Editorial

Is my paper relevant for an international audience?

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Abstract:
This is the first question one should consider before submitting a paper to an international journal. The answer is simple: If researchers or practitioners from another country can learn something from your paper that can influence a practice or a research they are involved in, then your paper is relevant for an international audience. There are many elements that can influence in this cross-border transferability. One could think that having a big "n", or performing complex statistical calculations, or using complicated study designs makes the paper more attractive to colleagues from other countries. These elements can help, but they are not sufficient. On the other hand, one could think that a study performed in a small hospital in a given country will never be of interest for these foreign colleagues. That is not necessarily correct. Let's burst some myths.

Keywords:
Internationality; Global Health; Writing; Publishing; Biomedical Research; Research Design; Peer Review, Research; Quality Control; Editorial Policies; Periodicals as Topic

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There are many elements that can influence in this cross-border transferability. One could think that having a big "n", or performing complex statistical calculations, or using complicated study designs makes the paper more attractive to colleagues from other countries. These elements can help, but they are not sufficient. On the other hand, one could think that a study performed in a small hospital in a given country will never be of interest for these foreign colleagues. That is not necessarily correct. Let's burst some myths.

Myth #1: Experimental studies are much more interesting than observational studies. Well, it depends on the specific experimental study and observational study we are comparing. Obviously, randomized controlled trials (RCTs) are the gold standard to identify causation in clinical research and the highest level of evidence among unfiltered studies. But it's important to acknowledge that an RCT achieves these attributes only when conducted under rigorous standards that will ensure a low risk of bias. These are not simple words because we can measure — in fact, we should always measure — the potential risk of bias of an RCT when designing the protocol, and then the risk of bias before writing the article.[1] Because, properly reporting an RCT is as important as properly conducting it. Some RCTs do not report all the data needed to include them in a meta-analysis: results at baseline and after follow-up in both groups with the corresponding dispersion measures, numbers of participants in each group, subgroups and additional analyses, etc.[2] Another common issue of RCTs, especially in pharmacy services, is a poor description of the intervention performed. Pharmacy interventions are complex interventions, but we have several tools to improve the descriptions of these interventions.[3-5] On the other hand, a well-conducted observational study can add much value to a research question. Newman, et al., compared case-control studies with the house-red, because they are "more modest and a little riskier than the other selections, but much less expensive and sometimes surprisingly good".[6]

Myth #2: Systematic reviews compile the evidence about a research question, so their relevance is guaranteed. This is true if the systematic review has a relevant research question and is conducted ensuring the highest levels of quality. Some supervisors design research plans for their Ph.D. students starting with a systematic review. Their procedure relies on the idea that a systematic review is the best way the Ph.D. student embraces the state of the art about the topic of thesis. Many of these newbies don't have experience or specific training on evidence synthesis, and they have a limited knowledge of the topic of the thesis. In this scenario, the probability of producing a poor systematic review, poorly conducted, and with a poor answer to a poorly established research question is very high. This might be one of the reasons why only 3% of systematic reviews are clinically sound.[7] A systematic review should be the final piece of research in a doctoral program, only achievable when the student has depth of knowledge of the topic, had time to be trained to synthesize evidence, and has skills to write a paper following, again, the reporting recommendations. Only an expert researcher can have the skills to critically evaluate the studies included in the meta-analysis.[8] (see PRISMA extensions for variants of a systematic review: http://www.prisma-statement.org/Extensions/).[9]

Myth #3: Replicating a good study is always a reasonable way of confirming the facts in our environment or setting. A study is a good study not only because it was correctly conducted, but because it tries to solve a relevant research question. The first study probably found the cause of a phenomenon, or simply identified an important association. Repeating the study by means of a 'me-too study' might not be relevant at all. If environmental conditions are similar to

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that of the first study, and nothing predicts different results, replicating the study and obtaining similar results could be a waste of resources. And, if nothing predicts different results but we obtained different results, unless we can explain or, at least, guess why these different results came out, replicating the study does not add much value. Adding analyses to the first study, perhaps with subgroup or sensitivity analyses, and explaining the results with a different view could warrant a new publication with interest for an international audience.[10]

Myth #4: Thoroughly describing how my setting performed in a period of time can help other researchers. This type of study is very common. Articles reporting the consumption of a therapeutic class during a period of time in a given hospital, or the number and type of drug-drug interactions pharmacists identified, or the characteristics of the students of a given university are frequently submitted as potential journal articles. These analyses are more appropriate for an annual report of the institution than for a research article. Two reasons limit the international relevance of these reports: 1) they depict the situation of a given setting in a given time, and nothing guarantees that the same institution in a different time or another institution at the same time would have similar results; and 2) these studies usually do not explain why that institution achieved those results. Are those DDDs consumed because some policy was implemented? Were those drug interactions identified after introducing a new system? The international reader will not be interested in a still image if nothing explains how this situation came about. Research should not only announce what happens, but it should also explain why that happened, or at least produce an educated guess.

Myth #5: Pilot studies should always be published before. A pilot study is probably the least interesting paper one could imagine. In fact, a pilot study serves only for the researchers of a full-length study to test whether the materials and methods are ready to start the big study. No conclusions, other than we are able to use these materials in our setting with the resources we have available, should be taken from a pilot study.[11] The conclusions of a pilot study cannot be inferred in a different scenario. Different from pilot studies, feasibility studies might be relevant for an international audience. Feasibility studies should be run after pilot studies, and they serve to obtain firsthand data that will influence the full-length study design. For instance, they serve to establish dispersion measures that will be necessary to establish sample size calculations, allow identifying smallest dose of the intervention required to obtain the effect, give an estimative of the drop-outs, etc.[12] To obtain reliable information, feasibility studies should be executed in a realistic population, similar to the one to be used in the full-length study. Thus, a researcher from another country can use this information to replicate the research, which is not possible with pilot studies.

Myth #6: Assessing obvious things is also relevant. We should not devote too much research time and efforts to publish a no-brainer. A frequently submitted type of article that could fit in this category are the KAP studies, where KAP stands for "knowledge, attitudes and practice." KAP studies are pre-defined questionnaire-based studies that aim to establish the relationship between the three domains: knowledge influences attitudes, attitudes influence practice.[13] Unfortunately, many KAP studies are limited to establish a baseline or a still picture of the knowledge and opinions of a group of individuals (e.g., patients, professionals, students) about a topic, usually concluding that these individuals have a limited knowledge about the topic of interest. These poor KAP studies gather the problems of the previous myth: They represent a small population with no interest outside that population. Researchers are interested in assessing KAP when they expect knowledge is limited, and not between experts in the topic. A KAP study could be interesting for international audiences if researchers can identify the reason why the performance (practice) is low based on negative attitudes supported in specific pieces of knowledge lacking. An alternative to make interesting KAP studies relies on increasing the number and characteristics of interviewees to be able to identify population subgroups with different KAP relations, and thus design tailored educational activities. And this links with the other type of obvious studies with limited interest for international audiences: those evaluating the increased knowledge achieved after a training activity. These studies usually consist of the repetition of knowledge evaluations before and after the educational/training activity and almost always conclude that the activity increased knowledge among participants. Should we expect that any educational activity would not increase knowledge among participants? Since 1990, when Miller published his pyramid, we should not be interested in what people know, but in what people do.[14] Again, we increase the knowledge to influence on attitudes and subsequently in practice, whether we educate patients or professionals.

So, in summary, international audience is interested in learning from others why things happen, and if these things could also happen in their environment/setting, perhaps because they want to imitate the first, or perhaps because they want to avoid others' failures. A study performed in a small hospital of a given country can be relevant for an international audience if it provides something more than a still picture of the scene. A general recommendation before submitting a paper could be thinking what you could learn from a paper like the one you're considering submitting if it would have been written by colleagues from another country.

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Original Research

Patient experience with clinical pharmacist services in Travis County Federally Qualified Health Centers

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Abstract

Background: Positive patient experiences with care have been linked to improved health outcomes. Patient experience surveys can provide feedback about the level of patient-centered care provided by clinical pharmacists and information about how to improve services.

Objectives: Study objectives are: 1) To describe patient experience with clinical pharmacist services in a federally qualified health center (FQHC). 2) To determine if demographic or health-related factors were associated with patient experience.

Methods: This cross-sectional survey included adult patients who were English or Spanish speaking, and completed a clinical pharmacist visit in March or April 2018. Patient experience was evaluated, on a 5-point Likert scale (1 = strongly disagree to 5 = strongly agree), with 10 items using four domains: pharmacist-patient interaction information provision, support for self-care, and involvement in decision making. In addition, one item was used to rate the overall experience. Demographic and health-related variables were also collected. Eligible patients completed the survey after their clinical pharmacist visit. Descriptive and inferential statistics, as well as Cronbach's alpha for scale reliability, were employed.

Results: Respondents (N=99) were 55.4 (SD=12.1) years and 53.1% were women. Overall, patients rated their experiences very high with the 10-item scale score of 4.8 (SD=0.4) out of 5 points and the overall experience rating of 4.9 (SD=0.4) out of 5 points. With the exception of race, there were no differences between patient experience and demographic and health-related variables. African Americans had significantly (p=0.0466) higher patient experience scores compared to Hispanics.

Conclusions: Patients receiving care in a FQHC highly rated their experience with clinical pharmacists. This indicates that clinical pharmacists provided a high level of patient-centered care to a diverse group.

Keywords

Attitude to Health; Patient Satisfaction; Self Care; Pharmacists; Patient-Centered Care; Ethnic Groups; Cross-Sectional Studies; Texas

INTRODUCTION

Although patient satisfaction has been evaluated and studied for some time, it was not linked to quality measures until the 2000s. In 2001, patient-centered care was considered when assessing the quality of the patient's experience with health care services.[1] According to the Agency for Healthcare Research and Quality, "patient experience includes several aspects of health care delivery that patients value highly when they seek and receive care, such as getting timely appointments, easy access to information, and good communication with health care providers".[2] Patient satisfaction and patient experience differ in that satisfaction measures a patient's expectations, whereas experience measures whether or not care processes that were supposed to happen occurred.[2,3] Considering these definitions, this means that patient experience is more objective (i.e., did something happen or not) than patient satisfaction which can be subjective and vary according to patient expectations for a particular service.[2,3] In prior pharmacy literature, most patient satisfaction studies examined elements of patient experience, although this was not differentiated from satisfaction.[4-9] This is not surprising since the terms satisfaction and experience are commonly interchanged.[2,3] For descriptive studies, satisfaction with pharmacist care tends to be high with ratings near the high end of a scale across care settings, including inpatient and community pharmacist services as well as pharmacist services delivered via the telephone.[5,6,10,11] A systematic review of pharmacist services included 41 studies that measured patient satisfaction and found that satisfaction with care was higher when pharmacists were involved compared to when they were not in half of the studies.[4]

Clinical pharmacists in ambulatory care settings specialize in chronic disease management and when collaborative practice agreements are in place, clinical pharmacists' roles typically allow for initiating new prescriptions, changing or discontinuing medications, and providing comprehensive medication reviews. Studies have shown positive clinical outcomes for chronic diseases when ambulatory care pharmacist-led management is involved.[4,6,11] Less has been reported about patient experience with clinical pharmacist services in an ambulatory care setting. However, there have been reports of satisfaction with pharmacist

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management of specific conditions such as hepatitis C virus (HCV) treatment and rheumatoid conditions.[7,9] In a US urban academic medical center hepatology outpatient clinic, 24 participants indicated the highest possible level of overall satisfaction (i.e., great) and similar ratings occurred for questions related to pharmacist education about the HCV infection, medication administration and storage, and medication adherence.[7] In an outpatient rheumatology clinic in Canada, overall scores across six care dimensions were significantly higher with a pharmacist-physician team vs. physician alone (4.6, SD=0.4 vs. 4.3, SD=0.4 on a 5-point scale).[9]

Despite the fact that pharmacists have a track record of being a member of care teams at federally-qualified health centers (FQHCs), little is known about patients' perceptions of clinical pharmacist care in this setting.[12-15] Patients served by a FQHC tend to be complex, often have multiple uncontrolled chronic conditions and are uninsured or underinsured, which means that tailoring care experiences is important for achieving optimal outcomes. At CommUnityCare Health Centers, which are FQHCs in Central Texas, clinical pharmacist appointment-based visits are focused on ensuring medication regimens are individualized to meet the patient's needs. In addition to medication reviews, patients receive medication and adherence counseling, as well as disease state education. Collaborative practice agreements guide medication management for the following conditions: diabetes, hypertension, hyperlipidemia, anticoagulation, heart failure, chronic obstructive asthma, pulmonary disease, primary hypothyroidism, gout, obesity, smoking cessation, depression, osteoporosis, and rheumatoid arthritis. CommUnityCare administrators were interested in assessing patient experience with clinical pharmacists to assess quality of care and identify opportunities to improve clinical pharmacist services as part of ongoing quality improvement monitoring. This study adds to the literature by assessing 4 components of patient experience (pharmacist-patient interactions, information provision, support for self-care, and involvement in decisions) with clinical pharmacist care in an ambulatory care setting in a diverse patient group. The study's objectives were to describe patient experience with clinical pharmacist services in a FQHC setting and to determine if demographic or health-related factors were related to patient experience.

METHODS

Study design and sample

A cross-sectional design was used to address the study objectives. The study sites included ten FQHCs in Travis County, Texas. FQHCs are funded by the United States Health Resources and Services Administration Health Center Program and provide health care for medically underserved areas using a sliding scale fee based on income levels.[16] Patients were included if they were >18 years old, completed a clinical pharmacist appointment in March or April 2018, and were English or Spanish speaking. To avoid confounding of the results, patients were excluded if they were seen during a co-visit, which included both the clinical pharmacist and physician.

Survey instrument

The primary outcome was patient experience and survey questions were developed utilizing previously validated surveys and adapted to align with the clinical pharmacist services provided at CommUnityCare Health Centers.[3,17-19] The Oxford Patient Involvement and Experience Scale was used as a guide for determining relevant patient experience domains, which included pharmacist-patient interactions (3 questions), information provision (5 questions), support for self-care (1 question) and involvement in decisions (1 question).[18] These 10 items were measured using a 5-point Likert scale ranging from 1 = strongly disagree to 5 = strongly agree. Domain mean scores and an overall mean score comprised of all 10 items were calculated. One additional item, measured on a 5-point scale anchored by 1=very poor to 5=excellent, was used to rate the overall patient experience. In addition to patient experience, demographic (age, gender and race) and health-related variables were measured (number of clinical pharmacist visits in last six months, self-reported health status, and type of health conditions). Prior to survey administration, survey items were assessed for content validity by clinical

Table 1. Summary of Demographic and Health-Related Information (N=99[a])

Variables	Mean, SD N (%)[b]
Demographics	
Age in years (n = 92)	55.4, SD=12.1
Gender	
Women	52 (53.1)
Men	46 (46.9)
Total	98 (100.0)
Race/Ethnicity	
Asian	1 (1.0)
Black	13 (13.3)
Hispanic	62 (63.3)
White	22 (22.5)
Total	98 (100.1)
Health-Related Information	
Number of clinical pharmacist visits	
1-2 visits	32 (33.0)
3-5 visits	41 (42.3)
6 or more	24 (24.7)
Total	97 (100.0)
Self-rated health	
1 = Poor	2 (2.1)
2 = Fair	37 (38.1)
3 = Good	33 (34.0)
4 = Very Good	16 (16.5)
5 = Excellent	9 (9.3)
Total	97 (100.0)
Presence of chronic diseases[b]	
Diabetes mellitus	76 (77.6)
Depression	11 (11.2)
Hypertension	56 (57.1)
Hypercholesterolemia	41 (41.8)
Hypothyroidism	7 (7.1)
Other[c]	16 (16.3)

[a]Not all respondents answered each question
[b]May not total to 100.0 due to rounding or if multiple responses were allowed
[c]Other reported health conditions where N≤3: Atrial fibrillation, arthritis, asthma, coronary artery disease, congestive heart failure, cancer, end stage renal disease, Factor 5 Leiden thrombophilia, human immunodeficiency virus, herniated disc, obstructive sleep apnea, venous thromboembolism
SD = standard deviation

Table 2. Means of Patient Experience Scale Items (N=99)

Items	Mean, SD
Pharmacist-patient interactions[a]	
My clinical pharmacist listens to my health concerns.	4.8, SD=0.4
My clinical pharmacist adequately answers my questions.	4.8, SD=0.4
My clinical pharmacist explains things in a way that I am able to understand.	4.8, SD=0.4
Domain Mean	4.8, SD=0.4
Information provision[a]	
Appointments with my clinical pharmacist have increased my understanding of what my medications are used for.	4.7, SD=0.5
My clinical pharmacist is able to help me understand how to take my medications.	4.8, SD=0.5
My clinical pharmacist makes sure my medication list is up-to-date.	4.8, SD=0.4
My clinical pharmacist provides useful information on helping me improve my health condition(s).	4.8, SD=0.4
My clinical pharmacist is able to provide explanations of my health condition(s) in a way that I am able to understand.	4.8, SD=0.5
Domain Mean	4.8, SD=0.4
Support for self-care[a]	
At the end of my appointment my clinical pharmacist reviews what we talked about and tells me what is important.	4.8, SD=0.4
Involvement in decisions[a]	
My clinical pharmacy appointments have positively affected my decision to remain a patient at CommUnityCare.	4.8, SD=0.4
Overall Total Scale	4.8, SD=0.4
Cronbach's Alpha	0.96
Overall rating of clinical pharmacist services[b]	4.9, SD=0.3

[a]1=strongly disagree, 2= disagree, 3 = neutral, 4 = agree, 5=strongly agree
[b]1=very poor, 2= poor, 3 = good, 4 = very good, 5=excellent
SD = standard deviation

pharmacists at each site. Pharmacist researchers with expertise in pharmacist services and survey design also assessed face and content validity of the survey. The survey was translated to Spanish by trained translators, back translated to English and re-reviewed for consistency. See Appendix A for the survey instrument.

Data collection and analysis

Upon completion of the clinical pharmacist visit, eligible patients were asked if they were interested in completing an anonymous patient experience survey. If they agreed, patients were handed a cover letter and survey in their preferred language (Spanish or English). Clinical pharmacists read out loud a script which described the survey purpose (i.e., to get feedback about and improve pharmacist services), directions, and privacy procedures. The patients then completed surveys in a designated area in the clinic, but away from their clinical pharmacist, and surveys were inserted into a sealed box. Data were collected from March to April 2018. Descriptive (means, standard deviations, frequencies, and percentages) and inferential statistics (analysis of variance (ANOVA)) were used to address the study objectives. Cronbach's alpha was utilized to measure scale reliability. The study was approved by the University of Texas at Austin Institutional Review Board.

RESULTS

From the convenience sample, a total of 99 patients completed the surveys. About half of the participants were women (53.1%), and the majority were Hispanic (63.3%). The mean age was 55.4 (SD=12.1) years. One-third of participants had 1 – 2 clinical pharmacist visits in the last 6 months, 42.3% had 3 – 5 clinical pharmacist visits, and 24.7% had 6 or more visits. Thirty-eight percent self-rated their health as fair and 34.0% rated their health as good. Diabetes, hypertension, and hypercholesterolemia were the most common chronic conditions with 77.6%, 57.1%, and 41.8% of participants reporting the presence of these conditions, respectively. Table 1 provides more detail regarding demographic and health-related information.

The overall 10-item scale score was 4.8, SD=0.4 (1 = strongly disagree to 5 = strongly agree) and the 1-item overall rating score was 4.9, SD=0.3 (1 = very poor to 5 = excellent). The 4 domains (pharmacist-patient interactions, information provision, support for self-care, and involvement in decisions) each had a mean score of 4.8, SD=0.4. These results show that patients were highly satisfied with their patient experience related to the clinical pharmacist visit. Reliability for the 10-item scale resulted in a Cronbach's alpha score of 0.96, which is deemed excellent. Table 2 summarizes the mean for each item and provides summary data and Figure 1 shows frequencies of responses for each item. None of the respondents selected "strongly disagree" or "disagree" for any of the items and the majority of responses were either "agree" or "strongly agree".

When examining the relationship between patient experience and demographic and health-related variables, ANOVA showed a significant difference in patient experience (mean, SD) and race/ethnicity (F=3.17, p=0.0466). Duncan's post-hoc test revealed that African Americans (5.0, SD=0.1) had significantly higher patient experience scores compared to Hispanics (4.7, SD=0.4); while there was no difference between whites (4.9, SD=0.3) and Hispanics nor whites and African Americans. No other demographic or health-related factors were significantly different.

DISCUSSION

Patients receiving care in a FQHC highly rated their experience with the clinical pharmacist visit, with high individual domain and overall scores. The lack of significant findings for the relationship between patient experience and most demographic and health-related factors indicates that clinical pharmacists consistently provided a positive care experience, regardless of demographic or health-related characteristics. Although, African Americans had a

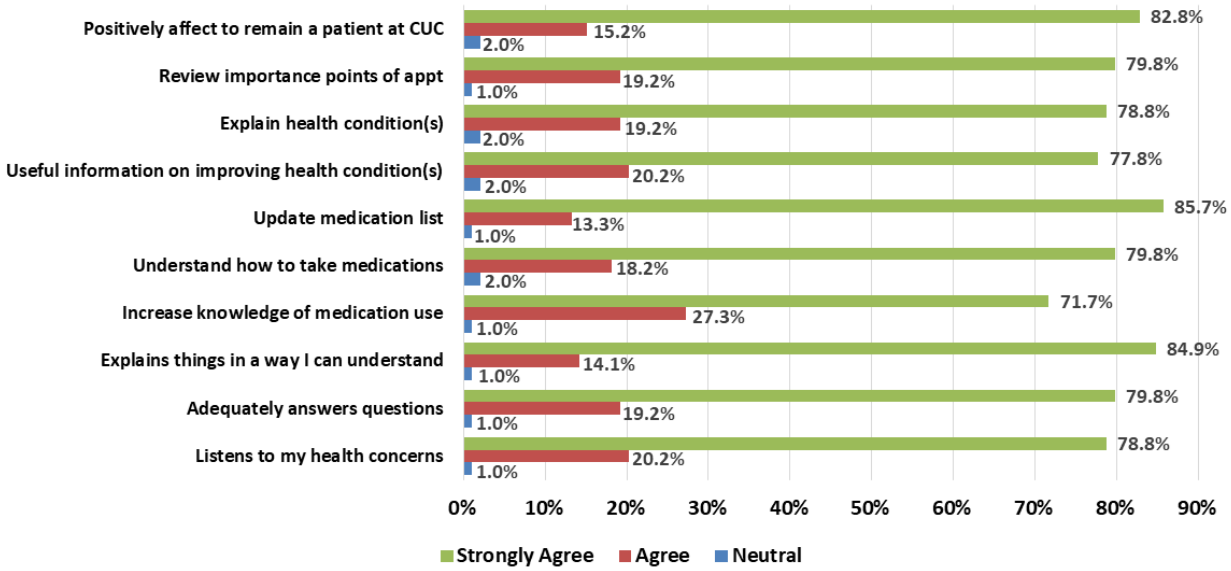

Figure 1. Frequency responses for 10-item patient experience scale (N=99)

significantly higher overall patient experience score when compared to Hispanics (5.0, SD=0.1 vs. 4.7, SD=0.1). The reason for this is not known but it may be due to language or cultural barriers that are not fully addressed in the clinical pharmacist visit. A previous study at CommUnityCare found that Spanish-speaking patients (n=101) reported a relatively high mean score of 3.6, SD=0.5 out of 4 points for their satisfaction with pharmacist communication and 3.6, SD=0.5 out of 4 points for their demonstration of cultural sensitivity.[17] Spanish-speaking clinical pharmacists are available at CommUnityCare, but it is possible that not all patients in the current study had access to one at their visit and had to use an interpreter instead, which may have impacted their experience. The Spanish speaking ability of clinical pharmacists was not collected on this survey, and is therefore unknown.

This study is one of the first to collect information on patient experience with clinical pharmacist services in a FQHC. Additionally, the participants were comprised primarily (63%) of Hispanic patients, which provides unique insight into this group. Patients in other studies in outpatient settings such as HCV, rheumatology, and Medicare annual wellness visit clinics also highly rated elements of patient experience and overall satisfaction with pharmacist services.[7-9] This study focused on patients that can be complex to manage and often require tailoring services to help patients meet treatment goals. The fact experience scores were so high indicates that clinical pharmacists were addressing important aspects of patient-centered care such as clear communication, provision of information for shared-decision making, and support for self-management of medications.[18,20] This is important because patient experience is now being used by health care payers as a quality measure and linked with payment for patient outcomes. While patient experience is commonly measured for physicians in outpatient settings, pharmacists in outpatient settings may not be routinely evaluated. Thus, pharmacists in these settings should be proactive in requesting patient experience surveys at least annually to obtain objective feedback from patients.

At CommUnityCare Health Centers, the standard of care for clinical pharmacist appointments aligns with the domains contributing to patient experience. The pharmacist-patient interaction encompasses listening and answering questions and addressing health concerns adequately for the patient. The information provisions domain primarily relates to the patient's understanding of their medications and disease state. For a condition such as diabetes, clinical pharmacists assess patient knowledge about diabetes and will then provide handouts about diabetes, hypoglycemia, and adherence to medications based upon the level of understanding of the patient. Involvement in decisions and support ensures patients understand the important discussions during the appointment so patients return to follow-up appointments ready to progress forward in the health condition(s). To reinforce key discussion points, appointments are concluded with a patient plan for patients to take home with them. Therefore, it is not a surprise that the results were positive, considering the current clinical pharmacist practice model has been developed to focus on patient experience. The study findings validate that an intentional approach to patient-centered care can result in a quality patient experience. The information provisions domain had a mean rating that was similar to the other domains. However, when examining individual questions, an opportunity to improve patient understanding about what medications are used for was evident given this item had the lowest percentage of "strongly agree" responses (see Figure 1). One strategy to address this is to include the purpose of each medication in the care plan that is given to each patient at the end of the visit.

Limitations

This study had several limitations that require consideration. First, a convenience sample was used, which means that only patients who had visits during the study period were invited to participate. Also, some patients were not able to participate due to transportation issues, inability to read, or having another doctor's appointment

after the clinical pharmacist visit. Finally, no information was collected about patients who chose not to participate, so we do not know if they differed from those who participated. All of these issues likely resulted in selection bias. Also, surveys were completed at ten clinics and multiple clinical pharmacists provided care which had the potential to bias findings based upon clinic characteristics or variations in clinical pharmacist delivered care. However, the impact on survey results was considered to be negligible based upon the upper range of responses (mostly 4s and 5s) for each question. One reason for this may be because CommUnityCare clinical pharmacists use the same care process in each clinic and practice using collaborative practice agreements. Generalizability of study findings may also be limited to other FQHCs or safety-net settings that have an embedded pharmacist model.

CONCLUSIONS

Patients indicated that care from clinical pharmacists in a FQHC resulted in a positive patient experience across four domains. An opportunity to improve patient understanding of what medications are used for exists in the information provisions domain. Patient experience should be regularly assessed, at a minimum annually, to ensure patients are having positive care experiences and to identify opportunities for improvement.

CONFLICT OF INTEREST

None declared.

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None.

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CPPI Practice Forum

Preparing for the next generation pharmacists

Joseph T. DIPIRO.
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Abstract

To address the changes in health care and the needs of society related to medicines, we must redefine the profession of pharmacy. We have defined the next generation pharmacists (NGP) as "a health care provider and change agent on the interprofessional health care team, personalizing medication use, managing safe and effective medication systems, and creating healthier communities." Schools and colleges of pharmacy should thoroughly examine their curriculum to ensure it is preparing pharmacists for this future. By creating a vision for the NGP and implementing the best curriculum, we ensure that pharmacists of the future will be up to the challenge of our society's health care needs.

Keywords

Pharmacists; Education, Pharmacy; Schools, Pharmacy; Curriculum; Pharmaceutical Services; Medication Systems; Patient Care Team; Delivery of Health Care, Integrated; Interdisciplinary Communication; Public Health

This is not the best era for traditionalists in pharmacy. So much of what I learned in pharmacy school no longer is relevant, or it has been supplanted with new technologies and health care approaches. The science of medicine, delivery of health care, extent of corporatization, and health care financing are far different from what we envisioned years ago. Add to that the greater availability of health care data in electronic medical records and information for the health consumer. However, these changes by no means lessen the need for pharmacists. In fact, given all the problems that people have with medicines, there is greater need than ever for pharmacists' skills and knowledge.[1,2] No one can say that problems related to preventable adverse drug events, medication errors, drug misuse and addiction, poor adherence, high medication expense, and counterfeit or adulterated medications have gone away. To address these problems and the reality of what has changed in health care will require that we redefine our profession.

At the Virginia Commonwealth University School of Pharmacy, our faculty have set about the task of defining the next generation pharmacists (NGP) and determining the curriculum that will be needed to produce such individuals. The big goal is to ensure that pharmacists of the future are well-prepared to address the needs and problems related to medicines using the latest in medical science and technology tailored to individual patients.

Our definition of NGP was created by faculty members with input from our external national advisory committee (consisting mostly of pharmacists from various health care sectors and industry) and alumni. The NGP is defined as "a health care provider and change agent on the interprofessional health care team, personalizing medication use, managing safe and effective medication systems, and creating healthier communities." We use "pharmacists" in the plural to indicate that there is more than one type of pharmacist. Pharmacists' careers span a wide range.[3] While graduates tend to focus on a few job sectors, individual careers often progress into many different pharmacist roles over time.

As a health care provider, it is necessary to be a change agent. The NGP change agent is a trusted leader with clear vision and goals who is a critical thinker and an excellent communicator. As a change agent the pharmacist must be able to recognize medication-related problems and also identify opportunities to solve them. A change agent knows how to effectively work with people to marshal collective wisdom and achieve common goals. This has been called "leading change" and refers to a book of the same name that provides a useful framework for achieving organizational change.[4] The 8-step Kotter approach to change begins with the need to develop a sense of urgency. People are usually reluctant to make a change if they do not understand the reason why it is necessary. In our school, we have spent multiple training sessions on leading change and understanding the change process for the purpose of revising our curriculum.

The NGP will think of their role and perform as part of a team as opposed to as independent practitioners. An interprofessional health care team includes all appropriate health professions and involves patients in their own care decisions. The NGP will value and respect the roles of other health professionals and use team-based care, laws and regulations, and financial systems to promote improvements in health care through patient-centered collaborative care. In addition to asking "How can I contribute to health care as a pharmacist?", the NGP will ask "How can I enhance the effectiveness of other health care professionals and the health care system by being a team-oriented pharmacist?" While there will be many pharmacists who practice in acute-care settings, the greatest need and opportunity is to expand pharmacist-led care to patients with chronic diseases. Pharmacists are well trained to provide chronic disease management, and there is a great need for care of patients with diabetes, hypertension, asthma, dyslipidemia and other common chronic conditions.[5]

The NGP will promote personalized medication use. This requires integration of core pharmacy knowledge, the

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latest in biomedical research and technology (such as telehealth), cultural competence and patient characteristics with clear health goals to create individualized patient medication plans. There are practices that pharmacists have been doing for many years, such as individualized drug dosing, tailoring of patient education, and medication adherence plans, that are ways to personalize medication use. The future will require the best available information (such as genomic data), cultural factors and social determinants of health to personalize medication use.

Pharmacists have always managed medication systems, but the way this is done is changing and will be much different in the future. The NGP will transition their role from the "hands on" person within the medication systems to more often supervising the technical personnel who will have primary roles in preparing, dispensing and delivering medications. We do not envision that the pharmacists of the future will or should relinquish overall responsibility for medication systems but will spend more time on high-level tasks within the medication systems to match their training and expertise. Also, the NGP will need to be able to use automation and manage the human-technology interface. As pharmacies have become data-intensive organizations, the NGP will need to be competent in use of clinical data, electronic data and data systems. This is applied as informatics and analytics to assure safe and effective medication use and to, ultimately, improve health.[6]

Beyond the immediate physical pharmacy or health system, the NGP will recognize a greater responsibility to assure healthier communities. The NGP will recognize social, scientific, and economic challenges and demonstrate dedication to service to the community at large and to all segments of it related to age, ethnicity, economic status, geographic location, gender and sexual orientation. The nature of community pharmacies is changing as they have become recognized as centers for health and wellness rather than as "stores." Providing care in a nontraditional setting (a barbershop) is another approach that was culturally relevant and can be successful in improving health outcomes.[7] The NGP will promote healthy lifestyles and wellness. This is a change already in the making where pharmacists provide immunization, smoking cessation services, diabetes prevention and weight reduction programs. As the most accessible health care professional, pharmacists can have significant influence over health and lifestyle behaviors. In some states, pharmacists can now test and treat common conditions such as streptococcal infection and influenza.[9,10] Recent state and federal regulations have also allowed pharmacists to provide testing for COVID-19.[11]

To achieve this vision of the NGP requires that schools and colleges of pharmacy thoroughly examine their curriculum to ensure that sufficient attention is paid to preparing pharmacists for this future. It is equally important to determine what can be removed from our curricula as it is to determine what should be added. It is more than the content alone. What method of instruction should be used to develop the proper skills and thinking of our graduates? Our current experience with remote teaching as a response to COVID-19 will inform us about improved methods to teach, combining remote with on-site approaches. How can practice experiences be reorganized to accomplish this? And how can practice experience in the pharmacy education be better coordinated with post-graduate training to maximize the learning and training experiences?

Pharmacists have had a valued role in the health care of their communities for many past generations. By creating a vision for the NGP and implementing the best curriculum to prepare student pharmacists, we ensure that pharmacists of the future will be up to the challenge of our society's health care needs. If some of the above description sounds familiar, it is because some pharmacists are already practicing as NGP. But this level of practice is not common enough; what we need is for all pharmacists to be NGP.

CONFLICT OF INTEREST

None.

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Kaday R, Ratanajamit C. Inpatient self-administered medication under the supervision of a multidisciplinary team: a randomized, controlled, blinded parallel trial. Pharmacy Practice 2020 Jan-Mar;18(2):1766.
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Original Research

Inpatient self-administered medication under the supervision of a multidisciplinary team: a randomized, controlled, blinded parallel trial

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Abstract

Background: Self-administered medication (SAM) is encouraged in many hospitals worldwide as it increases patients' knowledge and understanding of their medication, but the effects on other outcomes, e.g. compliance or medication errors, were unclear.

Objectives: To compare medication knowledge, adherence, medication errors, and hospital readmission among inpatients receiving SAM education under the supervision of a multidisciplinary team (study group) with those receiving routine nurse-administered medication (control group).

Methods: This study was a PROBE design. Inpatients with chronic diseases were randomly allocated (1:1) to either the study group or the control group using stratified-block randomization. Knowledge of medications was measured at hospital discharge and at the first two follow-up visits; adherence was measured at the first two follow-up visits, medication errors while in hospital, and hospital readmission within 60 days after discharge. For normally distributed continuous outcomes, mean difference and 95%CI were estimated; otherwise the median and the Mann-Whitney test p-value were reported. The percentage difference and 95%CI were reported for binary outcomes.

Results: 70 patients were randomized (35 in each group); all received complete follow-up. Both groups were similar at baseline. Mean (SD) age (years) were 59.2 (11.0) for the study group and 58.3 (12.0) for the control group. Percentages of females in the respective groups were 54.3 and 60.0. Mean time from discharge to the first follow-up visit was two weeks in both groups and time to the second follow-up visit were 68.8 days (study group) and 55.0 days (control group). The study group had significantly higher medication knowledge than the control group at hospital discharge (of the 10-point scale, medians, 8.56 and 6.18, respectively, p<0.001). The corresponding figures were similar in both groups at the first follow-up visit (medians, 8.25 and 6.26, respectively, p<0.001). Adherence to medication at the first visit in the study group (percentage mean 92.50% (SD=5.33%)) was significantly higher than that in the control group (79.60% (SD=5.96%)), percentage mean difference 12.90%, [95%CI 10.20%:15.60%], p<0.001. Medication knowledge and adherence were sustained at the second follow-up visit. During hospitalization, no medication errors were found in the study group, and minimal errors occurred in the control group (1.48%, [95%CI 0.68%:2.28%] of doses administered, p=0.001). Hospital readmission within 60 days after discharge was significantly lower in the study group (11.4%) than that in the control group (31.4%), percentage difference 20.0% (95%CI 1.4%:38.6%), 1-side Fisher exact p=0.039.

Conclusions: Among in-patients with chronic diseases, SAM program significantly increased knowledge of and adherence to prescribed medications. Medication errors regarding administration errors were infrequent but significantly higher in the control group. SAM reduced hospital readmission within 60 after discharge.

Keywords

Self Administration; Medication Errors; Medication Adherence; Patient Discharge; Patient Readmission; Patient Care Team; Hospitalization; Randomized Controlled Trials as Topic; Thailand

INTRODUCTION

In hospital setting in Thailand, patients play a limited role in administration of their own medications while in the hospital as medication administration is mainly responsible by nurses.[1] Pharmacists' roles for in-patient service are restricted to medication review, drug use evaluation, monitoring, and discharge counseling. In comparison with nurse-administered medication, self-administered medication (SAM) reduces omitted dosing and medication errors in hospitals and increases patient medication knowledge, adherence, and satisfaction; therefore, it has been encouraged in many hospitals worldwide.[2-5] Patient's self-administration could save 70 minutes/day for nurses to spend their time in informing patients on their medication.[6] Despite evidence on benefits, SAM implementation among in-patient service has still been limited, including in Thailand.[4,7-9] It was, therefore, not surprising that patients were lacking knowledge on medication side effects and on how to take medication after hospital discharge which could lead to non-adherence, drug related problems, or readmission.[3,10-12] A study conducted phone interview within 48 hours after discharge from a medical ward reported that only 43% of patients could specify the name of all medications received and 36% could specify the indications of the prescribed medications.[13] SAM program may involve pharmacists, nurses, or both to educate medication administration to the patient on a case-by-case basis.[4,14,15] SAM education conducted by clinical nurses often only provides simple drug-related information, but simplifying the drug regimen, an important component of the program's success, is more likely to occur if a pharmacist has participated in the multidisciplinary medication education program.[14,16] The national statistical office of Thailand recently reported that Thailand would become a complete aged society in the year 2021, and a super aged society in the year 2031.[17] In an aging society,

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patients are more likely to have chronic health problems, thus requiring more long-term medication than ever.[18] Effective medication management may reduce unnecessary treatment episodes and hospital readmissions.[12] A large systematic review evaluating the effects of SAM confirmed that patients participated SAM program increased medication knowledge, but the effects on side effects, compliance or medication errors, were inconclusive.[19] This might be a result of limited number of high quality studies and substantial methodological and clinical diversities across studies. This study, therefore, aimed to evaluate the efficacy of SAM education, mainly performed by a pharmacist, compared with routine nurse-administered medication among limited literacy patients with chronic diseases using a PROBE design. The primary objective was to compare patient knowledge about medication between the study group and the control group at hospital discharge. The secondary objectives were to compare (1) patient knowledge about prescribed medications measured at the first two follow-up visits, (2) adherence to prescribed medications measured at the first two follow-up visits, (3) medication error (administration error) while in hospital, and (4) hospital readmission within 60 days after discharge between the study group and the control group. The time nurses and pharmacists required for medication management was compared between groups.

METHODS

This was a controlled, parallel trial using PROBE (prospective randomized, open-label, blinded endpoint evaluation) design. The study protocol was approved by the Ethics Committee, Faculty of Pharmaceutical Sciences, Prince of Songkla University (reference no. 0521.1.07/1523, approval date was August 27, 2018). The study protocol had not been registered in clinical trial registries.

Participants

This study was conducted in a 60-bed community hospital located in southern Thailand near the Malaysian border, where 96.7% of population were Muslims and most of them used the local Malay language. Most of them were limited literacy in Thai and English. Patients admitted to male or female medical wards between October 2018 and March 2019 were the accessible population. The adult patients (aged 18 to 75 years old) diagnosed with at least one chronic disease (acute coronary syndrome, stroke, atrial fibrillation, heart failure, hypertension, diabetes mellitus, dyslipidemia, gout, chronic kidney disease, asthma, chronic obstructive pulmonary disease, thyroid dysfunction, thalassemia, HIV, or tuberculosis) were eligible for enrollment in the study. Patients were excluded if they met any of the following: Glasgow coma scale score less than 15 points, history or evidence of suicide, drug/alcohol abuse or uncontrolled psychiatric disorders.

Prior to participation to any study procedure, each patient was given a participant information sheet (PIS) which provided detailed information about the study. Written informed consent was obtained if the patient was willing to participate in the study after they thoroughly understood the information in the PIS, or the information was clearly explained as required by the research pharmacist.

Interventions

Study (SAM) group: Patients in the study group received in-patient SAM education. On the first day of hospital admission, the research pharmacist provided medication information (i.e. medication name, purpose, dose, frequency, dosing time related to meal, and side effects) to each patient on a one-to-one basis. The teaching materials as well as the medication labels were available in both text and symbols/images, instead of using only text, to increase patient understanding. Symbols/images included were: a circle (whole tablet), a semi-circle (half-tablet), one fourth-circle (one quarter-tablet), a star-shape (at bedtime), and a water glass (before meals). After the consultations, patients administered the prescribed medications on their own while in the hospital under the supervision of a multidisciplinary team consisting of medical, pharmacy and nursing staff. An alarm prior to each dosing notified a registered nurse to reach the patient's bed within 10 minutes. The patient was allowed to call the nurse if she did not arrive within 10 minutes after the alarm. Prior to each dosing, a registered nurse checked whether the patient picked up the medications correctly as prescribed. The role of nurses was to ensure that patients could administer medications safely. If the patient picked up the dose or the medications incorrectly, the attending nurse notified the patient to replace the incorrect dose or medications with the correct ones before dosing. The nurse subsequently consulted the research pharmacist to intervene with that patient thereafter. It was possible that some patients required consultation regarding the drug regimens with the research pharmacist more than once. Self-administered medications were limited to oral medications only. All oral dosing medications were placed in a box with a lid at a bedside locker. IV medications, PRN or opioid medications were stored in the medication cabinet in the ward and were administered by the nurses if required. The number of dosages per dispense was 4 days. If there were any changes of the regimens the patient was firstly notified by the medical doctor and subsequently educated by the research pharmacist prior to self-administration of the relevant medications. The pharmacy immediately managed the pill box according to the doctor’s order. At each dosing time, the nurse checked the remaining tablets to monitor patient adherence. Patient self-administration medication as well as dosing time was recorded in the medication administration record (MAR) immediately after each dosing by an attending nurse. This information was subsequently verified for identification of medication administration errors by the research pharmacist.

Control group: Pharmacists dispensed unit dose medications that were stored at the medication carts in the ward. Dispensing from the pharmacy department was done once a day. At the time of dosing, the nurse arrived at the patient's bed with the MAR and delivered a unit dose of prescribed medications to each patient in the control group, as routine practice. The nurse provided both written (texts only) and verbal essential medication information needed for dosing to each patient (dose, purpose, time related to meal, and side effects). The research pharmacist, was accessible to patients in the control group, but extra medication information, other than that provided by

nurses, was not provided to the patients. Medication administration was recorded in the same manner as described above.

Outcomes

Primary outcome was knowledge of the prescribed medications measured at hospital discharge. Secondary outcomes were (1) prescribed home medication knowledge measured at the first two follow-up visits; (2) patient medication adherence measured at the first two follow up visits; (3) medication errors (administration errors) while in hospital, and (4) hospital readmission over 60 days after discharge. Effects of SAM on nurse and pharmacist workload regarding medication dispensing, checking, and administering/supervising were measured as time required for performing these activities.

Assessment of medication knowledge: At discharge, patients in both groups were given the same medication packages i.e., blisters of individual medications put in separate zip-locked bags labelled with texts and symbols/images, which were the same as those dispensed for the in-patients in the study group. The labels of discharged medications were different from those the patients received prior to admission that contained only texts. Patients in both groups were allowed to use medication information labelled on the packages while answering the questions about their medications. Medication regimen data were retrieved from the computerized hospital database, printed out and reviewed by outcome assessors. Medication-related knowledge was assessed by asking each patient about their medication name, indication, dose, dosing frequency, dosing time related to meal, and side effects. Each question was given a weighted score based on its safety-related importance; medication name and side effects was given 1 point each, and the others (indication, dose, dosing frequency, and dosing time related to meals) were given 2 points each. The possible maximum score was 10. For 2-point questions, the patient received 2 points for the correct and complete answer, 1 point for partially correct answer and zero points for wrong answer. The 1-point question was rated in the same manner, i.e. 1 point for the correct and complete answer. In patients receiving more than one medication, the average score was used for analysis. Assessment of medication knowledge at each of the first two follow-up visits after discharge was done in the same manner.

Assessment of patient medication adherence: Patient adherence to medication was assessed using the pill count method. The percentage of the number of tablets/capsules consumed from the total amount prescribed was calculated for each patient. Medication adherence was assessed at the first and at the second follow-up visits after hospital discharge.

Assessment of medication errors: The study measured only administration errors, which might be classified as any of the following: omission dose, wrong drug, unordered drug, wrong patient, wrong-dose or wrong-strength, wrong-route, wrong-time, extra-dose, or wrong dosage-form. Wrong-time error was defined as a deviation of administration time more than 30 minutes from the scheduled time. The clinical risk of the event was rated into 9 levels (Level A to Level I) according to National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index.[20]

Hospital readmission after discharge: To measure the effect of SAM intervention on therapeutic outcome, hospital readmission was collected over 60 days after discharge. The length of time selected was related to the time the patients completed the second follow-up visit. The dates and causes of hospital readmission were recorded.

Staff workload and time spent on medication management: Data about staff (nurses and pharmacists) workload and time spent on medication management, based on 15 beds per day in each group, were measured. Nurse workload was measured as the time required for medication checking (for all patients in each of the two groups), administering (the control group), and supervising (the study group). Pharmacist time included the time spent on medication dispensing (for all patients in each of the two groups), and inpatient SAM educating (the study group).

Randomization

Patients were randomly allocated to either the study (SAM) group or the control group using stratified block randomization. Randomization was stratified by educational level (not higher than primary school or secondary school or higher) and age groups (<40 years, 40-60 years, or >60 years). These two stratifying variables were considered potential confounders for the outcomes measured and thus required to be balanced at baseline. The blocks of size 4 and 6 were used for generating the random allocation sequence for each of 6 strata, (allocation ratio 1:1), the sequences were put in sequentially numbered opaque containers until interventions were assigned. Random allocation sequence was generated manually by the co-investigator. Participant enrollment and assignment to intervention were performed by principal investigator. The randomized sequence was securely stored in the locker located in the in-patient pharmacy room and maintained by the third party. Allocation of the patients could not be influenced by the investigator, and selection bias was unlikely to occur.

Sample size

The variance of the estimate (mean difference) was not identified from previous studies. The difference of 1.5 points out of 10 in medication knowledge, and 12% in medication adherence were considered clinically significant. The sample size calculation assumed the effect size (group mean difference/standard deviation) of 0.75, with a power of 80%, and type I error at 5% (two-sided test). The study assumed a dropout rate of 20%; therefore, seventy (35 per group) patients were required for the study.

Blinding

The study was designed as a single blinded trial, i.e. only outcome assessors were blinded to the treatment status. There were 2 independent outcome assessors, one working in the in-patient pharmacy service and the other working in the out-patient pharmacy service. These two assessors were not involved in the intervention process. They were well trained on how to assess the outcomes and how to use

the research tools. Blinding to patients' treatment status was successful as computerized hospital prescription database did not indicate the way the medications were supplied to each patient, either the 4-day dispensing or the daily unit-dose dispensing. Outcome assessors did not involve in the dispensing process done for the patients participated in the present study. In addition, identification of the treatment groups could not be identified by discharge medications as they were packed and labeled in the same manner.

Research tools

The case record form and outcome assessment manual were approved by the Ethics committee. It recorded patient identification numbers, socio-demographic data (i.e., sex, age, education level), inclusion and exclusion criteria checklist, main diagnosis, main cause of admission, underlying diseases, number of medication items before admission, number of home medication items, visual capability, hearing capability, language, caregivers, and length of hospital stay. The number of times each patient in the study group was given counseling by the research pharmacist was also recorded. Outcome data for each patient were recorded as specified in the outcomes section.

Statistical analysis

Descriptive statistics were used to summarize patient baseline characteristics. All analyses were based on intention-to-treat population. For comparison of the study outcomes, an unpaired t-test was used if the data were normal; otherwise Mann-Whitney U-test was used instead. Group mean difference and 95%CI were estimated where appropriate. Adjusted analysis was performed, if required, to examine the effects of the differences in baseline variables. Kaplan-Meier failure estimate was performed posteriori to examine the probability of hospital readmission over 60 days after hospital discharge. P-values <0.05 were considered statistically significant. All analyses were performed using Stata SE (Version 15.0), StataCorp LP, USA).

RESULTS

Eighty in-patients admitted to male or female medical wards were screened between October 2018 and March 2019. Seventy patients were eligible and randomized, 35 patients in each group; all received complete follow-up (Figure 1). Ten patients were excluded due to a Glasgow coma score less than 15 (n=6) and uncontrolled psychosis (n=4). The time from hospital discharge to the first follow-up visits was approximately 2 weeks. Average time from hospital discharge to the second follow-up visit was slightly longer in the study group (68.8 days) than in the control group (55.0 days).

Patients in both groups were balanced at baseline (Table 1). Mean (SD) age (years) were 59.2 (11.0) for the study group and 58.3 (12.0) for the control group. Percentages of females were 54.3 and 60.0 in the study group and the control group, respectively. The major causes of hospital admission were hyperglycemia, acute exacerbation of COPD, and hypertensive urgency. Most of them had comorbidities; approximately a half of participants in both groups had at least two comorbidities. Two-thirds of both groups were educated not higher than primary school. However, they had fair medication knowledge at baseline, group means 6.4 and 6.6 (of maximum possible score 10) for the study group and the control group, respectively. The numbers of medication items before admission in both groups were similar, with the average being approximately 5 items. Most had good visual and hearing capabilities. The majority were Muslim. All, except one in the study group, speak Malay, and approximately half speak Thai. A higher percentage of self-care was noted in the study group, the difference was only borderline. The average length of

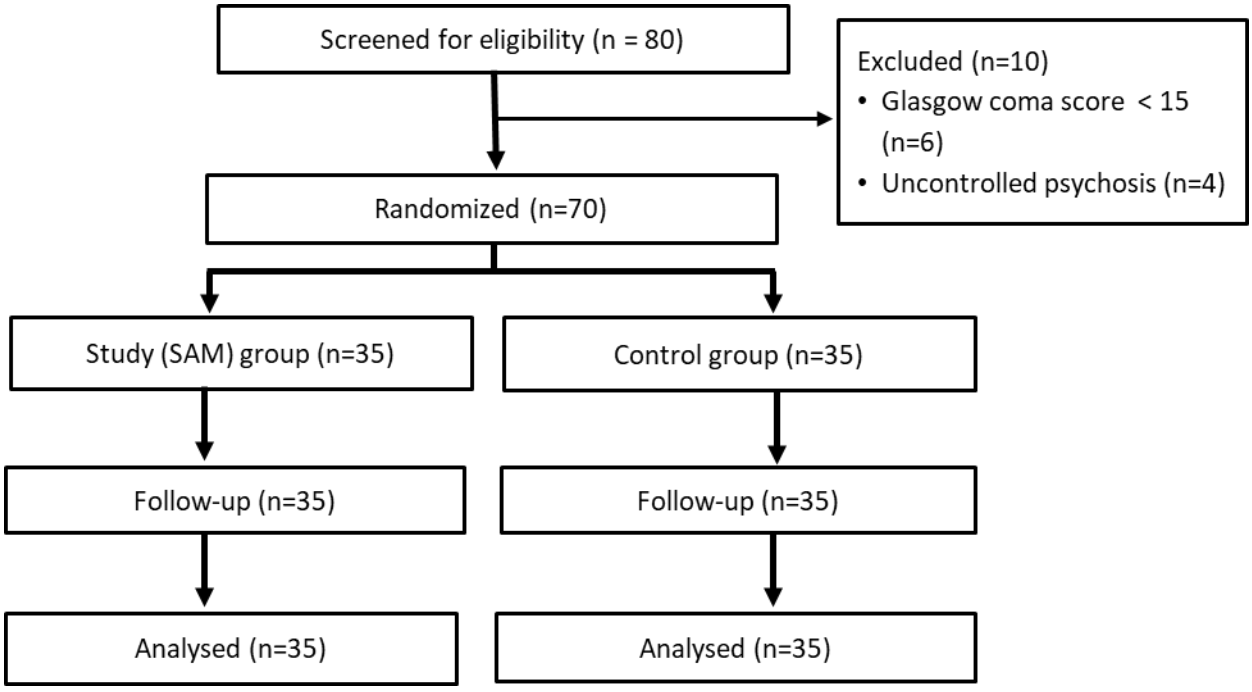

Figure 1. Flow chart of study participants

Table 1. Baseline characteristics of study sample

Variable	Statistic	
	Study group (n=35)	Control group (n=35)
Sex, n (%)		
Female	19 (54.3)	21 (60.0)
Age, mean (SD), years	59.2 (11.0)	58.3 (12.0)
Cause of admission, n (%)		
Hyperglycemia	8 (22.9)	7 (20.0)
Acute exacerbation of COPD	7 (20.0)	5 (14.3)
Hypertensive urgency	7 (20.0)	8 (22.9)
Congestive heart failure	5 (14.3)	4 (11.4)
Chronic kidney disease	3 (8.6)	5 (14.3)
Others	5 (14.3)	6 (17.1)
Number of comorbidities, n (%)		
0	1 (2.9)	4 (11.4)
1	13 (37.1)	12 (34.3)
2	19 (54.3)	17 (48.6)
3	2 (5.7)	2 (5.7)
Education level, n (%)		
Primary School or lower	21 (60.0)	21 (60.0)
Secondary School or higher	14 (40.0)	14 (40.0)
Number of Drug items before admission, mean (SD), [median, range]	4.9 (2.0), [5, 2-11]	4.66 (2.2), [4, 1-10]
Visual capability, n (%)		
Normal	27 (77.1)	29 (82.9)
Myopia or Presbyopia	8 (22.9)	6 (17.1)
Hearing capability, n (%)		
Normal	33 (94.3)	34 (97.1)
Poor	2 (5.7)	1 (2.9)
Language, n (%)		
Thai	1 (2.9)	0 (0)
Malay	19 (54.3)	13 (37.1)
Thai and Malay	15 (42.9)	22 (62.9)
Caregiver, n (%)		
Self-care	32 (91.4)	26 (74.3)
Spouse	1 (2.9)	3 (8.6)
Daughters or sons	2 (5.7)	6 (17.1)
Medication knowledge before admission, mean (SD)	6.4 (1.2)	6.6 (0.7)
Length of hospital stay (days), mean (SD), [median, range]	3.0 (2.5), [2, 1-14]	3.2 (2.4), [2, 1-10]

Abbreviations: SD=Standard Deviation

hospital stay were 3.0 (SD=2.5) and 3.2 (SD=2.4) days in the study group and the control group, respectively. The average number of times drug administration counseling was provided to the patients in the study group was 1.4 times (median 1, range 1-3). The number of doses administered by patients in the study group while in the hospital had a mean of 8.3 (SD=7.3) doses, a median of 6, and a range of 1-42. The number of doses administered by nurses in the control group while in hospital had a mean of 9.9 (SD=8.5) doses, a median of 6, and a range of 1-36.

Patient medication knowledge at hospital discharge in the study group was significantly higher than that in the other (median 8.56 vs 6.18, respectively, p<0.001) (Table 2). The study group achieved a higher score in every aspect measured, except medication name (mean 0.05 (SD=0.15) point for the study group and zero points for the control group) which might be due to the medication labels usually being presented in English while nearly all of the patients were unable to read English. All patients in the SAM group reached the maximum score (2 points) regarding knowledge about medication dose and dosing frequency at hospital discharge (Table 2). Likewise, knowledge on medication indication and time of dosing related to meals reached the maximum score in most patients. SAM slightly increased knowledge on medication side effects (mean 0.47 out of 1 score). The patients had knowledge about common side effects, but they did not know all the side effects that were measured for their medications. Knowledge of medication among patients in the control group (mean 6.40 (SD=0.78)) was similar with that measured at baseline (mean 6.56 (SD=0.67)). It was noted that patients in the control group had quite good knowledge on medication dose, dosing frequency, and time of dosing related to meals (Table 2). Discharged medications were very similar to those patients had received before admission in both groups. Although patients in both groups were allowed to use medication information labelled on the discharged medication packages, those in the control group were not familiar with symbols/images added as they had never seen and could not use the information properly.

