It is also

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Table 1. Mean and proportion of the population health domain with each demographic characteristics (n=121)	
Gender; n (%)	
Female	80 (0.7)
Male	41 (0.3)
Age; mean (SD)	43.2 (11.5)
Age categories; n (%)	
Under 40 years	54 (0.5)
40-49 years	27 (0.2)
50-59 years	28 (0.2)
60 years or older	12 (0.1)
Highest pharmacy-related degree; n (%)	
Bachelor Degree	41 (0.3)
Doctor of Pharmacy	62 (0.5)
Post-Graduate Residency	15 (0.1)
Other Degree	3 (< 0.1)
Practice Setting; n (%)	
Hospital	32 (0.3)
Independent Community	49 (0.4)
Chain Community	15 (0.1)
All Other Practice Settings	25 (0.2)
Respondent's Role; n (%)	
Pharmacy Manager	46 (0.4)
Staff Pharmacist	39 (0.3)
Clinical Pharmacist	26 (0.2)
All Other Roles	10 (0.1)
Population of Community Served; n (%)	
Under 5,000 Residents	21 (0.2)
5,000-24,999 Residents	21 (0.2)
25,000 or More Residents	79 (0.6)
Serve as an NDSU Pharmacy Preceptor; n (%)	
Yes, Serve as a Preceptor	57 (0.5)

unclear as to whether the additional information added by including responses from individuals who only partly completed the survey outweighs the inconsistency and increased information uncertainty introduced by allowing the sample size to vary from one survey item to the next. To avoid ad hoc or arbitrary decisions about whether and how to interpret missing values, a decision was made to include only those 121 individuals in the data analysis who provided a complete set of responses. Therefore, n=121 becomes the final sample size used in the analysis.

Descriptive statistics for all respondent demographics are presented in Table 1. Within the sample, 70% of respondents were female and 30% were male. The mean age of respondents was 43.2 years of age. Approximately 70% of respondents were less than 50 years of age. Approximately 50% of respondents held a Doctor of Pharmacy as their highest degree, while approximately 30% held a bachelor degree in pharmacy. A plurality of pharmacists (40%; n=49) reported working in an independent community setting, while another 26% (n=32) worked in a health system setting, and only 12% (n=15) reported working in a chain community pharmacy. These percentages are consistent with the pharmacy profession in North Dakota. More specifically, North Dakota has a legal requirement that (except for a few stores that were operating prior to the passage of the law) all community pharmacies in the state be majority owned by pharmacists licensed in the state.[18] With regard to position, 38% (n=46) reported holding the position of pharmacy manager, 32% (n=39) reported working as staff pharmacists, 21% (n=26) as clinical pharmacists, and 8% (n=10) in other practice settings. Approximately 60% of pharmacists work in urban communities and 40% in rural communities. Fifty percent of all respondents serve as preceptors for pharmacy students attending the state's lone school of pharmacy.

Descriptive statistics for all survey items in the PHP EPA domain (including supporting tasks) are presented in Table 2. The PHP EPA "Minimize adverse drug events and medication errors" was the highest reported EPA, and was performed an average of 3.4 times per month (SD=2.0). Within this EPA, the supporting task identified by respondents as the one most frequently undertaken was "Assist in the identification of underlying system-associated causes of errors" performed an average of 2.0 times per month (SD=1.9). The PHP EPA domain was undertaken the second most frequently was "Ensure that patients have been immunized against vaccine-preventable diseases", which (at the sample mean) was undertaken 2.3 times per month (SD=2.3). Within this domain, "Determine whether a

Table 2. Mean and proportion of entrustable professional activities (EPAs) by population health promoter domain (n = 121)			
		Number (proportion) of respondents who perform the EPA per week	
Population Health Promoter EPA Description	**Mean (SD)**	**< 5 times**	**5 or more times**
1. Identify patients at risk for prevalent diseases in a population.	1.3 (1.9)	102 (0.8)	19 (0.2)
a. Perform a screening assessment to identify patients at risk for prevalent diseases in a population (e.g., hypertension, diabetes).	0.7 (1.5)	110 (0.9)	11 (0.1)
2. Minimize adverse drug events and medication errors.	3.4 (2.0)	55 (0.5)	66 (0.5)
a. Assist in the identification of underlying system-associated causes of errors.	2.0 (1.9)	93 (0.8)	28 (0.2)
b. Report adverse drug events and medication errors to stakeholders.	1.5 (1.8)	102 (0.8)	19 (0.2)
3. Maximize the appropriate use of medications in a population.	2.2 (2.3)	74 (0.6)	47 (0.4)
a. Perform a medication use evaluation.	1.5 (2.0)	99 (0.8)	22 (0.2)
b. Apply cost-benefit, formulary, or epidemiology principles to medication-related decisions.	1.7 (2.1)	91 (0.8)	29 (0.2)
4. Ensure that patients have been immunized against vaccine-preventable diseases.	2.3 (2.3)	76 (0.6)	45 (0.4)
a. Determine whether a patient is eligible for and has received CDC-recommended immunizations.	2.2 (2.3)	76 (0.6)	45 (0.4)
b. Administer and document CDC-recommended immunizations to an adult patient.	1.5 (2.2)	88 (0.7)	33 (0.3)
c. Perform basic life support.	0.1 (0.6)	120 (> 0.9)	1 (< 0.1)

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Table 3. Entrustable professional activities (EPA) of population health promoter domain by practice setting (n = 121)

Population Health Description; mean (SD)	Hospital [n = 32]	Independent Community [n = 49]	Chain Community [n = 15]	All Other Practices [n = 25]	Kruskal-Wallis p value	Chi-Square p value *
1. Identify patients at risk for prevalent diseases in a population.	0.8 (1.5)	1.0 (1.9)	1.3 (1.6)	2.3 (2.3)	0.02	0.02
a. Perform a screening assessment to identify patients at risk for prevalent diseases in a population (e.g., hypertension, diabetes).	0.1 (0.5)	0.7 (1.5)	0.7 (1.4)	1.5 (2.1)	0.01	0.02
2. Minimize adverse drug events and medication errors.	3.6 (1.8)	2.8 (2.2)	3.9 (1.7)	3.8 (2.1)	0.08	0.15
a. Assist in the identification of underlying system-associated causes of errors.	2.4 (2.1)	1.8 (1.8)	2.3 (2.0)	1.8 (1.9)	0.65	0.28
b. Report adverse drug events and medication errors to stakeholders.	2.3 (2.1)	1.1 (1.8)	1.1 (1.3)	1.1 (1.5)	0.04	0.06
3. Maximize the appropriate use of medications in a population.	2.6 (2.5)	1.4 (2.1)	2.7 (23)	3.1 (2.3)	0.02	0.02
a. Perform a medication use evaluation.	2.6 (1.9)	1.0 (1.7)	2.2 (2.2)	2.2 (2.3)	0.05	0.09
b. Apply cost-benefit, formulary, or epidemiology principles to medication-related decisions.	1.4 (2.1)	1.6 (2.1)	2.0 (2.2)	1.8 (2.2)	0.82	0.91
4. Ensure that patients have been immunized against vaccine-preventable diseases.	2.0 (2.3)	2.2 (2.2)	4.3 (1.8)	1.8 (2.2)	0.01	0.01
a. Determine whether a patient is eligible for and has received CDC-recommended immunizations.	2.0 (2.3)	1.9 (2.3)	4.1 (1.8)	2.0 (2.3)	0.01	0.03
b. Administer and document CDC-recommended immunizations to an adult patient.	0.6 (1.7)	1.6 (2.3)	4.2 (1.8)	0.6 (1.7)	<0.01	<0.01
c. Perform basic life support.	0.2 (0.7)	0.0 (0.0)	0.3 (1.3)	0.0 (0.0)	0.03	0.12

*Less than 5 versus 5 or more times per week

patient is eligible for and has received CDC-recommended immunizations" was the most frequently performed supporting task (mean=2.2 times per month, SD=2.3), followed by "Administer and document CDC-recommended immunizations to an adult patient" (mean=1.5 times per month, SD=2.2). With the exception of "Minimize adverse drug events and medication errors"), 60% of respondents reported performing a task 4 or fewer times in a 30-day window.

An analysis of responses by practice setting is presented in Table 3. The most commonly reported activity across practice settings was "Minimize adverse drug events and medication errors." No significant differences exist across practice settings, suggesting that pharmacists in every setting perform this task with similar frequency. Significant differences were noted among practice settings for "Identify patients at risk for prevalent diseases in a population" (Kruskal-Wallis p=0.02; chi-square p=0.02), "Maximize the appropriate use of medications in a population" (Kruskal-Wallis p=0.02; chi-square p=0.02), and "Ensure that patients have been immunized against vaccine-preventable diseases" (Kruskal-Wallis p=0.01; chi-square p=0.01). When examining statistically significant differences across practice settings for these Core PHP EPAs, pharmacists working for chain pharmacies generally reported the highest mean values, while those working for independent community pharmacies reported and lowest means.

Table 4. Entrustable professional activity (EPA) of population health promoter by position (n = 121)

Population health promoter EPA description; mean (SD)	Manager [n = 46]	Staff Pharmacist [n = 39]	Clinical Pharmacist [n = 26]	All Other Positions [n = 10]	Kruskal-Wallis p-value	Chi-square p-value*
1. Identify patients at risk for prevalent diseases in a population.	1.6 (2.0)	0.8 (1.6)	1.7 (2.2)	0.3 (1.0)	0.02	0.17
a. Perform a screening assessment to identify patients at risk for prevalent diseases in a population (e.g., hypertension, diabetes).	0.7 (1.5)	0.6 (1.5)	1.1 (2.0)	0.0 (0.0)	0.26	0.29
2. Minimize adverse drug events and medication errors.	3.5 (1.9)	2.9 (2.2)	3.7 (1.8)	3.8 (2.0)	0.43	0.68
a. Assist in the identification of underlying system-associated causes of errors.	2.5 (2.0)	1.5 (1.8)	1.9 (1.9)	1.8 (2.1)	0.13	0.56
b. Report adverse drug events and medication errors to stakeholders.	1.9 (2.0)	0.9 (1.6)	1.6 (1.6)	1.1 (2.1)	0.05	0.20
3. Maximize the appropriate use of medications in a population.	2.3 (2.3)	1.7 (2.2)	2.8 (2.5)	3.0 (2.6)	0.19	0.06
a. Perform a medication use evaluation.	1.5 (1.9)	1.4 (2.0)	1.9 (2.3)	1.0 (2.1)	0.49	0.27
b. Apply cost-benefit, formulary, or epidemiology principles to medication-related decisions.	2.2 (2.1)	1.4 (2.1)	1.4 (2.1)	0.5 (1.6)	0.02	0.55
4. Ensure that patients have been immunized against vaccine-preventable diseases.	2.7 (2.3)	2.2 (2.3)	2.0 (2.2)	1.4 (2.0)	0.36	0.30
a. Determine whether a patient is eligible for and has received CDC-recommended immunizations.	2.4 (2.4)	2.0 (2.4)	2.5 (2.4)	1.0 (1.6)	0.51	0.28
b. Administer and document CDC-recommended immunizations to an adult patient.	2.2 (2.5)	1.8 (2.4)	0.0 (0.0)	0.8 (1.8)	0.01	0.01
c. Perform basic life support.	0.0 (0.0)	0.2 (0.9)	0.2 (0.6)	0.0 (0.0)	0.22	0.62

*Less than 5 versus 5 or more times per week

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Table 5. Entrustable professional activity (EPA) of population health promoter by preceptor status (n = 121)

Population health promoter EPA description; mean (SD)	Not Precept NDSU Students [n = 64]	Precept NDSU Students [n = 57]	Kruskal-Wallis p-value	Chi-Square p-value*
1. Identify patients at risk for prevalent diseases in a population.	0.9 (1.7)	1.7 (2.1)	0.01	0.04
a. Perform a screening assessment to identify patients at risk for prevalent diseases in a population (e.g., hypertension, diabetes).	0.5 (1.4)	0.9 (1.7)	0.05	0.25
2. Minimize adverse drug events and medication errors.	3.2 (2.1)	3.5 (1.9)	0.36	0.49
a. Assist in the identification of underlying system-associated causes of errors.	1.7 (1.9)	2.4 (1.9)	0.03	0.43
b. Report adverse drug events and medication errors to stakeholders.	1.3 (1.6)	1.7 (2.1)	0.50	0.04
3. Maximize the appropriate use of medications in a population.	2.1 (2.4)	2.5 (2.3)	0.31	0.75
a. Perform a medication use evaluation.	1.4 (2.0)	1.6 (2.0)	0.27	0.86
b. Apply cost-benefit, formulary, or epidemiology principles to medication-related decisions.	1.4 (2.1)	1.9 (2.2)	0.16	0.32
4. Ensure that patients have been immunized against vaccine-preventable diseases.	2.0 (2.2)	2.7 (2.4)	0.09	0.15
a. Determine whether a patient is eligible for and has received CDC-recommended immunizations.	1.8 (2.2)	2.6 (2.4)	0.09	0.07
b. Administer and document CDC-recommended immunizations to an adult patient.	1.5 (2.2)	1.5 (2.3)	0.85	0.85
c. Perform basic life support.	0.1 (0.3)	0.2 (0.8)	0.54	0.47

* Less than 5 versus 5 or more times per week

Table 4 contains an analysis of responses, disaggregated by position. As in Table 3, the item pharmacists reported the highest mean frequency was "Minimize adverse drug events and medication errors". However, these differences were not statistically significant (Kruskal-Wallis p=0.43; chi-square p=0.29). The next most commonly undertaken item was "Maximize the appropriate use of medications in a population," which also did not differ significantly by position type (Kruskal-Wallis p=0.19; chi-square p=0.06). Statistically significant differences by position did exist for the core EPA PHP domain "Identify patients at risk for prevalent diseases in a population" (Kruskal-Wallis p=0.02; chi-square p=0.17). In general, clinical pharmacists and pharmacy managers reported undertaking activities and tasks more frequently than staff pharmacists.

Table 5 reports the PHP domain by preceptor status (NDSU School of Pharmacy preceptor and non-preceptor). Statistically significant differences exist by preceptor status for the core EPA PHP domain "Identify patients at risk for prevalent diseases in a population" (Kruskal-Wallis p=0.01; chi-square p=0.04). For this item, preceptors self-reported undertaking the activity more frequently than non-preceptors. Mean values for "Minimize adverse drug events and medication errors" were very high, although significant differences did not exist across preceptors and non-preceptors (Kruskal-Wallis p=0.36; chi-square p=0.49). Concomitantly, two activity items within this domain, "Assist in the identification of underlying system-associated causes of errors," (Kruskal-Wallis p=0.03; chi-square p=0.43) and "Report adverse drug events and medication errors to stakeholders," (Kruskal-Wallis p=0.50; chi-square p=0.04) did elicit significant differences by preceptor status, with preceptors reporting higher mean values. For the remaining items, preceptor responses did not significantly differ from non-preceptors.

DISCUSSION

One of the most important contributions of Core EPAs is that they create a means to translate academic competencies to professional tasks. In that way, EPAs create a "shared language" inclusive of the evaluation of student performance - between academic and professional pharmacy.[7,8] Unfortunately, a dearth of evidence exists demonstrating the frequency with which these EPAs (inclusive of supporting tasks) are undertaken in various areas of pharmacy practice.[10,11] The primary contribution of this pilot study was to help address this knowledge gap by assessing the self-reported frequency with which pharmacists practicing in North Dakota undertake Core EPAs in the PHP domain.

Overall, the primary conclusion of the study was that pharmacists perform activities and supporting tasks in the PHP domain, but do so inconsistently and not at a high level. For the four EPAs in the PHP domain, North Dakota pharmacists reported most frequently performing "Minimize adverse drug events and medication errors" (mean=3.4, SD=2.0), followed by "Ensure that patients have been immunized against vaccine-preventable diseases" (mean=2.3, SD 2.3), "Maximize the appropriate use of medications in a population" (mean=2.2, SD=2.3), and "Identify patients at risk for prevalent diseases in a population" (mean=1.3, SD=1.9).

While disappointing, the results of the study were not entirely surprising. The relatively low level of public health involvement is also supported by a 2016 study of North Dakota pharmacists along with those in Iowa and Manitoba, Canada.[12,19] Most of the health prevention activities were medication-related and oriented towards individual patients (micro-level) rather than at a community (population-based) macro-level. Perhaps this was because most of the study participants worked in pharmacy settings that were: independents (n=49), hospital (n=32), chains (n=15), and other pharmacy positions (n=25), or they worked in pharmacy positions that were: managers (n=46),

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staff pharmacists (n=39), clinical pharmacists (n=26), and all other positions (n=10). In both cases, the primary activity is medication-related and most time is spent in dispensing activities, rather than population health promoter activities.[20] North Dakota has a unique state law requiring each community pharmacy to have a North Dakota-licensed pharmacist owning 51% or more of the pharmacy, thereby restricting the number of chain stores, and they are typically managed by the pharmacy owner who often serves as the primary pharmacist.[18] Clinical pharmacists and pharmacy managers reported performing most of the tasks at a higher frequency than did the independent community pharmacists.

It is also important to note that pharmacists in North Dakota are becoming more involved in certain aspects of care that fall within the PHP domain. For example, one study found that targeted education improved the rate with which community pharmacists provide immunizations.[21] Other initiatives are also underway in areas related to the PHP domain, including (but not limited to) opioid misuse.[22-24] This suggests that it is also important to assess the self-reported frequency with which pharmacists undertake EPAs regularly over time. As targeted education initiatives are successfully undertaken, the frequency with which pharmacists undertake tasks in the PHP domain will also improve. This change, in turn, provides greater educational opportunities for pharmacy students to improve their proficiency in these areas of practice.

In our study, the PHP EPAs were also reported by preceptor status (NDSU School of Pharmacy preceptor and non-preceptor). In the first core PHP EPA "Minimize adverse drug events and medication errors," one of two supportive tasks: "Assist in the identification of underlying system-associated causes of errors" was statistically significant, with NDSU preceptors performing those tasks more frequently, than did non-NDSU preceptors. In the second core PHP EPA "Identify patients at risk for prevalent diseases in a population," the supportive task "Perform a screening assessment to identify patients at risk for prevalent diseases in a population (e.g., diabetes)," showed a statistically significant difference for preceptors more than non-preceptors. This difference may be explained by the availability of human resources. For example, pharmacists may be assigned students on a regular basis precisely because they can have greater time and other resources to reallocate their efforts away from "traditional" activities, and towards other aims, including activities in the PHP domain and precepting students. Precepting students may also create synergies which lead to pharmacists undertaking activities within the PHP domain. As an example, students often take the lead on performing the assessments while being supervised by a pharmacist. This supervisory role is less time consuming, and more efficient than performing the entire screening process by themselves. Consequently, this process often allows for additional overall services to be provided by the pharmacy.

It is also interesting to note that pharmacists who work in hospital and chain community pharmacies performed most of the core EPA PHP domain items and their supportive example tasks more frequently than did independent community pharmacists. This may be due to infrastructure advantages accruing to larger, more integrated, organizations. For example, hospital pharmacists may have access to the patient's electronic medical record, which allows them greater opportunities to identify and provide services falling within the PHP domain. Chain community pharmacists often receive structured corporate support (directives and resources) to provide services including (but not limited to) immunization delivery and other preventive care programs (point-of-care testing, disease state management) that fall within the PHP domain. Independently owned pharmacies, which are the norm in North Dakota, typically do not have the same level of access to such infrastructure.

Limitations

This study is a part of a larger initiative undertaken by the North Dakota Institute of Pharmaceutical Care to assess the frequency with which pharmacists in North Dakota perform EPAs in all six major domains.[10,11] As such, the limitations inherent in those studies (and previously identified in the literature) are applicable here. One major limitation is that several PHP EPAs were not undertaken with the same frequency by all pharmacists. This implies that specific EPAs may have more relevance in certain areas of practice than others. This, in turn, may impact the validity of EPAs as an educational tool. In such cases, future research may be required to refine the construction and assessment of EPAs for specific pharmacist roles or who practice in different settings.

A second limitation is that the number of respondents included in the data analysis (n=121) are a relatively small proportion of the 990 individuals who were offered an opportunity to complete the survey. That is, the survey has a low response rate.[16] This may create a study limitation, especially if the n=121 respondents included in the study do not fully reflect the underlying population of pharmacists in North Dakota. Given the low response rate (as well as the other limitations identified in this section), the authors consider the current manuscript as a pilot study. While a low response rate is a study limitation, it is also important to note that the survey's actual response rate is much higher than 121/990, or 12.2%. To illustrate this, of the 990 people invited to complete the survey, 457 (46.2%) responded. But of these 457 respondents, 102 (22.3%) did not meet the study's inclusion criteria and should not be included in the determination of response rates. Again, this suggests that the study's effective response rate is much higher than the stated 12.2%. But even with this adjustment, the response rate for the survey likely remains sub-optimal. Future research that administers a similar survey and obtains a much higher response rate would provide a very valuable re-assessment of the current study.

A third limitation is that the use of survey methods can elicit only self-reported information. Such information is subject to errors of exaggeration or recall bias. This is especially true in instances where pharmacists do not practice on a full time basis, or when they perform a specific task on a very infrequent basis.

The survey's design creates a fourth limitation. It is difficult to obtain reliable self-reported frequencies from many

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respondents using a question with a limited response scale. In the case of the PHP EPA items, a 6-point response scale (0,1,2,3,4,5 or more times) was utilized. If the respondent performs a task infrequently, the survey provides valid and reliable inferences. But for tasks performed regularly, the responses become truncated on the right-hand side of the response scale. This type of truncation limits the information that can be gleaned from the survey. Futures surveys that utilize different response scales that are theoretically appropriate and avoid the possibility of truncation would provide deeper and more meaningful inferences than are contained in the current manuscript.

A fifth study limitation concerns the construction of some survey items that were taken from the PHP EPA domain (including supporting tasks).[10,11] This study used the 2015-2016 AACP published list of EPA domains, activities and supportive tasks.[7] The study findings suggest that the AACP core EPA list may lack validity for some of the survey items.[10] Some of the EPA activities and supportive tasks for the PHP domain are cross-cutting in nature (they include more than one concept) and therefore may have confused the respondent. EPAs must be independently executable, observable, and measurable in their process and outcome. There are some EPA's that do not meet with these characteristics, because they are a mix of activity (EPA) and a competency description. One example is “Minimize adverse drug events and medication errors”. This is a professional competency rather than an EPA description. Searching for these words in PubMed would likely generate many different ways to complete this task. Therefore, two different EPA’s are included in this competency. Another example is “Apply cost-benefit, formulary, or epidemiology principles to medication related decisions.” This includes three different principles into one item. These two examples, and potentially other EPAs, should be revised and then re-tested in future studies.

A sixth study limitation is that the study was conducted in a single, predominately rural state that emphasizes independent community pharmacy practice. Therefore, it is unclear whether, or how, the current study’s findings apply to pharmacy practice in other regions or states with predominately urban areas or those that have limited independent community pharmacy ownership.

Lastly, the study was conducted at a very specific point in time at the end of 2017 and the beginning of 2018. As noted in the Discussion section, the practice of pharmacy evolves over time. In North Dakota, for example, targeted education is being conducted to improve the rate at which pharmacists provide immunizations.[21-24] As this evolution occurs, the results contained in this study may lose relevance. Future research that updates our findings would provide additional, meaningful inferences about the use of EPAs in the PHP domain.

CONCLUSIONS

Pharmacists in North Dakota currently perform some population health promoter activities, but not at a consistent and high level. Most of the health prevention activities were medication-related and oriented towards individual patients (micro-level), rather than at a community (population-based) macro-level. With refinement, the EPAs in the PHP domain have potential as a means to assess outcomes in pharmacy education and practice. This study provides useful, but preliminary, basis for future research to further assess the use of EPAs in professional pharmacy practice (both more broadly across EPAs and deeply in the refinement of current EPAs), and how EPAs link to patient care outcomes.

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CONFLICT OF INTEREST

The authors report no conflict of interest in the conduction of this study or the preparation of this manuscript.

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Original Research

Clinical pharmacists´ interventions in the management of type 2 diabetes mellitus: a systematic review

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Abstract

Background: Type 2 diabetes mellitus is a chronic disease that is reaching epidemic proportions worldwide. It is imperative to adopt an integrated strategy, which involves a close collaboration between the patient and a multidisciplinary team of which pharmacists should be integral elements.

Objective: This work aims to identify and summarize the main effects of interventions carried out by clinical pharmacists in the management of patients with type 2 diabetes, considering clinical, humanistic and economic outcomes.

Methods: PubMed and Cochrane Central Register of Controlled Trials were searched for randomized controlled trials assessing the effectiveness of such interventions compared with usual care that took place in hospitals or outpatient facilities.

Results: This review included 39 studies, involving a total of 5,474 participants. Beneficial effects were observed on various clinical outcomes such as glycemia, blood pressure, lipid profile, body mass index and coronary heart disease risk. For the following parameters, the range for the difference in change from baseline to final follow-up between the intervention and control groups was: HbA1c, -0.05% to -2.1%; systolic blood pressure, +3.45 mmHg to -10.6 mmHg; total cholesterol, +10.06 mg/dL to -32.48 mg/dL; body mass index, +0.6 kg/m^2 to -1.94 kg/m^2; and coronary heart disease risk, -3.0% and -12.0% (among the studies that used Framinghan prediction method). The effect on medication adherence and health-related quality of life was also positive. In the studies that performed an economic evaluation, the interventions proved to be economically viable.

Conclusions: These findings support and encourage the integration of clinical pharmacists into multidisciplinary teams, underlining their role in improving the management of type 2 diabetes.

Keywords

Diabetes Mellitus, Type 2; Pharmacists; Pharmacies; Pharmaceutical Services; Blood Glucose; Glycated Hemoglobin A; Quality of Life; Medication Adherence; Cost-Benefit Analysis; Systematic Reviews as Topic

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a complex metabolic disease characterized by several pathophysiologic alterations, including insulin resistance and a progressive decrease in insulin secretion, ultimately leading to increased blood glucose levels.[1,2] This multifactorial disease results from the interaction between genetic, epigenetic and lifestyle factors that act in a specific sociocultural environment.[1] Diabetes-related complications such microvascular and macrovascular alterations, resulting from uncontrolled glycemic levels are responsible for an increased morbidity and mortality, and reduced health-related quality of life.[3,4] The burden of diabetes and diabetic associated complications results in worrisome increased global health expenditure.

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Evidences from the literature suggest that despite tighter control of blood glucose and other cardiovascular risk factors, such as blood pressure and serum lipids as well as the huge number therapies available, recommended targets are hardly achieved among patients with T2DM.[5-7] These unsatisfactory outcomes may result from inadequate intervention strategies by healthcare providers, or patient related problems, such as lack of compliance.[8,9]

To achieve these targets and improves therapeutic outcomes, new healthcare models, based in a collaborative, proactive and integrated team work in which patients play an active role should be implemented.[1,10-12] Some systematic reviews have addressed this topic however they failed in critical review the economic outcomes.[13-17]

The aim of this study is to review and investigate the effect of interventions performed by clinical pharmacists on the management of T2DM, considering clinical, humanistic and economic outcomes, and focusing solely on randomized controlled trials conducted in hospitals or ambulatory healthcare centers.

METHODS

Search strategy and inclusion criteria

Two electronic databases (PubMed and Cochrane Central Register of Controlled Trials) were searched from inception to 13th September 2017 and updated in 30th June 2020.

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The PubMed search strategy served as a template for the search strategy used in the Cochrane Central Register of Controlled Trials database. The search terms included medical subject headings and text terms combined with Boolean operators (Online appendix 1).

Studies were eligible for inclusion if they were in accordance with the following criteria: (1) randomized controlled trials evaluating the effectiveness of interventions provided by pharmacists for patients with T2DM in comparison to usual care were eligible; (2) Studies that took place in hospitals or outpatient centers (e.g. health care centers and clinics) and reported data on one or more of the following outcomes were suitable for this systematic review: glycosylated hemoglobin (HbA1c), blood glucose (fasting or postprandial), blood pressure, lipid profile [total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density (HDL) cholesterol and triglycerides], body mass index, 10-year coronary heart disease (CHD) risk, medication adherence, health-related quality of life (HRQoL) and economic analysis; (3) papers published in English, French, Spanish, or Portuguese; (4) no limitation regarding publication year was imposed.

Study selection

Two reviewers independently screened all titles and abstracts retrieved from the electronic databases using the prespecified inclusion criteria. Then, the full-text of each potentially eligible article was obtained and screened independently by two reviewers to further assess its suitability for inclusion in this review. Preferred reporting items for systematic reviews (PRISMA) standard guidelines were followed when applicable as per recommended practice.[18] Any disagreement was resolved through discussion.

Data extraction and synthesis

A single reviewer extracted data from included studies. Subsequently, another reviewer independently checked the extracted data. The data extracted were summarized in Online appendix 2. The study results for each outcome were presented as change from baseline to final follow-up in both intervention and control groups. When not reported, the difference in change between groups was calculated (change from baseline in intervention group minus change from baseline in control group). To allow comparisons, when necessary, the units of measurement of the clinical results were standardized.

Risk of bias assessment

Two reviewers independently assessed the risk of bias in included studies using the Cochrane risk of bias tool.[19] Due to the allocation concealment methods and cross contamination between participants, the evaluation of bias (blinding) in the included studies was difficult. Given the nature of the interventions under analysis, the criteria concerning blinding of participants and personnel were not considered.

RESULTS

The databases search yielded a total of 748 citations. After screening titles and abstracts, 84 citations potentially met the inclusion criteria. After full-reading, 39 studies met the inclusion criteria and were included in this systematic review (Figure 1).[20-58] Additionally, three study 59-61 reports found among the search results were also obtained and used to extract data as they contained relevant outcome information from some included studies.

Among the included studies, nine were conducted in North America, five in South America, three in Europe, one in Africa, and twenty one in Asia. The settings in which the studies took place included hospitals, primary care health centers and outpatient medical clinics. Pharmacist interventions varied across the studies and were summarized in Online appendix 2. Globally, the included studies involved a total of 6,411 participants. The duration of follow-up ranged from 45 days to 24 months. A detailed description of the characteristics of included studies is presented in Online appendix 2.

Study risk of bias

The risk of bias varied among the 39 studies (Figure 2 and Online appendix 1). In 18 (46.2%) of them, the allocation sequence was sufficiently generated. The allocation sequence was concealed, and outcome assessors were blinded in only a few studies (7.7% and 2.6%, respectively). In most studies (97.5%), there was or might have been a risk of bias due to selective outcome reporting. Only 13 studies (33.3%) reported outcome data completely, and 19 studies (48.7%) were free of other source of bias.

HbA1c and blood glucose

The mean HbA1c value decreased from baseline to follow-up in the intervention group in all studies (Online appendix 3), but this decrease reached statistical significant for only sixteen studies (47%).[23,25,27-29,35,37-39,41,42,45,50,52,56,57] In these studies, the difference showed in HbA1c change from baseline to final follow-up between the intervention group and the control group ranged from -0.05% to -2.1%. Regarding blood glucose, 22 studies reported this parameter as an outcome measure (Online appendix 3). Only six studies (27%) reported a statistically significant decrease in blood glucose (fasting or postprandial).[39,40,42,45,46,56] Overall, the difference in change between both groups, which ranged from -7.74 mg/dL to -76.32 mg/dL.

Blood pressure

Twenty studies evaluated the change in systolic blood pressure (SBP) during the course of the study (Online appendix 3). The difference in change between the two groups ranged from +3.45 mmHg to -10.6 mmHg and was shown to be statistically significant in only seven studies (33.3%).[31,35,39-42,45,50,53,56,57] As for diastolic blood pressure (DBP), 15 studies reported data on this outcome (Online appendix 3). However, only three studies revealed a statistically significant difference in change from baseline to final follow-up between both groups.[39,41,53] The difference in change between the two groups ranged from +1.32 mmHg to -9.1 mmHg.

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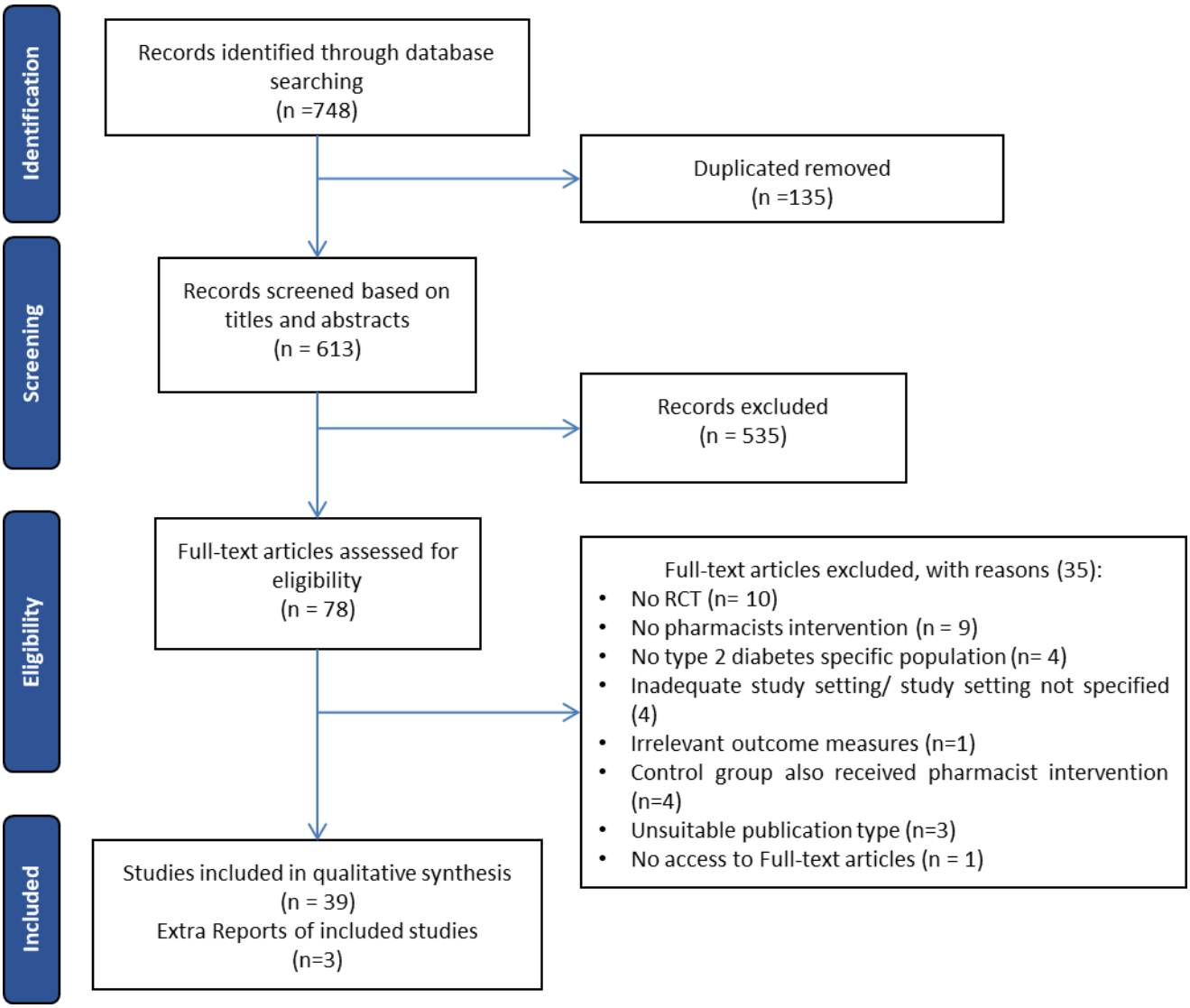

Figure 1. PRISMA flow-chart

Lipid profile

Fifteen studies described total cholesterol as an outcome measure (Online appendix 4). However, only four studies (26.7%) reported as statistically significant in only three studies.[39,41,45] The difference in change between both groups, ranged from +10.06 mg/dL to -32.48 mg/dL. Regarding LDL cholesterol, 21 studies reported data on this outcome (Online appendix 4). For this parameter, the difference in change between both groups ranged from +2.1 mg/dL to -27 mg/dL, and was reported as statistically significant in only seven studies (33.3%).[27,29,35,39,40,45,57]

Among the 15 studies that reported HDL cholesterol as an outcome measure (Online appendix 4), the difference in change between both groups was shown to be statistically significant in only one study (6.7%) 45. The difference in change between the two groups ranged from -5.8 mg/dL to +11 mg/dL. Finally, 16 studies reported data on triglycerides (Online appendix 4) and three studies (18.8%) 39, 40, 45, observed a statistical significance in change between the two groups, ranged from +21.26 mg/dL to -62.0 mg/dL.