Patient medication knowledge measured at the first follow-up visit after hospital discharge remained significantly higher in the study group than that in the control group (medians 8.40 and 6.53, respectively, p<0.001), and sustained at the second follow-up visit (Table 2). The knowledge about medication remained the same in both groups compared with that measured at hospital discharge. The knowledge on medication name was still low in both groups and unchanged compared with those measured at hospital discharge. No intervention other than routine counseling practice was provided at each visit. Medication knowledge was not systematically assessed to identify the areas of knowledge that the patients should be improved

Table 2. Patient medication knowledge, adherence, and medication errors

Mean (SD) [Median (range)]*	Study group (n = 35)	Control group (n = 35)	mean difference (95% CI)*	p-value
Primary outcome				
Medication knowledge at hospital discharge	8.59 (0.38) [8.56 (8.00-9.48)]	6.40 (0.78) 6.18 (5.00-8.00)		< 0.001[a]
Name	0.05 (0.15)	0.00 (0.00)		
Indication	1.96 (0.13)	0.94 (0.57)		
Dose	2.00 (0.00)	1.88 (0.26)		
Frequency	2.00 (0.00)	1.70 (0.38)		
Time related to meals	1.97 (0.12)	1.70 (0.33)		
Side effect	0.47 (0.32)	0.04 (0.13)		
Secondary outcomes				
Medication knowledge at the first follow-up visit	8.46 (0.42) [8.40 (7.66-9.45)]	6.52 (0.72) [6.53 (5.00-8.00)]		< 0.001[a]
Name	0.04 (0.11)	0.00 (0.00)		
Indication	1.96 (0.13)	0.96 (0.60)		
Dose	2.00 (0.00)	1.90 (0.20)		
Frequency	2.00 (0.00)	1.75 (0.36)		
Time related to meals	1.98 (0.08)	1.70 (0.42)		
Side effect	0.34 (0.35)	0.02 (0.07)		
Medication knowledge at the second follow-up visit	8.28 (0.46) [8.25 (7.20-9.16)]	6.30 (0.77) [6.26 (4.50-7.89)]		
Name	0.00 (0.00)	0.00 (0.00)		
Indication	1.93 (0.17)	0.76 (0.59)		
Dose	2.00 (0.00)	1.90 (0.20)		
Frequency	2.00 (0.00)	1.75 (0.40)		
Time related to meals	1.99 (0.06)	1.71 (0.29)		
Side effect	0.20 (0.36)	0.01 (0.08)		
Adherence to medications at the first follow-up visit	92.50% (5.33%)	79.60% (5.96%)	12.90% (10.20%:15.60%)	< 0.001[b]
Adherence to medications at the second follow-up visit	91.19% (6.24%)	79.14% (7.97%)	12.05% (8.64%:15.46%)	< 0.001[b]
Medication (administration) errors while in hospital, n/N[c] (%, 95%CI)	0/701 (0.00%, 0.00%:0.52%)[d]	13/877 (1.48%, 0.79%:2.52%)	1.48% (0.68%:2.28%)[e]	0.001[b]
Hospital readmission within 60 days after discharge, n/N (%, 95%CI)	4/35 (11.4%, 3.2%:26.7%)	11/35 (31.4%, 16.9%:49.3%)	20.0% (1.4%:38.6%)	0.039[f]
Nursing time on medication checking, min[g]	15.5 (1.9) [14.9 (13.8-18.3)]	40.5 (2.8) [40.5 (37.2-43.8)]	-25.0 (-29.1:-20.9)	< 0.001[b]
Nursing time on medication supervising, min[g]	124.0 (4.8) [125.3 (117.4-128.0)]	205.1 (5.6) [204.6 (199.0-212.4)]	-81.1 (-90.2:-72.0)	< 0.001[b]
Pharmacist time on medication supply, min[g]	92.6 (4.3) [93.0 (87.5-96.7)]	181.0 (4.0) 180.9 (176.5-185.6)]	-88.4 (-95.7:-81.1)	< 0.001[b]
Pharmacist time on SAM education, min[g]	33.2 (4.8) [33.2 (27.7-38.5)]	-	-	-

[*] Otherwise specified; [a] Mann-Whitney U test; [b] Unpaired *t*-test; [c] Number of administration errors/number of total administered doses; [d] One-sided 97.5%; [e] Percentage mean difference (95% CI); [f] 1-sided Fisher exact test; [g] Based on 15 beds in each group

during the routine counseling process. In-patient SAM intervention provided additional medication knowledge that could not be obtained from the routine practice.

Patient adherence at the first follow-up visit after discharge was higher in the study group than that in the control group. Percentage means were 92.50 (study group) and 79.60 (control group), percentage mean difference 12.90, [95%CI 10.20:15.60], p<0.001 (Table 2). Similarly, the corresponding figures at the second follow-up visit were 91.19, 79.14, and 12.05 [95%CI 8.64:15.46], p<0.001. Medication adherence was expected to maintain over time in the SAM group. Medication adherence in the control group that was relatively high at the first follow-up visit, no change was observed at the second follow-up visit. As a higher percentage of self-care was noted in the study group, an adjusted analysis was done to examine the effect of the difference in percentages of self-care between groups on medication adherence. However, imbalanced distribution of self-care in the two groups did not significantly confound the results.

Only administration errors were measured in this study. The estimate was the mean percentage of the doses administered where administration errors occurred while in the hospital. Very few administration errors were identified (Table 2). No administration errors were found in the study group, while 13 events were reported in 4 patients in the control group. All administration errors were “wrong time” medication administration initiated by nurses. For determining “wrong time” administration errors, the study allowed half an hour time deviation from that specified in the doctor’s order sheet. Having the patients initiated their medication management and the nurses’ role was as supervisory to correct any potential errors that were about to be made and therefore preventable. In the present study, patients in the study group were allowed to alert nurses in case nurses were engaged with an urgent task and did not arrived at the patients within 10 minutes of the

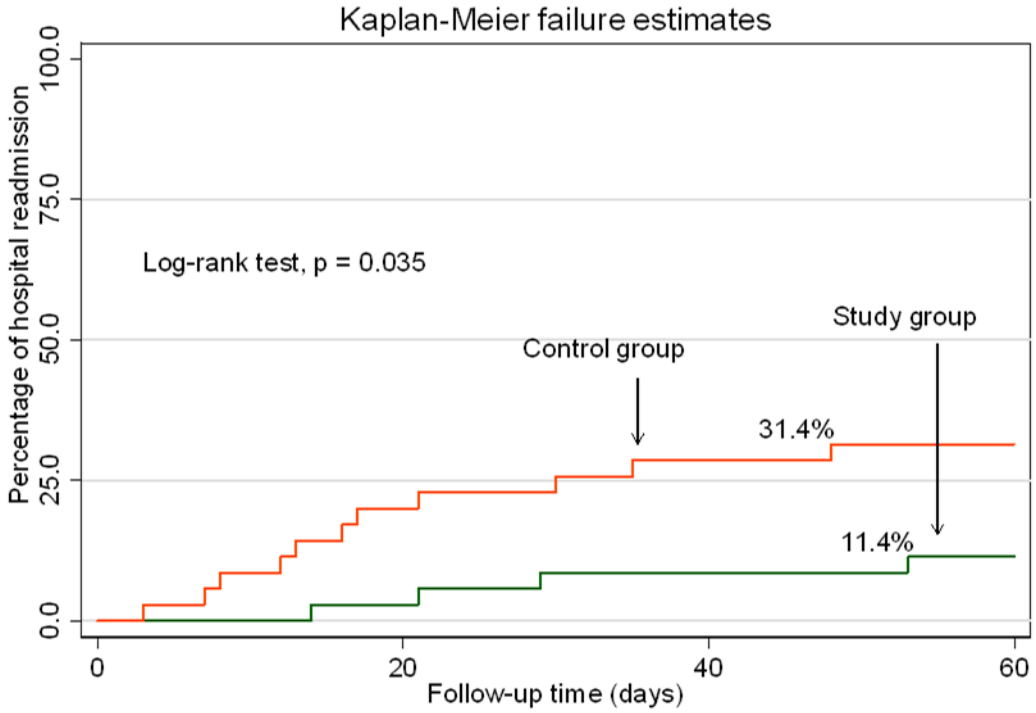

Figure 2. Probability of hospital readmission over 60 days after hospital discharge

scheduled time for dosing, wrong-time medication administration errors were therefore preventable. While all wrong-time administration errors found in the control group were originated by the nurses as they were being interrupted by unexpected and urgent tasks at the time of dosing. Eight events were classified as level C regarding NCC MERP index, but none caused harm to patients.[20] The remaining 5 events were level D medication errors (skipping the doses) which caused minor harm and required safety monitoring for patients.

Hospital readmission after discharge Impact of the intervention on therapeutic outcome, a percentage of readmission within 60-days after hospital discharge was performed. A significantly lower readmission among patients in the study group compared with that in the control group 11.4% (4/35) versus 31.4% (11/35), p=0.039, one-side Fisher's exact test) was observed (Table 2). The cause of hospital readmission was the same as that leading to previous admission in each and every patient. Kaplan-Meier curves showed that patients in the control group were readmitted earlier (the first case on day 3 after discharge) than patients in the SAM group (the first case on day 14 after discharge) (Figure 2). Within 20 days after discharge, 7 (20.0%) of patients in the control group and 1 (2.9%) of the SAM group were re-hospitalized. The results confirmed a positive effect of SAM on clinical outcomes.

SAM substantially reduced the amount of time nurses spent on medication management (checking, administering, and supervising). Based on 15 beds in each group, nurses required 25 minutes per day less on medication checking process for patients in the SAM group than that for the control group, p<0.001 (Table 2). Additionally, prior to each medication administration, time spent each day for supervising/ensuring patients taking self-managed medications in the SAM group was 81.1 minutes less, compared with that spent for medication distributing and dosing for patients in the control group, p<0.001. Overall, time nurses required for medication administration process was 2.3 hours per day for the SAM group and 4.1 hours per day for the control group. SAM saved overall nursing time on medication management 1.8 (95%CI 1.7:1.9) hours each day, p<0.001. Furthermore, time (minutes per day) pharmacists spent on medication dispensing process were 92.6 (4.3) for the study group, and 181.0 (4.0) for the control group, p<0.001. However, time the ward pharmacist required for educating patients on self-managed medication was 33.2 (4.8) minutes per day. Overall time (hours per day) pharmacists spent on medication dispensing and educating were 2.1 (study group) and 3.0 (control group). SAM significantly saved overall pharmacist time on medication management 0.9 (95%CI 0.7:1.1) hours each day, p<0.001. Time the pharmacist spent on educating the patients about their medications was relatively short as all patients were familiar with most of their medications they had previously used before admission. However, time needed for educating patients on new medication regimens might be greater. The present study demonstrated that SAM intervention significantly reduced nurse and pharmacist time spent on medication management, staff workload might not be the barriers on implementation of the SAM program.

DISCUSSION

SAM education significantly increased in-patient medication knowledge at hospital discharge compared with nurse administered medication (routine practice). The effect retained over the first two follow-up visits, approximately 2 months after hospital discharge. SAM also increased home medication adherence measured at the

first follow-up visit and sustained at the second follow-up visit. Medication errors, focusing on administration errors, initiated by patients were not found in the study group, while wrong time medication errors originated by the healthcare personnel were found occurred in 4 patients (overall 13 events) in the control group.

Hospital readmission over 60 days after discharge was lower in the study group compared with the control group. Lastly, the time nurses and pharmacists spent on medication management was reduced in the study group.

SAM substantially increased knowledge of medications, especially indication and side effects, that was unchanged in the control group throughout the study. Knowledge of dose, dosing frequency, and dosing time related to meals only slightly increased because they were relatively high at baseline, but all patients in the study group reached the maximum score (2 points for each aspect, except 1 patient did not get full score on the dosing time related to meals). This could partly be a result of incorporating the understandable symbols/images in the teaching materials or medication label. As most patients did not know Thai or English, the languages commonly used on the medication labels, symbols/images helped these patients pick up medication correctly. Thus, it could be seen that after being taught and counseled about medications by pharmacists using innovative symbols/images labels during hospitalization, the patients were more knowledgeable and able to take medication on their own more correctly as prescribed than they were with nurse-administered medication. At the time of knowledge assessment, although patients in both groups were allowed to use information labelled on the medication packages, patients in the study group should use the information more effectively as they were more familiar with the symbols/images than those in the control group. Knowledge on medication side effects in the SAM group that was less increased, compared with knowledge about medication indication at discharge might be related to inability to understand or remember medication side effect information or unable to distinguish side effects of individual drugs. Nevertheless, knowledge about common side effects the patients received from the intervention might help them manage their medications and improve medication adherence. However, SAM could not increase knowledge about medication names which was zero in both groups at baseline. This might be a result of patients' inability to read medication labels that were presented in English. Therefore, additional readable labels (in Thai or Malay) are suggested to increase patient knowledge of medication names. It was observed that the percentage of adherence was relatively high in both groups, lack of knowledge on medication name was unlikely to affect medication use, given that patients had knowledge about medication indication and dosage administration of individuals drugs. In the present study, patients in both groups were comparable in medication knowledge, and the numbers of drugs received prior to admission. Education level that might be associated with patient health literacy was used as a stratifying variable in the randomization process to generate the groups that were balanced in educational status (and health literacy). The greater in medication knowledge outcome in the study group should be the effect of SAM intervention. In a previous study involving 24 elderly in-patients, knowledge of medication name, dose, and dosing frequency slightly increased but significantly from 89.2% to 98.8% ($p<0.001$) at hospital discharge after using the SAM program.[21] SAM program provided by registered nurses increased patient knowledge of their drug regimen, dosing time and side-effect.[15] In addition, a systematic review reported consistent results that patients in the SAM group had higher knowledge about name, frequency, and dose of medications compared with nurse-administered medication group.[8,16]

Knowledge at the first follow-up visit after discharge from the hospital, an average of two weeks apart, remained the same in both groups compared with that at hospital discharge. In Thailand, patients are not registered to general practitioners (GPs), no appointments are made for patients to see GPs after discharge. The effect was therefore not influenced by GP visits. This effect was sustained at the second follow-up visit measured approximately 2 months after discharge. It was not surprising that knowledge on medication names was not improved as no additional readable labels were provided for patients after hospital discharge. A non-RCT reported the percentage of patients knowing about indication of drugs measured 10 days after hospital discharge was significantly higher in the SAM group (38/42, 90%) than that in the control group (17/37, 46%).[22]

In the present study, SAM program significantly increased patient adherence compared with nurse-administered medication measured at the first follow-up visit. This might be related to the knowledge received after SAM intervention, especially that regarding medication indication and side effects mentioned earlier. Knowledge about medication side effects that temporarily occurred and ceased over continuing use would enhance medication adherence. While patients in the control group were lack of awareness on medication indication and side effects that potentially affect the adherence and clinical consequences. Similar results were reported from a non-RCT that the SAM program provided by pharmacists significantly increased patient adherence to medications measured at 10 days after hospital discharge compared with nurse-administered medication group (95% vs 83%, respectively, percentage difference 12%, [95%CI 4%:21%], $p<0.02$).[22] Increased patient compliance by the SAM program was confirmed by an RCT, although a qualitative systematic review revealed diverse results among included trials.[19,23] However, results on compliance might be compromised in the validity as most of studies used pill count conducted by staff, very few used more reliable methods, such as urine tests or disguised observation. The present study also used pill count method, as no sensitive or specific methods were available in the study hospital. Medication adherence was retained at the second follow-up visit in both groups. The effects of SAM on adherence were expected to sustain over time.

The present study found a few administration errors in the control group (13 events out of 877 nurse-administered medication doses) and all were wrong time dosing (defined as the doses were not administered within 30 minutes of the scheduled time). Of these, 8 were clinical risk level C,

and the remainders were clinical risk level D. Factors contributing to wrong-time administration errors were staff working overload, being interrupted by emergency care or nursing staff forgetting to provide medications to the patients. The 5 missed doses of antihypertensive agents occurred in 2 patients and subsequently resulted in uncontrolled blood pressure. However, the problems were not clinically significant, and were resolved after administration of the missed doses with closely monitoring. This study found no "wrong time" administration error in the study group, because nurses were notified by the patients if they did not arrive at patient' bed within 10 minutes. Grantham, *et al*. Also reported no patient-initiated administration errors among patients in the SAM group during the 6-month study period, compared with one medication error occurred in the previous six-month historical data.[15] Two administration errors during the study were due to nursing staff.[15] A critical review confirmed that the proportion of medication errors in the SAM group was significantly lower when compared with healthcare personnel-administered medication group (0.045 versus 0.086, $p<0.001$).[23] In addition, patients practicing SAM in hospitals had fewer medication errors and medication-related problems post discharge.[5,24] Medication errors attributable to patients receiving SAM program were less than that attributable to nursing staff, equipment defects, or pharmacists.[15,24]

In the present study, increasing patients' medication knowledge and adherence were in accordance with a reduction in hospital readmission among patients in the SAM group. Hospital readmission occurred earlier, a few days after hospital discharge, in the control group. The result was, however, observed in a relatively short follow-up period and the impact measured in a longer period is required. The results confirmed the reduction in hospital readmission after the SAM program reported previously.[12]

SAM substantially reduced nursing time and nurse workload on medication checking, distributing, and administering. The present study demonstrated that SAM level 2 reduced nursing staff workload and saved 1.8 hours for nurse to spend on medication management each day. Similarly, SAM decreased overall pharmacist workload and saved 0.9 hour per day. SAM intervention consequently provided sufficient resource available for SAM implementation. The time nurses required for checking whether medications delivered from the pharmacy department were consistent with that appeared in the doctor's order sheet was reduced in the study group. The medication checking process required every 4-day for patients in the SAM group and less time was required if any changes of the regimens were made during the 4-day course. While medication checking process for patients in the control group was repeatedly performed and consumed similar time each day. SAM implementation, however, increased workload of the ward pharmacists on educating patients about their medications, but it greater reduced the workload in the 4-day medication dispensing process and decreased overall pharmacist workload. In addition, as patients in the SAM group had already known their medications during admission, time spent on counseling and dispensing medications at discharge would be reduced or eliminated. The impact on pharmacist workload was consistent with that reported in a systematic review.[19] The benefits of SAM in reduction of workload and time spent on medication management should promote SAM implementation.

Although components or intensity of SAM program might be divided up to 9 levels, probably depending on the level of patient independence, responsibility, and the safety policies of the study hospitals, it is generally divided into 3 levels. Level 1, medication counseling and administration, is provided by a nurse (current usual practice in hospitals in Thailand); level 2, in-patient self-administered medications, is under the supervision of nurses or pharmacists; and in level 3, in-patients are totally responsible for their own medication administration.[15,19,21-23] In this study, SAM level 1 (control group) which was a standard practice, was compared with SAM level 2 (study group) under supervision of the multidisciplinary team. Utilization of SAM should be individualized to match patients' ability to promote their responsibility, dependency, and convenience while patient safety is reserved or maximized.[22] Presently, the study hospital provides medication labels presented in Thai (medication name, indication and dosing information); only the medication names are available in both Thai and English. Nonetheless, the pronunciation of the medication name was usually a technical term or generic name that was difficult for lay persons to remember. A supplementary label in Malay was provided for patients in the study who could read Malay, unfortunately very few were able to do so. The use of SAM level 2 for patients in the study group seemed to be appropriate and patient safety was reserved. Hospital safety policies stated in the latest revision of in Thailand Hospital Accreditation standards preclude the use of SAM level 3, as patient safety might be compromised. In a study that SAM was divided into 3 levels according to patient responsibility, only half of patients achieved the SAM level two or level three, mostly within 5 days of hospital admission. Achievement of SAM level might be limited by age (as patients in the study were relatively old, mean age 68.3 years), and limited literacy.[15] Similar results were recently reported that four-stage SAM program improved rehabilitation patients' understanding and ability to self-managed medications in 14 out of 20 (70%) participants.[25] SAM has been recommended worldwide to promote patients' abilities in self-managed medications.[2-5] It has been implemented in acute hospitals in the United Kingdom and Belgium.[7,26,27] The Society of Hospital Pharmacists of Australia (SHPA) Committee of Specialty Practice in Rehabilitation and Aged Care has recommended SAM as a part of the discharge planning process in rehabilitation wards.[28] The program suggests that providing patients an opportunity to self-medicate in a supervised setting with education and support promotes patient confidence and competence in self-medication management at home after discharge.

Strengths and limitations

The strengths of this study were the use of randomized controlled blinded design, and all patients were completely followed-up. Stratified-blocked randomization gave nicely balanced (age, education level, and participant number) samples at baseline. In addition, other variables that might affect the outcomes, such as the present illness, comorbidities, number of prescribed medications, and

visual or hearing capabilities were similar between groups. Blinding outcome assessors to treatment status helped prevent/minimize detection biases. Complete measurement of outcome data gave rise to valid results. Assessment of the outcome variables was done at hospital discharge and extended until all patients completed the first two follow-up visits, while a systematic review revealed that less than a half of included studies did.[19] Furthermore, the benefits of SAM on improvement of medication knowledge and adherence was confirmed by a lower hospital readmission. Nevertheless, this study had some limitations. Firstly, most patients in the study hospital are unable to read Thai, and only some can speak or understand Thai language. Language barrier limited patient learning abilities in some areas, such as medication names and side effects, and thus the maximum effects of the intervention could not be reached. Therefore, additional educational materials understandable or readable for patients should be provided to maximize the intervention effects. Secondly, short-term follow-up at least confirmed the retention of intervention effects, but could not measure maximal long-term effects that should be achieved among those with chronic diseases. Thirdly, the present study did not assess satisfaction from either patient's or staff's perspectives, and financial costs, yet these data are important to be considered for implementation of SAM program. Further researches of good methodological quality are required to evaluate the effect of SAM schemes on a variety of patient, staff, setting, and clinical outcomes.

Implications

The results confirmed that SAM program among patients with chronic diseases increased medication knowledge, adherence and reduced administration errors. The effects of the SAM program on improvement of these surrogate outcomes were confirmed by a lower hospital readmission, which implicitly indicated a reduction in resource utilization. The study results were internally valid and consistent with those reported from studies different in methodologic aspects (patients, setting, SAM component, etc.).[19,25] The results, however, would be well generalizable to other settings with similar contexts. Generalizability of the results to other settings depends much on patient characteristics (competency and/or acuity), healthcare system, health personnel, and potential barriers. The treatment effects of a single staged SAM shown in the present study might be minimized in the setting of well literate or competent patients, as their baseline medication knowledge is expected to be adequate, unless the lacking knowledge area are identified and an appropriate intervention performed by a skillful personnel (educator) are provided to promote patients' success in self-managed medication. A recent study conducted out hospital in the US reported that QR code-based information (graphic and text) significantly increased patient safety of self-administered medications in both younger adults and the senior citizens compared with current bottle labelling, but the effect was greater in younger adults than the older.[29] The use of IT technologies, such as electronic health records, computerized order entry systems, bar-code medication administration systems, and electronic medication administration records effectively reduced medication errors, but not eliminated the potential for errors.[30] In addition, IT systems provide accurate and standardized measuring, and reporting, application of IT in SAM implementation should enhance the success of the SAM program. SAM reduced nurse and pharmacist workload in the present study, but this effect may be attributable to many factors such as SAM components, roles and responsibilities delegated to individuals in the team, patient competence, as well as hospital environment. In Thailand, where resource constraints are the leading problems especially in healthcare services, wide implementation of SAM might reduce utilization of healthcare resources as a whole. However, patients' views or responsibilities, as well as hospital policies should be considered in planning and implementation of SAM program. Medication regimens should be simple and flexible enough to adapt to patients' lifestyles and usual routines. Nurses and or pharmacists should also take responsibilities to support and facilitate patient autonomy, to enable more effective management of health care needs when patients return home.[31] Long term monitoring is suggested for evaluation and improvement of the SAM program. Further studies designed ad hoc are needed to confirm the effects of SAM on clinical outcomes such as long-term hospital readmission, resource utilization, ER visits, as well as drug-related problems.

CONCLUSIONS

In-hospital SAM education mainly performed by a pharmacist under a multidisciplinary team increased medication knowledge and adherence, and decreased medication errors among patients with chronic diseases. SAM extended the duration of out-patient status and decreased hospital readmission within 60 days after discharge, and reduced nurse and pharmacist time spent on medication management for in-patients. SAM contents and medication labels suitable with patient's learning ability were important components for the success of SAM program.

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CONFLICT OF INTEREST

None.

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Original Research

Training upcoming academicians through interviews of pharmacy resident teaching certificate leaders

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Abstract

Background: Discovering methods of Residency Teaching Certificate Programs (RTCPs) will allow for collaboration in developing best practices to ensure both high quality of programming and outcomes for participants.

Objective: The primary objective of this project is to describe and compare how RTCPs are conducted in the state of Ohio. Secondarily, to identify current practices in assessing RTCPs in both programmatic effectiveness and individual resident teaching outcomes.

Methods: The seven coordinators of the seven Ohio RTCPs (n=7) were contacted via email and asked to participate in an IRB-approved interview, either in-person or telephonically. Standardized questions were developed to inquire about six categories of interest: demographics/background, administration/logistics, content, assessment of the resident, program financing, and program continuous quality improvement (CQI). All seven programs participated in interviews. Data was coded by multiple members of the research team for presentation in aggregate form.

Results: RTCPs include seminar days at the respective pharmacy colleges; however, the number, length, and content of seminars vary. The majority of programs (n=5) stated using inherited curriculum and materials passed down from previous coordinators. While each RTCP requires participants to submit a teaching portfolio, only three of seven programs assess the summative portfolios. All programs (n=7) award participants a certificate based on completion of requirements without a defined minimum performance standard. Two programs are collecting participant feedback after every session for CQI however no programs are completing an annual programmatic assessment of resident outcomes. The majority of coordinators (n=7) are interested in collaborating and sharing "best practices" between RTCPs in the state.

Conclusions: Although published and available resources exist surrounding the development and delivery of RTCPs, in Ohio, their use varies greatly. The most striking outcomes highlighted the lack of resident and program assessment of outcomes in RTCPs. The research has brought forth ideas of ways to improve these programs through resident assessment, program assessment and also leads to reflection and innovation around the best way to deliver these programs.

Keywords

Internship and Residency; Education, Pharmacy; Faculty, Pharmacy; Schools, Pharmacy; Program Evaluation; Curriculum; Certification; Quality Improvement; United States

INTRODUCTION

As the number of pharmacy schools continues to rise, there has been an increasing need for qualified pharmacy faculty and, thus, programs to develop pharmacy educators.[1] The American Society of Health-Systems Pharmacists (ASHP) accreditation standards for postgraduate year one (PGY1) pharmacy residency programs outline "teaching, education, and dissemination of knowledge" as a required competency area within programs; however, methods to develop competency in this area are not clearly defined.[2,3] Coupled with the gap in qualified pharmacy educators, "teaching residents to teach" is a vital component of the residency experience. Resident teaching and learning curriculum (TLC), often referred to as resident teaching certificate programs (RTCPs), were developed to educate residents on academia related content and provide various teaching experiences, providing a structured approach to training future educators. Such programs have existed for twenty years and have been found to be effective in improving resident confidence in teaching, in addition to providing multiple other benefits both in service as preceptors and in traditional academia.[4-6] Additionally, Gettig and colleagues found the majority of Residency Teaching Certificate Program (RTCP) participants felt the experience aided in obtaining their current position.[7]

Despite a need for well-prepared educators and the availability of RTCPs, there is no standard structure or assessment for such programs. A White Paper published by the American College of Clinical Pharmacy (ACCP) in 2013 outlined guidelines for residency programs to incorporate various academic experiences, including teaching certificate programs.[8] In 2014, the Task Force on Student Engagement and Involvement of the American Association of Colleges of Pharmacy (AACP), in conjunction with ASHP, published 12 best practice recommendations to incorporate in postgraduate education experiences.[9] Both of these publications provide guidance to teaching certificate programs without giving specific requirements or outcome criteria for residents or programs (Table 1).

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Table 1. Best practice recommendations for teaching and learning curriculum programs

AACP/ASHP			ACCP White Paper
1. Systematic experiences in teaching and learning should collectively be termed Teaching and Learning Curriculum (TLC) programs.	7. Participants in a TLC program should be evaluated at regular intervals.		1. Pharmacy residency programs providing teaching certificate programs should be affiliated with a school/college of pharmacy or an academic institution.
2. TLC programs should be facilitated through a school/college of pharmacy or other postsecondary institution.	8. Participants should develop and maintain a teaching portfolio.		2. Participants should develop and/or revise a personal teaching philosophy as part of a teaching portfolio documenting all teaching experiences.
3. TLC program content should include a discussion of specified core topics at a minimum.	9. TLC programs should have adequate personnel and institutional resources.		3. Participants should be assigned a specific teaching mentor for guidance and evaluation of experiences.
4. TLC program content should be delivered using different teaching styles.	10. TLC programs should incorporate a system of assessment to enhance ongoing programmatic improvement.		4. Participants should actively participate in a series of core pedagogy seminars.
5. TLC program content should be delivered commensurate with the learning level of the participants.	11. TLC program offerings, features, and participant obligations should be clearly described in all recruitment materials.		5. Participants should have exposure to different teaching experiences (ex. formal lectures, experiential precepting, small group discussion, and patient case development).
6. Participants in a TLC program should be expected to gain experience in a variety of educational modalities.	12. A formal external validation process for TLC programs should be established.		6. Participant performance should be assessed and clear criteria should exist for successful completion of the program.

A study by Strang and Baia examined 19 publications that described 20 RTCPs and one faculty development program. The majority of programs (95.2%) included both didactic and experiential components. Only 12 programs described an evaluation of the program including outcome data. All of these programs collected information on participants' reactions to the program, while only seven collected data on improved confidence in teaching and only one program collected information on knowledge improvement. However, nine programs collected information on participants' behavior change, such as obtaining academic employment or demonstrating changes in teaching skills and behavior. While the study outlined several trends in the components of various programs, it also exposed several gaps in the literature related to RTCPs, particularly in regard to outcomes data for these programs.[10]

Despite guidance from multiple publications on thoughtful design of RTCPs, there is little indication that such guidance is routinely used as evidenced by Stang and Baia's variance in results.[8,9,11] A shared definition of successful RTCP completion is lacking and evaluation of outcomes related to teaching effectiveness are not universally collected or assessed. For example, residents can participate in and complete an RTCP simply by participating in certain activities, but without thoughtful evaluation of outcomes by program coordinators. This lack of assessment may perpetuate knowledge gaps within academic practice. Moreover, programmatic assessment to continually improve RTCPs is not standardized across programs, potentially leading to a lack of quality "control" for programs. Although RTCPs have the potential to fill a gap for qualified educators within the academy, thoughtful design, assessment, and programmatic evaluation is essential to ensure the integrity of such experience. Currently RTCPs themselves are not held to a shared national standard based on provided guidance. Cataloging current RTCP structure and assessment, identifying gaps in knowledge and achieved outcomes, and sharing best practices aids in characterizing the current landscape of programs. Understanding current RTCP offerings and potential areas for improvement will promote the development of effective experiences for residents and impactful preparation for future educators.

Study authors coordinate one RTCP in Ohio, which has been in existence for ten years. In order to assess and improve current practices, study authors wanted to determine alignment with the other six Ohio RTCPs as well as currently available literature and guidance. The primary objective of this project is to describe and compare how RTCPs are conducted in the state of Ohio. Secondarily, the authors hope to identify current practices in assessing RTCPs in both programmatic effectiveness and individual resident teaching outcomes. Discovering methods of other RTCPs will allow for collaboration in developing best practices to ensure both high quality of programming and outcomes for participants.

METHODS

This study received exempt review approval from the Ohio Northern University Institutional Review Board to conduct a standardized, question-based interview of Ohio RTCP coordinators. Contact information for each of the seven different coordinators from the seven different programs was obtained through university or college websites or department chairs. Either current or immediate past coordinators were contacted between November 2018 and January 2019 to gauge interest in participation. If interested, each coordinator was then contacted via email or in person again in February 2019 and asked to participate in an interview and identify a date and time to do so, either telephonically or in-person. Coordinators from all seven of the Ohio colleges of pharmacy were included, provided consent, and elected to participate. No programs were excluded. The individual interviews took place in February 2019, with each interview taking 30 - 60 minutes to complete. Coordinators were asked to answer the questions to the best of their ability. Six interviews took place via telephone and one interview was completed in person, as the coordinators for Ohio Northern University are a part of the research team for this project. At least two members of the research team were present for each telephonic interview. A list of standardized questions was

Table 2. Current individual residency teaching certificate program information; n (%)	
Length of RTCP Existence	
0 - 5 years	1 (14.3)
6 - 10 years	3 (42.9)
11 - 15 years	2 (28.6)
> 15 years	1 (14.3)
Number of Participants Currently in Individual RTCPs	
0 - 15 participants	3 (42.9)
16 - 30 participants	2 (28.6)
31 - 45 participants	0 (0)
46 - 60 participants	2 (28.6)
Number of Residency Programs Participating in Individual RTCPs	
6 - 10 programs	4 (57.1)
11- 15 programs	1 (14.3)
> 15 programs	1 (14.3)
Length of RTCP Existence	
0 - 5 years	1 (14.3)
6 - 10 years	3 (42.9)
11 - 15 years	2 (28.6)
> 15 programs	1 (14.3)

developed to focus on six categories of interest: demographics/background, administration/logistics, content, assessment of the resident, program financing, and program continuous quality improvement (CQI). Use of a standardized question list ensured that each coordinator was asked the same questions. Telephonic interviews were audio recorded and researchers typed answers during the interview into an electronic Google Doc shared amongst the research team.

Following the interviews, one of the researchers reviewed the audio-recording and updated the electronic documentation of responses to ensure accuracy and completeness for each interview. Once reviewed, members of the research team organized the responses into a summary chart categorized by question and school. Utilizing the organized data for each interview question, members of the research team coded responses by similarities without identifying the individual RTCP. Data was compiled in an aggregate form and analyzed using descriptive statistics where appropriate.

RESULTS

Data regarding the length of program existence and current participating residents and residency programs can be found in Table 2. Most RTCP coordinators were unable to provide exact data for the number of residents that have completed the program thus far in program existence. Most RTCPs only have PGY-1 resident participation; however, there have been occasional PGY-2 residents, fellows, or preceptor participants. No programs have included or collaborated with other healthcare professionals outside of pharmacists, based on received responses.

Data regarding the administration and logistics of the Ohio RTCPs can be found in Table 3 and Table 4. The number of faculty that direct and participate in RTCPs vary with each program. Generally, RTCPs were organized by one coordinator (n=4) and additional college of pharmacy faculty members, ranging from 1-12 people, serve as mentors or guest speakers (n=7). Most content is delivered by college of pharmacy faculty; however, some programs incorporate an administrative assistant to help with organization (n=2), an academic technology department (n=1), or faculty from other departments or colleges within their university (n=2). The faculty that participate in the program are not incentivized individually and most coordinators commented that their role is a voluntary position that is done "out of the goodness of their heart."

Table 3. RTCP program logistics and financing; n (%)	
Characteristic	**Yes**
Seminar days occur at respective college of pharmacy	7 (100)
Standardized program for all participants	4 (57.1)
RTCP requires submission of a teaching portfolio	7 (100)
RTCP pairs all residents with a teaching mentor	4 (57.1)
RTCP faculty provided incentive to participate in the RTCP	0 (0)
Financial assistance provided to RTCP from the residency program	1 (14.3)
Financial assistance provided to RTCP from the university or college	4 (57.1)

The content, design, and logistics of Ohio RTCPs vary greatly. Generally, each Ohio RTCP provides content through seminar days. The majority of programs front-load the content in the earlier part of the residency year (n=6). In addition, some RTCPs meet quarterly throughout the residency year (n=2) while some programs meet every month (n=1). Most programs stated that they provide full seminar days in the earlier months of the residency year (n=5) and additional seminar days may consist of shorter meetings. Content delivered during seminar days was delivered through interactive discussions (n= 5), lectures (n=1) and online modules (n=1). The most common content topics were teaching philosophies (n=7), assessment of learners (n=6), lecture delivery methods (n=6), learning styles (n=3), and careers in academia (n=3). Programs delineated and distinguished topics differently so there were some inconsistencies in how seminar topics were reported and inconsistencies in the number of hours reported on each topic. For example, teaching methodologies time varied from 1 hour to 16+ hours of content for the residents.

All of the programs required resident completion of a teaching portfolio (n=7) but actual teaching components varied from program to program. Only 3 programs stated that the teaching portfolio was evaluated by a faculty member. Hours spent teaching in the respective college of pharmacy varied from a one-time 2 hour requirement to a semester long teaching requirement incorporating 16+ hours of classroom teaching. There was no consistency in

Table 4. RTCP seminar day logistics	
Characteristic	**Range**
Number of seminar days	2 – 13 sessions
Length of seminar days	2 – 8 hours
Number of faculty who participate	1 – 12 faculty

Table 5. Teaching mentor pairing of participants by RTCP coordinators	
Number of programs pairing participants with a teaching mentor	**n (%)**
All participants	4 (57.1)
Some participants	2 (28.6)
No participants	1 (14.3)

Table 6. Assessment of residents	
Method	**n (%)**
Certificate earned based on completion of requirements	7 (100)
Review of teaching materials by mentor	5 (71.4)
Evaluation tool during teaching	3 (42.9)
Evaluation of summative portfolio	3 (42.9)
Evaluation tool of teaching materials	2 (28.6)
Review student feedback	2 (28.6)
Assessment of reflection materials	1 (14.3)
Exit survey	1 (14.3)

the number of hours or classroom setting for resident teaching experiences. Residents also had a variety of other requirements for each program that included monthly case development, assessment of students in patient simulations, involvement in skills based assessments, and precepting experiential education students.

Not all RTCPs pair participants with a teaching mentor (Table 5). One program even shared receiving "push back" from other faculty members and department leaders, while another program shared that typically residents are paired with each other. All RTCP coordinators confirmed that some past participants have obtained a position related to academia, however none were able to provide an exact number. Most feel that the percentage is low, but acknowledge that not all who participate in the RTCP are seeking full time positions in academia.

When interviewees were asked about resources used to create the program, apart from the ACCP white paper, results varied. The majority of programs (n=5) stated using inherited materials passed down from previous coordinators. One program referenced the AACP/ASHP recommendations for postgraduate pharmacy experiences in education and another program cited using previously published literature and available syllabi.

All programs were asked about financing related to the offering of their RTCP. Most programs (n=6) do not receive financial assistance or compensation from residency programs or participating residents. Only one program requires the participating resident to pay a fee; however, some programs noted that compensation comes in informal or non-monetary forms, such as teaching for the college or a resident "sponsor" that pays for the resident's dinner during the final banquet. Similarly, programs were asked if the college or university provides financial support for the program or if there is a specific budget for the RTCP. Generally, most programs do not have a specific budget (n=5) or stated their budget was absorbed in the college's budget as a line item without a set amount (n=2). It was implied that most colleges (n=6) did cover the cost of food and beverages for the seminar days, parking, room reservation fees, or copying costs. In summary, most RTCPs do not have a set budget or receive financial compensation from residents, residency programs, or their affiliated colleges for delivery of the program.

All programs noted that resident performance was evaluated, but the methods utilized varied among the programs. A summary of evaluation methods are summarized in Table 6. All interviewees stated that residents earned a certificate based upon the completion of program requirements, however, only 3 programs stated that the summative portfolios were evaluated. The majority of RTCP mentors reviewed residents' teaching materials (n=5) but there were inconsistencies in the use of an evaluation tool for resident teaching materials (n=2) and resident teaching (n=3). As shown in Table 7, CQI is not standardized among the Ohio RTCPs. CQI of programs range from an informal annual review (n=3) to written feedback from the participants after each seminar (n=2). One program noted getting feedback from a focus group of Residency Program Directors (RPDs) as a means of program improvement. Of note, all programs noted that they did not perform an annual programmatic assessment of resident outcomes (n=7). Most programs in Ohio (n=5) indicated specific interest in collaborating within the state of Ohio to develop a more standardized RTCP. The interviewees with reservations in creating a statewide program noted concerns with the potential loss of RTCP individualization, creativity, and flexibility.

DISCUSSION

This study sought to identify ways to improve Ohio Northern University's RTCP to ensure the program is preparing residents to meet the educational needs of a dynamic pharmacy landscape in accordance with national recommendations. By describing how Ohio RTCPs are conducted and identifying current practices in RTCP and resident assessment, the authors hoped to discern ways in which RTCPs could collaborate more productively to demonstrate that these programs are useful and effective in training future educators. As previously described, there is a lack of standardization in the delivery, assessment, and outcomes of RTCPs on a national level. Not surprisingly, there were inconsistencies found among the 7 Ohio RTCPs in terms of administration, logistics, content, program financing, assessment of participants, and program CQI. Of the various topics investigated, two of the most compelling areas in need of immediate and further development focus around assessment. The first being a lack of defined outcome measures surrounding resident effectiveness as educators and the second centering around the assessment of RTCP effectiveness in the form of CQI.

In hopes of gaining an understanding of how Ohio RTCPs determine if their residents are successful educators, this study explored how programs evaluate their residents as competent educators. Interviewers identified that there is not a standard definition of what it means to have "successfully" completed an RTCP. All programs stated that if the participant had completed the checklist of requirements, then the participant would receive the certificate. There was not a minimum performance standard for any of these requirements and no

Table 7. Teaching certificate program continuous quality improvement	
Type of CQI	**n (%)**
Informal annual review	3 (42.9)
Written feedback after each seminar	2 (28.6)
Grant funded one time programmatic review	1 (14.3)
No regular assessment	2 (28.6)
University level assessment	2 (28.6)
Exit Interview	1 (14.3)
Annual programmatic assessment of resident outcomes	0 (0)

interviewees referenced any of the available validated tools or assessment rubrics used. This highlights the need for some means of distinguishing and measuring resident effectiveness as an educator prior to being awarded the teaching certificate. This would hopefully add more meaning to actually having earned the certificate and assure that residents are adequately prepared to educate future pharmacists. RTCPs could potentially begin creating benchmarks that program participants must meet prior to being awarded a teaching certificate, instead of simply completing tasks or projects. Additional studies should be conducted to identify what outcomes should be measured to determine resident effectiveness or success in the different requirements of the RTCP (for example, in lecture delivery). By ensuring residents are adequately prepared as effective educators, it advances the knowledge, skills, and qualities of pharmacists that educate our future students in the traditional classroom setting and in experiential education. Locally, RTCPs are not currently evaluating resident outcomes on an individual level for the resident or even on a program level. Furthermore, RTCPs are also failing to self-assess in regards to their program's utility and effectiveness as an educator preparation tool and offers an opportunity to innovate and expand in the area of resident assessment.

While the majority of Ohio RTCPs have been in existence for six years or longer, most have been historically handed down to current coordinators and have often lacked specified outcomes and a routine CQI process. This has, in part, led most delivered content to be derived from academic inertia rather than utilizing evidence-based recommendations or published consensus statements. It was hoped that more RTCPs would have evidence-based curriculum and program design, however, the opposite was found through the interviews. This research emphasized the need to revisit the existing published recommendations for program requirements and programmatic assessment. Among the Ohio RTCP leaders interviewed, CQI was consistently noted as an area of opportunity for further development. RTCPs may benefit from a standardized process of implementing annual CQI, as well as a toolkit of resources that may outline the most effective means to do so. Additionally, it would be helpful to evaluate and share the strengths and limitations of RTCPs at a program level. General trends may become apparent at a program level that could be addressed collaboratively with enhanced seminars or teaching experiences. Through collaborative efforts, perhaps program leaders could identify outcome measures to show an RTCP participant's maturation as an educator while simultaneously improving the utility and functionality of the actual RTCP itself. Future research into effective means for CQI for RTCPs could be disseminated along with potential repositories of resources for all RTCPs to adopt and adapt for their institution. Hopefully in the future, this research coupled with more broad research into effective means for preparing future academicians, will lead to clearly defined and consistent outcomes for residents, greater recognition of programs, and greater collaboration among those who coordinate RTCPs. Ultimately, this should lead to better preparation of residents to tackle the challenges and opportunities in educating future pharmacists.

The biggest limitation of the study is that not all coordinators were able to provide concrete information regarding their RTCP, specifically relating to the historical elements such as number of total participants, collaboration efforts, and academia job placement after program completion. A few limitations exist in regards to the interview process. All coordinators did not receive a copy of the interview questions ahead of time, which prevented answering all questions during the phone call. Although means were provided for coordinators to provide additional responses via email, not many were received. Another limitation is that one telephonic interview was not recorded, which prevented the research team from reviewing the electronic responses for accuracy.

Due to the specific geographic focus on Ohio for this study, information provided within may not be generalizable to RTCPs outside of Ohio; however, these results do serve as a pilot study to investigate the dissemination of RTCPs nationally. These interviews serve as a starting point for subsequent work regarding how RTCPs are conducted outside of the state. Future studies should be conducted at a national level to review, compare, and contrast RTCP logistics, content inclusion and delivery, participant requirements, and assessment of both participants and the program itself.

CONCLUSIONS

Even within the same state, RTCPs vary widely in terms of logistics, content delivery, and assessment of participants and CQI of programs. This focused study helped to identify current similarities, but also highlighted the vast differences between programs in one state. The most striking and meaningful finding of the study surrounded the lack of both resident and program assessment found in RTCPs and points to a need for significant work in these areas. Moving forward there is opportunity to expand the way that programs are assessing resident success as well as program success. The research has brought forth ideas of ways to improve these programs through resident assessment, program assessment and also leads to reflection and innovation around the best way to deliver these programs. More research and collaboration in this area would lead to opportunities for more fruitful collaboration between RTCPs coordinators at a national level to help improve these programs in preparing future educators and also lead to potential innovation around these programs. Potential future research into more interprofessional delivery of the programs, varied tracks of the programs (ie experiential versus didactic teaching tracks) or even potential to move these programs prior to residency training. Further research and collaboration could improve these programs and ultimately better prepare future pharmacy educators.

CONFLICT OF INTEREST

The authors do not have any financial disclosures. Five of the authors are current coordinators of one of the Ohio Resident Teaching Certificate Programs.

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Original Research

FDA collaboration to improve safe use of fluoroquinolone antibiotics: an *ex post facto* matched control study of targeted short-form messaging and online education served to high prescribers

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Abstract

Objective: This *ex post facto* matched control study was conducted to evaluate the effect of targeted short-form messages or continuing medical education (CME) on fluoroquinolone prescribing among high prescribers.

Methods: A total of 11,774 Medscape healthcare provider (HCP) members prescribing high volumes of fluoroquinolones were randomized into three segments to receive one of three unique targeted short-form messages, each delivered via email, web alerts, and mobile alerts. Some HCPs receiving targeted short-form messages also participated in CME on fluoroquinolone prescribing. A fourth segment of HCPs participated in CME only. Test HCPs were matched to third-party-provider prescriber data to identify control HCPs. We used prescriber data to determine new prescription volume; percentage (%) of HCPs with reduced prescribing; new prescription volume for acute bacterial sinusitis (ABS), uncomplicated urinary tract infection (uUTI), and acute bacterial exacerbations of chronic bronchitis in those with chronic obstructive pulmonary disease (ABECB-COPD). Open rates for emailed targeted short-form messages were also measured.

Results: Targeted short-form messages and CME each resulted in significant new prescription volume reduction versus control. Combining targeted short-form messages with CME yielded the greatest percentage of test HCPs with reduced prescribing (80.1%) versus controls (76.2%; p<0.0001). New prescription volume decreased significantly for uUTI and ABS following exposure to targeted short-form messages, CME, or both. Targeted short-form messages containing comparative prescribing information with or without clinical context were opened at slightly higher rates (10.8% and 10.6%, respectively) than targeted short-form messages containing clinical context alone (9.1%).

Conclusions: Targeted short-form messages and CME, alone and in combination, are associated with reduced oral fluoroquinolone prescribing among high prescribers.

Keywords

Antimicrobial Stewardship; Drug Resistance, Bacterial; Fluoroquinolones; Prescription Drug Misuse; Inappropriate Prescribing; Education, Medical, Continuing; Peer Influence; Randomized Controlled Trials as Topic; United States

INTRODUCTION

Fluoroquinolones (e.g., ciprofloxacin, levofloxacin, moxifloxacin, ofloxacin, and gemifloxacin) are the third most commonly prescribed class of antibiotics in the United States in outpatient settings and the most commonly prescribed class of antibiotics in hospitals.[1,2] Resistance to fluoroquinolones among an important group of Gram-negative bacterial pathogens (e.g., *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumonia*) has increased significantly, highlighting the need for providers to scrutinize the use of fluoroquinolones in patients infected with these pathogens.[3,4] Of major concern is that fluoroquinolones are associated with a range of disabling and potentially irreversible adverse reactions, including reactions involving the musculoskeletal and peripheral nervous systems (tendonitis and tendon rupture, muscle and joint pain, peripheral neuropathy) and the central nervous system (psychosis, anxiety, insomnia, depression, suicidal thoughts, hallucinations); significant decreases in blood sugar and attendant risk for coma; and ruptures or tears in the aorta.[5]

In July 2016, the U.S. Food and Drug Administration (FDA) updated the boxed warning for fluoroquinolones to indicate that the serious side effects associated with fluoroquinolones generally outweigh the benefits for patients with acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis in those with chronic obstructive pulmonary disease (ABECB-COPD), and uncomplicated urinary tract infections (uUTIs).[6] Importantly, a recent study showed that 5% of all fluoroquinolone prescriptions in the United States in 2014 were given for conditions for which no antibiotics are indicated, and 20% were given for conditions for which fluoroquinolones are not recommended first-line therapy, including 6.3 million for sinusitis and uUTIs and 1.6 million for viral respiratory tract infections and bronchitis.[7] Any reduction in inappropriate prescribing of fluoroquinolones will reduce preventable harm from this class, with a concomitant reduction in associated health care costs such as the cost of drugs and their administration, costs of

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treatment of side effects, and costs of future antibiotic resistance.[8]

Many clinicians do not believe they prescribe antibiotics inappropriately, yet when faced with feedback comparing their own prescribing patterns with those of peers, they will modify their personal prescribing patterns.[9,10] Much of the power of feedback lies in showing clinicians that their own behaviors are inconsistent with a desirable target or with what their peers are doing.[11,12] To date, such feedback, delivered in verbal and written formats, has demonstrated moderate effectiveness in changing antibiotic prescribing behaviors.[13-15] Questions remain, however, about the degree of effectiveness associated with different feedback formats and how best to optimize the effect of feedback interventions designed to change prescribing behaviors.[12,16]

The FDA Safe Use Initiative funds research to develop innovative methods (including education, novel messaging strategies, and mobile technologies) to facilitate research in the area of safe medication use and was the impetus for this study, which is a collaboration between the FDA and Medscape, an online provider of medical information and continuing education for clinicians.[17] Medscape's parent company, WebMD, proposed this study in response to the Food and Drug Administration Broad Agency Announcement for the Advanced Research and Development of Regulatory Science (FDABAA-15-00121) and was awarded funding for research that the FDA anticipates "will serve to advance scientific knowledge to accomplish its mission to protect and promote the health of our nation." Interventions for this study were developed in collaboration with the FDA's Center for Drug Evaluation and Research. In this study, we investigate the effects of feedback and education about fluoroquinolone prescribing on high-volume prescribers of fluoroquinolones when delivered to them as 1) targeted short-form messages and 2) a continuing medical education (CME)-certified activity, individually and in combination. A targeted short-form message can be thought of as short form content targeted to a specific audience (in this case high prescribers) and delivered via a concise messaging format (in this case emails, web alerts, and mobile alerts). Short form content is typically 400-600 words, can be read in as little as two minutes, and doesn't require much critical thinking.[18] Primary outcomes were the volume of new prescriptions written and the number of providers reducing their prescribing (Prescriber Reducers). Subgroup analyses measured new prescription volume by tactics (targeted short-form message alone, targeted short-form message with CME, or CME alone), message (targeted short-form message format A, B, or C), and indication (ABS, ABECB-COPD, and uUTI), and Prescriber Reducers by specialty subgroup (PCPs, urologists, all other physicians, and nurse practitioners/physician assistants). Email open rates for targeted short-form messages were also measured to assess degree of engagement with three different messages.

METHODS

Study Design

We conducted an *ex post facto* matched control study between October 2016 and July 2017 using Medscape's online capabilities to drive targeted short-form messages and education to a large number of high-volume fluoroquinolone prescribers among Medscape's online clinician membership. We devised a three-phase approach to 1) define the target audience for messaging and education; 2) develop and implement targeted short-form messages and educational (CME and non-CME) content; and 3) evaluate the impact of targeted short-form messages and education.

Phase 1: Define the Target Audience

A population of 320,478 Medscape prescriber members, representing all prescribing deciles (1 to 10), prescribed approximately 14.5 million prescriptions for fluoroquinolones during a pre-intervention period from September 2014 to August 2015. From this population, we identified a target audience of 28,004 high-volume fluoroquinolone prescribers (deciles 6 to 10); this target audience, which included physicians, nurse practitioners, and physician assistants, wrote 7.3 million fluoroquinolone prescriptions over the 12-month period at an average of 260 prescriptions per member.

The target audience was identified by a process in which validated US-based Medscape members with a history of recent activity on Medscape and an email address registered with Medscape were matched to third-party data sources from IQVIA (formerly Quintiles and IMS Health). IQVIA is a global provider of data, technology, and analytics for the healthcare industry. IQVIA provided de-identified prescriber-level data for physicians, nurse practitioners, and physician assistants based on pre-intervention, 12-month (May 2015 to April 2016) fluoroquinolone prescribing activity using unique identifiers (Medical Education number or National Provider Identifier number and other data points such as specialty, profession, name, and geographic location). IQVIA analysis of provider total prescribing volume for the 12-month period included fluoroquinolone medications that are currently on the market and indicated for systemic administration. We also identified fluoroquinolone prescriber physician specialties using Medscape's membership records and determined the total prescribing volume by specialty using the IQVIA VOPEX (Vector One: Prescriber Extract) service offering, which tracks HCP medical claims data and prescription volumes by product.

Phase 2 A: Development and Implementation of Targeted Short-Form Messages and Non-CME Education

A series of targeted short-form messages was developed in collaboration with the FDA's Center for Drug Evaluation and Research. We tested thirteen subject lines, each with an average of 1,666 emails (range: 1,206 – 2,397). Engagement with each targeted short-form message was evaluated by unique (de-duplicated) email open rates. The three targeted short-form messages with the highest unique open rates were used in the full intervention. Targeted short-form messages included a link to an online (medscape.com) educational (non-CME) resources center that highlights key messages and clinical data on fluoroquinolone prescribing.

Each of the three targeted short-form message formats had a unique subject line and content:

1) Message A: Subject line: "Your fluoroquinolone usage data." Content: A brief message on the prescriber's current fluoroquinolone prescription volume as derived from IQVIA data compared with the national average for their specialty

2) Message B: Subject line: "Your fluoroquinolone prescribing volume exceeds the average." Content: A brief message on the prescriber's current fluoroquinolone prescription volume compared with the national average for their specialty, combined with clinical context (i.e., FDA drug safety review findings and label update with advisory on appropriate fluoroquinolone prescribing)

3) Message C: Subject line: "Serious side effects prompt FDA to change fluoroquinolone labeling." Content: Clinical context only

Phase 2 B: Development and Implementation of CME

An online CME activity (Improving the Safe Use of Fluoroquinolone Antibiotics, https://www.medscape.org/viewarticle/870313) was jointly developed by the FDA. This CME-certified activity (0.75 AMA PRA Category 1 Credit™) was co-authored by an FDA therapeutic expert and Medscape and provided a review of scientific advances in fluoroquinolone prescribing. Content was driven by an educational needs assessment which indicated HCP knowledge gaps regarding efficacy and safety data for fluoroquinolones and the appropriate role of this drug class in the context of treating patients for ABS, ABECB-COPD, and uUTI. Custom recruitment on medscape.org included targeted promotion to the entire 28,004-provider target list.

Phase 3: Evaluation of Intervention Impact

The outcome measures for evaluating the intervention impact were:

- Test versus control difference for new prescription volume of fluoroquinolones
- Test versus control difference for percentage (%) of HCPs reducing their prescribing of fluoroquinolones (Prescriber Reducers). In this study, Prescriber Reducers were defined as healthcare providers who reduced their average monthly prescribing of fluoroquinolones volume by any amount from the pretest period to the test/posttest period.

Subgroup analyses were performed to determine test versus control differences for:

1. New prescription volume by tactics (Targeted short-form message alone, Targeted short-form message with CME, or CME alone)
2. New prescription volume by message (Targeted short-form message format A, B, or C)
3. Prescriber Reducers by specialty subgroup (PCPs, urologists, all other physicians, and nurse practitioners / physician assistants)
4. New prescription volume by indication (ABS, ABECB-COPD, and uUTI)

Prescriber engagement with targeted short-form messages were evaluated by email opens.

Sample Size

It was estimated that a minimum of 10,000 members of the target audience would be engaged in one of the three tactics of the intervention: targeted short-form message alone, targeted short-form message with CME, or CME alone. An engagement is defined as opening an email, viewing an alert, or participating in CME The 10,000 member minimum engagement was estimated based on the size of the targeted audience, anticipated open rates for emails, anticipated views of web and mobile alerts, anticipated number of participants in the CME activity, and Medscape's experience communicating with health care provider audiences.

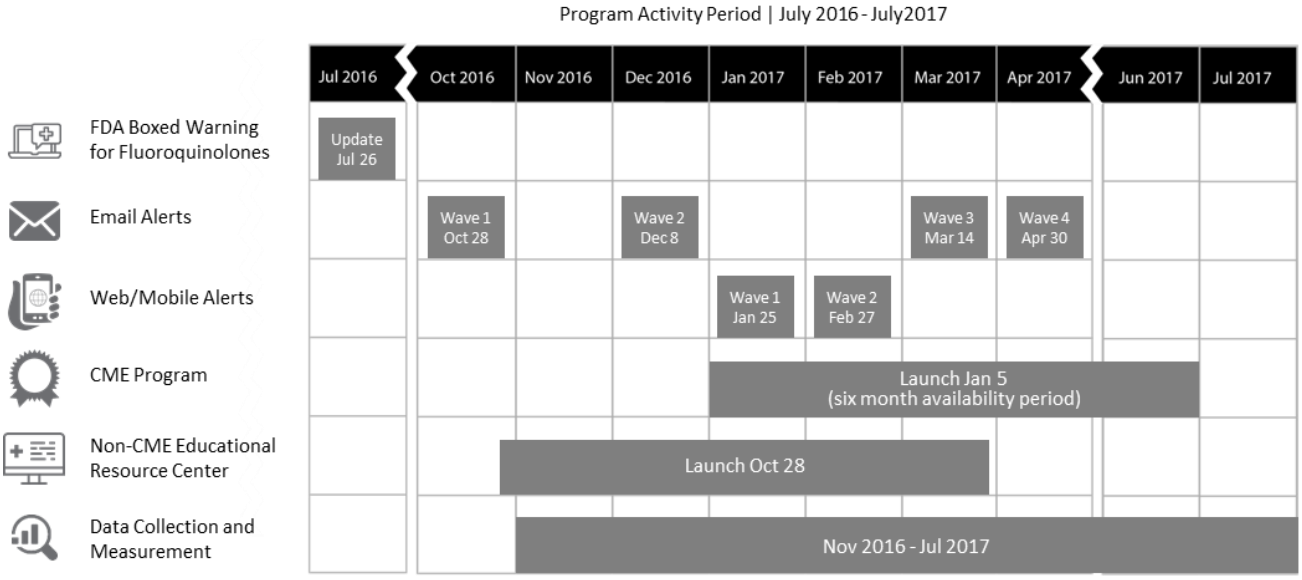

Figure 1. Timeline for delivery of tactic elements

Power analysis was also done to verify that with such a sample size there will be at least 80% power to detect a significant program effect, if it exists, for Message A only, Message B only, and Message C only segments. The sample size for CME content only, Message A with CME, Message B with CME, and Message C with CME was anticipated to be considerably lower and was thus not included in the power analysis.

Of the targeted high-prescribing HCPs, a participant test group of 11,774 HCPs was matched to the IQVIA prescriber universe to identify non-participant control HCPs based on the following criteria:

- Oral fluoroquinolone new prescription volume in the pretest period
- Market trend in oral fluoroquinolone new prescription volume in the pretest period
- Profession (physician, NP, PA)
- IQVIA physician specialty
- HCP geography
- Overall writing decile
- Intervention

Test HCPs were randomized into three segments to measure the effectiveness of three unique targeted short-form message formats (Message A, B, or C). Targeted short-form messages were delivered as emails and Medscape website and mobile alerts. A fourth segment of high-volume fluoroquinolone prescribers did not receive any targeted short-form messages but participated in the CME activity only.

Targeted short-form messages

Email. Targeted short-form message emails were sent from Medscape to test HCPs in four waves over the six-month period from late October 2016 to late April 2017 (Figure 1); each of the two initial email waves was followed by another email wave that targeted only test HCPs who did not open the initial email (for a total of four waves).

Website and mobile alerts. Targeted short-form message alerts appeared on a target provider's web browser or mobile device when visiting medscape.com. (Medscape users log on to the system and are thus identifiable.) High volume fluoroquinolone prescribers (deciles 6 to 10) were presented with a personalized message concerning fluoroquinolone prescribing. Alerts were displayed during an HCP's session in two different ways: as full messages that are displayed in the context of relevant content, and as linked headlines. Website and mobile alerts were delivered in two waves over the period from late January 2017 to late February 2017 (Figure 1).

Continuing medical education

Recognizing that urology and primary care are specialties commonly associated with fluoroquinolone prescribing, Medscape members who were high-volume fluoroquinolone prescribers were identified and grouped according to specialty (i.e., urologists, primary care physicians [PCPs], all other physicians, and nurse practitioners/physician assistants) and were recruited to an online, interactive, text-based, CME-certified activity on safe use of fluoroquinolones based on an analysis of prescriber-level data. Recruitment was conducted via unique messages strategically placed on targeted medical specialty homepages. The messages were placed in areas of the specialty homepages focused on educational content most relevant to treatment of ABS, chronic obstructive pulmonary disease (COPD), and uUTI in order to drive the most relevant HCPs to the available education. Recruitment to the activity occurred at activity launch and continued for the first 3 months. The activity was hosted on medscape.org from January 2017 to January 2018 and was available exclusively to the target audience during the first 6 months of its certification (Figure 1).

Data Analysis

The test period was defined as November 2016 to April 2017; the posttest (measurement) period was defined as November 2016 to July 2017 (Figure 1). Some HCPs who were late October 2016 participants were included as November 2016 participants. Statistical analysis was performed using the SAS 9.4 software program. ANCOVA was used to evaluate differences between test and control groups in new prescription volumes. Fluoroquinolone prescription volumes in the pretest period were used as a covariate in the ANCOVA model to adjust for pretest period prescription writing differences between the two groups. Program success was determined using a difference of adjusted means test with a p-value <0.05. All test versus control group differences were measured using a two-tail statistical testing method. Average differences in new prescription volumes were compared between participants receiving targeted short-form messages only, CME only, and targeted short-from messages combined with CME, using pairwise t-tests.

The impact of the total program (exposure to a targeted short-form message or CME) was determined as program-level new prescription volume and Prescriber Reducer differences. Test and control matches were time-aligned by the first program engagement to synchronize follow-up program periods.

Following program completion, analysis of program impact on new prescription volume by indication for ABS, ABECB-COPD, and uUTI was performed by IQVIA using ANCOVA for patient medical claims data. As medical claims data has

Table 1. HCP medical claims data coverage

Tier	Claims Coverage*
Tier 1	HCPs whose claims were considered 100% captured in IQVIA Medical data in every month of the test/posttest period (November 2016 – July 2017)
Tier 2	HCPs whose claims were considered less than 100% captured in IQVIA Medical data in some of the months of the test/posttest period (November 2016 – July 2017)
Tier 3	HCPs who are not classified in tier 1 and 2 in the test/post test period (November 2016 – July 2017)

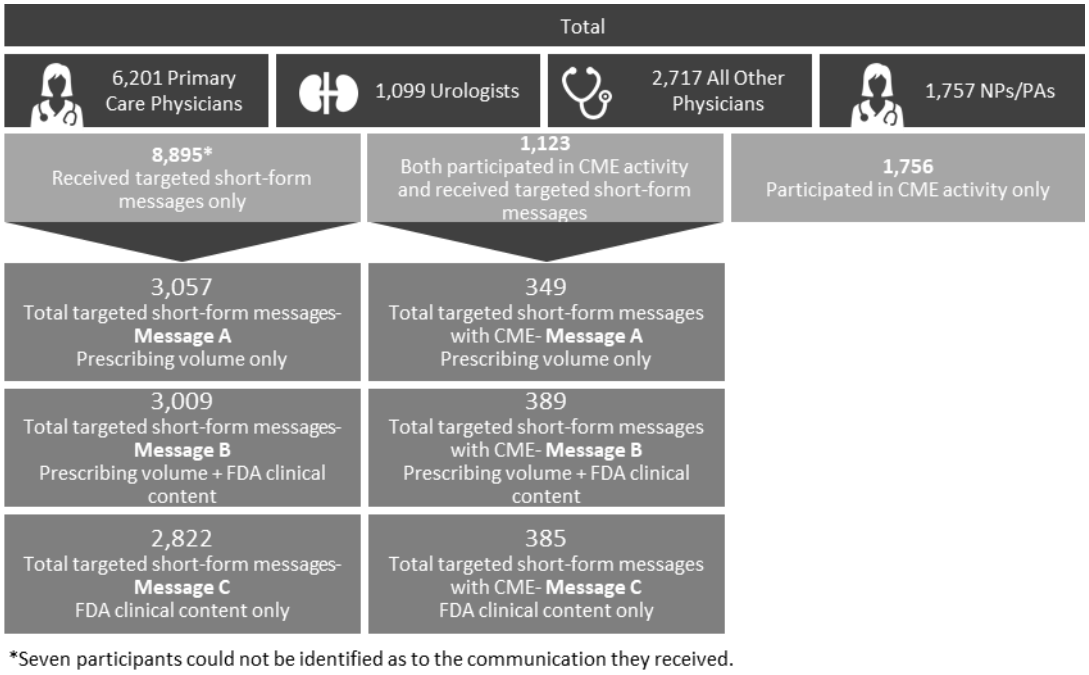

Figure 2. Exposed test group (n=11,774) specialties, intervention tactics, and messages

varying levels of coverage, IQVIA groups HCPs in three tiers for indication tracking, as defined in Table 1. Program participant fluoroquinolone prescribing volume changes by indication were analyzed by their tier membership. Only HCPs with patients with a relevant indication were included in the analysis.

Ethics and confidentiality

Neither the overall program nor the impact study recorded any protected information as defined in the 1996 Health Insurance Portability and Accountability Act (HIPAA). The study complied with Medscape's privacy policy as posted on medscape.com. IQVIA used patient data that were de-identified to ensure privacy and compliance with HIPAA and other relevant privacy legislation. Presentation of individualized prescribing data and practice patterns to prescribers was also de-identified and HIPAA-compliant. No specific permission from prescribers or patients was required to perform this education and analysis program.

RESULTS

The test group of HCPs, all matched to controls, consisted of 6201 primary care physicians, 1099 urologists, 2717 all other physicians, and 1757 nurse practitioners/physician assistants. Among the test group, 8895 participants received targeted short-form messages only, 1756 received CME only, and 1123 received both targeted short-form messages and CME. Figure 2 shows the distribution breakdowns for targeted short-form messages A, B, and C individually, and combined with CME.

On a program level across all three tactics, the test group showed a change in new prescription volume of -10.3% compared with the control group. Test group participants receiving targeted short-form messages alone, CME alone, and targeted short-form messages combined with CME showed a change in new prescription volume of -8.5%, -12.3%, and -21.7%, respectively, compared with the control group (Table 2).

Table 2. Oral fluoroquinolone new prescription volume comparison: total and by tactic

Tactic/Message	Test Cohort (n)	New prescription volume percent difference compared with control (95%CI)	p-value
All Tactics	Total (n=11,774)	-10.3% (-11.8%, -8.8%)	p<0.0001
Targeted short-form messages participants	Total (n=8,895)	-8.5% (-10.2%, -6.9%)	p<0.0001
	Message A*: Prescriber's fluoroquinolone prescription volume compared with national average for specialty (n=3,057)	-7.9% (-10.7%, -5.2%)	p<0.0001
	Message B*: Prescriber's fluoroquinolone prescription volume compared with national average for specialty, combined with FDA advisory on appropriate (n=3,009)	-9.4% (-12.0%, -6.7%)	p<0.0001
	Message C*: FDA advisory on appropriate fluoroquinolone prescribing (n=2,822)	-8.2% (-11.3%, -5.1%)	p<0.0001
CME	CME Only Participants (n=1,756)	-12.3% (-19.2%, -5.5%)	p=0.0004
	Both CME and Targeted Short-Form Messages Participants (n=1,123)	-21.7% (-26.6%, -16.9%)	p<0.0001
* There are no significant differences in level of impact resulting from exposure to Message A, B, or C (based on a pairwise comparison t-test)			

Table 3. Oral fluoroquinolone new prescription volume comparison (all tactics): by tier* and reverent indication

Tier*	Indication	New prescription volume percent difference compared with control (95% CI)	p-value
Tier 1	Acute Bacterial Sinusitis (ABS) (Test n=1,319, Control n=1,381)	-10.6% (-23.6%, 2.4%)	p=0.1091
	Acute Bacterial Exacerbations of Chronic Bronchitis in people with Chronic Obstructive Pulmonary disease (ABECB-COPD) (Test n=1,161, Control n=1,210)	-7.5% (-20.4%, 5.5%)	p=0.2586
	Uncomplicated Urinary Tract Infection (uUTI) (Test n=1,489, Control n=1,544)	-5.5% (-11.0%, -0.1%)	p=0.0470
	Any combination of the three indications (ABS, ABECB-COPD or uUTI) (Test n=1,555, Control n=1,622)	-6.7% (-12.1%, -1.3%)	p=0.0159
Tiers 2+3	Acute Bacterial Sinusitis (ABS) (Test n=6,500, Control n=6,412)	-14.0% (-23.8%, -4.3%)	p=0.0049
	Acute Bacterial Exacerbations of Chronic Bronchitis in people with Chronic Obstructive Pulmonary disease (ABECB-COPD) (Test n=5,027, Control n=4,830)	-3.5% (-11.6%, 4.6%)	p=0.3993
	Uncomplicated Urinary Tract Infection (uUTI) (Test n=7,957, Control n=7,769)	-10.0% (-14.8%, -5.3%)	p<0.0001
	Any combination of the three indications (ABS, ABECB-COPD or uUTI) (Test n=8,508, Control n=8,289)	-10.0% (-14.6%, -5.5%)	p<0.0001
Total (Tiers 1, 2, and 3)	Acute Bacterial Sinusitis (ABS) (Test n=7,819, Control n=7,793)	-12.8% (-20.7%, -4.9%)	p=0.0015
	Acute Bacterial Exacerbations of Chronic Bronchitis in people with Chronic Obstructive Pulmonary disease (ABECB-COPD) (Test n=6,188, Control n=6,040)	-4.5% (-11.4%, 2.5%)	p=0.2061
	Uncomplicated Urinary Tract Infection (uUTI) (Test n=9,446, Control n=9,313)	-9.0% (-12.8%, -5.1%)	p<0.0001
	Any of the three indications (ABS, ABECB-COPD or UTI) (Test n=10,063, Control n=9,911)	-9.2% (-12.8%, -5.5%)	p<0.0001

* See Data Analysis in Methods section and Table 1 for definitions of tiers.

Participants receiving targeted short-form messages A, B, or C showed a change in new prescription volume versus controls of -7.9% (p<0.0001), -9.4% (p<0.0001), -8.2% (p<0.0001), respectively (Table 2). There was no significant difference in level of prescribing volume resulting from exposure to one message versus another.

Program participation resulted in a significant (p<0.0001) reduction in new prescription volume for the test group (80.1%; 9427/11,774) as compared with the control group (76.2%; 8966/11,774). Test specialty subgroups, as compared with control specialty subgroups, showed a reduction in new prescription volume for PCPs of 4.0% (250/6,201; p<0.0001); urologists, 6.4% (70/1,099; p=0.0002); and all other MDs, 3.6% (98/2,717; p=0.0028). Only nurse practitioners/physician assistants did not show a significant reduction (2.4%; 43/1,757; p=0.0904).

New prescription volume for test participants versus controls decreased significantly across Tiers 1, 2, and 3 for ABS (12.8%) and uUTI (9.0%) following program participation (Table 3). Prescribing volume for ABECB-COPD was not significantly reduced. The differences between indications were not statistically significant: ABS vs. ABECB p=0.3325; ABS vs. uUTI p=0.5686; and ABECB-COPD vs. uUTI p=0.1414.

Emails of targeted short-form messages containing comparative prescribing information, with and without clinical context, were opened at slightly higher rates (10.6%; 2659/25,043 for Message A and 10.8%;2682/24,883 for Message B) than targeted short-form messages containing clinical context alone (9.1%;2318/25,470 for Message C). Denominators for these calculations were the sum of all four waves of emails for each message.

DISCUSSION

To help answer persistent questions regarding the degree of effectiveness associated with different feedback formats designed to change clinical behaviors—and how best to optimize the effect of feedback interventions — we evaluated the effect of targeted short-form messages or CME on prescribing of fluoroquinolones among high prescribers. Studies suggest that multifaceted approaches are likely to be most effective in behavior change, such as combining comparative data on clinical practice with education.[19-22] Results from this *ex post facto* matched control study show that exposure to targeted short-form messages (with and without personalized feedback) and CME significantly reduced fluoroquinolone new prescription volume among PCPs, urologists, and all other physician providers. While targeted short-form messages and CME reduced new prescription volume by 8.5% and 12.3%, respectively (p<0.0001), pairing both targeted short-form messages and education yielded the greatest impact in reducing new prescription volume, by 21.7% (p<0.0001). The difference between this combination and each tactic alone is significant at p<0.0001. Accordingly, to optimize the effect of feedback interventions, education can be considered as a valuable complement to feedback that may provide a synergistic effect on outcomes.

The increased effectiveness of messaging combined with CME, as compared with messaging alone, is suggested by another recent study that showed a 29% decrease in fluoroquinolone prescribing among high-volume antibiotic

prescribers who received peer comparison reports that included education about ways to reduce fluoroquinolone utilization for common diseases such as lower respiratory tract infections and asymptomatic bacteriuria.[23] The study investigators cited the educational feature as a possible explanation for the positive results achieved compared with a Swiss study that did not show any differences in outpatient antibiotic utilization after an intervention that provided peer prescriber comparison reports — but did not provide any educational resources — to prescribers.[24]

Our results also suggest that targeted short-form messages paired with online CME may be a viable alternative to other tactics that, depending on the systems that may or not be in place to carry out these tactics, are thought to be more time-consuming (e.g., carbon copy prescription pads that require collection and evaluation; telephone interviews with patients; day-long, small-group, academic detailing meetings plus follow-up meetings; point of care clinical decision support tools which require several weeks training), expensive (e.g., electronic clinical decision support systems; incentive payments for program participation), and not easily scalable (small group training sessions in communication skills; practice profiling for prescribing rates) drivers of practice change.[10,19,25-35]

Although not directly linked to outcomes measures for new prescription volume or Prescriber Reducers, we observed that targeted short-form messages with subject lines addressing personal fluoroquinolone prescribing (Messages A and B) were opened at slightly higher rates (10.6% and 10.8%, respectively) than targeted short-form messages with a subject line addressing fluoroquinolone safety data only (Message C, 9.1%). This result may suggest that feedback on personal prescribing had a somewhat greater effect on physician engagement than safety data alone and, by extension, was more likely to lead HCPs to education that may influence prescribing behavior.

The effectiveness of feedback on personal prescribing was recently demonstrated by a study in which the Chief Medical Officer for England mailed letters providing personal prescribing feedback to high-prescribing practices (n=791), resulting in a 3.3% reduction in the antibiotic prescribing rate compared with a control group (which received no letter) over a six-month period.[36] However, in contrast to our findings and those from the aforementioned study in England, a recent study by another government agency—the Centers for Medicare and Medicaid Services (CMS)—testing an intervention to reduce opioid prescribing reported an inability to detect a statistically significant effect of a letter on personal prescribing behavior sent to high prescribers from CMS; likely reasons cited for the failure to detect an effect involved whether the letters reached their intended targets and whether the letters, even if appropriately targeted, were effective at altering behavior.[25]

Interestingly, another recent study tested three digitally delivered interventions to reduce antibiotic use in acute respiratory infections among top prescribers in 47 primary care practices in Boston and Los Angeles (n=248).[37] The interventions included a suggested alternative therapy presented to prescribers via electronic health records (EHRs); an invitation to enter a free-text justification of antibiotic selection in the EHR; and an email providing peer comparison of prescribing behavior. Of the three interventions, peer comparison and justification resulted in decreased prescribing (-18.1% and -16.3%, respectively).

While further studies will be necessary to establish the degree of effectiveness of digital (emails, EHR, online education) versus analog (in-person small-group meetings and training sessions, carbon copy prescription pads, letters, telephone interviews) interventions, in our study the reduced new prescription volume among high-volume fluoroquinolone prescribers receiving targeted short-form messages and CME suggests that each of these online tactics may be superior to analog tactics as interventions for reducing prescribing.

It is also important to consider that many of the studies examining audit and feedback for antibiotic prescribing consist of relatively small sample sizes.[13] Our capacity to access a large volume of practitioner-level prescribing data and deliver comparative prescribing information to a large population of practitioners is a major strength of our study and has direct implications for impact on public health.

Possible limitations of our study are the inability to determine if all reductions in prescribing were for inappropriate uses; the inability to control for the potential influence of local antimicrobial stewardship programs or influences other than the intervention studied here; the inconsistent nature of Tier 2 and 3 medical claims data used to evaluate new prescribing volume by indication; the short-term nature of this study; the timing of our study in relation to the FDA safety alert; and the inability to evaluate whether reduced prescribing associated with Message C is a durable result, as the subject line of this message ("Serious side effects prompt FDA to change fluoroquinolone labeling") may provide an increased social incentive to respond due to participants' familiarity with the FDA. Finally, in contrast to many other studies where feedback is delivered by a peer or an employer, this intervention was delivered by Medscape, an online provider of medical education and news with a large membership database. Medscape's ubiquity in the medical community may present a challenge in distinguishing whether the effects attributed to our study interventions were not to some degree associated with the intervention provider. Additional studies will be needed to determine if this approach is equivalent to that delivered by a peer or employer, and to evaluate the applicability of our study results to other classes of drugs without labelling changes or safety warnings to attempt to isolate specific factors most responsible for driving the observed behavior change.

Several factors could explain our findings. We targeted a single behavior (antibiotic prescribing), addressed a measurable outcome (number of fluoroquinolone prescriptions), and communicated a clear action to test subjects (i.e., avoid prescribing fluoroquinolones for particular indications when there is an alternative).[12,16] We also designed and targeted the intervention to have the greatest potential effect. HCPs with lower baseline compliance with the desired outcome (i.e., higher prescribers of fluoroquinolones) were selected for the

intervention, as reviews of audit and feedback trials have demonstrated that low baseline performance is associated with a larger effect.[12,16]

CONCLUSIONS

Our study, conducted as part of an FDA initiative to reduce preventable harm from drugs, shows that targeted short-form messages on appropriate prescribing of oral fluoroquinolones reduced fluoroquinolone prescribing among high prescribers, and email targeted short-form messages with subject lines addressing personal fluoroquinolone prescribing were opened at a slightly higher rate than targeted short-form messages with subject lines addressing fluoroquinolone safety data only. Targeted short-form messages and CME each resulted in significant new prescription volume reduction versus control. Combining targeted short-form messages with CME yielded the greatest percentage of HCPs with reduced fluoroquinolone prescribing (80.1% for test versus 76.2% reduction for matched control [p<0.0001]). Targeted short-form messages paired with online CME is a fast-acting, easily implemented intervention for reducing prescribing of fluoroquinolones.

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CONFLICT OF INTEREST

All authors declared no conflict of interest.

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Original Research

Effect of different splitting techniques on the characteristics of divided tablets of five commonly split drug products in Jordan

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Abstract

Objective: To determine the accuracy, variability, and weight uniformity of tablet subdivision techniques utilized to divide the tablets of five drug products that are commonly prescribed for use as half tablets in Jordan.

Methods: Ten random tablets of five commonly subdivided drug products were weighed and subdivided using three subdivision techniques: hand breaking, kitchen knife, and tablet cutter. The five commonly subdivided drug products (warfarin 5 mg, levothyroxine 50 µg, levothyroxine 100 µg, candesartan 16 mg, and carvedilol 25 mg) were weighed. The weights were analyzed for acceptance, accuracy, and variability. Weight variation acceptance criteria were adopted in this work as a tool to indicate the properness of the subdivision techniques used to produce acceptable half tablets. Other relevant physical characteristics of the five products such as tablet shape, dimensions, face curvature, score depth, and crushing strength were measured.

Results: All tablets were round in shape, had weights that ranged between 100.63 mg (standard deviation=0.99) and 379.04 mg (standard deviation=3.00), and had crushing strengths that ranged between 23.29 N (standard deviation=3.58)and 103.35 N (standard deviation=14.98). Both candesartan and carvedilol were bi-convex in shape with an extent of face curvature equal to about 33%. In addition, percentage score depth of the tablets had a range between 0% and 24%. The accuracy and variability of subdivision varied according to the subdivision technique used and tablet characteristics. Accuracy range was between 81% and 109.8%. Moreover, the relative standard deviation was between 1.5% and 17.4%. Warfarin 5 mg subdivided tablets failed the weight variation test regardless of the subdivision technique used. Subdivision by hand produced half tablets that were acceptable for levothyroxine 50 µg and levothyroxine 100 µg. Subdivision by knife produced half tablets that were acceptable only for candesartan tablets. However, the tablet cutter produced half tablets that passed the weight variation test for four out of the five drug products tested in this study.

Conclusions: The tablet cutter performed better than the other subdivision techniques used. It produced half tablets that passed the weight uniformity test for four drug products out of the five.

Keywords

Self Administration; Tablets; Medication Errors; Drug Prescriptions; Reproducibility of Results; Jordan

INTRODUCTION

Tablet subdivision can be used by patients for a variety of reasons.[1-3] These reasons include reduced doses of the medication, smaller parts of the tablets to ease swallowing, and/or economic factors for which subdividing a higher strength drug product might be less expensive during the course of therapy. However, subdividing tablets might not be a recommended practice. Tablets for controlled release purposes and orally disintegrating tablets might lose predesigned properties when subdivided.[4-6] In addition, tablet subdivision might result in two halves that are different in weight and in the corresponding amount of active ingredient.[7-9] This can have a serious consequence for potent drugs with a narrow therapeutic index.[1,9-11] In an ideal situation, a split tablet should result in two halves that have equal weights and contain the same content of the drug. However, in real life practice, there is a variation in the degree of accuracy in obtaining equal halves.[8] Several factors could influence this accuracy such as the presence of scores on the tablet surfaces, depth of the scores, surface flatness of the tablet, tablet size, tablet shape, tablet crushing strength (hardness), tablet composition (excipients), and the technique used for subdivision of the tablet.[2,7,9,12-14] The presence of scores on a tablet surface could increase the chance of obtaining accurate subdivision especially if the scores are deep and are present on both faces.[13] In some cases the presence of scores can be misleading if they are not deep enough to facilitate subdivision.[7] Tablets with flat surfaces are expected to be more accurately subdivided into two equal halves compared to tablets with curved surfaces.[7] In addition, tablets that are oblong are expected to be more accurately subdivided.[12] Researchers reported that the choice of excipients such as fillers and binders affected the accuracy of tablet subdivision.[14] They found that dicalcium phosphate dihydrate produced tablets with higher subdivision accuracy compared to tablets made of microcrystalline cellulose. However, combination of the binder hydroxypropylcellulose with microcrystalline cellulose in the formulation improved the subdivision accuracy of the tablets.[14] Several techniques such as by hand, by knife, by tablet cutter, or by teeth can be used in order to subdivide tablets.[15]

Several studies have investigated the accuracy of different tablet subdivision techniques.[7,8,16] For example, van Riet-Nales *et al*. investigated the accuracy of tablet subdivision associated with the use of three subdivision techniques. Researchers compared the results of subdividing

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paracetamol 500 mg tablets which were round, flat, and uncoated obtained by tablet splitter (cutter), kitchen knife, and hand. They found that the accuracy of tablet subdivision was best achieved by hand.[8] Moreover, Habib *et al*. studied the accuracy of tablet subdivision of salbutamol tablets by hand and tablet cutter.[16] The results showed that the use of a tablet cutter is superior to hand subdivision in producing equal half tablets.

In 2017 the tablet subdivision practices in Jordan as well as the frequency of using different techniques for tablet subdivision were investigated.[15] The results showed that the majority of participants (63.5%) subdivided their drug products by hand, followed by kitchen knife (14.3%) and tablet cutter (9.0%). In addition, It was found that warfarin 5 mg, levothyroxine 50 µg, levothyroxine 100 µg, candesartan 16 mg, and carvedilol 25 mg are among the ten most commonly subdivided drug products.[15] The objective of this study was to investigate the accuracy, variability, and weight uniformity of half tablets produced by subdividing five commonly split medications in Jordan by different tablet subdivision techniques.

METHODS

The study protocol was approved by the Jordan University of Science and Technology Institutional Review Board (Research Number 8/101/2016) on 15 December 2016.

Tablets of five commonly subdivided medications in Jordan were used in this study. These drug products were warfarin sodium 5 mg (Orfarin® 5 mg, Lot #1793373, expiry date 06-2019; Orion Corporation, Finland), levothyroxine 100 µg (Euthyrox® 100 µg, Lot #244669, expiry date 10-2020; Merck KGaA, Germany), levothyroxine 50 µg (Euthyrox® 50 µg, Lot #247655), expiry date 12-2020; Merck KGaA, Germany), candesartan 16 mg (Blopress® 16 mg, Lot #756097, expiry date 04-2021; The Arab Pharmaceutical Manufacturing Co. Ltd., Jordan), and carvedilol 25 mg (Carvidol® 25 mg, Lot #18111, expiry date 02-2021; Pharma International Co., Jordan). Tablet dimensions were determined using a Vernier caliper. The thickness and diameter of ten tablets of each drug product were measured. The thickness of bi-convex tablets was measured in the center and on the side of the tablet. The difference was used as an indication of the extent of face curvature.

$$Extent\ of\ face\ curvature\ (\%) = \frac{thickness\ in\ the\ middle - thickness\ at\ the\ side}{thickness\ in\ the\ middle} \times 100\%$$

In addition, the thickness was measured from inside the score-line(s) if present on the tablet and used as an indication of score depth.

$$Score\ depth\ (\%) = \frac{thickness\ in\ the\ middle - thickness\ through\ score-line(s)}{thickness\ in\ the\ middle} \times 100\%$$

The crushing strength of tablets was analyzed using a hardness tester (Biobase Tablet Hardness Tester YD-3, Jinan, China). Ten tablets of each drug were analyzed. A 32-year-old right-handed female pharmacist volunteered to carry out all tablets subdivisions. Ten tablets of each drug product were subdivided by each of the studied subdivision techniques: by hand, by kitchen knife, and by a tablet cutter. The weight of each tablet and the resulting subdivisions were measured using a digital balance (Phoenix Instument-ASN324, Garbsen, Germany). All subdivisions were performed along the score-line if present. Subdivision by a kitchen knife was performed by placing the tablet on the bench top, placing the sharp side of the blade along the score-line, if present, and then pressing on the non-sharp end of the blade in one hand while holding the handle in the other hand. The kitchen knife blade was made of stainless steel with a length of 7.8 cm, and the blade thickness was 1.0 mm measured midway of the blade. The handle of the knife was made of plastic with a length of 11.4 cm, and the other two dimensions were 1.4 cm and 2.1 cm measured midway of the handle. The tablet cutter used in this study was a non-brand plastic splitter commonly available in the market in Jordan. The dimensions of the tablet cutter box were 7.0 cm, 2.9 cm, and 2.5 cm. The metal blade of the cutter had a thickness of 0.30 mm at the middle point. The tablets were placed at the closest point towards the hinge of the cutter inside the designated area on the base plate of the cutter which was parallel to the horizontal plane along the x-axis. This designated area resembled an oval in shape with axis of symmetry (major axis) along the direction of the cutting blade with a length of 3.0 cm. The wider region of the oval shaped area laid closer towards the hinge of the cutter. The maximum width of the oval region was 2.0 cm. This designated area had a wall (ridge) of a height of 4.0 mm all around it except for the side closest to the hinge of the cutter along the major axis. This opening in the wall had a width of 4.0 mm and was centered under the point where the cutting blade starts cutting the placed tablets. The distance between the hinge and the wall opening is equal to 1.25 cm. With this geometry, it is expected that the radii of tablets tested in this study had little effect on the distance between the hinge of the tablet cutter and the point at which the cutting blade starts acting on the placed tablets. Somogyi *et al*. proposed schemes of forces during tablet breaking for tablets of different shapes.[17] The geometry of the used device could influence these schemes. However, we anticipate that the scheme of forces during tablet breaking for all tested tablets in this study was similar to what was depicted by Somogyi *et al*. for a conventional splitting device available in the European market for round tablets.[17] Accuracy and variability (precision) of tablet subdivision were evaluated according to the suggestions of van Riet-Nales *et al*.[8]

$$Accuracy\ (\%) = \left[1 - \frac{\frac{tablet\ weight}{2} - split\ portion\ weight}{\frac{tablet\ weight}{2}}\right] \times 100\%$$

In addition, a two-tailed Welch's t-test statistical analysis (significance level=0.05) was performed to assess the means of % weights of the smaller tablet fractions produced by the applied subdivision techniques for each drug product. Accordingly, the means of % weights of the smaller fractions subdivided by the tablet cutter were assessed in relation to those subdivided by hand and those subdivided by knife for each drug product. In addition, the means of % weights of the smaller fractions subdivided by hand were assessed in relation to those subdivided by the knife for each drug product. A weight uniformity test was performed on half tablets produced by the subdivision techniques applied in this study. The weight uniformity test

Table 1. Tablet properties of drug products used in the study (n=10)

Drug product	Tablet weight	Tablet diameter	Thickness in the middle	Extent of face curvature (%)	Score depth (%)	Crushing strength (N)	Tablet shape	Presence of score-line
Warfarin	136.7 SD=1.58	7.05 SD=0.04	2.97 SD=0.02	0	23.77 SD=1.57	39.24 SD=5.01	Round	One side
Levothyroxine 50 µg	100.93 SD=1.32	7.13 SD=0.03	2.20 SD=0.04	0	21.63 SD=2.96	49.87 SD=7.22	Round	Both sides
Levothyroxine 100 µg	100.63 SD=0.99	7.12 SD=0.03	2.22 SD=0.03	0	22.97 SD=2.24	41.00 SD=9.56	Round	Both sides
Candesartan	130.55 SD=3.19	7.18 SD=0.05	3.14 SD=0.07	33.64 SD=3.62	10.98 SD=2.69	23.29 SD=3.58	Round	One side
Carvedilol	379.04 SD=3.00	10.52 SD=0.03	3.98 SD=0.04	30.94 SD=2.45	0	103.35 SD=14.98	Round	Non-scored

SD: standard deviation

for half tablets was applied according to the suggestions made by Polli *et al*. which was adapted from the U.S. Pharmacopeia's (USP) <905> "Uniformity of Dosage Units" test for whole tablets.[18,19] Accordingly, in this study 30 tablets of each drug product were weighed individually and the average weight was calculated. The average weight was divided by two to obtain an average weight for a uniformly subdivided half tablet. Ten tablets of each drug product were subdivided using one of the subdivision techniques applied in this study. The produced half tablets were weighed individually. The half tablets passed the test if no more than one half tablet of the produced twenty parts weighed less than 85% or greater than 115% of the average weight of the uniformly subdivided half tablet and no half tablet weighed less than 75% or greater than 125% of the average weight of the uniformly subdivided half tablet. In addition, the RSD (relative standard deviation) for the weights of the obtained 20 parts (half tablets) should be less than or equal to 10%.

If two half tablets weighed less than 85% or greater than 115% and no half tablet was less than 75% or greater than 125% of the average weight of the uniformly subdivided half tablet or if the RSD was greater than 10%, then the other 20 tablets were subdivided to produce an additional 40 parts which were individually weighed. The tablet halves were accepted if out of the 60 parts only two half tablets weighed outside the range of 85%-115% of the average weight of the uniformly subdivided half tablet and no half tablet was outside the range of 75%-125% of the average weight of the uniformly subdivided half tablet. In addition, the RSD should be less than or equal to 10%. The half tablets were rejected if more than two tablets weighed outside the range 85%-115%, if a half tablet was outside the range 75%-125% of the average weight of the uniformly subdivided half tablet, or if the RSD was greater than 10%. Similar testing criteria for weight uniformity adapted from the European Pharmacopoeia were used by other researchers.[8] In addition, the % weight of subdivided tablets were plotted against their number. Horizontal lines corresponding to the 85% and 115% weight limits were added to the plots in order to represent the individual tablet subdivision % weight in relation to these acceptance limits.

RESULTS

Table 1 shows the properties of the subdivided tablets of the studied drug products. All tablets had a round shape. The average weights of these tablets were between 100.63 mg (SD=0.99) and 379.04 mg (SD=3.00). Tablets of warfarin, levothyroxine 50 µg, levothyroxine 100 µg, and candesartan had relatively similar diameters. However, their thicknesses varied according to the corresponding weight. Carvedilol tablets had the largest weight, diameter, and thickness. In addition, they were the only ones without scores. Tablets of levothyroxine 50 µg and levothyroxine 100 µg had scores on both sides. Both candesartan and carvedilol tablets were bi-convex in shape with a similar extent of face curvature. Warfarin had the highest percent score depth among these tablets. The tablets had crushing strength values that ranged between 23.29 N (SD=3.58) and 103.35 N (SD=14.98). Candesartan tablets had the lowest crushing strength while carvedilol tablets had the highest crushing strength.

Table 2. Average accuracy (%) and relative standard deviation (RSD) of tablet subdivision of the subdivision techniques

Fraction	Average accuracy (%) by hand	RSD by hand (%)	Average accuracy (%) by cutter	RSD by cutter (%)	Average accuracy (%) by knife	RSD by knife (%)
Warfarin						
Small	90.7	9.0	89.8	15.7	87.4	8.0
Large	103.9	4.8	101.7	1.8	103.6	7.7
Levothyroxine 50 µg						
Small	89.7	3.2	93.9	2.6	86.3	6.2
Large	106.5	2.7	102.0	2.7	100.0	5.1
Levothyroxine 100 µg						
Small	90.3	2.0	91.7	3.3	81.0	17.4
Large	104.8	1.4	103.2	2.9	97.5	3.7
Candesartan						
Small	88.8	7.6	95.0	3.2	93.1	2.5
Large	109.8	6.1	103.4	2.9	102.4	3.5
Carvedilol						
Small	87.8	13.9	95.2	4.3	91.7	8.3
Large	108.3	5.1	103.8	4.0	107.0	7.1

Table 3. Summary of weight variation test results for half tablets produced by the different subdivision techniques

Subdivision technique	Half tablets outside 85%-115% and within 75%-125% (n=20)	Number of half tablets outside 75%-125% (n=20)	RSD (%) (n=20)	Result
Warfarin				
Hand	1	1	9.7	Reject
Cutter	0	1	12.1	Reject
Knife	5	0	11.5	Reject
Levothyroxine 50 µg				
Hand	1	0	9.3	Accept
Cutter	0	0	5.3	Accept
Knife	3	0	9.1	Reject
Levothyroxine 100 µg				
Hand	0	0	3.8	Accept
Cutter	0	0	6.9	Accept
Knife	3	2	14.6	Reject
Candesartan				
Hand	4	1	12.7	Reject
Cutter	0	0	5.4	Accept
Knife	0	0	5.8	Accept
Carvedilol				
Hand	2	1	14.2	Reject
Cutter	0	0	6.1	Accept
Knife	4	0	11.0	Reject

Table 2 shows the accuracy of tablet subdivision of the smaller and larger halves produced by different techniques. It can be seen that the accuracy range for the smaller fractions was between 81.0% and 95.2% for all techniques applied in this study. Moreover, the accuracy range for the larger fractions was between 97.5% and 109.8%. In addition, Table 2 shows that the range of the RSD was between 2.0% and 17.4% for the smaller fractions and was between 1.4% and 7.7% for the larger fractions. According to the Welch's t-test statistical analysis, there was a significant difference between the means of % weights of the smaller fractions of subdivided tablets in the following cases: subdivision by the tablet cutter compared to subdivision by hand for levothyroxine 50 µg (p=0.003) and candesartan (p=0.022) tablets and subdivision by the tablet cutter compared to subdivision by knife for levothyroxine 50 µg (p=0.001) and levothyroxine 100 µg (p=0.041) tablets.

A summary of the results of the weight variation test performed on the half tablets produced by the different subdivision techniques is shown in Table 3. No subdivision technique used in this study produced warfarin half tablets that passed the test of weight variation. However, subdividing tablets of levothyroxine 50 µg and levothyroxine 100 µg by hand and by the tablet cutter produced half tablets that passed the test. Subdividing tablets of candesartan by the tablet cutter and by knife produced half tablets that passed the test. Moreover, subdividing carvedilol tablets only by the tablet cutter produced half tablets that passed the test.

Figure 1 shows plots of the percentage weights of the 20 tablet divisions of each drug product produced by the applied subdivision techniques. The lower and upper horizontal lines in each plot represent the acceptance limits of 85% and 115 % of the weights of perfectly subdivided half tablets.

DISCUSSION

This was the first study to investigate the accuracy of tablet subdivision using different subdivision techniques for five of the most commonly subdivided drug products in Jordan.[15]

The tablets of the five drug products used in this study varied in terms of weight, diameter, thickness, presence of score, score depth, face curvature, and crushing strength. The closest average percent of accuracy to being perfectly subdivided of the smaller fractions was obtained for carvedilol tablets subdivided by the tablet cutter (Table 2). In this case, the larger fractions of subdivided carvedilol tablets had an average percent accuracy of 103.8 and the subdivided tablets passed the weight variation test (Table 3). This is probably due to the larger size of the tablets which facilitated more accurate subdivision using the tablet cutter. Thus, a score-line was not necessary to obtain an accurate tablet subdivision using the tablet cutter. In addition, the closest average percent of accuracy to being perfectly subdivided of the larger fractions was obtained for levothyroxine 50 µg tablets subdivided by knife. However, the smaller fractions of subdivided levothyroxine 50 µg tablets had an average percent accuracy equal to 86.3 and the subdivided tablets did not pass the weight variation test (Table 3). It is important to note that patients might use either the smaller or the larger subdivided fraction and discard the other, or might use one subdivided fraction of the tablet and save the other fraction for later use. Therefore, it is important to consider the accuracy of subdivision for both fractions. In addition, the least variability (lowest RSD value) for the percent accuracy values of the smaller subdivided fractions was obtained for levothyroxine 100 µg subdivided by hand. This is probably due to the fact that these tablets had score-lines on both faces of the tablets, the tablets faces were flat, and their percent score depth was relatively high.

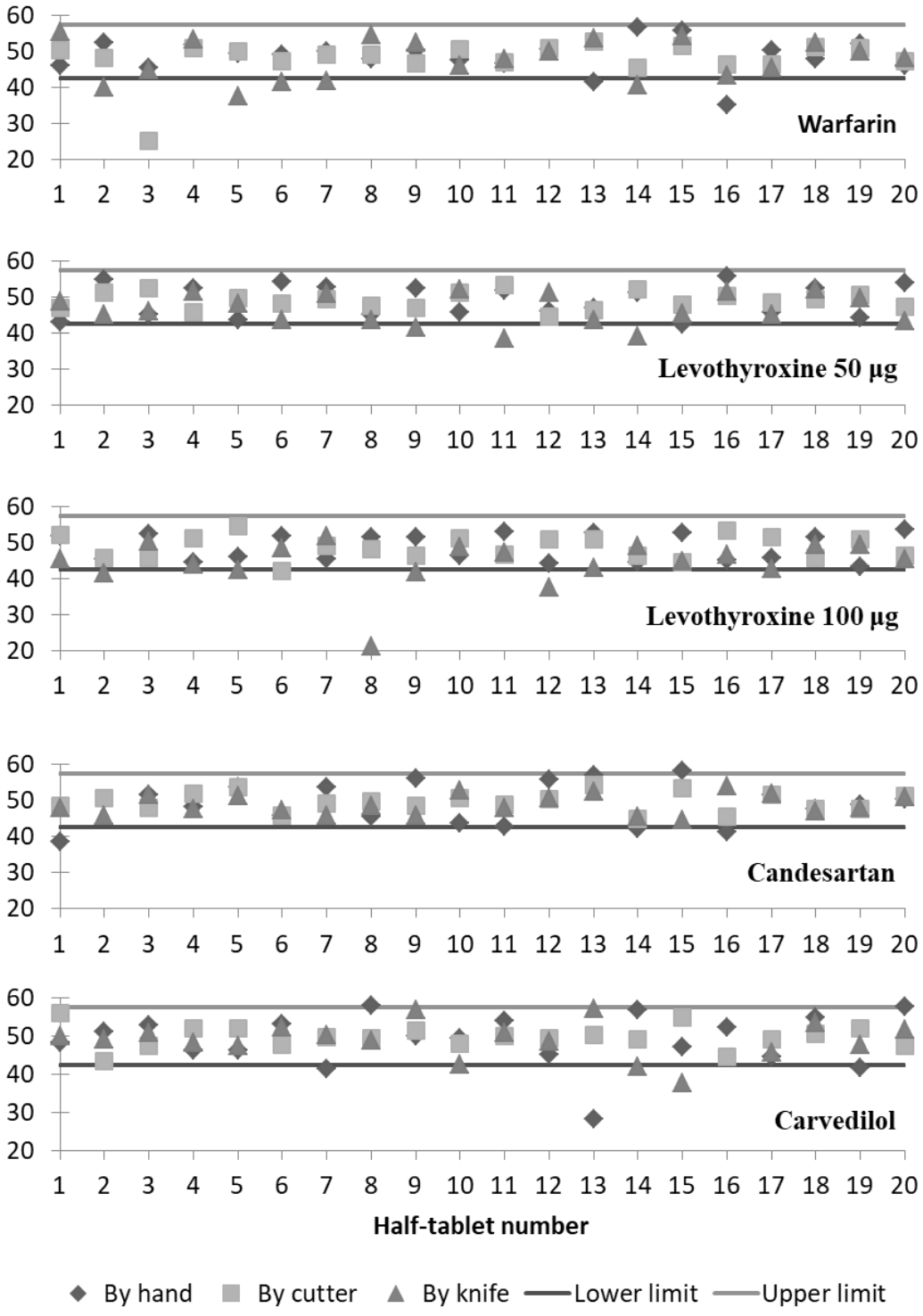

Figure 1. Plots of % weight vs. half-tablet number of subdivided tablets of the drug products using different subdivision techniques.

The results of the weight uniformity test used in this study show that the acceptance of the weights of produced half tablets depends upon both tablet properties and used subdivision technique. For example, warfarin half tablets failed the test regardless of the applied subdivision technique. Warfarin tablets were scored on one side, had flat faces, and a score depth of 24% which seems to be suitable for tablet subdivision. However, results of the weight uniformity test were opposite to that (Table 3). Moreover, Figure 1 shows a number of subdivided tablets of warfarin beneath the 85% limit line for all of the applied subdivision techniques. This could be due to the fact that these tablets had a relatively wide score line. The score line on warfarin tablets was about twice the thickness of the knife's blade and several times the thickness of the cutter's blade. Even for subdivision by hand, having a wide score line on tablets could lead to increased probability of having unequal and variable subdivisions. Interestingly, the results

of the current study differ from the results of a previously published study that found that subdividing warfarin tablets by a kitchen knife produced weight-uniform half tablets although both batches were produced by the same manufacturer.[7] This discrepancy can be attributed to differences in tablet thickness and hardness. According to the previously published study, the thickness and hardness (crushing strength) of studied warfarin tablets were 2.86 mm (SD=0.01) and 68.9 N (SD=3.4), respectively. In addition, these tablets had a percentage score depth of 28%.[7] Therefore, tablets of the previously tested batch had less thickness, higher percentage score depth, and higher tablet hardness. The aforementioned finding indicates that even with the same manufacturer, the practice of subdividing tablets may or may not result in acceptable subdivisions. In addition, different brands of warfarin tablets are expected to show dissimilar results due to variations in tablet properties. For example, subdivisions of Coumadin® 5 mg tablets, which are round, scored, and non-flat, passed the weight uniformity test set by the researchers when subdivided by a tablet cutter.[18]

Figure 1 shows the distribution of half tablet % weights of levothyroxine 50 µg and levothyroxine 100 µg compared to the 85-115% limits. Levothyroxine 50 µg and levothyroxine 100 µg half tablets were accepted in the weight uniformity test (Table 3) for subdivision by hand and by the tablet cutter. However, it can be seen that a number of half tablets were under the 85% limit for subdivision by knife. Other researchers investigated the subdivision of tablets of other marketed brands of levothyroxine by hand and by a tablet cutter.[11] They found that the two applied subdivision methods produced subdivided tablets that failed the content uniformity test at a rate higher than that for whole tablets. Variations in the formulation aspects in addition to other pre-mentioned variations in tablet properties and properties of the tablet cutter used could lead to different acceptance results for different drug products of the same active ingredient. Several of the % weights of the produced half tablets subdivided by hand were outside the acceptable 85-115% limits for candesartan tablets (Table 3 and Figure 1). This is probably due to the fact that candesartan tablets are bi-convex in shape which makes them more difficult to be subdivided by hand. Another study investigating the uniformity of tablet subdivision by hand and by a tablet cutter of another brand of candesartan found that both of these techniques produced tablet subdivisions that failed the content uniformity test.[20] Investigated tablets of candesartan 16 mg were round and scored on one side and had a similar size to the tablets used in this study.

Carvedilol tablets were bi-convex in shape and non-scored which resulted in failing the uniformity test of half tablets produced by hand and by knife (Table 3). Accordingly, Figure 1 shows the % weights of a number of subdivided half tablets outside the 85-115% limits for both by hand and by knife subdivision techniques. This finding does not coincide with what was suggested by Somogyi *et al*. regarding the method of choice for subdividing large unscored uncoated tablets (Algozone® tablets).[17] Somogyi *et al*. suggested that for such tablets a kitchen knife is the preferable subdivision technique. However, carvedilol tablets were bi-convex while those of Algozone® tablets were flat. This property would make the tablet more difficult to break by knife or by hand. A study on the subdivision of tablets by knife which included Dilatrend® tablets (carvedilol 25 mg) showed that the subdivision of the tablets of this drug product failed the weight uniformity test.[9] However, it is important to note that these tablets were round, flat-faced, and scored on both sides and had a smaller size when compared to the carvedilol tablets used in this study.

Most patients in Jordan use their hands to subdivide tablets.[15] However, the results of this study showed that hand subdivision produced half tablets that do not pass the weight uniformity test in the cases of warfarin, candesartan, and carvedilol. However, subdivision of tablets using the tablet cutter produced half tablets that were accepted for four of the five studied drugs in the current study.

Administering potent drugs with low therapeutic index as subdivided tablets can be of clinical significance. Thus, a small change in the dose can lead to the drug being ineffective or increasing the risk of side effects. All drugs tested in this study are potent and some with narrow therapeutic index (warfarin and levothyroxine). In addition, in most of cases these drugs are used chronically. Minimal dose change in one direction might lead to serious consequences. For example, if the patient routinely administers the larger subdivision fraction of the tablet and discards the other, then an unnecessary build up of plasma concentration might lead to subjecting the patient to additional risk of side effects. In addition, if the patient routinely administers the smaller fraction, then a failure to achieve a required therapeutic level might also arise. The pharmacists are required to educate patients about the best available method for subdivision of tablets. The current study has limitations. The subdivision of tablets was conducted by a pharmacist who was expected to be more accurate than the patient in performing the subdivisions. In addition, results may not be generalizable to patients with physical disabilities. Moreover, one kind of tablet cutter and kitchen knife was used, but different tablet cutters and kitchen knives could bring different results.

CONCLUSIONS

The effectiveness of subdivision techniques to produce uniform weights of half tablets varies according to tablet properties of the drug product and the subdivision technique. In this study, the tablet cutter seemed to be the most suitable technique for producing uniformly subdivided half tablets for all five studied drug products except for warfarin.

CONFLICT OF INTEREST

The authors report no conflicts of interest.

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Original Research

Inpatient prescribing of dual antiplatelet therapy according to the guidelines: a prospective intervention study

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Abstract

Background: In dual antiplatelet therapy (DAPT), low-dose acetylsalicylic acid is combined with a P2Y12 inhibitor. However, combining antithrombotic agents increases the risk of bleeding. Guidelines on DAPT recommend using this combination for a limited period of between three weeks and 30 months. This implies the risk of DAPT being erroneously continued after the intended stop date.

Objective: The primary objective of this study is to assess the proportion of hospitalized patients treated with DAPT whose treatment deviated erroneously and unintentionally from the guidelines. We also assessed risk factors and the effect of a pharmacist intervention.

Methods: All patients admitted to the Spaarne Gasthuis (Haarlem/ Hoofddorp, the Netherlands) who used DAPT between March 25th, 2019, and June 14th, 2019, were, in addition to receiving regular care, reviewed to assess whether their therapy was in line with the guidelines' recommendation and whether deviations were unintended and erroneous. In the event of an unintended deviation, the pharmacist intervened by contacting the prescriber by phone and giving advice to adjust the antithrombotic therapy in line with the guideline.

Results: We included 411 patients, of whom 21 patients (5.1%) had a treatment that deviated from the guidelines. For 11 patients (2.7%), the deviation was unintended and erroneous. The major risk factor for erroneous deviation was the use of DAPT before hospital admission (OR 18.7; 95%CI 4.79–72.7). In patients who used DAPT before admission, 18 out of 58 (31.0%) had a deviation from the guidelines of whom 8 (13.8%) were erroneous. For these eight patients, the pharmacist contacted the prescriber, and in these cases the therapy was adjusted in line with the guidelines.

Conclusions: Adherence to the guidelines recommending DAPT was high within the hospital. However, patients who used DAPT before hospital admission had a higher risk of erroneous prescription of DAPT. Intervention by a pharmacist increased adherence to guidelines and may reduce the number of preventable bleeding cases.

Keywords

Platelet Aggregation Inhibitors; Fibrinolytic Agents; Guideline Adherence; Medication Errors; Hemorrhage; Risk Factors; Pharmacists; Clinical Audit; Netherlands

INTRODUCTION

The use of antithrombotic agents involves a delicate balance between the risk of bleeding and the risk of thrombotic events.[1] Thrombocyte aggregation inhibitors (TARs) are used to prevent thrombo-embolic events. Dual antiplatelet therapy (DAPT) is the simultaneous use of two TARs and is recommended for various cardiologic, neurologic and surgical indications in which the need to prevent thrombo-embolic events outweighs the increased risk of bleeding (Table 1).[2-9] The use of both acetylsalicylic acid and clopidogrel is associated with a 1.4 to 1.6 times greater risk of bleeding compared to acetylsalicylic acid monotherapy and a 1.5 times increased risk of fatal bleeding.[10-13] In the guidelines, DAPT is only recommended for a restricted time depending on the indication, the individual risk of thrombo-embolic events and the individual risk of bleeding (Table 1).

In the first period after events such as myocardial infarctions and cerebrovascular accident or after interventions such as percutaneous coronary intervention (PCI) and coronary artery bypass grafting, the risk of thrombo-embolic events is the highest, and treatment with DAPT is indicated. However, DAPT is not intended to be continued indefinitely, implying a risk of erroneous continuation beyond the intended stop date. Continuation results in an increased risk of bleeding with no added benefit for the patient. These errors negatively affect the benefit-to-risk ratio of DAPT, so non-adherence to the guidelines should be avoided.[14,15] In a study by Warlé-van Herwaarden *et al*. in a Dutch community pharmacy, 24% of all therapies with DAPT were found to not be prescribed in accordance with the guidelines.[16] Nearly half of these non-adhering therapies were a result of DAPT continuation beyond the recommended treatment period. Breuckmann *et al*. found a 38.2% level of compliance with European Society of Cardiology (ESC) guidelines for unstable angina pectoris in German hospitals.[17]

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Table 1. Guidelines with the recommendations for dual antiplatelet therapy

Indication for DAPT	Recommended duration of DAPT	Guideline (reference #)
Minor non-cardioembolic ischemic stroke (NIHSS score≤3) who did not receive IV alteplase	ASA + clopidogrel; 21 days	2,3
Acute coronary syndrome	DAPT; 3-36 months, in general 12 months	4
PCI in stable CAD setting	DAPT; 1-12 months	4
TAVI without high bleeding risk	ASA + clopidogrel; 3-6 months	5
Below the knee bypass with a prosthetic graft	ASA + clopidogrel; at least 1 year	6,7
Carotid artery stenting	ASA + clopidogrel; at least 1 month	8
Revascularization percutaneous in patients with lower extremity artery disease or infra-inguinal stent implementation	ASA + clopidogrel; at least 1 month	6,7,9

DAPT: dual antiplatelet therapy; NIHSS: National Institutes of Health Stroke Scale; PCI: Percutaneous Coronary Intervention; CAD: Coronary artery disease; TAVI: Transcatheter aortic valve implantation; ASA: acetylsalicylic acid

The majority of therapies with DAPT begin during hospital admission and continue after discharge. It is a pharmacist's duty to prevent medication errors and to reduce erroneous non-adherence with guidelines in patients using DAPT. However, it is unknown whether deviations occur due to erroneous initiation of DAPT during admission or whether deviations occur due to erroneous continuation of DAPT after the intended stop date. To distinguish between erroneous initiation during hospital admission and erroneous continuation after the intended stop date, we reviewed all patients using DAPT during their hospital stay. The primary objective of this study was to assess the proportion of hospitalized patients treated with DAPT whose treatment deviated erroneously and unintentionally from the guidelines outlined in Table 1. The secondary objectives were to assess potential risk factors for erroneous deviation from the guidelines and to assess the impact of a pharmacist's intervention on adherence to the guidelines.

METHODS

Study population

This prospective intervention study was initiated by the Pharmacy Foundation of Haarlem Hospitals (Haarlem, the Netherlands), the hospital pharmacy providing pharmaceutical care for the teaching hospital Spaarne Gasthuis (Haarlem/ Hoofddorp, the Netherlands). All patients over the age of 18 admitted between March 25th, 2019, and June 14th, 2019, to the Spaarne Gasthuis and using low-dose acetylsalicylic acid or carbasalate calcium (≤ 100 mg/day) and a P2Y12 inhibitor (clopidogrel, prasugrel or ticagrelor) were included in this study. Carbasalate calcium is a chelate of calcium acetylsalicylate and urea and is converted into acetylsalicylic acid in the gastrointestinal tract. Patients using carbasalate calcium were therefore analyzed as acetylsalicylic acid users. Patients using vitamin K antagonists, direct oral anticoagulants (DOACs), heparin or therapeutic doses of low-molecular-weight heparin (nadroparin >5700 IE/day or equivalent doses) as therapeutic anticoagulants in addition to DAPT were excluded from this study. We excluded these patients because the combination of DAPT with an anti-coagulant is used for the treatment of at least two indications, making the therapy much more complex and not comparable to treatment with DAPT alone. For patients who were readmitted during the study period only the first admission was included.