Body mass index

Sixteen studies described body mass index (BMI) as an outcome measure (Online appendix 4. Although eleven studies reported a greater reduction in this group in comparison with the control group, Only one study (6.3%) revealed a statistically significant difference in change between both groups.[41] The difference in change between the two groups ranged from +0.6 kg/m^2 to -1.94 kg/m^2.

10-year CHD risk

CHD risk was predicted among study participants in five studies. As observed in Online appendix 4, different methods were used to estimate this outcome. In comparison with the control group, the difference in change between the two groups was reported as statistically significant in only two studies (40%).[27,53] Because the methods used to assess this risk varied among studies, it is not possible to define a range for the difference in change between both groups across all studies. However, among the studies that used the Framingham prediction method, this difference was -3.0% and -12.0%, respectively.

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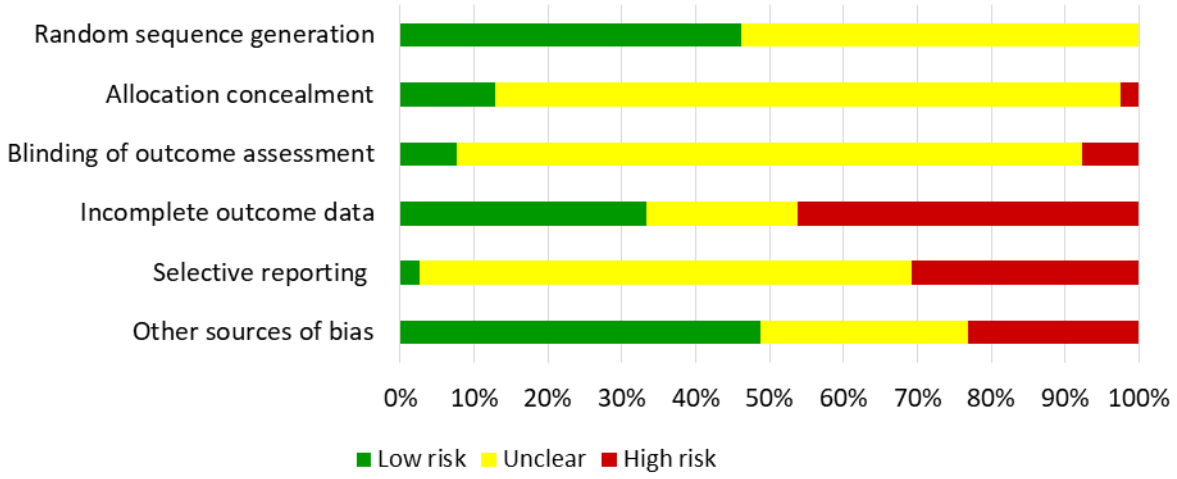

Figure 2. Risk of bias in included studies (percentage across all studies)

Medication adherence and Health-related quality of life

Medication adherence was evaluated, using different methods, in 20 studies. In 12 studies, a greater improvement in medication adherence was observed in the intervention group when compared with the control group, but only four studies reported a statistically significant difference.[23,25,27,35] Regarding HRQoL, despite, the different tools used, only one 25 of the twelve studies that measures this outcome reported a statistically significant difference in change between the two groups (Online appendix 5).

Economic outcomes

Six studies performed an economic analysis, but only 2 provided the p-values, and only one of these was <0.05. Adibe *et al*. conducted a cost-utility analysis of the pharmaceutical care intervention implemented in their study.[59] This analysis was based on the followed resources: the "cost of the intervention," the "cost of drugs," and the "cost of other health care resource use" (including primary care, hospital care, and auxiliary health care). The total cost per patient per year was USD 326 for the control group and USD 394 for the intervention group (p=0.1009). In addition, quality-adjusted life-year (QALY) per patient per year was 0.64 for the control group and 0.76 for the intervention group p<0.0001).[59] Thus, the authors found that the intervention led to an incremental cost of USD 69 and an incremental effect of 0.12 QALY gained, with an associated incremental cost-utility ratio of USD 571 per QALY gained, demonstrating that the intervention was very cost-effective.[59]

Chan *et al*. estimated the cost-effectiveness of the pharmacist care program based on based on projected cost savings anticipated due to CHD risk reduction.[27] The estimated potential saving in costs was USD 5,086.3 per patient.[27]

Simpson *et al*. also conducted a cost-effectiveness analysis.[61] This analysis was based on followed resource costs: the pharmacist intervention, prescription medications, healthcare services provided by physician specialists and other healthcare professionals, emergency department visits and hospitalizations. The authors found that the total cost per patient per year was CAD 190.00 (USD 151.88) lower in the intervention group compared with the control group, and that the intervention group had a 0.26% greater reduction in the annualized risk of cardiovascular event in comparison with the control group.[61] The cost-effectiveness analysis showed that at a societal willingness-to-pay of CAD 4,000.00 (USD 3,196.22) per 1% reduction in annual cardiovascular risk, the probability that the intervention was cost-effective compared with usual care reached 95%.[61]

In the study reported by Chen *et al*., medical expenses were not significantly different between intervention and control groups (p=0.767).[28] However, regarding pharmacist intervention expenditure based on pharmacist's salary, telephone fees and supplies cost, the mean cost per patient was NTD 1,336. 9 (USD 44.10) in the intervention group and NTD 132 (USD 4.35) in the control group, representing an increase of NTD 1,204.9 (USD 39.73) in cost per patient.[28] Since a decrease of 0.83% in HbA1c mean levels was achieved in the intervention group, the incremental cost per 1% reduction in HbA1c mean levels was NTD 1,451.69 (USD 47.87), which could in part be covered by health insurance reimbursement.[28]

Siaw *et al*. also performed an economic evaluation by calculating direct outpatient medical costs, taking into account consultation visits, laboratory tests and procedures, and medications.[52] The mean cost for direct outpatient diabetes-related care was USD 516.77 in the intervention group and USD 607.78 in the control group, which translated into an average cost saving of USD 91.01 per patient.[52]

Wu *et al*. performed an economic evaluation based on the costs of medical visits (only for the intervention arm), medications, hospitalizations, emergency department visits, laboratory testing, procedures, outsource referral or transfer to other facilities and outpatient clinic visits and observed a decreased by 6% for the group visit but increased by 13% for the standard care arm 13 months post-study (p<0.01).[58]

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DISCUSSION

This systematic review analyzed randomized controlled trials that investigated the effects of different interventions performed by clinical pharmacists on various outcomes related to T2DM care. It stands out from previous systematic reviews because besides demonstrating the positive contribution of clinical pharmacists in the metabolic control of patients with T2DM, it also includes economics and humanistic outcomes of pharmacist's interventions.[13-16,62] Considering, that the role of pharmacists remains undervalued in the context of clinical interventions, specifically directed to patients, in contrast to what happens with other healthcare professional with this work, we also intend to underline that pharmacists are highly capacitated professional that are able to integrate multidisciplinary teams for improving practice strategies such patient's educations, drug review and case management with routine follow up. Frequently, pharmacist interventions involved medication management, educational interventions and referrals to other healthcare professionals or services. The diversity of interventions observed may be related to the difference in roles and integration of pharmacists within healthcare systems in different countries, particularly concerning prescribing authority and autonomy to make medication changes. Evidences from the studies included in this review indicate that clinical pharmacists contribute positively to the management of patients with T2DM. For instance, these types of interventions could be even more effective if they were part of the routine follow-up of the patients.[63]

Indeed, an improvement in HbA1c, blood glucose, blood pressure, lipid profile and BMI in the intervention group was reported in almost all studies.

Our findings are consistent with those of other systematic reviews on this topic. In their review on pharmacist interventions in primary care for patients with diabetes, Wubben *et al*. reported an overall improvement in HbA1c mean levels in the intervention group and the difference in change between intervention and control groups ranged from +0.2% to -2.1%.[16] The fact that pharmacist interventions resulted in a reduction in HbA1c and blood glucose is of great importance, since an improvement in glycemic control is linked to a decreased risk of diabetes-related microvascular complications namely a reduced risk of stroke by 12%, a reduced risk of myocardial infarction by 14% and a reduced risk of heart failure by 16%.[64] Inclusion of fasting or non-fasting blood glucose levels as a primary outcome is of far less clinical relevance than that of HbA1c, especially since so few of these studies showed a statistically significant difference.

Regarding blood pressure, lipid profile and BMI, our findings add to the evidence described in other studies.[15-17,62] For instance, in their review assessing the effects of pharmacist care among outpatients with cardiovascular risk factor in diabetes, Santschi *et al*. reported that pharmacist interventions were associated with significant reductions in SBP and DBP, total cholesterol, LDL cholesterol and BMI compared with usual care, but the same was not observed with HDL cholesterol.[15] Wubben *et al*. also found decreases in blood pressure, low-density cholesterol or triglycerides in the intervention group in most studies, although the difference in change between groups was not significant.[16]

There are few studies assessing CHD risk, after pharmacist interventions, however these interventions have been associated with an improvement in CHD risk. Since the tools/formulas used to calculate this risk include some clinical outcomes mentioned above, such as HbA1c, SBP and cholesterol, the decrease in CHD risk can be in part attributable to an improvement in these parameters.[65-67] Pharmacist interventions also had a positive impact on medication adherence in most studies that included this outcome. Although adherence might have been subject to overestimation, since the majority of methods used to assess this outcome were based on self-reported adherence, the existing findings demonstrate that pharmacists have the potential to improve medication adherence among patients with T2DM, which in turn can translate into a beneficial effect on clinical outcomes, as observed in some studies.[68,69]

The fact that pharmacist interventions did not result in a significant increase in HRQoL in the majority of the studies could be explained by the lack of sensitivity of the existing tools in detecting subtle changes on this outcome, since there is no tool specifically designed to determine the effect of pharmaceutical care on patient quality of life.[70]

Although pharmacist interventions have shown to be cost-effective, evidence is limited by the small number of studies that carried out an economic analysis. However, in order to inform and influence the decision of policymakers regarding the widespread involvement of clinical pharmacists in the care of patients with T2DM, economic analyses are essential due to the current resource restraints in healthcare systems. Therefore, pharmacist interventions should be assessed in a comprehensive manner, considering clinical, humanistic and economic outcomes (ECHO approach).[71]

Limitations

This review has some limitations. First, although randomized controlled trials have the most robust study design, the included studies presented some methodological weaknesses, as assessed by the Cochrane risk of bias tool. However, it should be highlighted that some risk of bias criteria, such as random sequence generation, allocation concealment and blinding of outcomes assessment, were rated as "unclear" in a large proportion of studies because the study reports did not provide sufficiently detailed information to enable a more precise evaluation of the risk of bias. Second, because pharmacist interventions were somehow heterogeneous, it is difficult to identify the most effective intervention. In this work, we observed that educational interventions and medication management performed by pharmacists could be a good approach to the management of type 2 diabetes mellitus.

Future prospective

Future studies evaluating the humanistic and economic outcomes of pharmacist interventions must be performed to facilitate policy makers to develop healthcare models, in

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which pharmacists have a proactive role in the improvement of the well-being of the patients.

Moreover, the evaluation of patient related-outcomes such medication adherence should be done using more accurate methods in order to provide more realistic data regarding the effect of pharmacist interventions. Finally and taking into account that the lack of a standard tool to evaluate some outcomes (e.g. medication adherence and HRQoL) limited the direct comparison of the results of different interventions, a well-validated tool to access the most relevant outcomes should be developed in order to identify the best assertive strategy in the management of T2DM.

CONCLUSIONS

The findings from this systematic review strengthen the evidence that pharmacist interventions contribute positively to the control and management of T2D. Patients suffering from this chronic disease often present other comorbidities, such as hypertension and dyslipidemia, and require complex drug regimens. By monitoring drug therapy, educating the patient and promoting medication adherence, pharmacists play an important role on achieving therapeutic outcomes. In fact, the results of the randomized controlled trials analyzed in this review demonstrated that several pharmacist interventions had a beneficial effect on metabolic control, cardiovascular risk factors, medication adherence and HRQoL among patients with T2DM. Therefore, these findings support the idea of considering the clinical pharmacist as an integral element of multidisciplinary health care teams in T2DM care, encouraging the implementation of this approach in health care systems around the world where pharmacists are still not actively involved in the management of this patient population.

CONFLICT OF INTEREST

None to declare.

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Original Research

Pharmacist's attitudes and knowledge of pharmacogenomics and the factors that may predict future engagement

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Abstract

Background: While pharmacists are well positioned to implement pharmacogenomic testing in healthcare systems, uptake has been limited.

Objective: The primary objective of this survey was to determine how post-graduate education and training influences pharmacist's knowledge and attitudes of pharmacogenomic testing.

Methods: Survey questions were developed by the study team, and responses were collected electronically using REDCap™. The electronic survey was sent to all pharmacists (n=161) within a large, multi-state healthcare system by email.

Results: A total of 75 (47%) respondents completed all aspects of the survey. The majority of respondents were female (60%), worked in acute care settings (57%), were full-time employees (80%), and worked in an urban area (85%), with many graduating in or after 2010 (43%). For post-graduate education, 36% of respondents completed a Post-Graduate Year One Residency (PGY-1), and 27% had a board certification. Those that completed a PGY-1 residency were significantly more likely to have received formal training or education on pharmacogenomics than those who had not. They also assessed their own knowledge of pharmacogenomic resources and guidelines higher than those without PGY-1 training. More recent graduates were also significantly more likely to have received formal training or education on pharmacogenomics. Additionally, pharmacists who completed a PGY-1 residency were more likely to respond favorably to pharmacogenomics being offered through pharmacy services. Pharmacists with board certification were more comfortable interpreting results of a pharmacogenomic test than those without board certification.

Conclusions: Pharmacists who have completed a PGY-1 residency or received board certification appear more comfortable with interpretation and implementation of pharmacogenomic testing.

Keywords

Pharmacogenomic Testing; Pharmacogenetics; Pharmacists; Pharmaceutical Services; Certification; Attitude of Health Personnel; Health Knowledge, Attitudes, Practice; Surveys and Questionnaires; United States

INTRODUCTION

Pharmacogenomic research and implementation have increased in recent years as healthcare moves towards precision medicine.[1] A driving force behind pharmacogenomics are drug-gene interactions that affect the patient's response to a medication and may inform treatment choices.[2] Currently, there are several published guidelines on drug-gene interactions from the Clinical Pharmacogenetics Implementation Consortium (CPIC), which provide specific dosing recommendations with a corresponding level of evidence.[3] Additionally, the Food and Drug Administration (FDA) has published a compiled table of gene-drug interactions of significance.[4]

As the medication expert on interdisciplinary teams, pharmacists are well positioned to drive this implementation. The American Society of Health-System Pharmacists (ASHP) has called for "pharmacists to take on a prominent role in the application of pharmacogenomics".[3] Accordingly, pharmacogenomic educational elements were recently incorporated into the accreditation standards for the didactic Doctor of Pharmacy curriculum starting in 2011 by the Accreditation Council for Pharmacy Education (ACPE). Thus, many practicing pharmacists who graduated prior to implementation of these standards may have inadequate exposure to pharmacogenomics in general, as evidenced by a recent survey showing that older pharmacists are less aware and less confident in their knowledge of pharmacogenomics.[5,6] An additional survey in the Netherlands found that the biggest barrier to implementation of pharmacogenomics by pharmacists is a lack of knowledge.[7]

Other health care professionals have also expressed a lack of knowledge and experience with pharmacogenomics. A prior survey of primary care providers (e.g., physicians, nurse practitioners, and physician assistants) in the same

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large, multi-state, health system as the survey presented herein showed a lack of comfort ordering and interpreting pharmacogenomic results. This survey also demonstrated a high level of support for testing being offered through pharmacy services as well as concerns regarding cost and insurance coverage, evidence and benefits of testing, and a general lack of knowledge on pharmacogenomics testing.[8]

While several pharmacy organizations have expressed support of pharmacists leading implementation of pharmacogenomics, there are a lack of surveys specifically asking pharmacists their opinions of implementing pharmacogenomics and how their own knowledge and experience may impact this. Thus, the primary objective of this survey was to determine how post-graduate education and training and other factors influence pharmacist's knowledge and attitudes of pharmacogenomic testing.

METHODS

Survey development

This survey was developed as a follow-up to a previous survey at the same institution of prescribing primary care clinicians (e.g. MDs, DOs, NPs, and PAs) to ascertain pharmacist's attitudes and knowledge of pharmacogenomic testing.[8] The thirteen-question survey was developed by the study team consisting of two pharmacists with pharmacogenomics expertise, two ambulatory care pharmacists, an acute care pharmacist, a research scientist, a study coordinator, and a pharmacy student. Questions were asked to pharmacists to determine information on their attitudes, comfort level, and knowledge regarding pharmacogenomics. Respondents self-reported gender, year of graduation with highest clinical degree, post-graduate training, board certification, primary practice site, full-time equivalent employment hours, time spent performing different pharmacy-related activities, and their prior pharmacogenomics education. This survey was developed and validated internally by the study team based on experience and expertise, as well as on the previous pharmacogenomics survey administered to prescribing clinicians. The full version of the survey can be found in the supplemental materials.

Sampling methods

This survey was sent to all pharmacists in a large, multi-state health system by pharmacy management through a pharmacy list serve. Study data were collected and managed using REDCap™ electronic data capture tools.[9]

The survey link was sent out by email and was open for a total of four weeks. A reminder email was sent out one week prior to the survey closing. Responses were anonymous through an automatically generated participant ID in REDCap™.

Data analysis

Survey results were compiled into data tables with frequencies for each survey question. Frequencies were stratified based on demographic parameters to determine differences between rural and urban pharmacists, year of graduation, post-graduate training, practice area, and previous education in pharmacogenomics.

Chi-squared tests were used to test statistical significance between groups analyzed. Nominal logistical regression was used to assess demographic and pharmacy training factors associated with survey responses. Statistical significance was defined as p-value <0.05 using 95% confidence intervals. JMP® Pro 14 was used for all statistical analyses.

RESULTS

The survey was distributed to a total of 161 pharmacists with 75 (47%) completing all aspects. No surveys were returned incomplete. Complete demographic information of survey respondents is listed in Table 1. Of the respondents, 60% were female and 43% graduated with their clinical degree after the year 2010. For post-graduate training and education, 36% of respondents completed a Post-Graduate Year One (PGY-1) residency and 27% were board certified. Of 19 pharmacists that are board certified, seven were Board Certified Pharmacotherapy Specialists (BCPS), six were Board Certified Ambulatory Care Pharmacists (BCACP), one was a Board Certified Cardiology Pharmacist (BCCP), two were Board Certified Oncology Pharmacists (BCOP) and three reported other board certification. Eighty percent of respondents worked a full-time equivalent (FTE) and 85% worked in an urban area.

Table 1. Demographics of respondents

	N (%)
Gender	
Female	44 (60.3)
Male	29 (39.7)
Not Reported	2 (2.7)
Year of Graduation with highest clinical degree	
2010-2018	32 (42.7)
2000-2009	24 (32)
Before 2000	18 (24)
Not Reported	1 (1.3)
Did you receive post graduate training?	
Yes	30 (40)
No	45 (60)
What type of post graduate training did you receive? (select all that apply)	
PGY-1	27 (90)
PGY-2	0 (0)
Fellowship	2 (6.7)
Other	2 (6.7)
Do you have a Board Certification?	
Yes	20 (26.7)
No	55 (73.3)
Current Practice Site Based on RUCA Score*	
Rural	10 (15.2)
Urban	56 (84.8)
Not Reported	9 (12)
Current FTE	
Full-time	60 (80)
Part-time	15 (20)
Primary Practice Setting (select all that apply)	
Ambulatory Care Clinic	18
Outpatient Pharmacy	13
Acute Care Pharmacy	43
Clinical Management	3
Operations Management	5
Other (i.e. home health/infusion pharmacies, nuclear, telephone, or mail service, etc.)	5

*RUCA= Rural-Urban Commuting Area

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The majority of respondents (75%) had not received any formal training or education on pharmacogenomics. Of those that had received formal training or education, the most common method was through their school curriculum. When asked about current knowledge of pharmacogenomic resources and guidelines, over half (58%) did not feel knowledgeable. Most respondents indicated they would consult drug resources (64%) and colleagues with expertise (52%) when interpreting pharmacogenomic test results.

Survey questions and responses are listed in Table 2. Nearly 20% of pharmacists recalled a patient or provider bring them a pharmacogenomic test result for consult on dosing recommendations or medication selection; however, 65% stated they were uncomfortable recommending pharmacogenomic tests to providers and patients. When asked about interpreting results of a pharmacogenomic test, 62% were uncomfortable. Furthermore, 59% of respondents felt uncomfortable providing recommendations to a provider or patient based on pharmacogenomic test results and 58% of pharmacists were unsure on where to best document pharmacogenomic test information in a patient's electronic medical record.

Fifty-seven percent of pharmacists felt that pharmacogenomics does have a significant impact on current practice. Additionally, 89% of respondents supported a clinical decision support tool to alert them to potential drug-gene interactions while the other 11% were unsure. When asked about barriers to implementation of pharmacogenomic testing, education (88%) and limited resources (77%) were the two biggest factors noted.

In total, 58% of pharmacists surveyed agreed that pharmacists are the best suited clinicians to implement pharmacogenomic testing, while 39% percent were unsure.

Table 2. Survey questions and responses

	N (%)
1. Have you received any formal training or education on pharmacogenomics?	
Yes	18 (24)
Unsure	1 (1.3)
No	56 (74.7)
2. How comfortable do you feel recommending pharmacogenomic tests to providers and patients?	
Very comfortable	5 (6.7)
Somewhat comfortable	12 (16)
Neither comfortable nor uncomfortable	9 (12)
Somewhat uncomfortable	21 (28)
Very uncomfortable	28 (37.3)
3. How comfortable are you interpreting the results of a pharmacogenomic test?	
Very comfortable	4 (5.3)
Somewhat comfortable	15 (20)
Neither comfortable nor uncomfortable	10 (13.3)
Somewhat uncomfortable	16 (21.3)
Very uncomfortable	30 (40)
4. How comfortable do you feel providing recommendations to a provider or patient based on pharmacogenomic results?	
Very comfortable	4 (5.3)
Somewhat comfortable	12 (16)
Neither comfortable nor uncomfortable	15 (20)
Somewhat uncomfortable	18 (24)
Very uncomfortable	26 (34.7)
5. How would you assess your current knowledge of pharmacogenomic resources and guidelines?	
Knowledgeable	5 (6.7)
Somewhat knowledgeable	23 (30.7)
Not knowledgeable	44 (58.7)
Unsure	2 (2.7)
Not reported	1 (1.3)
6. Which sources would you consult when interpreting pharmacogenetic test results?	
Medical Association Meetings/Guidelines/Recommendations	29 (38.7)
Scientific Literature	35 (46.7)
Drug Resources (e.g. Micromedex, Lexicomp, etc.)	48 (64)
Internet	21 (28)
Drug Labeling/FDA website	22 (29.3)
Colleague with expertise	39 (52)
Other	6 (8)
7. Has a patient or provider brought a pharmacogenomic test result to you for guidance in medication dosing or selection or to explain previous medication experiences?	
Yes	12 (16)
Unsure	2 (2.7)
No	61 (81.3)
8. How significant of an impact do you believe pharmacogenomics has on current practice?	
Very significant	12 (16)
Somewhat significant	31 (41.3)
Neither significant nor insignificant	10 (13.3)
Somewhat insignificant	14 (18.7)
Very insignificant	8 (10.7)

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Table 2. Survey questions and responses (cont.)	
9. How would (have) you document(ed) pharmacogenomic test results in a patient's electronic medical record? (Check all that apply)	
Enter notes into electronic health record	25 (33.3)
Scan test results into the electronic health record	24 (32)
List major findings as an allergy	14 (18.7)
List major findings in the problem list	13 (17.3)
Flagging a medication that has CPIC guidance	10 (13.3)
Unsure	44 (58.7)
Other	5 (6.7)
If other, please describe: • Add a flag to the header in the patient chart along with allergies, ht, wt, CrCl, etc. • Ivent of recommendations, did not scan information into chart • Kept out of chart due to current protocol issues • Lab results • Near microbiology section in results	
10. Do you support offering pharmacogenomic testing and interpretation though Pharmacy Services?	
Yes	54 (72)
Unsure	19 (25.3)
No	2 (2.7)
11. Would you want a decision support tool to alert you to potential drug-gene interactions in patients with pharmacogenomic results?	
Yes	67 (89.3)
Unsure	8 (10.7)
12. What barriers do you think are preventing/slowing the implementation of pharmacogenomic services?	
Insurance	44 (58.7)
Willingness to take on a new task	23 (30.7)
Education	66 (88)
Process of ordering to putting in the medical record	32 (42.7)
Limited resources for interpretation and application of pharmacogenomic test results	58 (77.3)
13. Do you agree with the following statement: Pharmacists are the best suited clinicians to implement pharmacogenomic testing.	
Yes	44 (58.7)
Unsure	29 (38.7)
No	2 (2.7)
If yes, where within the practice of pharmacy is pharmacogenomics the best suited?	
Acute and Ambulatory	2 (5.4)
Ambulatory Care	17 (45.9)
Clinical Pharmacists	7 (18.9)
Multiple areas of pharmacy	3 (8.1)
Specialists that achieved certification	1 (2.7)
Specialty Clinics (behavioral health, oncology, neurology, cardiovascular)	6 (16.2)
Unsure	1 (2.7)

Of those who felt pharmacists were best suited, most felt that it should be implemented in the ambulatory care or clinical pharmacy areas of pharmacy services.

Those that completed a PGY-1 were significantly more likely to have received formal training or education on pharmacogenomics than those who had not (p=0.02) (Figure 1A), and assessed their own knowledge of pharmacogenomic resources and guidelines higher than those without a PGY-1 (p=0.03). More recent graduates were significantly more likely to have received formal training or education on pharmacogenomics (p<0.0001) (Figure 1B). Female respondents were significantly more likely to be supportive of pharmacogenomic testing and interpretation through pharmacy services as compared to males (p=0.005) (Figure 1C), and were also more likely to have graduated after 2005 (p=0.001). Additionally, pharmacists who completed a PGY-1 residency were more likely to respond favorably to pharmacogenomics being offered through pharmacy services (p=0.01) (Figure 1D) and a decision support tool to alert them to drug-gene interactions (p=0.04) (Figure 1E) as compared to pharmacists without PGY-1 training. In the same comparison, they also agreed pharmacists are the best suited clinician to implement pharmacogenomic testing (p=0.01) (Figure 1F). Pharmacists with board certification were more comfortable interpreting results of a pharmacogenomic test than those without board certification (p=0.02).

Year of graduation was independently associated with receipt of formal PGx training (p<0.01), while gender (p=0.99) and PGY1 training (p=0.61) was not. Female gender was independently associated (p=0.02) with supporting PGx service through pharmacy services and those with PGY-1 training were also more likely to be supportive; however, this did not meet significance (p=0.12). Year of graduation, gender and PGY-1 training was not associated with agreement that pharmacists are the best suited clinicians to implement PGx testing.

DISCUSSION

In general, pharmacists surveyed reported pharmacogenomic testing to have a somewhat or very significant impact on current practice. In spite of this, only 58% thought pharmacists were the best suited clinician to implement pharmacogenomic testing into practice. Consistent with prior surveys, the biggest barriers to implementation were identified as limited resources and education, supported by the finding that most pharmacists do not feel comfortable ordering or interpreting a

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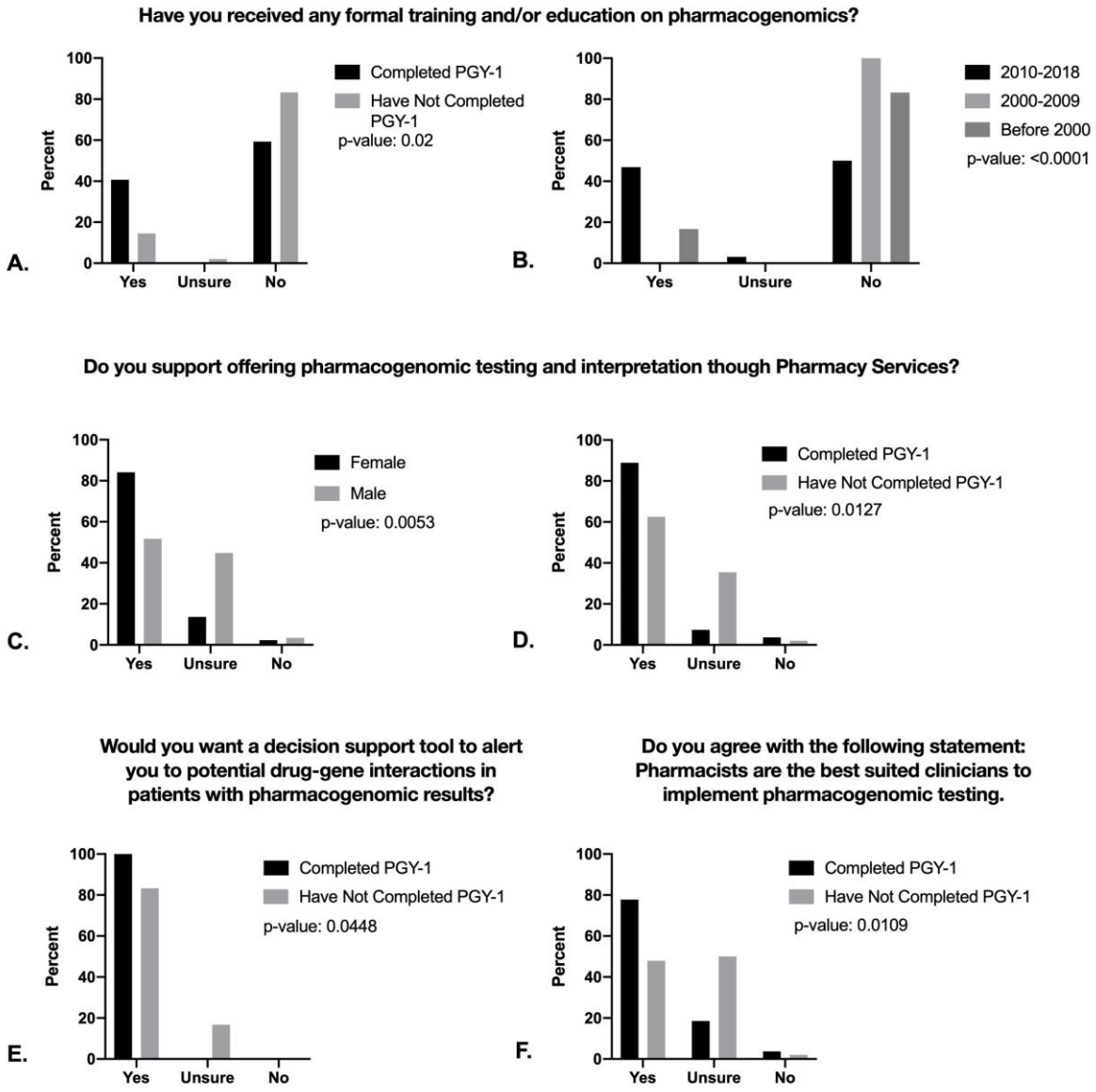

Figure 1. Questions stratified based on demographics.
All demographics were analyzed for each question using a Fisher's exact test with a p-value <0.05. Graphs A and B show the difference between graduation year (p <0.0001). and completion of a PGY-1 (p= 0.0222) in responses to having formal education and/or training in pharmacogenomics. Graphs C and D show the differences that gender (p=0.0053) and completion of a PGY-1 (0.0127) have on pharmacist support for pharmacogenomic testing and interpretation being offered at Pharmacy Services. Graph E depicts the difference completion of a PGY-1 (p=0.0448) has on support for a clinical decision support tool. Graph F shows how the completion of a PGY-1 (p=0.0109) leads to more agreement with the statement "pharmacists are the best-suited clinicians to implement pharmacogenomic testing."

pharmacogenomic test and would need additional education.[6,7] Most notably, pharmacists with more post-graduate training (e.g. residency or board certification) were more comfortable in interpreting and recommending results as compared to those without, while no respondents were against a clinical decision support tool to aid in identifying drug-gene interactions. Post-graduate education and training was also associated with more knowledge and comfort in pharmacogenomics testing. To the best of our knowledge, this is the first survey to assess the impact of post-graduate education and training on attitudes and knowledge of pharmacogenomic testing amongst pharmacists.

Although most pharmacists surveyed felt that they are the best suited clinicians to implement pharmacogenomic testing, a surprisingly high number (39%) were unsure. In our previous survey, 73% of primary care clinicians were interested in pharmacogenomics testing being available through the Medication Therapy Management Program, which is consistent with the responses of pharmacists herein.[8] The uncertainty pharmacists have in implementing pharmacogenomics in their own practice may be due to inadequate education and will need to be further discussed to ensure that pharmacists are confident in this field prior to implementation. Of note, acute care pharmacists, a number of whom completed this survey, may recognize the importance of pharmacogenomics but not feel that it should be emphasized in their setting as much as

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ambulatory care. Additionally, pharmacists working as generalists, who made up the majority of the respondents herein, may not see as great of an impact as a specialist on the need to be knowledgeable in pharmacogenomics.