Study design and flow

At Spaarne Gasthuis, the hospital information system Epic, version 2019 (Epic, Verona, WI), featuring integrated computerized physician order entry, is used. In Epic, we built a patient list that presents all inpatients using DAPT. The medical records of these patients, including the physician's notes and the prescribed medications, were reviewed daily during weekdays by a pharmacist or pharmacist in training on top of regular medication surveillance. Patients admitted during the weekend or on a holiday were reviewed the next working day if they were still hospitalized. All pharmacists and pharmacists in training were trained in the indications and treatment guidelines for DAPT in advance. Regular medication surveillance consists of surveillance for drug-drug interactions and duplicate medication alerts, among others, using the database built and maintained by the Royal Dutch Association for the Advancement of Pharmacy. These alerts are shown to the physician during order entry and are subsequently reviewed by a pharmacist. During the study period, for all patients on the patient list, potential indications for DAPT were searched for in the patient's medical records. Both the medical history as described in the notes of the admitting physician and the notes of previous admissions were searched. During admission, the patient's medical history is written in the admission note, including information from previous admissions and information from the general practitioner and the patient. If the information was insufficient, the physician was contacted and asked to contact the patient's previous healthcare providers for more information. Subsequently, the potential indications for DAPT were compared with the indications as described in the guidelines in Table 1.[5-9] If a deviation was present, the patient's medical record was searched for notes of whether there was a reason to intentionally deviate from the guidelines. The pharmacist in training discussed with a pharmacist whether the reason to deviate was clinically sound. In case of disagreement, a third pharmacist decided. If there was a deviation and no clinically sound reason to intentionally deviate from the guidelines was found in the patient's medical record, an intervention was performed. In the intervention, the treating physician was contacted by telephone. The physician was informed about the indication and duration of DAPT, how this treatment deviated from the guidelines and that a potential reason was not found in the patient's medical record to deviate from the guidelines. A recommendation was given to adjust the therapy to comply with the guidelines outlined in Table 1.[5-9] If the physician

Table 2 baseline characteristics of patients using dual antiplatelet therapy during hospitalization (n=411)	
Male	244 (59.4%)
Mean age in years (range; SD)	70.1 (30 - 96; 12.0)
DAPT before hospital admission	58 (14.1%)
DAPT therapy	
ASA + clopidogrel	258 (62.8%)
ASA + prasugrel	2 (0.5%)
ASA + ticagrelor	151 (36.7%)
Indication for DAPT	
Neurologic	193 (47.0%)
Cardiovascular	213 (51.8%)
Surgical	3 (0.7%)
Multiple	2 (0.5%)
SD: standard deviation; DAPT: dual antiplatelet therapy; ASA: acetylsalicylic acid	

mentioned that the deviation from the guidelines had been intentional, the deviation was discussed, as mentioned before. After the intervention, the patient's medical record and prescribed medication were reviewed on the same day and on subsequent days during the admission, to verify whether the therapy was adjusted in line with the advice.

Data collection

The reviews and potential interventions were registered in the patient's medical record in Epic. Data acquisition was performed using Crystal Reports (Walldorf, Germany). The following patient data were collected from the patient's medical record to determine whether these risk factors contribute to failure to adhere to the DAPT guidelines without a valid reason: gender, age, DAPT combination, whether DAPT was used before admission and treating specialty. The use of DAPT before admission was defined as having the medicines in the list of pre-admission medication. These factors were chosen because automated selection by a hospital information system on these factors is possible.

Outcome measure

The primary outcome was the proportion of hospitalized patients treated with DAPT whose treatment deviated erroneously and unintentionally from the guidelines. The secondary outcomes were the risk factors associated with erroneous deviations from the guidelines and the proportion of advice in the interventions that was accepted by the physician.

Data analysis

Descriptive statistics were used to describe the proportion of patients using DAPT therapy with an erroneous deviation from the guidelines. With a univariate logistic regression analysis, the association of potential risk factors (gender, age, whether DAPT was used before admission, DAPT combination and indication) for erroneous deviation from the guideline was analyzed. Analyses were performed using IBM SPSS Statistics for Windows, version 24.0 (IBM Corp. Armonk, NY).

Ethics

The intervention was part of regular pharmaceutical care in the hospital and was discussed with the Anticoagulation Committee of the hospital before implementation. Members of all relevant medical specialties are involved in this committee. The study was reviewed by the institutional review board of the Spaarne Gasthuis.

RESULTS

During the study period, 411 patients were included, of whom 353 (85.9%) started with DAPT during the admission (Table 2). For 390 of the 411 patients (94.9%), the DAPT treatment did not deviate from the guidelines, while for 21 of the 411 patients (5.1%), the treatment deviated from the guidelines. For 10 of the 21 patients (48%) whose treatment deviated from the guidelines, the deviation was intentional. These 10 patients were treated for a longer duration than recommended in the guidelines. The reasons that were given for these deviations were stent thrombosis or occlusion (five patients), multiple events for which DAPT is indicated (four patients) and thrombocytosis in addition to a history of PCI and cerebrovascular accident (one patient). For 11 patients (52%), the deviation was unintended and erroneous. Five of the 11 patients had their DAPT treatment continued after the intended treatment period, two patients for less than a month, two patients for between one month and one year, and one patient for more than a year. Six of the 11 patients with unintended and erroneous deviations never had an indication for DAPT.

The pharmacist contacted the physician to discuss the treatment for 8 of the 11 patients with unintended and erroneous deviations. The DAPT treatment was changed following the intervention for these eight patients. The pharmacist did not contact the prescriber for three patients because one patient had passed away before intervention was possible and for two patients the physician had changed the DAPT treatment in line with the guidelines before the pharmacist could contact the prescriber.

Various covariates were analyzed as potential risk factors (Table 3). In the univariate analysis, whether DAPT was prescribed before hospital admission was statistically significantly associated with an erroneous deviation from the guidelines (OR 18.7; 95%CI 4.79-72.7). In 8 of the 58 patients (14%) who were hospitalized and used DAPT before admission, the deviation was erroneous, while in 3 of the 353 patients (0.8%) who started DAPT treatment during hospitalization, the deviation was erroneous. Of the eight patients with erroneous DAPT before admission, five were a result of DAPT treatment continuing after the intended stop date, and three patients never had an indication for DAPT. The three patients who started DAPT during admission had no indication for DAPT. Ten of the 58 patients using DAPT before admission had an intended deviation from the guidelines.

DISCUSSION

Around 1 in 20 hospitalized patients treated with DAPT was not treated according to the guidelines, nor was there an intentional deviation due to patient-specific characteristics. In the eight cases with an erroneous deviation from the guidelines for which the pharmacist contacted the prescriber and gave advice to adjust the therapy, the DAPT was adjusted in line with the guidelines. The use of DAPT before admission was a potential risk factor for erroneous deviations.

Table 3. Risk factors for erroneous and unintentional deviations from the guidelines in inpatients using dual antiplatelet therapy

Risk factor	n/N (%) in erroneous deviation from guidelines		Univariate logistic regression		
			OR	95% CI	p-value
Gender					
Male	9/244	3.7 %	Ref.		
Female	2/167	1.2 %	0.32	0.07-1.48	0.14
Age			1.06	1.00-1.12	0.06
DAPT before admission					
No	3/353	0.8 %	Ref.		
Yes	8/58	13.8 %	18.7	4.79-72.7	<0.0001
DAPT					
ASA + clopidogrel	10/258	3.9 %	Ref.		
ASA + prasugrel	0/2	N/A	0.16 [a]	0.02-1.29	0.09
ASA + ticagrelor	1 / 151	0.7 %			
Indication					
Cardiovascular	6/213	2.8 %	Ref.		
Neurologic	4/193	2.1 %	0.73	0.20-2.63	0.63
Surgical	0/3	N/A	8.63 [a]	0.83-89.3	0.07
Multiple	1/2	50 %			

[a] the DAPT therapies ASA + prasugrel and ASA + ticagrelor and the indications surgical and multiple were analyzed as one group in the regression analyses due to low numbers.
DAPT: dual antiplatelet therapy; ASA: acetylsalicylic acid; N/A: not applicable; OR: odds ratio; CI: confidence interval

The majority of patients who used DAPT in this study had started this treatment during the current hospitalization, and adherence to the guidelines mentioned in Table 1 was high in this patient group. Guideline adherence levels of 84% and above in hospitalized patients have also been reported by other studies analyzing adherence to guidelines recommending antithrombotic therapy.[18-20]

Regarding patients who used DAPT before admission, 18 out of 58 (31%) cases deviated from the guidelines; of these deviations 8 (14%) were erroneous. These results are in line with the findings of Warlé-van Herwaarden *et al*., who stated that 24% of patients from a community pharmacy who used DAPT had a deviation from the guidelines.[16] In the study by Warlé-van Herwaarden *et al*., the prescriber was not contacted, and it was therefore unknown whether the deviations were intentional or erroneous. In the present study, three of the eight patients with an erroneous deviation from the guidelines never had an indication for DAPT, while in five patients one of the two agents should have been stopped in the past. The guidelines recommend the use of DAPT for a limited period of between three weeks and 30 months, depending on the indication. These recommendations involve the risk of the patient or healthcare providers overlooking that one of the TARs should be stopped. Our results suggest that erroneous DAPT continuation contributes substantially to guideline non-adherence in primary care, a conclusion that supports the findings of Warlé-van Herwaarden *et al*.[16]

DAPT is most frequently initiated in the hospital, for example, after a myocardial infarction or a cerebrovascular accident. This treatment is continued after discharge and should be stopped in the outpatient setting. Errors occur if the neurologist, cardiologist or surgeon communicate to the patient that one of the TARs should be stopped without effect or if there are no follow-up visits at the time the DAPT should be stopped. The intended stop date is often mentioned in the discharge letter sent to the primary care physician, but this is often archived. A notification to the prescriber is needed at the time the DAPT therapy should be stopped, during either prescribing or dispensing. Improved collaboration between physicians and pharmacists is needed to avoid the continuation of DAPT after the intended stop date. Treating patients for a longer period results in a 1.4 to 1.6 times greater risk of bleeding.[10-13] Pharmacists have an important role in reducing medication errors. Since the proportion of errors was higher in patients who were admitted with DAPT versus patients who started DAPT during admission, the focus should be on patients in primary care. Better cooperation between pharmacists in the hospital and community pharmacists, along with communication on the intended DAPT stop date after discharge from the hospital, is an intervention of interest to improve guideline adherence and reduce preventable bleedings.

Our study has several potential strengths and limitations. First, due to the prospective design, we were able to discuss the indication for the antiplatelet therapy with the prescriber in case there was doubt about it, and we could analyze the effect of a pharmacist intervention. Second, we collected various potential risk factors for analysis, including the indication and whether the patients used DAPT before admission. By analyzing potential risk factors, we could identify patients using DAPT before admission as a group to whom extra attention should be given to avoid erroneous prescribing of DAPT. A potential limitation of this study is the single-center setting, which potentially limits the generalizability of the results. However, the results were in line with a previous study performed in a community pharmacy in another region of the Netherlands. Since the guidelines for the prescription of DAPT are similar between countries, we expect this problem to also exist in other countries. Third, we used the information from the patient's medical record, information that may not be complete or correct. For example, we may have missed patients who used DAPT before admission if the pre-admission medication list was incomplete, or we may have missed patients who had temporarily stopped DAPT during admission due, for example, to surgery. Fourth, we performed this study without a control group, and we do not know whether erroneous deviations would have been corrected without intervention by a pharmacist. Fifth, only a limited number of variables were assessed as potential risk factors. Finally, the number of patients with erroneous

deviations from the guidelines was limited, making the power for statistical analyses low.

CONCLUSIONS

To conclude, adherence to guidelines that recommend the prescription of DAPT is high within the hospital. The use of DAPT before admission is a potential risk factor for erroneous deviations from the guidelines, which suggests that the intended stop date after discharge needs to be better communicated to improve guideline adherence in primary care. Intervention by a pharmacist increased adherence to the guidelines in patients using DAPT and may thus reduce the number of preventable bleeding cases.

CONFLICT OF INTEREST

None of the authors has any conflict of interest.

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Al-Jumaili AA, Ahmed KK, Koch D. Barriers to healthcare access for Arabic-speaking population in an English-speaking country. Pharmacy Practice 2020 Apr-Jun;18(2):1809.
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Original Research

Barriers to healthcare access for Arabic-speaking population in an English-speaking country

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Abstract

Objective: To identify barriers to healthcare access, to assess the health literacy levels of the foreign-born Arabic speaking population in Iowa, USA and to measure their prevalence of seeking preventive healthcare services.

Methods: A cross-sectional study of native Arabic speaking adults involved a focus group and an anonymous paper-based survey. The focus group and the Andersen Model were used to develop the survey questionnaire. The survey participants were customers at Arabic grocery stores, worshippers at the city mosque and patients at free University Clinic. Chi-square test was used to measure the relationship between the characteristics of survey participants and preventive healthcare services. Thematic analysis was used to analyze the focus group transcript.

Results: We received 196 completed surveys. Only half of the participants were considered to have good health literacy. More than one-third of the participants had no health insurance and less than half of them visit clinics regularly for preventive measures. Two participant enabling factors (health insurance and residency years) and one need factor (having chronic disease(s)) were found to significantly influence preventive physician visits.

Conclusions: This theory-based study provides a tool that can be used in different Western countries where Arabic minority lives. Both the survey and the focus group agreed that lacking health insurance is the main barrier facing their access to healthcare services. The availability of an interpreter in the hospital is essential to help those with inadequate health literacy, particularly new arriving individuals. More free healthcare settings are needed in the county to take care of the increasing number of uninsured Arabic speaking patients.

Keywords

Health Services Accessibility; Preventive Health Services; Medically Uninsured; Health Literacy; Communication Barriers; Cultural Competency; Surveys and Questionnaires; Focus Groups; United States

INTRODUCTION

The Arabic community is a growing minority in the United States. In 2017, there were approximately 3.7 million Arab Americans living in the United States.[1] Arab Americans live in all 50 states with about half of them residing in California, Florida, Michigan, New Jersey, and New York.[2] In the state of Iowa in the Midwest, Arabs constitute about 0.15% of the total state population.[2] Health data on Arab Americans are lacking mainly due to the lack of an Arab identifier in healthcare records and surveys.[3] Like other minorities, the healthcare needs of Arab Americans and their access to healthcare needs more focus.

Lack of insurance subjects individuals to the economic burden of needed medical care expenses and pertains to infrequent or no regular checkups and screenings for major health problems like diabetes mellitus (DM), cardiovascular diseases, and cancer.[4,5] Minorities have been reported to largely contribute to the uninsured population in the U.S. and this was attributed to low income or new arrival.[6] Lack of health insurance was one of the main barriers to accessing healthcare for Latinos in South Carolina.[7] and was found to correlate positively with having a regular healthcare provider and completing diagnostic tests for African Americans.[8] Similarly, unaffordable healthcare services were reported as a barrier to healthcare services by Arab Americans in Brooklyn as well as other minorities.[7,9]

Language is another barrier that has been reported to impact the access and quality of healthcare.[7] For non-English speaking individuals, language barriers can affect the frequency of visits, willingness to get healthcare and knowledge about available healthcare services. It was found that the self-rated health of Arabic-speaking immigrants was lower than that of both English-speaking Arab immigrants and U.S. born Arab Americans, suggesting language as a contributing factor to differences in health status and healthcare access.[10] Several approaches have been reported to successfully bridge the gap in healthcare services for non-English speakers in the U.S. including professional translators, employment of bilingual physicians, and provision of non-English health educational materials.[11-13] Several studies have demonstrated that the presence of professional interpreters or bilingual providers during physician visits for individuals with limited English proficiency had a positive impact on patient satisfaction and the outcomes of the healthcare services provided.[14-17]

Healthcare access was mostly studied in the term of enablers and barriers to required intervention as in the case of sickness.[18] Fewer studies have explored preventive healthcare use among Arab Americans (for the purpose of this study, the term preventive healthcare includes physician visits for non-urgent needs, regular checkups/physician visit for existing health conditions, clinic visits for vaccination, and clinic visits for screening).

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Individuals usually seek healthcare services in urgent illnesses regardless of the ease of access, while non-urgent healthcare needs (such as vaccination, screening and regular check-up) can be overlooked according to the ease of access. Hence, in this study we focused on the barriers and enabling factors influencing the access to preventive healthcare services. Access to healthcare for minorities has been the focus of many studies.[7,17,19,20] However, limited data is available on Arabic minority communities in given geographic parts of the U.S. including the Midwest region. This study has not only focused on barriers and enabling factors to preventive health care access, but also assessed the pattern of access to preventive healthcare among this minority in this understudied region of the United States. To the best of our knowledge, this is the first study to use survey to examine the healthcare needs of the Arabic speaking minority in the Midwest region of the United States.

The objectives of this study were to identify barriers to healthcare access, to assess health literacy level of the Arabic speaking (foreign-born) population in Johnson County, Iowa, USA and to measure their prevalence of seeking preventive healthcare services.

METHODS

This cross-sectional study involved two methods: A focus group and an anonymous survey of Arabic speaking individuals in Johnson County in the state of Iowa, USA. The interview guide of the focus group was developed in collaboration with Johnson County Public Health (JCPH) to assess the difficulties, concerns, and suggestions regarding healthcare access for the Arabic speaking community (Online appendix). The JCPH has experience to conduct need assessment interviews among minority communities every five years. The focus group took place at the Iowa City Mosque, and the focus group team included a note taker, a translator/assistant moderator, and the group leader. It was recorded using two tape recorders.

To analyze the verbatim transcript of the focus group, we followed the six phases of thematic analysis described by Braun and Clarke which include familiarizing oneself with the focus group verbatim, generating initial codes, searching for themes, reviewing themes, defining and naming themes and producing the report.[21] The coding process was conducted by three researchers and the final themes agreed on by all or at least two of three team members. To enhance the credibility and trustworthiness of the findings, peer debriefing / member checking was conducted to validate the qualitative analysis. The process of member checking to test the findings and interpretations was conducted with five of the participants.

After conducting the focus group, the authors created a survey in English based on the Andersen Model for healthcare service utilization (Figure 1) and employing the findings of the focus group.[22] Andersen model can help to measure predisposing, enabling and need factors that influence the use of healthcare services (preventive physician visits).

The survey contained 20 questions covering predisposing items (age, gender, ethnicity, education), enabling items (health insurance, residency and health literacy), need items (presence of chronic diseases) and healthcare utilization item (frequency of physician visits), which represent the outcome variable (Online appendix). Health literacy was assessed using the Arabic version of Single Item Literacy Screener (SILS).[23] The SILS has one question: "How often do you ask someone for help to read the instructions and leaflets from a doctor or pharmacy?".[24] The participants were asked to choose one of the followings (5-point Likert scale): 1-never, 2-rarely, 3-sometimes, 4-often, or 5-always.[25]

To eliminate the language barrier, the survey was translated to formal Arabic by the authors and the translation was validated by two different native Arabic scholars living in the county. The survey was pretested in pilot study with few native-Arabic speakers before administering to all participants. Two questions were revised according to the pilot study feedback. We added other answer choices. First change was conducted to question "Do you have a family member who is fluent in English helping you during physician/pharmacy visits? "when we added 4th choice of "No need". The second revision included adding "visitor" to demographic section when we ask about the resident status. The inclusion criteria of the survey participants were being first generation Arabic immigrants, adult (>18 years) and living in Johnson County. A bilingual English/Arabic researcher (AA) screened participants for eligibility. Visitors and students were also surveyed as they constitute an important component of the community due to the presence of the University of Iowa that attracts a considerable number of international students and visiting scholars and their dependents (4011 international students and scholars out of 86,769 total residents).[26,27] A bilingual English/Arabic researcher (AA) approached customers at Arabic grocery stores in Coralville, worshippers at the Iowa City Mosque and patients at the free University Mobile Clinic and asked if they were willing to complete the survey. Subsequently, people who gave verbal consent were provided a 2-page paper survey, which the authors collected in-person. The research team distributed the paper-survey in-person and waited till participants filled it out. Only people who agreed to participate received the

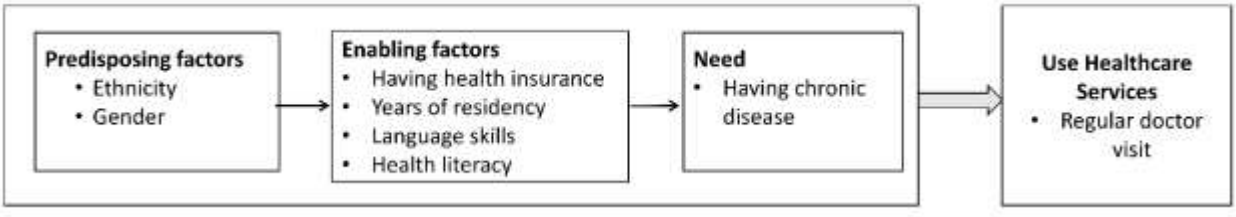

Figure 1. The Andersen model of preventive health care utilization

survey (convenience sample). We did not measure the response rate because we were unable to count all people available at the three included settings. In general, most eligible people were cooperative and agreed to participate.

The study proposal was exempted by the University of Iowa Human Subject Office/ Institutional Review Board (IRB).

Quantitative Statistical Analyses

Means, frequencies and percentages of participant characteristics were calculated. The data analyses were performed utilizing the IBM SPSS Program for Windows, version 22.0. The chi-square test was used to measure the relationship between the categorical participant factors (no health insurance, language barrier, health literacy, no barrier, chronic disease, gender, ethnicity, and residency years in the U.S.) and the outcome variable (preventive / regular physician visits). The chi-square analysis was also conducted to measure the relationships between health literacy level and both language barrier and interpreter need. The statistically significant value was p-value<0.05.

RESULTS

Qualitative findings

The focus group included seven native Arabic speaking residents who were married with children, and all had at least a college degree. The main theme of the qualitative findings of the focus group was barriers facing Arabic speaking population regarding access to healthcare services. Lack of health coverage/insurance or instability of insurance status was noted as the major barrier to healthcare access in this community and can be put into the following three subthemes. First, lack of coverage due to eligibility issues. For example, a participant (P3) in the focus group stated "concerning my family, we are six including my kids and wife. We have insurance from Medicaid for the kids, but for me and my wife, we do not have insurance". The adult parents were not eligible to be covered according to Iowa Medicaid rules at the time focus group conducted. The second subtheme was lack of health insurance due to affordability. For instance, P2 mentioned "through my employment I can't afford it [health insurance], it's too high!" The third subtheme was the limited availability and accessibility of medical services for residents without health insurance. For example, P4 stated, "Regarding the free clinic, before I got my insurance, I was getting the services from there; it's a good clinic but it's a very small clinic, and the most [/biggest/] problem with that is that you can't just walk in and get services". Regardless of the cause of having no access to healthcare services, individuals might find themselves forced to use the emergency room (ER), which sends them home with overwhelming bills: "After that, we kept going to the ER and they kept sending us the bill, right now I have more than USD 250,000 [debt]" (P6).

Quantitative results

We received 196 surveys from adult native Arabic speakers who lived in Johnson County, Iowa, USA during fall 2017. Participants gender and ethnicity are detailed in Table 1. The participants were all native Arabic speakers who have been residing in the U.S. for varying durations ranging from less than a year to more than 15 years (Table 1).

Regarding immigration status, survey participants were initially grouped into two main groups: citizens/residents and international students/visitors. Approximately 80% of the participants were citizens/permanent residents while

Table 1. The demographics and health literacy of native Arabic speaking participants

Characteristics	Number of participants (N)	%
Residency status (N=196)		
Citizen	68	34.7
Permanent resident	92	46.9
Student	23	11.7
Visitor	13	6.6
Gender (N=196)		
Male	119	60.7
Female	75	38.3
Age (years) (N=193)		
18-29	33	16.8
30-39	67	34.2
40-49	51	26
50 +	42	21.4
Education degree (N=194)		
Elementary school	7	3.6
Middle school	13	6.6
High school	28	14.3
College degree	103	52.6
Graduate degree	43	21.9
Current or former student at a US college (N=194)		
Yes	114	58.2
No	80	40.8
Ethnicity (country of origin) (N=195)		
Sudanese	131	66.8
Middle East	37	18.9
North Africa	20	10.2
Arabic-Gulf country	7	3.6
Residency years in the U.S. (N=196)		
Less than 1 years	26	13.3
1-5 years	91	46.4
6-10 years	28	14.3
11-15 years	19	9.7
More than 15 years	32	16.3
Single Item (SILS) health literacy Screener: Need help to read physician/pharmacist instructions (N=196)		
Always	24	12.2
Often	24	12.2
Sometimes	45	23
Rarely	21	10.7
Never	82	41.8
Need an interpreter during hospital/clinic visits (N=196)		
Always	46	23.5
Sometimes	57	29.1
Never	93	47.4

Citizens/permanent residents=160 and students/visitors=36. Participants of Sudan ethnicity were separated from North Africa as Sudanese represent the largest component of the Arabic speaking minority in the study area. 131 are Sudanese, 23 from Middle East and 17 of them are Iraqis and 6 from Levant. All the 14 students from Middle East are Iraqis. North African Arabic countries include Egypt, Libya, Algeria, Tunisia & Morocco; Middle Eastern Arabic countries include Iraq, Jordan, Syria and Lebanon; Gulf-Arabic countries include Saudi Arabia and United Arab Emirates.

Table 2. The frequency and barriers of healthcare access of native Arabic speaking participants

Characteristics	Num.	%
Having Health insurance (N=196)		
No	74	37.7
High Co-payment (N=196)		
Yes	25	12.8
Having language barrier (N=196)		
Yes	31	15.8
Having barrier(s) to healthcare access (N=196)		
Yes	84	42.9
Have a family member helps in interpretation during physician/ pharmacy visits (N=196)		
No	76	38.8
Sometimes	25	12.8
Yes	48	24.5
No need	47	24
*Health Insurance type (N=122): Choose all that apply		
Medicaid	52	26.5
Employer/University	47	24
Private	15	7.7
Medicare	8	4.1
Visit doctor/clinic (N=196)		
At Regular basis/For Preventive measures	93	47.4
When very ill/ To get prescription	103	52.6
**Having chronic disease(s)		
DM	22	11.2
Hypertension	30	15.3
Heart Disease(s)	7	3.6
Asthma	11	5.6
Arthritis	19	9.7
No chronic disease	132	67.3

* One resident was dual Medicaid and Medicare insured, while other participant did not specify his type of health insurance.
** N=122 because several participants had multiple chronic diseases.

the remaining 20% were students and visitors temporarily residing in the United States (Table 1). Upon initial chi-square analysis, no significant differences were found in terms of barriers to healthcare service use reported by participants in the two groups (citizens/residents and international students/visitors). Hence, for subsequent chi-square tests, all participants were grouped together.

Looking at the pattern of physicians visits, about 70% of participants reported visiting the physician to seek treatment when they are very ill or to request a prescribed medication from their physician, while preventive and regular physician visits were reported by only half (52.6%) the participants (Table 2). Chi-square analyses showed that having any barrier significantly influenced regular physician visits by participants. Barriers surveyed and reported in this study were lack of health insurance, co-payment, and language (Table 2). Approximately 43% of all participants reported having one or more barriers (no health insurance, language barrier and/or high co-payment) to using healthcare services (Table 2). There was a significant ($p<0.05$) association between the presence of barrier(s) to healthcare and the use of preventive healthcare (Table 3) such that participants experiencing any barriers had fewer regular physician clinic visits than those without barriers. Looking more specifically at select barriers/factors, three participant factors significantly influenced the regular visit

Table 3. Factors influencing visiting doctor/clinic regularly

Factors (total num.)	Regular visit n (%)	Chi-square p-value
No health insurance		0.0001
No (122)	79 (64.8)	
Yes (74)	14 (18.9)	
Language barrier		0.781
No (165)	79 (47.9)	
Yes (31)	14 (45.2)	
Gender		0.473
Male (119)	54 (45.4)	
Female (75)	38 (50.7)	
*Residency Years		0.0001
≤ 5 (117)	42 (35.9)	
5 < (79)	51 (64.6)	
Ethnicity		0.735
**Others (63)	31 (49.2)	
Sudanese (133)	62 (46.6)	
Chronic disease		0.003
With (64)	40 (62.5)	
Without (132)	53 (40.2)	
***SILS (health literacy)		0.542
Inadequate (93)	42 (45.2)	
Adequate (103)	51 (49.5)	

*Years of residency in the US: 1=5 years or less, 2=more than 5 years.
**Others: North African Arabic, Middle-Eastern Arabic, Yemeni and Gulf-Arabic participants.
***Adequate health literacy=those answered "never or rarely" to the SILS question, while inadequate health literacy=those answered "always, often or sometimes" to the SILS question.

of physician clinic and these were having health insurance (enabling factor), having chronic disease(s) (need factor), and the number of residency years (5 years or less vs more than 5 years) in the U.S. (enabling factor) (Table 3).

Regarding health insurance, which is an enabling factor in the Anderson model, more than one-third (38%) of the participants had no health insurance (Table 2). All the 23 participating international students had health insurance. The majority of participating permanent residents (61.5%) had no health insurance while a small percentage (15.3%) of the citizens was without health insurance. Most of the insured participants had health insurance provided through an employer or the university or through Medicaid and Medicare while only less than 10% of the insured participants had to pay for private health insurance (Table 2). There was significant positive association between seeking preventive/regular healthcare services and having health insurance. The majority (64.8%) of participants with health insurance visit the physician clinic seeking regular/preventive healthcare services, while most participants without health insurance (81.1%) do not visit the physician clinic for regular/preventive measures (Table 2).

The second factor with a significant positive association with preventive physician clinic visit was experiencing one or more chronic disease(s). About one-third (32.7%) of the participants had one or more chronic disease(s) such as diabetes mellitus (DM), hypertension, heart disease, asthma, or arthritis with the most common diseases being hypertension (15.3%) and DM (11.2%) (Table 2). Approximately two-thirds of participants with chronic diseases reported regularly/preventively visiting the physician clinic compared to only one-third of those

without chronic disease performing such regular/preventive visits (Table 3). The third and last factor significantly affecting the use of regular/preventive physician visits was participant's residency period. Participants less than five years of residency had significantly less regular physician clinic visits than those with more than five years of residency in the States.

Other barriers/factors examined in this study did not have significant association with preventive physician visits. For example, high co-payment of healthcare services for insured individuals was reported as a barrier by only about 15% of insured participants.

We measured three related factors: Language barrier, interpreter need, and health literacy level. Additionally, the survey asked about the availability of the hospital interpreter and preferences of using Arabic speaking providers. Regarding the provider preference, about 80% of participants had no preference for Arabic speaking providers. While around 35% of participants reported the constant availability of interpreters at the hospital/clinic, approximately half of total participants reported not needing/using the service. Approximately 16% of participants perceived having a language barrier and the remaining 84% did not report language as a barrier to healthcare (Table 2). Additionally, the perception of language as a barrier to healthcare was found to associate positively with the level of education of the participant such that those with college education and higher have no issues with comfortably communicating in English (Table 1). On the other hand, the Single Item health Literacy Screener (SILS) test revealed that only half of the participants were considered having good health literacy (52.6% reported never/rarely needing help read physician/pharmacist instructions) (Table 1). Finally, neither health literacy level nor language barrier had significant relationship with the outcome variable (regular/preventive physician visits) (Table 3).

The chi-square analysis showed that there were significant ($p < 0.05$) relationships between health literacy level and both language barrier and interpreter need (Table 4). To elaborate, almost all participants with limited English proficiency (30/31) were also specified as having inadequate health literacy. On the other hand, more than one-third (63/165) of the participants who reported having no language barrier were designated as having inadequate health literacy according to SILS results (answered sometimes, often or always need help in understanding health-related materials). Considering the association between using an interpreter service and health literacy, we found that 81.6% (84/103) of those reported needing an interpreter were considered to have low health literacy and the remaining 18.4% (19/103) of those who needed an interpreter were considered to have good health literacy (Table 4).

To further explore the association of health literacy level (SILS) with the health insurance status, we did Chi-square test which showed that percentage of people having adequate health literacy was significantly higher among people with health insurance compared to people without health insurance. We also conducted Chi-square test to measure association between the residency years (<5 vs 5+ years) and the health literacy level (SILS). We found a significant association which means people who lived for five years or more in the U.S., had significantly higher level of health literacy.

Table 4. Relationship between health literacy level and hospital interpreter need, language barrier and health insurance

Variable (total num.)	Adequate SILS n (%)	Chi-square p-value
Interpreter need		0.0001*
Never (93)	84 (90.3)	
Sometimes/Always (103)	19 (18.4)	
Language barrier		0.0001*
No (165)	102 (61.8)	
Yes (31)	1 (3.2)	
Health insurance		0.0001*
Yes (123)	45 (36.6)	
No (73)	48 (65.8)	
Years in the US		0.017*
<5 (164)	84 (51.2)	
5≤ (32)	9 (28.1)	

* Significant relationship ($p<0.05$)
SILS=Single Item Literacy Screener.

Focusing only on Sudanese participants, being the largest Arabic speaking population in the study areas (67.9%), around 70% reported having one or more barriers to health care access with 51% of those reporting health insurance as the barrier to healthcare access. Moreover, there was a significant difference between Sudanese participants compared to other Arabic ethnicities grouped in term of lack of health insurance and having a language barrier. However, the ethnicity (Sudanese vs others) had no significant relationship with seeking preventive healthcare.

In summary, these findings denote the significance of health insurance and years of residency as enabling factors and existence of chronic disease as a need factor for seeking preventive/regular physician visits. However, health literacy, language barriers, gender and ethnicity had no significant association with performing preventive physician visits (Table 3).

DISCUSSION

In this study, we investigated barriers to receive preventive healthcare services and assessed health literacy level of the Arabic speaking community in select parts of Johnson County in the state of Iowa. The study area was chosen to focus on the overlooked Arabic speaking minority living in the Midwest. This is because most studies examining Arabic speaking minority were conducted in states where the majority of the Arabic speaking minority is residing.[9,10] Additionally, our unique approach in this study involved using a focus group and conducting a short paper survey. The Arabic version of the survey can be used as a tool for future studies conducted in any country containing Arabic minority.

Access to healthcare services is governed by many factors, mainly having health insurance.[8,18] In cases of regular physician visits, lack of health insurance and subsequent service costs can lead to patients abandoning required visits normally scheduled for treatment follow-up, annual

checkups, screening for certain diseases and simply follow-up on an existing condition.

The focus group in our study pointed out lack of health insurance as the main barrier to healthcare access. The focus group also noted that years of residency are important to receive governmental health insurance (Medicaid) and subsequently seeking preventive care. These conclusions were confirmed quantitatively and specifically in the context of preventive healthcare where chi-square analyses of the survey results showed three factors significantly influencing the outcome of the Anderson Model (preventive/ regular physician visit): Two enabling factors (health insurance, and residency years in the U.S.) and one need factor (having chronic disease(s))(Table 3). Because of these factors, only 52.6% of the participants visit clinic regularly and for preventive measures. According to the chi-square analysis of the survey answers, lack of health insurance had significant negative association with regular physician visits. There were 64.8% participants from those who had health insurance were visiting physician clinic regularly/for preventive measures, while only 18.9% of those who did not have health insurance were visiting physician regularly/ for preventive measures (about 3.5 to 1 ratio) (Table 3). These findings agree with previous reports on health insurance being the main barrier to general healthcare access regardless of citizenship, immigration status and ethnicity in the United States.[4,28]

First generation minorities might be facing more barriers to healthcare services than later generations possibly due to difficulties in communications and short residence time in the U.S. for newly arriving immigrants. Indeed, statistical analysis showed that participants with residency of five years or less had significantly fewer regular visits to clinics than those with more than five years residency in the U.S. which comes in agreement with focus group findings. These finding might be explained by the fact that new immigrants will have to wait for five years to be U.S. citizens before they are eligible for Medicaid according to the Iowa Department of Human Services (DHS). During this period, individuals would mostly stay without insurance as they cannot afford private insurance. Even though children and pregnant women can receive free basic health needs (vaccination, dental, healthy foods and nutrition) from the County Public Health Department through the Women, Infants & Children (WIC) program these services do not eliminate the need for health insurance to seek preventive healthcare.[29]

While in our survey sample, Sudan ethnicity was the main component (about two thirds), both predisposing factors (ethnicity and gender) had no significant relationship with the outcome variable (regular physician visit). This is worth mentioning as Sudanese were the main contributors to the uninsured participants with 51% of Sudanese uninsured compared to only 9.5% of all other participants being uninsured. This difference in the insurance status based on ethnicity might be due to differences in residency status where the majority of Sudanese were permanent residents/citizens while international students were mainly from all other ethnicities and they had to have health insurance as per university regulations.

The other modulating factor for preventive healthcare seeking is the need factor represented in this study by existence of chronic disease(s). Experiencing chronic disease(s) had a significant positive association with preventive clinic visits. This is an expected finding since those patients need regular follow-up visits to treat complications, conduct tests and receive prescribed medications. These results come in agreement with previously reported positive association between the existence of chronic disease and receiving recommended regular healthcare services.[30,31]

Another commonly reported barrier to healthcare access for non-English speaking minorities in the U.S. is language.[19] Notably, language barrier did not have any significant relationship with preventive physician visits in this study (Table 3). It is important to note that English proficiency does not reflect health literacy where individuals can communicate efficiently and still need help reading medical materials. This is well seen in our study where more than one-third of participants who reported having no language barrier were designated as having inadequate health literacy according to SILS results. However, almost all participants with limited English proficiency were designated as having inadequate health literacy (Table 4). These results agree with previously reported findings of inadequate health literacy among limited English proficiency individuals.[32,33]

In our study, neither language nor health literacy had significant impact on acquiring preventive care (Table 3). This is possibly due to the elimination of language gap through the availability of professional interpreter service at the healthcare centers. Our study showed that hospital interpreter service is highly used especially by participants with inadequate health literacy (90%) and even by some participants with adequate health literacy (18.4%). These findings highlight the importance of implementing professional interpreter services and comes in agreement with previously reported findings of a significant increase in patient satisfaction and healthcare delivery for both preventive and clinical services after the implementation of a professional interpreter service compared to a control group for Portuguese and Spanish speaking population.[14,15] Additionally, health literacy level was significantly associated with the status of being insured and being residents for five years or more. These findings might be explained because people having health insurance were residents for longer time in the U.S. and this longer period of residency contributed to their improved health literacy level.

We also conducted chi-square test to measure association between the residency years (<5 vs 5≤ years) and the health literacy level (SILS). We found a significant association which means people who lived for five years or more in the U.S., they have significantly higher percentage of those having adequate health literacy

This study had some limitations. Mainly, it was conducted in one county which may limit the generalizability of our findings. However, this county has different cities which contain a good number of Arabic speaking residents. One focus group with a limited number of participants was the other limitation. However, we used the verbatim of the

focus group to generate the survey items and generalize the healthcare barrier findings among this minority. Lastly, some surveys had missing answers.

CONCLUSIONS

This theory-based study provides a tool that can be used in different Western countries where Arabic minority lives. Andersen model helped us to identify factors associated with preventive/regular physician visits among native Arabic speaking population in Johnson County. Two enabling factors (health insurance, and residency years in the U.S.) and one need factor (having chronic disease(s)) significantly influence preventive/regular physician visits. Both the survey and the focus group results agreed that lacking health insurance is the main barrier to accessing healthcare services. The availability of an interpreter in the hospital is essential to help those with inadequate health literacy, particularly new arriving individuals.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Original Research

Exploring learning needs for general practice based pharmacist: Are behavioural and influencing skills needed?

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Abstract

Background: Embedding pharmacists in general practice has been shown to create cost efficiencies, improve patient care and free general practitioner capacity. Consequently, there is a drive to recruit additional pharmacists to work within general practices. However, equipping pharmacists with behaviour and influencing skills may further optimise their impact. Key elements which may enhance behaviour and influencing skills include self-efficacy and resilience.

Objective: This study aimed to: 1) Assess general practice pharmacists' self-efficacy and resilience. 2) Explore differences primarily between pharmacists reporting lower and higher self-efficacy, secondarily for those reporting lower and higher scores for resilience.

Methods: All 159 NHS Greater Glasgow and Clyde general practice pharmacists were invited to complete an online survey in May 2019. The survey captured anonymised data covering: demographics; professional experience; qualifications, prescribing status and preferred learning styles. Unconscious learning needs for behavioural and influencing skills were assessed using validated tools: the new general self-efficacy scale (GSES) and short general resilience scale (GRIT). Participants' responses were differentiated by the lowest quartile and higher quartiles of GSES and GRIT scores, and analysed to identify differences.

Results: The survey was completed by 57% (91/159) of eligible pharmacists; mean age 38 (range 24-60) years; 91% were of white ethnicity and 89% female. The median time qualified was 14 (1-38) years and 3 (1-22) years working in general practices. Overall pharmacists scored well on the GSES, mean 25 (SD 3; 95%CI 24.4-25.6), and GRIT, mean 30 (SD 4; 95%CI 29.6-30.4), out of a maximum 32 and 40 respectively. A significant positive correlation between GSES and GRIT scores was found (Pearson's r=0.284, p=0.006). However, no significant differences were identified between pharmacists scoring in the lower and upper quartiles by GSES or GRIT. Overall respondents reported their preferred learning styles were activists (46%) or pragmatists (29%). The majority (91%) preferred blended learning methods as opposed to 38% or less for a range of online methods.

Conclusions: General practice pharmacists on average scored highly for self-efficacy and resilience. Higher scores did not appear to be associated with demographic, years of practice, professional or educational experience. Prospective interventions to support those with lower scores may enhance and optimise pharmacists' effectiveness in general practice.

Keywords

Pharmacists; General Practitioners; Patient Care; Delivery of Health Care, Integrated; Family Practice; Adaptation, Psychological; Resilience, Psychological; Surveys and Questionnaires; United Kingdom

INTRODUCTION

There is a significant drive to recruit more pharmacists to work within general practices in the United Kingdom (UK).[1,2] In part this aims to help address the current general practice workforce crisis through new ways of working; freeing general practitioners (GPs) capacity and time by targeting specific prescribing activities: hospital discharge prescriptions, outpatient clinic requests, and other medicines issues e.g. addressing medicines shortage issues by providing alternatives, medicines information, etc.[3] For over 20 years, specially trained pharmacists have worked within general practices and alongside GPs to optimise prescribing and improve patient care. This has included delivering patient-level face-to-face polypharmacy reviews; achieving and delivering prescribing cost efficiencies; ensuring appropriate prescribing (e.g., patients with left ventricular systolic dysfunction, chronic obstructive airways disease); tackling difficult areas of prescribing as non-medical prescribers (that is prescribers who are not doctors) such as inappropriate anxiolytic or hypnotic prescribing,.[4-9]

In 2015 however, the Scottish Government announced the details of the Primary Care Fund to support primary care services, including GPs, and improve patient access to primary care services.[1] This has led to a significant increase in the number of pharmacists working with general practices. The majority of whom are employed by National Health Service (NHS) in Scotland, and complete their regional mandatory training and induction, and start the NHS Education for Scotland general practice training prior to working with general practices.[10] However, existing training does not include behaviour and influencing skills; such as greater self-awareness and 'soft skills' that can enable adaptability, and have positive effects on persuasion, conflict resolution, and communication skills.

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Previous research demonstrates that pharmacists trained in, and using, behaviour and influencing skills as part of GP education and facilitation models, have achieved positive sustainable changes with statin and antidepressant prescribing.[6,7] Two potential key unconscious elements of behaviour and influencing skills include self-efficacy and resilience. Self-efficacy, or perceptions of one's own abilities, is a core component of Bandura's Social Cognitive Theory.[11] In brief, Bandura's Social Cognitive Theory outlines that individuals' are capable of altering behaviour and environment through their perceived self-efficacy or belief in their abilities. Bandura's model suggests that people are more likely to engage in tasks or activities that they feel confident and competent doing and avoid those they do not. For individuals, the greater their sense of self-efficacy the greater their effort, persistence and perseverance they invest and commit to tasks and activities. Previous studies have also indicated that self-efficacy represents an important predictor of resilience, with resilience characterised as the ability to withstand, recover, learn from difficulties and continue despite blocks to progresses.[12,13] Therefore identifying pharmacists with low self-efficacy and/or resilience could be useful in targeting and supporting those that may not engage or whom struggle with tasks and activities.[14] Moreover, addressing training gaps and supporting and growing individual's to increase and improve their self-efficacy may enhance service performance and delivery, as well as their wellbeing.[13-15]

Therefore this study aimed to: 1) Assess general practice pharmacists' self-efficacy and resilience. 2) Explore differences primarily between pharmacists reporting lower and higher self-efficacy, secondarily for those reporting lower and higher scores for resilience.

METHODS

Study design

On consultation with the West of Scotland Research Ethics Service this study was deemed not to require ethical approval as it related to service improvement and evaluation, primarily undertaken to support pharmacists' development and to optimise normal patient care. However, we sought participants consent to participate prior to completing the questionnaire.

This study applied a cross sectional survey design, and utilised an online website based Webropol questionnaire specifically designed, tested and developed to elicit response from general practice pharmacists. Participants were recruited and employed within one large health board area in Scotland, in May 2019.

The UK's National Health Service (NHS) is taxpayer funded and devolved to the national assemblies and parliaments in the home nations. The NHS in Scotland is organised into 14 regional health boards serving a population of 5.3 million people; living in highly rural to highly urbanised areas with large variations in socioeconomic deprivation. NHS Greater Glasgow and Clyde (NHSGGC) provides healthcare services for a diverse population of approximately 1.2 million people across a varied urban area containing 235 general practices across six Health and Social Care Partnership (HSCP). The HSCP brings together community primary care health services and social work services to support patients in the locality, with each HSCP containing pharmacy teams working with general practices within the locality.

Data collection and tools

All 159 NHSGGC's general practice pharmacists were invited to participate through an email from their HSCP lead pharmacist. The email briefly outlined the study, provided a link for the online Webropol questionnaire and requested that participants completed within a 2 week timeframe. After the first week a reminder email, containing the same information, was sent to all practice pharmacists. The Webropol questionnaire included a study information sheet, and consent form which required completion prior to participants being allowed to progress and complete the questionnaire. Participants' anonymised data were captured and included: demographics (age, gender and ethnicity); professional experience; postgraduate qualifications; active or inactive independent prescriber status; preferred learning style - as measured by the learning styles questionnaire; and preferred learning method using a 5 point Likert scale from 'not favoured to favoured' (Table 1).[16]

Previous literature informed the assessment of behavioural and influencing skills, of which self-efficacy and resilience are two inter-related potential key elements. To our knowledge previous studies involving pharmacists have been limited to pharmacist students and academics;

Table 1. Definitions of learning styles and methods

Item	Definition/Description
Learning style	
Activist	Learn by doing and through participation
Pragmatist	Learn through practical tips and techniques from an experienced person
Reflector	Learn by watching others and tend to think before action
Theorist	Learn by understanding theory very clearly
Learning method	
Face to face learning	
Blended	A mix of lecture and interaction/collaboration
Classroom	Lecture style
Intense mentoring	One to one intensive mentoring/support e.g. shadowing
Small group	Small group based learning
Online learning	
Audio visual	Video
Computer based online	Learning package
Self-directed	
Text	

although, two large studies involving nurses working in secondary care across a range of disciplines has also identified similar associations between self-efficacy and resilience.[12,17-20] These constructs were considered as unconscious learning needs for behavioural and influencing skills and were assessed and captured using validated tools embedded within the questionnaire: the new General Self-Efficacy Scale (GSES), and resilience from the Short General Resilience Scale (GRIT).[17,21,22] These tools were also consider appropriate, within the demands of routine clinical practice, as they are self-reported, self-administered and take less than 5 minutes to complete.[21,22]

Statistical analysis

Anonymised data from the Webropol questionnaire were collated centrally using Microsoft Excel, and further analysed using SPSS version 25. Primarily, participants were categorised into two groups according to their total GSES score by quartile; lowest quartile (quartile 1) group score being ≤23 and >23 for upper group (quartile 2 to 4). Secondarily, participants were categorised into two groups according GRIT scores; lowest quartile ≤27 and upper group >27. Due to the small number of participants (n=9) scoring in the bottom quartiles for both measures, further analysis was considered inappropriate. Parametric and non-parametric statistical tests were applied where appropriate as guided by data viability. In particular where continuous data were non-normally distributed and remained so after transformation appropriate non-parametric tests were applied.

RESULTS

Of the 159 general practice pharmacists eligible to participate, 57% (91/159) responded and completed the survey. The participating pharmacists had a mean age 38

Table 2. Pharmacist demographics and preferences; categorised by self-efficacy quartile scores

Characteristics	Lower quartile (Quartile 1, n=23)	All higher quartiles (Quartiles 2 to 3, n=68)	Total (n=91)	Test p-value[a]
Gender, Female (%)	22 (96)	59 (87)	81 (89)	
Age, mean (SD), [range]	37 (7) [29 to 53]	39 (9) [24 to 60]	38 (9) [24 to 60]	t-test p=0.253 n/s
Ethnicity, Caucasian (%)	22 (96)	61 (67)	83 (91)	
Professional experience				
Years qualified as a pharmacist, median, [range]	10 [4 to 32]	15 [1 to 38]	14 [1 to 38]	Mann-Whitney p=0.326
Years as a general practice pharmacist, median, [range]	3 [1 to 19]	3 [1 to 22]	3 [1 to 22]	Mann-Whitney p=0.228
Previous work experience (%)				df=2, cs=0.469 p=0.469
Community	19 (83)	58 (85)	77 (85)	
Community locum	14 (61)	35 (51)	49 (54)	
Other (hospital, locum hospital, educational, academia, etc.)	11 (48)	48 (71)	59 (65)	
Independent prescriber (%)[b]				df=1, cs=0.52 p=0.637
Yes – Active	13 (56)	45 (66)	58 (64)	
No	9 (39)	21 (31)	30 (33)	
Postgraduate qualifications: attained or studying for (%)				df=1, cs=0.004 p=0.949
Any level	12 (52)	36 (53)	48 (53)	
Postgraduate qualifications: attained or studying for (%)				df=2, cs=0.264 p=0.876
Certificate	5 (22)	11 (16)	16 (18)	
Diploma	8 (35)	21 (31)	29 (32)	
MSc to PhD	6 (26)	19 (28)	25 (27)	
Learning styles and methods				
Preferred learning style (%)				df=1, cs=1.601 p=0.205
Activist	8 (35)	34 (50)	42 (46)	
Pragmatist	11 (48)	15 (22)	26 (29)	
Reflector	4 (17)	13 (19)	17 (19)	
Theorist	0 (0)	6 (9)	6 (7)	
Preferred method of learning: Most favoured and favoured (%)				df=7, cs=2.001 p=0.959
Blended learning	20 (87)	63 (93)	83 (91)	
Small group: face to face	19 (83)	57 (84)	76 (84)	
Intense mentoring	15 (65)	53 (78)	68 (75)	
Classroom	14 (61)	41 (60)	55 (60)	
Computer based online	11 (48)	27 (40)	38 (42)	
Audio visual online	6 (26)	26 (38)	32 (35)	
Online self-directed	6 (26)	19 (28)	25 (27)	
Online text	6 (26)	12 (18)	18 (20)	
Self-Efficacy and resilience				
General Self-Efficacy Score (GSES), mean (SD) [range]	22 (1) [17 to 23]	26 (2) [24 to 32]	25 (3) [17 to 32]	t-test p=0.008
General Resilience scale (GRIT), mean (SD) [range]	28 (4) [20 to 35]	31 (4) [21 to 38]	30 (4) [20 to 38]	t-test p<0.001

a. Test carried out between lower quartile (quartile 1 GSES ≤23) and other higher scoring quartiles (quartile 2 to 4, GSES >23)
b. Small cell sizes removed, as per CONSORT reporting guidelines. Therefore number may appear different, e.g. inactive prescribers not included in table.
SD: standard deviation; cs: chi-square; df: degrees of freedom

Table 3. Pharmacist demographics and preferences; categorised by resilience quartile scores

Characteristics	Lower quartile (Quartile 1, n=23)	All higher quartiles (Quartiles 2 to 3, n=68)	Total (n=91)	Test, p-value[a]
Gender, Female (%)	20 (87)	61 (90)	81 (89)	
Age, mean (SD), [range]	39 (9) [24 to 58]	38 (9) [25 to 60]	38 (9) [24 to 60]	t-test p=0.970
Ethnicity, Caucasian (%)	22 (96)	61 (90)	83 (91)	
Professional experience				
Years qualified as a pharmacist, median, [range]	13 [1 to 33]	15 [2 to 38]	14 [1 to 38]	Mann-Whitney p=0.668
Years as a general practice pharmacist, median, [range]	4 [1 to 22]	3 [1 to 21]	3 [1 to 22	Mann-Whitney U-test p=0.974
Previous work experience (%)				df=2, cs=0.656
Community	18 (78)	59 (87)	77 (85)	p=0.720
Community locum	14 (61)	35 (52)	49 (54)	
Other (Hospital, locum hospital, educational, academia, etc.)	17 (74)	42 (62)	59 (65)	
Independent prescriber (%)[b]				df=1, cs=3.304
Yes – Active	11 (48)	47 (69)	58 (64)	p=0.069
No	11 (48)	19 (28)	30 (33)	
Postgraduate qualifications: attained or studying for (%)				df=1, cs=0.004
Any level	12 (52)	36 (53)	48 (53)	p=0.949
Postgraduate qualifications: attained or studying for (%)				df=1, cs=2.322
Certificate or Diploma	5 (22)	28 (41)	33 (36)	p=0.0.127
MSc to PhD	8 (35)	17 (25)	25 (27)	
Learning styles and methods				
Preferred learning style (%)				df=2, cs=2.071
Activist	8 (35)	34 (50)	42 (46)	p=0.355
Pragmatist	9 (39)	17 (25)	26 (29)	
Reflector or Theorist	6 (26)	17(25)	23 (25)	
Preferred method of learning: Most favoured and favoured (%)				df=5, cs=3.083
Blended learning	22 (96)	61 (90)	83 (91)	p=0.687
Small group: face to face	18 (78)	58 (85)	76 (84)	
Intense mentoring	13 (57)	55 (81)	68 (75)	
Classroom	12 (52)	43 (63)	55 (60)	
Computer based online	11 (48)	27 (40)	38 (42)	
Audio visual online, Online self-directed or online text	7 (30)	36 (53)	43 (47)	
Self-Efficacy and resilience				
General Self-Efficacy Score (GSES), mean (SD), [range]	24 (3) [17 to 29]	25 (3) [20 to 32]	25 (3) [17 to 32]	t-test p<0.001
General Resilience scale (GRIT), mean (SD), [range]	24 (3) [20 to 28]	32 (2) [29 to 38]	30 (4) [20 to 38]	t-test p<0.001

a. Test carried out between lower quartile (quartile 1 GRIT ≤28) and other higher scoring quartiles (quartile 2 to 4, GRIT >28)
b. Small cell sizes removed, as per CONSORT reporting guidelines. Therefore number may appear different, e.g. inactive prescribers not included in table.
SD: standard deviation; cs: chi-square; df: degree of freedom

(range 24 to 60) years; 91% identified as being of white ethnicity and 89% were female (Table 2). The median years qualified was 14 (1 to 38) years and 3 (1 to 22) years working within general practices. The majority (n=77) had previously worked for community pharmacy prior to their current role within general practice. Approximately two thirds (n=58) were active independent prescribers and approximately half had completed and attained postgraduate qualifications.

The respondents scored highly for self-efficacy (GSES mean of 25 (SD 3; 95%CI 24.4-25.6) and GRIT mean of 30 (SD 4; 95%CI 29.6-30.4), out of a maximum 32 and 40 respectively. No significant differences were identified between the characteristics of the pharmacists categorised in the lowest quartile and the higher quartiles by self-efficacy (Table 2) or resilience (Table 3). A significant positive correlation was identified between GSES and GRIT scores (Preason's r=0.284, p=0.006), indicating that increases in self-efficacy correlated with increases in resilience (Figure 1).

Of the 91 respondents, less than half (46%) reported that their preferred learning style was activist, followed by pragmatist (29%) and reflector (19%) with the least preferred option being theorist (7%). The pharmacists ranked their preferred learning methods, in descending order, as blended learning (91%) and small group – face to face learning (84%), with less than 42% of respondent preferring computer-based online methods; dropping to a third (32%) and less favouring different online learning methods. There were no significant variations in preferred learning styles or methods between younger and older pharmacists.

DISCUSSION

In this study general practice pharmacists working with general practices scored highly for self-efficacy and resilience. This study did not identify any significant differences in demographics, professional experience, education, years of employment, preferred learning styles or learning methods between those scoring in the lowest quartile and upper quartiles of either the self-efficacy or

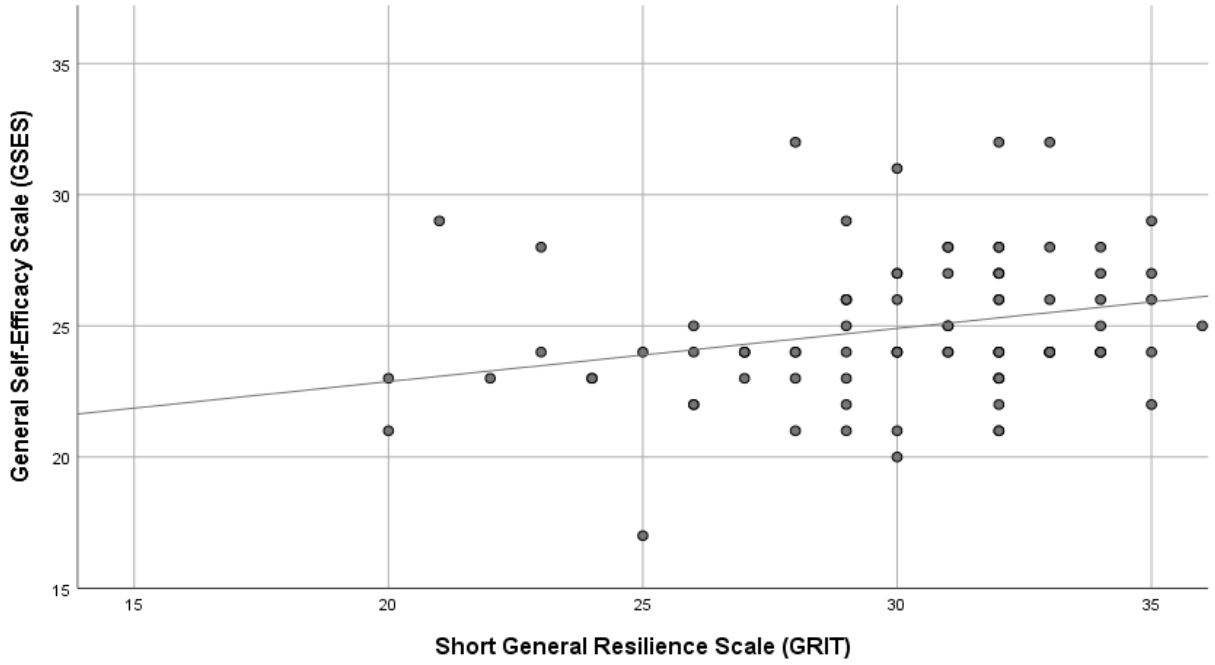

Figure 1. General Self-Efficacy Scale (GSES) and Short General Resilience Scale (GRIT) correlation

resilience scores. However, a positive correlation was identified between self-efficacy and resilience scores for pharmacists working in general practices. The two most preferred learning styles reported by the pharmacists were activist followed by pragmatist, with the majority of pharmacists favouring blended learning methods as opposed to online based learning methods.

Strengths and limitations

The main strength of this study, to authors' knowledge, is that this is the first study to consider, assess and measure general practice pharmacists' self-efficacy and resilience. As such, it may be helpful to others developing training for pharmacists and other multidisciplinary team members supporting general practices and GPs where burnout and work related stress are common.[23-25] Moreover by conducting this study in one large health board there are continuities across the working environments with the same management structures, the same local and national policies and guidelines, as well as having completed similar induction training; involving training and familiarisation in the use of: general practice electronic systems and clinical records; health board clinical guidelines, clinical systems and process; as well as pharmacy services systems, guidelines and prescribing initiatives; although training content and structures have varied over the years, due to changes in local and national priorities such as prescribing cost-efficiencies and the introduction of the new general practice contract in Scotland in 2018 that proposed that all practice would receive more pharmacy support for a greater range of prescribing and clinical activities.[26] This has also lead NHS Education for Scotland to develop national resources to support and enable general practice pharmacists to support GPs to deliver the general practice contract.[10]

Another strength to the authors' knowledge, is that this is also the first study to capture general practice pharmacists' preferred learning styles and preferred learning method. Exploring learning styles will be of interest to national pharmacy bodies and organisations that develop and implement training resources to support and develop general practice pharmacists.[10,27] Yet another strength was the use of an online questionnaire which enabled a large proportion of pharmacists working in 235 general practices across NHSGGC to participate. Furthermore, online data collection enabled the participation of a large number of pharmacists within a short time period. Nevertheless we acknowledge participants could be motivated to provide socially desirable responses, particularly in self-reported perceptions of abilities, skills and self-efficacy. Online surveys may also introduce potentially biased samples, both due to internet access as well as attracting and collecting 'interested respondent' viewpoints.

Despite the limitations of self-reported methods, our findings that pharmacists scored highly for self-efficacy and that there was a correlation between self-efficacy and resilience are comparable to previous pharmacy and nursing studies the UK and internationally.[17,19,20,28] Although this study focused on pharmacist demographic and professional factors that may potentially be associated with their self-efficacy and resilience scores, we did not include environmental workplace factors which may also have influenced findings, such as general practice dynamics and staffing, or pharmacists' personal or social factors that may influence behaviours such as lack of interest or burnout. Pragmatic resource and methodological constraints prevented exploration of environmental factors, however future research such as interview studies or ethnographic studies may identify new themes and factors that impact the behaviour and training needs of pharmacists.

We also acknowledge that we cannot draw conclusions in relation to time and the observed self-efficacy and resilience correlation due to the cross sectional nature of

our study. Findings that more experienced pharmacists did not score significantly higher on either rating scale is of interest as this runs contrary to a previous primary care study which demonstrated that perceived knowledge, skills, and confidence did significantly increase with time, although this may be due to differences in the measured constructs.[29] In relation to learning styles and methods, although blended methods were preferred and definitions were provided, the terms may have meant different things to different people. Moreover the working style of general practice pharmacists, such as working in professional isolation being the only pharmacist working within a practice may have impacted the findings. Additionally barriers associated with online methods such as the lack of face to face contact, collaborative engagement and social interaction could have influenced findings.[30,31] The cross sectional nature of the survey design did not allow for prospective exploration of pharmacists' perceived self-efficacy and resilience or changes in preferred learning style and methods depending on the problem or issue being addressed. Finally although this study was set in a single urban health board, findings may potentially be generalisable; as the survey population's demographics, professional experience, proportion with postgraduate and independent prescribing qualifications were comparable to a large national study.[28]

Comparison with literature

This study's response rate of 57% is higher than two previous UK studies (42% and 46%), but lower than the 83% achieved in a recent national study in Scotland involving general practice pharmacists.[28,29,32] In part this may be due to different recruitment methods, and commentaries associated with requests to complete such surveys. As pharmacists' roles within general practices continue to evolve, participation in such surveys may help to shape the future of the role and general practices' contractual expectations given the inclusion of pharmacotherapy services within the general medical services contract in Scotland.[26] This study's findings are also in line with large studies conducted in Australia and China, involving nurses working in secondary care where similar associations were observed between self-efficacy and resilience.[19,20] Whereas the nursing study in Australia, as with this study, indicated that age, experience, education and years of employment did not appear to contribute to resilience, the study conducted in China however did find that higher levels of education were associated with greater resilience. Lastly in relation to preferred learning methods, this study's findings that pharmacists preferred blended learning are in line with previous studies in different disciplines and settings.[31,33]

Implications for practice and research

A significant challenge for employers, managers and teams is supporting and enabling staff to be effective in delivering services. By identifying and addressing staff training gaps for pharmacists and others with lower self-efficacy and resilience scores, employers may engage and enable more of their staff and teams to improve team dynamics and service delivery, thereby creating a greater culture of excellence within pharmacy and multidisciplinary teams, as well as enabling and encouraging staff to overcome barriers and challenges within routine practice.[15] However individuals' with lower self-efficacy and resilience may represent an unidentified minority group.[34] Some of whom may not voice their concerns, as improving one's own self-efficacy may be an unconscious learning need which individual's may require support in identifying. While others may self-identify and have greater self-awareness regarding belonging to a lower self-efficacy group which may negatively impact their productivity and psychological wellbeing; increasing their risk of emotional exhaustion, burnout and potentially avoidable ill health.[23,35] Yet more controversially perhaps, others may argue that potential candidates for advanced pharmacy practice positions should have their self-efficacy and resilience scores assessed and included as part of the recruitment and selection process to ensure that employers can recruit more resilient staff. However, we would encourage pharmacists, trainers, policy makers and employers to consider self-efficacy and resilience when designing general practice pharmacist training schemes and frameworks to enhance and grow individuals' resilience and enhance the overall wellbeing of the pharmacy workforce.[36]

Pharmacists in this study identified and ranked blended learning as their preferred learning method with computer/online based being the least preferred with no clear intergenerational differences associated with a preferred learning method. However, as more postgraduate training and courses are delivered in online formats from tertiary education centres and professional bodies, the online methods may present a barrier or possibly a deterrent to some.[30] Although in relation to evidence based medicine teaching blended learning was no more effective than classroom or online methods for increasing knowledge and skills, but did have a positive effects attitudes and use of learning.[31,37]

Finally, greater self-efficacy and resilience has also been shown to be an important factor associated with academic success and achievement.[18,38] Therefore as continuing professional development is a key component in ensuring a fit for purpose workforce, supporting staff to address and develop their skill gaps - especially for those with lower self-efficacy and resilience – would potentially have a positive effect on their capabilities as well as their careers and wellbeing.

Lastly, although current general practice pharmacist training does not include behaviour and influencing skills; such as greater self-awareness and "soft skills" that can enable adaptability, and have positive effects on persuasion, conflict resolution, and communication skills. Future research should consider exploring the impact that these "softer skills" have on pharmacist-related patient care and service delivery, as well as on key elements such as self-efficacy, resilience and wellbeing. The use of more in-depth qualitative studies to explore pharmacists' experiences and training needs may help to address some of this study's limitations. Future research with sensitivity to behavioural learning needs of pharmacists in general practice may also open up other opportunities to inform strategies to improve service performance and delivery for our patients, as well as the wellbeing of the individual's delivering pharmacy services within general practices.

CONCLUSIONS

General practice pharmacists on average scored highly for self-efficacy and resilience. Higher scores did not appear to be associated with demographic, years of practice, professional or educational experience. Prospective interventions to support those with lower scores may enhance and optimise pharmacists' effectiveness in general practice.

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CONFLICT OF INTEREST

None.

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Original Research

The impact of a self-management educational program coordinated through WhatsApp on diabetes control

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Abstract

Background: Social media can effectively mediate digital health interventions and thus, overcome barriers associated with face-to-face interaction.

Objective: To assess the impact of patient-centered diabetes education program administered through WhatsApp on glycosylated hemoglobin (HbA1c) values, assess the correlation, if any, between health literacy and numeracy on intervention outcomes

Methods: During an 'intervention phase' spread over six months, target diabetic patients (N=109) received structured education through WhatsApp as per the American Association of Diabetes Educators Self-Care Behaviors recommendations. The control group with an equal number of participants received 'usual care' provided by health professionals void of the social media intervention. Changes in HbA1c levels were recorded thrice (at baseline, 3 and 6 months) for the test group and twice (baseline and 6 months) for the control group. Change in HbA1c values were compared and statistical significance was defined at $p<0.05$. Baseline health literacy and diabetes numeracy were assessed for both groups (N=218) using the Literacy Assessment for Diabetes (LAD), and the Diabetes Numeracy Test (DNT), respectively, and values were correlated with HbA1c change $p<0.05$. Participants' satisfaction with the intervention was also assessed.

Results: The average age of respondents was 41.98 (SD 15.05) years, with a diabetes history of 10.2 (SD 8.5) years. At baseline, the average HbA1c in the control and test groups were 8.4 (SD 1.06) and 8.5 (SD 1.29), respectively. After six months, a significant drop in HbA1c value was noticed in intervention group (7.7; SD 1.35; p= 0.001); with no significance in the control group (8.4; SD 1.32; p=0.032, paired t-test). Moreover, the reduction in HbA1c was more in the test group (0.7%) than the control group (0.1%) with a difference of 0.6% which is considered clinically significant. There was no significant correlation between LAD score and HbA1c at baseline (r=-0.203, p=0.064), 3 months (r=-0.123, p=0.266) and 6 months (r=-0.106, p= 0.337) Pearson correlation. A similar result was observed with DNT, where DNT score and HbA1c at baseline, 3 months and 6 months showed no correlation (r=0.112, 0.959 and 0.886; respectively) with HbA1c levels. Eighty percent of the respondents found the social media intervention 'beneficial' and suggested it be used long term.

Conclusions: Diabetes education via WhatsApp showed promising outcomes regardless of the level of patients' health literacy or numeracy.

Keywords

Social Media; Patient Education as Topic; Self Care; Health Literacy; Patient-Centered Care; Personal Satisfaction; Diabetes Mellitus; Glycated Hemoglobin A; Non-Randomized Controlled Trials as Topic; United Arab Emirates

INTRODUCTION

Diabetes mellitus is a chronic disease affecting millions of individuals worldwide and impacting on patients' quality of life, often leading to morbidity and mortality.[1] The incidence of diabetes rapidly increased worldwide in the last few decades as documented in the International Diabetes Federation Atlas (IDF). There is a high prevalence of diabetes mellitus in the United Arab Emirates (UAE), reaching around 21.4% in 2030 according to IDF 2017 report.[2] This pattern is expected due to rapid economic growth and associated lifestyle changes such as reduced physical activity and increased caloric intake.[3] Diabetes self-management education reinforces lifestyle modification as part of diabetes management.

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Diet and physical activity are aspects of lifestyle modification which lead to improved glycemic control and a decrease in morbidity.[3-7] Worldwide, previous studies reported that diabetes self-management education improves glycosylated hemoglobin (HbA1c) levels and reduces the risk of life-threatening complications.[1,8] However, patients with diabetes face many obstacles adhering to traditional self-management education protocols such as lack of knowledge about potential benefits of education, absence of personalized education, diabetes education costs, and time limitations.[1,5,9,10]

There have been growing efforts to implement new approaches for self-management interventions that improve diabetes control.[1] Recently, information technology use has increased dramatically resulting in improved communication.[11] Social Media is defined as the Internet-based tools that allow individuals to communicate, gather and share information, ideas and images, and to team up with other users in real-time.[12] Social media channels such as Facebook, Instagram, WhatsApp, Snapchat, Twitter may mediate digital health interventions, which provide continuous support and effective communications, and overcome barriers associated with face to face modalities.[4,5] Patients consider social media as a source to get disease-specific information, interact

quickly and efficiently with others and share medical information with a community of patients having similar problems.[3,11]

Social media has become a valuable resource for people with diabetes to enhance self-management skills. Patients who have similar conditions and similar experiences connect very easily through Social media, providing a suitable environment to share knowledge and peer support.[7] However, there is little evidence to support the role of social media in improving self-management behavior and health outcomes in patients with diabetes.[4] Lifestyle changes such as diet adjustment and physical activity involvement, blood glucose monitoring, online education, peer support and real-time interaction between patients and healthcare professionals, are all facilitated through social media.[1,6,7] Hence, healthcare professionals have recommended using social media to improve diabetes self-management skills and consequently improve glycemic control.[6,13]

Patient health literacy levels have a crucial role in patient response to diabetes education efforts.[14] Patients with low health literacy often face obstacles in understanding instructions on prescribed drug labels, comprehending medical education leaflets, consuming healthy diet, and achieving better control of their diabetes.[15,16] Similarly, diabetic patients with low numeracy skills face difficulties in interpreting glucose readings, determining serving portions, applying medications dose changes, and performing daily self-management tasks.[17] Many tools have been used to assess diabetic patients health literacy and numeracy levels, this will help in developing effective educational strategies that are designed to fit patient health literacy and numeracy levels.[18,19] The Literacy Assessment of Diabetes (LAD) is a test of patients' ability to pronounce diabetes-related terms commonly used during clinic visits or when reading food menu and self-care instructions.[20] It is word recognition test, which is considered an indirect measurement of the level of patient comprehension.[21] Diabetes Numeracy Test (DNT) is designed to assess diabetes - related numeracy skills that are required in performing daily diabetes self-management. DNT covers general mathematical skills and concepts such as addition, subtraction, multiplication, division, fractions, and multi-step calculations.[22]

The UAE population is considered one of the world's highest users of mobile phones and social networking avenues which makes social media-related interventions to improve diabetes control possibly successful.[23] Studies evaluating the use of social media to enhance diabetes management in the Middle East are sparse.[3,11] Additionally, a recent literature review showed no previous studies that explored social media interventions in improving diabetes control in the UAE.[3] Therefore, the aim of this research was to assess the impact of a structured patient education coordinated through WhatsApp on diabetes control, and to assess any effect of health literacy and/or numeracy levels of patients undergoing through this education on diabetic control.

METHODS

Study design

This study was approved by Ajman University Research Ethics Committee (approval number: P-F-H-18-11-16), dated 19th January, 2019.

This research was a randomized, two-arm parallel interventional study with a 6 months patient follow-up conducted among diabetic patients. The intervention group received diabetes self-management education through social media network application (i.e., WhatsApp) while the control group received usual care.

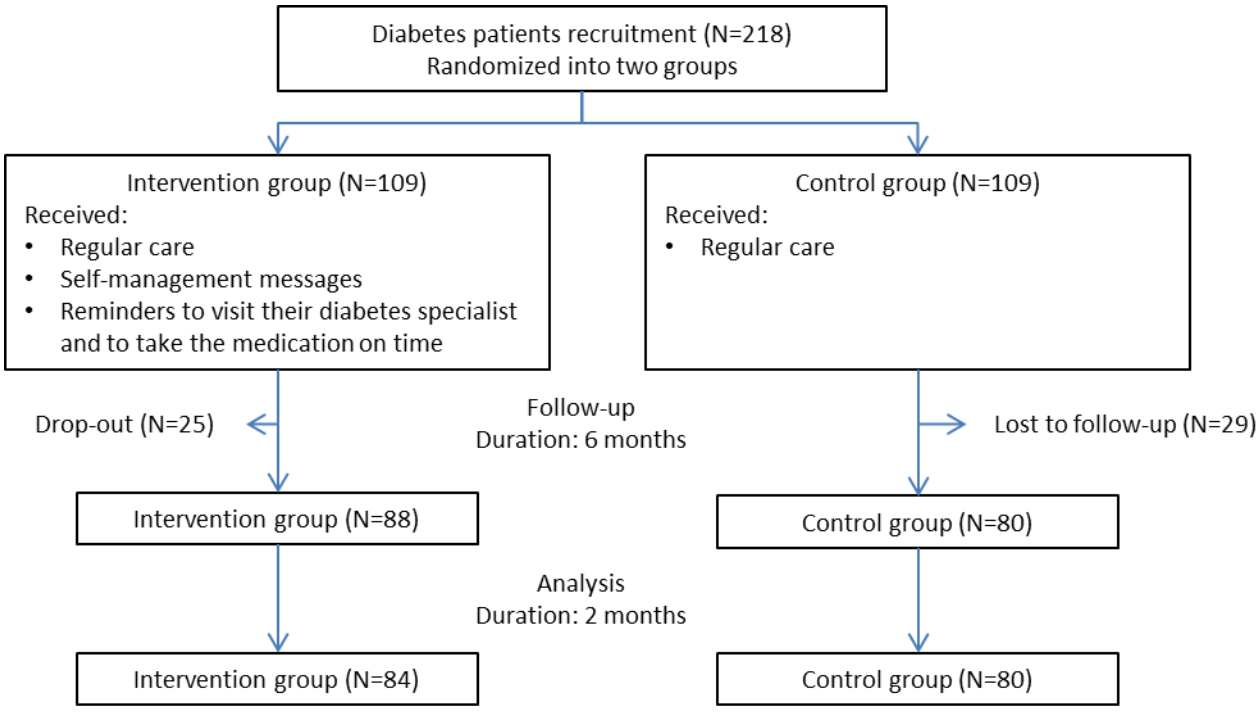

Figure 1. Participant enrollment and follow-up

Participants

Recruitment: Participants from seven emirates (Abu Dhabi, Dubai, Ajman, Fujairah, Ras al Khaimah, Sharjah and Umm al Quwain) were conveniently recruited from private medical centers.

Sample size: This was part of a larger study to translate and culturally adapt the LAD and DNT into the Arabic context.[21] Four hundred patients participated in the original study but only 218 agreed to continue with the six months social media intervention and were hence included.

Inclusion and exclusion criteria: Those whose age is between 18 to 80 years, diabetes mellitus type 1 or 2, could speak Arabic or English, with an HbA1c>7.5%, and were regular users of WhatsApp were included in the study. Those who had severe hearing or visual impairment, or did not know how to use WhatsApp were excluded. Those with gestational diabetes were excluded because their condition required different clinical management procedures (Figure 1).

Randomization: All agreeing participants were randomized into one of two groups using simple randomization method: the interventional group (n=109) and the control group (n=109).

Participant enrollment and consent: Prior to starting the study, participants were asked to sign a consent form and fill out background information including participant demographic and clinical information such as diabetes duration, treatment regimen and if the participants had received diabetes education previously.

Health literacy assessment: Participant's health literacy and numeracy levels were assessed using LAD and DNT before starting the intervention. LAD test was administrated by requesting participants to loudly read and pronounce 60 words. Five seconds were given to read each word, if a particular participant needed more than 5 seconds, he/she was asked to pass to the next word.[20] Participants were then asked to complete the DNT. Here, participants were asked to answer 43 questions related to diabetes numeracy skills required to perform daily diabetes self-management such as nutrition, exercise, managing symptoms of uncontrolled diabetes such as hypoglycemia, oral medications and insulin dosing adjustments.[22]

Structured intervention

During a six months follow-up period, participants in the intervention group received daily educational information through WhatsApp. The educational material related to diabetes self-management behaviors (AADE7 Self-Care Behaviors®) recommended by the American Association of Diabetes Educators (AADE) and the American Diabetes Association (ADA) (Online appendix 1).[24] The AADE7 Self-Care Behaviors® guidelines are suitable for both Type 1 and Type 2 diabetes mellitus. The messages contained information about healthy eating, food portion management, physical activity, self-monitoring of blood glucose, reminders for medication intake, insulin use and coping with and adjusting to living with diabetes.[24]

Each day, participants received WhatsApp messaging about self-management behaviors. Messages were sent at a particular time of the day; though they were opened at the participant's convenient time. WhatsApp broadcast provided private bidirectional communication between the participants and the investigators, which allowed participants to seek advice and get free-of-charge feedback.

Intervention procedure

Step 1: A WhatsApp group was initiated involving participants from the intervention group. This intervention was moderated by the researchers (licensed pharmacists) who were responsible for all communications (Online appendix 2).

Step 2: The original English messages were translated by the research team to Arabic; they were adapted and refined to suit the local cultural context. Before starting the study, participants were asked about their language preference in which messages were to be communicated. All questions sent by participants to the research team through WhatsApp broadcast were treated confidentially.

Step 3: Three months into the study, participants were contacted via WhatsApp to obtain their most recent HbA1c value. HbA1c values were collected via phone calls from those who did not respond to WhatsApp.

Step 4: Six months into the study, participants were contacted again to obtain their HbA1c value and to determine participants' satisfaction level concerning the social media intervention.

Meanwhile, participants in the control group were offered usual diabetes care without the WhatsApp intervention; they only received phone calls 6 months into the study to obtain their most recent HbA1c value. The control group subjects were followed twice versus thrice for the test group. Since the main purpose of the control group was to compare the test group outcome with a similar control in order to quantify the impact of the intervention, the research proposal included only twice measurement for the control group subjects against three for the test group.

The main outcome of the study was the mean change in HbA1c level by comparing the control group and intervention group values at different time intervals. Self-reported HbA1c value was obtained from participants in the intervention group at baseline, 3 months, and 6 months post study initiation, while for the control group, baseline and 6 months HbA1c values were collected.

On the LAD test, scores were totaled and converted to a reading grade level. Scores between 0 and 20 were considered of fourth grade level and below; participants who achieved scores between 21 and 40 were considered of fifth to ninth grade levels, while those achieving scores between 41 and 60 were considered above ninth grade level.[20] DNT scores, however, were reported as a percentage of the total correct answers.[22]

Participant satisfaction level with the social media intervention was assessed online through WhatsApp using a self-developed satisfaction tool at the end of the study. Participants responded on a three-point Likert-type scale (ranging from agree to disagree) to items regarding how much the intervention was beneficial, convenient, and if they agreed to continue using social media to help in monitoring their disease.

Table 1. Participants' demographic and other information.

	Intervention group (N= 84)	Control group (N= 80)	p-value*
Age mean (SD)	43.9 (15.4)	40.06 (14.7)	0.51
Duration of diagnosis of diabetes mean (SD)	9.4 (8.9)	11.2 (8.1)	0.86
	N (%)	**N (%)**	
Gender			
Women	52 (61.9%)	43 (53.8%)	
Men	32 (38.1%)	37 (46.3%)	
Marital status			
single	15 (17.9%)	26 (32.5%)	
married	66 (78.6%)	50 (62.5%)	
divorced	1 (1.2%)	3 (3.8%)	
widowed	2 (2.4%)	1 (1.3%)	
Educational Level			
Never attended school	1 (1.2%)	1 (1.3%)	
Elementary (grade 1-6)	4 (4.8%)	2 (2.5%)	
Intermediate (grade 7-9)	2 (2.4%)	3 (3.8%)	
High school (grade 10-12)	16 (19.0%)	17 (21.3%)	
Collage Graduate	61 (72.6%)	57 (71.3%)	
Medical Insurance			
Yes	38 (45.2%)	36 (45%)	
No	46 (54.8%)	44 (55%)	
Diabetes Type			
Type 1	27 (32.1%)	38 (47.5%)	
Type 2	57 (67.9%)	42 (52.5%)	
Diabetes specialist Visit			
never	1 (1.2%)	0 (0%)	
every month	13 (15.5%)	17 (21.3%)	
every 3 months	20 (23.8%)	23 (28.7%)	
more than 3 months	1 (1.2%)	1 (1.3%)	
as needed	49 (58.3%)	39 (48.8%)	
Diabetes Education			
Yes	34 (59.5%)	50 (62.5%)	
No	50 (40.5%)	30 (37.5%)	
(*) independent sample t-test.			

Prior to starting the main study, a small pilot test was conducted over 3 months on 10 diabetic patients. The pilot study aimed to assess the feasibility and acceptability of the social media intervention procedures. Results obtained were used to refine the main study protocol. The pilot study revealed that patients' desired to continue diabetes follow up through social media for more than 3 months. Participants gave positive feedback about the medical information received through WhatsApp.

Data analysis

The IBM SPSS version 26 was used for data analysis. Descriptive statistical parameters of mean, standard deviations (SD), frequencies and percentages were used to analyze the demographic information and clinical characteristics of the participants. The data was normally distributed as determined by histograms and normality plots. Paired t-test was used to compare HbA1c change in the intervention group at different time intervals (baseline, after 3- and 6-months period) and for the control groups at the baseline and at 6 months. Pearson Correlation was used to assess the association between participants' health literacy level (LAD, DNT scores) and HbA1c change during the social media intervention. Independent sample t-test was used for one variable comparison between two groups. One-way ANOVA was used in multiple group comparisons. Study findings were considered statistically significant if p-value <0.05.

RESULTS

Two hundred and eighteen participants were randomized into two groups: 109 in the interventional group and 109 as the control group. However, 84 participants from the intervention group and 80 participants from the control group completed the study through the 6-month follow-up (Figure 1). The reason for drop outs were participants refuse to continue the program due to social obligations (not interested anymore and not having time, traveling overseas and disconnections in WhatsApp due to change in their telephone number and subsequently the WhatsApp number.

The mean (SD) age of the participants was 41.98 (15.05) years; they had diabetes duration of 10.2 (8.5) years, the earliest 40 years ago, and the most recent was 1 month before the start of the study. Most (57.9%) of the participants were women; (71.9%) were college graduates. More than 60% of the participants had type 2 diabetes mellitus and visited their diabetes specialist only as needed. There was no significant difference of patients' characteristics between the intervention and the control group at baseline (Table 1).

HbA1c decreased significantly in the intervention group from 8.4% (SD=1.06) to 7.7% (SD=1.35) after 6 months (p=0.001) (Table 2).

Table 2. HbA1c change in the intervention and the control groups.

HbA1c	Intervention group (N= 84)		Control group (N= 80)	
	Mean (SD)	p-Value	Mean (SD)	p-Value*
Baseline	8.4 (1.06)		8.5 (1.29)	
3 months	7.9 (1.26)	0.001†	**	**
6 months	7.7 (1.35)	0.001††	8.4 (1.32)	0.032†††
mean change (SD)	-0.7 (0.84)		-0.1 (0.58)	

* Paired t-test at alpha less than 0.05
** no HbA1c value obtained from the control group at 3 months
† statistically significant while comparing baseline with 3 months
†† statistically significant while comparing baseline with 6 months
††† statistically significant while comparing baseline with 6 months

In addition, in both diabetes type 1 and 2 significant differences in HbA1c values between the baseline and after 6 month follow up in the intervention group were seen, see Figure 2.

There were also significant differences in the intervention group between baseline and after 6 months HbA1c values for those younger than 30 years versus those older than 30 years (Figure 3).

However, no significant differences were seen in HbA1c values at different time intervals based on gender, diagnosis duration, obtainment of diabetes education, and availability of medical insurance. Statistical assessments showed no significant differences among different nationalities after the intervention (ANOVA p=0.44).

The results showed that there was no correlation between LAD score and HbA1c value at baseline, 3 months and 6 months (p=0.064, 0.266 and 0.337 respectively). In addition, there was no correlation between DNT score and HbA1c value at baseline, 3 months and 6 months (bivariate Pearson correlation p=0.112, 0.959 and 0.886, respectively).

Only 30 (35.7%) participants responded to the patient satisfaction assessment. Twenty-seven (90%) participants' answers showed preference to continue long-term social media intervention, 24 (80%) said that social media intervention was beneficial, and 20 (67%) classified the WhatsApp intervention as convenient.

DISCUSSION

This study evaluated the usefulness of WhatsApp as a tool to improve communication and achieve better glycemic control among diabetes patients. This study gains importance as there is an increase use of social media in pharmacy practice.[25-29] It is imperative for pharmacy practitioners to explore social media as a potential tool to educate, monitor and assess clinical outcomes. The present research approach involved a direct communication with diabetic patients using social media overcoming the barriers associated with direct personal contact. The intervention provided diabetic patients with readily available, easily accessible, quality information at no cost.

Acute and chronic complications associated with diabetes have been shown to be delayed or prevented by offering patients self-management education.[30] Use of social media in healthcare has widely been encouraged to enable quick, direct and effective communication between patients and health professionals.[4,31,32] This is especially true since smartphone use is now a common trend among most people, adding to their exceptional ability to share data in a

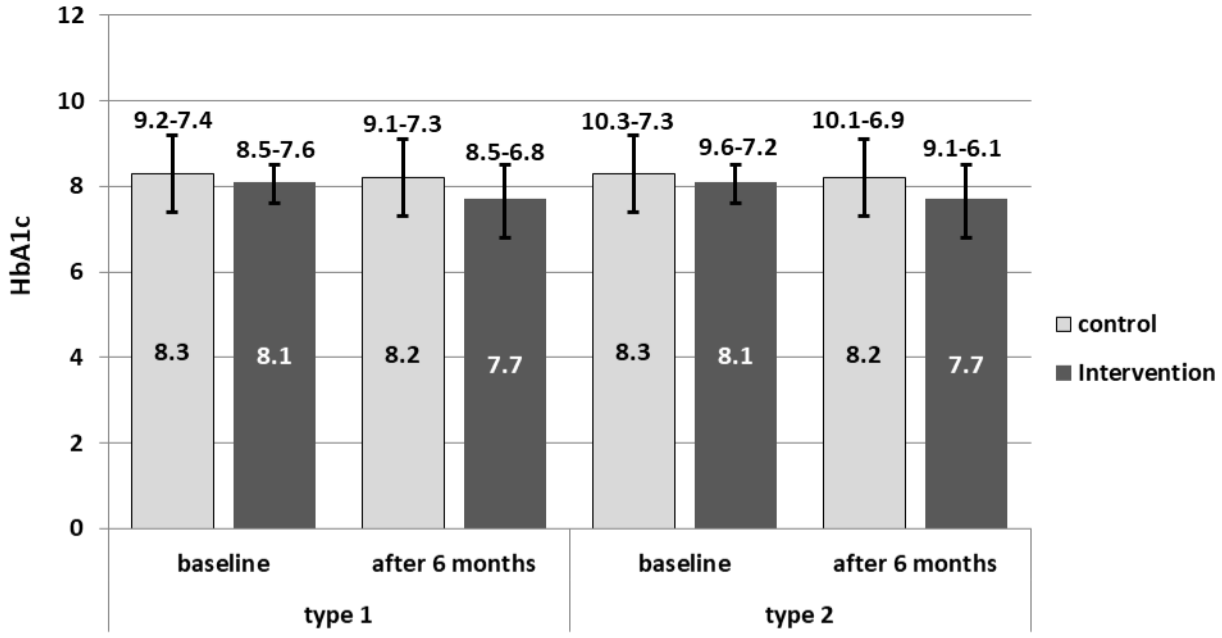

Figure 2. HbA1c change in type 1 and type 2 diabetes mellitus

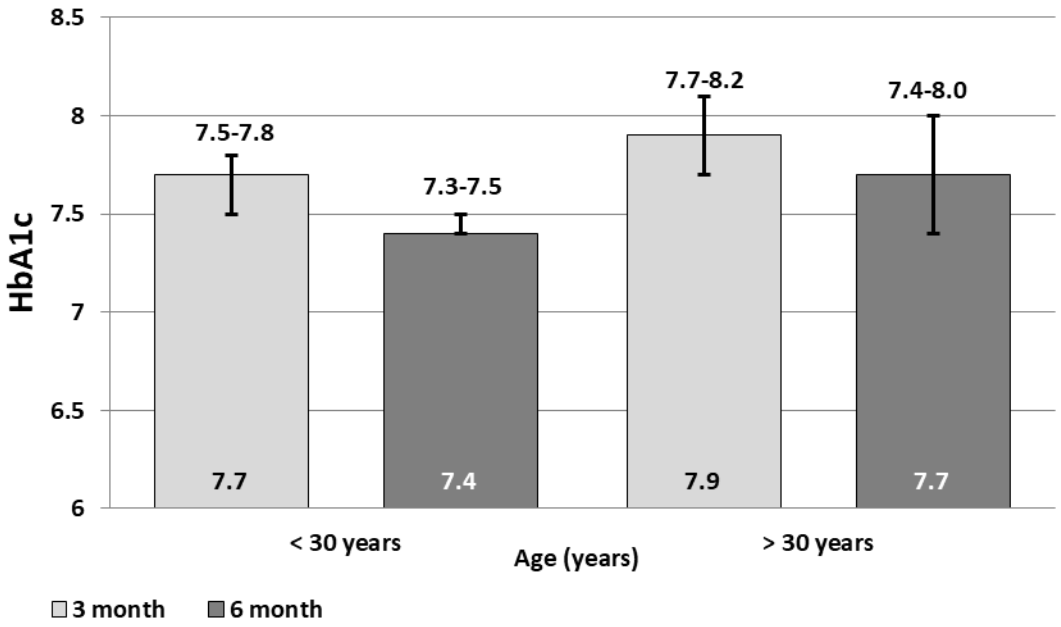

Figure 3. HbA1c change comparison between <30 and >30 years old Diabetes patients in the intervention group

simple, effective, and timely manner.[33] Moreover, patients benefit more with self-management plans if interventions were conducted in a familiar and more convenient environment such as their homes.[34] Hence, it is crucial to design interventions which could be delivered at recipients' convenience regarding time, place and direct human interference.

As a measure of diabetes glycemic control, lowering HbA1c is an important outcome for diabetes interventions.[33] In the current research, after six months of intervention, a significant change in HbA1c value was shown. This reduction was attributed to adherence to medications, timely follow-ups and other tips provided by the pharmacist (Online appendix 1). Moreover, the intervention group had a lower HbA1c values after six months compared to the control group with a difference of 0.6 percent. As per the American diabetes association, a half percentage difference in HbA1c is considered clinically significant change to reduce risk of comorbidities.[8,35] Other studies reported that a one percentage reduction in HbA1c was linked to twenty one percentage risk reduction in diabetes mortality and thirty seven percentage reduction in microvascular complications.[36] These research findings were consistent with previous studies which showed that social media was an innovative and feasible method of improving glycemic control in people with diabetes.[6,8,11] In addition, previous studies proved that traditional or unconventional interventional methods of patient education and reminders were both associated with improvements in patient adherence to guidelines and improvements in patient outcomes.[33,37] However, one study reported that using social media for one year yielded HbA1c reduction similar to that of applying other interventions for three years.[38] It is better to provide long-term diabetes self-management education to avail more effective and efficient patient care services.[39] However, the duration of our intervention was only six months. Interestingly, a previous meta-analysis investigated the effect of antidiabetic medications like thiazolidinedione and sulfonylureas on reduction in HbA1c levels which were reported at 0.5 to 1.25 percentage, respectively.36 Our findings, thus, showed an effect from the social media intervention on HbA1c level reduction as that reported from using pharmacological approaches.

This study also revealed that participants' health literacy and numeracy levels had no effect on HbA1c change after the social media intervention. This was a positive outcome that was worth noting - the social media intervention seemed effective in all patients including those with low health literacy and numeracy skills. In this regard, our findings agreed with those of previous studies which also used social media-based interventions to manage patients with diabetes regardless of their health literacy levels.40 This outcome may be related to the simple language used in the intervention program, in addition to the use of visual aids such as videos and pictures that suited all patients including those with low health literacy.[40,41]

Our results also indicated a greater reduction in HbA1c value among type 2 diabetic patients with a mean change of 0.8 percent compared to 0.4 percent for type 1 patients in a six month intervention period. A possible explanation for this difference in response is that social media intervention through WhatsApp messages targeted factors such as sedentary lifestyle and unhealthy diet whose modification would affect type 2 diabetes control to a larger extent.

The reduction in mean HbA1c value in participants younger than 30 years in our study was significantly higher than that of participants who were older. Results close to the desired HbA1c value were reported to reflect higher social media engagement from younger participants.[8] Similar findings were reported by previous studies which considered age as a barrier to achieving glycemic control related to social media interventions in older patients.[34]

The suitability and sustainability of interventions could be ensured only if the recipients were satisfied with the interventions. A high satisfaction level was reported among participants about using the social media intervention. The findings suggested this approach could potentially encourage participants to adopt a healthy lifestyle and enhance their diabetes self-management behaviors with minimal cost and effort.

in this study, the results revealed the potential of investing in social media programs to improve healthcare outcomes. Several previous studies showed that the use of social media in clinical practice enabled healthcare providers to implement effective patient support, and improve patient engagement and satisfaction.[42]

Strengths and limitations

The strength of this study lies in the use of a larger sample size compared to other studies.[3,35] The treatment regimen with which each participant started was maintained throughout the intervention period; participants whose treatment regimen was changed were removed from the study. Although message content relied on standard guidelines that suited all participants, the content was tailored and customized depending on each participant's needs. This adaptation included different strategies such as message frequency and timing as well as providing options for the participants to select messages from specific self-management domains.[35]

In the WhatsApp application, messages are marked with two blue checkmarks that appeared near to the message after being opened by the recipient. However, the investigators could not be sure that each message sent was actually opened and read. Confidentiality is an issue in using social media especially in the cases of other persons accessing WhatsApp massages. Also, since the effective sample size was decreased to 84 in intervention group and 80 in control group the power of the study could have been compromised.

CONCLUSIONS

Using social media (i.e., WhatsApp) to improve self-management education had a positive influence on glycemic control of patients with diabetes. On average, the social media intervention produced a 0.7% change in HbA1c compared to routine care. The effect of social media on HbA1c change was not influenced by patients' health literacy and numeracy skill levels; this attests to the simplicity of the messages and the efficacy of the intervention. Patients were satisfied with the intervention and agreed to continue to use it if it were to continue in the future. Future research could focus on other outcomes of social media interactions such as the level of patients' engagement, patient behavior and attitudes, and the efficacy of patient-healthcare provider communication levels.

CONFLICT OF INTEREST

The Authors declare no potential conflicts of interest with respect to research, authorship, or publication of this article.

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Original Research

Work fatigue among Lebanese community pharmacists: prevalence and correlates

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Abstract

Objective: To assess work fatigue and its associated factors among community pharmacists in Lebanon.

Methods: This cross-sectional study was conducted between March and July 2018. A proportionate sample of 435 community pharmacists was selected from all regions of Lebanon. A standardized self-administered questionnaire, distributed by trained interviewers, was used to assess the studied variables.

Results: The results showed that 50.12% of the pharmacists had emotional work fatigue [95%CI 0.454-0.549], 55.01% had mental work fatigue [95%CI 0.503-0.597], and 54.78% had physical work fatigue [95%CI 0.501-0.595]. Higher mental work fatigue was significantly associated with higher stress (Beta=0.185) and having a master's degree compared to a bachelor's degree (Beta=2.23). Higher emotional work fatigue was significantly associated with higher stress (Beta=0.219), working more than 40 hours compared to ≤ 16 hours (Beta=2.742), and having 6 months to less than 1 year of practice compared to less than 6 months (Beta=-5.238). Higher physical work fatigue was significantly associated with higher stress (Beta=0.169) and having better soft skills (Beta=-0.163).

Conclusions: Work-related fatigue is high among community pharmacists and touches all aspects: physical, mental, and emotional. In our study, community pharmacists' fatigue levels were associated with educational level, years of experience, working hours, stress, depression, and soft skills, while no relation was found with gender, age, position in the pharmacy, and economic status. Interventions are recommended to tackle this public health problem that affects pharmacists, and eventually, patients.

Keywords

Pharmacists; Occupational Stress; Fatigue; Depression; Professional Practice; Pharmacies; Community Pharmacy Services; Risk Factors; Multivariate Analysis; Lebanon

INTRODUCTION

Work fatigue is related to extreme tiredness and diminished functional capacity that is experienced during and at the end of the workday. Work fatigue has three main dimensions which are physical, mental, and emotional. Physical work fatigue represents massive physical exhaustion and reduced capacity to get involved in physical activity that is experienced during and at the end of the workday. Whereas, mental and emotional work fatigue come from extreme mental and emotional tiredness and decreased ability to engage in cognitive and emotional activities respectively.[1] However, prolonged or chronic work stress can lead to burnout which is characterized by physical and emotional exhaustion that also involves a sense of reduced accomplishment and loss of personal identity.[2]

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The pharmacy profession is a highly demanding career; however, this does not usually contribute to work fatigue. Instead, work fatigue generally occurs when the pharmacist feels overwhelmed or underestimated, with professional and personal pressures also playing a role (3). Pharmacists' work fatigue generally results from sustained stress, work-life imbalance, unproductive work environments, and injustice in the workplace; its prevalence increases when pharmacists are required to deal with multiple duties including dispensing medications, counseling, and answering phone calls. Having to multitask without taking breaks would also lead to depersonalization and apathy.[4,5] Such environment can be detrimental to health institutions. When multiple workflow factors seem hazardous or uncontrollable, the pharmacy environment becomes progressively chaotic, especially during emergency situations, vacations, or regular rush hours.[6,7]

Pharmacists' work fatigue can have significant consequences, including lower quality of patient care, patient safety issues, and increased employee turnover; it can also have an impact on personal and social life and make the pharmacist more susceptible to illness.[8] Several mechanisms can explain susceptibility to illness. Firstly, work fatigue rewires the brain. In fact, people complaining from work fatigue symptoms have a lower control on their emotions in stressful situations. The more stressed the person is, the more difficult it is to handle further stressors in different aspects of life.[9,10] Work fatigue can, therefore, impede both personal and social aspects of life, and may lead to a deterioration in work and personal relationships.[11] Secondly, professional work fatigue hugely interferes with

personal life. When workplace requirements exceed the pharmacists' capabilities during the day, many of them try to complete their tasks at home, thereby affecting their relationship with their families. In addition to this, work fatigue usually leads to depression and hence can affect all types of personal relationships.[12] Work fatigue may affect the pharmacists' health, as several studies have found a positive correlation between work fatigue and psychological and physical illnesses.[13] Symptoms described by pharmacists at the end of their working day included neck pain (62%), eye fatigue (44%), hand pain (38%) and insomnia (34%).[8,14]

Work fatigue among pharmacists is still increasing worldwide, varying by countries. Previous findings demonstrated that 66% of pharmacists acknowledged their workload being high to excessively high, which was reported to adversely affect the emotional and mental health of 45% of the participants. Another study among U.S. hospital pharmacists revealed that the work fatigue rate was high (61.2%) and mainly caused by high emotional fatigue.[5,15] A 2017 study among U.S. clinical pharmacists found that more than 61% complained of work fatigue.[16,17] In 2018, a survey conducted by the American Society of Health-System Pharmacists showed that 53% of pharmacists reported a high degree of work fatigue due to increasing stress and job requirements.[16,17] In France, a recent nationwide study revealed that the reported prevalence of burnout among community pharmacists was 56.2%, while in Turkey, 71.3% of community pharmacists had a high level of inefficacy due to work fatigue.[14,18]

As for Lebanon, data are scarce. A recent study has shown that the financial situation of community pharmacists has deteriorated; monthly sales and profits have dramatically declined in the last years, as has the number of patients.[19] On the other hand, pharmacy expenses, such as the rent, salaries of employees, taxes, the total bills (electricity, water, cleaning), and the disposal of expired products, have significantly increased.[19] In this context, this study was conducted to assess work fatigue and its associated factors among community pharmacists in Lebanon.

METHODS

Study design

Between March and July 2018, a cross-sectional study was conducted using a proportionate number of community pharmacies from all Lebanese districts, according to the exhaustive list of pharmacies issued by the Order of Pharmacists of Lebanon (OPL) [N.B.: the official association of pharmacists in Lebanon].

The study protocol was approved by the Ethics committee at the Psychiatric Hospital of the Cross (HPC-006-2019). Each pharmacist signed a written informed consent prior to enrollment.

The Epi info software calculated a minimal sample size of 350 pharmacists to provide adequate power for bivariate and multivariate analyzes, based on a total number of 3,762 pharmacists working in community pharmacies in Lebanon, expected frequency of 50% of pharmacists with work fatigue (as there are no comparable studies in Lebanon), a confidence interval of 95%. At the end of the data collection, 435 (87%) out of 500 questionnaires were collected back.

Questionnaires and variables

The self-administered questionnaire was distributed in either French or English, (the teaching languages of pharmacy in Lebanon), and required 20 minutes approximately to complete. It was distributed to pharmacists by well-trained interviewers, who did not guide the participants in their answers to ensure optimal objectivity. Each pharmacist would put the filled survey in a closed box to preserve his/her anonymity. Data analysis was anonymous and confidential.

The questionnaire consisted of two sections. Information about socio-demographics and practice features were collected in the first section, as well as the geographic area of residence, pharmacy location, the average patients' number visiting the pharmacy daily, years of experience and the house crowding index. In addition, the social status of the patients entering the pharmacy was self-reported by each community pharmacist. The second part included the following scales:

The Three-Dimensional Work Fatigue Inventory (3D-WFI)

It consists of 18 questions divided into 3 parts of 6 questions each, evaluating physical, mental and emotional work fatigue respectively.[1] In all 3 dimensions, work fatigue increases with higher scores. The Cronbach's alpha values were as follows: physical (0.880), mental (0.710) and emotional (0.848).

Hamilton depression rating scale (HDRS)

The validated Arabic version of HDRS was used in this study.[20] The score is based on the first 17 items, with higher scores indicating higher depression (Cronbach's alpha=0.870).[21]

Beirut Distress Scale (BDS-22 scale)

This scale, validated in Lebanon, consisted of 22 questions that assess the level of stress during the last week, with higher scores reflecting higher levels of stress (Cronbach's alpha=0.935).[22]

Lebanese Insomnia Scale (LIS-18)

This 18-item scale, developed from several validated and universally applicable self-report scales and recently validated in Lebanon, is used to screen for insomnia in adults.[24] Higher scores indicate higher insomnia (Cronbach's alpha =0.811).

Soft Skills Questionnaire: The Social and Emotional Nationwide Assessment (SENNA 1.0) short version

This 24-item questionnaire is used to evaluate soft skills. It measures six dimensions: Conscientiousness, Neuroticism, Agreeableness, Openness to Experience, Extraversion, and External Locus of Control.[23] Higher scores indicate better soft skills (Cronbach's alpha=0.757).

Forward and back-translation procedure

A forward (from English to French) and backward translation process was performed by two independent translators. Discrepancies were resolved by consensus. Before starting data collection, both versions were pilot-

Table 1. Sociodemographic and socioeconomic characteristics of the participants (n= 435)

Factor	N (%)
Gender: Male	223 (52.0%)
Governorate	
Beirut	77 (18.0%)
Mount Lebanon	150 (35.1%)
North	66 (15.5%)
South	48 (11.2%)
Bekaa	48 (11.2%)
Educational level	
Bachelor of science	250 (58.4%)
Pharm.D.	106 (24.8%)
Masters	60 (14.0%)
PhD	12 (2.8%)
Professional status	
Owner	299 (68.7%)
Assistant pharmacist	128 (30.0%)
Experience	
Less than 6 months	24 (5.6%)
6 months to 1 year	20 (4.6%)
1 year to less than 3 years	36 (8.4%)
3 years to less than 6 years	64 (14.8%)
6 years to less than 12 years	118 (27.4%)
More than 12 years	169 (39.2%)
Approximate number of patients seen per day in the pharmacy	
< 10	3 (0.7%)
10-50	131 (30.8%)
50-100	188 (44.2%)
> 100	103 (24.2%)
Working hours per week	
1-16 hours per week	27 (6.3%)
17-31 hours per week	48 (11.2%)
32-40 hours per week	96 (22.3%)
More than 40 hours per week	259 (60.2%)
Social status of the majority of patients	
Poor	26 (6.1%)
Middle	193 (45.6%)
High	16 (3.8%)
Do not know	185 (43.7%)
Family income per month	
<1000 USD	35 (8.9%)
1000-2000 USD	90 (20.7%)
2000-3000 USD	129 (32.7%)
>3000 USD	140 (35.5%)
	Mean (SD)
Age (in years)	38.97 (11.13)
House crowding index	0.89 (0.44)

tested on 20 pharmacists; the results recorded were disregarded in the final database.

Data analysis

The data entry was carried out by a study-independent person, and statistical analysis was performed on SPSS version 23. The Student t-test was used to compare work fatigue and dichotomous variables, and the ANOVA test was applied to compare between 3 or more groups. Finally, a stepwise linear regression was computed by taking the scores of work fatigue subscales as dependent variables, and variables showing a significant association in the bivariate analysis as independent variables. A $p<0.05$ was considered statistically significant.

RESULTS

Out of the 500 distributed questionnaires, 435 (87%) were completed and collected back. The socio-demographic characteristics are summarized in table 1. The mean age of participants was 39 ± 11years, with 206 (47.4%) females. The majority of participants were pharmacy owners (n= 299, 68.7%), 169 (38.9%) had more than 12 years of experience, around 60% (n=259) worked more than 40 hours a week, and 188 (43.2%) reported a daily patients' load between 50 and 100 patients (Table 1). In the absence of cutoff points for the 3D-WFI scale, the medians of the physical, mental, and emotional work fatigue scores were taken as the cutoff points. The results showed that 50.12% of the pharmacists had emotional work fatigue [95%CI 0.454-0.549], 55.01% had mental work fatigue [95%CI 0.503-0.597], and 54.78% had physical work fatigue [95%CI 0.501-0.595].

The scores of the scales included in the survey are presented in Table 2. The emotional work fatigue score was the highest among fatigue scores. The remaining scores, such as stress, insomnia, and soft skills were high, while the mean of depression score (6.9) was less than 10, indicating no symptoms of depression among community pharmacists.

A significantly higher mean mental work fatigue was found among pharmacists with a Master's degree compared to those with other degrees. Higher stress, insomnia, and depression were significantly associated with higher mental work fatigue.

A significantly higher emotional work fatigue was found in those having between 3 and less than 6 years of experience compared to all other categories, in those working up to 16 hours compared to all other categories, and in owners compared to assistant pharmacists. Moreover, higher stress, insomnia, and depression were significantly but weakly associated with higher emotional work fatigue. Higher stress, insomnia, depression, and having better soft skills were significantly but weakly associated with higher physical work fatigue (Table 3).

Higher mental work fatigue was significantly associated with higher stress (Beta=0.185) and having a master's degree compared to a bachelor's degree (Beta=2.23) (Table 4, Model 1).

Higher emotional work fatigue was significantly associated with higher stress (Beta=0.219), working more than 40 hours compared to up to 16 hours (Beta=2.742), and having 6 months to less than 1 year of practice compared to less than 6 months (Beta=-5.238) (Table 4, Model 2).

Higher physical work fatigue was significantly associated with higher stress (Beta=0.169) and having better soft skills (Beta=-0.163) (Table 4, Model 3).

Table 2. Scores for different questionnaires in the surveys delivered for community pharmacists

Score	Mean (SD)
Stress score	42.37 (13.49)
Insomnia score	37.53 (8.44)
Depression score	6.90 (7.01)
Emotional work fatigue score	17.38 (10.42)
Mental work fatigue score	8.36 (6.50)
Physical work fatigue score	7.63 (8.29)
Soft skills score	75.80 (10.88)

Table 3. Bivariate analysis of factors associated with the work fatigue subscales scores

Variable	Mental work fatigue		Emotional work fatigue		Physical work fatigue	
	Mean (SD)	p-value	Mean (SD)	p-value	Mean (SD)	p-value
Gender		0.135		0.093		0.778
Female	8.82 (6.61)		18.25 (10.75)		7.75 (8.43)	
Male	7.87 (6.37)		16.55 (9.95)		7.52 (8.11)	
Education		0.008		0.133		0.648
BS	7.72 (5.70)		16.79 (10.01)		7.72 (8.10)	
Pharm.D	8.65 (6.29)		17.46 (10.37)		6.67 (7.56)	
Master	10.79 (9.38)		20.37 (11.94)		7.94 (9.52)	
PhD	6.66 (4.00)		17.50 (10.75)		8.66 (9.69)	
Family monthly income		0.732		0.332		0.103
<1000 USD	7.80 (5.71)		15.62 (8.87)		9.82 (8.91)	
1000-1999 USD	8.21 (6.70)		18.60 (10.46)		8.36 (8.52)	
2000-2999 USD	8.96 (7.31)		16.46 (10.97)		8.10 (8.55)	
3000 USD and above	8.31 (6.10)		17.81 (10.25)		6.43 (7.98)	
Years of experience		0.078		0.005		0.236
Less than 6 months	8.50 (5.52)		12.45 (8.23)		6.20 (4.73)	
6 months to less than 1 year	4.42 (4.12)		11.15 (9.62)		5.10 (1.17)	
Between 1 and less than 3 years	9.66 (6.85)		15.47 (8.45)		10.08 (10.62)	
Between 3 and less than 6 years	8.75 (7.48)		18.85 (9.98)		7.58 (7.72)	
Between 6 and less than 12 years	8.88 (6.11)		18.37 (10.33)		8.12 (8.43)	
12 years and above	8.00 (6.57)		18.15 (10.04)		7.26 (8.38)	
Number of working hours		0.338		0.016		0.830
Up to 16 hours	10.51 (6.45)		19.70 (10.38)		8.03 (9.79)	
Between 17 and 31 hours	8.04 (5.33)		15.56 (9.33)		7.20 (5.99)	
Between 32 and 40 hours	7.98 (6.02)		15.11 (9.10)		8.26 (8.21)	
> 40 hours	8.40 (6.89)		18.52 (10.90)		7.43 (8.51)	
Patients' load per day		0.828		0.906		0.570
< 50	6.00		17.05 (10.88)		7.19 (7.64)	
50-100	-		17.56 (10.33)		7.61 (7.83)	
>100	-		17.44 (9.62)		8.35 (9.83)	
Position in the pharmacy		0.925		0.037		0.324
Owner	8.42 (6.75)		18.12 (11.09)		7.38 (8.44)	
Assistant pharmacist	8.36 (5.94)		15.79 (8.66)		8.26 (7.92)	
Age	r=-0.016	0.750	r=0.038	0.440	r=-0.071	0.155
House crowding index	r=-0.04	0.443	r=-0.001	0.979	r=-0.037	0.485
BDS-22 score	r=0.408	<0.001	r=0.284	<0.001	r=0.341	<0.001
Insomnia score	r=0.127	0.009	r=0.111	0.023	r=0.188	<0.001
Soft skills	r=0.053	0.280	r=0.088	0.069	r=-0.220	<0.001
Hamilton depression score	r=0.116	0.017	r=0.113	0.020	r=0.118	0.016

DISCUSSION

This study is the first to assess work fatigue among Lebanese community pharmacists nationwide. The scores of emotional, mental, and physical work fatigue indicated a considerable level of fatigue among community pharmacists, whether pharmacy owners or assistant pharmacists. In our study, levels of work fatigue among community pharmacists were associated with educational level, years of experience, number of working hours, stress, depression, and soft skills. However, no relation was found between work fatigue and gender, age, position in the pharmacy, and economic status.

Our results showed that stress score was positively associated with mental, emotional, and physical fatigue scores, in line with former findings among New Zealand health professionals, where high levels of stress among pharmacists were associated with severe work fatigue, and a decline in quality of life and service provision.[24] Stress

Table 4. Multivariable analysis of factors associated with the burnout subscales scores.

Variable	Unstandardized beta	Standardized beta	p-value	Confidence Interval
Model 1: Stepwise linear regression taking the mental work fatigue score as the dependent variable. Variables entered in model 1: stress, insomnia, depression, soft skills.				
Stress (BDS-22 score)	0.185	0.381	<0.001	0.141:0.228
Master degree compared to bachelor	2.230	0.119	0.008	0.590:3.870
Model 2: Stepwise linear regression taking the emotional work fatigue score as the dependent variable. Variables entered in model 2: Education level, stress, insomnia, depression.				
Stress (BDS-22 score)	0.219	0.284	<0.001	0.149:0.290
Working more than 40 hours compared to ≤ 16 hours	2.742	0.129	0.006	0.810:4.673
Having 6 months to less than 1 year of practice compared to less than 6 months	-5.238	-0.105	0.025	-9.801:-0.676
Model 3: Stepwise linear regression taking the physical work fatigue score as the dependent variable. Variables entered in model 3: Years of practice, working hours, stress, insomnia, depression.				
Stress (BDS-22 score)	0.169	0.272	<0.001	0.115:0.222
Soft skills score	-0.163	-0.191	<0.001	-0.236:-0.091

levels among Lebanese community pharmacists have been reported to be highly correlated with various socioeconomic issues in the country.[25] Moreover, work-related stressors such as excessive workload, frequent interruptions by phone calls or others, and lack of adequate staff were associated with high work stress. Lebanese pharmacists also reported being frequently engaged in stressful activities such as those related to drug repricing and changes in reimbursement conditions; these tasks that do not require pharmaceutical knowledge or skills, lead to an increased risk of stress.[19] Another study of stress and job satisfaction among pharmacists in Saudi Arabia highlighted similar job-related stressors, such as the pharmacy setting, long working hours, difficulty in obtaining casual or sick leave, and low salaries.[26] Several other studies have also demonstrated a high level of stress among pharmacists due to workload, work environment, and decreased quality of work. A study in France had found a high level of work-related stress in a large number of community pharmacies, with more than 30% of participants massively affected, whether owners or assistant pharmacists.[27] Also, a study in Japan reported a high prevalence of psychological distress, thus high work fatigue among pharmacists, while a study in Ireland showed that community pharmacists had high levels of work-related stress.[26,28]

In our study, the level of education was found to be a major determinant of mental work fatigue. Holders of a master's degree had significantly higher levels of mental work fatigue compared to holders of a BS degree. To have a better understanding, it is worth describing the pharmacy curriculum in Lebanon. The pharmacy curriculum consists of studying 5 years leading to a Bachelor of Science (BS) degree with an additional year to obtain a Doctor of Pharmacy degree (PharmD) which is optional in some universities. In addition, there are several specialties for postgraduate studies such as Masters and PhD. Regardless the obtained degree, the pharmacist should pass the "colloquium" – which is the national licensure examination necessary to apply for a license to practice pharmacy – and then become registered in the OPL to be eligible to practice pharmacy profession.[29]

Regarding our finding, there are several possible explanations: higher involvement in patient care activities, including patient education and counseling for chronic diseases; the major changes in the pharmacy profession, emphasizing the pharmacist's role as a medication therapy expert rather than a drug expert solely; and demotivation resulting from the feeling of being overqualified for the job required.[30-32]

Our results also demonstrated a negative association between the number of years of practice and emotional work fatigue. Indeed, pharmacists with more than six months of practice had lower emotional work fatigue compared to those with less than a 6-month practice. These results are consistent with those of a study among hospital pharmacists in Japan reporting that work-related fatigue decreased with years of experience.[28] This finding was also similar to that of a systematic review on the prevalence of work fatigue among health care professionals in the Arab countries where a higher number of years of experience was associated with lower levels of work fatigue among Iranian nurses and Saudi Arabian physiotherapists.[7] This can be explained by a resistance to work fatigue that may develop over the years of experience.