According to AACP in 2017, 62% of PharmD graduates were female, which was consistent with the demographics seen in this survey.[10] Interestingly, female respondents were more likely than males to be supportive of pharmacogenomic testing and interpretation through pharmacy services.

The results of this survey are similar to previous findings amongst hospital pharmacists regarding pharmacogenomic testing. Previous surveys found that most pharmacists believed that pharmacogenomics will benefit their patients. Those pharmacists were also interested in continuing education, as they lacked confidence in their ability to use pharmacogenomic information. The variable most likely predict a pharmacist's adoption of pharmacogenomics into their practice was confidence in their ability to counsel patients on their test results.[6]

Similar to the reported survey, primary care clinicians have also reported that pharmacy services should take on the role of implementing pharmacogenomics, specifically in the ambulatory care setting. They similarly supported a clinical decision support tool and more education regarding pharmacogenomic testing.[8] An additional study in the Netherlands found that despite having a clinical decision support tool containing the nationwide guidelines, implementation of pharmacogenomics was less than expected because pharmacists did not feel adequately informed on pharmacogenomics.[7] Although clinical decision support impacts usability of pharmacogenomic information in the medical record, without basic education on pharmacogenomics it may not have a meaningful impact on implementing testing.

More recent graduates reported more education in pharmacogenomics than more experienced pharmacists, possibly as a result of recent requirements to include didactic pharmacogenomic educational elements within pharmacy school curriculums. However, survey participants who had completed a PGY-1 noted greater comfort with pharmacogenomics, while no differences were seen with year of graduation and level of comfort with pharmacogenomics. Per the most recent accreditation standards set by ASHP for PGY-1 Residencies, there are no specific requirements for education on pharmacogenomic testing.[11] The increased comfort seen with pharmacists that completed a PGY-1 may be due to other factors associated with completing a residency such as experience in specialty areas and not the residency itself, suggesting that more practice-based experiences may be needed to increase pharmacists comfort level with pharmacogenomics.

For pharmacists already in practice, there are numerous pharmacogenomics certificate programs administered by pharmacy associations, health systems and colleges of pharmacy to help pharmacists increase their knowledge in this area. Other continuing education and site-specific trainings can also aid in pharmacists obtaining competencies in pharmacogenomics. For example, a pharmacogenomics educational program developed at the Mayo Clinic to educate their pharmacists was well received, showed a positive influence in pharmacy practice, and a significant increase in competency based on a pre and post-test on pharmacogenomics.[12]

Perhaps the most effective method of retaining pharmacogenomics education is practice-based application of pharmacogenomic concepts.[13] Pharmacogenomic certificate training programs have been shown to raise pharmacist's perceived competence related to specific drug-gene interactions in simulated patient encounters.[14] Traditional continuing education methods have proved to not be as effective since it has been shown that pharmacists don't change their behaviors afterwards.[13]

This study was limited by several factors. First, the distribution of pharmacists responding to the survey was not uniform, as the majority came from more urban areas and not all pharmacies in the health-system were represented. Second, the survey was localized to one health-system and not externally validated. Finally, while there were respondents representing several practice areas of pharmacy, the majority of respondents practiced in the acute care setting.

CONCLUSIONS

In summary, pharmacists with more post-graduate education and training responded more favorably to taking on pharmacogenomic testing. In order to best implement wide-spread testing, pharmacists with post-graduate training could be utilized first as a basis of knowledge for adoption of pharmacogenomics programs. Increased visibility and usage of educational resources will be needed for the majority of pharmacists to have a baseline knowledge of pharmacogenomic testing.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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Original Research

Prevalence of potentially inappropriate prescriptions in primary care and correlates with mild cognitive impairment

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Abstract

Background: Potentially inappropriate prescribing is clearly associated with adverse health consequences among older people. Nevertheless, scarce evidence exists regarding the prevalence of potentially inappropriate prescriptions (PIP) in Albania, a Western Balkans country.

Objective: The aim of this study was to assess the prevalence of PIP among older Albanian patients in primary care and to determine the associated sociodemographic and medical factors, including the presence of mild cognitive impairment (MCI).

Methods: Cross-sectional study in two primary healthcare centers located in two different cities of Albania, a middle-income country in the Western Balkans. The Montreal Cognitive Assessment (MoCA) tool was applied to evaluate MCI. PIPs were assessed by two trained pharmacists using the Beers criteria 2019 update. Multivariate logistic regression analysis was conducted for possible risk factors predicting PIP in the study population.

Results: At least one PIP was identified among 40.23 % of the participants (174 older patients) and 10.35 % had more than one PIP. MCI was detected among 79.31 % of the patients. The most commonly represented drug groups in PIP were diuretics (24.71 %), benzodiazepines in the presence of MCI and antidepressants (both 8.62 %). The lack of electrolytes monitoring was the most common reason for PIP. According to the multivariate analysis, the only statistically significant association observed was between PIP and number of drugs prescribed [three to four drugs (OR 3.34; 95% CI 1.65:6.76), five or more than five drugs (OR 4.08; 95% CI 1.42:11.69)].

Conclusions: About four out of 10 older Albanian patients experience PIP in primary care. Further studies are needed for a comprehensive estimation of the prevalence and factors associated with PIP, particularly among elderly with mild cognitive impairment.

Keywords

Inappropriate Prescribing; Potentially Inappropriate Medication List; Cognitive Dysfunction; Antidepressive Agents; Benzodiazepines; Aged; Risk Factors; Pharmacists; Cross-Sectional Studies; Multivariate Analysis; Albania

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INTRODUCTION

Drug prescribing is an important and necessary part of patients´ treatment, however it can become a source of particularly hazardous and adverse effects, especially among vulnerable populations such as older people with or without cognitive impairment.[1-3] There is conflicting evidence among studies regarding the occurrence of potentially inappropriate prescriptions among people living with undetected dementia or MCI.[1,3,4] However, strong evidence shows that the use of drugs with anticholinergic properties has a negative impact on cognition and increases the risk of Alzheimer.[5] Several tools and approaches have been developed to support prescribers and researchers for PIP detection and prescribing optimization. Beers criteria, which were recently updated in 2019, represent the most applied tool for this purpose.[6,7]

There is scarce published research with regard to suboptimal prescribing in the Western Balkan countries, either in hospital settings, nursing homes, or focused on specific drug groups like benzodiazepines and antibiotics.[8-13] Only few studies have reported inappropriate prescribing in primary care among older patients of the Western Balkans, and just one in Albania, a middle-income country.[14-17]

Obviously, in order to design and implement effective interventions to reduce improper prescribing, measuring the extent and factors related to this issue is essential.

The aim of our study is to assess the prevalence of PIP among older Albanian patients and its correlates with the presence of mild cognitive impairment, as well as with sociodemographic and medical factors.

METHODS

Study design

Cross-sectional study. We included in the study older patients (60 years old or more) attending the primary healthcare centers from two cities in Albania (Tirana and Shkodra, respectively capital and larger northern city of Albania). Patients were consecutively selected. Study period comprised three months (from 1 March to 31 May 2019). All patients gave their consent to participate in the study, by previously signing the document of informed consent. We excluded patients with no official diagnosis or who did not use any medication.

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Table 1. Description of the study population	
Variable	**N (%)**
Gender	
Female	75 (43.1)
Male	99 (56.9)
Age (years old)	
60-65	49 (28.2)
66-70	53 (30.5)
71-75	50 (28.7)
≥ 76	22 (12.6)
Median (IQR)	73.5 (8)
Years of formal education	
0 (illiterate)	19 (10.9)
1 – 7	18 (10.3)
8 – 12	101 (58.1)
13 – 17	36 (20.7)
Median (IQR)	12 (4)
Number of drugs prescribed	
1 – 2	105 (60.3)
3 – 4	51 (29.3)
≥ 5	18 (10.3)
Median (IQR)	2 (2)
Number of diagnoses	
1 – 2	154 (88.5)
3 – 5	20 (11.5)
Median (IQR)	1 (1)
MoCA score	
≥23	36 (20.7)
<23	138 (79.3)
Median (IQR)	19 (4)

The study was performed in accordance with the ethical standards as displayed in the 1964 Declaration of Helsinki, as revised in Brazil 2013. It was approved by the University of Medicine of Tirana (no. 154).

Collected data

Data were extracted by two trained pharmacists from patients´ medical records, interviews with patients and answers to the MoCA tool. All data were assigned an alpha-numeric code, in accordance with The General Data Protection Regulation (EU) 2016/679. Study variables were sex, age, years of formal education, number of drugs prescribed, number of diagnoses, MoCA score, number and type of potentially inappropriate prescriptions according to Beers criteria (2019 update).

To evaluate potential mild cognitive impairment (MCI) we applied the MoCA tool (Montreal Cognitive Assessment). It is a simple, relatively short (time of administration about 10 minutes, one page length) and validated instrument for detecting MCI. The MoCA assesses several domains which are often impaired among people with cognitive and behavioural deterioration, namely, short-term memory; visual, spatial and orientation abilities; executive functions and language skills; attentiveness and dealing with numbers. To each of these domains there are corresponding specific questions and respective scores with a maximum of 30 points. For illiterate patients or those with low-level of education, MoCA Basic was applied

Table 2. Drugs involved in potentially inappropriately prescribed (PIP) and PIP-qualifying criteria according to Beers 2019

	Number (%)	Reason	Recommendation (Strength of recommendation)	Quality of evidence
Drugs potentially inappropriate in most older people				
Paroxetine (Antidepressants)	5 (2.9)	Highly anticholinergic, sedating, and cause orthostatic hypotension	Avoid (Strong)	High
Glimepiride (Sulfonylureas, long acting)	4 (2.3)	Higher risk of severe prolonged hypoglycemia	Avoid (Strong)	High
Insulin, sliding scale	3 (1.7)	Higher risk of hypoglycemia without improvement in hyperglycemia management regardless of care setting. It does not apply to regimens that contain basal or long-acting insulin.	Avoid (Strong)	Moderate
Methyldopa (Central alpha-agonists)	2 (1.2)	High risk of adverse CNS effects; may cause bradycardia and orthostatic hypotension; not recommended as routine treatment for hypertension	Avoid (Strong)	Low
Benzodiazepines	15	Risk of delirium, falls, fractures, cognitive impairment	Avoid (Moderate)	Strong
Antipsychotics	3	Higher risk of stroke	Avoid, except schizophrenia, bipolar disorder, or antiemetic in chemotherapy (Strong)	Moderate
Zolpidem (Nonbenzodiazepine, benzodiazepine receptor agonist hypnotics, Z-drugs)	1 (0.6)	Adverse events similar to those of benzodiazepines in older adults (eg. delirium, falls, factures); increased emergency room visits/ hospitalizations: motor vehicle crashes; minimal improvement in sleep latency and duration	Avoid (Strong)	Moderate
Amiodarone	1 (0.6)	Greater toxicities than other antiarrhythmics used in atrial fibrillation.	Avoid as first-line therapy for atrial fibrillation unless patient has heart failure or substantial leftventricular hypertrophy (Strong)	High
Ibuprofen	1 (0.6)	Increased risk of GI bleeding or peptic ulcer disease in high-risk groups, can increase blood pressure and induce kidney injury. Risks are dose related.	Avoid chronic use, unless other alternatives are not effective and patient can take gastroprotective agent (Strong)	Moderate

Ethics approval

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Table 2 (cont.). Drugs involved in potentially inappropriately prescribed (PIP) and PIP-qualifying criteria according to Beers 2019

	Number (%)	Reason	Recommendation (Strength of recommendation)	Quality of evidence
Drugs potentially inappropriate in older people with certain conditions				
Dementia or cognitive impairment				
Benzodiazepines	15 (8.6)	Avoid because of adverse CNS effects, behavioural problems	Avoid (Strong)	Moderate
Anticholinergics	6 (3.5)			
Zolpidem	1 (0.6)			
Drugs to be used with caution in older people				
Hydrochlorothiazide (Diuretics)	34 (19.5)	May exacerbate or cause SIADH or hyponatremia; monitor sodium level closely when starting or changing dosages in older adults	Use with caution (Strong)	Moderate
Escitalopram (Antidepressants)	10 (5.7)			
Furosemide (Diuretics)	8 (4.6)			
Carbamazepine (Antiepileptics)	2 (1.2)			
Risperidon (Antipsychotics)	2 (1.2)			
Olanzapine (Antipsychotics)	1 (0.6)			
Spironolactone (Diuretics)	1 (0.6)			
Potentially clinically significant drug-drug interactions to be avoided in older people				
Escitalopram	1 (0.6)	Any combination of three or more of these CNS-active drugs (Antidepressants, Antipsychotics, benzodiazepines)		
Olanzapine				
Mexazolam				
Drugs with strong anticholinergic properties				
Paroxetine (Antidepressants)	5 (2.9)			
Olanzapine (Antipsychotics)	1 (0.6)			

instead. A score of less than 23 points obtained in the MoCA was considered to indicate MCI.[18]

To assess potentially inappropriate prescriptions two trained pharmacists independently applied the Beers criteria (2019 update). Due to the unavailability of information on renal function, we did not include those criteria on drugs to be avoided or used with reduced dosage because of varying levels of kidney function.

Data analysis

STATA/SE software version 12 was used for data analysis. Firstly, a bivariate analysis was applied to identify which variables were associated with PIP; the statistical tests applied were the Chi-Square test or Fisher's exact test, as appropriate. Also, the odds ratio (OR) and 95% confidence interval (95%CI) for every independent variable was estimated. Finally, we conducted a multivariate logistic regression analysis to assess possible risk factors predicting PIP in the study population. The variables that initially entered in the multivariate model were those with p-value < 0.2 in the bivariate analysis. The final models were derived by backward stepwise logistic regressions based on likelihood ratio test statistic G.[19]

RESULTS

After initial assessment of 206 patients, we excluded 32 patients who were not prescribed any medication or had no official diagnosis. Final sample consisted of 174 patients (56.9% male), 50.00 % from Tirana, with a mean age of 69.49 (SD=19.09) years old. Most of the participants (88.5%) had one or two official diagnoses and the most frequent was arterial hypertension among 71.3% of the participants, followed by diabetes mellitus among 17.4 % of them. Mean number of drugs was found 2.56 (SD=1.53), ranging from one to eight drugs simultaneously prescribed. Polypharmacy defined as five or more than five drugs prescribed was present among 10.34% of the participants. Anticholinergic drugs were prescribed to 6 patients (4.0%). MCI was detected among 79.3% of the participants who obtained less than 23 points after applying the MoCA tool (Table 1).

In approximately four out of ten patients was identified at least one PIP (70 patients; 40.2%) and 10.4% of them had more than one PIP according to the applied criteria (two PIP among 16 patients and three PIP among 2 patients). The overall number of PIP found among the study sample was 90 (42.9% of all drugs prescribed), accounting for 18 different PIP. The average number of PIP per patient was calculated 0.53. With reference to the Beers 2019 tool, only 11 different PIP-qualifying criteria contributed to the detected PIP. The most commonly represented drug groups among PIP were diuretics (hydrochlorothiazide, furosemide, and spironolactone), benzodiazepines (mexazolam, lorazepam, diazepam, and alprazolam), and antidepressants (escitalopram, paroxetine). Diuretics on the one hand are the drugs of choice in many indications, on the other hand they are among the drugs to be used with caution in older people due to the risk of SIADH (syndrome of inappropriate antidiuretic hormone secretion) and hyponatremia. We identified 43 cases (24.7% of patients) with diuretics prescriptions without sodium level monitoring when starting or changing doses, most frequently hydrochlorothiazide (34 patients). Benzodiazepines are listed in Beers criteria as PIP in the

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presence of dementia or cognitive impairment with a strong recommendation to avoid in older people with this condition. Fifteen patients were prescribed benzodiazepines and all of them had MCI according to MoCA. The improperly used antidepressants were escitalopram (10 patients; 5.7%) and paroxetine (5 patients; 2.9%). We identified one potentially clinically significant drug-drug interaction, the combined prescription of three drugs acting in the central nervous system – escitalopram, olanzapine, and mexazolam. Only two types of drugs with strong anticholinergic properties were prescribed, the antidepressant paroxetine and the antipsychotic olanzapine (Table 2). The mean MoCA score of the six patients taking drugs with strong anticholinergic properties was 18.17 (SD=1.94).

With regard to the results obtained in the bivariate analysis, it was found that PIP were more common among females, however this was not statistically significant (OR 1.32; 95%CI 0.71:2.43). Age, years of formal education, and number of diagnosed diseases were not significantly associated with PIP. Increasing number of prescribed drugs was a significant risk factor for PIP, as shown in Table 3.

The candidate variables to enter into the multivariate model were age, number of prescribed drugs and MoCA score (p-value < 0.20). According to the likelihood test, only the number of prescribed drugs and MoCA score finally contributed to the multivariate model. Patients with a MoCA score of less than 23 (cut-off for MCI), had increased odds for PIP (OR 2.11; 95%CI 0.91:4.89), although results did not achieve statistical significance. Higher number of prescribed drugs remained a significant risk factor for PIP even according to the multivariate model. Patients who were prescribed five or more than five drugs (OR 4.08; 95%CI 1.42:11.69), as well as those with 3 to 4 drugs prescribed (OR 3.34; 95%CI 1.65:6.76), showed significantly higher risk for PIP compared to patients with two or less drugs prescribed.

DISCUSSION

To our knowledge, this is the first study reporting PIP identified by Beers criteria in primary care in Albania, a Western Balkan country. We applied the most recent version of Beers criteria (2019 update) as a detection tool for PIP among older patients in two primary healthcare settings located in two Albanian cities. The prevalence of PIP calculated as percentage of patients with at least one PIP was 40.2% and about one tenth of the participants had two or three potentially inappropriately prescribed drugs. These figures are consistent with the recent published literature on PIP measured by Beers criteria in populations with and without cognitive impairment. A systematic review by Redston *et al.* in 2018 found a wide variation of potentially inappropriate medications according to Beers criteria among 35 studies in patients with cognitive impairment, ranging from 20.6 % to 80.5%.[1] Another systematic review by Johnell included 11 studies that identified PIP applying former versions of Beers criteria and reported an inappropriate drug use ranging from 10.2% to 56.4%.[4] In our study, the most frequent drug categories involved in PIP were diuretics, benzodiazepines and antidepressants. These groups of drugs are included in the 2019 AGS Beers Criteria with a strong recommendation to be used with caution in older people (certain diuretics and antidepressants) or to be avoided in the presence of cognitive impairment (benzodiazepines). However, clinicians as well as other health professionals and patients should bear in mind that potentially inappropriate prescriptions (PIP) are not necessarily always inappropriate. The lack of electrolytes monitoring was the most common reason for potential inappropriateness of drugs in our study. It is imperative to understand the rationale behind each recommendation and adjust treatment accordingly. For instance, in order to reduce the risk of SIADH or hyponatremia, sodium levels should be strictly monitored when hydrochlorothiazide and escitalopram are prescribed. As already commented by Steinmann & Fick, Beers criteria

Table 3. Bivariate and multivariate logistic regression analysis on factors associated with potentially inappropriate prescribed drugs (n=70; 40.2%)

Variable	Bivariate			Multivariate
	N	(%)	OR (95%CI)	OR (95%CI)
Sex				
Male	37	37.4	(ref)	
Female	33	44.0	**1.32** (0.71-2.43)	
Age (years old)				
60-65	22	40.9	(ref)	
66-75	16	30.2	0.53 (0.24-1.20)	
71-75	21	42.0	0.89 (0.40-1.97)	
>76	11	50.0	**1.22** (0.45-3.36)	
Years of education				
0	10	52.6	(ref)	
1-7	10	55.6	**1.13** (0.31-4.14)	
8-12	40	36.1	0.59 (0.22-1.58)	
13-17	10	27.8	0.35 (0.11-1.10)	
Nº of prescribed drugs				
1-2	30	28.6	(ref)	
3-4	29	58.9	**3.30** (1.64-6.62)	**3.34** (1.65-6.76)
>4	11	61.1	**3.93** (1.39-11.09)	**4.08** (1.42-11.69)
Nº of diagnosed diseases				
1-2	60	39.0	(ref)	
>2	10	50.0	1.57 (0.62-4.00)	
MoCA score				
≥23	10	27.8	(ref)	
<23	60	43.5	**2** (0.90-4.47)	**2.11** (0.91-4.89)

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become a valuable support tool if applied wisely.[20]

The only significant factor associated with PIPs resulted the number of prescribed drugs. Two studies conducted in Serbia detecting PIP with the STOPP-START tool also identified benzodiazepines as frequent inappropriately prescribed drugs and higher number of medications as risk factor for PIP.[14,15] Indeed, polypharmacy was a strong predictor for PIP in most published research worldwide.[21,22]

We chose to identify potential MCI by applying the MoCA tool because several studies have shown that it is more appropriate than other screening tools (such as the Mini Mental State Examination) for the detection of MCI among patients over 60 years old.[23,24] Despite the absence of an official diagnosis of MCI, this condition was present in almost 80% of the participants of our study according to the MoCA tool. Undetected MCI contributed to more PIP among this population, although this was not statistically significant. This is in line with the findings by Johnell, who did not find an association between inappropriate drug use and cognitive impairment or dementia, probably explained by increased awareness among physicians when prescribing for this vulnerable group.[4] Nevertheless, this explanation does not seem plausible for our study, as MCI was undetected and not considered by prescribers in this population. Additional multicenter studies are needed to elucidate the prescribing patterns in older people with cognitive decline. This research was limited to one country (Albania) and two primary healthcare centers of the cities of Tirana and Shkodra. Therefore, findings cannot be extrapolated to the entire older population receiving primary care. Limitations of this study include the non-random selection of patients, the unavailability of clinical data and lack of patient assessment which might have influenced the results obtained. Furthermore, these results should be interpreted with caution in the context of limitations related to the accuracy and sensitivity of the employed tools to detect PIP and MCI, respectively, Beers criteria 2019 update and MoCA tool.[7,25]

CONCLUSIONS

Potentially inappropriate prescribing affects approximately four out of 10 older patients in primary care and three or more than three drugs prescribed is the most significant factor associated with it. The improper use of diuretics, antidepressants and benzodiazepines needs to be addressed. Cautious and tailored prescribing for patients with cognitive impairment should be encouraged, taking into account all patients´ conditions and specific needs. Explicit tools such as Beers criteria aiming to optimize prescribing might help in careful decision-making regarding pharmacological treatment selection. Further studies are needed entailing larger populations and complete patient assessment for a comprehensive estimation of the prevalence and factors associated with PIP.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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Original Research

Evaluation of traditional initial vancomycin dosing versus utilizing an electronic AUC/MIC dosing program

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Abstract

Background: Area under the curve to minimum inhibitory concentration (AUC/MIC) has been recommended by the 2020 updated vancomycin guidelines for dosing vancomycin for both efficacy and safety. Previously, AUC/MIC has been cumbersome to calculate so surrogate trough concentrations of 15-20 mg/dL were utilized. However, trough-based dosing is not a sufficient surrogate as AUC/MIC targets of 400-600 can usually be reached without achieving troughs of 15-20 mg/dL. Targeting higher trough levels may also lead to adverse events including acute kidney injury (AKI) and nephrotoxicity.

Objective: To compare the mean total first day vancomycin dose in traditional trough-based dosing versus dosing recommended by an AUC/MIC dosing program.

Methods: Adult inpatients who received at least 24 hours of IV vancomycin treatment were included in this single-center, retrospective cohort study. The primary endpoint was difference in mean total first day vancomycin dose in milligrams (mg) received between patients' traditional trough-based dosing and recommended dose via AUC/MIC electronic dosing calculator. Patients served as their own control by analyzing both actual dose received and dose recommended by the electronic AUC/MIC program. Rates of vancomycin induced adverse events, including acute kidney injury, elevated steady-state trough concentrations, and Red Man's syndrome were also compared between patients who received doses consistent with the AUC/MIC dosing recommendation versus those who did not.

Results: 264 patients were included in this study. Initial 24-hour vancomycin exposure was significantly lower with the recommended AUC/MIC dose versus the dose received (2380.7; SD 966.6 mg vs 2649.6; SD 831.8 mg, [95% CI 114.7:423.1] p=0.0007).

Conclusions: Utilizing an electronic AUC/MIC vancomycin dosing calculator would result in lower total first day vancomycin doses.

Keywords

Vancomycin; Drug Monitoring; Area Under Curve; Microbial Sensitivity Tests; Acute Kidney Injury; Software; Inpatients; Retrospective Studies; United States

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INTRODUCTION

Vancomycin is a glycopeptide antibiotic that has been in clinical use since 1958.[1] Despite its frequent use, gaps still exist in our knowledge of optimizing therapy and avoiding adverse events in patient care. The area-under the curve to minimum-inhibitory concentration (AUC/MIC) dosing method has been identified as the most appropriate monitoring target for vancomycin.[1] Previously, the AUC/MIC ratio has been cumbersome to calculate, and monitoring with targeted trough levels of 15-20 mg/dL as a surrogate marker for AUC was recommended.[1] However, additional research has shown that trough-based monitoring is not a sufficient surrogate marker for AUC/MIC targets.[2-4] Target AUC/MIC levels can be achieved without a trough concentration of 15-20 mg/dL.[2] Therefore, current expert consensus recommends an AUC/MICBroth-Micro-Dilution target of 400 to 600 to achieve clinical efficacy while improving patient safety.[1]

Vancomycin-associated acute kidney injury (AKI) occurs in 5-43% of treated patients.[5] AKI has been shown to significantly decrease long-term survival rates, increase morbidity and prolong hospitalizations in critically ill patients.[6] Literature suggests risk of AKI increases with increasing vancomycin exposures and trough concentrations (>15-20 mg/dL), and there is additional evidence that AKI risk increases when daily AUC exceeds 700-1300 mg*hr/L.[5,7-8]

A 2017 retrospective study by Zasowski analyzed 323 patients receiving vancomycin for bacteremia or pneumonia for at least 72 hours.[9] After excluding patients' confounding risks for decline in renal function, such as Elixhauser comorbidity index and receipt of IV contrast dye, rates of nephrotoxicity were significantly higher in patients who received a concomitant nephrotoxin, and patients with AUC≥677 mg*hr/L.[9]

Two approaches exist for monitoring AUC/MIC, the use of Bayesian software programs to estimate the 24-hour area under the curve (AUC_{24}) with minimal pharmacokinetic sampling, or the use of two concentrations (peak and trough) and simple PK equations to estimate AUC_{24} values.[1] The Bayesian approach provides some advantages. It provides accurate estimates of AUC_{24} values with trough-only sampling, however, given limited data it is recommended to be used with two vancomycin concentrations.[1,10] A major disadvantage to this approach is the costly nature of the software programs. The advantage of using two concentrations is it is simpler and relies on fewer assumptions than the Bayesian approach. The main limitation of this approach is it is not adaptive like the

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Clcr / Weight	*50-59 kg*	*60-69 kg*	*70-79 kg*	*80-89 kg*	*90-99 kg*	*100 kg*
Initial Dose	*1000mg*	*1250mg*	*1250mg*	*1500mg*	*1500mg*	*1750mg*
Over 90 ml/min	1000mg q12h	1000mg q12h	1250mg q12h	1500mg q12h	1500mg q12h	1500mg q12h
80-89 ml/min	750mg q12h	1000mg q12h	1250mg q12h	1250mg q12h	1500mg q12h	1500mg q12h
70-79 ml/min	750mg q12h	1000mg q12h	1000mg q12h	1250mg q12h	1250mg q12h	1500mg q12h
60-69 ml/min	750mg q12h	750mg q12h	1000mg q12h	1000mg q12h	1250mg q12h	1250mg q12h
50-59 ml/min	750mg q18h	1000mg q18h	1000mg q18h	1250mg q18h	1250mg q18h	1500mg q18h
40-49 ml/min	750mg q18h	750mg q18h	1000mg q18h	1250mg q18h	1250mg q18h	1250mg q18h
30-39 ml/min	750mg q24h	750mg q24h	1000mg q24h	1250mg q24h	1250mg q24h	1250mg q24h

Figure 1. Institution nomogram for initial vancomycin dosing

Bayesian approach, and works best when levels are obtained at/near steady state.[4,11]

The purpose of this study was to compare mean initial 24-hour vancomycin exposure using traditional trough-based dosing versus dosing recommended by an electronic AUC/MIC dosing program.

METHODS

The single-center, retrospective cohort study was conducted at Cape Fear Valley Medical Center in Fayetteville, North Carolina, a 670-bed community hospital. Vancomycin dosing and monitoring is accomplished via pharmacy to dose consult service. Initial dosing regimens and therapeutic adjustments are determined per a hospital-wide nomogram (Figure 1) or utilizing first-order kinetic equations with goal trough concentrations of 10-20 mg/dL. Trough concentration goals are specific to infection location with lower trough targets of 10-15 mg/dL utilized for less severe infections such as skin and soft tissue infections and urinary tract infections. Trough concentrations of 15-20 mg/dL are used for all other infections. Therapeutic monitoring is based on trough-only serum levels. The institutional review board granted exempt status for this study.

Patients were identified via a report run in Epic© (electronic medical record) of inpatient vancomycin orders for patients admitted to a general medicine service from May 1, 2019 to December 31, 2019. To be included in the analysis, patients needed to be at least 18 years of age and have been treated for a suspected or documented infection with vancomycin for at least 24 hours. Patients were excluded if they were admitted to the intensive care unit during hospitalization, required hemodialysis or had unstable renal function on admission (increase of at least 0.3 mg/dL or 50% in SCr from known baseline), were treated for meningitis, were pregnant or received only one dose of vancomycin in the emergency department or for an indication of surgical prophylaxis.

The primary outcome was to compare mean total first day vancomycin dose between recommended AUC/MIC dosing and traditional trough-based dosing. For this endpoint each patient served as their own control by analyzing both the actual dose received and the dose recommended by the electronic AUC/MIC program. Secondary outcomes included comparing mean predicted AUC/MIC and trough concentrations between patients who received doses consistent with AUC/MIC recommendations versus those who did not. For these secondary endpoints, patients were assigned to groups based on whether they received dosing which was consistent with AUC/MIC recommended dosing or did not (trough-based dosing). Doses were considered consistent with AUC/MIC recommended dosing if the calculated AUC/MIC associated with the dose was between 400-600. We also sought to describe rates of vancomycin induced adverse events such as vancomycin induced acute kidney injury (defined as an increase in SCr level of at least 0.5 mg/dL or a 50 % increase from baseline in consecutive daily readings or a decrease in calculated CrCl of 50 % from baseline on two consecutive days in the absence of alternative explanation), Red Man syndrome and allergic reaction. A validated online calculator was used to calculate recommended AUC/MIC dosing, predicted AUC/MIC and trough values. This calculator utilizes published pharmacokinetic equations and principles to estimate a vancomycin dosing regimen for a patient utilizing body weight and creatinine clearance. After a regimen is calculated each step utilized in the calculations is available for the clinician to review for accuracy.[12] Trough-based dosing was calculated using Cape Fear Valley's nomogram, which recommends dosing based on creatinine clearance and weight in kilograms, (Figure 1) or utilizing first-order kinetic equations, based on pharmacists' clinical judgement, if the patient did not meet parameters for the nomogram. Data collected included: patient demographics (gender, age, height, weight, body mass index, SCr and estimated creatinine clearance), vancomycin dosing information (indication for therapy, dose, frequency, total initial 24-hour vancomycin received and serum concentrations), and concomitant nephrotoxin use (piperacillin/tazobactam, loop diuretics, IV contrast dye, and ACEi/ARB). Vancomycin MICs were assumed to be <1 mg/L for this study as culture data was not collected. Data was collected by two investigators and checked by another

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Table 1. Baseline Characteristics	
Parameter	**All patients**
Male, n(%)	142 (53.8%)
Mean Weight, kg (SD)	88.1 (26.7)
Mean BMI[a], kg/m2 (SD)	29.9 (8.9)
Mean Age, years (SD)	55.7 (18.9)
Mean Scr, mg/dL (SD)	1.1 (0.4)
Indications, n(%)	
Skin and Soft Tissue	97 (36.7%)
Sepsis	69 (26.1%)
Other[b]	63 (23.9%)
Pneumonia	52 (19.7%)
Bacteremia	23 (8.7%)
[a.] Body Mass Index [b.] Includes urinary tract infection, osteomyelitis, and intra-abdominal infections	

investigator for completion and accuracy following the initial 10 entries as specified in the protocol. Data were input into Microsoft Access (Redmond, WA) and stored on secured network computers. . Categorical variables were compared using Pearson's chi-square test. Continuous variables were compared using the Student t-test. A p-value of less than 0.05 was considered statistically significant. All statistical tests were run using JMP-14 Pro (SAS. Cary, NC).

RESULTS

Of the 619 patients evaluated, 264 (42.6%) met inclusion criteria. Patients were excluded for the following: surgical prophylaxis (n=45), treatment for less than 24 hours (n=273), unstable renal function (n=5), hemodialysis (n=21), treatment for meningitis (n=8), and pregnancy (n=1). Two patients were also excluded due to having documented allergies to vancomycin, vancomycin was ordered for these patients but never documented as given in the EMR. The study population was predominately male with an average age of 55.7 years. Remaining subject demographics are summarized in Table 1. For secondary outcomes, the AUC/MIC group included 127 patients; the trough-based group included 137 patients (Table 2). Most patients were treated for skin and soft tissue infections (Table 1).

For the primary endpoint, mean total first day vancomycin dose was significantly higher (2649.6 mg; SD 66.6 mg) than the AUC/MIC recommended dosing (2380.7 mg; SD 831.8 mg) [95%CI 114.7:423.1] p=0.0007.

Once patients were divided into groups based on their dosing consistency with the AUC/MIC calculator recommendations, predicted mean AUC/MIC and trough concentrations were calculated and found to be significantly lower in the AUC/MIC group (510.9 [SD 54.6], 13.5 mg/dL [SD 2.3]) than in the trough-based group (639.4 [SD 136.7], 18.3 mg/dL [SD 5.0]) [95%CI 102.9:154.1, 95%CI 3.9:5.8] both p values<0.001 (Table 2).

Rates of acute kidney injury were similar between groups. Ten patients in the AUC/MIC group experienced an AKI compared to 11 in the trough-based group (Table 2). Of the 21 total patients who experienced an AKI, 17 (81%) were receiving at least one concomitant nephrotoxin. Overall, the incidence of AKI was 8%. Nephrotoxins included piperacillin/tazobactam (n=13), ACEi/ARB (n=6), IV contrast dye (n=5), and loop diuretics (n=4). Rates of other adverse events were low; two patients had allergic reactions to vancomycin and one patient developed Red Man syndrome. No other drug related adverse effects were reported.

DISCUSSION

The results of our study found that traditional trough-based dosing led to an increased total first day vancomycin dose compared to AUC/MIC recommended dosing. AUC/MIC recommended dosing also resulted in lower predicted AUC/MIC and trough concentrations. Our results support the guideline recommendations set forth in the 2020 IDSA guidelines of a target range of 400-600.[1] These results were also described by Covvey *et al*., in their analysis of total daily dose of vancomycin in patients with MRSA bacteremia and a body mass index (BMI) greater than 30.[13] Notably, the predicted trough concentration in the AUC/MIC group was 13.5 mg/dL which was almost 5 mg/dL lower than the mean trough-based concentration of 18.3 mg/dL; this depicts the ability to achieve AUC/MIC targets without trough concentrations of 15-20 mg/dL.[2] It should be noted that total weight-based first day vancomycin dose was not calculated in this analysis, which may confound results as patients with lower weights may have reduced lower doses.

Lodise and colleagues explained the existence of an exposure-response relationship between initial vancomycin trough value and the occurrence of nephrotoxicity, as nephrotoxicity significantly increased with increasing initial trough concentration.[8] Based on this relationship, lowering initial vancomycin exposure via utilizing AUC/MIC dosing recommendations may lower risks for nephrotoxicity that accompany elevated initial trough concentrations. A prospective study by Neely and colleagues utilized Bayesian estimations to calculate AUC/MIC and discovered AUC-guided dosing was associated with decreased nephrotoxicity.[14] Additionally, Finch *et al*., found that AUC-guided dosing is independently associated with less nephrotoxicity and trough-concentrations, which they hypothesized is likely due to decreased vancomycin exposure.[15] The results of our current study agree with their findings.

There are multiple potential obstacles to overcome when considering transitioning to an AUC/MIC-based dosing strategy, including increased workload on clinical pharmacists, the need for extensive education for multiple members of the healthcare team, and determining inclusion criteria for the new dosing strategy. Heil *et al*. provides advice for overcoming these obstacles including ideas for continued education for pharmacists, physicians,

Table 2. Secondary endpoints				
Endpoint	**AUC/MIC recommended dosing (n=127)**	**Trough-based dosing (n=137)**	**Difference [95% CI]**	**p-value**
Estimated AUC/MIC, mg*hr/L	510.9 SD:54.6	639.4 SD:136.7	128.5 [102.9:154.1]	p<0.001
Estimated Trough, mg/dL	13.5 SD:2.3	18.3 SD:5.0	4.8 [3.9:5.8]	p<0.001
AKI, n (%)	10 (7.9)	11 (8.0)		p=0.9629

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nurses, and phlebotomists.[11] Additionally, new and innovative programs to calculate AUC/MIC exist which alleviate the excess workload that long-hand calculations place on clinical pharmacists. These programs include electronic calculators, such as what was utilized in this study, spreadsheets, calculators built into electronic medical records, and commercially available dosing calculators.[11,12]

Rates of acute kidney injury were similar between the two groups, although this study was not adequately powered to find differences in safety endpoints. The incidence of kidney injury was 8% which is consistent with rates reported in a recent meta-analysis.[5] Additionally, most patients in this study were receiving concomitant nephrotoxins in addition to vancomycin. The effects of these nephrotoxins could not be adequately described in this evaluation, which is a limitation.

Furthermore, most patients in this study were treated for skin and soft tissue infections; the trough-based target for these infections is 10-15 mg/dL which may have induced bias by lowering the true vancomycin exposure in the trough-based group. Skin and soft tissue infections are also not considered invasive infections and it is currently unknown whether AUC/MIC based dosing is the best form of monitoring.[1]

CONCLUSIONS

AUC/MIC recommended dosing resulted in lower total first day vancomycin dose and lower predicted AUC/MIC and trough concentrations. The results of our study support the newly released IDSA guideline recommendations of an AUC/MIC target of 400-600.

CONFLICT OF INTEREST

The authors of this manuscript have nothing to disclose regarding conflicts of interest or funding information.

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Original Research

Venous thromboembolism prevention protocol for adapting prophylaxis recommendations to the potential risk post total knee replacement: a randomized controlled trial

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Abstract

Background: Total knee replacement (TKR) is a major orthopedic surgery that is considered high risk for the development of venous thromboembolism (VTE).

Objective: The aim of this study is to evaluate the clinical outcomes that resulted from the use of a new proposed VTE risk stratification protocol for selecting a suitable extended VTE prophylaxis for post TKR surgery patients administered in conjunction with patient education programs.

Method: A randomized controlled trial was conducted in two medical centers in Saudi Arabia. A total of 242 patients were enrolled in the study, 121 patients in each group. The experimental group (A) was assessed by using the proposed VTE risk stratification protocol and also took part in patient education programs about TKR and its complications. The control group (B) was assessed by using the 2005 Caprini risk assessment tool and no education programs were given to this group. Both groups were followed for 35 days post operation.

Results: The mean age of the participants was 65.86 (SD 8.67) and the majority of them were female 137 (56.6%). The mean body mass index of the study sample was 32.46 (SD 5.51). There were no significant differences between the two groups except for surgery type; the proportion of bilateral TKR in group A was higher than in group B (69/121 (28.5%) vs. 40/121(16.5%), p<0.05). There were no confirmed pulmonary embolism cases in the study sample and diagnosis of deep-vein thrombosis was confirmed in 12/242 (5.0%) of patients: 1/121 (0.8%) in group A and 11/121 (9.1%) in group B (p<0.05). The readmission rate for all patients was 2.5% (6/242), all of whom were in group B (p<0.05).

Conclusion: The proposed VTE risk stratification protocol that was applied in conjunction with patient education programs reduced VTE complications and readmission events, post TKR surgery.

Trial Registration: ClinicalTrials.gov Identifier: NCT04031859.

Keywords

Venous Thromboembolism; Arthroplasty, Replacement, Knee; Patient Education as Topic; Risk Assessment; Patient Readmission; Outcome Assessment, Health Care; Randomized Controlled Trials as Topic; Saudi Arabia

INTRODUCTION

Total knee replacement (TKR) is a major orthopedic surgery, which is considered high risk for the development of venous thromboembolism (VTE).[1] Limiting both VTE events and bleeding episodes in this type of surgery is therefore essential. However, excessive anticoagulation should be avoided because it has a negative impact on the surgical outcome.[2] In the last 10 years, there have been major changes in the delivery of orthopedic surgeries.[3] This has included the implementation of strategies such as day surgery admission as well as the use of spinal anesthesia which has resulted in a reduction in the duration of operations.[4] In addition, the use of appropriate analgesia allows early mobilization and aggressive rehabilitation, resulting in a mean length of hospitalization of 5 days.[5] These strategies also contribute to decreasing the risk of death in the perioperative period and may also reduce incidences of VTE, which can be caused by restricted movement and prolonged length of stay and which were common after joint replacement surgeries.[4,6]

The annual incidence of VTE in the United States is estimated to range between 350,000 and 900,000, and approximately 100,000 die of the condition each year. Moreover, among those that survive, 30–50% will go on to develop post-thrombotic syndrome and as much as 30% will develop a second deep-vein thrombosis (DVT) within 5 years.[7,8]

To this end, the author designed a new risk stratification tool for TKR surgery after reviewing all of the related literature. Hence, all surgical and patient-related factors that show significant associations with the incidence of VTE events are included in the proposed risk stratification tool. The aim of this study is to assess the performance of the developed VTE risk stratification protocol by evaluating the

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clinical outcomes that resulted from the use of this new proposed protocol for selecting a suitable extended VTE prophylaxis for post TKR surgery patients administered in combination with patient education programs. It is hypothesized that the use of a new proposed VTE risk stratification protocol for selecting the extended VTE prophylaxis post TKR Surgeries along with patients' educational programs will be able to decrease the complications post total knee replacement surgery. This research will answer the following question: Whether the use of a new proposed VTE risk stratification protocol for selecting the extended VTE prophylaxis post TKR Surgeries along with patients' educational programs will be able to decrease the complications post total knee replacement surgery or not?

METHODS

In order to obtain the required data to test the proposed tool, a randomized controlled trial was conducted during the period of October 2018 to July 2019 in two medical centers in Saudi Arabia, namely, Prince Sultan Military Medical City (PSMMC) and the King Abd Allah University Hospital (KAAUH). The PSMMC is located in Riyadh and is considered to be one of the most advanced medical centers in the Middle East. It has a capacity of about 1,200 beds and is accredited by the International Joint Commission. The KAAUH is located in the southern area of Princess Noura University (PNU) Campus and it is a 300-bed teaching hospital serving the PNU faculty. The study was approved by the Institutional Review Board of both centers (reference numbers HP-01-R-079 and H-01-R-059 for PSMMC and KAAUH, respectively; ClinicalTrials.gov identifier: NCT04031859).

All patients who were scheduled for elective TKR surgery in the period between October 2018 and July 2019 in both medical centers were eligible for the study. After admittance, those who signed the informed consent form and met the inclusion and exclusion criteria were included in the study. One group (A) was designated as the experimental group. The VTE risk stratification tool that was designed by the first author (see Appendix) was applied to group A in order to choose the tailored extended VTE prophylactic agent. The patients in group A also took part in patient education programs about TKR and its complications (these programs on TKR and the preventive measures that should be taken to avoid TKR complications were given by clinical pharmacist). The other group (B) was designated as the control group. Group B was not assessed by the proposed tool; rather, the Caprini risk assessment tool was used.[9] The Caprini tool is the routine hospital protocol employed at the two centers for choosing the VTE prophylactic agent and is a widely used, standard, validated tool. The patients in group B did not participate in any educational programs on TKR; rather, they were given the usual counseling tips regarding possible post-surgery risks. All the patients in group B were categorized as high risk according to the Caprini total risk score. Therefore, each of the patients in group B was prescribed an anticoagulant either orally (rivaroxaban) or subcutaneously (enoxaparin) at a dosage and for a period of time determined by the surgeon according to his/her experience. For group A, the educational programs were done for each patient individually, starting from patients' admission day, through hospital stay, and during all the follow up visits. Patients were educated on the preventive measures, the exercises that should be done on regular basis to prevent blood clots, and the best way in which VTE prophylactic medications are administered. The authors have recommended the Knee replacement guide of North Bristol, through the educational programs.[10]

Both groups of patients were followed for 35 days post operation, during which time all VTE or bleeding events were recorded by data collectors using a prospective data collection sheet. In addition, the HAS-BLED score was used to assess the bleeding risk factor for each patient.[11]

In order to allocate the participants to group A or B, randomization of the study sample was done using random permuted blocks, and a randomization sequence was created by an independent physician using Microsoft Excel version 10 with a 1:1 allocation using random block sizes of 6, 8, 10 or 20. The independent physician provided the data collectors (clinical pharmacist and physicians) with a sealed envelope containing details of the group to which each participant had been allocated. In studies of this type, the best practice is to perform a double-blind randomization. However, in this study, only the participants (patients) were blinded to their group. The data collectors (clinical pharmacist and physicians) were non-blinded, meaning that they were aware of the group to which each participant had been allocated. No changes were made to the trial method or to the outcomes after trial commencement. Moreover, due to the high cost of the adjudication committee we could not use it; because this research was not funded by any institution.

The inclusion criteria for participation in this study were as follows: Male or female patients scheduled for elective TKR surgery (primary only), signed informed consent form, and aged older than 18 years. The exclusion criteria were as follows: Patients receiving anticoagulant treatment, patients with a history of DVT or pulmonary embolism (PE), patients with renal or hepatic failure (where renal failure was defined as end-stage kidney disease (on dialysis) and hepatic failure was defined as complete liver cirrhosis), patients who were pregnant, and patients who were scheduled to have revision surgeries.

Design of the proposed VTE risk stratification protocol

The author designed the proposed VTE risk stratification protocol specifically for TKR patients. In this protocol or tool, the VTE risk factors are divided into two types: patient-specific risk factors and surgery-specific risk factors. The following steps explain how the tool is used and the rationale behind the scoring of the various risk factors:

First step: Identification of patient-specific VTE risk factors

The patient-specific VTE risk factors in the proposed tool are the same as those that are evaluated by the 2005 Caprini risk assessment tool.[9] This is because several studies have proven the superiority of the Caprini tool over other tools.[12] Therefore, the first step in the VTE risk stratification protocol actually involves using the Caprini tool to calculate the total VTE risk score for each patient,

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according to the points scored by the patient for each patient-specific risk factor in the Caprini assessment.

Second step: Identification of surgery-specific VTE risk factors

In the second step the surgery-specific VTE risk factors are calculated. These risk factors are length of stay (LOS), operating time, and type of anesthesia. These risk factors were selected due to their positive association with the incidence of VTE events as reported in the literature. First, with regards to LOS, according to Zhang *et al*. (2018) a hospital stay of longer than 3 days is considered a prolonged stay that will increase post-surgical complications.[13] On the other hand, Afshari *et al*. (2018), considered that day surgery and fast-track surgery are low-risk procedures, where they defined day surgery (or ambulatory surgery) as "a surgical procedure for which the patient is released from the hospital on the same day as surgery or admitted and discharged within 24 h" (p. 78) and fast-track as "surgery after which patients are mobilized within hours after the operation and fully mobilized no later than on the day after surgery, with discharge no later than the fifth day" (p. 78). Therefore, a LOS of more than 5 days will increase VTE risk.[14] Hence this risk factor was given a score of 2. As for operating time, Duchman *et al*. (2017) stated that an operative time >120 minutes is associated with increased short-term morbidity and mortality after primary total joint replacement.[15] Therefore, this risk factor was given a score of 1. As regards type of anesthesia, a meta-analysis by Hu *et al*. (2009) revealed that regional anesthesia seems to improve the outcomes of patients who have undergone total hip or knee replacement by reducing the operating time, the need for transfusion, and the incidence of thromboembolic disease.[16] Moreover, compared with general anesthesia, spinal anesthesia can reduce postoperative pain (which helps with early ambulation), morphine consumption, nausea and vomiting.[17] Accordingly, general anesthesia was given a score of 2 as a surgery-specific VTE risk factor due to its multiple effects on VTE events, duration of surgery, and pain management.

Third step: Calculation of the total VTE risk for patient group stratification

In this step, the total score for the patient-specific VTE risk factors and the total score for the surgery-specific risk factors for each patient are summed to arrive at a total VTE risk factor score for each patient. Then, based on their score, the patients are categorized into one of three groups: low high risk, moderate high risk, and very high risk. To generate the cutoff points for these three groups, the author referred to the cutoff points employed by a standard tool, namely, the 2005 Caprini tool. According to the Caprini risk assessment tool, a total risk score of 1–2 is considered to represent a low level of risk. Therefore, the author selected a cutoff point of 7 for the low high risk group in the proposed risk stratification tool, since TKR surgery has a 5 points score, add to this 2 points for other VTE risk (which represent the minimal risk according to Caprini), so it's a low risk added above the surgery risk, by this it will be considered as low high risk group in the proposed risk stratification tool. On the other hand, a total VTE risk score of 3–4 according to the Caprini tool is considered to denote a moderate level of risk. Hence, 3–4 points were added to the basic 5 points for surgery-specific risks, resulting in a range of 8–9 points for the moderate high risk group in the proposed risk stratification tool. Finally, 5 or more added VTE risk points is considered to indicate a very high risk group according the Caprini approach. Therefore, the author decided that a score of 10 or more should denote a very high risk level in the proposed risk stratification tool.

Fourth step: Prescription of the extended VTE prophylaxis based on patient group

Based on the results of the VTE risk stratification, the physician was able to select the appropriate extended VTE prophylaxis to administer upon discharge; during hospitalization the patient was prescribed any recommended anticoagulant according to the American College of Chest Physicians guidelines, but upon discharge the extended VTE prophylaxis choice depended on the patient's risk group.[18] If the patient was categorized as low high risk, they were prescribed aspirin as the extended VTE prophylaxis. On the other hand, if their score puts them in moderate high risk category, they were prescribed an oral anticoagulant. Finally, if the patient was categorized as very high risk, they were prescribed a parenteral or oral anticoagulant, depending on the patient's preference, but the parenteral anticoagulant was reserved for the very high risk group only. Please see the Online appendix for dose and duration of each prophylaxis.

Statistical analysis

In this study, the primary outcome was symptomatic VTE events (DVT or PE) within 35 days post TKR surgery. The secondary outcomes were bleeding (minor or major bleeding), surgical site infection, sudden death and readmission within 35 days post TKR surgery. These outcomes were assessed during the hospital stay as well as during the follow-up visits. Major bleeding is defined as bleeding severe enough to require significant medical intervention, such as transfusions or surgery, or those results in serious morbidity or mortality. Minor bleeding is any mild bleeding that does not match the criteria of major bleeding.

It has been reported that the symptomatic VTE rate during the first 3 months post orthopedic surgery is within the range of 1.3% to 10%, while the cumulative incidence of VTE within 90 days of surgery is 3.29%.[19,20] A recent study that was done in Saudi Arabia stated that the incidence of symptomatic VTE is 1.9%.[21] As the context of this study is also Saudi Arabia, the author used the estimated proportion in the previous Saudi study to calculate the sample size. The formula used to calculate the sample size was based on an estimation of the proportion of patients who were expected to experience symptomatic VTE outcome as follows:

$$\text{Sample size} = 3.84 \times p(1-p)/(\text{precision})^2$$

at a 95% confidence interval, where p =estimated proportion (cumulative incidence) =1.9% and precision =0.05. Accordingly, the minimum sample size was calculated as 237. As the sample size for this study was 242, the minimum sample size criterion was achieved.

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At the end of the 35-day follow-up, the collected data were analyzed using the Statistical Package for the Social Sciences version 20 at a precision of 0.05 and a confidence interval of 95%. Descriptive analysis was used to describe the characteristics of the sample. The chi-square test and analysis of variance (ANOVA) were used to identify any significant differences between the groups: ANOVA was used to test for differences between the continuous variables and to compare means, while the chi-square test was conducted to examine the discrete variables (frequencies).

RESULTS

A total of 276 patients were eligible for this study. However, 18 patients were excluded after applying the inclusion and exclusion criteria and four declined to participate, leaving 254. A further 12 patients were dropped from the study for the following reasons: Six were lost to follow-up, surgery was postponed for two patients due to unstable vital signs, and surgery was canceled for four patients for different reasons. The remaining 242 patients signed the informed consent form, indicating their agreement to participate in the study.. The patients in group A were subdivided into three groups according to the level of VTE risk (Figure 1). Group B was designated as the control group. The risk stratification tool was not applied to this group; rather, they were evaluated by using the Caprini (2005) risk assessment tool.

The patients' demographic characteristics are shown in Table 1. The mean age of all the participants was 65.86 (SD 8.96) years and most of them were female (137/242, 56.6%). The mean body mass index of the study sample was 32.46 (SD 5.51). From a comparison of the characteristics of the experimental group (A) and the control group (B), there were no significant differences between groups in terms of age, gender, BMI, or lifestyle.

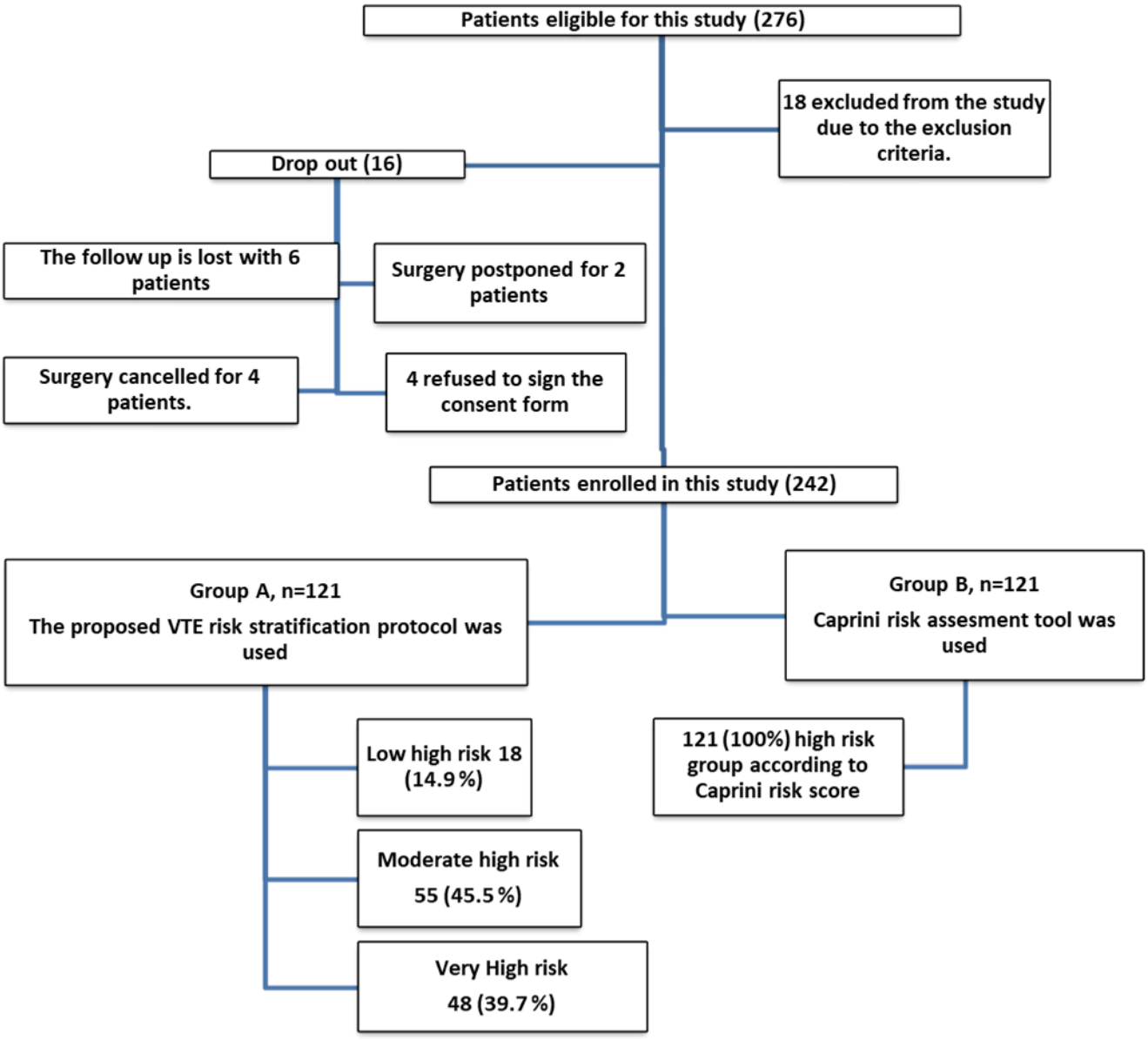

Figure 1. Study flow chart

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Table 1. Demographic data, medical illness and medication comparisons

Demographics/ Clinical data	Group A N=121 (50.0%)	Group B N=121 (50.0%)	All N=242	p-value
Age Mean (SD)	65.23 (9.4)	6.49 (8.5)	65.86 (8.67)	0.279
Gender Male (N,%)	54 (44.6%)	51 (42.1%)	105 (43.4%)	0.697
BMI Mean (SD)	32.8 (5.89)	32.1 (5.10)	32.46 (5.51)	0.318
Lifestyle*(N,%)				
Restricted	58 (47.9%)	63 (52.1%)	121 (50.0%)	0.522
Normally Active	63 (52.1%)	58 (47.9%)	121 (50.0%)	
Highly Active	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Type of surgery(N,%)				<0.001
Unilateral TKR	52 (43.0%)	81 (66.9%)	133 (55.0%)	
Diseases (N,%)				
Rheumatoid arthritis (RA)	7 (5.8%)	4 (3.3%)	11 (4.5%)	0.355
Dyslipidemia	29 (24.0%)	33 (27.3%)	62 (25.6%)	0.556
Osteoarthritis OA	114 (94.2%)	117 (96.7%)	231 (95.5%)	0.355
Benign prostatic hyperplasia (BPH)	5 (4.1%)	3 (2.5%)	8 (3.3%)	0.472
Asthma	5 (4.1%)	4 (3.3%)	9 (3.7%)	0.734
Diabetes mellitus (DM)	69 (57.0%)	71 (58.7%)	140 (57.9%)	0.795
Chronic kidney disease (CKD)	0 (0.0%)	2 (1.7%)	2 (0.8%)	0.156
Hypertension (HTN)	76 (62.8%)	88 (72.7%)	164 (67.8%)	0.099
Ischemic heart disease (IHD)	13 (10.7%)	14 (11.6%)	27 (11.2%)	0.838
Gout	2 (0.8%)	2 (0.8%)	4 (1.7%)	1.000
Hypothyroidism	27 (22.3%)	26 (21.5%)	53 (21.9%)	0.876
Medications				
H2 blocker (Famotidine or Ranitidine)	25 (20.7%)	19 (15.7%)	44 (18.2%)	0.317
Analgesic	121 (100.0%)	121 (100.0%)	242 (100.0%)	-
A. B	121 (100.0%)	121 (100.0%)	242 (100.0%)	-
VTE-Prophylaxis during hospital stay	121 (100.0%)	121 (100.0%)	242 (100.0%)	-
Diabetic medication	69 (57.0%)	71 (58.7%)	140 (57.9%)	0.795
Hypertension medication	77 (63.6%)	87 (71.9%)	164 (67.8%)	0.169
IHD-Medication	13 (10.7%)	14 (11.6%)	27 (11.2%)	0.838
Gout medication	2 (0.8%)	2 (0.8%)	4 (1.7%)	1.000
Proton pump inhibitors (PPIs)	86 (71.1%)	75 (62.0%)	161 (66.5%)	0.134
Antiemetic	121 (100.0%)	121 (100.0%)	242 (100.0%)	-
Levothyroxine	27 (22.3%)	24 (19.8%)	51 (21.1%)	0.636
Statins	26 (21.5%)	31 (25.6%)	57 (23.6%)	0.449
Antiplatelet	7 (5.8%)	9 (7.4%)	16 (6.6%)	0.605

AB=antibiotics, BMI= Body Mass Index, CKD = chronic kidney disease, DM = diabetes mellitus, HTN = Hypertension, IHD = ischemic heart disease, N= number or frequency of patients, OA = osteoarthritis, PPIs= Proton pump inhibitors, RA = rheumatoid arthritis, SD = standard deviation, TKR = total knee replacement, VTE = venous thromboembolism. To test the difference between continuous variables, compare means ANOVA test was used. Chi square was conducted to test discrete variables (frequencies).
* Lifestyle: restricted means always sitting, normal means everyday life activity and highly active means exercising on daily basis.

The main difference found between the two groups was in respect of the surgery type. For unilateral TKR, group B was higher than group A with 81 (33.5%) vs. 52 (21.5%) patients, respectively. As regards bilateral TKR, group A was higher than group B with 69 (28.5%) vs. 40 (16.5%) patients, respectively, at a significant p-value < 0.05. As for the comorbidities and medications of the two groups, as shown in Table 1, there were no significant differences in either medical illnesses or medications between groups A and B. All patients were prescribed the following four types of medication as preventive measures and as prophylaxis during their hospital stay: antibiotics, proton pump inhibitors or H2 blockers, VTE prophylaxis and antiemetic, in addition to analgesics post operation.

Table 2 shows the hospitalization details for all the participants from admission to discharge. It can be seen that there were no significant differences between the control group (B) and the experimental group (A). The mean duration of hospital stay was 5.68 (SD 1.32) days for all participants. All the artificial implemented knees were the cemented type. The mean duration of surgery was 2.15 (SD 0.618) hours. Regional anesthesia was used for the majority of participants (79.8%), while general anesthesia was given to 20.2%. As regards post-operation pain, 70.2% of the participants reported severe pain 24 hours post operation, 78.5% of participants were prescribed a strong opioid. As an anticoagulation treatment, 96.3% of participants were prescribed Enoxaparin before surgery and 97.1% were prescribed Enoxaparin after surgery. Upon discharge, 52.9% of the participants were prescribed Rivaroxaban (10 mg daily) as the extended VTE prophylaxis, without any significant differences between the two groups. The majority of the participants could not walk on day 0 which is defined as 'hours post operation' (98.8%) or on day 1 post operation (93.0%). The mean number of days needed for all patients to start walking post operation was 2.50 (SD 1.08) days, whereas they needed 4.13 (SD 1.5) days to achieve full mobilization post operation. A comparison of VTE and bleeding risk factors are shown in Table 2, according to the HAS-BLED score, the numbers shown in Table 2 represent the number of patients classified as high risk for major bleeding

In the experimental group (A), most patients were classified as moderate high risk (45.5%, 55/121), while 39.7% (48/121) were classified as very high risk and 14.9% (18/121) were classified as low high risk.

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Table 2. Surgical procedure, treatment, recovery measures, and risk factors

Clinical data	Group A 121 (50.0%)	Group B 121 (50.0%)	All (N,%)	p-value
Duration of hospital stay; Mean (SD)	5.58 (1.53)	5.79 (1.08)	5.68 (1.32)	0.227
Type of metal implants; (N,%)				-
Cemented	121 (100.0%)	121 (100.0%)	242 (100.0%)	
Cementless	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Others	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Length of surgery; Mean (SD)	2.08 (0.550)	2.22 (0.674)	2.15 (0.618)	0.088
Type of Anesthesia; (N,%)				0.426
Regional	99 (81.8%)	94 (77.7%)	193 (79.8%)	
Pain score; (N,%)				
Mild pain	7 (5.8%)	13 (10.7%)	20 (8.3%)	
Moderate pain	30 (24.8%)	22 (18.2%)	52 (21.5%)	
Severe pain	84 (69.4%)	86 (71.1%)	170 (70.2%)	
Type of analgesia;(N,%)				0.947
No analgesia	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Non-opioid	3 (1.3%)	3 (1.3%)	6 (2.5%)	
Weak opioid	22 (18.2%)	24 (19.8%)	46 (19.0%)	
Strong opioid	96 (79.3%)	94 (77.7%)	190 (78.5%)	
VTE-Prophylaxis pre-operation; (N,%)				0.498
NON*	1 (0.4%)	2 (0.8%)	3 (1.2%)	
Enoxaparin	118 (97.5%)	115 (95.0%)	233 (96.3%)	
UFH	1 (0.4%)	3 (1.3%)	4 (1.7%)	
Rivaroxaban	1 (0.4%)	0 (0.0%)	1 (0.4%)	
Aspirin (N,%)	0 (0.0%)	1 (0.4%)	1 (0.4%)	
VTE-Prophylaxis Post-operation; (N,%)				0.564
NON	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Enoxaparin	119 (98.3%)	116 (95.9%)	235 (97.1%)	
UFH	1 (0.8%)	3 (2.5%)	4 (1.7%)	
Rivaroxaban	1 (0.8%)	1 (0.8%)	2 (0.8%)	
Aspirin	0 (0.0%)	1 (0.8%)	1 (0.4%)	
Extended VTE after discharge				0.093
Enoxaparin 30mg	0 (0.0%)	1 (0.8%)	1 (0.4%)	
Enoxaparin 40mg	41 (33.9%)	43 (35.5%)	84 (34.7%)	
Rivaroxaban 10mg	59 (48.8%)	69 (57.0%)	128 (52.9%)	
Rivaroxaban 20mg	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Aspirin 160mg	20 (16.5%)	8 (6.6%)	28 (11.6%)	
Aspirin 325mg	1 (0.8%)	0 (0.0%)	1 (0.4%)	
Mobility within hours post operation (D0) (N,%)	0 (0.0%)	3 (2.5%)	3 (1.2%)	0.081
Fully mobilized no later than D1 (N,%)	9 (7.4%)	8 (6.6%)	17 (7.0%)	0.801
Day for start walking post operation; Mean (SD)	2.51 (1.10)	2.49 (1.06)	2.50 (1.08)	0.859
Day of achieving Fully mobilization post operation; Mean (SD)	4.06 (1.7)	4.20 (1.3)	4.13 (1.5)	0.476
VTE risk factors other than the surgery; (N,%)				0.386
Weak risk factors	41 (33.9%)	49 (40.5%)	90 (37.2%)	
Moderate risk factors	77 (63.6%)	67 (55.4%)	144 (59.5%)	
Strong risk factors	3 (1.3%)	5 (2.0%)	8 (3.3%)	
Caprini Score; Mean (SD)	7.84 (0.89)	7.83 (0.91)	7.83 (0.90)	0.886
Sheet Score (Group A only); Mean (SD)	9.62 (2.01)	-	-	-
Sheet category (Group A only); (N,%)				-
Low high risk	18 (14.9%)	-	-	
Moderate high risk	55 (45.5%)	-	-	
Very High risk	48 (39.7%)	-	-	
Risk for bleeding; (N,%)	4 (3.3%)	7 (5.8%)	11 (4.5%)	0.355

D0= same operation day, D1= after 24 hours post operation, SD=standard deviation, UFH= unfractionated heparin, VTE= venous thromboembolism. To test the difference between continuous variables, compare means ANOVA test was used. Chi square was conducted to test discrete variables (frequencies). * NON: indicates that no VTE prophylaxis was prescribed before surgery.

In this study, both the experimental (A) and control group (B) were followed up for 35 days post operation. During this follow-up period all complications were recorded and summarized, as shown in Table 3. A total of 15/242 participants (6.2%) experienced DVT symptoms, while PE symptoms were seen in one case 1/242 (0.4%). In contrast, diagnosis using Doppler ultrasound was confirmed for DVT in 12/242 (5.0%) patients but there were no confirmed PE cases. Among the confirmed DVT cases, one was in group A (1/121, 0.8%) and the rest were in group B (11/121, 9.1%), with a significant difference between the two groups ($p<0.05$). All the VTE complications were seen before day 14 post surgery; however, the follow-up was continued up until 35 days post operation. There were no significant differences between the two groups in respect of bleeding, surgical site infection (SSI), or sudden death post TKR surgery; the total bleeding rate was 0.8% (2/242), the total SSI rate was 0.8% (2/242), and sudden death occurred in

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Table 3. Frequency of all complications post surgeries during follow up period

Clinical data	Group A N=121 (50.0%)	Group B N=121 (50.0%)	All N=242	p-value
Sudden death (N,%)	0 (0.0%)	1 (0.4%)	1 (0.4%)	0.318
Confirm VTE cases (PE or DVT) (N,%)				0.007
None	118 (98.3%)	107 (88.4%)	225 (93.4%)	
Confirmed DVT	1 (0.8%)	11 (9.1%)	12 (5.0%)	
Confirmed PE	0%	0%	0%	
Not confirmed DVT	1 (0.8%)	2 (1.7%)	3 (1.2%)	
PE (N,%)	0%	1 (0.8%)	1 (0.8%)	
Bleeding (N,%)				0.157
No	120 (100.0%)	119 (98.3%)	239 (99.2%)	
Yes, minor	0 (0.0%)	2 (1.7%)	2 (0.8%)	
Yes, major	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Surgical site Infection (N,%)	0 (0.0%)	2 (1.7%)	2 (0.8%)	0.157
Readmission (N,%)	0 (0.0%)	6 (5.0%)	6 (2.5%)	0.014
Did you take the VTE prophylactic medication as prescribed for you? Yes (N,%)	120 (100.0%)	118 (97.5%)	238 (98.8%)	0.083
Can Tell medication name, dose, and schedule	88 (73.3%)	83 (68.6%)	171 (71.0%)	0.418

DVT= Deep vein Thrombosis, PE=Pulmonary embolism, SD=standard deviation, VTE= venous thromboembolism. To test the difference between continuous variables, compare means ANOVA test was used. Chi square was conducted to test discrete variables (frequencies).
*This is patients' understanding of the medications.

one case (0.4%, 1/242). The readmission rate for all patients was 2.5% (6/242), all of the patients who were readmitted were from group B with a significant difference between the two groups at a p-value < 0.05. As regards the compliance measure, 98.8% of all patients claimed that they took their VTE prophylaxis medication as prescribed, while 71.0% were able to relate the name, dose, and schedule for their medication. At the first follow-up visit, which was on day 14 post operation, all patients had taken their prophylaxis medication for the past 14 days. After that, some patients completed an extended course of VTE prophylaxis medication for a period of more than 14 days post operation, with an average of 19.91 (SD 7.45) days for all patients. There were significant differences between the two groups in respect of the prophylaxis medications. Firstly, the mean duration for extended VTE prophylaxis postoperatively was 22.70 (SD 7.90) days for group B, which was higher than for group A whose mean duration was 17.12 (SD 5.78) days (p<0.05).