Our results also showed that work fatigue significantly increased with prolonged working hours (more than 40 hours). This finding was reported in previous studies highlighting its massive consequences on professional practice. The detrimental effects of fatigue on both the pharmacist and the patient are well documented in the literature. Indeed, long working hours and subsequent exhaustion trigger an alarm for patient safety, with the increased risk of medication errors that might result.[7,33,34]

Furthermore, our study showed that work fatigue significantly decreased with higher soft skills, similar to findings from other studies conducted on different health care providers. These studies revealed that fatigued workers usually have poor communication with their work environment and get easily angry with others, and thus have the highest rate of disastrous incidents. However, pharmacists with higher soft skills have higher self-confidence and improved interpersonal relationships and communication skills, which improves their performance with fewer efforts. Therefore, training pharmacists in communication skills improves their self-efficacy in stressful situations and increases their adaptability, as well as work accomplishment and success.[35,36]

Clinical implications

This study triggers an alarm towards the increasing levels of work fatigue among community pharmacists and unveils several associated factors. Hence, from the findings of our study, several interventions can be recommended to reduce the burden of work fatigue and avoid its massive consequences on physical and psychological health, and thus improve pharmacists' performance and the quality of services provided. Working hours can be reduced, and work appreciation increased on the financial and personal levels. Training pharmacists to improve their communication skills is as important as monitoring their work fatigue to develop strategies aiming to prevent this global problem.

Limitations and strengths

This study has some limitations. Its cross-sectional design does not allow for any clear temporal sequence between socioeconomic or psychological factors and work fatigue. The 3D-WFI is not validated for use in Lebanon. An information bias is possible because of over/under estimation of an answer and subjectivity (patients' social status). Thus, associations need to be further assessed by qualitative and longitudinal studies. Furthermore, additional confounding related to personality characteristics and work fatigue could be examined in future research.

However, some strengths could be highlighted. Indeed, this study is the first to address work fatigue among a representative sample of Lebanese community pharmacists. Moreover, selection bias was minimized by sampling from different geographical areas and the high response rate (87%). Finally, information biases were limited by the use of a self-administered anonymous standardized questionnaire and validated scales to measure subjective data.

CONCLUSIONS

In conclusion, work-related fatigue is high among community pharmacists and touches all aspects: physical, mental, and emotional. In our study, community pharmacists' fatigue levels were associated with educational level, years of experience, working hours, stress, depression, and soft skills, while no relation was found with gender, age, position in the pharmacy, and economic status. Interventions are recommended to tackle this public health problem that affects pharmacists, and eventually, patients.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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Original Research

Cost of hospitalisation and length of stay due to hypoglycaemia in patients with diabetes mellitus: a cross-sectional study

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Abstract

Objective: This study aims to estimate the length of stay and hospitalisation cost of hypoglycaemia, and to identify determinants of variation in the length of stay and hospitalisation cost among individual patients with type 1 or 2 diabetes mellitus.

Methods: A cross-sectional study was conducted using inpatients records for patients with diabetes mellitus who had been hospitalised due to hypoglycaemic events in two private hospitals in Amman, Jordan between January 2009 and May 2017. All hospitalisation costs were inflated to the equivalent costs in 2017. Hospitalisation cost was estimated from the patient's perspective in Jordanian dinars (JOD). Descriptive analyses and correlation between sociodemographic or clinical characteristics with the cost and length of stay were explored. Predictors of hypoglycaemic hospitalisation cost and length of stay were determined using logistic regression.

Results: During the study period a total of 126 patients with diabetes mellitus were hospitalised due to an incident of hypoglycaemia. The mean patient age was 64.2 (SD=19.6) years; half were male. Patients admitted for hypoglycaemia stayed in hospital for a median duration of two days (IQR=2 days). The median cost of hospitalisation for hypoglycaemia was 163.2 JOD (USD 230.1) (IQR=216.3 JOD). We found that the Glasgow coma score was positively associated with length of stay (0.345, p=0.008), and older age was correlated with higher hospitalisation cost (0.207, p=0.02). Patients with a family history of diabetes had higher hospitalisation costs and longer duration of stay (0.306 and 0.275, p<0.05). In addition, being a male patient (0.394, p<0.05) and with an absence of smoking history was associated with longer duration of stay (0.456, p<0.01), but not with higher hospitalisation cost.

Conclusions: Costs associated with the incidence of hypoglycaemic events are not low and constitute a large cost component of managing and treating diabetes mellitus. Male patients and patients having a family history of diabetes should receive extra care and education on the prevention of hypoglycaemic events, and a treatment de-intensification approach should be considered if necessary, so we can prevent its associated hospitalisation costs and length of stay.

Keywords

Hospital Costs; Length of Stay; Hospitalization; Diabetes Mellitus; Hypoglycemic Agents; Hypoglycemia; Incidence; Logistic Models; Cross-Sectional Studies; Jordan

INTRODUCTION

Diabetes mellitus (DM) is considered one of the most common life-threatening conditions due to its association with various fatal chronic and acute complications.[1] In 2015, DM affected around 415 million patients worldwide; this figure is expected to reach 642 million by 2040.[2] The majority of patients with DM are diagnosed with type 2 DM, making up around 90% of cases.[2,3] The estimated cost of treating diabetic patients in 2015 had reached USD 673 billion and is expected to reach USD 802 billion by 2040.[2] The costs of diabetes include direct medical costs such as hospital inpatient care, emergency department visits, diagnostic tests, and prescription drugs; indirect costs such as productivity losses related to morbidity and mortality, in addition to other direct non-medical costs and intangible costs.[4]

One of the main problems encountered in the treatment of DM is the incidence of hypoglycaemic events.[5,6] Hypoglycaemia is a serious adverse event in patients with DM. Although the risk of hypoglycaemia is higher among patients with type 1 DM, patients with both type 1 DM and type 2 DM are prone to hypoglycaemic events due to their use of antidiabetic medications such as insulin in type 1 DM and type 2 DM, and intensive antidiabetic therapy, commonly associated with insulin secretagogues, and intensive antidiabetic therapy.[6,7] Previous studies have found that the hypoglycaemia incidence rate among patients who are on oral antidiabetic medications ranges between 16% and 39% [8, 9]. Prevalence of hypoglycaemia was 45.0% (95%CI 0.34 - 0.57) for mild/moderate events, and 6.0% (95%CI 0.05 - 0.07) for severe events.[10] Incidence of hypoglycaemic episodes per person-year for mild/moderate and for severe episodes was 19.0 (95%CI 0.00-51.08) and 0.8 (95%CI 0.00-2.15), respectively.[10]

Costs associated with the incidence of hypoglycaemic events are not low, and constitute a large cost component of managing and treating diabetes.[11-14] Costs associated with hypoglycaemia involve direct, indirect, and intangible costs, which differ significantly according to the severity of the hypoglycaemic event experienced by the patient.[15] Estimating the economic impact of hypoglycaemia on healthcare services is important as it helps in the development of effective interventions that improve diabetes management and the overall process of patient care.[16] This study aimed to estimate the length of stay and cost per hypoglycaemia episode, and to identify

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determinants of variation in length of stay and hospitalisation cost among individual patients with either type 1 or type 2 DM.

METHODS

Study design

This study employed a cross-sectional study design of patients with DM and confirmed diagnosis of hypoglycaemic events for the period between January 2009 and May 2017. Hypoglycaemic events can be broadly defined as either severe, when the patient is admitted to hospital because of hypoglycaemia; moderate, when the patient seeks medical attention for hypoglycaemia but is not admitted to hospital overnight; or mild, when the patient requires no medical attention and needs only assistance from family or friends.[17] In this study, we defined hypoglycaemia as an event that required hospitalisation or admission, which included only severe and moderate hypoglycaemic events.

Study population

Inclusion criteria for this study were: 1) patients were required to have been diagnosed with either type 1 or type 2 DM, and 2) visited the emergency department of a hospital because of a hypoglycaemic episode during the study's time frame (from January 2009 to May 2017). Patients who did not meet the inclusion criteria mentioned above were excluded.

Study site

Two private hospitals in Amman, the capital of Jordan, were selected as the sites of data collection for this study. The two hospitals have a total capacity of 285 beds, providing advanced inpatients and outpatients health care services for the Jordanian population, with more than 700 physicians from different specialities.[18,19]

Data extraction

Data were obtained from the electronic database at each hospital as well as from medical records for each eligible patient. Patients' records were identified using the diagnostic codes E16.0, E16.1, E16.2 from the 10th version of the International Statistical Classification of Diseases (ICD) system. Data collected includes patient demographics, medical history, DM-specific information (such as type of DM, duration of the disease, and family history of the disease), medications use history (including antidiabetic medications and other prescribed medications), patient-specific clinical information (such as history of previous surgery, engagement in daily exercises, living status and their dependency in activities of daily living "degree of help they need to perform their daily activities"), patient admission-related information (such as behaviour during admission, mental health status, communication barrier, admission time, length of stay, and status on discharge), patients' health score at the time of admission (such as Glasgow coma scale, venous thromboembolism risk factor score, and Braden risk assessment score), and hypoglycaemia-specific information (such as the time of the event and blood glucose level (mg/dL) at the time of the event).

Study outcomes

Study outcomes included the median cost of hospitalisation and length of stay, and rate of mortality. The mortality rate of patients admitted for hypoglycaemia was calculated by dividing the number of patients who died during their admission by the total number of admitted patients.

Costs estimation

Direct costs were identified as the costs of the management of hypoglycaemic events such as hospitalisation and emergency department services.[20] Data on individual patient treatment costs were obtained from the financial departments of the participating hospitals, where it was presented as total cost per admission. Hospitalisation costs included: a) emergency management care such as ambulance service, emergency department visit, and the cost of the observation period by healthcare professionals, costs of medical procedures and medications provided, and b) hospital stay cost for admitted patients.

Hospitalisation cost was estimated in Jordanian dinars (JOD) (exchange rate is USD 1.41) as reported by the central bank of Jordan.[21] All costs were inflated to costs in 2017; the inflation rate was averaged as 5.3% from 1977 until 2017, as reported by the Department of Statistics in Jordan.[22] The following formula was used to calculate the inflated cost:

$$Inflated\ cost = Initial\ cost * (1 + inflation\ rate)\text{^}n$$

Initial cost: the cost in any year before 2017; inflation rate: average inflation rate during the years of interest (which is 0.053); n: number of years before 2017.

Costs of hospitalisation that were associated with the hypoglycaemic event were analysed from the patients' perspective, and the average direct economic cost of hypoglycaemic event per patient was estimated. Indirect costs such as productivity losses resulting from lost workdays and direct non-medical costs were not available in patients' records at the hospitals and thus, not considered.

Data quality

The data was extracted by one of the authors (AN) using a pre-designed data extraction sheet. The accuracy and quality of the data entry was checked by a pharmacist to guarantee the accuracy of data entry. Another quality check was performed through a random selection of 20 records and checking the accuracy of the extraction.

Ethics approval

Ethical approval was obtained for this study from the University College of London Research Ethics Committee (Project ID: 7915/001). The study protocol was reviewed and ethics approvals were granted by the Research Ethics Committees of the two hospitals selected as sites of data collection. This was a retrospective analysis of previously collected data, and involved no change in the management of patients. Obtaining individual consent was not feasible, so patient records were anonymised and de-identified before analysis.

Data analysis

Data was analysed using SPSS (version 22). Continuous data were reported as a mean (SD) and median (IQR) for non-normally- distributed variables, and categorical data were reported as percentages and frequencies. Descriptive statistics were used to describe patient demographic characteristics, medication use, and comorbidities. Due to the skewed distribution of hospitalisation cost and length of stay, Spearman's correlation coefficient and the Mann-Whitney test were used as appropriate. Multiple linear regression analysis was conducted after applying log-transformation for the data. In addition, significant predictors of hypoglycaemic hospitalisation cost and length of stay were determined using logistic regression analysis. A confidence interval of 95% ($p<0.05$) was applied to represent the statistical significance of the results. The level of significance was assigned as 5%.

RESULTS

A total of 129 patients were admitted with an incident of hypoglycaemia during the study period. The medical records of all identified patients were reviewed to determine whether they met the inclusion criteria of the study. A total of 126 patients had a clear diagnosis of type 1 or type 2 DM, while one patient was diagnosed as pre-diabetic and two did not have a clear diagnosis of DM, and thus were excluded from the study.

A total of 126 patients were included in the analysis, of whom half were male (n=63, 50.0%). The average age was 64.2 (SD=19.6) years. The average BMI of the patients was 28.5 kg/m^2 (SD=6.4). The most common type of diabetes was type 2 DM, contributing to 86.5% (n = 109) of the sample. The average duration of DM was 12.1 (SD=8.4) years. Around 21.4% of the patients had reported a family history of DM. Other characteristics are presented in Table 1.

The glucose level was available for 84 patients out of 126 (66.0%), and their mean glucose level was 39.8 mg/dL (SD 15.07). The majority of the patients (n=96, 76.2%) were suffering from more than one chronic condition and receiving treatment for them. The two most common chronic conditions across the study sample were hypertension and cardiovascular diseases (such as atrial fibrillation, chronic heart failure and ischaemic heart disease), which were affecting around 76.2% and 49.2% of the patients, respectively. Dyslipidaemia and thyroid problems were also prevalent conditions among the patients, contributing to 19.8% and 17.5%, respectively.

The majority of the patients were receiving oral antidiabetic therapy (n=56, 44.4%), followed by the use of insulin injection only (n=34, 27.0%), then the use of a combination of tablets and insulin injection, which contributed to (n=29) 23.0%, and (n=7) 5.6% of the patients were on diet and exercise only. Insulin was the most commonly used antidiabetic therapy (n=34, 27.0%), followed by metformin and sulfonylurea combination therapy (n=23, 18.3%). Combination therapies based on sulfonylurea or insulin medications were the most prevalent therapies, and accounted for 46.0% (n=58) of the patients. In general, 43.7% of the patients were on antidiabetic dual therapy, followed by 7.1% (n=9) for the use of antidiabetic triple therapy and 0.8% (n=1) for the use of quadruple therapy. A total of 54 patients (42.9%) were using antidiabetic monotherapy. Cardiovascular system medications such as aspirin, beta-blockers and diuretics were commonly used by the patients, contributing to 50.8% (n=64), 39.7% (n=50) and 34.9% (n=44), respectively.

Patients admitted for hypoglycaemia stayed for a median duration of two days (IQR=2 days). Some of the patients

Table 1. Demographic and clinical characteristics of patients admitted with hypoglycemic events

Characteristics	Mean (SD)
Age on the day of the event (years);	64.18 (19.6)
	N (%)
Gender	
Male	63 (50.0)
Female	63 (50.0)
Nationality	
Jordanian	106 (84.1)
Non-Jordanian	20 (15.9)
Marital status (n=125)	
Married	114 (91.2)
Unmarried	11 (8.8)
Smoking status	
Non-smoker	95 (75.4)
Ex-smoker	9 (7.1)
Smoker	22 (17.5)
Alcohol consumption status	
Yes	1 (0.8)
No	125 (99.2)
Body mass index (n=87); mean (SD)	28.50 ± 6.4
Type of diabetes mellitus	
Type 1 patients	17 (13.5)
Type 2 patients	109 (86.5)
Duration of diabetes mellitus (years) (n=91)	12.14 ± 8.4
Family history of diabetes	27 (21.4)
Number of comorbidities	
0	13 (10.3)
1	17 (13.5)
2	46 (36.5)
>2	50 (39.7)
Behaviour during admission (n=115)	
Cooperative	100 (87.0)
Uncooperative	2 (1.7)
Anxious	9 (7.8)
Unconscious	3 (2.6)
Sedated	1 (0.9)
Mental health (n=112)	
Normal	109 (97.3)
Dementia	3 (2.7)
Patients with communication barrier (n=106)	10 (9.4)
Living status (n=114)	
Single	1 (0.9)
Spouse	1 (0.9)
With family	112 (98.2)
Activity of daily living (n=115)	
Dependent	37 (32.2)
Independent	52 (45.2)
Need assistance	26 (22.6)
Insured patients	48 (38.1)
Patients performing 30 minutes of exercise daily (n=109)	7 (6.4)
Patients with history of previous surgery (n=121)	79 (65.3)
Patients with history of previous hypoglycaemia admission in the past year	9 (7.1)

*Total number does not add up to 126 because of missing data

Table 2. Median hospitalisation cost and length of stay stratified by patient characteristics

	Cost		Lenght of stay	
	Median (IQR)	**p-value**	**Median (IQR)**	**p-value**
Age		0.320		0.335
Below 18 years	110.9 (187.5)		1 day (2.0)	
19 – 39 years	105.3 (115.6)		1 day (0.5)	
40 – 59 years	158.0 (116.9)		2 days (2.0)	
60 years and above	194.2 (270.4)		2 days (3.0)	
Gender		0.705		0.152
Male	151.2 (223.1)		1 day (2.0)	
Female	184.3 (215.8)		2 days (2.0)	
Type of diabetes		0.163		0.049*
Type 1 DM	123.0 (119.8)		1 day (2.0)	
Type 2 DM	184.3 (250.6)		2 days (2.5)	
Severity of hypoglycaemia		0.099		
Moderate	111.7 (207.1)			
Severe	185.7 (250.9)			

(n=16, 12.7%) only needed to be observed by the medical team for a few hours, and were discharged on the same day. The majority stayed four days or less (n=109, 86.5%). Other patients needed to stay for longer periods because their case deteriorated after admission, or due to the development of further life-threatening complications. This led to a longer stay, up to a maximum of 33 days in one case (Table 2).

On the discharge sheet, the health status of the patient was reported to describe the improvement after the admission period. A total of 118 patients (93.7%) recovered after being admitted for hypoglycaemia and 6.3% (8 patients) had died due to acute complications during their duration of stay.

The study cohort, which comprised 126 patients hospitalised for hypoglycaemia, had a total inflated cost of 40,232 JOD (USD 56,712). The median cost of hospitalisation for hypoglycaemia was 163.2 JOD (USD 230.1) (IQR=216.3 JOD). When we excluded the one outlier patient with 33 days of stay, the median cost of hypoglycaemia hospitalisation reached 160.0 JOD (USD 225.6) (IQR=211.7 JOD). There was no statistically significant difference between different demographic groups (Table 2).

Using Spearman correlation, we found that hospitalisation cost was significantly correlated with length of stay (0.705, $p<0.001$). We further examined correlation between length of stay, hospitalisation cost, and several patients' demographics using Spearman correlation coefficient. Older age was correlated with higher hospitalisation cost (0.207, $p=0.02$), but not with length of stay (0.159, $p=0.076$). We found a positive correlation between Glasgow coma score and length of stay (0.345, $p<0.05$), but not hospitalisation cost (0.241, $p=0.068$). We found a strong correlation between number of comorbidities and length of stay (0.263, $p=0.003$), but not hospitalisation cost (0.143, $p=0.111$). We found no significant correlation between glucose level on admission, duration of diabetes, and length of stay or hospitalisation cost ($p>0.05$). We examined whether length of stay and hospitalisation cost differed based on gender, family history of diabetes, and independence with daily activity using the Mann-Whitney test. We found no significant differences between male and female patients in length of stay or hospitalisation cost. In addition, we found no significant differences between type of insurance and length of stay or hospitalisation cost. On the other hand, we found that patients with a family history of diabetes had a longer length of stay and higher hospitalisation cost ($p=0.008$ and 0.01, respectively). Patients who were dependent in their daily activities were found to have higher length of stay and hospitalisation cost ($p=0.009$ and 0.004, respectively). We did not assess the differences in hospitalisation cost between users of different antidiabetic medications, such as insulin or sulfonylurea users, or the users of different combination therapies. These comparisons were not feasible in our study as we had a small sample size in some subgroups.

Using linear regression models, we found that family history of DM and dependency in daily activities were potential confounders that affected the cost of hypoglycaemia and length of stay.

A multiple linear regression was used to explore determinants of hospitalisation cost and length of stay due to hypoglycaemia. Multiple regression analysis was conducted using two models; the first one was conducted using patients' demographic characteristics (age, gender, and marital status) which we anticipated to have effects on hospitalisation cost and length of stay, and the second one included patients' demographics and other clinical factors (smoking status, type of diabetes, duration of the disease, family history of DM, dependency in daily activities, communication barriers, and exercise practice). We did not find any statistically significant association between age, gender, and marital status and hospitalisation cost or length of stay using the first model ($p>0.05$). The second model showed that patients who had a family history of DM had higher hospitalisation cost and longer length of stay ($p<0.05$). In addition, it showed that being male and without a previous history of smoking was associated with having longer length of stay ($p<0.01$), but not higher hospitalisation cost. For further details about the multiple regression analysis for determinants of hypoglycaemia hospitalisation cost and length of stay, please refer to Online appendix 1 and Online appendix 2.

DISCUSSION

Our study found that hospitalisation due to hypoglycaemic events has a substantial cost in hospital settings. The median hospitalisation cost for a hypoglycaemic event was 163.2 JOD (USD 230), which contributed to the per capita

expenditure for healthcare in Jordan (USD 257 in 2015).[23] The findings of our study confirmed those of previous studies in identifying hypoglycaemia as a costly diabetic complication with a negative impact on the economic resources of the society and the overall healthcare system.[24] However, hypoglycaemia hospitalisation cost is considered low compared to other major health conditions such as acute myocardial infarction, unstable angina, and acute ischaemic stroke.[25]

The costs associated with hypoglycaemia differ significantly according to the severity of the case, which determines the type of medical support needed and ultimately its associated costs. Previous studies mentioned that the highest costs associated with hypoglycaemic events are costs associated with hospitalisation, followed by ambulance cost and emergency room visits.[26-28] Several previous studies using different methodologies have provided results that are in broad agreement with our study findings. A previous study estimated the cost of hypoglycaemic events in three European countries and reported costs that differ slightly from our estimates: EUR 533 (USD 658.83) in Germany, EUR 537 (USD 663.77) in the UK, and EUR 691 (USD 854.13) in Spain.[29] Parekh *et al*. calculated the average cost per episode of insulin-related hypoglycaemia in adults in Spain as EUR 716.82 (USD 885.99) for severe and EUR 7.09 (USD 8.76) for non-severe episodes in type 1 DM, and EUR 680.49 (USD 841.08) and EUR 14.61 (USD 18.06) for severe and non-severe, respectively. It is worth mentioning that the per capita expenditure on health for these three countries is 10 to 20 times higher than that for Jordan, namely USD 4,592, USD 2,354, and USD 4,356 for Germany, Spain and the UK, respectively, whereas in Jordan it is only USD 257.[30]

For type 2 DM the majority of the cost for severe episodes consisted of hospitalisation and ambulance use.[26] Jönsson *et al*. estimated the costs of severe hypoglycaemic events in Sweden to be EUR 3,917.4 (USD 4,841.89) (combined direct costs of EUR 2,806.8 (USD 3,469.19) and indirect costs of EUR 1,110.6 (USD 1,372.70).[17] Jönsson *et al*.'s study considered direct and indirect costs and included hypoglycaemic events that ranged in severity from mild to severe events. Kim *et al*. estimated medical costs per person per hypoglycaemic event in Korea to range from USD 17.28 to USD 1,857.09 for secondary and tertiary hospitals.[15] Kim *et al*. estimated hypoglycaemic event costs through the implementation of modelling techniques that simulate the procedure of managing patients with hypoglycaemia and cross-sectional survey to evaluate the resource usage of patients with hypoglycaemia. Possible reasons for the difference in hospitalisation cost across studies from different countries could include differences in the definition of a hypoglycaemic event, cost analysis perspective, unit costs, the methods used in data collection, drugs/procedures considered, and different patient populations. Another explanation could be that the cost was higher in those countries, which may be related to per capita expenditure for health care; for example in Portugal (USD 1,722), which is almost seven times higher than in Jordan.[23] The length of stay due to admission for hypoglycaemia in our study was less than what has been observed in previous studies in Portugal and Spain: the Portuguese study had reported a mean duration of 8.8 days, and the Spanish one reported a median of 10.82 days, compared to our estimate of 2 days.[31,32] This difference could be due to the variability in the patient population being studied in terms of demographics, different treatment procedures, the varying severity of hypoglycaemic events, and sociocultural factors. For instance, it is very common for old people to live with their families in Jordan, while this is uncommon in European countries, where many people live in care homes when they are old.

Unlike a previous study that reported having a smoking history is associated with higher risk of comorbidities, mortality and length of hospital stay [33], we found that not having a smoking history was associated with longer duration of stay, but this could be due to the small sample size in our study.[33] In addition, due to the cross-sectional study design, we were not able to draw a causal inference. Previous studies reported that marital status can affect the length of stay at hospital; this could be due psychological and social causes, as unmarried patients usually suffer a more severe form of illness compared to married patients. Also, patients who are married usually have better care at home and could be more keen to return home.[34,35] However, in our study there was no significant association between marital status and length of stay or hospitalisation cost.

Patients with higher BMI are at greater risk of developing cardiac problems including atrial fibrillation and other cardiovascular diseases.[36,37] Hypoglycaemia is associated with an increased risk of atrial fibrillation and cardiac complications [38, 39]; it is therefore, reasonable to assume that patients with a higher BMI will have a longer hospital stay time and more severe cases of hypoglycaemia [40]. However, we did not find this association significant in our study, as the BMI value was available for only 87 patients (69.0%).

According to the International Diabetes Federation, in 2017, around 408,100 patients were diagnosed with DM in Jordan [2]. A previous systematic review had reported a prevalence rate of severe hypoglycaemic events of 6.0% (95%CI, 0.05-0.07).[10] Based on the available estimates from the International Diabetes Federation and the systematic review, we can estimate that each year a total of 24,486 patients in Jordan with DM could experience a severe hypoglycaemic event that requires hospitalisation. Applying our median hospitalisation cost to this number means a hospitalisation cost of around 4.0 million JOD (USD 5.6 million) per year. The high estimated costs of hospitalisation due to hypoglycaemia should be taken into consideration by decision-makers in the healthcare sector from both economic and clinical points of view. The findings of our study are of added value and can be used in healthcare economic analyses in Jordan. Our estimates should increase the awareness of the economic impact of this adverse event and the need for adoption of healthcare strategies to decrease its burden, by promoting the individualisation of HbA1c goals in physicians' practices and increasing the patients' awareness and abilities when encountering this adverse event. At the practice level, antidiabetic therapy de-intensification, treatment protocols revisions, and enhancing patients' awareness of symptoms and prevention methods are needed.[41] Regular HbA1c

levels monitoring, and educating patients on how to deal with their hypoglycaemia and how to avoid future hypoglycaemic events, are important approaches to decrease the clinical and ultimately the economic burden of hypoglycaemia. Similarly, at the individual level, patients can follow advice and simple steps to avoid hypoglycaemia such as regular self-monitoring and administration of glucagon or any other sugar component to reverse the hypoglycaemic attack.[42]

Strengths and limitations

To the best of our knowledge, this is the first study conducted within hospital settings performed in Jordan or elsewhere in the Middle East that estimates direct costs related to hospitalisation for hypoglycaemia. Our study has several strengths. First, data collection was done using real-world patients' records for each hypoglycaemic episode admitted to the emergency department. Second, our study estimated the hospitalisation cost for hypoglycaemic events for moderate and severe episodes and was not restricted to severe cases only. Third, we adjusted the costs, inflating them to equivalent costs as per the costs in 2017, to provide more meaningful estimations of the incurred costs.

Our study also has some limitations. Firstly, our study only estimated direct medical costs related to hospitalisation incurred by the patients, and did not include costs related to follow-up visits, treatments after the event and further examination procedures required after discharge, direct non-medical or indirect costs. However, hospitalisation cost is the main cost driver for severe hypoglycaemic events.[24] Secondly, indirect costs such as costs related to loss of productivity or early retirement were not examined in our study. Thirdly, our cost estimation was based on costs incurred within private rather than governmental hospitals, which might differ and limit the generalisability of the results to the private sector only. Private hospitals provide medical care of higher quality for the patients compared to public hospitals, but at the same time, private hospitals charge higher prices to make a profit.[43] Fourth, the use of charges as a proxy to estimate costs is not free from criticism.[44,45] Finally, the sample size was small. Despite these limitations, we believe our paper makes a real contribution to awareness of the hypoglycaemia burden in Jordan. It should also stimulate further research in this area such as studies that adopt a wider perspective and a longer time frame, which would be needed to comprehensively assess the impact of hypoglycaemia on resources utilisation. This should include direct and indirect costs from both the governmental and private sectors to increase the generalisability of the current estimated costs.

CONCLUSIONS

This study confirmed that hospitalisation due to hypoglycaemic events among patients with DM represents a substantial economic burden within hospital settings. Our study findings provide implications for healthcare providers to target patients at high risk of hypoglycaemia such as males and patients with a family history of DM, to avoid their hospitalisation. Targeting such groups through health educational programme and treatment de-intensification (if necessary) approaches could help reduce their propensity to hypoglycaemia and ultimately reduce their length of hospital stay and cost.

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest.

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Original Research

Survey of undergraduates' perceptions of experiential learning in the MPharm programme: The TELL Project

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Abstract

Objective: To determine the perception of undergraduate pharmacy students of their experiential learning (EL) placements both in the community and hospital settings.

Methods: A cross-sectional survey was conducted utilizing a six-item online survey consisting of one open-ended and five closed-ended questions, the latter utilising five-point Likert-type scales ranging from strongly disagree (1) to strongly agree (5). All undergraduate pharmacy students from the School of Pharmacy (N=496) were included in the study. Survey questions assessed students' perceptions on the effectiveness of the EL, tutors and placements sites, and organisation and structure of the EL. Thematic content analysis was performed on the open-ended comments, where relevant themes were generated.

Results: From the 139 responses (response rate: 28%), 121 responses were analysed, and of these, 72.5% already had part-time jobs in community pharmacies. Close to 85% felt that their part-time work should contribute to EL hours, which is currently not recognised by the university. Respondents were positive about the effectiveness of EL in developing their professionalism and communication (M=3.84, SD=1.05), clinical (M=3.42, SD=1.22), and technical skills (M=3.32, SD=1.25) Respondents provided favourable feedback about their experience in the hospital as it gave them a real-world exposure to the role of a hospital pharmacist. Community placements were not viewed favourably and this was mainly attributed to the poor experience with tutors whom they felt used them as an extra pair of hands. This was thought to impede their learning experience. They also felt that hospital placements were of insufficient duration, reported by 72.5% of respondents. Respondents also felt they should be sent to other sites such as primary care for placements.

Conclusions: Tutor-training is key to ensure tutors are aware of the responsibilities and expectations. Similarly, quality assurance measures should be adopted to ensure tutors and placement sites are capable of providing students with an effective placement experience. While placement durations are a concern, the focus should be on the quality of the placement experience, and ensuring there is structure and flexibility. Content changes are also needed to include emerging placement sites such as primary care to prepare students for evolving pharmacist roles in the changing healthcare system.

Keywords

Students, Pharmacy; Education, Pharmacy; Pharmacy Residencies; Professionalism; Motivation; Pharmacists; Pharmacy Service, Hospital; Pharmacies; Primary Health Care; Cross-Sectional Studies; Scotland

INTRODUCTION

Experiential learning (EL) has long been adopted by pharmacy schools worldwide and finds its roots in Kolb's experiential learning theory, which is typically represented in a four-stage cycle of learning (Figure 1).[1] Through placements at practice sites, and under the guidance of tutors, students are able to transform the experience into knowledge. This is achieved through reflection and the development of new concepts. Students then apply the new skills gained in practice, thereby creating a new experience and a continuation of the cycle.[1] In the United Kingdom (UK), the term 'tutor' is used to denote a 'registered, practising pharmacist who supervises pharmacy students during placements'.[2] EL plays a key role in equipping pharmacy students with the necessary skills needed by a pharmacist such as professionalism, clinical, technical, and communication, in an effort to enable them to transition seamlessly into the practice environment. Indeed, studies have found that EL provided students with real-world experiences to help them obtain a more realistic perspective of the role of pharmacists and the healthcare system, increased students' confidence in patient-facing roles such as counselling, and helped reinforce previous learning.[3-6]

Students have, however, reported feeling overwhelmed during their hospital placements.[7] Students also expressed that there was a disconnect between what is studied at university, and what actually happens in the practice environment - often struggling to apply their knowledge during their placements.[7,8] As it pertained to assessments, students found reflection activities difficult, and felt journaling was too time consuming.[9,10] These suggest shortcomings, perhaps in the design and execution of EL.

In the UK, EL is still developing where there are no stipulated placement hours by the General Pharmaceutical Council (GPhC), the regulator of pharmacists. There is only the specification that the amount of EL needs to increase over the years.[11] As such there is variation between the different universities in terms of placement hours, and the structure and governance of EL.[12] Funding depends on each university's resources as well as any external funding.

The EL at the School of Pharmacy has been part of the four-year undergraduate Master of Pharmacy (MPharm) curriculum for over 20 years and focuses predominantly on community and hospital settings (Table 1). At the time of this evaluation, placement sites were volunteered by

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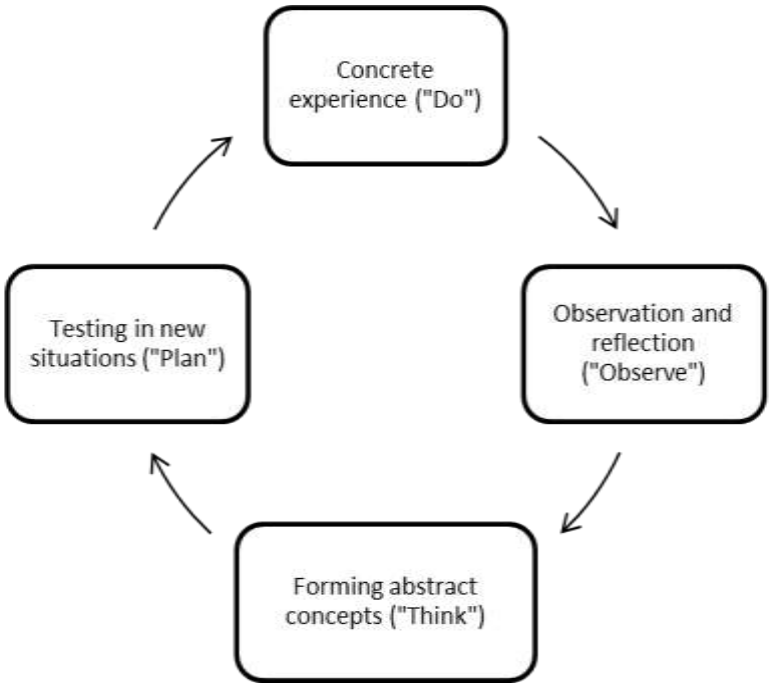

Figure 1. Four-stages of Kolb's experiential learning cycle

hospital and community practitioners, no payment was made for supporting students' EL, and placement site visits are not undertaken. Prior to the placement, students are given a handbook which outlines their responsibilities while on placements as well as the learning objectives for all four years. Students also attend a preparation briefing workshop which covers topics such as professionalism, expectations, and dealing with different behaviours. Workshops teaching them about how to write reflections are also held. Tutors are sent a handbook which details their role as well as the learning outcomes the students have to achieve each year.

Post-placement, students are required to submit reflective diaries on their placement experience for assessment by members of academic staff including GPhC-registered pharmacists, some of whom are responsible for oversight of the EL programme. Students are not required to provide feedback on the placement site or tutors, and tutors are also not required to provide any formal feedback to the university. Students may also undertake paid or unpaid summer placements in community, hospital, and primary care practice but students bear the sole responsibility of planning these placements and they are not part of the University requirements for study. Summer placements and part-time work are optional and do not contribute to EL hours.

In 2011, the GPhC introduced the Standards for the Initial Education and Training of Pharmacists which mandated that all undergraduate MPharm programmes in the UK include EL in their curriculum.[11] This then prompted an increase in EL adopted by the various universities.[12] However, there have been few studies undertaken in the UK since then to obtain feedback from current students on what they think of the EL, what works for them, and what doesn't. As such the objective of this study was to obtain students' perception of the EL. As the School of Pharmacy prepares for a potential new programme, feedback from students about the EL would be of great importance to identify gaps and areas for improvement.

Table 1. Placement allocation by year and site

Year of study*	Community practice	Hospital practice
2	2 x ½ days	1 x ½ day
3	6 x ½ days	1 x ½ day
4	8 x ½ days	1 x day
5	10 days in one or two areas of practice	

*In this School, students start the first year of the MPharm programme in Year 2.

METHODS

Data and participants

The TELL Project is a Three-60 degree evaluation of the ExperientiaL Learning at the School of Pharmacy, where the prime objective is to allow students, graduates, tutors, and stakeholders to TELL us what they think of the EL and what they want from it. We report here the findings from the study involving undergraduates of the MPharm programme.

Study design

This was a cross-sectional survey of undergraduates of the MPharm programme. Data collection occurred over a three-month period between March and June 2019. The university ethics committee confirmed that ethical approval was not required for this evaluation. The survey was hosted on an online platform, Qualtrics, and an anonymous link along with the Participant Information Sheet was placed on the University virtual learning environment. No financial incentives were offered and a reminder email was sent after one month. Number of students registered by year was as follows: Year 2 (136), Year 3 (116), Year 4 (140), and Year 5 (104). Assuming an overestimated response distribution of 50%, a minimum effective sample size of 81 was needed to achieve a confidence interval of 95% and a 10% margin of error.[13]

Table 2. Characteristics of respondents (n= 120)					
	Total, n (%)	**Year 2, n(%)**	**Year 3, n(%)**	**Year 4, n(%)**	**Year 5, n(%)**
Gender					
Female	89 (74.2)	22 (64.7)	26 (81.3)	29 (76.3)	12 (75.0)
Male	27 (22.5)	11 (32.4)	5 (15.6)	7 (18.4)	4 (25.0)
Non-binary	1 (0.8)	1 (2.94)	0 (0)	2 (5.26)	0 (0)
Prefer not to say	3 (2.5)	0 (0)	1 (3.13)	0 (0)	0 (0)
Part-time job in community pharmacy	87 (72.5)	18 (52.9)	27 (84.4)	32 (84.2)	10 (62.5)
Summer placement					
Hospital and community	36 (30.0)	7 (20.6)	6 (18.8)	16 (42.1)	7 (43.8)
Community	19 (15.8)	1 (2.94)	3 (9.38)	7 (18.4)	4 (25.0)
Hospital	6 (5.0)	0 (0)	1 (3.13)	2 (5.26)	0 (0)
Hospital and primary care	1 (0.83)	1 (2.94)	0 (0)	0 (0)	0 (0)
All three settings	2 (1.67)	0 (0)	0 (0)	1 (2.63)	1 (6.25)
Future area interested to work in					
Hospital	46 (38.3)	17 (50.0)	13 (40.6)	12 (31.6)	4 (25.0)
Community	28 (23.3)	8 (23.5)	7 (21.9)	9 (23.7)	4 (25.0)
Primary care	17 (14.2)	1 (2.94)	4 (12.4)	8(21.1)	4 (25.0)
Don't know	24 (20.0)	7 (20.6)	1 (3.13)	7 (18.4)	3 (18.8)

The survey was a six-item anonymous self-report consisting of one open-ended and five closed-ended questions, the latter utilising five-point Likert-type scales ranging from strongly disagree (1) to strongly agree (5). The survey contained questions assessing students' perceptions on the effectiveness of the EL, tutors and placements sites, and organisation and structure of the EL. Demographic details such as summer placement experience, part-time work in community pharmacy, and future areas of interest to work in were also collected. Respondents were allowed to omit responses to the open-ended question if desired. The survey was developed based on UK educational practice, the standards set by the GPhC, the study objectives, and a review of the literature.[11] Face and content validation was done by five academics with varying expertise in EL and pharmacy education, one English expert, one hospital pharmacist, and two community pharmacists, one of whom was working with the contractor negotiating body, Community Pharmacy Scotland. The survey was also pilot tested on three academics. Following the pilot study, suggestions were given on ways to improve the technical aspects of the survey, and these were amended accordingly. The survey took approximately five to 10 minutes to complete.

Data analysis

Baseline demographic data were presented using descriptive statistics. To create a composite picture of what respondents disagreed and agreed on for questions employing the five-point Likert scale, responses were collapsed to a three-point scale (agree, neutral, disagree), where the scores for the first two columns ("strongly disagree" and "disagree") were added up to show what they disagreed on, while the scores for the last two columns ("agree" and "strongly agree") were totalled to show what they agreed on. Mean values of students' feedback on tutors as well as the structure and effectiveness of the EL were generated by tabulating their responses on the five-point Likert scale, which were numbered as follows: 1 – Strongly disagree, 2 – disagree, 3 – neutral, 4 – agree, 5 – strongly agree.

General linear regression was employed to examine predictors of perceptions of undergraduates with regard to the effectiveness of the EL in developing their professionalism and communication, clinical, and technical skills. The same variables were used to examine predictors on feedback of tutors and placement sites. The following three independent variables were included in the models: year of study, if they did a summer placement, and if they had a part-time job. The latter two variables were selected as research has shown that they have an impact on students' perception of EL.[14] Variance Inflation Factor (VIF) values were inspected for the possibility of multicollinearity, with results higher than 10 being considered as indicative of this problem. The a priori level of significance was 0.05, and all analyses were performed using Microsoft Excel and SPSS 24.0 statistical software (SPSS Inc, Chicago, IL, USA).

Thematic content analysis was performed on the open-ended comments, as it allows researchers to not just focus on code-counting but highlight as well key themes that emerge.[15] All open-ended comments were read and re-read and keywords were identified. These keywords were sorted into categories, and then subjected to thematic analysis.[16] Respondents of open-ended comments were identified according to their year of study (e.g. Y2) and part-time job status (P; Y indicating they had part-time jobs).

RESULTS

There were 139 responses (Response rate: 28%) and of these, 18 only provided demographic details and were removed. As such, 121 responses were analysed and of these, 102 answered all sections, while one did not provide demographic details. Mean age of respondents was 21.2 (SD=3.68) and 87 (72.5%) had a part-time job, while 56 (46.7%) did not undertake any summer placements. With regard to future areas they wanted to work in, five noted 'other' areas which included industry and research (Table 2).

Overall, students were positive about the effectiveness of EL in developing their professionalism and communication, clinical, and technical skills (Table 3). General linear regression found that Year 3 and Year 4 students had significantly more negative views about the effectiveness of EL in developing their clinical skills compared to those in Year 2. With regard to the effectiveness of EL in developing their technical skills, Year 3 students had significantly more

Table 3. Effectiveness of the EL in developing clinical, professionalism and communication, and technical skills

Statements	The EL prepared me in the following skills				
	Disagree n(%)	Neutral n(%)	Agree n(%)	Did not do during EL	Mean (SD)
Clinical skills (n=121)					
Undertake health promotion activities	33 (27.3)	17 (14.0)	45 (37.2)	26 (21.5)	3.20 (1.21)
Identify patient-specific factors that affect health, pharmacotherapy, or disease management	21 (17.4)	21 (17.4)	62 (51.2)	17 (14.0)	3.47 (1.05)
Formulate/develop pharmaceutical care plans	35 (28.9)	8 (6.6)	47 (38.8)	31 (25.6)	3.16 (1.25)
Perform medication reconciliation	24 (19.8)	15 (12.4)	54 (44.6)	28 (23.1)	3.43 (1.23)
Perform discharge planning	31 (25.6)	11 (9.1)	38 (31.4)	41 (33.9)	3.11 (1.27)
Assess patient adherence	33 (27.3)	16 (13.2)	50 (41.3)	22 (18.2)	3.26 (1.17)
Take part in the Acute Medicines Service (AMS) (processing prescriptions)	15 (12.4)	14 (11.6)	85 (70.2)	7 (5.8)	3.95 (1.07)
Undertake a Minor Ailments Service (MAS) consultation	15 (12.4)	11 (9.1)	74 (61.2)	21 (17.4)	3.83 (1.11)
Undertake a Chronic Medication Service (CMS) consultation	31 (25.6)	15 (12.4)	37 (30.6)	38 (31.4)	3.12 (1.33)
Overall mean clinical					3.42 (1.22)
Professionalism and communication (n=118)					
Communicate and interact effectively with patients and/or caregivers	13 (11.0)	13 (11.0)	86 (72.9)	6 (5.1)	3.94 (0.99)
Counsel patients and/or caregivers	15 (12.7)	12 (10.2)	78 (66.1)	13 (11.0)	3.80 (0.98)
Participate and contribute as a member of an interprofessional healthcare team	12 (10.2	15 (12.7)	85 (72.0)	6 (5.1)	3.94 (1.03)
Behave in a professional manner	2 (1.7)	8 (6.8)	108 (91.5)	0 (0.0)	4.42 (0.77)
Speak up when I have concerns or when things go wrong	10 (8.5)	27 (22.9)	74 (62.7)	7 (5.9)	3.79 (0.97)
f) Demonstrate leadership	34 (28.8)	28 (23.7)	41 (34.7)	15 (12.7)	3.08 (1.11)
Overall mean professionalism and communication					3.84 (1.05)
Technical skills (n=112)					
Perform calculations required to dispense and administer medications	33 (29.5)	8 (7.1)	41 (36.6)	30 (26.8)	3.11 (1.38)
Interpret and evaluate patient information (e.g. medical/medication history, laboratory tests, etc.)	18 (16.1)	8 (7.1)	59 (52.7)	27 (24.1)	3.58 (1.17)
Prescription screening	9 (8.0)	22 (19.6)	68 (60.7)	13 (11.6)	3.77 (0.98)
Demonstrate skills in drug administration techniques (e.g. inhalation devices)	35 (31.3)	11 (9.8)	28 (25.0)	38 (33.9)	2.91 (1.30)
Recommend appropriate drug therapy: medication, doses, and dosage schedule	20 (17.9)	14 (12.5)	54 (48.2)	24 (21.4)	3.49 (1.18)
Document information, interventions, and recommendations of pharmacist-delivered patient care	28 (25.0)	15 (13.4)	41 (36.6)	28 (25.0)	3.20 (1.20)
Demonstrate problem-solving skills	17 (15.2)	20 (17.9)	61 (54.5)	14 (12.5)	3.56 (1.07)
Recommend appropriate medication dosing using pharmacokinetic principles	39 (34.8)	13 (11.6)	22 (19.6)	38 (33.9)	2.65 (1.44)
Overall mean technical					3.32 (1.25)

EL: Experiential learning; SD: Standard deviation

negative views while Year 4 students had significantly more positive views, compared to those in Year 2 (Table 4).

Calculation of mean revealed that students were more positive about their experience with tutors at the hospital (M=3.79, SD=1.18), compared to the community (M=3.30, SD=1.27). Students were ambivalent with regard to the preparedness of tutors in the community, as well as their perception of their overall experience in the community setting (Table 5). General linear regression found no significant relationship between feedback on tutors and placement site, and the independent variables. With regard to structure and coordination, overall perception was neutral (M=3.39, SD=1.27). More than 70% disagreed that hospital attachments were sufficient, while more than 80% agreed that their part-time work should contribute toward their EL hours (Table 6).

Forty-five students left open-ended comments, with five, 18, 12, and 13 comments from Years 5, 4, 3 and 2 respectively. Responses were an average of 93 words, with a range of 19 to 210 words. There were nine positive and 72 negative comments about community placements, with the latter mainly related to placement experience and tutors. For the hospital settings, there were 40 positive comments and 13 negative comments with the majority highlighting the limited duration of attachment. The number of comments according to the different categories is illustrated in Table 7.

Thematic analysis revealed three key themes: (1) Perceived experience of placements, (2) Impact of tutors and site on placement experience, and (3) Key influence of having a part-time job. These are described below.

Theme 1: Perceived experience of placements

Hospital placements received positive feedback, with students describing it as "brilliant" and "extremely beneficial". Among the benefits noted were the fact that the placements influenced their decision to work in the hospital, and that it gave them a good insight into the daily role of a hospital pharmacist. One noted that it was:

Table 4. Multiple linear regression analysis

	Clinical skills (R^2=012)				Technical skills (R^2=0.25)			
Model	Adj.b	95% CI	t-stat	p-value	Adj.b	95% CI	t-stat	p-value
YearA[a]	-0.933	-1.51 : -0.36	-3.24	0.020	-1.09	-1.78 : -0.40	-3.13	0.002
YearB[b]	-0.745	-1.31 : -0.18	-2.64	0.010	0.669	0.04 : 1.29	2.13	0.036

Both models reasonably fits well; model assumptions are met; there is no multicollinearity problems
[a]YearA coded as follows: Year 2 = 0, Year 3 = 1, Year 4 = 0, Year 5 = 0
[b]YearB coded as follows: Year 2 = 0, Year 3 = 0, Year 4 = 1, Year 5 = 0
Adj.b: Adjusted regression coefficient

Table 5. Tutors and placement site

Experiential learning statements	Community (n=104)				Hospital (N=104)			
	Disagree n(%)	Neutral n(%)	Agree n(%)	Mean (SD#)	Disagree n(%)	Neutral n(%)	Agree n(%)	Mean (SD#)
a) Tutors provided feedback after my EL	50 (48.1)	19 (18.3)	35 (33.7)	2.81 (1.23)	34 (32.7)	15 (14.4)	55 (52.9)	3.23 (1.29)
b) Workload allocation during my EL was carefully planned by tutors	46 (44.2)	19 (18.3)	39 (37.5)	2.88 (1.34)	10 (9.6)	17 (16.3)	77 (74.0)	3.97 (1.03)
c) Tutors were prepared for my arrival	38 (36.5)	18 (17.3)	48 (46.2)	3.13 (1.36)	3 (2.9)	6 (5.8)	95 (91.3)	4.36 (0.84)
d) Tutors were able to spend time with me (n=103)	27 (26.2)	17 (16.5)	59 (57.3)	3.42 (1.21)	4 (3.9)	7 (6.8)	92 (89.3)	4.38 (0.82)
e) The EL site allowed me to interact with other healthcare professionals (n=103)	34 (33.0)	18 (17.5)	51 (49.5)	3.12 (1.27)	21 (20.4)	17 (16.5)	65 (63.1)	3.57 (1.17)
f) The EL site allowed me to interact with patients (n=103)	14 (13.6)	14 (13.6)	75 (72.8)	3.79 (1.09)	48 (46.6)	14 (13.6)	41 (39.8)	2.91 (1.32)
g) It was easy to get to my EL site(s)	25 (24.0)	13 (12.5)	66 (63.5)	3.54 (1.36)	33 (31.7)	15 (14.4)	56 (53.8)	3.33 (1.31)
h) The EL site had enough space to accommodate me as a student	15 (14.4)	20 (19.2)	69 (66.3)	3.69 (1.10)	2 (1.9)	13 (12.5)	89 (85.6)	4.17 (0.79)
i) Overall, I had a good experience in the EL site	23 (22.1)	28 (26.9)	53 (51.0)	3.38 (1.14)	4 (3.8)	15 (14.4)	85 (81.7)	4.19 (0.89)

SD: Standard deviation

> "Much more interactive and engaging and a very worthwhile glimpse into the role of a hospital pharmacist." (Y4, PY)

Two commented that the placements were better than community placements. Students did, however, lament the short placement duration as well as limited allocation in the hospital, which were thought to restrict the placement experience. Indeed, they felt a longer duration would allow them to get a better idea about the different sectors it involved. One Year 4 student commented:

> "The full day hospital placement provided a very good insight as to what a clinical pharmacist does on a daily basis as opposed to the half days we had in the last 2 years where there was a lack of time." (Y4, PY)

Students were very critical of their experience in the community, describing it as a "waste of time". The main complaint students had was the fact that they were often used as a free set of hands and tasked with preparing Dosette boxes (a multicompartment compliance aid) or dispensing, which they felt did not contribute to their learning. This is illustrated in the following comment:

> "I popped out tablets for 2 hours and dispensed prescriptions for the rest of the time. When I went back for a second afternoon, I made up dosette boxes for a few hours and then they said I could leave." (Y2, PY)

This prompted one student to say,

> "There seems to be a pertinent issue with community pharmacists elsewhere not understanding why we are supposed to be there; that is to learn and meet the requirements of our competencies to be completed, not dispense generic prescriptions, clear shelves, make up dosette boxes or be the equivalent of an extra staff member." (Y4, PY)

As they were mainly dispensing, this did not allow for much or any time to complete their own learning objectives, obtain a better exposure to the different processes and roles of a community pharmacist, or "…engage with customers or see a consultation." Indeed, many noted that there wasn't much teaching or that they didn't learn anything from their community placements:

> "I had little opportunity to spend time with patients

Table 6. Structure and coordination (n=102)

Statements*	Disagree n(%)	Neutral n(%)	Agree n(%)	Mean (SD)
a) I think the number of EL hours I have spent in community pharmacy will be sufficient to prepare me for practice	29 (28.4)	15 (14.7)	58 (56.9)	3.41 (1.22)
b) I think the number of EL hours I have spent in hospital pharmacy will be sufficient to prepare me for practice	74 (72.5)	15 (14.7)	13 (12.7)	2.10 (1.07)
c) I should be allowed to undertake EL in other settings e.g. hospices, general practice surgeries etc.	1 (1.0)	7 (6.9)	94 (92.2)	4.43 (0.67)
d) Part-time pharmacy employment should be recognised as EL	6 (5.9)	10 (9.8)	86 (84.3)	4.26 (0.90)
e) I should be allowed to select my own EL sites	16 (15.7)	24 (23.5)	62 (60.8)	3.68 (1.11)
f) I was able to complete the activities outlined in the EL handbook	31 (30.4)	20 (19.6)	51 (50.0)	3.28 (1.24)
g) EL should take place in every year of the MPharm	11 (10.8)	7 (6.9)	84 (82.4)	4.24 (1.02)
h) I want to be able to do my EL during my summer break	42 (34.7)	26 (25.5)	34 (33.3)	2.91 (1.31)
i) Attendance at EL sites should be recorded by tutors	22 (21.6)	29 (28.4)	51 (50.0)	3.40 (1.15)
j) There should be a formal process for me to provide feedback on my EL experience	9 (8.8)	22 (21.6)	71 (69.6)	3.80 (0.96)
k) I receive sufficient support from the university on matters related to EL	27 (26.5)	28 (27.5)	47 (46.1)	3.21 (1.01)
l) The EL is well coordinated between the university and the tutors	37 (36.3)	29 (28.4)	36 (35.3)	2.94 (1.08)
m) The EL is unnecessary	65 (63.7)	17 (16.7)	20 (19.6)	2.25 (1.22)
n) Overall, I think the EL will prepare me for practice	21 (20.6)	15 (14.7)	66 (64.7)	3.56 (1.07)

*EL: Experiential learning;
SD: Standard deviation

Table 7. Content analysis		
Categories*	**Number of comments**	
Organisation and structure (n=29)		
Hospital placements too short or more needed	14	
Placement in other settings e.g. primary care	7	
Community placements too long	6	
More experiential learning needed	2	
Placement sites too far way	4	
Gaps in communication between university and site	2	
Part-time work (n=23)		
Similar tasks done during part-time work or didn't learn anything new from EL	7	
Better experience compared to EL	6	
Experiential learning unnecessary or should be optional	5	
Experience of placement (n=57)	**Community**	**Hospital**
Perceived as beneficial or effective	2	20
Poor experience	26	3
Tutors and site (n=48)		
Engagement		
Lack of engagement or interaction	7	1
Actively engaged	4	8
Preparation		
Well-prepared or organised for students	1	12
Not prepared	7	0
Not aware students were coming for placements	5	0
Site		
Too busy	2	0

and was in the dispensary which wasn't very patient facing. I spent most of my time dispensing and wasn't shown any new processes... I was standing around without much to do at times, despite asking for tasks and offering to do things. I think my time would have been better spent in another pharmacy type setting." (Y3, PY)

With regard to challenges, logistics was mainly highlighted by students, with many lamenting the far distances they had to travel to get to their placement sites. It was thus suggested that placements should take into consideration where students lived. Students also noted gaps in communication between the university and placement site, attributing this to the reason why some tutors were not aware that students were coming.