DISCUSSION

To the best of the author's knowledge, this study is the first to provide an easy, quick VTE risk assessment protocol for TKR patients, by applying a risk stratification protocol; to ensure that each patient is receiving the tailored VTE prophylactic agent. In addition to the new proposed risk stratification protocol, patients educational programs that was done by the clinical pharmacist have added a synergistic effect. Both interventions have proven their efficacy in reducing complications post TKR surgeries, and this agrees with several studies that have proven the effective role of anticoagulation services presented by pharmacists.[22] In this study, a debate could emerge about what is exactly behind the findings, what is the real effect of patients' educational programs or even the novel risk stratification procedure. Actually, these findings should be attributed to the clinical pharmacists' interventions, whether in patients' educational programs or VTE prophylaxis recommendations through the usage of the novel risk stratification procedure, as stated by Scrimenti *et al* (2019), that all clinical pharmacists can provide education and make recommendations, interpret, and adjust VTE prophylaxis medications' dosing, and this is exactly what is done in this study, when the clinical pharmacist are allowed to intervene, directly the differences in the outcomes will be apparent.[23] Caprini risk assessment tool includes general points for all medical and surgical patients, but the novel risk stratification procedure is specific for TKR patients, in which TKR patients can be categorized into low, moderate, or high VTE risk, which is, in turn, will allow to choose the suitable preventive therapy and duration for each patient according to his/her risk category. While in group B all the patients' level of risk was high according to Caprini risk assessment tool. In this study, the two randomized groups were similar in terms of patient characteristics. The only difference between the two groups was the type of surgery; a higher number of patients in group A had bilateral TKR as compared to patients in group B. In this study, the total symptomatic VTE within 35 days post operation was 4.95% (12/242), which is within the international range for VTE incidence rate. According to the literature, the symptomatic VTE rate during the first 3 months post orthopedic surgery is within the range of 1.3% to 10%.[19] According to Murnaghan *et al*. (2012), who conducted a study on VTE and bleeding events following elective joint replacement surgeries, 12 out of 2342 patients (0.6%) developed DVT, while 16 out of 2342 (0.7%) patients developed PE.[24] On the other hand, Loh *et al*. (2019) reported a rate of symptomatic DVT post TKR of 4.5%.[25] Moreover, Murnaghan *et al*., 2012 concluded that all the early PE complications were seen in TKR surgeries, while late VTE events were seen in Total hip replacement (THR).[24] Meanwhile, Fuji *et al*. (2017) found that the DVT, PE, and bleeding incidence rate by surgery type is 1.3, 0.2, and 1.0% for TKR.[26] Thus, in concordance with most studies, in this study, two cases of minor bleeding were seen during follow-up period, with a bleeding rate of 0.8% (2/242). The authors use HAS-BLED to estimate bleeding risk, while this stratification tool has mainly been used in atrial fibrillation populations, still it could be used in patients receiving anticoagulants.[27]

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As regards major bleeding events, the incidence rate was 0% because no cases of major bleeding were seen during the follow-up period. This outcome is comparable to the bleeding rate post TKR reported in the literature, where the major bleeding events rate is 0.04%.[24] The zero incidence rate may be due to the need to have a larger sample size to be able to detect major bleeding events. Regarding SSIs, in this study, the overall rate was 0.8% (2/242) for all patients, which is within the estimated international range. The overall rate of infection post orthopedic surgeries has been reported to range from 0.55% up to 1.77% for primary surgeries, while for revision surgeries it is 2.37%.[28] In this study, sudden death occurred in one case, with a rate of 0.4% (1/242), and this case had a bilateral TKR under general anesthesia. According to the National Center for Health Statistics in the United States, VTE is responsible for around 100,000 deaths each year in the United States, and 25% of hospital sudden death cases are due to PE.[29]

In this study, the readmission rate for all patients was 2.5% (6/242), all of whom were from group B with a significant difference between the two groups at a p-value <0.05. This readmission rate is lower than the rate of 4% for 30 days post TKR surgeries reported in the literature.[30] For group A in this study, aspirin was one of the VTE prophylaxis choices, which is in line with several studies that have shown that aspirin represents an effective choice post elective TKR or THR.[31] Also, in a recent systematic review Mistry *et al*. (2017) concluded that aspirin is an effective and safe prophylactic agent post elective arthroplasty.[32]

Lastly, as a study limitation, when considering the above results, it should be noted that this study was a randomized controlled study, and in these types of studies, the best practice is to use double-blind randomization. In this study, only the participants (patients) were blinded to their group, while the data collectors (clinical pharmacist and physicians) were unblinded so that they could administer the appropriate interventions. While it is recognized that this could be a source of experimenter bias, it was necessary to adopt this approach because the data collectors and physicians needed to know to which group each patient belonged in order to be able to follow the relevant protocol in choosing the VTE extended prophylaxis and whether or not to provide the educational programs. Nevertheless, this study met the most important conditions for successful randomization, i.e., "adequate generation of an unpredictable allocation sequence and concealment of that sequence until assignment occurs".[33]

CONCLUSIONS

This study was a randomized controlled trial that demonstrated the positive outcomes of using a new proposed VTE risk stratification protocol which provides an easy, quick procedure for patient-specific VTE risk assessment in order to ensure that each patient is given a tailored VTE prophylactic agent. The results showed that the VTE risk stratification protocol, which was administered in conjunction with patient education programs on TKR, can reduce VTE complications and readmission events post TKR surgery.

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CONFLICT OF INTEREST

The authors declare that they have no competing interests.

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International Series: Integration of community pharmacy in primary health care

Primary health care policy and vision for community pharmacy and pharmacists in Portugal

Nadine RIBEIRO, Helder MOTA-FILIPE, Mara P. GUERREIRO, Filipa A. COSTA.
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Abstract

The central role of the Portuguese National Health Service (P-NHS) guarantees virtually free universal coverage. Key policy papers, such as the National Health Plan and the National Plan for Patient Safety have implications for pharmacists, including an engagement in medicines reconciliation. These primary health care reform, while not explicitly contemplating a role for pharmacists, offer opportunities for the involvement of primary care pharmacists in medicines management. Primary care pharmacists, who as employees of the P-NHS work closely with an interdisciplinary team, have launched a pilot service to manage polypharmacy in people living with multimorbidities, involving potential referral to community pharmacy. Full integration of community pharmacy into primary health care is challenging due to their nature as private providers, which implies the need for the recognition that public and private health sectors are mutually complementary and may maximize universal health coverage. The scope of practice of community pharmacies has been shifting to service provision, currently supported by law and in some cases, including the needle and syringe exchange program and generic substitution, remunerated. Key changes envisaged for the future of pharmacists and their integration in primary care comprise the development and establishment of clinical pharmacy as a specialization area, peer clinician recognition and better integration in primary care teams, including full access to clinical records. These key changes would enable pharmacists to apply their competence in medicines optimization for improved patient outcomes.

Keywords

Pharmacies; Primary Health Care; Delivery of Health Care, Integrated; Ambulatory Care; Community Health Services; Pharmacists; Community Pharmacy Services; Professional Practice; Portugal

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HEALTH CARE IN THE PORTUGUESE CONTEXT

Portugal has a population of around 10.5 million inhabitants, which is mal distributed with a high coastal urbanized population density and low in rural areas.[1] Data for 2017 indicate that Portugal is in the group of countries with highest ageing indexes, together with Japan, Germany and Italy.[2] In 2017 the elderly were 17% of the population. Estimates for 2050 suggest that 35% of the population will be aged over 65 and 13.4% aged over 80.[3] In line with the demography, the patterns of disease are those of industrialized countries, with most adults having two or more chronic illnesses.[4] When compared to the OECD average, Portugal has higher prevalence of diabetes and dementia, and conversely a higher survival for breast cancer.[5]

The gross domestic product (GDP) per capita for 2018 was 34,272 USD, with slight increases in the last 20 years, albeit with some exceptions during recession years.[5,6] The Portuguese health care system is well structured, as a result of the creation of a Portuguese National Health Service (P-NHS) in 1979, offering universal health coverage. The P-NHS follows a Beveridge model, where health care is funded by the government through tax payment.[7]

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In 2019 the Government's expenditure on health was 6% of the GDP with an out-of-pocket expenditure by citizens estimated at 3.1% of GDP.[5] In 2020, around a third of Portuguese citizens have private health insurance, not because of ineligibility for P-NHS care, but mostly because of a perception of low quality of the public system or delays in access to specific treatments (e.g. surgery).[8] The health care workforce has been increasing, with 5.2 physicians, 7.2 nurses and 1.3 pharmacists per 1,000 inhabitants in 2018.[9]

GENERAL HEALTH POLICY IN PORTUGAL

The dominant feature of the health program presented by the Government for the period 2019-2023 lies in the introduction of new forms of services provision and organizational structures with objective to better respond to societal needs and improve the efficiency and quality of care.[10,11] These forms of delivery intend to promote innovation and disruption of traditional approaches, improving access to health services, whilst maximizing integration of local responses between different levels of care to achieve continuity of care.[10] Public participation emerges as a fundamental axis of the P-NHS reform, aligning its services with citizens' expectations and needs, both in hospitals and in primary health care. Special emphasis is given to activities and services that may contribute to promote healthy ageing. These comprise alternative ways of service provision, resorting to digital technologies, creating IT systems for data management and data consolidation. Finally, the Government program also addresses current challenges in achieving universal health coverage without the risk of financial hardship, by reinforcing the Government's responsibility of ensuring health for all and subjecting third party contracting for P-NHS services to a needs and capacity assessment.[10]

The main strategic lines of the national health policy reported by the Portuguese General Health Directorate are brought together in the "National Health Plan", based on four strategic axes:

1. Public participation in health, reinforcing the citizen's power and responsibility towards individual and collective health;
2. Equity and adequate access to health care;
3. Health quality, where emphasis is given to person-centered care and value-based outcomes;
4. Health in all policies.[12]

The National Health Plan sets specific goals to be met in 2020, some of which highlight the role of patient health-related behaviors in achieving optimal health outcomes (e.g. to reduce the prevalence of smoking behaviors in population aged over 70); and identifies challenges that must be overcome to meet the set targets. None of the goals are specifically directed to pharmacists, although several challenges are specifically relevant for primary care, and by implication for pharmacists and pharmacies. One of the strategies refers to providing person-centered care instead of disease-focused care; the latter resulted in fragmented care arising from uncoordinated specialists treating multimorbidity. Worth noting is the challenge of information technologies for timely and coordinated access to clinical data for all professionals, so that patient safety is guaranteed.

Another key policy paper is the National Plan for Patient Safety 2015-2020. Strategic goal #4 aims at increasing medication safety. One of the actions under this goal is the provision of medication reconciliation; with an implementation goal of 90% of all P-NHS units by the end of 2020. The Quality and Safety Commissions of hospitals and primary health care units have the responsibility for the implementation of the National Plan for Patient Safety.[13] This commission includes the participation of publicly employed primary care pharmacists.

PRIMARY CARE HEALTH POLICY AND THE ROLE OF THE PHARMACIST

Primary health care is considered as the basis for achieving universal health coverage and optimal care outcomes. This view has been endorsed by the current Government but also by former administrations. The Portuguese primary health care reform in 2006 was characterized by the organization of health care centers into larger administrative units, designated Health Centre Groups, and the creation of Family Health Units.[9,14] Health Centre Groups are under the direct responsibility of Regional Health Administrations (ARSs). There are five of these regional branches of the P-NHS in mainland Portugal, with the mission of guaranteeing population access to health care, adapting available resources to local needs, complying with and enforcing health policies and programs in their areas of jurisdiction.

A significant feature of the primary health care reform is to expand and give greater autonomy to family health units; this is expected to leverage local responses by creating more community care units and strengthening the links between primary health care, long-term care and palliative care. Another policy priority is providing primary care with additional multidisciplinary specialties and to encourage the adoption of new workflow models. Family nurses are an example of these new specialties. Integration of clinical psychologists and nutritionists in primary health care units has also been announced. To date, there is no mention of pharmacists and their role in this setting or their inclusion in family health units. However, the multidisciplinary approach may be an enabler for including additional health care professionals, who can add value to care provision.[15] In fact, the Portuguese Family Health Units National Association (USF-AN) has advocated for greater skill-mix, through the incorporation of primary care pharmacists with advanced competencies in clinical pharmacy into these multidisciplinary teams.[16] Currently, the regulatory body of the pharmacy profession in Portugal, the Portuguese Pharmaceutical Society, does not endorse clinical pharmacy as a specialty. In theory both hospital and community pharmacists may qualify as clinical pharmacists, depending on their level of practice, and be subjected to standards that remain to be defined. Staff pharmacists from the ARSs, who have a hospital background, have occasionally taken up this role in primary care units. These primary care pharmacists represent a limited pharmacy workforce for clinical services as they are only 33 for the entire country. They are public servants and their main roles are managing medicines procurement (all 100% engage in these activities), public health activities (including provision of scientific and technical counselling at an ARS level, involvement in policy recommendations, drug use studies, monitoring indicators for contracted services; around 70% engage in such activities) and clinical pharmacy (including prescription validation and medicines reconciliation; around 30% engage in these activities).

Although no specific mention is made to the role of pharmacists in primary health care in existing health policies papers, many strategic goals for this setting include activities where pharmacists' training is an asset for the multidisciplinary team and, more importantly, for people living with illness. An example is the "pharmacotherapy prescription qualification" strategy, aiming to reduce costs whilst achieving maximum benefits for people using medicines. This strategy relies on recommendations issued by Pharmacy and Therapeutics Committees in primary health care, underpinned by scientific evidence. Primary care physicians and pharmacists are, by law, members of these Committees, and exemplify a bottom-up approach to change addressing unmet needs of clinical practice.[15]

Polypharmacy management in people living with multimorbidity

To address population ageing and the absence of structured programs to manage polypharmacy in primary care, a pilot service was designed and implemented in two ARSs by an interdisciplinary team involving primary care pharmacists, general practitioners (GPs) and nurses.[17] This service targets chronic, complex and fragile people over 65 years old and entails a structured initial face-to-face medication review performed by the primary care pharmacist in patients referred by the GP, followed by a discussion about opportunities for medicines optimization

and a follow-up, based on an agreed plan, with safety and effectiveness indicators for medicines and other pertinent strategies, such as education, lifestyle counselling and medication adherence enabling interventions.[18] Where appropriate, usually in the less complex cases and subjected to patient's agreement, community pharmacies are contacted to ensure continuity of care. This collaborative model is new and has so far, no remuneration. In this novel service primary care pharmacists have access to medical records and can discuss the case with patient's care team. The service is currently available in three primary care units, and the expansion to the remaining 12 units depends on workforce availability. It represents an opportunity to foster the integration of community pharmacies in primary health care. Even though the inclusion of a primary care pharmacist in primary care units is currently centered in the management of polypharmacy, it may encourage involvement in other activities, including physician and nurse education on new therapies. This service may be considered disruptive in the Portuguese context, since multidisciplinary teams in this area are new. Such programs fit into the major changes planned and designed by policy makers in the scope of primary care provision.

COMMUNITY PHARMACY IN PORTUGAL

There were 14,423 registered pharmacists in Portugal in 2017, 59% of whom practice in community pharmacy, 9% in hospital pharmacy and the remainder distributed through other areas of pharmaceutical sciences.[19] In 2016, according to the FIP, there were, 14.9 registered pharmacists per 10,000 inhabitants, quite high in relative terms to other countries.[20] The number of pharmacists has progressively been growing in Portugal, aligned with international projected trends.[21] Interestingly the pharmacists in Portugal are young, with 41% below 35 years of age and 10% aged between 35 and 44 years.[19]

In 2018, the 2,923 community pharmacies were distributed throughout the country.[22] Ownership rules and geographical distribution changed in 2007 with legislation that terminated the exclusivity of pharmacy ownership by pharmacists. Community pharmacies may be owned by non-pharmacists, but each pharmacy must have a pharmacist technical director responsible for the functioning of the pharmacy and compliance with good pharmacy practice. The ownership of a pharmacy is, however, restricted to individuals or corporations that have a conflict of interests in medicines dispensing, such as wholesalers, pharmaceutical industry, associations representing pharmacies, prescribers, private entities providing health care and P-NHS subsystems that co-pay for medicines.[23] The legislation also states that for a new pharmacy to be opened, there must be a minimum of 3500 inhabitants in the location, unless the pharmacy is opened at a distance of more than 2 km from the closest pharmacy or, within residential areas, 350 meters between pharmacies in a direct line; 100 meters between the pharmacy and the health care unit, except in places with less than 4,000 inhabitants.[24]

There are two associations representing the interests of community pharmacy owners in Portugal, the National Association of Pharmacies [Associação Nacional das Farmácias - ANF] and the Association of Pharmacies of Portugal [Associação de Farmácias de Portugal – AFP]. Membership is voluntary for both associations. ANF represents 95% of pharmacies in Portugal and has the mission "to make pharmacies the most valued primary health-care network by Portuguese citizens". To achieve this goal, ANF has developed companies, structures and projects which cover areas relevant to pharmacies, in political, professional (education and pharmaceutical services), and financial areas. One of the main activities for both organizations is the relationship and advocacy with government and health administration, in order to ensure that pharmaceutical legislation and regulation, as well as operationalization, take into account the actual and potential added-value community pharmacies can bring to the health of the population.[25] The plan of activities of ANF for 2020 identifies as key intervention areas for investment: the development of new services that meet the health-needs of the Portuguese population; perusal of the pilot to dispense HIV medication in community pharmacies and investment in developing methodologies for extending to oncology; supporting pharmacies in the implementation of point of care services for HIV and viral hepatitis; implementation of a service to respond to minor health problems, including physician referral when appropriate; promote remuneration of pharmaceutical intervention; developing clinical pathways integrated into a clinical support system for pharmacies.[26]

Pharmacies in Portugal may sell medicines for human use, medical devices, veterinary medicines, homeopathic medicines, herbal products, medical devices, nutraceutics, cosmetics, products for childcare, products of comfort and food supplements.[23] In addition, the legislation foresees the services that may be provided in pharmacies by qualified pharmacists and other allied health care professionals (Table 1).[27,28]

Community pharmacies' revenue come mostly from a mark-up margin on the price of medicines dispensed. In the case of prescription medicines, the remuneration system is set by the Government. Major changes were implemented in 2012 and further adjusted in 2014.[29] The system combines a regressive mark-up based on a percentage of the medicine ex-factory price (from 18.4 to 27.9%) and a progressive dispensing fee per package (from 0.63 EUR to 8.28 EUR).[30] For most non-prescription medicines and medical devices, as well as other products available in the pharmacy, the selling price is freely established by each pharmacy and remuneration is a percentage mark-up, on average estimated to be around 28%.

In terms of service remuneration, the system is quite different, and these are, in general, charged using retrospective or prospective analysis.[31] Retrospective methods are the most commonly used in the outpatient setting and include for example the fee-for-service, whereas prospective methods tend to be adopted in the hospital setting and an example is a coding system for diagnostics and associated procedures entitled the homogeneous diagnostic groups.[32] In Portugal, the two community pharmacy services remunerated use fee for service, established nationally by the Government by law and regardless of clinical outcomes for the patients.

Table 1. Community pharmacy services established by law.[27,28]

- Home support
- First aid
- Administration of medicines
- Use of diagnostic and therapeutic auxiliary means
- Administration of vaccines not included in the National Vaccination Plan
- Pharmaceutical care programs
- Nutrition appointments
- Adherence programs, medicines reconciliation, services making use of multicompartment aids, health education programs for the use of medical devices
- Point of care testing for the screening of HCV, HBC and HIV, including counselling pre and post-test and referral of positive cases to hospital care following referral channels established by the Ministry of health
- Nursing services, including wound treatment and care of people with ostomies
- Level I care to diabetic foot, according to the recommendations of the Department of Health
- Promotion of campaigns for health literacy, disease prevention and healthy lifestyle promotion.

In 2016, legislation was passed for contracting public health services to community pharmacies. Interventions aligned with health policy priorities, such as programs integrated in primary care, needle and syringe exchange program and medication adherence interventions are mentioned in this regulation.[33] One of the two services currently remunerated is the needle and syringe exchange program available in community pharmacies since 1993. This internationally acclaimed program for its contribution to minimize HIV and other blood–borne diseases was initially delivered pro bono by pharmacies.[34] Program evaluation indicated that pharmacies' contribution resulted in a net benefit of 3.01 EUR per needle exchanged, originating overall system savings of over 2 million euros in a 5-year period.[35] The reimbursement system reflected these data, pricing at 2.40 EUR each package of 2 needles exchanged.[36] This program is closely monitored and the most recent data available shows a 7% increase in the number of needles exchange in pharmacies between January and June 2019, compared to January to June 2018, corresponding to a monthly average of 11,472 needles, totaling 137,272 in the period considered.[37]

The other remunerated service is generic substitution, which aims to the increase of generic market share. Legislation to reward generic substitution and incentivize dispensing the least costly options has been active since 2015 and the most recent update refers to 0.35 EUR/package.[38] The market share of generics for 2018 was 48.4% in units or 53.7% if measured in defined daily doses. This corresponds to an increase near 17 percentual points since 2000.[39]

Despite legal coverage, no other services were contracted to date. Other services (Table 1) are freely priced by pharmacies and paid out-of-pocket by users. The price of these services vary widely (including services delivered for free) and there is no publicly available data on number of services or pricing. Nevertheless, it is compulsory by law that all pharmacies display in a public area (physical space and website) the full list of services available and price charged for each service. As an example, the administration of vaccines in pharmacy may be charged between 0 and 5 EUR.

The Ministry of Health has promoted a reinforced public health role for community pharmacies, namely by enabling certified community pharmacists to dispense HIV medication, previously dispensed exclusively in hospital, in a pilot program and to reinforce the responsible use of these medicines in stable patients, working in articulation with P-NHS hospitals. The pilot is ongoing in one region, and depending on success, is foreseen to be broadened to also cover oncology medication.[39] Currently, the regulatory agency has a system in place to monitor the effectiveness and safety of health technologies. This system is mainly focused on high-cost medicines, i.e., oncology, orphan drugs, antivirals, etc., and relies mostly on hospital-based data sources, or on population-based registries when available.[40] However, considering a potential shift of some of these medicines to the community pharmacy, the intention to also resort to the pharmacies' information system for health technology assessment has been announced.[39]

Félix *et al*. have estimated that community pharmacy services in Portugal provide a quality of life gain for citizens of 8.3%, resulting in savings for the P-NHS and general population over 800 million EUR.[41] Services valued by citizens, include the immunization service, point of care testing and medication review, to name a few.[42-44] In fact, there are a number of services paid out-of-pocket, e.g. point of care testing (blood pressure, glycaemia, cholesterol, etc.), totaling more than 20 different services (Table 1).

Recently, the government started a pilot program providing influenza immunization in community pharmacies. People aged over 65 years could have their vaccine administered in a healthcare center or in a community pharmacy at no cost and with no prescription order required. During 2018 winter season, 7,000 individuals from the municipality of Loures preferred their community pharmacy to the healthcare center. This suggests the potential benefit of providing access through community pharmacy however it cannot yet be determined if the target to increase vaccination coverage was achieved.[45]

The implementation of technology in community pharmacy practice has been growing, including using robots to aid in dispensing to maximize workforce, and using algorithm-based programs to support identification of medication errors.[46] Electronic prescribing has become fully implemented in Portugal in 2020, through which people no longer need to resort to paper prescriptions and shows that technology barriers and information access may be overcome.[47] Full use of technology is likely to contribute to further development of advanced services in the best interest of people living with illness, if pharmacists and

representative associations see it as an opportunity and not as a threat.[48]

Challenges in integrating community pharmacy and pharmacists into primary health care

One of the main challenges for community pharmacies to become integrated in the P-NHS is their private ownership. A paradigm change by government is required, to regard private providers as a supplementary or complementary source of health care, similarly to what occurs with privately managed hospitals. Another key challenge is to achieve full data integration, so that community pharmacists may have access to patients' data and can contribute to updated information by registering their interventions. This is an important prerequisite to some of the services mentioned such as medicines reconciliation. It is also important for national public health information particularly in the context of vaccination coverage, for which some pilot experiences are already in place, that vaccine administered in the pharmacy are registered in the online health bulletin. These pilot experiences show that the access of data is more a matter of political will then a technical issue.

Crisis may lead to opportunities and the current COVID-19 pandemic is a good example of how pharmacies can contribute to the seamless supply of medicines.[49] There were two main measures, supported by legislative changes that created the possibility for community pharmacies to deliver hospital-only medicines for extended periods (including antiretrovirals, immunotherapy, etc); and the possibility for renewal of chronic medication in community pharmacies.[50,51] Both measures were created and implemented in order to provide access overcoming existing barriers and recognizing competences of professionals involved. Such measures became possible in troubled times, which shows that when there is an urgent need, barriers may be overcome.

CONCLUSION

Epidemiological trends in Portugal clearly show there is an ageing population with a growing prevalence of non-communicable diseases. Societies are also growingly more technological and more empowered. Services should be redesigned to serve societal needs and not to foster professional interests. Pharmacists may have an enormous contribution to meet sustainable development goals (SDG), particularly in ensuring healthy lives and promoting wellbeing at all stages (SDG #3) as well as promoting a more effective use of limited resources. There are missed opportunities, including for instance, engagement in exercise and health promotion through liaising with local communities, schools or residential facilities.[52] There are also unmet needs in primary care services in marginalized groups, including those living in prisons, the homeless and migrants, where pharmacists could make a difference working collaboratively.[53] There are activities being implemented in community pharmacy solely for commercial reasons, even if there is no real need or gaps in service provision, including optometry, audiology and other services. Pharmacists have no competence in this areas and merely make their space available to external providers. Clearly one area for continued and reinforced investment will be the establishment of clinical pharmacy as a competence or as a specialization area, which can support medicines optimization across the entire patient pathway, from community, to primary care, to hospital and ultimately to specialized care.

CONFLICT OF INTEREST

Filipa Alves da Costa declares to have an advisory role for the Portuguese Pharmaceutical Society. The other authors declare no conflict of interests.

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International Series: Integration of community pharmacy in primary health care

Primary health care policy and vision for community pharmacy and pharmacists in Indonesia

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Abstract

The practice of community pharmacy in low and middle-income countries, including in Indonesia, is often described as in the state of infancy with several intractable barriers that have been substantially and continuously hampering the practice. Such description might be valid in highlighting how pharmacy is practiced and the conditions within and beyond community pharmacy organizations. Therefore, it is not surprising that the concept of integrating community pharmacy into the primary care system may not be considered in the contemporary discourse despite the fact that community pharmacy has been operating within communities for years. However, in the case of Indonesia, we argue that changes in the health care system within the past decade particularly with the introduction of the universal health coverage (UHC) in 2014, may have significantly amplified the role of pharmacists. There is good evidence which highlights the contribution of pharmacist as a substantial health care element in primary care practice. The initiative for employing pharmacist, identified in this article as primary care pharmacist, in the setting of community health center [puskesmas] and the introduction of affiliated or contracted community pharmacy under the UHC have enabled pharmacist to work together with other primary care providers. Moreover, government agenda under the "Smart Use of Medicines" program [Gema Cermat] recognizes pharmacists as the agent of change for improving the rational use of medicines in the community. Community pharmacy is developing, albeit slowly, and is able to grasp a novel position to deliver pharmacy-related primary care services to the general public through new services, for example drug monitoring and home care. Nevertheless, integrating community pharmacy into primary care is relatively a new notion in the Indonesian setting, and is a challenging process given the presence of barriers in the macro, meso- and micro-level of practice.

Keywords

Pharmacies; Primary Health Care; Delivery of Health Care, Integrated; Ambulatory Care; Community Health Services; Pharmacists; Community Pharmacy Services; Professional Practice; Indonesia

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INTRODUCTION

The Indonesian health care and primary care system

Indonesia is one of the largest archipelagic countries in the world comprising 17,504 islands stretching in an area between two oceans (the Pacific and Indian oceans) with three different time zones and connecting two continents (Asia and Australia).[1] It has a population of approximately 267 million people representing more than 300 ethnicities with 700 local languages and dialects blending in with expatriates from numerous nationalities making it the fourth most populous country in the world.[2,3] The geographic and demographic size of Indonesia presents major barriers, including to health care delivery.

Indonesia remains saddled with a huge burden of a number of communicable tropical diseases – some of which are classified by the World Health Organization (WHO) as neglected tropical diseases – such as dengue, malaria, filariasis, leprosy, schistosomiasis, soil-transmitted helminths and yaws.[4] The list is not exhaustive with the inclusion of tuberculosis, lower respiratory infections and diarrheal diseases which often sits in the top ten causes of mortalities.[3] Although the overall trend is a steadily decreasing number, the persistent presence of communicable diseases has been an ongoing challenge for any government ruling the country.

Within the past two decades, major noncommunicable diseases related to several risk factors such as tobacco smoking, obesity, unhealthy diet, physical inactivity and high blood pressure have shifted the trend of disease burden in Indonesia.[5] For instance, a study in 2015 estimated that the morbidity of smoking-related diseases accounted for almost one million cases, about 21.6% of total cases of chronic diseases in Indonesia, with the treatment cost was estimated at least US$2,177 million, approximately 2.5% of the 2015 gross domestic product (GDP).[6] Chronic diseases such as ischemic heart disease, stroke, diabetes, hypertension and cancer remain the top cause of health loss and disabilities among Indonesians.[7]

The prominent "double burden" of persistent communicable diseases and increasing noncommunicable diseases has resulted in a huge cost for the country to maintain the health care sector. It was reported that nominal health spending had been steadily increasing within the past decade by 222% overall.[8] This has created a pressure on Indonesia's health expenditure which remains on the level of 3% of the GDP despite the mandate of Health Law 2009 stating that 5% of the national budget must be attributed to the health sector.[9] Health expenditure was reported at USD 125 per capita in 2018, which was the lowest among Low Middle-Income Countries (LMICs) and particularly within the developing Southeast Asian countries.[1,3,10]

The country also faces a critical shortage of health care workers and facilities. As of 2019, Indonesia only had 0.4

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physicians and 1.3 nurses per 1,000 people.[11] This is exacerbated by the uneven distribution of these workers, with the majority (67%) being located in Java Island – the most heavily populated island in the country.[11] Whilst the number of health facilities has nearly doubled within the past two decades, reaching 2,877 hospitals and 10,134 government-financed community health center [Puskesmas] in 2019, maldistribution and underperformance of these facilities have been evident, leading to a serious problem of accessing health care in the rural and suburban areas.[11]

Puskesmas and their auxiliary network in the district level are among the frontline primary care providers along with the private sector which is dominated by individual practice such as general practitioners, nurses, midwives and a range of private clinics.[8] Although puskesmas has been playing a vital role in providing promotive, preventive, curative services in a range of areas including maternal and child health, family planning, communicable disease, community nutrition and environmental health, their role has been underutilized. Its role remains marginalized with some fractions of the community still perceive that "puskesmas is for the poor and private practice is for the rich".[12]

The performance of puskesmas arguably has improved after an accreditation system was implemented in 2015.[13] Nevertheless, their functioning has been highly variable, and huge disparities have been noted among districts. Some puskesmas perform well, but the remaining facilities face various issues, including inadequate staffing, inability to provide basic care and poor relationships with the communities.[8,14] The decentralization system partly contributes to this disparity.[15] With the greater authority of the local head of the government at the district level, the functioning of puskesmas heavily relies on the district funding and commitment from the local leaders, leading to puskesmas in several districts suffering from poor functioning due to insufficient district funding, or shifted agendas and priorities from the district leaders.[16-18]

The introduction of Universal Health Coverage

Despite the intractable and persistent problems in the health care system and its delivery, the Indonesian government has made a significant investment over the years, aiming to improve the health care environment and funding. An ambitious program was set, i.e. Universal health coverage (UHC) for all Indonesians by 2019 in light of the United Nations (UN) Sustainable Development Goals (SDGs) 2030.[19] The UHC program was firstly designed in 2004, yet, hampered by the political and financial circumstances of the nation, it took ten years for the program to be finally introduced in 2014.[20] The UHC, on the one hand, has been viewed as a promising initiative to finance the health care sector, improve health equity and accessibility of health services.[1] It has been claimed to having features of protecting Indonesians from catastrophic payments for health care.[21] On the other hand, concern was raised over how the country would be able to continuously fund the scheme, given the complexity and diversity of resources and conditions in Indonesia.[22] Despite this discourse, the UHC program continues to grow and becomes a large single-payer scheme as it has covered roughly 90% of the population by the end of March 2020.

UHC is a game-changer for Indonesian health care. The program has changed the landscape of health care which was originally fragmented with private health insurance – provided only for those who could afford – and government insurance for a small portion of the population – mainly government workers, police and military, and very poor or vulnerable people – into a single national health insurance system.[23] The universal coverage system provides major benefits for Indonesians, particularly for covering the cost of medical bills for most diseases and health problems. As predicted, however, the program has a severe funding deficit every year. It is estimated that there will be a USD 2 billion (IDR 26 trillion) cash shortfall by the end of 2020, which may grow double by the end of 2025.[1] One of the contributing factors for this deficit is the low compliance in paying for the monthly insurance payment, particularly among the informal sector workers, which constituted 37% of the UHC members.[24] As a consequence, the government increased the payment package on May 2020 leading to a heated debate given that such initiative was previously annulled by the Supreme Court roughly two months before the policy was revoked.[25,26]

The UHC has transformed the referral system of health care. Previously any patient was able to go directly to hospitals or specialists when seeking medical help without referral even for minor cases. Staged referral mechanism has now been put in place between the three tiers of care: primary, secondary and tertiary care, with puskesmas as the gatekeeper for higher levels of care.[8] What might be relevant to pharmacy practice is that the UHC has opened up new opportunities for pharmacist involvement in primary care, which will be explained in the subsequent section.