Theme 2: Impact of tutors and site on placement experience

Placement experience was said to be dependent on the tutors as well as placement sites, with one student noting,

> "EL experience varies a lot depending on which pharmacies we are assigned to. There is not much consistency in what different tutors offer - some students get to engage with patients and take an active role, and others are expected to just watch and ask questions." (Y3, PY)

This was especially true in community pharmacies, with busy sites impeding effective learning, as noted by a student:

> "My community pharmacy was very busy and I did not get much chance to practice things myself and learn." (Y2, PN)

Students complained that tutors in the community were often unaware that they were coming, and had nothing planned for their attachment. This is illustrated in the following comment,

> "I was asked what I wanted to do when I arrived as no plans had been thought through and I was left to do what I wanted." (Y2, PY)

Students also commented on the lack of support and engagement by tutors as they were often too busy. Due to this, students often felt like they were in the way and a distraction:

> "Community pharmacy placement is more challenging as the pharmacist is always very busy checking prescriptions, that they have little time to spend with me." (Y4, PY)

On the contrary, tutors from the hospital received very favourable feedback, with many students noting that they were well-organised and had tasks planned for students. One student shared,

> "Hospital placement was much better, more informative and easy to reach. Better organised and showed me a lot of areas in the hospital and what pharmacists do to sort out issues and how they deal with new patients and patients getting discharged." (Y2, PN)

Hospital tutors were very helpful and eager to equip students with as much information as possible to ensure they had a good placement experience. Tutors made the effort to demonstrate the necessary skills to students, and time was also allocated to allow for discussions in greater depth:

> "The tutor was very keen and professional in demonstrating what he does and was actively engaging us through asking us clinical questions."(Y4, PY)

Theme 3: Key influence of having a part-time job

Having a part-time job in the community seemingly had a major influence on students' perceived placement experience and feedback, with students noting that community placements were pointless or should not be

compulsory as they were learning more from their jobs and were not learning new skills from their placements. Indeed, students noted that they were able to complete most of their learning outcomes at their jobs. One reflection stated,

> "Most (if not all) students have part time jobs in community pharmacy by the time they reach final year which they learn a lot more from and would be a better use of time to encourage overtime etc. instead of carrying out a community placement." (Y2, PY)

A few did note that the familiarity at their work-site allowed for better learning, as students had, among others, already established a rapport with work staff. One student shared the following reflection:

> "People in part-time pharmacy work get a much better chance in the workplace to enhance their clinical skills and problem-solving ability due to being in a familiar environment without the need to travel elsewhere, meet people they don't know and familiarise themselves to another system that hinders their ability to move on to more important topics like prescription checking, clinical and legal matters and patient monitoring and counselling because they have a pre-established positive relationship with their colleagues and can ask questions much more regularly and freely."(Y4, PY)

It also impacted their perception of placement allocation, with many noting that community placements were too long especially in later years, and especially by those who already had part-time jobs. Indeed, one student noted that it felt like the university was trying to steer students toward a career in community pharmacy, thus side lining the other practice sites:

> "Overall not focus on community so much as many of us know what that's like as we work in one, and help experience different types of pharmacy we haven't be exposed to, "broaden our horizons" and help us find the perfect sector of pharmacy for each student. It just seems like you're just pushing us all to become community pharmacists and don't want us to go into other sectors." (Y3, PN)

As such, there were calls for more placements in the hospital and emerging settings such as primary care as they would provide experiences that were different from their part-time jobs. One student commented that

> "…having no opportunities for primary care etc. doesn't prepare us for practice if we don't have the chance to see what it's like." (Y3, PY)

DISCUSSION

This study sought to assess students' perception of their EL experience. Students were generally positive about their experience in the hospital, despite the lack of time spent there. On the contrary, feedback about community placements was largely negative, especially with regard to the tutors. Having a part-time job appeared to have a major impact on students' perceived experience of their placements.

The majority of students were not happy with the limited time spent in the hospital. There is much ambiguity with regard to placement duration, with some preferring shorter placements, and others preferring the opposite.[7,8,17] More important than simply focusing on duration, there should be a focus instead on quality – ensuring placements are not too short that they only provide a superficial experience where students are merely 'tourists', and not too long that tasks become too repetitive and the experience turns more to 'working' instead of 'learning'.[18,19] One way of ensuring this is by adopting a mixture of structure and flexibility in placements. The latter is especially crucial given the dynamic nature of the healthcare environment which might pose a barrier to students achieving their learning objectives if they were too rigid.[9] Flexibility will also allow for more consideration of the different student learning styles, needs, and interests.[9,20] A mixture of structure and flexibility will also assist students in writing reflections which are useful, while at the same time enabling greater depth of reflection.[9,21]

There were numerous comments about students being used as an extra pair of hands during their placements in the community, with minimal to no teaching taking place. This has been highlighted previously, and indeed there have been concerns about the quality of placements, particularly in the community setting.[9,18,22] While pharmacists see the value in EL, they do face a burden when taking on students for placements, as they do not have protected time, resulting in an increase in workload and stress when students are there, and limited time to engage with students.[2,23-28] This is similar to that highlighted in this study, where many perceived community tutors as too busy to engage with students. However, as placements in the hospital are of a shorter duration (Table 1), it is most likely easier to organise and for tutors to spend time with students.

Community placements were longer in duration, which likely allowed for opportunistic learning and more patient interactions to occur. Nevertheless, students still had a more negative perception of community placements, despite the fact that there was limited interaction with patients in the hospital setting. This can be explained by the psychology of learning environments where being in, what is perceived as, a more positive environment will elicit more favourable emotional responses to that place, and lead to enhanced learning.[29] Kaplan and Kaplan's Predictors of Environmental Preference is also significant here, where four cognitive predictors of environmental preference have been highlighted namely coherence, complexity, legibility, and mystery.[30,31] The latter would seem appropriate to explain students' perception of a better experience in the hospital environment given the novelty of the environment and the level of intrigue it presents to students. This contrasts with the community setting, which the majority of students already work in, and is thus perceived as being less mysterious. Due to having a part-time job, students also have higher expectations of community sites versus hospitals sites, and have been found to be more critical when their expectations were perceived as not met.[14]

In 2019, the Scottish Government announced the Additional Cost of Teaching Pharmacy (ACTp) funding where placement sites will be provided with funds to

support the training of students. This money can be used to hire additional staff when students are there, allowing tutors to fully engage with students.[32] Indeed, studies have found that tutors view money as a valuable incentive to compensate them for their time, and providing monetary compensation was found to improve the relationship between tutors and the university, as well as increase tutor retention, recruitment, and loyalty.[27,28,33]

Tutor training is key to ensure tutors are aware of their roles and responsibilities, as well as feedback from students. There has indeed been a call for more tutor-training programmes as tutors have acknowledged that they lack the necessary skills to supervise students.[10,34,35] The Preparation for Facilitating Experiential Learning Training (PFEL) introduced in 2019 by NHS Education for Scotland (NES) and the two universities in Scotland should be made compulsory for all tutors as it will prepare them on how to provide quality experiences for students, which includes giving feedback. The latter is a practice not commonly adopted by tutors, as noted in our findings, and a skill they often struggle with.[2,34] During these sessions, universities should also signpost relevant support staff tutors can access should they face challenges or have questions while tutoring students.

Stakeholder such as pharmacists and academics have highlighted that the lack of quality assurance of tutors was a barrier to the training of pharmacists.[22] While the GPhC has stipulated in the Standards that tutors and placement sites for undergraduate programmes must be quality-assured, there is no specification as to how or how frequently this should be undertaken.[11] Indeed, a recent nationwide survey conducted in the UK found that less than five universities had regular and standardised placement visits once or more per year. Survey respondents also ranked the lack of quality assurance of tutors as the third most important challenge they faced with EL.[12]

In a survey of placement tutors in the United States (US), there was strong support for site visits by the university, with tutors acknowledging that it assisted them in planning and improving the placement experience for the students, and enabled them to address issues related to students and the universities' expectations of them. The majority preferred monthly visits.[36] As such to ensure that the sites provide an optimal learning environment which will allow students to obtain the appropriate practical experience unhindered, it would seem prudent that regulated and ongoing site visits should be undertaken, similar to that currently being undertaken by NES on pre-registration sites and tutors.[36,37] This is, however, not without its barriers. In the US, students have to complete 300 mandated hours of placements, which are typically undertaken in blocks. As EL in the UK is limited to short periods, monthly or frequent visits may then not be feasible or practical. To accommodate this, Schools of Pharmacy can potentially look to conducting quality assurance 'visits' virtually or even over the phone, as is practised elsewhere.[12]

In the current GPhC model, pre-registration pharmacists are allowed to delegate tutoring, but not assessment, duties to other competent pharmacy staff such as technicians and pharmacy assistants. A similar model is followed for undergraduate placements, highlighting the need to include them in quality assurance measures. While it would not seem feasible to include other pharmacy staff in training sessions, tutors attending tutor-training programmes must be told to ensure these staff are aware of their roles and responsibilities when tutoring students.

More than 80% of respondents agreed that part-time work should contribute toward their EL hours. This was supported by respondents in the aforementioned nationwide survey of UK universities, where more than 50% believed that students should receive EL credit for pharmacy employment.[12] There is, however, no stipulation in the Standards which allow students to be excluded from EL because of their part-time work. The School of Pharmacy's philosophy is that all students should have equitable access to EL to enable the School to ensure all students have a similar experience, independent of their part-time work. In addition, the Standards stipulate that students should practice in a safe and effective manner. To achieve this, EL should be progressive, where students deal with issues with increasing complexity until sufficient comprehension and competency is achieved.[11] This will be difficult to monitor and govern if students are allowed to undertake EL at their part-time jobs.

Discussions with graduates as part of our TELL project have also revealed that during their part-time jobs they mainly assumed the role of a technician as opposed to a pharmacist, and the focus was more on working instead of learning.[14] Crucially, there is no time for reflection. A central element of Kolb's experiential learning theory is reflection of the experience which helps students make the link between theories and the knowledge acquired in university, with the intricacies of practice. Indeed, effective learning is thought to occur only when students have completed all four stages of Kolb's experiential learning model.[38] Reflection is also a crucial practice, especially for pharmacy students and in higher education, as it develops self-regulated, critical-thinking, and problems-solving skills - important arsenals for healthcare professionals who traditionally work in dynamic work settings.[39] While it has been argued that tutors will be more amenable to putting in the effort to train students who will then work for them, it is imperative that should this be allowed, that it is well-structured similar with their EL and closely regulated.[40]

More than 90% of respondents wanted to be able to undertake placements in other settings such as primary care, a call further underlined in the open-ended responses. Projected increases in ageing and the number of those living with multiple comorbidities in the UK will likely place a burden on the primary care system.[41] To support the shift from care in the institutions to primary care and to help manage the increasing complexity of cases being treated in primary care, Achieving Excellence in Pharmaceutical Care – a Strategy for Scotland, was launched by the Scottish government where one of the key objectives is to prepare pharmacists to assume positions in this sector.[42-44] As such, there is a need to adopt these emerging placement sites to provide students with the necessary exposure and training, as already done by a number of universities.[12] The ACTp funding will also help funnel resources to allow for more placements in these sites.[45] Given the multidisciplinary nature of primary care,

this will also require more interprofessional training opportunities to be embedded within the placements – a requirement also stipulated in the Standards by the GPhC.[11]

Limitations

There was a low response rate, however the number attained fulfilled the minimum sample size requirement. Demographics of respondents were also representative of the current student population, which are predominantly females. The survey was not pilot tested on undergraduates. However, pilot testing was undertaken involving academics who were recent graduates of the MPharm programme and who had recently undergone EL while at the School of Pharmacy. Responses with missing data were included in the analyses, and as such this may limit interpretation of the results. Although the researchers sought participation from students to participate in qualitative interviews, there were no volunteers. As such, researchers were not able to explore in more depth the findings and themes as well as other factors which might have impacted students' views and experience such as organization of placements. There should be an effort in future to explore salient issues identified through qualitative interview to provide more depth to the findings.

CONCLUSIONS

Undergraduate pharmacy students voiced concerns about placement duration and tutors, the latter underlining the importance of tutor-training programmes to ensure tutors are aware of the responsibilities as well as expectations from Schools. While increasing the duration of placements may not be feasible for all universities due to issues with funding and resources, Schools could focus instead on ensuring placements are well-structured yet flexible to accommodate different learning styles and interests of undergraduates. Quality assurance measures are also imperative to ensure all tutors and placement sites are able to provide students with an effective and equitable placement experience. Changes should be made to the curriculum to include emerging areas such as primary care as a placement site, and further investigations should be undertaken to assess the advantages and disadvantages of allowing undergraduate students to undertake their EL at their place of work.

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CONFLICT OF INTEREST

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Original Research

Evaluation of risk factors and drug adherence in the occurrence of stroke in patients with atrial fibrillation

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Abstract

Background: Atrial fibrillation (AF) patients are at high risk of developing a stroke and anticoagulant medications are generally prescribed to prevent stroke in AF population.

Objective: This study aims to evaluate stroke risk factors among hospitalized patients with AF and to assess the level of adherence to medications in AF patients and their relation with stroke.

Methods: This is a case-control study conducted between June 1st, 2018 and December 31th, 2018 among AF patients admitted to seven tertiary Lebanese hospitals. Data were collected using a standardized questionnaire. Adherence to medications was assessed using the Lebanese Medication Adherence Scale-14. Odds ratios (OR) expressed the strength of association between the independent variables and the dependent variable and were estimated using unconditional logistic regression adjusted for confounding factors. P<0.05 determined statistical significance.

Results: In total, 174 cases of AF patients were included with 87 cases and 87 controls. The risk of stroke among AF significantly increased with the presence of a history of hypertension, aOR 16.04 (95%CI, 2.27-113.37; p=0.005), history of coronary heart disease/myocardial infarction, and history of obesity. Anticoagulant medication significantly decreased the risk of stroke among AF patients, aOR 0.27 (95%CI, 0.07-0.98; P=0.047). High adherence to medications was significantly associated with a reduced risk of stroke, aOR 0.04 (95%CI, 0.01-0.23; p<0.001).

Conclusions: Having a history of hypertension is one of the strongest risk factors for stroke among AF patients in Lebanon. While anticoagulant medication use was associated with a reduced risk for stroke, high adherence to medications is critical for stroke prevention. Public health interventions are needed to tackle low-adherence to medication and prevent stroke among AF patients.

Keywords

Atrial Fibrillation; Stroke; Inpatients; Risk Factors; Anticoagulants; Medication Adherence; Hypertension; Coronary Disease; Obesity; Odds Ratio; Logistic Models; Case-Control Studies; Lebanon

INTRODUCTION

The World Health Organization defines stroke as "rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin".[1] The Middle East has limited information in regard to stroke, including Lebanon.[2] However, a recently published study in Lebanon identified atrial fibrillation history as one of stroke risk factors, OR 2.67 (95%CI, 1.16-6.11; p=0.02).[3]

According to the Framingham study, Atrial Fibrillation (AF) is a significant risk factor for stroke, increasing the relative risk of ischemic stroke by 4 to 5 times.[4] Among people older than 70 years of age with AF, it is estimated that the absolute stroke rate averages about 3.5% per year, however, this rate may increase significantly depending on age and other clinical features.[5] Advanced age, hypertension, diabetes, and previous stroke or transient ischemic attack (TIA) are four key risk factors that have been independently associated with stroke in AF patients as has been demonstrated in many studies.[5]

Anticoagulant medications should be used in most patients with AF to prevent stroke.[6] Many prospective randomized controlled trials documented the beneficial outcome of anticoagulant with warfarin for stroke prevention among AF patients.[7] Despite the significant effectiveness of anticoagulant therapy for stroke prevention, strict adherence to medication is vital for treatment success.[8,9] The World Health Organization defines medication adherence as "the extent to which a person's behavior, taking medication, following a diet, and/or executing lifestyle changes, corresponds to agreed recommendations from a healthcare provider".[10] Currently, it is estimated that only 1 out of 6 patients perfectly adhere to their medication, and data from ATRIA study (AnTicoagulation and Risk Factors In Atrial Fibrillation) suggests that 25% of newly prescribed patients of warfarin will discontinue in almost one year.[11] Serious and fatal bleeding is usually a major concern associated with anticoagulant with warfarin treatment, RR 1.56 (95%CI, 1.03-2.37).[12] This is also confirmed in a cross-sectional study conducted in Turkey to measure adherence to non-vitamin K antagonist oral

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anticoagulants where nonadherence had been related to stroke rates (5.6% vs 2.5%, p<0.001), and minor and major bleeding rates, (21.2% vs 11.1%, p<0.001) and (6.1% vs. 3.7%, p=0.004), respectively.[13] Additionally, in 12 months follow-up of 2259 patients with AF, the multivariate analysis indicated that nonadherence to antithrombotic treatment was associated with an increased risk of stroke for primary prevention, OR 2.95 (95%CI, 1.26-6.90) and recurrent stroke for secondary prevention, OR 2.80 (95%CI, 1.25-6.27) as well as all cause death, OR 2.75 (95%CI, 1.33-5.69).[14]

In this study, we aimed to evaluate stroke risk factors among hospitalized patients with AF and to assess the level of adherence to medications in AF patients and their relation with stroke.

METHODS

Study design

This is a case-control study conducted between June 1st, 2018 and December 31th, 2018. Adult participants were selected from 7 tertiary hospitals in Lebanon (private and governmental hospitals). Cases were AF patients admitted to the included hospitals with a stroke diagnosis confirmed by brain computed tomography (CT) scan or magnetic resonance imaging (MRI). Controls were AF patients admitted to the participating hospitals during the same time period of cases with a diagnosis other than stroke. This study didn't require an institutional review board approval because it is only observational with no traceability of patients. However, a verbal consent was obtained from each patient prior to the participation in the study.

Data collection

Data were collected prospectively by the main researcher of the study based on information present in the patient's hospital file or from patients. We used a standardized questionnaire written in English and translated into Arabic. The questionnaire was pilot tested in Arabic language on a small group of individuals in order to exclude any potential contradictions. It included five sections related to patient's identification and diagnosis, socio-economic and demographic factors, stroke risk factors, medications, and laboratory data. The main researcher of the study approached the patient or a relative - if the patient was incapable of answering - with the questionnaire and personally collected the answers. A relative must be a person living with the patient and knowing about the patient's medical history and medication in order to answer the questionnaire.

Sample size calculation

The sample size calculation was performed using Epi Info Program, assuming a 5% alpha risk, a study power of 80%, and a case: control ratio of 1:1. As, no data was found in the literature regarding the percentage of exposure among controls (AF patients non-adhering to anticoagulant medications and free of stroke), therefore a 50% of controls exposed was considered. In addition, according to Mazurek *et al*., the odds ratio of stroke risk for primary prevention in non-adhering patients is 2.95.[14] As a result, the total sample size required was 122 AF patients with 61 cases and 61 controls.

Assessment of the adherence to medications

The list of medications assessed in this study includes antihypertensive, lipid-lowering, anti-diabetes, anticoagulant, aspirin, clopidogrel, and anti-depressant medications. Adherence to medications was assessed using the fourteen-item LMAS-14 (Lebanese Medication Adherence Scale-14).[15] The LMAS-14 is a validated and practical tool used to assess adherence to medications among Lebanese hypertensive patients. However, this scale may also be used to measure patients' adherence to treatment in chronic diseases. The LMAS-14 contains 14 questions related to occupational, psychological, annoyance, and economical factors that may interfere in patient's adherence to treatment. Each question has 4 answers for the patient's to choose from, ranging from low adherence (code 0) to high adherence (code 3). Therefore, a patient's score may range from 0 (lowest adherence) to 42 (highest adherence). A cut-off point of 38 is used to class patients as adherent or non-adherent to medications.[15] For this study, we calculated each patient's score on LMAS-14 in order to assess adherence to treatment.

Statistical analysis

Data were analyzed using SPSS version 24. Bivariate and multivariate analyses were conducted. Continuous variables were presented as means with standard deviation and categorical variables as percentages. Sample t-test analyzed the difference in baseline characteristics between stroke and stroke-free patients for quantitative variables and Chi-square test analyzed the difference for qualitative variables. Fisher's exact test was used when the expected cell size was less than 5. ANOVA was used instead of t-test to compare the means of more than two groups. Only variables with p<0.2 in the bivariate analysis were included in the multivariate logistic regression. Odds ratio expressed the strength of association between the independent variables (stroke risk factors / adherence to medication) and the dependent variable (presence of stroke or not) with 95% confidence interval. P<0.05 determined statistical significance.

RESULTS

In total, 174 cases of AF patients were admitted to the 7 hospitals between June 1st, 2018 and December 31th, 2018 with 87 patients admitted for stoke diagnosis and 87 patients admitted for diagnosis unrelated to stroke. All AF patients admitted to the 7 participating tertiary hospitals (governmental and private), agreed to be included in the study. However, no statistically significant differences between hospitals was found (one-way ANOVA test p=0.416). Among included stroke cases, 10.3% had TIA, 17.2% had hemorrhagic stroke, and 72.4% had ischemic stroke. Moreover, 78.2% had CT scan, 16.1% had MRI, and 5.7% had both imaging techniques. None of the control patients had a CT scan or MRI.

The mean age of stroke was 72 (SD 10) years. Stroke patients statistically differed from stroke-free patients in regard to age (>65 years) and sex (female). The majority of stroke patients were unemployed, married, medically insured, and had a lower education level (Table 1).

Table 1. Socio-economic and demographic characteristics of the study's participants

Variables	Total (N=174)	Stroke Patients (N=87)	Stroke-free Patients (N=87)	p-value
Age in years, mean (SD)	71.63 (10.17)	72.43 (9.63)	70.84 (10.67)	0.280
Age in categories, (N%)				0.040*
< 65 years	47 (27.0)	17 (19.5)	30 (34.5)	
> 65 years	127 (73.0)	70 (80.5)	57 (65.5)	
Sex, N(%)				0.044*
Male	70 (40.2)	28 (32.2)	42 (48.3)	
Female	104 (59.8)	59 (67.8)	45 (51.7)	
Employment status, N(%)[€]				0.080
Unemployed	101 (64.7)	50 (72.5)	51 (58.6)	
Retired	41 (26.3)	12 (17.4)	29 (33.3)	
Employed	14 (9.0)	7 (10.1)	7 (8.0)	
Education N(%)[€]				0.468
Low education[µ]	86 (92.5)	52 (91.2)	34 (94.4)	
Intermediate	3 (3.2)	1 (1.8)	2 (5.6)	
Secondary	1 (1.1)	1 (1.8)	0 (0)	
Higher education	3 (3.2)	3 (5.3)	0 (0)	
Marital status, N(%)[€]				0.684
Single	1 (1.1)	1 (1.8)	0 (0)	
Married	53 (57)	31 (54.4)	22 (61.1)	
Widowed/Divorced	39 (42)	25 (43.9)	14 (38.9)	
Medical insurance, N(%)[€]				0.518
Insured	97 (61.0)	51 (58.6)	46 (63.9)	
Uninsured	62 (39.0)	36 (41.4)	26 (36.1)	

*, statistically significant; [€], Missing data for some patients: considered missing at random in the analysis; [µ], elementary education or no education

Stroke patients statistically differed from stroke-free patients in respect to anticoagulant, aspirin, and clopidogrel medications. They also differed in regard to medical history including hypertension, diabetes, coronary heart disease/myocardial infarction, peripheral artery disease, previous TIA/stroke, and family history of stroke as well as physical activity, waterpipe smoking (Table 2). Stroke patients also showed significantly higher values of blood pressure than stroke-free patients.

Among the 174 included AF patients, only 49 patients were under oral anticoagulant treatment with 17 (34.7%) patients being admitted for stroke diagnosis. Around 88 AF patients were taking aspirin alone where 51 (58%) patients

Table 2. Medical and health characteristics of patients according to stroke status

Variables N(%)	Total (N=174)	Stroke Patients (N=87)	Stroke-free Patients (N=87)	p-value
Medication History				
Antihypertensive	157 (90.2)	77 (88.5)	80 (92)	0.611
Lipid lowering medication	67 (38.5)	37 (42.5)	30 (34.5)	0.350
Anti-diabetes	55 (31.6)	29 (33.3)	26 (29.9)	0.745
Antidepressant	26 (14.9)	16 (18.4)	10 (11.5)	0.288
Anticoagulant	49 (28.2)	17 (19.5)	32 (36.8)	0.018*
Aspirin	88 (50.6)	51 (58.6)	37 (42.5)	0.048*
Clopidogrel	29 (16.7)	19 (21.8)	10 (11.5)	0.103
Medical History				
Hypertension	144 (82.8)	82 (94.3)	62 (71.3)	<0.001*
Diabetes Mellitus	64 (36.8)	37 (42.5)	27 (31.0)	0.157
Dyslipidemia	62 (35.6)	31 (35.6)	31 (35.6)	1.000
Coronary Heart Disease/Myocardial Infarction	67 (38.5)	51 (58.6)	16 (18.4)	<0.001*
Peripheral Artery Disease	21 (12.1)	14 (16.1)	7 (8)	0.161
Heart Failure	44 (25.3)	23 (26.4)	21 (24.1)	0.862
Deep Venous Thrombosis/Pulmonary Embolism	19 (10.9)	10 (11.5)	9 (10.3)	1.000
Chronic Kidney Disease	20 (11.5)	10 (11.5)	10 (11.5)	1.000
Obesity	78 (44.8)	45 (51.7)	33 (37.9)	0.093
Previous TIA/stroke	30 (17.2)	30 (34.5)	0(0)	<0.001*
Physically active[µ]	41 (23.7)	17 (19.3)	27 (30.6)	0.223
Cigarette smoking status				0.126
Non-smokers	107 (61.5)	49 (56.3)	58 (66.7)	
Current smokers	56 (32.2)	34 (39.1)	22 (25.3)	
Previous smokers	11 (6.3)	4 (4.6)	7 (8)	
Waterpipe smoking status				0.019*
Non-smokers	157 (90.2)	73 (83.9)	84 (96.6)	
Current smokers	11 (6.3)	9 (10.3)	2 (2.3)	
Previous smokers	6 (3.4)	5 (5.7)	1 (1.1)	

*, statistically significant; [µ], a patient was considered physically active based on the WHO recommendations: 150 minutes of moderate physical activity per week, or 75 minutes of vigorous physical activity per week, or a combination.[16]

Table 3. Factors associated with the risk of stroke among atrial fibrillation patients			
Variable	**aOR**	**95%CI**	**p-value**
History of Hypertension	16.04	2.27-113.37	0.005*
History of coronary heart disease/myocardial infarction	5.15	1.75-15.14	0.003*
History of Obesity	4.93	1.7-14.26	0.003*
Anticoagulant	0.27	0.07-0.98	0.047*
OR_a, Adjusted Odds Ratio; CI, Confidence Intervals; *, statistically significant; -2 Log likelihood 109.815; Nagelkerke R Square 0.653			

developed a stroke. Both medications, oral anticoagulant and aspirin, were taken by 13 patients and 5 patients (38.5%) developed a stroke. However, 50 AF patients were not taking neither oral anticoagulant nor aspirin and 24 patients (48%) were admitted for stroke diagnosis (data not shown).

In the multivariate logistic regression model, age (≥ 65 years), gender and employment were considered as confounding factors and controlled in the analysis. The risk of stroke among AF patients significantly increased with the presence of a history of hypertension, aOR 16.04 (95%CI, 2.27-113.37; p=0.005), history of coronary heart disease/myocardial infarction, and history of obesity. Anticoagulant medication was significantly associated with a reduced risk of stroke among AF patients, aOR 0.27 (95%CI, 0.07-0.98; P=0.047) (Table 3).

The cut-off point 38 was considered to classify patients on LMAS-14 as adherent or non-adherent to medications. Around 6 AF patients were excluded from this analysis since they were not taking any medications prior to their admission to the hospital (patients did not know of their AF conditions prior to admission to the hospitals). Among the 168 patients included in the analysis of adherence to medication, 82 patients were admitted to the hospital for a stroke diagnosis and 86 patients were not admitted for stroke diagnosis. About 56 stroke patients (68.3%) had a high adherence to medication compared to 83 stroke-free patients (96.5%) (p<0.001).

In the multivariate model, adherence to medications was assessed after adjustment on all potential confounders including socioeconomic and demographic, vascular, behavioral, and stroke risk factors. High adherence to medications was significantly associated with a reduced risk of stroke among AF patients, aOR 0.04 (95%CI, 0.01-0.23; p<0.001) (Table 4).

DISCUSSION

This study confirms that a history of hypertension, coronary heart disease/myocardial infarction and obesity may increase the risk of stroke among AF population. Taking oral anticoagulant medication decreases the risk of stroke. Moreover, high adherence to medication is found to be statistically and significantly associated with a reduced risk of stroke.

Atrial fibrillation is an independent risk factor for stroke. AF patients have double the risk of death from stroke compared to stroke patients with other stroke causes and surviving patients are often left with increased disability.[17] Many studies identify increasing age as an important factor to be associated with stroke among AF patients.[18-20] It is estimated that 84% of the AF population ages 65 years and above and that 32% are older than 80 years of age.[18] Our results are in line with those findings where 80.5% of our AF sample is above 65 years of age and around 26.4% is more than 80 years old. However, our evidence was inconclusive that increased age is an independent predictive of stroke, probably due to a low number of subjects included in the study.

A history of hypertension is a powerful and consistent risk factor for stroke among AF patients.[18,19] Our findings confirm the strong relationship between AF and hypertension with aOR 16.04 (95%CI, 2.27-113.37; p=0.005) as well as a statistically significant association between coronary heart disease/myocardial and stroke among AF patients, which is in correlation with other published findings.[21] Therefore, this study agrees with a recently conducted research in Lebanon where hypertension and coronary heart disease/myocardial infarction were considered as predictive factors for stroke.[22]

According to Khoury and Jazra, AF patients in the Gulf and Middle East differ from the West mainly by being younger and having high prevalence of obesity, diabetes, and smoking.[18] However, it is expected that better management of stroke among this population would advance with the use of anticoagulant medicines.[18] In our sample, oral anticoagulant treatment showed a decrease in the risk of stroke, aOR 0.27 (95%CI, 0.07-0.98; p=0.047). Anticoagulant treatment is recommended for AF patients to prevent stroke with the exclusion of patients at high risk of bleeding complications.[23] The percentages of stroke found in this study suggest a superiority of oral anticoagulant treatment compared to aspirin for stroke prevention with similar risk of hemorrhage. However, the purpose of this study was not to compare both treatment among AF patients, but it is essential to highlight the necessity of examining the underlying causes for reduced

Table 4. Adherence to medication and the risk of stroke among atrial fibrillation patients			
Variable	**aOR**	**95% CI**	**p-value**
High adherence to medication	0.04	0.01-0.23	<0.001*
History of hypertension	13.09	1.83-93.74	0.01*
History of coronary heart disease/myocardial infarction	3.58	1.24-10.34	0.018*
History of Obesity	4.26	1.43-12.72	0.009*
Current waterpipe smoking	4.95	1.23-19.89	0.024*
OR_a, Adjusted Odds Ratio; CI, Confidence Intervals; *, statistically significant; -2 Log likelihood 102.054; Nagelkerke R Square 0.677 Age (≥ 65 years), gender, employment, history of hypertension, history of diabetes, history of coronary heart disease/myocardial infarction, history of peripheral artery disease, history of stroke/TIA, history of obesity, cigarette smoking, and waterpipe smoking were controlled in this multivariate analysis.			

prescription of anticoagulants among AF patients.

The effectiveness of aspirin for stroke prevention in AF patients remains unclear particularly for cardioembolic stroke especially as anticoagulant has shown a superiority in success.[24] Aspirin is usually used among young patients with low risk of stroke or with those presenting contradictions to warfarin.[5] Our data showed that aspirin use was not restricted to a younger age among AF patients; 37.5% and 48.9% of patients were 61-70 and 71-90 years old, respectively.

Adherence to antihypertensive medication is believed to better predict the risk of stroke.[22] Many studies have demonstrated that low adherence to antihypertensive treatment is associated with high risk of stroke and cardiovascular diseases.[25] Additionally, low adherence to this medication among hypertensive patients increases the risk of dying from a stroke by 4 times by the second year of prescribed treatment compared to high adherent patients.[26] In this study, high adherence to medications, in general, has proved to be associated with reducing the risk of stroke among AF patients, aOR 0.04 (95% CI, 0.01-0.23; p<0.001). The percentages of adherence ((68.3%) among stroke patients and (96.5%) among stroke-free patients) were higher than the percentage of adherence reported in our previous study among Lebanese outpatients with chronic diseases (42.6%).[27] This could be explained by the fact that adherence to medications used to treat some other chronic conditions such as oral antidiabetic medication was found to be low for Lebanese patients as reported in our previous study among Lebanese diabetic patients.[28]

Our findings also suggest that more stroke risk factors are found to be predictors of stroke along with high adherence to medications, including hypertension, coronary heart disease/myocardial infarction, obesity, and waterpipe smoking. For instance, among the 174 patients included in the study, 157 patients were under antihypertensive treatment with 144 patients being hypertensive. And although hypertensive patients were prescribed antihypertensive medication, only 45.6% had a controlled blood pressure while 27.9%, 16.2%, and 10.3% had a grade 1, grade 2, and grade 3 blood pressure, respectively, indicating an issue in adherence to antihypertensive medications among this population.[29] This is similar to what was found in Lebanon with Matar and colleagues study in regards to hypertensive patients and antihypertensive treatment, however, it is important to emphasize on the low adherence to this medication which resulted in uncontrolled blood pressure and stroke.[30] More studies are called for in order to assess why patients do not adhere accurately to their prescribed medications.

This study has many strengths: (1) this study is original in assessing the relationship between adherence to medications and stroke among AF patients in Lebanon; (2) data were included from 7 different tertiary hospitals in Lebanon in order to be as representative as possible of the Lebanese population; (3) data were collected prospectively; (4) common potential bias of case-control studies were controlled; cases and controls were from the same hospitals and a standardized questionnaire and protocol were used for data collection and analysis.

This study has also many limitations: (1) the limited number of subjects included didn't allow to better explore the relationship of certain risk factors and stroke among AF patients, including cigarette and waterpipe smoking; (2) classification bias may have had an impact on the adherence to medication since this is a self-reported questionnaire and some patients may have provided socially desirable responses in regard to their adherence to medications.

CONCLUSIONS

In conclusion, our findings suggest that having a history of hypertension is the strongest risk factor for stroke among AF patients in the Lebanese population along with other important factors. While anticoagulant medication use was associated with a reduced risk for stroke, high adherence to medications is critical for stroke prevention. Implementing public health interventions are needed in order to tackle low-adherence to medication in AF population and reduce the number of stroke.

CONFLICT OF INTEREST

The authors declared no potential conflicts of interest with respect to the research, authorship, or publication of this article.

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Original Research

Exploring Australian pharmacists' perceptions and attitudes toward codeine up-scheduling from over-the-counter to prescription only

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Abstract

Objective: Explore the perceptions, attitudes and experiences of pharmacists relating to the up-scheduling of low dose codeine containing analgesics and the impact on pharmacy practice.

Methods: A mixed design method was used consisting of an anonymous online questionnaire survey to quantitatively capture broad pre-scheduling change perceptions paired with a series of in-depth post-scheduling semi-structured interviews to provide a qualitative picture of the impact of codeine up-scheduling on pharmacy practice in Australia.

Results: A total of 191 pharmacists completed the quantitative survey and 10 participated in the in-depth interview. The majority of respondents supported the decision to up-schedule over-the-counter combination products containing codeine to some degree. Three main themes emerged from the data: pharmacists' perceptions of the codeine up-scheduling decision, preparing for the up-schedule and impact of the up-schedule on pharmacy practice. Pharmacists were concerned about the impact of up-scheduling on the pharmacy business, patient access to pain relief and the diminishment of their professional role.

Conclusions: There were diverse perceptions, preparedness and impact on practice regarding the up-scheduling of low dose codeine products. Further research should be conducted to gauge if and how these perceptions have changed over time and to identify whether pain is being managed more effectively post codeine up-scheduling.

Keywords

Analgesics; Codeine; Nonprescription Drugs; Pharmacies; Pharmacists; Professional Role; Attitude of Health Personnel; Health Knowledge, Attitudes, Practice; Surveys and Questionnaires; Qualitative Research; Australia

INTRODUCTION

Excessive use of codeine containing analgesics can result in codeine dependence and life-threatening adverse effects, often due to ingestion of supratherapeutic doses of ibuprofen or paracetamol present in combination products.[1-6] As such, regulatory controls are required to assist in minimising codeine-related harm. Regulations dictating codeine accessibility differ around the world. Codeine containing analgesics are readily available over-the-counter without a prescription in several countries including the United Kingdom, South Africa and Ireland.[7] In other countries such as Austria, France, Germany and the United States, codeine is only available on prescription.[8] In those countries with fewer restrictions, there is greater potential for codeine misuse, as these products are easily accessible by the general population.[7]

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In Australia codeine-containing analgesics were up-scheduled from 'Pharmacy Only Medicines', available over-the-counter in pharmacies without pharmacist involvement to 'Pharmacist Only Medicines', requiring pharmacist input in the sale in 2010, due to increasing concern regarding inappropriate use. At this time pack sizes for low dose (up to 15 mg) codeine containing analgesics were also restricted from up to 100 tablets to a maximum of 50 tablets in an attempt to minimise harm.[1]

These regulatory measures were evaluated in a number of ways. A qualitative study confirmed up-scheduling achieved one aim, in that pharmacists became more aware of those who were misusing codeine, through monitoring frequency of supply.[9] However, pharmacists still described some difficulties relating to their capacity to have challenging conversations in a busy pharmacy setting, establishing appropriate therapeutic need, not being able to monitor supply from other pharmacies and a lack of knowledge of appropriate referral pathways for pain and dependency issues.[9]

Despite the 2010 scheduling change, concerns surrounding harm associated with over-the-counter codeine persisted. In 2016 the Australian National Drug Strategy Household Survey established that 75% of people who had misused pharmaceuticals had used over-the-counter codeine, an increase from 33% reporting such use in 2013.[10,11] Similarly, calls to an Australian poisons centre regarding codeine misuse increased from 2004-2015, with no change in call trends post 2010, and the proportion of people seeking opioid substitution therapy for codeine dependence

continued to climb, increasing from 2.7% in 2014 to 4.6% in 2016.[12,13] Subsequently, the Australian Therapeutic Goods Administration (TGA) determined the risk of potential harm outweighed the likely benefit gained from over-the-counter access to low-dose codeine-containing products, and in December 2016, announced the decision to further up-schedule codeine containing analgesics to become Prescription Only Medicines from February 2018.[13,14]

Review of pharmacy-based medications and regulation changes such as this are important for the continued safe and effective practice of pharmacists and to maintain the confidence people have in their pharmacist. Chan and Tran showed this in their study looking at what pharmacy customers value and expect from their pharmacy. They found that pharmacy customers expect the pharmacy/pharmacist to provide trusted and factual information and be a knowledgeable resource in providing safe products.[15]

When medication-scheduling changes, it is important to assess the impact of the change to ensure the regulation achieves intended outcomes. There have been some limited studies emerging investigating the impact post up-scheduling of codeine containing analgesics in Australia in 2018 but as the majority of these studies were quantitative in nature it did not allow for exploration of reasons behind the opinions of some pharmacists. Using a mixed-method design, this study aimed to explore in more depth some of the perceptions, attitudes and experiences of pharmacists in Victoria and South Australia relating to the 2018 up-scheduling of low dose codeine analgesics to prescription only. In particular this study explores the impact of up-scheduling on pharmacy practice.

METHODS

A mixed design, consisting of an anonymous online survey to quantitatively capture broad pre-scheduling change perceptions was paired with a series of in-depth post-scheduling change semi-structured interviews completed during 2018, just post the up-schedule. to provide a qualitative picture of the impact of codeine up-scheduling on pharmacy practice in Australia.

Quantitative survey prior to codeine-scheduling change

An 18-item survey was piloted with a convenience sample of 16 pharmacy staff and reviewed by an independent researcher with experience in survey development to minimise question bias. Subsequently, the survey was amended to include an additional 2 items, yielding a final 20-item survey. The final survey included two sections, the first included items regarding participant demographics, role and practice setting; knowledge, attitude and preparation regarding the codeine scheduling change; and participant education preferences. The second section assessed knowledge regarding over-the-counter analgesic dosing and perceived efficacy and safety of specific codeine containing analgesic products. The results of the second section of the survey are beyond the scope of this project.

A convenience sample of pharmacists practicing within Australia was recruited over a 6-month period in late 2017 using the snowball method via social media, pharmacy organisation newsletters and investigators' networks. All pharmacists registered within Australia were eligible to participate. Pharmacists were provided with written information regarding the purpose of the study and the duration of the survey. Consent was implied through completion of the survey, which was available online (via the University of South Australia survey platform 'TellUs 2') or in print with return via reply paid mail. A subset of survey response data, including the questions relevant to codeine up-scheduling specifically are presented here. Pharmacists who completed the survey are referred to as respondents when presenting results. Data were summarised using quantitative descriptive statistics (Microsoft Excel® for Mac, Version 14.6.9).

Qualitative interviews post codeine-scheduling change

A semi-structured interview schedule consisting of open-ended questions was derived from current literature and the pre up-scheduling survey data. Purposive sample was used to recruit community pharmacists practicing in either Victoria (VIC) or South Australia (SA). Community pharmacists were the focus for this component of the study as they are most likely to be impacted by the scheduling change. A random number generator was used to select ten community pharmacies from the state-wide pharmacy listings supplied by the Victorian Pharmacy Authority and the Pharmacy Regulation Authority South Australia website. Pharmacies were contacted via telephone and invited to participate in semi-structured telephone interviews if the pharmacist was a registered pharmacist practicing in SA or VIC and was practicing in community pharmacy for the last 12 months. If eligible, they were forwarded the participant information consent form and given a week to consider participating. A follow up telephone call was made to determine the outcome. Due to resource constraints this process was repeated until five pharmacists agreed to participate each from SA and VIC, or until data saturation was reached. Once the signed consent form was returned, the semi-structured interview was conducted over the telephone and audio recorded. Ten over the phone semi-structured interviews were conducted, lasting between 10 and 20 minutes. Interviews were transcribed verbatim and then open coded by two researchers using NVivo.[16] Initial codes generated by the two researchers were compared and refined. Code were then sorted and analysed for themes and sub-themes.

Ethics

Ethics approval for this project was granted by the University of South Australia Human Research Ethics Committee (HREC 0000036702) and the Science, Health & Engineering College Human Ethics Sub-Committee of La Trobe University (HEC18153).

RESULTS

Quantitative survey prior to codeine-scheduling change

A total of 191 pharmacists completed the quantitative survey between March and September 2017, of these 5 were excluded as they were practicing outside of Australia, yielding 186 responses for analysis. Percentage responses were calculated based on the total response for each

Table 1. Demographic summary of quantitative questionnaire respondents and qualitative interview pharmacists

Characteristic	Questionnaire respondents n (%)	Interview pharmacists n (%)
Gender		
Male	NA	4 (40)
Female	NA	6 (60)
Years of practice		
0 - 5 years	61 (33)	2 (20)
6 – 10 Years	46 (25)	5 (50)
11-15 Years	20 (11)	1 (10)
>15 Years	59 (32)	2 (20)
State of practice		
South Australia	59 (32)	5 (50)
Victoria	37 (20)	5 (50)
Other states	90 (48)	0 (0)
Location of practice		
Metropolitan and inner regional	121 (65)	6 (60)
Outer regional, rural and remote	65 (35)	4 (40)

induvial question to accommodate for missing data. Most respondents were practicing in community (n=136, 73%), with a smaller proportion practicing in hospital (n=40, 22%) or other settings (n=25, 13%) (respondents could select multiple practice settings). Pharmacists reported working in their current role for an average of 14 years (SD 13 years). The majority of respondents (n=121, 65%) were practicing in metropolitan or inner regional areas. See Table 1 for a summary of respondent demographics.

The majority of respondents (n=146, 78.5%) supported the decision to up-schedule over-the-counter combination products containing codeine to some degree, with 28.5% (n=53) indicating they strongly supported the decision. Eighteen percent of respondents (n=34) did not support the up-scheduling decision.

A significant proportion of pharmacists rated their own perceived efficacy of over-the-counter combination products containing codeine in managing acute nociceptive pain as high, scoring such products 8, 9 or 10, on a scale from 1 indicating 'not effective' to 10 indicating the product was 'extremely effective'. For a dose of paracetamol 1000 mg / codeine 30 mg, 47% of pharmacists (n=87) rated perceived efficacy in acute nociceptive pain as 8/10 or greater, and for ibuprofen 400 mg / codeine 25.6 mg, 42% of pharmacists rated perceived efficacy as 8/10 or greater (n=79).

Most survey respondents (n=108, 59%) reported they were confident or extremely confident in providing pain management solutions for their patients after over-the-counter combination products containing codeine change to prescription only. Despite confidence in providing pain management solutions, many respondents did not have a clear understanding of the processes involved with referring patients to the nearest multidisciplinary pain management clinic. Forty one percent of respondents (n=77) reported they were 'not sure of the referral process', whilst only 19% (n=35) reported a good or excellent understanding of the process.

At the time of survey completion, 64% (n=119) of respondents had not taken any specific steps to prepare themselves for the scheduling change. The remainder of respondents indicated they had undertaken educational activities to prepare for codeine up-scheduling. Educational activities completed by those that had taken specific steps to prepare included; attending Pharmaceutical Society of Australia workshops and conference sessions, reading journal articles and newsletter from professional bodies, undertaking pain management courses, reviewing the Therapeutic Goods Administration website, and completing other relevant online modules.

Survey respondents were asked if and how they were working to prepare their patients prior to the up-scheduling of codeine. The majority of pharmacists (n=125, 67%) reported they were informing their patients of the pending changes verbally, with a smaller proportion (n=25, 13%) reporting using written information (leaflets, posters) to provide patients with information around codeine up-scheduling.

Qualitative interviews post codeine-scheduling change

For the qualitative component of this study a total of 10 community pharmacists were interviewed, with five practicing in Victoria and five in South Australia. Participant demographics are presented in Table 1. Three main themes emerged from the data: pharmacists' perceptions of the codeine up-scheduling decision, preparing for the up-schedule and impact of the up-schedule on pharmacy practice. These themes are discussed in detail below.

1.Pharmacists' perceptions of the codeine up-schedule

Pharmacists expressed varying opinions regarding the decision to up-schedule codeine, with some pharmacists for the change, others against; and some unsure. Some of the reasons that pharmacists were against the up-schedule included limiting patient access to pain relief, the unaddressed risk of patients doctor shopping, removal of pharmacists' professional judgment and concerns about potential impact on business. Some pharmacists were positive about the up-schedule as they believed it would be beneficial to patients and would ensure therapeutic need is confirmed.

1.1 Negative perceptions of the up-schedule

Some pharmacists indicated they felt the up-schedule was not warranted and could have been avoided if there was real time prescription monitoring and mandatory recording of codeine sales through a real-time monitoring program. They indicated that this was "a really good tool to refer people" and provided the opportunity "to liaise better with

other medical professions" (Participant 8), and further from Participant 4 "I think my stance was that it should be mandatory to record the codeine product on MedsAssist [a real-time monitoring tool] because I've worked as a locum at many pharmacies that don't record it at all, they just wave off those who were misusers of codeine for sure but I think making it mandatory was another option that they should have gone with".

Some pharmacists indicated they do not believe the codeine up-schedule will be effective in reducing misuse or increasing identification of those who may be misusing or dependent on codeine containing products. Participant 8 stated he believes that "it's just sort of passing the buck really" and that real-time monitoring is the key in allowing pharmacists to monitor codeine misuse effectively.

Furthermore, Participant 2 believes that the up-schedule is a negative change for both pharmacists, as it limits opportunity for pharmacists to use professional judgement, and patients as it will limit the patient's ability to treat their pain effectively, as a result of having limited access to GPs in a rural environment:

> "I don't think it's a good thing, to tell you the truth. It's limiting access to people who genuinely need it…it's also small regional communities and difficulties in accessing doctors to get scripts for these items…I think it's a step backward, and the relationship between pharmacists and the community in the country is a lot closer than the larger communities in the city. You know where you have a lot of anonymous people coming into the pharmacy, so to me overall I think it's a negative thing for patients and for the pharmacist [be]cause it removes another aspect of how we can help people using our professional judgment. Just that our judgment has been taken away now" (Participant 2).

Pharmacists indicated that the impact of up-scheduling on the pharmacy business was of concern. There were fears about a decrease in sales, loss of business and the corresponding impact on the business financially. Some pharmacists indicated that there has been a "decrease in sales" (Participant 5) and that the up-schedule has "cost us a lot of money" (Participant 9).

Even if pharmacists were not in support, they could still see the rationale for the change "I understood why they were doing it. I think the, like the evidence for low dose codeine was never all that great" (Participant 8).

1.2 Positive perceptions of the up-schedule

Some pharmacists stated that the up-schedule was useful as "there was a lot of misuse of medication" (Participant 7) and therefore it "took a lot of pressure" (Participant 9) off the pharmacist, in regard to determining whether the product was appropriate and whether to supply it. Pharmacists indicated codeine up-scheduling is beneficial for patients as it forces them to discuss pain management with the GP to develop an effective pain management plan. However, there are concerns that the up-schedule may lead to patients visiting multiple GP's to obtain prescriptions for opioid analgesics (also known as "doctor shopping"), which at the time of the up-schedule was not being monitored.

Some pharmacists expressed that despite the potential impact on their business, the up-schedule had merit and could reduce the misuse of codeine as patients would be required to consult with their GP:

> "I was a little bit disappointed because I knew there was gonna[sic] be a decrease in sales so from a business point of view, it was disappointing. But from an ethical point of view, I could see the merit of it [be]cause we would have you know regular people coming in, yes my doctor knows about it, yes I talk to him about it so it was actually nice to be able to put it in the doctors ball park." (Participant 5).

2.Preparing for the codeine up-schedule

When discussing preparation for the up-schedule, pharmacists discussed how they prepared themselves and how patients were prepared by pharmacists and more broadly, they also discussed the mixed reactions from patients to the proposed change.

2.1 Pharmacist preparation

There was a perception amongst some pharmacists that no training was required in the lead up to the up-scheduling of codeine "when you been put on the spot in community pharmacy you got to deal with all of the customers, how much training can you even get to do with that" (Participant 1). Despite this, most pharmacists talked about information regarding the change coming from professional associations like the Pharmaceutical Society of Australia (PSA) and the Pharmacy Guild of Australia. Manufacturers also provided information. This information and education consisted of information booklets, online modules and professional development activities "there were lots of manufacturers' stuff coming through…emails, not emails, faxes and things coming about the change but also the PSA had a module that we all did in regards to what was happening" (Participant 5). Some pharmacists undertook additional pain management courses and received specific information from their pharmacy banner group head office. Overall, all pharmacists that had received education and training indicated the level of education and training provided was adequate in preparing them for the up-schedule.

2.2 Patient Preparation and response to up-schedule

A variety of strategies were used to inform patients about the up-schedule, these included advertising and signage in the pharmacy and talking to patients. Media advertising was also expressed as being helpful for preparing patients:

> "leading up to it we had signage saying that things were changing...but also all the media hype was you know getting to people as well. So, I suppose people were well informed either by us or by the media, but we did see an increased amount of requests leading up to the 1st of February" (Participant 5).

When pharmacists were asked about patient reactions to the decision to up-schedule, there were mixed responses,

with some patients very accepting of the change and others less accepting. "I think most of them were, were pretty like, a few people were annoyed with it… but most people were pretty, pretty receptive to it and that, and I suppose that, they sort of understood more why we were, had been recording previously" (Participant 8). How pharmacists framed the message to patients varied, with pharmacists often removing themselves from the decision making, with one participant stating "we just tell them, this is the decision taken by the TGA, and supported by AMA [Australian Medical Association] so they probably need to go back to talk to their GP" (Participant 4).

Pharmacists believe that preparing patients early reduced the amount of hostility that was received once the up-schedule was implemented. "We kind of expected that we'd get a bit of backlash but we didn't really, yeah most people were quite okay with it" (Participant 10). "Like I know this is gonna[sic] sound cliché but we didn't really have anyone abusing or being irritated like it was quite well documented" (Participant 8). Despite this, some pharmacists reported there were a few annoyed patients, whom perceived the up-schedule to indicate "…the government thinks they can control everything and that kind of general thing" (Participant 9).

One pharmacist indicated that some patients were not happy as they were no longer able to manage their own pain "Mmmm were not happy. They weren't able to manage their own pain by themselves …by sending it to prescription only means that I get patients now who just are in pain and can't have anything that they think is controlling their pain over-the-counter" (Participant 4). Some pharmacists took this as an opportunity to discuss with patients alternative options "So what we did when we were informing the customers of the change was that "hey, just so you know there's gonna[sic] be up-schedule, its gonna[sic] be on a script, you can't access it over-the-counter anymore" and they get "Oh no! What will I do"? Well look, you need to get your pain management looked at anyway, be reviewed anyway. So, I recommend you go and see a doctor, find a GP, you know. Really find out, come up with a plan and actually when you tell them that way, when you give them a plan, they felt a little bit more settled, they're not so stressed and it was more assuring for them that you know it's not taken off the market" (Participant 1).

3.Impact of up-schedule on pharmacy practice

When asked about the impact the up-schedule has had on pharmacy practice, pharmacists discussed themes such as how they were managing codeine prior to the up-schedule including the storage, recording mechanisms and their role in determining therapeutic need. They also discussed the positive impacts the up-schedule has had on practice as well as some of the challenges.

3.1 Management of codeine requests and supply pre up-schedule

Most pharmacies took a similar approach when managing over-the-counter codeine containing product requests prior to the implementation of the up-schedule. Interviewed pharmacists reported codeine-containing products, including analgesics and cough and cold preparations, were kept near the dispensary, within the professional services area as per legislative requirements in Australia. For patients to access these products, they were required to undergo a "pharmacist consult" (Participant 3), where the pharmacist is legally required to conduct "individual assessments" (Participant 2) to determine whether there is a therapeutic need. Some pharmacists also indicated that pharmacy assistants would occasionally ask some of the assessment questions such as "Who is it for, what's it for, how long have you had it" (Participant 1) and then refer onto the pharmacist to make the final decision.

All pharmacists in this study stated they recorded sales, either through the real time monitoring program (MedsAssist) or on their dispensing software, to monitor frequency of purchase and identify potential misuse. Despite this, Participant 4 indicated he had previously worked in pharmacies where using the MedsAssist program was not mandatory. "… I've worked as a locum at many pharmacies that don't record it at all, they just wave off those who were misusers of codeine for sure". In addition, Participant 1 stated their pharmacy also used the "What Stop" protocol to "assess and determine whether they would supply it". Despite using these methods to manage codeine requests, Participant 1 also indicated:

> "…it was really hard to wean out the ones who really needed it. It was really hard to identify the ones who yeah who are abusing it as well".

A few pharmacists noted there was an increase in the number of requests for codeine containing products just prior to the up-schedule in anticipation that patients would find it difficult to access their GP, to obtain a prescription once it was made prescription only.

> "We did see an increased amount of requests leading up to the 1st of February. You know because they knew things were changing" (Participant 5).

In situations where pharmacists suspected potential misuse of codeine containing products they would refuse supply and suggest a suitable alternative or refer the patient to their GP to discuss how to manage their pain effectively:

> "…I suppose there were requests where it wasn't warranted but then that was looked at case by case as to you know, what we did with that person, whether we referred them on or we did supply it…and just referring them back to the doctor to speak about that, codeine and whether there's an alternative to the analgesic they're using." (Participant 5).

3.2 Benefits to practice

Pharmacists identified that they thought the up-schedule would have an impact on their practice. However, this has not been the reality for many pharmacists. Most have not seen an increase in GPs prescribing stronger pain relief, and the volume of prescriptions for low dose combination codeine has reduced.

> "… the number of scripts for codeine have dropped. Even like the over-the-counter strengths,

> it's nowhere near as many as how many we were getting walking in" (Participant 6).

One participant did report that they had seen an increase in GPs prescribing products such as Panadeine Forte®.

> "There's increase in the Panadeine Forte® prescriptions…I recommended one patient to have Panadeine Extra® at one point of time and he came back with a 240 tablet script from the doctor, so I don't know what to say about that" (Participant 4).

Some pharmacists believe that changes in prescribing patterns may be because many patients were not visiting their GP to have their pain management reviewed, and doctors may be being more vigilant when prescribing codeine combination products, "I think based on the scripts I've seen, it hasn't really changed very much. It hasn't pushed them to prescribe them any stronger" (Participant 1).

Since the up-schedule came into effect, pharmacists reported that recommending pain management alternatives has become easier "it's probably made it easier to recommend better products for migraines and yeah obviously referral to a doctor too…I haven't found it difficult to recommend different products from codeine…[be]cause yeah as I said the evidence just wasn't there for them anyway really" (Participant 8). There was concerned expressed that as a result of the up-schedule and pharmacists recommending pharmaceutical alternatives that some patients may misuse these and experience negative side effects "...concern now is everybody's gonna[sic] end up with stomach ulcers cause they're using the anti-inflammatories, diclofenac and stuff now" (Participant 3). Recommending non-pharmaceutical therapies such as heat packs, cold packs, transcutaneous electrical nerve stimulation (TENS) machines and referral to a physiotherapist was now also common practice among pharmacists. Participant 6 expressed the importance of counselling patients, and the need to inform patients these products will not necessarily mean that they "…will be pain free but getting the pain to a level where they can manage it" and "that it might be unrealistic to expect to be completely pain free".

Pharmacists communicated that the up-schedule was generally useful in encouraging patients to visit their GP and discuss how to effectively manage their pain. Participant 7 expressed "pain is actually managed I guess more appropriately" and that consultation with the GP provides the option to trial new things. "I'd say that yeah pain is obviously managed better potentially in different ways now". Pharmacists also believed that "a lot of people, like obviously were just using it as it's easily accessible and their underlying pain was never actually managed by the doctor".