CONTEMPORARY COMMUNITY PHARMACY PRACTICE IN INDONESIA

Overview

Community pharmacy services in Indonesia exist in public and private health sectors. Pharmacists in the public sector work in puskesmas are employed by the government, in this article they are referred to as primary care pharmacist. Unlike the public sector, pharmacists in the community pharmacy are generally private practitioners, in this article referred to as community pharmacist. The income of private community pharmacy is largely derived from the sales of medicines and other products. Additional services, such as consultation and prescription review, are often not remunerated. Also, the pharmacy owner determines the income of individual pharmacists if the pharmacists do not own the pharmacy. Ownership of pharmacy is open to anyone leading to a significant portion of pharmacies (roughly 70%) being owned by non-pharmacist.[27,28] However, a pharmacy cannot be opened without the pharmacist. Each pharmacy must, therefore, employ a minimum of one pharmacist to be in charge of the operation of the pharmacy.

In 2019, there were approximately 30,000 community pharmacies employing approximately 62,000 pharmacy personnel, including pharmacist and pharmacy support workforce, which represents one of the largest health care settings in the country.[11] In addition, community pharmacy

is among the most accessible and frequently used health care facilities. It operates within the heart of the communities, with more than 90% of the population having visited community pharmacy.[29] Moreover, clients do not need to spend a long time queuing, and most pharmacies open seven days in a week with nearly 15 hours of operation per day.[30]

Community pharmacists in Indonesia contribute to health care through the delivery of medicines and health-related products and services either independently or in collaboration with other primary care members, particularly General Practitioners (GPs).[31-33] Dispensing has been the predominant activities in community pharmacy.[34-36] However, the sale of over the counter medications and practice consultations are also common with pharmacist plays a role in providing advice and assistance for self-medication. These features might imply that community pharmacies are strategically placed and can offer a unique role to relieve strains on the health care system and reduce the over-reliance on the major primary care providers, e.g. GPs and the hospital admissions by operating at their full scope of practice.

There are two main legislations underpin pharmacy practice in Indonesia: the President Regulation number 51 of 2009 (Pharmacy Practice Act of 2009) and the Minister of Health (MoH) Regulation number 9 of 2017 (Community Pharmacy Decree of 2017).[37,38] The Pharmacy Practice Act provides the main policy framework ensuring that pharmacists have the solely responsibility for conducting pharmacy practice, including in puskesmas and community pharmacy. More importantly, the Act defines the scope of practice of pharmacist from the planning and procurement of pharmaceutical products to activities ensuring the use of quality medicines for the patients and communities. The Community Pharmacy Decree, on the other hands, regulates specific features of community pharmacy operation such as premise, ownership, pharmacy location, workforce and provision of services which align with the standards governing pharmacy services.

The MoH has issued standards for pharmacy services at the community pharmacy (under the MoH Regulation Number 73 of 2016) and puskesmas level (under the MoH Regulation Number 74 of 2016), respectively.[39,40] These standards are intended to serve as a basic guide for the provision of pharmacy services; outlining the minimum level of services that should be consistently delivered by the pharmacist in each setting. In these standards, pharmacists are encouraged to provide two elements of services namely (1) the supply and management of pharmaceuticals, health devices and other medical products and (2) clinical pharmacy services (Table 1). While the implementation might vary across sites, these standards have set the baseline for any pharmacist - related activities.

Integration of community pharmacy into the primary care system

Recognizing the potential of pharmacist in primary care particularly in the era of UHC, the government has introduced three scenarios for pharmacist integration within the primary care system. First, community pharmacy has now had the opportunity to become part of a network of primary care providers under the contractual agreement with the prescribers or the UHC insurance agency.[23] Second, as aforementioned, the allocation of pharmacists at puskesmas which was virtually nonexistent prior to UHC.[23] Third, the "Gema Cermat" program – a national campaign aimed at improving awareness and rational use

Table 1. The difference in pharmacy practice standard across sites.

Pharmacy Practice Standard	Community Pharmacy[39]	Community health center [puskesmas][40]	Hospital[41]
Supply and management of pharmaceuticals, health devices and other medical products			
Selection			√
Planning process	√	√	√
Procurement	√	√	√
Receiving process	√	√	√
Storage	√	√	√
Distribution		√	√
Recall			√
Disposal	√		√
Controlling	√	√	√
Documentation		√	
Administration	√	√	√
Report	√	√	
Monitoring and evaluation		√	
Clinical pharmacy services			
Prescription assessment	√	√	√
Medication reconciliation			√
Drug information center	√	√	√
Dispensing	√	√	√
Counselling	√	√	√
Independent ward round or collaboration ward round		√ (specific for inpatient care)	√
Drug therapeutic assessment	√	√	√
Monitoring of medication side effect	√	√	√
Drug use evaluation		√	√
Aseptic dispensing			√
Therapeutic drug monitoring (TDM)			√
Home pharmacy care	√		√

√ available in this setting

Table 2. Dispensing fee for pharmacy under the contracted scheme[43]

Drug price on e-catalogue system (IDR)	Coefficient for dispensing fee
< 50,000	0.28
50,000 – 250,000	0.26
250,000 – 500,000	0.16
1,000,000 – 5,000,000	0.11
5,000,000 – 10,000,000	0.09
> 10,000,000	0.07
(USD1 equals to IDR 14,000 as of June 2020)	

of medicines – has been launched with pharmacist holds the key player for delivery of the program.[42]

Under the UHC, community pharmacy can opt for any of the three models: as a pharmacy affiliated with a network of primary care provider (affiliated pharmacy), as a pharmacy commissioned for providing back referral program (contracted pharmacy), or both.[23] An affiliated pharmacy works in partnership with other primary care providers, particularly GPs, dentists and clinics. These community pharmacies are responsible for supplying pharmaceuticals and providing services for patients taken care of by the network. The pharmacy is reimbursed for pharmaceuticals based on the electronic catalogue (e-catalogue) pricing system. In addition, the pharmacy fee for dispensing the medicine is negotiated with the network based on the proportion of capitation payment for treating each individual patient. Each network receives capitation payment ranges from IDR 8,000 to 10,000 (less than USD 1) per patient, and ideally, this should be distributed within the network, including pharmacy.[43]

A contracted pharmacy is only responsible for providing services and pharmaceuticals for patients following hospital discharge. At the time of discharge, the patient can collect their discharge prescription either at puskesmas or at the contracted pharmacy. In this manner, the patient can continue to receive their medication for up to 30 days and consultation from the pharmacist for any medication problems. However, this service is only available for patients with certain chronic diseases, including hypertension, diabetes mellitus, heart failure, chronic obstructive pulmonary disease, stroke, asthma, epilepsy, schizophrenia, and systemic lupus erythematosus.[44] Community pharmacy under this scheme is reimbursed for the pharmaceuticals based on the e-catalogue pricing and the dispensing fee is paid using the formula on Table 2. For example, if a pharmacy dispensed a medicine which costs IDR 50,000, they would receive IDR 13,000 for the dispensing fee. Please note that this fee is paid for the pharmacy and not the pharmacist.

It was reported that only less than 9% of community pharmacies have participated in the UHC scheme, with the large portion of the remaining is independent of it.[45] The number was even smaller for contracted pharmacy as there are only 469 contracted pharmacies across the country in 2020, representing less than 2% of the total community pharmacy population.[45] Factors contributing to the low participation of pharmacy has been mixed and anecdotal. On the one hand, the BPJS Health – the insurance agency responsible for organizing UHC – claimed that the low participation had been associated with the uneven distribution of pharmacy, making it difficult to recruit more pharmacies in an area in which ratio between pharmacy and population has not been met. On the other hand, pharmacies, which were not willing to participate or those who already discontinued their affiliation, complained about the late payments which may take several months after submitting the claims.[46,47]

The allocation of primary care pharmacist in puskesmas cannot be separated from the MoH Regulation number 46 of 2015 concerning puskesmas accreditation which states pharmacy service as an essential part of puskesmas operation.[13,40] Such allocation is critical because prior to 2014, pharmacy practice in puskesmas was mainly provided by non-pharmacists i.e. other health care professionals. The regulation mandates that every puskesmas needs to have at least one pharmacist as the pharmacist in charge. The pharmacist in charge is responsible for the operation of the pharmacy unit and the provision of pharmacy services. The regulation also specifies a ratio for pharmacists to patients of 1:50 for outpatient services and 1:30 for inpatient services. This regulation has enabled puskesmas to have more flexibility in recruiting pharmacists, either on a contractual basis or in a permanent position as a government official. The pharmacist receives a fixed monthly salary from the government and other incentives to top up their income. The incentives may include dispensing fee following to the formula on Table 2, an income from the portion of capitation payment which ranges from IDR 3,000 to IDR 6,000 (less than USD 0.5) per patient paid to puskesmas and other sources of income funded by the district government such as merit reward and incentive for delivering health campaign which may vary between Puskesmas.[43]

The involvement of pharmacists in puskesmas allows for collaboration with other primary care providers within puskesmas. For example, pharmacists can assess medication appropriateness, ensure the safety, efficacy and adherence to medication, as well as provide recommendations to the other providers (Table 1). In addition, pharmacists' role in puskesmas can also include the delivery of home care pharmacy programs and public health campaigns to the general public. The degree of pharmacist's involvement and collaboration, however, may vary across puskesmas, depending on their workload, given that most puskesmas have only one pharmacist in charge of providing a service to roughly 300 patients per day.[48,49]

Another scenario for pharmacist involvement in primary care both for community and primary care pharmacist is through the “Gema Cermat” (smart use of medicines campaign) program. However, unlike the other two scenarios, “Gema Cermat” which was launched in 2015, in principle is a campaign program to improve the community awareness in using medicines.[50] The campaign has been recruiting pharmacist as the trainer of the program conveying public educational message regarding self-

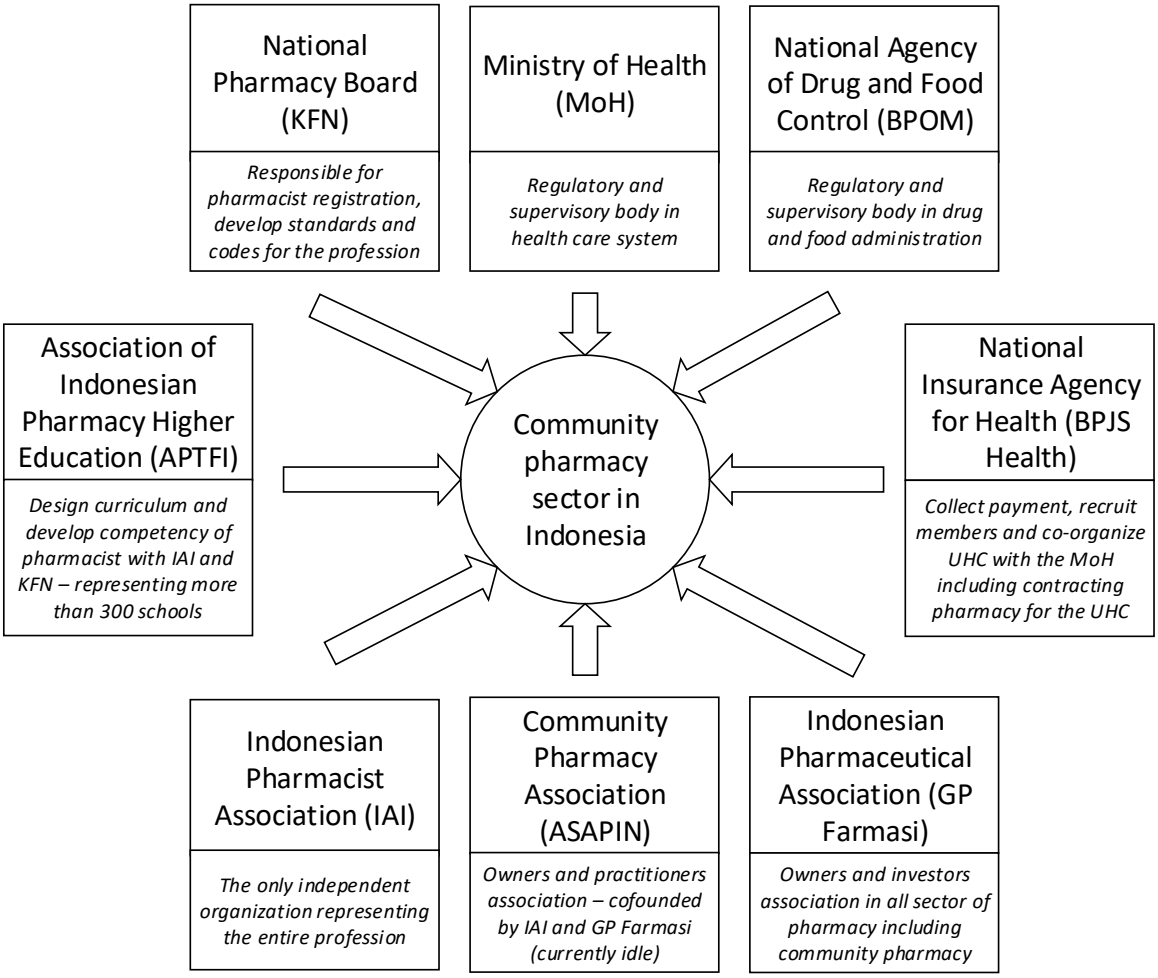

Figure 1. Stakeholders in Indonesian Community Pharmacy Sector

management and rational use of medicines. The program uses the jargon of "DAGUSIBU", an acronym from words of DApatkan (to obtain), GUnakan (to use), SImpan (to keep) and BUang (to dispose of) medication properly. The pharmacist has been participating in the program actively, conducting several public education activities within and beyond the community pharmacy settings including at the schools, community gatherings and other public spots.[51]

The funding for "Gema Cermat" program is shared between the MoH and the provincial or district health offices. There is limited information about the amount and proportion of each party on financing the program. This also implies a lack of information regarding remuneration received by individual community pharmacy joining the program. Nevertheless, there is evidence on the positive impact of the program on improving public knowledge and attitude in using medicines as well as increased recognition towards pharmacist existence.[35,52] However, whether the program has been successfully translated into sustainable practice and eventually changed the way the public properly use the medicines remains unknown. The fact that most of the activities of the program are one-off campaign, knowledge-based rather than practice-focused, and do not necessarily correlate with the pharmacy services may highlight challenges for its effectiveness in daily practice.[42,53,54] Additionally, due to the decentralization system, the evaluation of the "Gema Cermat' implementation has been heavily relied on the commitment of the provincial or district health offices, with few attention has been put towards systematic nationwide evaluation efforts.

STAKEHOLDERS IN INDONESIAN COMMUNITY PHARMACY SECTOR

Many different actors form the community pharmacy sector in Indonesia (Figure 1). Community pharmacy operates in a highly regulated environment with regulatory function is formally set up by the Ministry of Health (MoH). One of the current initiatives by the MoH to leverage community pharmacy practice is to promote the use of electronic pharmacy (e-pharmacy) system.[55] This will allow a licensed community pharmacy to go digital and online with medicines can be delivered to the patient via a courier. Another influential institution is the National Agency of Drug and Food Control (BPOM) with its auxiliary network at the provincial level. The BPOM plays a regulatory and supervisory role for drugs and food products marketed in Indonesia. This includes conducting inspection and monitoring to pharmacy outlets and their facilities.

In the context of professional practice, the Indonesian Pharmacist Association (IAI) is the largest association of pharmacists in Indonesia. It is the solely responsible organization representing and advancing the profession of pharmacist. The IAI sets the standard of practice for

Table 3. Summary of the five pillars of action for strengthening the profession

Pillar 1. Advocating the philosophy of the responsible and professional practice of pharmacist The strategic position of pharmacist for public health must be preserved by delivering practice that is not only professional but also responsible. The responsible practice reflects pharmacist integrity, including moral and ethical value and becomes sensible to public health issues. The IAI ensures this approach by investing on a certification program for pharmacists, initiating credit system for licensure and re-certification, creating pharmacist group of interest – including the group of community pharmacist and the Young Pharmacist Group (YPG), and series of activities focusing on the mentoring, coaching and advocacy program for pharmacists.
Pillar 2. Improving the good governance of the organization As the solely responsible organization representing the pharmacist profession, the IAI strives to provide benefits for the member and maintain good governance of the organization, including the management of financials, assets and human resources. With respect to this strategy, IAI introduces leadership training for the member, sets up accountability measures for the good management of the organization including audit for the financials, builds an expert group as advisor to the organization, and assigns three main area coordinators following to the geographical division of the country (western, central and eastern coordinator) for handling issues in the management of IAI at the local level.
Pillar 3. Enhancing pharmacist recognition and acceptance The profession of the pharmacist has been known for its role in the supply of medicine. However, there is a lack of awareness from the public and other health professionals regarding pharmacist potentials beyond dispensing medication, particularly on the public health and clinical related issues. The IAI enhances pharmacist recognition through partnership and networking with other stakeholders within and beyond health care sector, rebranding the image of the profession by introducing a policy on pharmacist wearing a coat and name badge during practice, signboard for pharmacist name and practice hours and invites members to involve in the IAI and MoH campaign events such as Gema Cermat and disaster responses.
Pillar 4. Contributing to pharmacy education development and practice transformation The IAI understands that education is an essential element to change practice and therefore, strategic action towards improving the quality of education and transforming practice must be prioritized. IAI facilitates continuing professional education for pharmacist, promotes research-based evidence and the use of digital and information technology in practice by developing a division for research and digitalization of practice, sets up a new platform for facilitating pharmacist continuing education, activity management, membership administration and documentation, called as "SIAP [Sistem Informasi Apoteker] (Pharmacist Information System)".[57]
Pillar 5. Actively involved in the policymaking and legislation Pharmacists are an established profession in the health sector. The scope of practice of pharmacists and the legal position of pharmacists have been acknowledged in the Indonesian regulation and legislation. Nevertheless, challenges regarding pharmacist role and authority, including ethical dilemma and lawsuits involving pharmacist often occurs. The IAI implements this pillar by actively involved in the legislation making at the national and local level. One of the regulations that was promoted by the IAI and is currently being drafted at the national parliament level is the Omnibus Law on Pharmacy, which will become the overarching law governing pharmacy sector in Indonesia, including community pharmacy practice.[58] In addition, IAI protects and supports the member through advocacy, providing legal assistance and mediation for those who need it.

pharmacist and continuously strengthen the profession through five pillars of action (Table 3).[56]

The pillars are short-term action introduced by the National Committee of the IAI serving period of 2018-2022. It was formed in 2018 in response to the changing landscape of pharmacy and health care sector after the introduction of the UHC, which at the same time has presented both opportunities and challenges for the profession. The pillars are implemented at all level of the organization focusing on the commitment of pharmacist member to change and to work at their full capacity with integrity for the public health.

CHALLENGES OF PHARMACY SERVICES DELIVERY

Several challenges are hampering the sustainability of pharmacy services delivery in the primary care setting in Indonesia, which should be considered and addressed in the future. These challenges range from macro-level, meso-level, and micro-level.[59,60]

The macro-level challenges include the legal, regulatory and economic barriers of pharmacy services as part of the health care system. In the Indonesian context, the health system constraints include lack of recognition and decisive supports from the health authorities, absence of funding supporting pharmacy viability, and lack of investment in the pharmaceutical supply chain leading to some events of pharmaceutical shortages.[61-63] Apart from the health system constraints, the poor coverage of pharmacy participation in the UHC scheme is another challenge in this level. This, in turn, has limited client's access to services covered by their JKN insurance scheme. Also, poor law enforcement mechanisms happen at the root level. For example, there is a regulation that antibiotics can only be dispensed by pharmacists with a prescription.[37] However, several studies have noted that a significant percentage of pharmacies in the country dispensed antibiotics without prescription.[64-66] Lack of monitoring mechanism and poor law enforcement from the district government, due to the insufficient human resources or financial constraints have exacerbated this situation.[8] The absence of community pharmacy accreditation and poor remuneration system for pharmacy services are also among the factors hindering the sustainability of pharmacy service delivery.[51]

The meso-level challenges include the organizational and cultural barriers of pharmacy services and the determination of the level and quality of services provided by community pharmacies.[67] Community pharmacies operate in a dynamic environment. To remain competitive, they should be able to adapt to service implementation. However, the traditional culture of community pharmacy which has predominantly been focused on dispensing has, in some way, resulted in unpreparedness and inability of community pharmacy to, for example, adopt and adapt new technology and informational system.[68]

The UHC arguably has improved the access of the public to health care. However, it may also bring consequence to overcrowding in puskesmas due to an increased number of daily visits by patients. The excessive workload for all health professionals is inevitable with a pharmacist is arguably worst affected by this situation.[69] Only less than half of puskesmas (4,986 puskesmas) are equipped with pharmacist reflecting that there are still major imbalances

and gaps in the availability and distribution of pharmacist across puskesmas.[11] The high workload experienced by primary care pharmacists has been evident, often due to understaffing, and the need to deal with many administrative and technical tasks.[23,61,70] Lack of performance indicators to assess the quality of services provided is also among the challenges.[71] Despite the health reform in the Indonesian health systems, which regulates pharmacy's roles in the primary care network, few formal performance indicators are available to monitor the implementation of these roles. This situation challenges the comparison of pharmacy performance across districts and poses difficulties in evaluating the implementation of health reform.

The micro-level challenge includes the capacity of individual pharmacists themselves. Community pharmacists typically work in a silo within the walls of pharmacy. The problem arises when there is a need for interprofessional collaboration which requires communication and teamwork skills. In addition to the lack of interprofessional skills, individual pharmacists have often had a lack of knowledge in particular topics and lack of individual confidence, which affects the variety of service provision to the patients.[61,72] A shortcoming in the graduate's competence themselves could also be one of the causes of the lack of pharmacists' competency.[23] Other obstacles from the individual pharmacists relate to the poor motivation from the pharmacist to be more involved in patient care, to adopt new roles and to participate in Continuing Professional Development (CPD) program.[30,62,73]

WAY FORWARD

Health inequalities and inequitable access to health care have been a concern in many parts of Indonesia, affecting a significant portion of the populations, particularly those living in rural and remote areas. Decentralization policy has been introduced to address this issue; however, its implementation varies across districts, challenging its ability to address health care inequality at the local level. We argue that increasing access to community pharmacy and pharmacist network might assist in addressing this challenge.

Community pharmacy has been a stronghold for the general public to obtain medication.[74-76] Besides, the current policy under the UHC has been a steppingstone for the pharmacist to involve in the primary care system. There is a nexus between pharmacy services and other health services; therefore, an expansion of pharmacist's roles in partnership with the GPs and other health professionals might be promoted as a new model of comprehensive care, in the prevention, service integration and continuity of care within the system.

There has been a lack of attention to the role of the community pharmacist in the prevention and early intervention. There is only a small portion of pharmacies providing health screening services, such as blood pressure monitoring, blood glucose level measurement, cholesterol and uric acid check as an adjunct to dispensing services, may highlight the potential venue for early intervention.[29] Particularly in Indonesia, this is not yet the norm of contemporary pharmacy practice and might be introduced in the future once the public trust to the role of pharmacists in providing health and medicine information is high.[77]

Service integration can be implemented in various activities, including medication reviews and pharmacovigilance. Community pharmacist can be appropriately positioned to review and monitor the use of medicines. In fact, pharmacovigilance has been an emerging role for primary care pharmacist to tackle misuse and abuse of medicines, including the opportunity for antimicrobial resistance surveillance.[78,79] Also, due to the unique position of community pharmacies as the first point of contact to the health care system, they can help in providing information on the trend of medicine purchased or dispensed at the community level over time, thus providing us with critical early warning system in the event of a disease outbreak.[80]

Whilst the UHC offers a promising pathway for community pharmacy to provide continuity of care for patients at hospital discharge under the contracted pharmacy scheme, the small number of community pharmacies involved in the program has limited the program effectiveness. The role of pharmacists in providing care on discharged medication can be improved by strategically recruiting more contracted pharmacies. Additionally, continuity of care can be effectively delivered using Information and Communication Technology (ICT) system, one of which through developing patient Electronic Health Record (EHR) and shared databases.[81] Although the implementation of EHR is common in most hospitals and puskesmas, it has not facilitated data sharing between organizations and across the three tiers of care. A strategy to facilitate this data sharing would be a way to move forward to ensure all patients EHR are safe and kept sustainably.

Since the integration of pharmacists and their services into primary care is essential, community pharmacist must be equipped and trained to keep up with the expanded services. Indeed, expanding clinical skills and expertise of pharmacist can contribute to the significant impact on the health of Indonesians. New roles and services of pharmacists, including therapeutic outcome monitoring and primary disease prevention as aforementioned, suggest that pharmacists are important stakeholders to contribute to the provision of care through encouraging a healthy lifestyle, preventing disease, and contribute to better therapeutic outcomes to the population.[32] This opportunity means that pharmacists need to advance their practice and maintain a high standard of practice throughout careers to assure the quality of health service delivery.

Pharmacy education in Indonesia has reacted to adapt their curricula to prepare pharmacy students entering their practice. Changes to the curricula were firstly brought into discussion through the Health Professional Education Quality (HPEQ) Project initiated by the Ministry of Education in 2010.[82] The aim was to transform the curricula which was predominantly pharmaceutical science based into problem-based curricula which promotes skill development and clinical knowledge. However, the most significant change in the education is the introduction of competency examination.

The exam was firstly designed in 2013, pilotted in 2015, but it was finally implemented in 2017. The exam consists of of two types of test: the Computer Based Test (CBT) with an emphasis on knowledge test and Observed Structured Clinical Examination (OSCE) on skill test.[83] Passing the exam is a requirement for prospective pharmacist to obtain competency certificate prior to registration. The number of students undertaking the exam has been fluctuative every year with the portion of students passed the exam at the first trial tended to decrease.[84] On the one hand, this indicates an improvement on the difficulty and quality of the assessment. However, on the other hand, this also highlights a gap in the quality of education across fifty schools of pharmacy which are eligible to deliver pharmacist program - these are the accredited A and B schools which conduct four years bachelor program and one year pre-pharmacist program.

The failure to pass the exam would also affect to students' motivation and financials as they have to wait longer to get their first job as pharmacist. In addition, the negative result has worsened the bottleneck issue in the contemporary education system as there are fewer eligible schools (50 schools accredited A and B) as compared to schools offering only four year bachelor of pharmacy program (265 schools with lower accreditation level).[85] As a result, waiting time is even longer for students from these schools to start practicing as pharmacist as they have to enroll in one of the eligible schools to start pre-pharmacist education program.

It is fair to say that the pharmacy education system in Indonesia has significantly changed over a decade. However, the challenge as aforementioned is to prepare graduates that can collaborate and communicate with other professionals and the patients. It is indeed an explicit call from the Association of Indonesian Pharmacy Higher Education (APTFI) for the integration of curriculum content and practice experience i.e. period of workplace learning in form of interprofessional education. There is evidence that interprofessional education can contextualize learning, develop skills, knowledge and values to become professional pharmacist.[86] Whilst there is a small portion of pharmacy schools strive to pursue such integration, the majority might need to be stimulated.[87]

Apart from the efforts in updating pharmacy curriculum to prepare future generation, there is also an effort to support the pharmacy profession after graduated, i.e. pharmacists. The Indonesian Pharmacists Association (IAI) is working collaboratively with the International Pharmaceutical Federation (FIP), on a Workforce Transformation Program (WTP), which aims to advance pharmacy practice in Indonesia by developing a professional recognition system to signpost pharmacists advancement.[88,89] The professional recognition system is a quality assured process, which aimed to be independent, credible, fair, transparent and robust, to recognize an individual's achievement of defined levels of performance. The principles of professional recognition system can be explained within three themes: in the context of the "profession as a whole", in the context of the "individual practitioner", and in the context of "the practice of pharmacy".[90] In the context of the profession as a whole, a professional recognition system aims to provide credible evidence of the pharmacist role in medicines expertise, patient safety and in enhancing the quality and impact of pharmaceutical care provision. The idea of professional recognition is based on the needs of quality assured professional development of health professionals. In the context of individual practitioners, a credentialing system should support pharmacists' professional development and career progression principally by identifying and providing evidence on their performance at defined stages of practice. A credentialing system should motivate and inspire pharmacists to develop them to the next professional stage of development. In terms of the practice, through professional recognition, patients have the right to receive the highest level of care depending on their need.

In order to develop a professional recognition system, an establishment of a set of criteria - framework – can be a starting point to support this advancement. The Indonesian Pharmacists Association (IAI) has addressed this, by developing an Indonesian Advanced Development Framework (IADF), which serves as a tool to identify pharmacists' learning gaps and skills to advance their careers and practice.[33] The IADF will be used as a tool to map useful and relevant education and training provisions as well as a tool for credentialing or professional recognition. The professional recognition model could be linked to a clear career pathway, and staff remuneration in the workplace. Career pathway and remuneration availability could affect the motivation of pharmacists which also linked to the performance of the pharmacy workforce in delivering the service.[51,61,91,92] There is evidence suggesting that credentialed practitioners deliver improved therapeutic outcomes, quality of care, and better patient safety compared with non-credentialed practitioners.[90] This, therefore, will assure the quality of practitioner services for the public. Recognition of practitioners will also address patient safety issues and provide the trust about the role of pharmacists in the delivery of universal health care.

CONCLUSION

Community pharmacists are highly trained professionals, have been central to the delivery of medicines, and are located within the heart of the communities. Community pharmacy is also a highly regulated industry which operates under dynamic health sector landscape allowing for innovation and changes in the contemporary practice. These features are the key drivers in leveraging the full potential of community pharmacy and pharmacist to meet the changing societal needs and to expand their roles within the primary care system in Indonesia.

This article promulgates the notion that the integration of community pharmacy into primary care in Indonesia is an incremental process and often requires policy initiatives to drive such changes. Community pharmacy in Indonesia can be a great example to untap the tremendous opportunity to deliver greater health outcomes. The conditions under which pharmacists are able to play a role in primary care services either via puskesmas or the network of primary care providers may suggest that pharmacist is an essential part of allied health services and integrated care. Arguably, the "Gema Cermat" program has improved pharmacist

engagement with the communities which is vital for any practitioners working in the primary care sector.

Despite the presence of persistent barriers which are often exacerbated by a range of system constraints, we argue that there has been some progress in the integration process. Major reforms are needed to reduce the barriers, improve the quality of pharmacy services and enable pharmacists to establish their ground within the primary care system strategically.

CONFLICT OF INTEREST

None declared.

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International Series: Integration of community pharmacy in primary health care

Primary health care pharmacists and vision for community pharmacy and pharmacists in Chile

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Abstract

The Chilean healthcare system is composed of public and private sectors, with most of the higher-income population being covered privately. Primary healthcare in the public system is provided in more than 2,500 public primary care centers of different sizes with assigned populations within territories. Private insurance companies have their own healthcare networks or buy services from individual health providers. Patients from the public system receive most medications free of charge in primary care pharmacies embedded in each care center. Private patients must purchase their medicines from community pharmacies. Some government policies subsidize part of the cost of medications, but original medicines remain as the most expensive of Latin America. Three chain pharmacies have more than 90% of the market share, and these pharmacies have negative public perception because of price collusion court sentences. A non-profit, municipal pharmacy model was developed but has limited implementation. Most privately owned independent and chain community pharmacies do not provide pharmaceutical services as there is no remuneration or cover by insurers. The limited number of publicly owned Municipal pharmacies could implement pharmaceutical services in community settings as they are non-profit establishments and have full-time pharmacists but are not resourced for these services. A limited number of pharmaceutical services are almost exclusively provided in public primary care, including medication reviews, pharmaceutical education, home visits and pharmacovigilance services, but several barriers to their implementation remain. A risk-based multimorbidity care model was implemented in 2020 for public primary care with additional employment of part-time pharmacists to provide services. We believe that this model will help pharmacists to optimize their time by prioritizing the much-needed clinical tasks. We propose within this multimorbidity care model that the more time-consuming services are provided to higher risk patients. Pharmacy prescribing i.e. amending or approving changes in medications in primary care for chronic conditions could also be useful for the health system, but pharmacists would require additional training. The landscape for pharmaceutical services for primary care in Chile is promising, but the integration with community pharmacies will not be possible until they are funded by public and private insurance, and the public perception of these establishments is improved.

Keywords

Pharmacies; Primary Health Care; Delivery of Health Care, Integrated; Ambulatory Care; Community Health Services; Pharmacists; Community Pharmacy Services; Professional Practice; Chile

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CHILEAN HEALTHCARE SYSTEM AND PRIMARY CARE

Chile is a country of 17.5 million people, composed of 16 regional governments, and 349 local governments called municipalities.[1] Chile's gross domestic product (GDP) per capita for 2019 was USD 14,896.[2] Chile is a member of the Organization for Economic Co-operation and Development (OECD) and is classified as a high-income country but has a very high inequality index (Gini coefficient of 0.46).[3] Twenty percent of the country's population earns 51.3% of the GDP.[2] In 2019 Chile spent USD 2,159 per capita or 9.1% of its GDP in healthcare, which is about half the OECD average of USD 4,224 per capita. Of this spending, 34% were out-of-pocket payments made by patients, the third largest of the OECD.[3]

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The Chilean healthcare system is a two-tier system with a public and private sector. Chileans are mandated to pay 7% of their salaries for health insurance (except for retired older adults who continue working) with an option to choose either public or private health cover.[4] Private health companies [Instituciones de Salud Previsional] (ISAPRESs) cover 19.6% of the population but receive about 54% of health funding.[5] These private companies tend to cover younger men with higher income driven by unregulated premiums that discriminate by sex and age.[5] Eighty percent of the citizens are covered by the public national health fund [Fondo Nacional de Salud] (FONASA) including high-risk groups that use more resources posing an increased burden.[5-6] In 2006, the government implemented the Explicit Health Guarantees System [Garantías Explícitas en Salud] (GES). GES is a group of enforceable benefits for FONASA and ISAPREs beneficiaries. Their main objective is to ensure timely access to healthcare while protecting the extent of the population out of pocket expenditure. Currently, GES covers 85 conditions.[6-7] Nonetheless, conditions that are not covered by GES have long waiting times, and usually will require high out-of-pocket payments. An additional program was introduced in 2015 to avoid catastrophic health expenses by covering high-cost rare diseases such as multiple sclerosis and Huntington's disease.[8]

Most patients insured by ISAPREs use private providers for primary, secondary and hospital care. Their focus is on treatment of diseases, with little incentive to perform health prevention activities.[5] In contrast, the public system has its own infrastructure and is mandated by the Ministry of Health. The public health sector is coordinated by the sub secretariat of Assistance Networks of the Ministry of Health, regulating and supervising healthcare services.[9] This sub secretariat coordinates the National System of Health Services, or 29 autonomous administrators that oversee their local network of primary and secondary care, as well as emergency and hospital treatment.[9] From 2004, the main objective of the Ministry of Health has been to build a healthcare model based on primary care, emphasizing population health, and focusing on health promotion and prevention, following the guidelines for Sustainable Development Goals of the World Health Organization (WHO).[10,11]

In Chile, public primary care is mostly overseen by each Municipality (346 local governments) with 10% being managed directly by the local health care service administrator. These primary care centers are divided by size as small (rural health posts, 4,000 average population), medium (community health centers, 8,000 average population) and large (family health centers, 20,000 average population).[12] These centers are organized using the family medicine model, proposed by WHO, with a multi-professional practice that encompasses not only the patient, but the family and the community.[13] Centers are composed of one or several multidisciplinary teams (depending on size of the center) that provide healthcare for a geographically defined population. Family health centers [Centro de Salud Familiar] (CESFAM) are the larger providers of local primary care and also coordinate the smaller centers in their territories. Healthcare teams are composed by health professionals, including physicians, registered nurses, dietitians, psychologists, dentists, physiotherapists, and midwives. Other professionals such as social workers, speech therapists and pharmacists are not part of the core teams but are present in some centers.[14]

Interventions performed by these healthcare teams must encompass promotion, prevention, recovery, and rehabilitation actions over the lifespan of the individual. To carry out these actions, primary care has dual funding system, with a per capita system as well as a pay-for-performance scheme.[14] The per capita system is the main source of funding, and covers most health services, medications and personnel for each center based on the assigned geographic population. In the pay-for-performance scheme or primary care reinforcement program, specific interventions such as respiratory health care, dental care and dispensing of chronic medications receive additional funding depending on some health outcomes and the number of patients' visits and health checks. Additional remuneration is provided when predefined goals are achieved.[14] Both schemes are determined by the Ministry of Health, while the latter scheme is used as a leverage to encourage primary care providers to engage with public health objectives, including effective collaboration with other levels of care.[15]

MEDICATION ACCESS IN PRIMARY HEALTH CARE

In 2019 Chile had the highest price for original branded medicines in the Latin American region, with USD 14.1 per unit. In contrast, generics prices were one of the lowest with USD 1.30 per unit. Generics represented only 48% of total sold units for prescription medicines.[16] As a consequence, medications are more than 50% of out-of-pocket payments in Chile, influencing the use of chronic medicines.[3]

Patients from ISAPREs must purchase their medicines from privately owned community pharmacies. For some chronic conditions, following the GES policy, ISAPREs cover part or all the out-of-pocket payments of some medications (15 to 35% for original medications and >80% for generics). This occurs only if the patients attends an approved healthcare provider and has the prescriptions dispensed in certain specifically contracted community pharmacies (mostly chain companies).[7] Patients can pay for additional medication coverage (up to 80%) on their ISAPREs or from another insurance company, but this does not include all medicines, and patients are still required to attend certain contracted pharmacies. There is also an annual cap.[5]

Patients that belong to FONASA receive their medications free of charge in state owned pharmacies embedded in each public health center. These pharmacies have limited availability of chronic and acute medications depending on the level of healthcare provided in the establishment. Physicians are encouraged to prescribe these specific medications.[6]

To reduce out-of-pocket payments and improve medication accessibility, publicly owned pharmacies have programs that guarantee most chronic medications for FONASA users: The Ministry program and the Pharmacy Funds program [Fondo de Farmacia] (FOFAR) and both provide additional funding to avoid supply issues.[6] In the Ministry program, the primary care division of the ministry of health buys and distribute to each health service coordinator or municipality all medications covered by FONASA for epilepsy, chronic obstructive pulmonary disease (COPD), asthma, osteoarthritis, depression, Parkinson's disease, hypothyroidism, insulin for type-2 diabetes mellitus, and contraception. FOFAR includes additional funding for the treatment of hypertension, type-2 diabetes and dyslipidemias.[19] However, it is not uncommon that patients must buy a proportion of their medicines in community pharmacies, as public pharmacies usually have shortages on medicines not included by these programs and/or have outdated medications.[20] In 2019 FONASA implemented a coverage program for these patients (12% to 30% of discounts) in a small number of selected community pharmacies, but it has low implementation and only in a reduced list of medicines.[21]

To reduce out-of-pocket payments in medications, a non-profit model of pharmacies, called municipal or solidary pharmacies, were created by some municipalities in 2015, providing medications at almost cost-prices to their population. In 2020 there are more than 160 municipal pharmacies, with their prices being at least 50% lower than privately owned community pharmacies.[21]

COMMUNITY PHARMACIES AND PHARMACEUTICAL SERVICES

In 2019 there were 3,818 community pharmacies, including municipal pharmacies, in Chile, with almost half of them belonging to three chain pharmacy companies. These chain pharmacies represent more than 90% of the national market and are mostly located in urban areas, as there are no geographic restrictions for opening pharmacies in Chile. The rest of community pharmacies are mostly small or medium businesses that are evenly distributed over the country. Interestingly there are 54 small municipalities in Chile that do not have a community pharmacy on their territories, and municipal pharmacies have been proposed as a solution to this lack of medication access.[21]

There is no obligation for pharmacy owners to be pharmacists, however, since 1984 the employment of pharmacists during operating hours is mandatory, and they must be available for patient counselling, prescription supervising and dispensing of certain medications. Since 2015, the legislation identified community pharmacies as healthcare centers, guaranteeing the rational use of medicines and providing pharmacovigilance services.[22] However, the role of these community pharmacists is mostly in management, with little to no direct contact with patients and with pharmacy technicians performing most of medication dispensing. Community pharmacists are often described as 'behind-the-counter professionals' with a minor health role, especially in chain pharmacies. On the other hand, smaller pharmacies usually provide some patient counselling, but their market share is low and as these services are not funded, so it is not prioritized.[23]

Community pharmacies, especially those owned by the chain companies, have a negative public perception.[24] In 1995 and 2008 the three main chain pharmacies were found guilty of collusion due to price-fixing of several products.[25-26] The companies were penalized with a fine of USD 60 million as compensation.[25-26] As prices of medications continue to increase, Chilean consumers are reported to have one of the worst opinion of pharmacies and the pharmaceutical industry in the Latin American region.[24]

Interestingly, one of the chain pharmacies between 2003 and 2005 developed a pharmaceutical care program, with pharmacists providing medication reviews to chronic patients. The service was free of charge, and patients signed up voluntarily at their local chain pharmacy. A randomized-controlled trial of 6 months duration was conducted in 2003 to evaluate the program, finding a statistically significant reduction on lipid levels.[16] Nevertheless, the program was discontinued in 2005.

There is a perception that most small privately owned and publicly owned municipal pharmacies provide patient counselling and other services, however, there has been no evaluation and these services are also not standardized.

PRIMARY HEALTH CARE SYSTEM AND PHARMACEUTICAL SERVICES

The presence of pharmacists in the primary care network has been historically low. Prior to 2014 (and FOFAR), a small team of pharmacists from each of the 29 autonomous health services coordinators remotely supervised the public primary care pharmacies in their territories. As there was no legal obligation to employ pharmacists, less than 10% of the primary care centers had a full-time pharmacist. Since 2014, FOFAR has included funds to employ pharmacist in the larger primary care centers, reaching more than 100 by 2016.[14] These pharmacists were used mostly for management functions, but some of them have started to provide clinical services at their own initiative or by requests from local clinical teams.

Because of the increasing number of pharmacists and growing interest from health centers and the Ministry of Health, a 6-months randomized controlled trial was conducted in 2016 in the largest primary care center in Chile to explore the impact of medication reviews with follow-up on 212 cardiovascular older patients. The study provided initial evidence that pharmacists could significantly improve the control of hypertension, type-2 diabetes and dyslipidemias in the Chilean primary care setting.[27] The Ministry of Health, responding to these results, added pharmacists to the 2017 national cardiovascular care program guidelines, stating that where available, pharmacists should participate in clinical teams providing services for cardiovascular patients. These guidelines were the first in Chile to include pharmacists in primary health care teams.[28]

Following this study, a cluster randomized controlled study, the Polaris trial, was conducted between 2018 and 2019 to provide further evidence on clinical and economic outcomes of the inclusion of pharmacists in primary care teams. The results provided evidence that the intervention, a comprehensive medication review with follow up, was a cost-effective addition to control cardiovascular risk factors. After the Polaris trial, and as more clinical guidelines included pharmacists in 2018 and 2019, the Ministry has been increasing the number of full-time pharmacists in primary care centers, reaching more than 450 or >80% of the largest centers in 2020.[14]

Prior to 2018, there were only two pharmaceutical services defined in the official national registry determined by the Ministry: pharmacovigilance services and pharmaceutical care. As the provision of pharmaceutical services grew, this registry was not sufficient to describe all of pharmacists' actions taking into account that primary care pharmacists have access to all clinical information of their patients. In 2019, major modifications were made. An official list of pharmaceutical services, with some of them using the Pharmaceutical Care Network Europe (PCNE) classification for medication reviews, was published (see Table 1).[29]

Despite the inclusion of these services on the list of official clinical activities for the primary care network, most pharmacists are unable to provide them, as they are predominantly focused on management tasks. This was observed and reported in the Polaris trial and has been reported by the international literature as one of the main barriers for the implementation of pharmaceutical services.[30]

In 2020 the Ministry of Health implemented a multimorbidity care model in some primary care centers.

Table 1. Official pharmaceutical services for the public primary health care network.

Pharmaceutical service	Description	Patient-per-hour rates
Clinical services		
Medication review without visit (type 2b or intermediate by PCNE)	Pharmacists conduct medication reviews using all information available in official medical records and pharmacological prescriptions. Pharmacists would add their findings and suggestions to the medical records to be considered by physicians.	4 – 6 PPH
Medication review with visit (type 3 or advanced by PCNE)	A one-or-twice yearly visit added to the previous service to detect nonadherence motives and include additional patient's information.	3 – 4 PPH
Medication review with follow-up (type 3 or advanced by PCNE)	A systematic, structured service using the Polaris method as guideline. The service consists in at least three visits with the patient (initial, intervention and follow-up). The pharmacist meets with the physician after the initial visit to discuss the findings and suggest pharmacotherapy modifications if needed. Any agreed intervention would be directly implemented and registered by the pharmacist in the next visit, depending on the patient's acceptance. The pharmacist would monitor the results of the interventions in follow-ups and perform the service until every health problem is resolved, if the patient does not want to continue or if the pharmacist discharges the patient.	2 PPH for initial visit 3 PPH for follow-ups
Individual education	Pharmacists implement educational programs to increase patient's knowledge and health literacy. This program would be comprehensive, adapting to the patient's needs and in agreed topics.	3 – 4 PPH
Pharmacovigilance	Detection, report and solving of adverse drug reactions.	4 – 6 PPH
Medication reconciliation	A simplified review of the medications conducted when a patient changes their level or site of care (e.g. hospital to primary care or private to public system) to prevent therapeutic duplicities and omissions.	6 – 12 PPH
Group education	A group session where the pharmacist carries out a flexible activity according to the group of patients' needs and the educational objective. Pharmacists can implement group education in subjects such as the use of medicines, medication adherence, medicinal herbs, and others. The pharmacist can also contribute to group educations organized by other professionals.	2 PPH
Home visit	Pharmacists provide pharmaceutical services at the patient's home. This service is reserved for dependent patients and their caregivers.	1 PPH
Non-clinical services		
Medication quality control	Pharmacists must report to the health authorities when medication quality issues are detected in the health center, sending samples to be analyzed.	--
Adverse drug events	Pharmacists must report and resolve adverse drug events that occur in the health center.	--

PCNE: Pharmaceutical Care Network Europe; PPH: patient-per-hour.

This is a health stratification model. It uses the number of chronic conditions (from an official list of more than 50 diseases) and socioeconomic and psychosocial factors, which are then used as risk scores. Some health conditions such as cardiovascular diseases, severe kidney disease and dementia are defined as 'critical' and provide double scoring. Patients are then classified as healthy or having a null risk (score 0), low risk (score 1), intermediate risk (score 2 to 4) and high risk (score ≥5), and health services are provided depending on each patient classification. The Ministry is employing more professionals, including part-time pharmacists, to support the implementation of multimorbidity care, and it is planned that all the primary care networks will use this model by 2030. Pharmacists are expected to provide pharmaceutical services to the higher-risk patients, but the nature and details of these services have not been defined.[31]

In contrast, the private primary care network does not provide pharmaceutical services, as they are not funded by ISAPREs. FONASA is commonly used as reference by private companies for service coverage, but pharmaceutical services have not received a specific codification or pricing.[7]

PHARMACIST TRAINING AND PROFESSIONAL REPRESENTATION

In Chile, to be a pharmacist one must complete a 10-to-11 semester academic program. There are currently 17 pharmacy schools. The academic level of a pharmacy degree is at a level between a bachelor and a master's degree if compared to international standards ('professional' level in Chile). More than 50% of these programs consist of basic science training such as chemistry and biology. Health-related subjects are scarce and represent less than 10% of the programs. Furthermore, most pharmacy schools do not provide training on interviewing skills, and pharmacists usually lack the abilities and experience needed to provide patient counselling.[23]

As a response to a need for pharmacists with clinical skills in the hospital healthcare system, the Ministry of Health approved a specialist clinical pharmacist program in 2018, recognizing that additional training was required for this level of care.[32] It is a two-year program and is being provided only by two pharmacy schools in 2020, with a quota of less than 10 graduates every year. From 2021, the ministry will require a 3-year program. In 2020, there are still less than 100 clinical pharmacy specialists in Chile. Nevertheless, the employment of these specialists is funded only for hospital care. Some universities have

developed additional postgraduate courses for ambulatory pharmacists, and these are increasingly being funded by public entities to incentivize the provision of pharmaceutical services in primary care centers.

After graduating, pharmacist can pay a monthly fee to join the Chilean Pharmacists Association [Colegio de Químicos Farmacéuticos y Bioquímicos de Chile]. The role of this organisation is primarily political advocacy and does not receive funding from the government. About 10% of pharmacists in Chile belong to the Association. The Pharmacists Association represents pharmacists on government committees and is usually invited to participate as a stakeholder. However, as most pharmacists are not part of the Pharmacists Association, it has a limited influence. There are a number of smaller independent organizations focused on segments such as the pharmaceutical industry, community pharmacies and some scientific associations for primary or hospital care pharmacists. They often play a similar role to the Association.

OPPORTUNITIES FOR PHARMACEUTICAL SERVICES IN CHILE

Chilean pharmacy program and the Pharmacists Association

The pharmacy programs should be modified to reinforce clinical skills from the initial undergraduate years, as these competencies must be developed over time. We understand that pharmacists can work in very different areas and they require a wide scope of skills, but Chilean healthcare system is requiring more clinical involvement. The international literature supports the provision of pharmaceutical care.[33] Training should provide direct contact with patients at different levels (hospital and ambulatory care), and pharmacists should be able to provide clinical services such as basic or intermediate medication reviews, pharmacovigilance services and patient counselling without additional postgraduate courses.

As for the Pharmacists Association, its role should be expanded to provide more than political advocacy and representation of the pharmaceutical profession. The Pharmacists Association should influence pharmacy undergraduate and postgraduate programs, establishing and certifying professional standards for all pharmacy segments, as well as participating in developing policies related to medicines. The Pharmacists Association should also negotiate medication coverage, provision of pharmaceutical services and pharmacists' involvement in the health care system. It could provide guidance to the government and generate evidence related to the efficiency and effectiveness of pharmaceutical services, as is the case in other countries such as Australia, Canada, and Spain. To accompany and support this expanded role, Association membership should be mandatory for all pharmacists.

Opportunities to further develop pharmaceutical services in primary health care

Most recent primary health care policies in Chile recognize the role of primary care pharmacists, employing pharmacists and in most instances including them in in care teams. Therefore, it is necessary that all large primary care centers have a full-time pharmacist (or more than one if the center is large enough). With the implementation of the multimorbidity care model, pharmacist would be able to provide specific services depending on patients' needs. Within this model we propose a risk-based approach using the official classification and the number of medications, where higher-risk patients receive more complex and time-consuming pharmaceutical services. The proposed structure is described on Figure 1.[31] Pharmaceutical services such as medication reconciliation, pharmacovigilance, individual education, home visits, and non-clinical services are not included in the proposal as we believe that they do not depend on this classification and should be provided when necessary.

Medication review with follow-up has been shown to improve the control of some chronic conditions, as

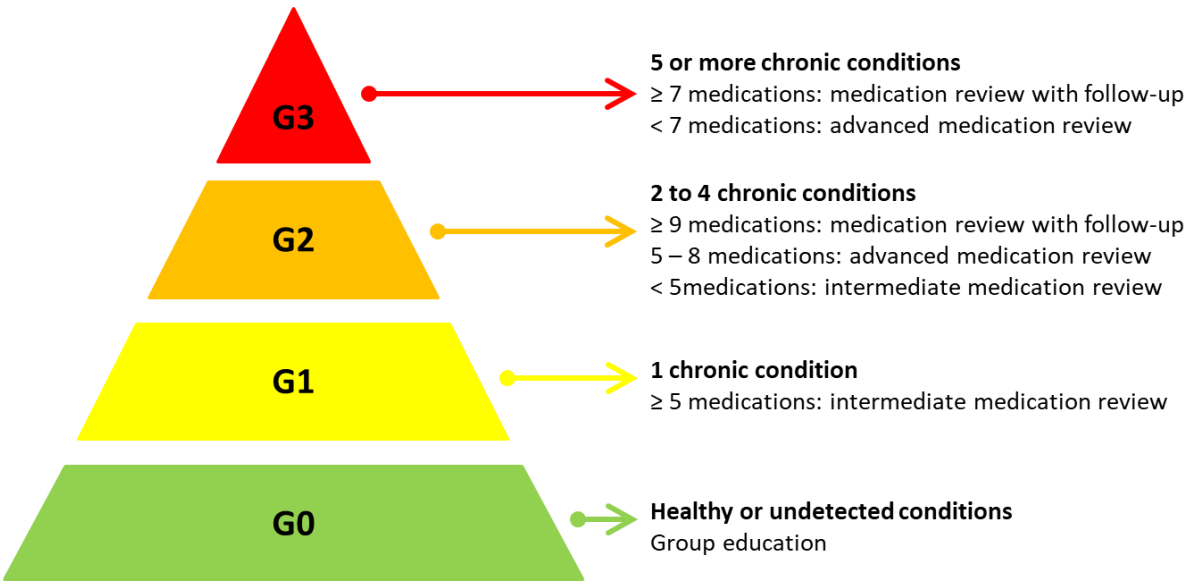

Figure 1. Proposed structure for pharmaceutical services on the multimorbidity care model.
G0: null or unknown risk; G1: low risk; G2: intermediate risk; G3: high risk.

demonstrated in the Polaris trial, but its implementation may be constrained as it requires physicians' time. Allowing pharmacists to initiate or modify existing pharmacological treatments for chronic conditions could improve the efficiency of the health system. This has been successfully tested in similar settings such as the UK's General Practice Pharmacists program.[34] Primary care pharmacists could receive additional 3 to 6 months certified training by academic institutions on prescribing of medicines and other clinical skills. Furthermore, the role of specialist pharmacists, currently restricted to hospitals, could be expanded to primary care, where they could enhance quality of care and provide more complex services.

The implementation of pharmaceutical services in private primary care will not be possible until coverage and remuneration is provided by ISAPREs. It is imperative that FONASA specifies reference pricing for pharmaceutical services to encourage the private sector. They could use the costs of services provided by other health professionals such as general practitioners or physiotherapists, the list of services and patient-per-hour rates specified for the public system.

CONCLUSION

As the provision of pharmaceutical services in community pharmacies in Chile is almost non-existent, there are many potential opportunities. Municipal pharmacies, being non-profit establishments, have a great opportunity to provide services, but there is a need for an extensive implementation program. Municipal pharmacies have several differences with primary care pharmacies as most of them lack private attention zones and access to the patient's medical records, and there is no structured communication method with primary care physicians or pharmacists.

For other community pharmacies, if pharmaceutical services are not covered by insurance, it is unlikely that they will be implemented. The literature has described some models of funding, where patients or the government pay for these services based on their impact on health outcomes.[35] However, apart from small pharmacies, we believe that these programs would not be successful until patients' perception of pharmacies is improved, and pharmacists can provide pharmaceutical services as part of their main tasks. Furthermore, these services should not duplicate those provided at primary care centers to avoid repeating tasks and professional conflicts. Community pharmacies could integrate new services such as tobacco cessation programs, pharmaceutical immunization, and minor ailments prescription, all described by the literature as effective.[36-38]

CONFLICT OF INTEREST

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International Series: Integration of community pharmacy in primary health care

Primary healthcare policy and vision for community pharmacy and pharmacists in the United States

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Abstract

The United States (US) has a complex healthcare system with a mix of public, private, nonprofit, and for-profit insurers, healthcare institutions and organizations, and providers. Unlike other developed countries, there is not a single payer healthcare system or a national pharmaceutical benefits scheme/plan. Despite spending over USD 10,000 per capita in healthcare, the US is among the worst performers compared to other developed countries in outcomes including life expectancy at birth, infant mortality, safety during childbirth, and unmanaged chronic conditions (e.g., asthma, diabetes). Primary care is delivered by physicians and advanced practice providers (i.e., nurse practitioners and physician assistants) in a variety of settings including large health systems, federally qualified health centers or free clinics that provide care to the underserved, or specific facilities for veterans or American Indian and Alaska native peoples. Since 2010, primary care delivery has shifted toward providing patient-centered, coordinated, comprehensive care focused on providing proactive, rather than reactive, population health management, and on the quality, versus volume, of care. Community pharmacy comprises a mix of independently owned, chain, supermarket and mass merchant pharmacies. Community pharmacies provide services such as immunizations, medication therapy management, medication packaging, medication synchronization, point-of-care testing and, in specific states where legislation has been passed, hormonal contraception, opioid reversal agents, and smoking cessation services. There has been criticism regarding the lack of standard terminology for services such as medication synchronization and medication therapy management, their components and how they should be provided, which hampers comparability across studies. One of the main challenges for pharmacists in the US is the lack of provider status at the federal level. This means that pharmacists are not allowed to use existing fee-for-service health insurance billing codes to receive reimbursement for non-dispensing services. In addition, despite there being regulatory infrastructure in multiple states, the extent of service implementation is either low or unknown. Research found that pharmacists face numerous barriers when providing some of these services. State fragmentation and the lack of a single pharmacy organization and vision for the profession are additional challenges.

Keywords

Pharmacies; Primary Health Care; Delivery of Health Care, Integrated; Ambulatory Care; Community Health Services; Pharmacists; Community Pharmacy Services; Professional Practice; United States

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HEALTHCARE DELIVERY IN THE US

The United States (US) has a population of approximately 330 million people from diverse backgrounds and cultures.[1] The US spends nearly 17% of its gross domestic product (GDP) on healthcare at over USD 10,000 per capita, which is twice the average compared to other developed countries.[2] Yet, the US is among the worst performers compared to other developed countries in key health outcomes, including life expectancy at birth, infant mortality, safety during childbirth, and unmanaged chronic conditions like asthma and diabetes.

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The US is one of the few developed countries without universal healthcare coverage; it does not have a single payer healthcare system or a national pharmaceutical benefits scheme/plan. The healthcare system includes a mix of public, private, nonprofit, and for-profit insurers, healthcare institutions and organizations, and providers. Modern healthcare coverage in the US began in the 1920s when hospitals offered pre-paid services to individuals, and a group of teachers in Dallas, Texas joined the first employer-sponsored hospitalization plan in 1929. During World War II, employer-sponsored health insurance became more popular in response to freezes on wage increases by the federal government. Employers could provide non-wage benefits (e.g., health insurance, sick leave) which were considered tax exempt, instead of increasing wages. Today, half of Americans receive health insurance coverage from their employer.[3]

The first major step toward government-sponsored healthcare coverage came with an amendment to the Social Security Act in 1965, which created Medicare and Medicaid and provides healthcare benefits to select groups of individuals. Medicare covers individuals age 65 years or older, those under age 65 who are disabled, and select disease states (e.g., end-stage renal disease), while Medicaid applies to eligible low-income individuals, pregnant women, children under 18 years of age, and those

with disabilities. In 1997, federal legislation increased the number of children covered with the Children's Health Insurance Programs, also administered via Medicaid. Importantly, each state is responsible for administering Medicaid programs and providing a safety net for those who do not qualify for Medicaid, and this state-level administration results in different coverage across states. Medicare Part D is the federal-government program initiated in 2006 that subsidizes the costs of prescription drug coverage to Medicare enrollees via contracts with numerous insurance companies (Part D sponsors), and it was enacted via the Medicare Prescription Drug, Improvement, and Modernization Act in 2003.[4] While optional, all states currently provide coverage for outpatient prescription drugs to categorically eligible individuals, as well as most other enrollees.[5]

Yet, given the nearly 46.5 million individuals that remained uninsured in 2010, the Patient Protection and Affordable Care Act (ACA, also known as "Obama care") was passed in 2010 and implemented in 2014 to expand healthcare coverage.[6] The ACA created health insurance exchanges, or marketplaces, where low- and middle-income individuals could purchase their own insurance and receive government subsidies to offset the costs. States also received additional federal funding if they agreed to expand eligibility for Medicaid; however, not all states took advantage of this. Young people can also remain covered under their parent's plan until age 26.[7] Debate continues in the US regarding the role of government in providing healthcare insurance.

Demand on the US healthcare system has led to a significant expansion of jobs in healthcare. Between 2006 and 2016, jobs in healthcare settings increased by 20%, compared to only 3% job growth in the general economy.[8] The job growth has been primarily in personal care aides, registered nurses, nursing assistants, and home health aides, likely due to the rapidly aging population in the US. Physician shortages, especially in primary care, are a key issue in the US with a projected shortage between 21,400 and 55,200 by 2033.[9] In response, there has been a sharp increase in the number of nurse practitioners in the US, which are now approaching 300,000.[10] Likewise, the number of physician assistants is increasing with expected job growth of 30% through 2028. With full prescribing privileges (unlike pharmacists), nurse practitioners and physician assistants are well positioned to fill gaps in the US primary care system.

The projected outlook for pharmacists in the US is widely debated. The optimistic outlook suggests that evolving practice roles for pharmacists will create new opportunities for employment in direct patient care roles. This is evident by the increased demand for specialty trained pharmacists to work in health systems and clinics.[11] On the other hand, there is no doubt that the exponential growth in the number of graduating pharmacists provides increased supply and that overall demand for pharmacists is shrinking, especially in the traditional community pharmacy sector. This can largely be due to losses of revenue, attributable to decline in reimbursement for dispensing medications and lack of significant reimbursement for clinical services. The US Bureau of Labor Statistics projects 0% growth for pharmacists through the year 2028.[12] The surplus of US pharmacists is largely related to the 38% increase in the number of pharmacy schools and 48% increase in the number of graduates over the past decade. It is possible, however, that this issue may correct itself as the mean number of applications per pharmacy school has declined over 50% in the past decade.[13]

Primary care in the US

Primary care in the US is delivered by three medical specialties: family medicine, general internal medicine, and general pediatrics. Additionally, other non-physician primary care providers (e.g., registered nurses, nurse practitioners, physician assistants, pharmacists) provide care alongside physicians.[14,15] To further the objective of improving primary care, the American Academy of Family Physicians proposed the Health Care for All framework whose goal is to "ensure healthcare coverage for everyone in the United States through a foundation of comprehensive and longitudinal primary care".[16]

Since the passage of the ACA, there has been a shift toward transforming primary care to provide patient-centered, coordinated, comprehensive care focused on providing proactive, rather than reactive, population health management. One such approach is the patient-centered medical home (PCMH) which facilitates partnerships between individual patients, their families, and their personal physicians.[17] The main principles of the PCMH outlined by the Agency for Healthcare Research and Quality are that: 1) it provides comprehensive care by a multidisciplinary team being accountable for meeting physical and mental healthcare needs; 2) it is patient-centered, in that it considers the patients' and their families' unique needs, culture, values and preferences, and it promotes patients' involvement in their care and disease management; 3) care is coordinated or integrated across specialty care, hospitals, home healthcare, and community services and supports, especially during transitions of care; 4) it offers accessible services wherein urgent needs are addressed, hours of operation are expanded, a member of the care team is available electronically or via the telephone, and there are alternative methods of communication such as email and telephone; 5) it is committed to quality and safety by engaging in performance measurement and continuous quality improvement, and adopting a population health management approach to care. In the PCMH model, payment recognizes patient-centered care management work beyond face-to-face visits, supports the use of health information technology for quality improvement, recognizes remote monitoring of clinical data using technology, allows additional payments for achieving quality improvement measures, and allows practices to share in savings generated from reduced hospitalizations.[18]

Another approach to improve primary care delivery is through accountable care organizations (ACOs), which are groups of providers who share the joint responsibility for the costs and quality of care provided to an assigned group of Medicare patients.[19] In addition to receiving reimbursement based on the traditional fee-for-service model, ACOs are eligible to voluntarily participate in the Centers for Medicare & Medicaid Services (CMS) Shared Savings Program, a program that focuses on value and

patient outcomes, rather than the number of encounters or procedures. As of January 1, 2020, there were 517 ACOs participating in the Shared Savings Program that provided care to 11.2 million (16.5%) Medicare beneficiaries.[20]

The PCMH and ACO are complementary approaches to reformed care delivery. Despite notable progress in the past years, not all primary care in the US is provided through PCMH and ACOs. There are still many independent primary care physician practices and large health systems that do not provide care by either of these models.

Finally, primary care is also provided in an array of other clinics focused on specific populations. Federally qualified health centers (FQHCs) are community-based health centers that provide primary care in underserved areas.[21] The Indian Health Service provides care in federal facilities to American Indian and Alaska native peoples.[22] As well, the Veterans Health Administration serves about 9 million veterans yearly.[23] Each of these systems is funded by the federal government. In addition, many communities also have free clinics that use volunteer/staff to provide healthcare services to disadvantaged individuals.[24]

In summary, primary care is provided in many different types of clinics and the providers are paid from numerous sources. Three medical specialties, advanced practice providers, and other clinicians support the delivery of primary care, and there is no single model of practice or reimbursement.

COMMUNITY PHARMACY IN THE US

Community pharmacy in the US is comprised of a number of sub-types of practice settings including independent, traditional chain, supermarket, and mass merchant pharmacies (Figure 1). The National Community Pharmacists Association (NCPA) reported that there were 61,800 community pharmacies in the US in 2018.[25] Of the 314,300 pharmacists in the US in 2018, more than 135,000 (43%) worked as community pharmacists.[26] Substantial differences in the number of pharmacies by county and region of the country have been identified with counties possessing the highest density of pharmacies per population having nearly three times as many pharmacies compared to those with the lowest density of pharmacies.[27] Thus, where a patient lives in the US greatly impacts their access to community pharmacy services.

Some pharmacies are able to generate revenue via clinical services (described below), but the primary business model for community pharmacies continues to focus on dispensing prescription medications to patients. In 2019, almost 3.8 billion prescriptions were filled in US pharmacies.[28] While the majority (about 1.9 billion) were paid for by commercial insurers, which includes some government programs like the Children's Health Insurance Program, Veterans Administration, and Indian Health Service, approximately 1.67 billion prescriptions were paid for, at least in part, by either Medicare or Medicaid, with patients being responsible for a co-payment.[28] Payers' coverage of prescriptions varies greatly across community pharmacy sub-type.[25] In 2019, prescription dispensing revenues in the US reached a record USD 446 billion, with the top seven dispensing pharmacies (i.e., CVS Health, Walgreens Boots Alliance, Cigna, UnitedHealth Group, Walmart, Kroger, and Rite Aid) accounting for about 70% of the market.[29] Detailed data from 2018 showed that independent pharmacies represented a USD 75.8 billion in prescription revenue, while CVS represented USD 102 billion, followed by the Walgreens Boots Alliance at USD 74.4 billion, Walmart at USD 20.9 billion, Kroger at USD 13.4 billion, and Costco at just USD 2.6 billion.[30]

In the US, medications are typically dispensed inside prescription vials or bottles that are filled at the pharmacy from bulk containers, rather than in individual blisters within boxes sold by the pharmaceutical industry, as is the case in Europe. Thus, the primary role of pharmacy technicians is to fill prescriptions and label medications in prescription bottles that the pharmacist then verifies. A growing body of literature supports expanding the role of technicians to administrative roles such as managing patient appointments, collecting comprehensive medication histories, and collecting clinical data to be reported to the pharmacist.[31] The Pharmacy Technicians Certification Board provides national standards for technicians. Regulations and requirements for certification, registration, and licensure vary by state. To date, 24 states require pharmacy technicians to attain national certification, either as a requirement to be registered or licensed, or to perform certain duties.[32]

Policy considerations affecting community pharmacy in the US

One of the most significant barriers to advancing

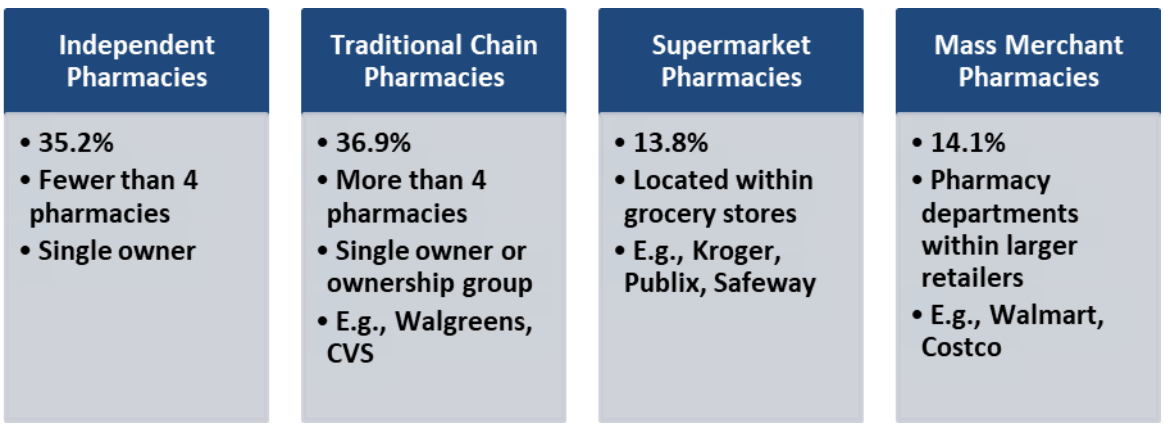

Figure 1. Sub-types of community pharmacies in the US and estimates for each type based on NCPA data[25]

community pharmacy practice in the US is the current payment structure. When the Social Security Act was passed in 1965, pharmacists were omitted from the definition of healthcare providers, resulting in pharmacists not being able to be paid by the Federal government for most services under Medicare Part B (i.e., while Medicare Part A covers hospital care, Medicare Part B covers services provided by physicians and other providers in outpatient settings). Because other payers generally follow Medicare payment policies, there are limited opportunities for pharmacists to receive reimbursement from public, private or commercial payers. Being recognized by CMS as a provider would enable pharmacists to use existing fee-for-service health insurance billing codes when they provide non-dispensing services. Some exceptions exist for specific services provided to Medicare beneficiaries in Part D programs, such as medication therapy management (MTM) and immunizations.

Achieving this objective requires working with the federal government to develop and pass legislation to add pharmacists to its list of providers.[33] To that end, 11 pharmacy organizations and other stakeholders are working together towards achieving provider status for pharmacists and studying possible options for legislative language that are primarily focused on amending the Social Security Act.[34] Given the myriad pharmacy organizations in the US prioritizing their own agenda (e.g., American Pharmacists Association, American College of Clinical Pharmacy, American Society of Health-System Pharmacists, Academy of Managed Care Pharmacy, American Society of Consultant Pharmacists, among others), having a unified voice for the pharmacy profession is a challenge. The fact that 11 organizations have united efforts to advocate for provider status underscores the importance of such legislation for the profession.

Passing such federal legislation is likely to take considerable time, and several individual states (e.g., California, Washington) have passed provider status legislation for pharmacists, though they continue work on how these statutes will be implemented.[35,36] Achieving provider status at the state-level, in theory, may allow pharmacists to negotiate reimbursement for services directly with insurance companies; however, payment may still not follow provider status recognition at the state level.

Community Pharmacy Enhanced Services Network

The Community Pharmacy Enhanced Services Network (CPESN) is a clinically integrated network of community pharmacies (mostly independent), that resulted from the expansion of the Community Care of North Carolina in 2014 with funding from a 3-year grant by the Centers for Medicare and Medicaid Innovation (CMMI). The goal was to provide a structure for community pharmacies to expand primary care efforts, as well as a means to negotiate reimbursement for services with payers as a group.[37,38] This model has now spread to 44 states and includes 2,700 community pharmacies that offer enhanced services for high-risk patients. The core services that pharmacists are required to offer to be a part of the network include medication reconciliation, medication synchronization, immunizations, comprehensive medication reviews, face-to-face access to a pharmacist, and creating a comprehensive medication list. Additional enhanced services provided by select pharmacies comprise: 24-hour emergency services, collection of vital signs, home delivery/home visits, tobacco cessation program, durable medical equipment, point-of-care testing, long-acting injections, naloxone dispensing, nutritional counseling, and specialty medication compounding.[39] To the best of our knowledge, no public information exists regarding the percentage of pharmacies providing each of the services and the reimbursement rates negotiated (if any) for each service across states. Several challenges were reported by pharmacists in the North Carolina CPESN offering medication management services related with initiating services, accessing internal and external information, documenting, among others. This same study found that 73 (59.3%) of the 123 participating pharmacies did not complete service requirements within the first 3 months.[40]

In 2019, the Community Pharmacy Foundation and CPESN partnered to fund the Flip the Pharmacy initiative which aims to transform community pharmacy practice, moving away from point-in-time and prescription-level to longitudinal and patient-level care processes and business models.[41] Six transformation domains comprise the initiative, namely: leveraging the appointment-based model, improving patient follow-up and monitoring, developing new roles for non-pharmacist support staff, optimizing the utilization of technology and electronic care plans, establishing working relationships with other care team members, and developing the business model and expressing value.[42] The initiative is currently underway, thus limited evidence regarding its impact on community pharmacy processes, volume and payment of services, or patient outcomes exists.[43] The ultimate goal is to gather evidence of the contribution of community pharmacists to improved patient care to serve as a means to negotiate reimbursement for pharmacist services with payers.

Pharmacy education and training in the US

Since 2000, the recognized professional degree that can be obtained from schools of pharmacy in the US is the Pharm.D. (doctoral degree). However, there remain a significant number of practicing pharmacists who were not trained at the doctoral level and have bachelor's or master's degrees.[44] The 2016 American Council on Pharmaceutical Education's set of educational standards were designed to ensure that all graduating pharmacists were prepared to contribute meaningfully to patient-centered care and interdisciplinary team practice, use evidence-based practice, apply quality improvement strategies, and utilize informatics.[44] While community-based pharmacy residencies are not currently required, the number of such residencies has grown in the last 20 years to more than 130 accredited post-graduate year 1 (PGY1) programs.[45] However, this growth has not kept pace with demand by student pharmacists or professional organizations such as the American College of Clinical Pharmacy, which previously advocated that starting in 2020 all pharmacists involved in direct patient care complete an accredited residency.[45]

Integration of community pharmacy and primary care

Pharmacists are integrated into primary care in a number of important ways, which continue to evolve over time. In support of better coordination between community pharmacy and primary care, the Centers for Diseases Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention developed a practitioner and a pharmacist guide for "Creating Community-Clinical Linkages Between Community Pharmacists and Physicians" in collaboration with the American Pharmacists Association and the American Medical Association.[46,47] Community-clinical linkages are defined as connections between the community, clinics, and other settings where primary care is provided to improve population health.[46] The pharmacist guide provides a framework called LINKAGE outlining how community pharmacists and physicians can develop community-clinical linkages.[47] Suggested activities to be performed by both parties as part of these linkages include: pharmacists conducting health assessments and referring patients to physicians for diagnosis or treatment; pharmacists triaging patients with medication-related problems or new/worsened health conditions into primary care; and physicians referring patients to pharmacists for medication and chronic conditions management.[47]

One way for community pharmacists to provide services and be reimbursed is by extending beyond the walls of the pharmacy and establish collaborations with primary care clinics. An example of such a model is pharmacists from an independent community pharmacy in the state of North Carolina providing services at an independent primary care clinic three days a week.[48,49] Over and above improving patient outcomes, this service also gained the clinic an additional USD 16,920 in annual reimbursement.[49] Pharmacists provide chronic care management services (i.e., services aiming to improve health outcomes by enhancing care coordination for patients with multiple chronic conditions) to Medicare beneficiaries, reimbursable since January 2015 via the Medicare fee-for-service program.[50] The goal is to help the primary clinic achieve the quality measures set by CMS, while also arranging a way for both parties (physician and pharmacists) to be reimbursed, even if billing is under the physician's fee schedule. This model is by no means widespread in the US and requires collaboration with a provider.[50]

Primary care is also moving inside pharmacies. Several community pharmacy chains and mass merchants have opened walk-in clinics inside their stores as a means to increase access to care. For example, CVS has co-located Minute Clinics that provide walk-in care for minor illnesses, minor injuries, skin conditions, travel health, vaccinations and injections, wellness and physicals, women's services, and screenings and monitoring. Cost of services can be covered by insurance plans or paid out-of-pocket. Treatment for minor illnesses, minor injuries, skin conditions, wellness and physicals, and screenings and monitoring cost between USD 99-139/visit; cost for travel health related items ranges between USD 59-142; women's services cost between USD 59-250; and vaccinations and injection administration between USD 50-250.[51] Care is provided by nurse practitioners and physician assistants (not pharmacists) to both adults and children.[52,53] The CEO of CVS Health has publicly stated that "retailization of healthcare" will continue to evolve, with service convenience being a top priority.[54] Walgreens had a similar arrangement up until 2019, but decided to outsource the service to VillageMD, a group of primary care physicians, in July 2020. They plan to open 500-700 "Village Medical at Walgreens" physician-led primary care clinics in more than 30 US markets in the next five years. The press release mentions that pharmacists will be integrated as a critical member of the VillageMD's multi-disciplinary team, but no further details are provided.[55]

Pharmacist prescriptive authority

In the US, pharmacists who are able to prescribe, monitor, and adjust medications independent of or in collaboration with physicians can generally provide associated clinical services. The National Alliance of State Pharmacy Associations (NASPA) is a trade association that tracks pharmacy legislation and regulations across all 50 states and the District of Columbia.[56] NASPA and the Idaho State Board of Pharmacy proposed a framework to characterize

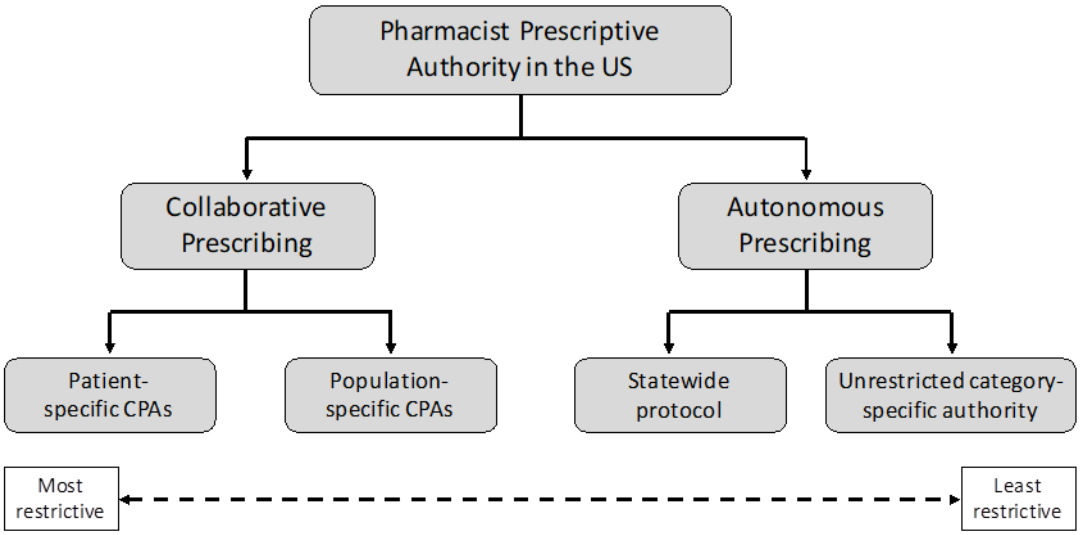

Figure 2. Summary of available practice models adopted by states that allow pharmacists to prescribe in the United States (CPAs, collaborative practice agreements)

existing models of pharmacist prescriptive authority along a continuum from most restrictive to least restrictive (Figure 2).[57] At present, 49 states and the District of Columbia have passed legislation that allows pharmacists to prescribe medications under CPAs, standing orders, or statewide protocols.

In a collaborative prescribing model, pharmacists and prescribers create formal relationships through the establishment of collaborative practice agreements (CPAs) wherein the latter grant prescriptive authority to the former.[58,59] CPAs can be patient-specific (i.e., individual patients or a collaborating prescriber's patient panel) or population-specific (i.e., categories of patients). While population-specific CPAs are commonly used for acute care (e.g., treatment of influenza in patients with certain characteristics that do not meet criteria for automatic referral), both patient- and population-specific CPAs are established for chronic disease management (e.g., diabetes, hypertension, hyperlipidemia, asthma).[57]

Autonomous prescribing can occur via statewide protocols or unrestricted category-specific prescribing. In these situations, CPAs are not required to be in place for pharmacists to prescribe; however, pharmacists are still responsible for coordinating care with the primary care provider. Statewide protocols are set by an authorized body or state government (e.g., Board of Pharmacy, Department of Health) and allow pharmacists to prescribe medications that are intended for preventive care or for acute or self-limiting conditions that require a limited process to diagnosis. The scope of statewide protocols is generally narrow and often arises in response to a public health crisis. Any pharmacist who fulfills the requirements specified in the protocol is authorized to prescribe without supervision from a collaborating physician, unlike CPAs.[57] Unrestricted category-specific prescribing applies to a limited range of medications for which no specific diagnosis is needed. Instead of following a state-derived protocol, states refer pharmacists to other authority documents, such as practice guidelines, to guide prescribing. Autonomous and collaborative prescribing supplement each other, rather than being mutually exclusive.[57]

A standing order is a statewide prescription issued by a state designated prescriber under which pharmacists are allowed to fill a prescription to dispense a product (e.g., naloxone, smoking cessation products). In this model, pharmacists are not the prescribers.

Community pharmacy services

As described above, pharmacy practice legislation varies across all 50 states and the District of Columbia. Likewise, reimbursement for specific services also differs at the state level, unless reimbursement is based on federal legislation, as is the case of services for Medicare beneficiaries. In the US, there is a history of pharmacy services innovations, but state fragmentation and the lack of a single payer system and a single vision and voice for the pharmacy profession prevent scaling these innovations at the national level. Chain pharmacies play a pivotal role in scaling service innovation in community pharmacy beyond dispensing services through counseling, MTM services, and several disease state management initiatives.[60,61] Due to their dissemination across the country, scale up of services is maximized. For example, reports demonstrate chain pharmacies positioning themselves to meet demand for convenience in offering immunization services.[62] However, work in a busy chain pharmacy can lead to pharmacist burn out, which in turn compromises patient safety.[63,64]

The services described below represent the mainstream services that pharmacists currently provide and, in particular circumstances, for which they can obtain reimbursement (Table 1). Due in part to the fragmented nature of the healthcare system in the US, it is not currently possible to report the extent to which these services are provided. Existing evidence usually derives from research studies that academics conduct with data obtained from either local Boards of Pharmacy or state-wide surveys, the latter usually limited by a low response rate. More recent reports of MTM have used Medicare Part D claims to examine some services.

Immunizations

All 50 states and the District of Columbia have legislation allowing pharmacists (and student pharmacist interns operating under the supervision of the pharmacist) to administer immunizations. States allow vaccine administration via any of the prescribing mechanisms described above, except one (Alabama) which only allows vaccine administration by prescription. The types of vaccines that pharmacists can administer and the minimum age of patients to whom they are allowed to administer also vary across states. While some allow any vaccine to be administered to any patient regardless of age, others do not allow pharmacists to administer certain vaccines (e.g., human papillomavirus vaccine) or restrict administration to adults or children older than a certain age.[65] Immunization administration in some states also extends to CDC-recommended travel vaccinations. As of June 2020, six states allowed pharmacy technicians who completed immunization certificate training to administer vaccines under the direct supervision of a certified pharmacist.[65]

The 2019 National Pharmacist Workforce Study reported that 90% of community pharmacists administered vaccines.[66] In Westrick et al.'s study of a nationally representative sample of 292 community pharmacies, 80% reported that they had provided immunization services in 2016, the most common vaccines being influenza, herpes zoster, pneumococcal 13-valent conjugate (PCV13) and pneumococcal polysaccharide (PPSV23).[67] Pharmacy-based immunization services have been associated with an increase in the likelihood of being immunized.[68] As an example, influenza vaccinations dispensed in community pharmacies increased from 3.2 to 20.9 million between 2007 and 2013.[69]

In order to bill for immunization administration, pharmacies need to contract with the appropriate payers (i.e., pharmacy benefits managers, Medicare, Medicaid, third-party medical plans). Pharmacies bill for both the product and the administration service. Administration fees vary between USD 15 and USD 40.[70] Additionally, pharmacies can charge customers or private employers with whom they contract directly. The average direct costs paid per adult vaccination were shown to be lower in

Table 1. Pharmacist services available in the community pharmacy setting.

Service/Activity	Availability status (date)	Regulation level	Reimbursement
Immunizations	• All 50 states and the District of Columbia (Jun. 2020) • 1 state (Alabama) only by prescription (Jun. 2020) • 6 states allow pharmacy technicians with required training to administer vaccines under the supervision of a certified pharmacist (Jun. 2020)	State	• Via contract with the appropriate payers (i.e., pharmacy benefits managers, Medicare, Medicaid, third-party medical plans) • Bill payers for both the vaccine and administration service (varies between USD 15 - 40) or paid by patients out-of-pocket
Medication Therapy Management (MTM) program	• All 649 Medicare Part D contracts use pharmacists to provide MTM (2019)	Federal	• Reimbursement provided by CMS • Billing in 15-minute increments using current procedural technology codes
Medication packaging	• Implementation status unknown	N/A	• Paid by customers out-of-pocket or offered as part of a medication synchronization program
Medication synchronization	• 22,000 community pharmacies (2015)	N/A	• No reimbursement. MTM billing codes apply if offered as part of the service
Hormonal contraception prescribing	• 9 states and the District of Columbia (Dec. 2019)	State	• Reimbursement varies by state
Point-of-care (POC) testing	• All 50 states and the District of Columbia - for approved tests with pharmacy CLIA waiver from CMS (1988)	Federal	• Paid by customers out-of-pocket
Naloxone prescribing or dispensing	• All 50 states and the District of Columbia (Jan. 2019) o 17 states and the District of Columbia - statewide protocol/pharmacist prescribing (Jan. 2019) o 12 states - statewide standing order (Jan. 2019) o 4 states - dispense without a prescription (Jan. 2019) o 17 states - standing order (Jan. 2019)	State	• Variable out-of-pocket costs depending on the patient's health insurance • Pharmacist counseling not reimbursable
Tobacco cessation aid prescribing	• 37 states (Nov. 2019) o 12 states - statutes or regulations allowing pharmacists to prescribe (Nov. 2019) o 17 states - prescribe under population-based CPAs (Nov. 2019) o 7 states - prescribe via autonomous prescribing (Nov. 2019) o 1 state - independent prescribing (Nov. 2019)	State	• Reimbursement varies by state

pharmacies compared with other medical settings, likely because in medical settings additional billing codes can be applied (e.g., billing codes covering patient counseling).[71]

Medication therapy management

MTM is a service included in Medicare Part D plans that aims at improving medication use and reducing the risk of adverse events in eligible Medicare beneficiaries.[72] MTM includes five core elements: 1) comprehensive medication review (CMR); 2) provision of a personal medication record; 3) construction of a medication-related action plan consisting of a list of actions for patients to track progress for self-management; 4) intervention to address medication-related problems or referral to a physician or other healthcare professional; and 5) documentation of MTM services and follow-up visit.[73,74] Part D plans are required to provide and automatically enroll in their MTM programs beneficiaries who meet pre-specified CMS criteria, namely: having multiple chronic diseases, taking multiple Part D medications, and being likely to incur annual Part D medication costs that meet or exceed a certain threshold every year (e.g., USD 4,044 in 2019).[75] However, 27% of MTM programs in 2019 used expanded eligibility requirements beyond the minimum required by CMS.[76] MTM services may be provided by pharmacists or other healthcare professionals. For example, of the 649 Part D contracts with an approved MTM program in 2019, 100% used pharmacists to provide MTM services, 74% used a registered nurse, 24.5% a physician, and 15.1% a physician assistant (multiple selections were allowed, thus categories were not mutually exclusive). Beneficiary enrollment into MTM programs should be at least quarterly (47.1% of plans in 2019), but could also be every other month, monthly, weekly or daily. Eligible beneficiaries are mainly identified via medication claims data.[76]

The CMR is a core element of MTM and it consists of an "an interactive person-to-person or telehealth medication review and consultation conducted in real-time between the patient or other authorized individual, such as prescriber or caregiver, and the pharmacist or other qualified provider and is designed to improve patients' knowledge of their prescriptions, over-the-counter (OTC) medications, herbal therapies and dietary supplements, identify and address problems or concerns that patients may have, and empower patients to self-manage their medications and their health conditions". Part D sponsors are required to provide a CMR at least annually or targeted medication reviews (TMR) quarterly. TMRs are shorter duration medication reviews to assess medication use, monitor unresolved issues, identify new drug therapy problems, and assess whether beneficiaries experienced a

transition of care. CMR delivery method can be face-to-face, over the phone or through telehealth.[76] The benefits from obtaining a CMR include the identification of effectiveness and safety issues with prescribed medications, as well as identification of less expensive alternative medications for patients.[77] Despite the benefits of CMRs, the uptake of the service is low – less than 20% of eligible Medicare beneficiaries in 2013 and 2014 received the service –, either because patients are unaware of it or because they perceive it as unnecessary.[77-79] Data from the 2019 National Pharmacist Workforce Study indicated that 66.7% of respondents provided MTM services.[66] Additionally, analyses of Medicare claims data from 2014 revealed that community pharmacies provided only 22% of the CMRs, with the remainder provided by either other types of pharmacists or other professionals.[80] In 2018, the CDC launched a statewide initiative focused on implementing and evaluating evidence-based strategies to manage diabetes and prevent or delay onset of type 2 diabetes in high-burden populations and communities, and one of the strategies proposed is to expand MTM services provided by pharmacists to patients with diabetes.[81]

The effectiveness of MTM services remains a contested topic because of heterogeneity of previous studies' populations, settings, and outcomes.[82] In addition, contemporary MTM definitions found in the professional literature differed from the early definition in the regulatory reference, making meaningful evaluations over time difficult.[83]

Reimbursement to pharmacists (and other professionals) rendering MTM services is provided by CMS. Billing is in 15-minute increments using current procedural technology codes (specific codes used for medical billing). The initial 15-min face-to-face assessment is reimbursed at a rate of USD 50 and is covered once a year per provider per beneficiary. Follow-up assessments of 15-minute increments are reimbursed at a rate of USD 25 and providers can bill up to seven times in a year. Additional 15-minute increments to the two previous codes can be billed up to four times per provider per beneficiary per date of service at a rate of USD 10.[84] Lack of standardization for documentation and billing is an important limiting factor of MTM programs.[85] Another potentially contested aspect is the effectiveness of a CMR without access to the electronic health record (EHR).

Medication adherence

Similar to other countries, community pharmacists in the US offer services aimed at improving medication adherence.[86,87]

Medication packaging is one such service. Packaging interventions significantly improved medication adherence in a meta-analysis of 52 studies.[88] This study demonstrated that interventions using blister packs compared with pill boxes, and delivered in pharmacies compared to interventions delivered elsewhere were significantly more effective at improving adherence.[88] It is unclear what percentage of community pharmacies in the US offer medication packaging services. The service is not reimbursed by CMS or prescription insurance plans. While some pharmacies may offer the service as part of their medication synchronization service, others may charge an out-of-pocket fee to customers.

Medication synchronization is a process by which a patient's medications refill dates are aligned so that patients only come to the pharmacy once a month. Prior to preparing the medication, pharmacy staff call patients to identify whether any changes to medications occurred and to confirm what medications should be dispensed. This contributes to a higher efficiency of the pharmacy workflow, in addition to presenting an opportunity for pharmacists to perform a medication review and identify any therapeutic or compliance issues.[89] As of 2015, this service was being offered by more than 20,000 chain and 2,000 independent community pharmacies across the country and 66.5% of participants in the National Pharmacist Workforce Study reported that they offered the service.[66,90] However, service provision varies across pharmacies – while some focus exclusively on the alignment of refill dates, others conduct an appointment-based medication synchronization where patients meet with the pharmacist to discuss their medications, any adherence issues, or receive MTM services.[91,92] Unfortunately, the extent to which each modality occurs is unknown and even if it were self-reported, it is legitimate to expect response bias. The service itself is not reimbursable but it may contribute to increased monthly prescription volume.[93] Additionally, if MTM services are provided with medication synchronization, the pharmacy receives reimbursement via the MTM billing mechanisms. Retrospective analyses of the service showed that appointment-based medication synchronization increased the odds of being adherent by 2 to 6 times compared to patients not enrolled in the service.[94-96] Patients in a synchronization program also presented rates of hospitalization and emergency department visits and rates of outpatient visits that were 9 and 3 percent lower, compared to a control group obtained via propensity score matching.[94] However, it is unclear which components of the service contribute to these improvements due to the lack of a consensus definition of medication synchronization.[92]

Hormonal contraception

As of December 2019, nine states and the District of Columbia had statewide authority for autonomous pharmacist contraception prescribing.[97] Each statewide authority has different prescribing protocols, patient age limitations, contraceptive formulations allowed (e.g., oral, patch), and pharmacist training requirements.[97] Many included a patient self-screening assessment, blood pressure measurement, documentation requirements, and patient education materials in the prescribing procedure.[97] Reimbursement exists on a state-by-state basis. For example, in the state of Oregon, certified pharmacists prescribe hormonal contraception and are reimbursed by Medicaid and private payers at the same rate as physicians and nurse practitioners for both the product and the assessment.[98] Since April 2019, California's State Medicaid program (Medi-Cal) reimburses pharmacist services furnishing hormonal contraception at a rate of 85% of the fee schedule for physician services.[99] A time and motion study conducted in community pharmacies in the state of Oregon found that pharmacists spent approximately 18 minutes to screen a patient for eligibility, document the

encounter, and provide a written prescription for contraceptives in an uncomplicated patient.[100] A descriptive study of 391 supermarket-based pharmacies in California and Oregon revealed that 1970 service visits resulted in birth control prescriptions by 381 pharmacists, 95.7% of which were for the pill, 2.1% for the vaginal ring, 1.6% for a transdermal patch and 0.1% for an injectable.[101] In other studies, pharmacists described time constraints, lack of access to EHRs, lack of reimbursement, additional training needs, and liability concerns as potential barriers to prescribing contraception.[102-104] State practice laws, workflow design, and perceived barriers by pharmacists will need to be addressed to fully expand patient access to pharmacist-prescribed hormonal contraception.

Point-of-care testing

Point-of-care (POC) testing, such as blood glucose, hemoglobin A1c, cholesterol and international normalized ratio testing are some of the available community pharmacist-provided services and may be included under a CPA. In order to perform POC tests, pharmacies must obtain a certificate of waiver from CMS to perform a Clinical Laboratory Improvement Amendment (CLIA)-waived test.[105] A CLIA-waived test is designed for screening, monitoring, or diagnosis outside of a laboratory setting and are used within a community pharmacy setting.[106]

In recent years, POC testing has expanded beyond glucose and cholesterol (Table 2). Community pharmacists providing POC testing for group A streptococcus and influenza under a CPA increased access by administering POC tests outside of normal clinic hours, conducting tests in patients without a primary care provider, and providing appropriate medication based on test results.[107-109] Similarly, POC testing for human immunodeficiency virus and hepatitis C was provided by trained community pharmacists.[110-112] The availability of these tests is not widespread and patient awareness, willingness to receive, and payment mechanisms for community-based POC infectious disease testing remain a concern.[113] While POC testing may be an important means to screen patients and provide care, the business model for it must be developed.

Opioid reversal agents

In response to the opioid epidemic in the US, efforts to increase access to naloxone in community pharmacies have been widespread. Each state and the District of Columbia has varying levels of how pharmacists may prescribe or dispense naloxone, ranging from a statewide protocol, including pharmacist prescribing authority, to the ability to dispense without a prescription.[116,117] In the 2019 National Pharmacist Workforce Study, 72.2% participants reported dispensing naloxone.[66] Despite 57% pharmacists working in community settings feeling confident recommending naloxone, only 28.3% felt confident administering it.[66] A greater proportion of mass merchandiser (76.6%) and large chain (63.3%) pharmacies dispense naloxone via a standing order compared to independent and small chain pharmacies. The latter dispense naloxone more frequently based on a prescription order (44.4% each).[66]

An analysis of community pharmacy records revealed that naloxone dispensing increased from 1,282 prescriptions (0.4 per 100,000) in 2012 to 556,847 (170.2 per 100,000) in 2018. Individuals with commercial insurance represented the largest percentage of dispensed naloxone prescriptions in 2018 (51.1%), followed by Medicare (35.9%), Medicaid (10.7%), and self-pay (2.4%). A majority (42.3%) of prescriptions did not require out-of-pocket costs, while 24.5% required out-of-pocket costs of less than USD 10.00, 21.9% between USD 10.01–50.00, and 5.8% over USD 50.00. Counties with high naloxone-dispensing also had more high-dose opioid dispensing rates, higher drug overdose deaths rates, higher potential buprenorphine treatment capacity, and higher rates of Medicaid enrollment. Micropolitan and rural counties were less likely to be a high naloxone-dispensing county compared to metropolitan ones. However, in this study, pharmacists were grouped under "other" specialty prescribers, thus limiting the ability to determine the amount of pharmacist-provided naloxone.[118] Differences in state practice laws, required pharmacist training, pharmacist time, pharmacist confidence in naloxone prescribing, inadequate pharmacist reimbursement, and patient out-of-pocket costs present current challenges to widespread adoption of naloxone dispensing.[119,120]

Smoking cessation

Prescription of tobacco cessation therapy can be achieved through the establishment of population-based CPAs, standing orders, statewide protocols, or independent prescribing. In the latter two cases, pharmacists not only prescribe but are also able to bill the patient's insurance for any covered smoking cessation services in addition to the prescription medication dispensed (reimbursement variable).[121] For example, in California, the Medicaid program (Medi-Cal) covers smoking cessation services at 85% of the physician's fee.[99] The products covered under statewide protocols vary across states, with some including varenicline and bupropion, in addition to non-prescription and prescription nicotine replacement therapy products. Pharmacists must meet minimum education requirements to engage in autonomous prescribing of tobacco cessation products.[122] Provision of this service is sporadic, despite legislation being passed in many states.

Table 2. Point-of-care tests available in community pharmacy in the United States*

Blood glucose
Cholesterol
Group A *Streptococcus*
Helicobacter pylori
Hemoglobin A1c
Hepatitis C Virus
Human Immunodeficiency Virus
Influenza
International Normalized Ratio
Pharmacogenetics

*Note that this is not a complete list of all possible tests.
Adapted from information provided by NCPA[105] and previous literature.[114, 115]

FUTURE DIRECTIONS IN COMMUNITY PHARMACY IN THE US

Community pharmacy practice in the US contains multiple stakeholders whose interests often compete. To discuss the future of community pharmacy in the US we will use Donabedian's structure, process, outcomes framework.[123]

Structure

One of the most significant barriers is the current payment structure and pharmacists not being recognized as providers by CMS, as discussed above. While achieving provider status is an important step for the profession to bill under fee-for-service, it is also important to acknowledge a growing shift from this model to pay-for-performance healthcare reimbursement. Similar to other jurisdictions around the world, the US is facing precipitous increases in healthcare costs. One method for beginning to address these increases is shifting incentive structures away from the quantity of services provided to one focused on the quality of services provided. Quality measures have been proposed and adopted at multiple levels of the healthcare system including hospitals, physicians, nursing homes and health plans, to drive improvement, inform consumers, and determine payment. Of particular relevance to community pharmacy is the Medicare Star Ratings program which evaluates the quality of Medicare prescription drug plans on a 5-star system where higher is better.[124] There are currently five active medication-related measures, which have been developed in collaboration with the Pharmacy Quality Alliance, whose mission is to optimize health by advancing quality medication use.[125] The five measures are: 1) medication adherence (via calculation of the proportion of days covered) for 1a) diabetes, 1b) hypertension, and 1c) cholesterol medications; 2) CMR completion rate as part of the MTM program; and 3) statin use in persons with diabetes.[126,127] Though not specific to community pharmacy, community pharmacists have the potential to impact all these measures through many of the services outlined previously. Importantly, health plans in select states have started paying bonuses to high performing pharmacies (i.e., those who positively impact medication-related quality measures) and including them in preferred pharmacy networks, meaning that patients who utilize these pharmacies will have reduced or no co-pays for their prescriptions.[128] Although value-based reimbursement continues to evolve, it does present community pharmacy with a unique opportunity to build a new community pharmacy practice model.

Another significant barrier, but also a potential opportunity, comes from needed improvements in access to technologies such as EHRs, use of mobile health applications, and telemonitoring.[129,130] Success in accessing patients' EHRs from a community pharmacy setting to help coordinate care and communicate with other providers is achievable, though would require collaborations across multiple health systems and EHRs.[131] Access to EHRs helps community pharmacists gain access to the current medication list, doses, and laboratory results to monitor medication effectiveness and disease control or progression.[132] The use of mobile health apps for sharing of health information between the community pharmacy, the patient, and other healthcare providers is growing. For instance, the MEDIvate iOS smartphone application using cloud architecture allows patients to scan a vaccine prescription QR code to import their vaccine data and vaccine information into the app.[133]

Failing to adequately address these barriers will leave community pharmacy open to a substantial threat from disruptors such as Amazon. In addition to its recent acquisition of the online pharmacy PillPack, Amazon's operations are specifically designed for efficiency, have extensive transportation networks, and can leverage the presence of Whole Foods (a groceries store) to provide great customer experience.[134,135] Amazon can offer substantial discounts to cash-paying customers because of its size and will present a viable alternative to the employers searching for pharmacy benefit plans for their employees.[134] Finally, it is also nearly prepared to meet the needs of the Drug Supply Chain Security Act, which will come into effect in 2023, that requires that all prescription medications be traceable from manufacturer to patient.[134]

Process

The success of structural adaptations will only be achieved if corresponding adjustments are made to processes taking place within the community pharmacy. To begin, all technical duties should be transitioned to pharmacy technicians. There is growing evidence supporting technicians' participation in MTM sessions, serving as pharmacist extenders, and completing tech-check-tech dispensing.[136,137] Some states have passed legislation allowing technicians to provide some immunizations.[138] Before these tasks can be given entirely to technicians, the laws governing technician practice across the country must be standardized to ensure adequate levels of training and competency.[137]

The COVID-19 pandemic has also further accelerated the process of giving and receiving care via telehealth.[139] This represents an opportunity for community pharmacy to transition some services to this delivery format to save patients time and pharmacy resources. For example, it could be a means to standardize the provision and increase uptake of MTM among Medicare Part D plan beneficiaries.

As technicians release pharmacists' time for clinical duties and new opportunities for the provision of care via telehealth are adopted, the profession should acknowledge and lessen the impact of "community pharmacy practice inertia", characterized by a reliance on outdated protocols and practices in the face of new evidence.[140] Despite various legislative advances, uptake of community pharmacist services is generally low across states, speaking further to the need to address both structure and process aspects.

Outcome

Once structure and process adjustments have been made, community pharmacists can focus on service expansion and clinical, humanistic and economic outcomes. A common criticism to the pharmacy practice literature relates to the poor and inconsistent intervention reporting.[141-144] As mentioned above, a challenge with MTM and medication synchronization is the lack of standardized definitions and process of how these services are provided across multiple studies.[82,83,92] In order for services to be integrated in routine community pharmacy practice and sustained over time, it will be helpful to draw from the implementation science discipline. Implementation science focuses on methods to "promote the systematic uptake of research findings and other evidence-based practices into routine practice".[145] Implementation science emphasizes systematic thinking about healthcare delivery and has developed numerous frameworks for, not only rethinking

practice change implementation, but also for guiding ongoing data collection and monitoring.[146] These data will be as equally important as patient outcomes as current and future practice scope expansion legislation is passed.

CONCLUSION

Community pharmacy is the US offers some clinical services to support primary care, but the business model retains a focus on dispensing. Chain pharmacies (and potentially pharmacies within CPESN) offer important opportunities to scale clinical services nationwide. Yet, the delivery of medications to homes via incredibly efficient modes – whether Amazon or automated transportation – offers significant opportunity beyond dispensing for helping healthcare providers and patients obtain the best outcomes from medications. When we overcome structural barriers to care such as limited reimbursement and lack of coordination with the EHR, then community pharmacists will be able to adapt their processes of care to achieve improved patient outcomes.

CONFLICT OF INTEREST

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