3.3 Challenges for practice

Pharmacists discussed a number of challenges post up-schedule. These include limited ability to assist people with short-term pain, concerns about side-effects and misuse of alternatives and they also discussed the challenges of identifying misuse; something that was also seen as a challenge prior to the up-schedule. Pharmacists discussed that the recent up-schedule had limited their ability to assist people with severe or short-term pain. Participant 10 stated that "there's been just a few cases where people have come in and it's been difficult to give them any pain relief cause they might not be able to take anti-inflammatories and they've tried Panadol® [paracetamol] and you know sometimes it just leaves us a little bit limited, but those cases are not very common".

An additional challenge experienced by pharmacists has been the supply of codeine products, with some pharmacists reporting that there were wholesale supply issues when codeine was first up-scheduled "…even when someone had a script, they couldn't necessarily get the product" (Participant 8). Supply issues were also a challenge prior to the up-schedule and are linked to patients negative reactions to the up-schedule, "well initially people were annoyed and they were also annoyed because I think mid-January a lot of the manufacturers weren't able to supply as well, even though it was still S3, we couldn't supply it because there was no stock. So that was frustrating for people" (Participant 5).

A further challenge expressed by pharmacists was that of identifying people misusing codeine. Identifying misuse was identified as a challenge both pre and post up-schedule. While a few were confident if patients were regular customers or there were obvious signs such as "…from their behaviour, they tend to over describe what they need it for" (Participant 9), a number of pharmacists indicated it could be difficult, but that there was an opportunity to refer patients back to the GP "a bit of a difficult one, it's hard to distinguish people that are, have a genuine need for it and those that, might be misusing it, but yeah it's a really difficult area" (Participant 10) Pharmacists indicated if they suspected someone was misusing or dependent on codeine products, they would refer them to their doctor for assessment. "It's certainly referral back to the doctor or it you've got a patient, getting large amounts through prescription, obviously your first point of call is to contact the prescriber" (Participant 8). There was recognition from one participant that the up-schedule had made it more difficult to identify misuse of codeine, as they may no longer be the patients "first point of call" (Participant 9).

DISCUSSION

There are numerous studies emerging investigating the impact and changes seen post up-scheduling of codeine containing analgesics in Australia in 2018, from being available without a prescription over-the-counter in pharmacies to only being available on a prescription. As the majority of these studies are quantitative in nature this study aimed to explore in more depth some of the perceptions and experiences of Pharmacists in Victoria and South Australia. Using both quantitative and qualitative data from pre and post the up-schedule it was identified that pharmacists had varying perceptions about the changes, what they did to prepare and the impacts they felt it had or would have on their practice.

Some pharmacists in this study expressed a negative perception towards the up-schedule as they believed it would limit their patients' ability to access effective pain relief. They suggested it may be difficult for patients to visit

their doctor to obtain a prescription. Disadvantages similar to this were identified by Mishriky *et al*. and McCoy *et al*. including fewer analgesic options, and increased burden for patients, General Practitioners, and the health system.[17,18]

However, evidence from an overview of Cochrane reviews of non-prescription (over-the-counter) oral analgesics for acute pain disputes the notion low dose codeine provides more effective pain relief than other readily available alternatives.[19] They identified combinations of ibuprofen plus paracetamol worked in 7 out of 10 people, and fast acting ibuprofen formulations 200 mg and 400mg, ibuprofen 200 mg plus caffeine 100 mg, and diclofenac potassium 50 mg worked in over 5 out of 10 people. Paracetamol plus aspirin at various doses worked in 1 out of to 4 out of 10 people and they found no information on many of the commonly available combinations containing low doses of codeine. Most of these alternative medicines are available in a pharmacy without a prescription.

Although there were concerns that pharmacists would not be able to provide options for managing pain without access to codeine containing analgesics over-the-counter, there were mixed views both within this study and from other research about the perceived efficacy of analgesics containing codeine thus their benefit as an analgesic option. Prior to the up-schedule the quantitative questionnaire used in this study identified that a significant proportion of pharmacists rated the perceived efficacy of over-the-counter combination products containing codeine as high. Post the up-schedule pharmacists in the qualitative interviews indicated that the evidence for low dose codeine is weak and that low doses of codeine (8 mg & 15 mg) are not considered effective doses to provide an adequate therapeutic effect. This was re-iterated by Mishriky *et al*.[17] This may reflect increased education and awareness around the efficacy of codeine provided during the up-schedule process.

Many pharmacists in this study understood the reasons behind the up-scheduling of codeine containing analgesics, in particular the increasing rates of misuse and related harm from these products. However, they did not believe this was the most effective way to address codeine misuse, this has also been identified as a theme by other studies.[17,18] The Mishriky *et al*. study identified that pharmacists felt the up-scheduling of codeine did not solve the wider codeine misuse issue as patients have simply gone from "pharmacist shopping" to "doctor-shopping", and escalation to inappropriate use of other medicines or stronger opioids.[17] This was not the findings of the current study in which pharmacists felt that despite concerns before up-scheduling, sales of over-the-counter codeine products were not being translated into an increase of prescriptions for either low dose codeine preparations, higher dose codeine preparations, or other opioids. Middleton & Nielsen further confirm this with their analysis of Phamaceutical Benefits Scheme data post the 2018 up-schedule.[20] They found rescheduling of codeine to remove non-prescription supply did not have an immediate effect on the prescription rates of codeine, and there were no significant changes in these rates in the months following. The data showed decreasing trends for codeine and most other Schedule 8 prescription opioids, with no increase in any prescribed opioids associated with codeine up scheduling.

Pharmacists interviewed raised concerns about "Dr. shopping" but this has been somewhat mitigated with the introduction of real time prescription monitoring (RTPM) in Victoria, joining Tasmania, with the other states also now following suit. As at the time of writing RTPM is only mandatory in Victoria, it therefore would be interesting to compare the thoughts of Victorian and South Australian pharmacists at this point in time and whether the introduction of real time prescription monitoring has had an impact on the practice of pharmacists in this post up-scheduling era.

Regardless of the lack of success from the first codeine up-scheduling in 2010, there appears to have been some success with the further measure in 2018. A 2020 study by Cairns *et al*. looking at data from a New South Wales poisons information Centre and national sales data, found that the further codeine re-scheduling to prescription only in Australia appears to have reduced codeine misuse and sales and has successfully reduced use and harm from codeine.[21] They also report no evidence for substitution with high-strength codeine products or other pharmaceutical opioids in the poisoning data.

It appears from the data in this study that preparation had an influence over outcomes experienced by some pharmacists, including the use of "borrowed protection". That is, putting the onus back on the government which took the blame and responsibility from the pharmacist allowing an opening for conservations about alternative options. Pharmacists believe that preparing patients early reduced the amount of hostility that was received once the up-schedule was implemented. This was surprising, as media hype, prior to the up-schedule suggested that pharmacists were likely to receive a lot of backlash from the community regarding the up-schedule.[22] These findings highlight that preparing the public, as well as practitioners in advance of any changes to pharmaceutical scheduling, is an important factor in the implementation of such changes.

There appears to be a mixed response in all studies to date investigating the impact of the codeine changes on the practice of Pharmacists in Australia.[17] Pharmacists in this study appeared torn between the potential business and professional impacts with regard to scope of practice and reputation, of the change, versus the improved person centered care and safety aspects of the up-schedule. These included removal of opportunities for pharmacists to help people using their professional judgment such as the ability to identify misuse and the opportunity to intervene. Despite this, pharmacists have the opportunity to intervene if they suspect misuse when they are presented with prescriptions for codeine containing products or other opioids and there is opportunity for improved collaboration with prescribers of these medications.

There is also opportunity for pharmacists to undertake chronic pain interventions and improve chronic pain health outcomes as discussed in the narrative from Mishriky *et al*. International studies investigating the effectiveness of pharmacist-driven interventions have demonstrated that there are benefits of pharmacists going beyond standard

primary care practice for chronic pain management but further work is still required in the Australian context where research around the application of pharmacist-driven chronic pain interventions is lacking.[23] The recent Chronic Pain MedsCheck trial in Australia which ended February 2020, may provide further information about the role of Australian pharmacists in this space.[24]

There was an indication by some pharmacists that the impact of up-scheduling on the pharmacy business was of concern. There were fears about a decrease in sales, loss of business and the corresponding impact on the business financially. This could be influenced by bias towards self-preservation. Further work should be done analyzing actual figures to see if there was a loss in sales overall or if sales transferred to other products such as alternative analgesics or pain management options including rubs, heat or ice packs. As mentioned above, data show these sales have not been transferred to prescription opioid medications, but researchers have not investigated other prescription medications such as pregabalin, non-steroidal anti-inflammatory drugs and paracetamol which potentially still contribute business to the pharmacy.

Some pharmacists interviewed for this study were relieved to have the pressure of having to determine if supply was warranted taken from them. This was identified as an issue by Hamer *et al*. when codeine containing analgesics were first up-scheduled in Australia from a Pharmacy Medicine to a Pharmacist Only Medicine in 2010.[9] They found that pharmacists found it challenging to establish a therapeutic need, in particular due to the subjective nature of pain. There were also concerns regarding the lack of time to have detailed consultations with people about their use of these products. Since the up-schedule came into effect, pharmacists reported that recommending pain management alternatives had become easier and was generally useful in encouraging patients to visit their GP and discuss how to effectively manage their pain.

A strength of this study was its mixed-methods approach to gain insights into the perceptions of pharmacists post the 2018 up-scheduling of OTC codeine containing analgesics in Australia. However, this is limited by the fact that the participants in the qualitative phase were only practicing in South Australia and Victoria therefore the results may not be generalisable to all Australian pharmacists. A further limitation was the timing of the study. As the study was conducted just after implementation it may not be a true reflection of the longer-term impacts. Additionally, further information around whether participants were pharmacy owners or employees within the pharmacy would have been beneficial to determine if the perceived impacts, from a business perspective, were different and this could be the focus of future research.

CONCLUSIONS

Overall pharmacists expressed diverse perceptions, preparedness and impact on practice regarding the up-scheduling of low dose codeine products. Many pharmacists indicated that the up-schedule had not affected their practice to a great degree. This study was completed during 2018, just post the up-schedule. As a number of the perceptions expressed have proven not to be backed by the emerging evidence, further research should be conducted to gauge if and how these perceptions have changed over time. Further research could also be conducted to identify whether pain is being managed more effectively post codeine up-scheduling and if so how and why. A strength of this study was the ability to explore more in depth the perceptions of the up-schedule and reasoning behind these perceptions.

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CONFLICT OF INTEREST

There are no conflicts of interest to declare.

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Original Research

Prevalence of tablet splitting in a Brazilian tertiary care hospital

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Abstract

Background: Although a highly common practice in hospital care, tablet splitting can cause dose variation and reduce drug stability, both of which impair drug therapy.

Objective: To determine the overall prevalence of tablet splitting in hospital care as evidence supporting the rational prescription of split tablets in hospitals.

Methods: Data collected from inpatients' prescriptions were analyzed using descriptive statistics and used to calculate the overall prevalence of tablet splitting and the percentage of split tablets that had at least one lower-strength tablet available on the market. The associations between the overall prevalence and gender, age, and hospital unit of patients were also assessed. The results of laboratory tests, performed with a commercial splitter, allowed the calculation of the mass loss, mass variation, and friability of the split tablets.

Results: The overall prevalence of tablet splitting was 4.5%, and 78.5% of tablets prescribed to be split had at least one lower-strength tablet on the market. The prevalence of tablet splitting was significantly associated with the patient's age and hospital unit. Laboratory tests revealed mean values of mass loss and variation of 8.7% (SD 1.8) and 11.7% (SD 2.3), respectively, both of which were significantly affected by the presence of coating and scoreline. Data from laboratory tests indicated that the quality of 12 of the 14 tablets deviated in at least one parameter examined.

Conclusions: The high percentage of unnecessary tablet splitting suggests that more regular, rational updates of the hospital's list of standard medicines are needed. Also, inappropriate splitting behavior suggests the need to develop tablets with functional scores.

Keywords

Drug Stability; Tablets; Drug Prescriptions; Inpatients; Prevalence; Medication Errors; Reproducibility of Results; Drug Industry; Cross-Sectional Studies; Brazil

INTRODUCTION

The oral intake of tablets is the most common method of drug administration.[1] Individualized oral drug therapy may require tablet splitting, or tablet subdivision because appropriate doses are not always available on the market.[2] For that reason, as well as to lower costs and facilitate swallowing, tablet splitting is a widespread practice, especially in hospitals.[3-5] However, splitting tablets can cause dose variation and reduce drug stability.[6-8] The negative effects of tablet splitting in drug therapy are more pronounced for tablets containing drugs with low therapeutic indexes.[7] Nevertheless, published studies on tablet splitting in hospital care have been few.[4,9]

Unnecessary splitting should be avoided in order to minimize eventual adverse impacts on drug therapy. Tablet division performed when at least one pharmaceutical alternative (i.e., a tablet containing the same active pharmaceutical ingredient at the required or lower strength) is commercially available can be considered unnecessary. In identifying unnecessary tablet splitting in hospital environments, it is important to consider that, for logistical reasons, hospitals keep a limited number of drug products in stock. Therefore, if any pharmaceutical alternative available on the market is not included in the hospital's list of standard medicines, then it is not an option.

The quality of the halves needs to be guaranteed to minimize the adverse impacts of tablet splitting on drug therapy, especially the inaccuracy of desired doses. The quality of split tablets can be expressed by several parameters, including mass loss, mass variation, friability, hardness, drug stability, tablet disintegration, and drug dissolution. The quality depends upon several factors, including tablet properties, splitting technique, and the manipulator's ability.[10-13] In particular, the presence and depth of the tablet's scoreline and the tablet's size, shape, production method, and composition can significantly affect the quality of split tablets.[9,14]

Although criteria for decisions to split tablets remain undefined, knowledge about their composition, manufacture, and drug release mechanism is essential to

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assist such decisions.[3] In that context, though pharmacists play a fundamental role in multi-professional health teams as capable guides in tablet subdivision, they also face challenges with identifying theoretical grounds to perform the practice appropriately.

In the study presented here, a survey on the overall prevalence of tablet splitting in a tertiary care hospital in Brazil was performed to shed light on trends in tablet subdivision in hospitals. Laboratory tests were performed with a view of evaluating the potential impacts of tablet splitting on drug therapy.

METHODS

A cross-sectional descriptive study was conducted that involved the analysis of prescriptions for inpatients in a public tertiary care hospital, specifically Hospital das Clínicas, a 258-bed teaching institution in Goiânia, Goiás, in central Brazil. Based on the findings, drug products that were frequently split were submitted to a laboratory study in order to evaluate the impact of splitting on the physical and mechanical characteristics of subdivided tablets.

The study met the ethics requirements established in Brazilian legislation and was approved by the Ethics Committee of the Clinical Hospital of the Federal University of Goiás (approval number 1.822.184).[15]

Data collection and evaluation of prescriptions

All legible prescriptions containing drug products and sent to the hospital's pharmacy were collected every 7 days for 3 months in 2016. Prescriptions containing medication not supplied by the pharmacy were also included, although repeat prescriptions were not. Data collected from the prescriptions included age (until 11 years old; 12 to 18 years old; 19 to 59 years old; equal or greater than 60 years old), gender (female; male), inpatient unit (surgical clinic; medical clinic; obstetric clinic; orthopedic clinic; pediatric clinic; emergency adult; emergency pediatric; tropical medicine; surgical ICU; medical ICU; neonatal ICU), drug name, number of tablets fragments (two; four; others), tablet splitting decision (prescriber; pharmacist).

Data from the prescriptions were used to calculate (1) the overall prevalence of tablet splitting, defined as the number of tablets prescribed to be split, divided by the total number of tablets in the sample and multiplied by 100; (2) the prevalence of tablet splitting of a given product, defined as the number of tablets of a given product prescribed to be split, divided by the total number of tablets of this product in the sample and multiplied by 100; and (3) the percentage of unnecessary tablet splitting, defined as the number of tablets prescribed to be split that had at least one pharmaceutical alternative, divided by the total number of tablets in the sample and multiplied by 100. Pharmaceutical alternatives are defined as tablets available in the Brazilian market that have the same active pharmaceutical ingredient at the required or lower strength. The search for pharmaceutical alternatives was performed concerning an official list published by the Brazilian Health Agency.[16]

All collected data were analyzed using descriptive statistics and the SPSS version 20.0 (IBM, Armonk, USA). The associations between the overall prevalence of tablet splitting and the gender, age, and hospital unit of patients were assessed using the nonparametric Mann-Whitney test.

Laboratory tests of tablet splitting

The 14 most frequently prescribed split tablets (Table 1) were submitted to mechanical and physical assays in order to determine the appropriateness of splitting in each specific case. Three lots of each innovator drug product were purchased from a drugstore, whereas propranolol tablets, currently unavailable on the market, were substituted with a generic drug product for laboratory tests.[17]

A commercial tablet splitter (Inconterm, São Paulo, Brazil) was used to split the tablets, which were assessed for mass loss, mass variation, and friability. In particular, 10 tablets from each batch were individually weighed using an analytical balance (Bel Engineering, model S203, São Paulo, Brazil) before and after splitting. The results are expressed as a mean of 3 batches (n=30). Mass loss (ML) and Mass variation (Mv) were calculated according to Equations (1) and (2).

$$M_L = \frac{2Mh}{Mw} \; x\; 100 \qquad \text{Equation (1)}$$

$$M_V = 1 - \left(\frac{Mh}{\frac{1}{2}Mw}\right) x\; 100 \qquad \text{Equation (2)}$$

Where, M_w is the whole tablet mass, and M_h is the mass of one halve.

Table 1. Drug products submitted to laboratory tests

Drug	Dose	Brand	Manufacturer	Score	Coat	Batch number
Amiodarone	100 mg	Atlansil®	Sanofi-Aventis	Yes	No	713934; 515709; 539029
Carbamazepine	200 mg	Tegretol®	Novartis Biociências	Yes	No	1646087; 1719841; 1720167
Clonazepam	0.5 mg	Rivotril®	Roche	Yes	No	RJ1052; RJ1048; RJ1051
Furosemide	40 mg	Lasix®	Sanofi-Aventis	Yes	No	6E9360; 721584; 717735
Hydralazine	25 mg	Apresolina®	Novartis Biociências	No	Yes	1706811; 1706808; 1711869
Hydrochlorothiazide	25 mg	Clorana®	Sanofi-Aventis	Yes	No	636404; 524009; 717869
Lamotrigine	25 mg	Lamictal®	GlaxoSmithKline	No	No	1613900051;1613900052; 1627900064
Losartan	50 mg	Cozaar®	Merck Sharp & Dohme	Yes	Yes	N004622; N016050; N007232
Methyldopa	250 mg	Aldomet®	Aspen Pharma	No	Yes	A862697; A860288; A863491
Prednisone	5 mg	Meticorten®	Merck Sharp & Dohme	No	No	N013489; N009888; M003377
Propranolol	40 mg	Generic Teuto	Laboratório Teuto	Yes	No	1057586;1057565; 1057585
Quetiapine	25 mg	Seroquel®	AstraZeneca	No	Yes	45200; 43969; 43878
Sodium warfarin	5 mg	Marevan®	Farmoquímica S/A	Yes	No	161744; 161743; 162104
Ursodeoxycholic acid	50 mg	Ursacol®	Zambon	Yes	No	1052493;1041362; 1050363

Table 2. Splitting data of the fourteen most prescribed split tablets

Drug	Frequency of splitting in the entire sample (%)	Prevalence of splitting (%)	Alternatives in the hospital	Alternatives[c] In the Brazilian market
Clonazepam	25.2	38.5	No	Yes
Sodium warfarin	11.3	44.3	No	Yes
Propranolol	7.1	25.4	No	Yes[b]
Amiodarone	5.8	15.9	No	Yes
Hydralazine	4.6	47.8	No	Yes
Prednisone	3.3	4.2	Yes[a]	Yes
Carbamazepine	2.9	15.6	No	No
Methyldopa	2.9	13.6	No	Yes
Quetiapine	2.9	25.9	No	Yes
Losartan	2.1	3.0	No	Yes
Furosemide	2.1	4.0	No	No
Ursodeoxycholic acid	2.1	55.6	No	Yes
Lamotrigine	2.1	83.3	No	Yes
Hydrochlorothiazide	1.6	3.2	No	No

[a] Two prescriptions for prednisone 5 mg have been identified. There is no pharmaceutical alternative for this strength.
[b] Two prescriptions for propranolol 10 mg have been identified. There is no pharmaceutical alternative for this strength.
[c] Tablets available in the Brazilian market that have the same active pharmaceutical ingredient at the required or lower strength

Last, friability was calculated as the percentage of mass loss of 10 whole tablets, or 20 halves of each drug product tumbled at 25 rpm for 4 min (Nova Ética friabilometer, model 300, São Paulo, Brazil). Following international specifications, values of mass loss and friability above 3% and 1%, respectively, were considered to be inadequate.[18,19] Mass variation exceeding 10% was also considered to be inappropriate, because tablet splitting by pharmacy personnel is a form of extemporaneous compounding and, therefore, the specification is stricter than that of United States Pharmacopeia for intact dosage units.[20]

Statistical analysis was performed using GraphPad Prism (version 7.0). Possible differences in mass variation, mass loss, and friability among the groups (i.e., scored vs. unscored tablets and coated vs. uncoated tablets) were investigated by performing the Welch unequal variance t-test or the Mann-Whitney U test.

RESULTS

A total of 2,942 prescriptions for 2,674 inpatients were collected and analyzed. The prescriptions included 5,303 tablets, 238 of which were prescribed to be split, for an overall splitting prevalence of 4.5%. The entire sample of split tablets comprised 44 drugs, and the splitting prevalence was calculated for the 14 most prescribed drug products (Table 2), which corresponded to nearly 80% of all split tablets in the sample. As shown in Table 2, 78.5% of the split tablets had at least one pharmaceutical alternative available on the Brazilian market when the study was conducted. Tablets containing clonazepam, sodium warfarin, and propranolol were the most frequently split and showed a high splitting prevalence as well (Table 2).

Another aspect investigated relates to decisions to split tablets, which are informally delegated to the prescriber, represented by the physician in most cases. At the hospital examined, the decision to perform the subdivision of

Table 3. Statistical evaluation of the overall prevalence of splitting and age, sex and inpatient unit

Variables	Total	Patients with split tablets prescribed (%)	p-value[a]
Sex[b]			0.426
Female	1433	8.3	
Male	1144	7.5	
Age group[c]			0.001
up to 11 years	229	5.6	
12 to 18 years	132	7.5	
19 to 59 years	1164	8.4	
>60 years	658	12.9	
Inpatients units			0.004
Surgical clinic	686	6.2	
Medical clinic	625	15.2	
Obstetric clinic	291	6.1	
Orthopedic clinic	256	0.3	
Pediatric clinic	90	16.6	
Emergency adult	260	4.2	
Emergency pediatric	87	3.4	
Tropical medicine	107	6.5	
Surgical ICU	99	3.0	
Medical ICU	70	12.8	
Neonatal ICU	103	0.9	
TOTAL	2674	7.7	

[a] Mann-Whitney test for valid data.
[b] 91missing cases
[c] 491missing cases

Table 4. Mass loss, mass variation, and friability of the most frequently split tablets

Drug name	Mass loss % (SD)	Mass variation % (SD)	Friability (%)	
			whole tablet	split tablet
Ursodeoxycholic acid	**4.7 (1.4)**	6.4 (0.8)	**1.3**	**11.4**
Amiodarone	**24.5 (6.1)**	**15.2 (4.7)**	0.1	**6.4**
Carbamazepine	**5.2 (1.8)**	**17.3 (4.0)**	0.0	0.1
Clonazepam	**13.9 (1.7)**	9.6 (2.0)	0.6	**2.9**
Furosemide	**14.6 (2.3)**	12.5 (1.0)	0.4	**6.2**
Hydralazine	**6.6 (3.0)**	13.3 (4.9)	0.0	0.6
Hydrochlorothiazide	**10.1 (0.7)**	10.9 (1.7)	0.1	**8.6**
Lamotrigine	**16.8 (1.9)**	12.9 (2.5)	0.2	**4.8**
Losartan	**4.8 (1.6)**	10.7 (1.4)	0.0	0.0
Methyldopa	**4.9 (0.8)**	13.4 (1.2)	0.0	**6.0**
Prednisone	0.9 (0.4)	5.0 (1.3)	0.1	0.0
Propranolol	2.5 (1.5)	6.9 (1.5)	0.4	0.3
Quetiapine	1.8 (0.3)	**20.5 (3.8)**	0.1	**2.3**
Sodium warfarin	**11.5 (1.5)**	9.5 (1.6)	0.9	**1.3**
Mean	8.7 (1.8)	11.7 (2.3)	0.3	3.6

The results out of specification are in bold. SD = Standard deviation

tablets was most often made by the physician (77.8%). In only 22.2% of cases the pharmacist made that decision.

Table 3 presents the associations of the overall prevalence of splitting with the gender, age group, and hospital unit of patients, among which the associations with age group and hospital unit were significant ($p<0.05$). It was also observed that most of the tablets were split in half (95.8%), whereas few (4.2%) came with prescriptions recommending tablet splitting in quarters.

The 14 most frequently split tablets were submitted to laboratory tests in order to determine the quality of the halves. The mean mass loss was 8.7% (SD 1.8) (Table 4), whereas the mean mass variation was 11.7% (SD 2.3). To clarify the influence of a tablet's properties on the quality of the halves, a statistical analysis of those parameters was performed, the results of which appear in Figure 1. As shown in Figure 1a, coated tablets exhibited less mass loss (4.5%; SD 1.7) than uncoated ones ($p=0.01$). By contrast, as shown in Fig. 1b, mass variation was significantly higher for coated tablets ($p=0.03$). Figure 1c and 1d reveal that the presence of a scoreline increased mass loss after splitting; however, no significant differences in splitting accuracy (i.e., mass variation) emerged between scored and unscored tablets.

Last, the friability of the halves increased compared to that of the whole tablets (Table 4). Nine of the 14 tablets did not meet the United States Pharmacopeia requirements for the friability of split tablets (<1%).[18,21]

DISCUSSION

In the few studies on the frequency of tablet splitting in hospitals, Arnet *et al*. and Quinzler *et al*. have observed higher splitting frequency (10.1% and 8.5%, respectively) than the one observed in the study reported here (4.5%).[9,22] The differences may stem from the varying characteristics of the hospitals, including the number of beds, medical specialties available, and patient profile. Regardless of the inter-hospital variation, the prevalence of tablet splitting is clearly high, which underscores the need to understand its causes and propose alternatives to mitigate its potential adverse effects.

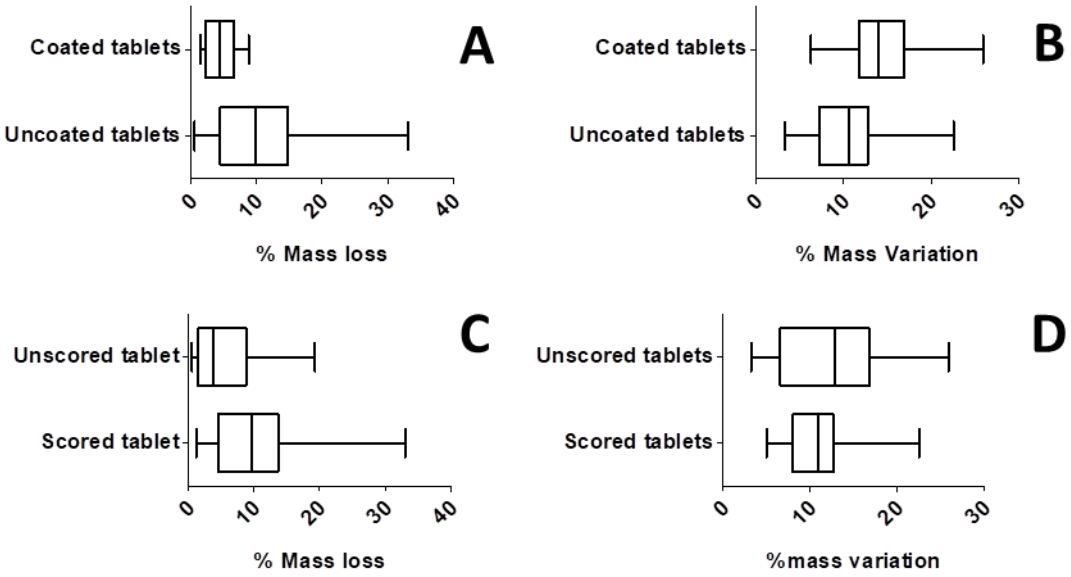

Figure 1. Mass loss and mass variation as functions of the presence of tablet coating and scoreline

In a Swiss hospital, Arnet *et al*. examined the frequency of inappropriate tablet splitting, which they defined as occurring when at least one pharmaceutical alternative was available on the Swiss market, when scored tablets were available, and when manufacturers had expressly prohibited splitting.[9] Applying those criteria to their data, the authors detected a frequency of inappropriate tablet splitting of 2.8%. Although somewhat similar, the percentage of unnecessary tablet splitting in our study was 3.53%. The higher percentage suggests that more regular, rational updates of the hospital's list of standard medicines may dramatically decrease of overall prevalence of tablet splitting and the percentage of unnecessary tablet splitting.

The effectiveness of health systems and the safety of all individuals require the careful selection of medicines by drug and therapeutics committees in hospitals.[23] Such committees should select drug products based on evidence of efficacy, safety, and cost-effectiveness for a particular disease or clinical situation, as well as compare them to therapeutic alternatives available, in order to obtain an appropriate list for rational use.[24-26] Our findings also suggest the need to take into account tablet divisibility as an important factor in choosing standard drug products for use in hospitals.

Clonazepam, sodium warfarin, and propranolol tablets were the three most frequently split tablets in the hospital examined. Although clonazepam and propranolol have a broad therapeutic window that ensures their safety and effectiveness against potential dose fluctuations, clonazepam adverse effects, like drowsiness, dizziness, and confusion, are related to its plasma concentration and dose.[27] In its turn, the splitting of sodium warfarin tablets is especially risky. Because sodium warfarin has a narrow therapeutic range, and dose variation can cause severe bleeding, a hospital's standardization of lower-strength warfarin tablets is crucial for the rational management of therapy with the drug.[28-30] Differences in the pharmacological properties of propranolol, clonazepam, and warfarin also highlighted the need for the evaluation of each drug product in order to assess better the risks involved in splitting them.

Prescriptions for splitting controlled drug release tablets based on polymeric coating (nifedipine retard, n=1, and quetiapine XR, n=3) appeared in the study sample. Such systems are designed to release drugs gradually in the body, and their splitting, especially when against the manufacturer's instructions, can significantly impair the effectiveness of treatment, as well as increase the risk of adverse effects.[31] The prescriptions for splitting controlled drug delivery tablets likely stem from the lack of technical training among physicians; after all, the safest evaluation of tablet splitting involves an analysis of the pharmacological and toxicological aspects of the drug, together with knowledge of the drug product composition and drug release mechanisms. For those reasons, pharmacists are the most qualified healthcare professionals for the task.[3,32]

The statistical analysis of the overall prevalence of tablet splitting revealed a significant relationship between the age group of patients and tablet splitting. That association was expected because tablet splitting is exceptionally common in geriatric and pediatric populations, which are also known to be the most susceptible to the adverse clinical consequences of tablet splitting.[3,33,34] Splitting-related toxicity is more severe among elderly patients due to altered pharmacokinetics that increases the occurrence of adverse effects.[34]

Another relevant aspect of the prescription of split tablets is the number of tablet fragments to be generated. In our study, about 95% of tablets were split in half, whereas researchers in Switzerland observed a two-part tablet division in 87.6% of cases.[35] The subdivision of a tablet into more than two parts considerably increases mass loss and mass variation, which makes tablet splitting even riskier.[36] Moreover, the functional score of most tablets is generally intended for mid-fractionation, and any other technique would not have the support of the pharmaceutical laboratory and, in turn, not be recommended.

Laboratory tests revealed that the mean mass loss was 8.7% (SD 1.8) (Table 4), which is far superior to that reported by Teixeira *et al*. (<2%), who studied the tablet subdivision of drug products available on the Brazilian market.[3] Other researchers have also reported lower values of mean mass loss (0.2–3.8%).[3,5,37,38] By contrast, the mean mass variation was 11.7% (SD 2.3), which is within the range of previously reported data (9.9–25%).[3,5,11,38]

A multitude of factors can affect the practice of tablet splitting and tablet behavior as a result, as well as explain the differences mentioned above. Tablet size, shape, and presence of a scoreline can determine the accuracy of tablet subdivision. Tablet composition, method of manufacture, and splitting procedure can also determine a tablet's behavior during subdivision.[30,39,40] In general, the subdivision of oblong, coated, and scored tablets results in halves of quality higher than that of round, unscored, and uncoated ones.[3] Also, denser and more uniform structures have exhibited better subdivision behavior.[40,41]

Statistical analysis was also performed to identify any significant differences between coated and uncoated as well as scored and unscored split tablets. Coated tablets showed lower percentages of mass loss, possibly because harder tablets have often been produced to accommodate coating, which has resulted in tablets with higher mechanical resistance and, in turn, less mass loss after splitting. However, those stronger tablets can also cause more irregular subdivision, which increases mass variation.[3]

Surprisingly, the presence of a scoreline did not result in better splitting accuracy. In addition to the multiple variables that simultaneously affect the performance of tablet splitting, many of the tablets evaluated probably had aesthetic scores only. In those cases, the depth and shape of the aesthetic scores might not contribute to a more regular subdivision, unlike functional scores, which have previously been evaluated by manufacturers as being adequate guides for splitting.[14,18]

Friability tests showed that nine of the 14 tablets did not meet the FDA requirements for split tablets.[18] Not coincidentally, eight of these nine tablets also showed mass loss greater than 3%, presumably because of tests for both mass loss and friability related to the mechanical strength of the tablets. In practice, such a result impedes the subsequent use of the other half of each divided tablet, the

physical integrity of which cannot be guaranteed in handling required for storage, even for a brief period. In our sample, for instance, amiodarone tablets failed in all laboratory tests and exhibited a remarkable mass loss of 24.5% (Table 4). In that case, the need to resort to the pharmaceutical alternative is clear. Similarly, sodium warfarin tablets, which had a high prevalence of splitting (Table 2) and present a recognized pharmacological threat of dose variation, resoundingly failed the mass loss test (Table 4) and demonstrated exceptionally high mass variation. Contrary to current clinical practice, the mentioned tablets should not be subjected to splitting in any case.

Because 12 out of 14 split tablets failed in at least one parameter of quality, the need to improve drug standardization in the examined hospital is clear, particularly as a means to avoid or minimize the occurrence of adverse effects caused by tablet splitting. Moreover, those data suggest that manufacturers should re-evaluate most of the drug products studied in order to improve their capacity to be split.

CONCLUSIONS

A high prevalence of the tablet splitting was observed in the public tertiary care hospital examined, and based on the data collected, more regular, more rational updates of the list of standard medicines in the hospital could dramatically reduce it, especially with the acquisition of lower-strength tablets available on the market. Data from the laboratory tests revealed that 12 out the 14 studied tablets presented deviation at one of the selected parameters of quality (i.e., mass loss, mass variation, and friability), which indicates the need to increase the commercial availability of drug products designed to be split.

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CONFLICT OF INTEREST

No conflicts of interest have been declared.

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Original Research

Prescribers' perceptions of benefits and limitations of direct acting oral anticoagulants in non-valvular atrial fibrillation

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Abstract

Background: There is an acknowledged lack of robust and rigorous research focusing on the perspectives of those prescribing direct acting oral anticoagulants (DOACs) for non-valvular atrial fibrillation (AF).

Objective: The objective was to describe prescribers' experiences of using DOACs in the management of non-valvular AF, including perceptions of benefits and limitations.

Methods: A cross-sectional survey of prescribers in a remote and rural area of Scotland. Among other items, the questionnaire invited free-text description of positive and negative experiences of DOACs, and benefits and limitations. Responses were independently analysed by two researchers using a summative content analysis approach. This involved counting and comparison, via keywords and content, followed by interpretation and coding of the underlying context into themes.

Results: One hundred and fifty-four responses were received, 120 (77.9%) from physicians, 18 (11.7%) from nurse prescribers and 10 (6.4%) from pharmacist prescribers (6 unidentified professions). Not having to monitor INR was the most cited benefit, particularly for prescribers and patients in remote and rural settings, followed by potentially improved patient adherence. These benefits were reflected in respondents' descriptions of positive experiences and patient feedback. The main limitations were the lack of reversal agents, cost and inability to monitor anticoagulation status. Many described their experiences of adverse effects of DOACs including fatal and non-fatal bleeding, and upper gastrointestinal disturbances.

Conclusions: While prescribers have positive experiences and perceive benefits of DOACs, issues such as adverse effects and inability to monitor anticoagulation status merit further monitoring and investigation. These issues are particularly relevant given the trajectory of increased prescribing of DOACs.

Keywords

Attitude of Health Personnel; Atrial Fibrillation; Factor Xa Inhibitors; Drug Prescriptions; Health Knowledge, Attitudes, Practice; Cross-Sectional Studies; Scotland

INTRODUCTION

Direct acting oral anticoagulants (DOACs) have superseded warfarin as the treatment of choice for stroke reduction in non-valvular atrial fibrillation (AF).[1-4] Guideline recommendations have translated to practice, with UK primary care prescribing data showing a 17-fold increase in new DOAC users from 2012 to 2015.[5] There is, however, a gap in the literature concerning the experiences of those prescribing DOACs. The one systematic review, published in 2018, identified only ten studies, nine surveys and one qualitative study.[6] Survey participant numbers ranged from 38 to 450 (total of 1,246) with response rates of 9.0-35.9%, with outcome measures of oral anticoagulant of choice, factors influencing prescribing, and experiences.[7-13] While the one qualitative study provided rich data of physicians' decision-making processes regarding DOACs, the sample size of seven limits the likely transferability of findings.[14] One further key limitation of these studies was the omission of theory (e.g. cognitive, behavioural, organisational) in questionnaire development. There is acknowledgement that considering the theoretical basis is likely to yield a data collection tool with comprehensive coverage of all key factors.[15,16]

Quantitative data of a recent cross-sectional survey of medical and non-medical prescribers (nurse and pharmacist independent prescribers) in a remote and rural area of Scotland were recently reported.[17] The study was a cross-sectional survey of medical and non-medical prescribers in all settings of NHS Highland, an area of low population density with 40% of residents living in 'remote rural' locations (defined as settlements <3000 people with a drive time of >30 minutes to a settlement of ≥10,000).[18] Survey outcome measures were: prescribing of DOACs (as a pharmacological group); views of potential influences on DOAC prescribing; knowledge of prescribing guidelines; and experiences. Items on potential influences were based on the Theoretical Domains Framework (TDF, which is derived from 33 theories of behaviour change).[19] Principal component analysis identified four components of potential influences on DOAC prescribing. Component scores for (a) role of professionals, their knowledge and skills and (b) influences on prescribing were somewhat

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positive. Those for (c) consequences of prescribing and (d) monitoring for safety and effectiveness were more neutral. There were generally low levels of respondent agreement for statements about DOACs being more effective, safer and cost-effective than warfarin.

Open response options were included in the questionnaire to provide the respondents with opportunities to describe in their own words their perceptions of the benefits and limitations of prescribing DOACs. The aim of this paper is to describe these perceptions of benefits and limitations of using DOACs in the management of non-valvular AF.

METHODS

Study methods have been previously described, and are briefly outlined for completeness.[17] The study was conducted within NHS Highland in Scotland, an area of low population density covering approximately 40% of the land mass of Scotland yet representing only 6% of the Scottish population.

An online questionnaire was developed, pretested and piloted prior to use. Questionnaire items were in sections of: demographics; DOAC prescribing; potential influences on DOAC prescribing; knowledge of local prescribing guidelines; and experiences. While most question types were closed, 5-point Likert scales, respondents were invited to describe: (i) their perceptions of benefits and limitations of prescribing DOACs; (ii) positive patient experiences; and (iii) negative patient experiences, whilst respecting anonymity. The questionnaire was formatted in Snap 10 Professional® (software for web and email questionnaire design, publication, data entry and analysis) and tested for compatibility with platforms (e.g., laptop, tablet and smartphone), browsers, and NHS email and internet filters. Data collection took place from April to July 2017. An email from a senior member of the research team based within NHS Highland was sent all prescribers (medical and non-medical), with a link to the participant information leaflet and the questionnaire. The questionnaire was to be completed only by those prescribing oral anticoagulants at the time of the study or likely to do so in the near future. Two email reminders were sent to all prescribers at 4-weekly intervals. Free text comments relating to benefits, limitation and experiences were analysed using a summative content analysis approach.[20] This involved counting and comparison, via keywords and content, followed by interpretation and coding of the underlying context into themes. Analysis was undertaken independently by two researchers (DG, DS) and a third (SC) consulted when non-consensus arose.

This study was approved by the Ethics Committee of the School of Pharmacy and Life Sciences at Robert Gordon University, UK; the study was deemed exempt from NHS ethical review by the North of Scotland Research Ethics Committee. Management approval was obtained from NHS Highland Research and Development Committee (ID1158).

RESULTS

One hundred and fifty-four responses were received, 120 (77.9%) from physicians (76 general practitioners), 18 (11.7%) from nurse prescribers and 10 (6.4%) from pharmacist prescribers (6 unidentified professions). As the questionnaire was to be completed by those for whom DOAC prescribing was relevant to their practice, a response rate could not be calculated. Respondent mean age was 43.3 years (standard deviation 11.9 years); just over half (n=84, 54.5%) had >20 years' experience as health professionals and slightly less (n=61, 39.6%) as prescribers; two thirds (n=100, 64.9%) were based in primary care. Counts of the number of respondents and illustrative quotes are given for the major themes identified in the summative content analysis.

Ninety-nine respondents (71.7%) provided responses around perceived benefits and limitations.

Perceived benefits

The overwhelming benefit, cited by 47 respondents, was the absence of need for INR monitoring,

> "We have been overwhelmed with the need to do regular blood monitoring of patients in recent years…No additional resources have been made available in spite of a 300% increase in blood tests…anything which reduces this, such as the use of DOACs instead of warfarin, helps us to survive."

The absence of need for monitoring was often mentioned in the context of other benefits such as particular patient groups,

> "No need for monitoring, especially practical in elderly/housebound."

This was also relevant to those in remote settings,

"It is much easier for patients who live in rural areas to be prescribed a DOAC especially in the winter where it is difficult to travel to have INR checked."

Cost was also a consideration,

> "No need to monitor therefore cost-effective"

Thirteen respondents commented on the likelihood of better adherence,

> "Patients understand why they take these drugs and often state how it is much easier to take than warfarin especially with the interactions of diet."

Eleven noted benefits in terms of the evidence base,

> "Overall the evidence is that DOACs are at least as good as warfarin for preventing stoke and have a lower incidence of fatal bleeding".

Ten commented on the more favourable dosing regimens compared to warfarin,

> "…and a single daily dose, not changing like warfarin."

Ten respondents remarked on the benefits in those with labile INRs,

> "less likely to get out of therapeutic range…suitable for patients with fluctuating INR."

Less commonly cited benefits were better use of general practitioner (GP) time, especially in remote areas, reduced

frequency of adverse drug reactions (ADRs), and easier patient management.

Perceived limitations

The key limitation, cited by 31 respondents, was the lack of a suitable reversal agent,

> "Significant concerns regarding how to reverse anticoagulation in patients who then sustain injury/ head trauma."

> "No antidote yet for rivaroxaban or apixaban."

The high acquisition costs of DOACs compared to warfarin was considered a limitation by 17 respondents,

> "I'd prescribe it more for patients with AF if health board not breathing down my neck about cost."

One respondent commented that whilst the drug costs were higher, there were savings when considering other associated costs,

> "Costly but saves on nurse/lab/doctor time to dose warfarin."

Ten respondents were concerned by the lack of ability to monitor anticoagulation status,

> "the main negative is the lack of longer term follow up to ensure patients CONTINUE to take the drug as prescribed regularly and on time."

This was a particular concern in specialist areas of practice,

> "When injecting a joint I prefer to know a patient is on warfarin as I can just check their INR. If they are on DOAC, they have to stop their medication the previous day, I then have to book them in early in the morning and then they take their next dose mid-day."

Eight noted concerns over the lack of long-term evidence of benefit,

> "Concerned that long term benefits may not be as great as expected, i.e. problems of this group of drugs will show after they have been used for more years"

Less commonly cited limitations were around increased prevalence of adverse effects and dose adjustment in renal impairment.

Positive patient experiences

Seventy-two respondents (52.2%) described positive experiences of DOACs. As with benefits, the main positive experiences surrounded the absence of need to monitor INR, cited by 38 respondents,

> "90 year old on warfarin for AF for 20 years. Became unable to drive and a lot of strain on family for weekly INR with no capacity in single handed GP to visit frequently."

Several described similar experiences, which were considered particularly relevant to those living in remote areas,

> "Initiating anticoagulation in patient who lives miles away, avoiding blood tests, living over 30 miles from GP surgery".

Nineteen respondents described positive feedback from patients,

> "Feedback from patients has been positive - they no longer have to frequently attend the surgery, they can go on holiday more easily, they can be more relaxed with the choice of diet."

In some situations, patients had declined warfarin but were willing to commence DOACs,

> "Another patient would not accept warfarin but did DOAC".

Seven respondents commented on enhanced management of those with previously labile INRs,

> "A patient whose INR was impossible to keep in therapeutic range was able to get proper treatment".

Less commonly cited experiences were around better patient management and more rapid, effective anticoagulation.

Negative patient experiences

Descriptions of negative patient experiences were provided by 64 respondents (46.4%), with an additional 19 (13.8%) stating that they had no negative experiences to report.

The key negative experience was around adverse events of bleeding, described by 24 respondents,

> "Patient admitted with severe upper GI bleed while on prophylactic dose after hip replacement",

Two respondents reported that bleeding had led to patient death. One noted particular concerns for those in more remote areas,

> "In the first month of prescribing DOACs we had 2 major bleeds. Likely coincidence but shook everyone's confidence a bit, especially in a rural setting."

An additional five respondents commented on issues related to bleeds,

> "Emergency admission for surgery - prolonged operation due to increased bleeding".

Thirteen commented on their experiences of non-bleeding adverse events of varying severity and with diverse consequences,

> "Patient developed side effect from DOACs (severe nausea) and returned to warfarin",

> "Terrible oesophagitis with dabigatran".

Three described issues relating to the consequences of rapid anticoagulation reversal on discontinuing DOACs,

> "We have had 3 patients who have had strokes shortly after discontinuing DOACs".

Table 1. Summary of key themes identified

Perceived benefits	Perceived limitations	Positive patient experiences	Negative patient experiences
Absence of the need for INR monitoring (n=47)	Lack of suitable reversal agents (n=31)	Absence of the need for INR monitoring (n=38)	ADRs, bleeding (n=24)
Better patient adherence (n=13)	High acquisition costs (n=17)	Positive patient feedback (n=19)	ADRs, non-bleeding (n=13)
Positive evidence base (n=11)	Lack of ability to monitor anticoagulation status (n=10)	Enhanced management in those with labile INRs (n=7)	Rapid anticoagulation reversal on discontinuation of DOACs (n=3)
More favourable dosing regimen compared to warfarin (n=10)	Lack of long-term evidence (n=8)	Less commonly cited – better patient management, more rapid and effective anticoagulation	Less commonly cited – inadequate monitoring prior to commencing DOACs, poor clinician recognition of DOAC names as anticoagulants, patient anxiety
Useful in those with labile INRs (n=10)	Less commonly cited – increased prevalence of ADRs, dose adjustment in renal impairment		
Less commonly cited – better use of GP time, reduced frequency of ADRs, easier patient management			

Less commonly cited negative experiences included issues relating to inadequate monitoring of patients prior to commencing DOACs,

> "Colleagues not monitoring renal function and LFTs so overdosed DOAC and patient admitted."

There were also issues related to clinician lack of recognition of the names of DOACs as anticoagulants,

> "DOAC not stopped despite bleeding as not noted as a blood thinner in same way as warfarin."

Patient anxiety was noted as a concern,

> "patients are often wary to start treatment with a DOAC as they are aware of the lack of antidote."

Table 1 provides a summary of the key themes identified.

DISCUSSION

Content analysis of the textual comments captured in this survey complement the quantitative data recently published.[17] Not having to monitor INR was the most cited benefit, particularly for prescribers and patients in remote and rural settings, followed by potentially improved patient adherence. These benefits were reflected in descriptions of positive experiences and patient feedback. The main limitations were the lack of reversal agents, cost and inability to monitor anticoagulation status. Many described experiences of adverse effects including fatal and non-fatal bleeding, and upper GI disturbances.

This study adds to the limited evidence base of prescribers' experiences of DOACs, and is timely given that DOACs are now recommended first line for those with non-valvular AF.[1-6] However, given that data were collected in one remote and rural area of Scotland, the results may lack generalisability and transferability to other settings. Furthermore, the data were collected using a cross-sectional survey methodology rather than through a qualitative approach (e.g. interviews and focus groups) which limited the depth of enquiry. As the findings represent perceptions of benefits and limitations, the analysis was not informed by any theoretical framework.

Studies of healthcare provision in remote and rural areas have identified access as an issue, particularly in older populations and those with higher healthcare utility.[21-26] While many positive perceptions of DOACs identified in this study may be generic to all settings, these are particularly relevant in such areas. The specific site of action of DOACs on the coagulation cascade, predictable pharmacokinetic and pharmacodynamic properties and fixed dosages eliminate the need and usefulness of INR monitoring.[27] Not having to monitor was perceived as a major benefit, and was highlighted in descriptions of patient positive experiences. However, lack of monitoring was also perceived a limitation, specifically the lack of ability to closely monitor coagulation status. These are original findings, not having been reported in the systematic review of clinicians' experiences, nor any systematic reviews of patients' experiences.[6,28,29]

Adverse reactions, most notably bleeding related, were described by many respondents. It is, however, worth noting that evidence so far indicates that DOACs are associated with clinically important reductions in the frequency of major bleeding, including life-threatening bleeding events and, especially, intracranial bleeding, when compared with patients receiving warfarin.[2-4] In the UK, DOACs are labelled 'black triangle drugs' meriting reporting of all adverse reactions (irrespective of severity) to the Medicines and Healthcare products Regulatory Agency.[30] Given that under-reporting is a major limitation of pharmacovigilance processes, further research on DOAC reporting is warranted. There were also descriptions of adverse events attributed to rapid reversal of anticoagulation following DOAC discontinuation prior to surgical intervention, as noted by others.[31,32] Guidelines on the management of patients prescribed DOACs requiring elective and emergency procedures are emerging.[27] Concerns of managing DOAC related bleeding may also diminish with the licensing of idarucizumab to reverse dabigatran in patients with life threatening haemorrhage or need for urgent surgery.[33] Andexanet alfa, a class-specific antidote for the factor Xa inhibitors, is now available and other DOAC reversal agents are in development.[34]

Different views were given in relation to DOAC cost, with some describing cost as a limitation while others believed

costs reduced given the additional resources incurred in warfarin monitoring. Systematic reviews and meta-analyses of the cost-effectiveness of DOACs versus warfarin have recommended that, while further real world data are required, DOACs are more cost-effective despite higher prescribing costs.[35,36]

There was a range of views around the widespread adoption of DOACs with some supporting the evidence base of effectiveness, cost-effectiveness and safety while others were more cautious due to the lack of real-life, long-term evidence. This finding has been identified for many newly launched agents; in a recent study of the adoption of cardiovascular drugs in the United States, physicians were found to be generally conservative, with a minority adopting dabigatran, aliskiren or pitavastatin in the first 15 months of market launch market.[37]

Given the findings of this study and the change in Scottish national recommendations, there is a need for quantitative and qualitative data on views and experiences of prescribers and patients. Focus should be placed on identifying, characterising and reporting adverse drug reactions.

CONCLUSIONS

Prescribers in the Scottish Highlands highlighted positive and negative perceptions of DOACs in the management of non-valvular AF. While absence of INR monitoring was considered a key benefit, there were concerns around adverse effects, most notably bleeding. These issues merit further monitoring and investigation, particularly relevant given the trajectory of increased prescribing of DOACs.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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Letter to the editor

Advanced pharmacy practice experiences (APPE) in academia as strategy to fill the gap on transgender health

Dear editor,

We read the CPPI Pharmacy Forum article entitled "Strategies for inclusion of lesbian, gay, bisexual, transgender, queer, intersex, and asexual (LGBTQIA+) education throughout pharmacy school curricula" by Llayton CK, and Caldas LM, published by Pharmacy Practice and would like to make some contributions.[1]

Llayton and Caldas provide excellent approaches for the inclusion of LGBTQIA+ education into pharmacy school curricula. However, psychosocial focused strategies to transgender care should be emphasized. In 2017, the American Society of Health-System Pharmacists (ASHP) adopted a policy to promote research on, education about, and development and implementation of therapeutic and biopsychosocial best practices in the care of transgender patients.[2]

A previous assessment of pharmacist's readiness and the transgender patient's perception of their readiness in Puerto Rico showed an overall positive attitude towards transgender care.[3] Despite these perceptions, providers and transgender patients pointed out stigma, discrimination and lack of knowledge as barriers during healthcare process.[3] The latter study correlates with national findings and suggest that, rather than mainly focusing on pharmacotherapy and clinical considerations, incorporating learning experiences with psychosocial emphasis may reduce the insensitivity and enhance cultural competence during provision of care.[4,5] Moreover, educational efforts should foster empathy trainings that would allow the student to treat the transgender patient as a person and not as a medical condition.[6]

Future strategies may benefit from formats beyond the lecture style or panel discussion.[5] For example, pharmacy schools may coordinate Advanced Pharmacy Practice Experiences (APPE) in academia where the student can address clinical and psychosocial aspects by engaging on activities such as research, literature review, design and implementation of educational initiatives like lectures, informational material and audio-visual production.[4] A selective academia rotation offers the student an opportunity to work with pharmacy and non-pharmacy faculty members with expertise on transgender health. Furthermore, pharmacy schools can create agreements with LGBTQIA+ specialized clinics to provide the student with utmost experiences in ambulatory care settings. Ultimately, adopting a gender-inclusive curriculum that is not limited to clinical consideration and integrate social, economic and ethical principles may reduce stigmatization and discrimination while enhancing health outcome for transgender persons.[2-6]

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International Series: Integration of community pharmacy in primary health care

Community pharmacy and primary health care in Sweden - at a crossroads

Tommy WESTERLUND, Bertil MARKLUND.
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Abstract

The overall goal of Swedish health care is good health and equitable care for the whole population. The responsibility for health is shared by the central government, the regions, and the municipalities. Primary care accounts for approximately 20 percent of all expenditures on health care. About 16% of all physicians work in primary health. The regions have also employed a large number of clinical pharmacists, usually hospital-based, but many perform a variety of different primary care services, the most common of which is patient medication reviews. Swedish primary health care is at a crossroads facing extensive challenges, due to changes in demography and demanding financial conditions. These changes necessitate large transformations in health services and delivery. Current Government inquiries have primarily focused on two ways to meet the challenges; a shift towards more local care requiring a transfer of resources from hospital care, and a further development of structured digi-physical care, that is both digital ("online doctors") and physical accessibility of care. While primary care at present is undergoing processes of change, community pharmacy has done so during the past decade since the re-regulation of the Swedish pharmacy market. A monopoly was replaced by a competitive system, where five pharmacy chains now share most of the market, a competition that has made community pharmacy very commercialized. A number of different, promising primary care services are being offered, but they are usually delivered on a small scale due to a lack of remuneration and philosophy of providers. Priority is given to sales and fast dispensing of prescriptions, often with a minimum of counseling. Reflecting primary health care, community pharmacy in Sweden is at a crossroads but currently has a golden opportunity to choose a route of collaboration with primary health care in its current transformation into more local and digi-physical care. A major challenge is that primary health care inquires, strategic plans, and national policy documents usually do not include community pharmacy as a partner. Hence, community pharmacy have to be proactive and seize this chance of changes in primary health policy and organization in order to become an important link in the chain of health care delivery, or there is a significant risk that it will predominantly remain a retail business.

Keywords

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

THE SWEDISH HEALTH CARE SYSTEM

Sweden has a population of 10.3 million people and spends 11% of its gross domestic product (GDP) on health and medical services, which is on par with most other European countries.[1] In 2018, 313.6 billion SEK was allocated to health care in Sweden, out of which 55.9 billion was assigned to primary care.[2] General government financed 85 percent of the total costs, while households paid 14 percent of the total costs via patient fees and other fees.[3] Private health care, accounting for 12% of total healthcare costs, mainly offers primary care, such as health care centers or homes for the elderly.[1]

According to the Swedish Health and Medical Services Act, the overall goal of Swedish health care is good health and care on equal terms for the whole population. The care shall be based on the following three basic principles:

- Human dignity: All human beings have an equal entitlement to dignity and have the same rights regardless of their status in the community.
- Need and solidarity: Those in greatest need take precedence in being treated.

Cost-effectiveness: When a choice has to be made, there should be a reasonable balance between costs and benefits, with cost measured in relation to improvement in health and quality of life.[4,5]

Sweden is divided into 21 regions and 290 municipalities. The responsibility for health and medical care in Sweden is shared by the central government, the regions, and the municipalities. All of Sweden's municipalities and regions are members of the Swedish Association of Local Authorities and Regions (SALAR) [Sveriges Kommuner och Regioner (SKR)], which is an employers' organization that represents and advocates local government in Sweden. The regions have the primary responsibility for planning and providing health and medical services and decide on the allocation of resources. The regions own and operate the hospitals, health care centers, and other institutions. The municipalities are responsible for the disabled, home health care of the elderly, and nursing homes. They are also responsible for providing care for people with mental disorders, support and services for people released from hospital care, and school health care. Outpatient care is organized into primary care districts, each with 5,000 to 50,000 inhabitants. There are 100 hospitals in Sweden, of which about 85 are run by regional governments; the remainders are private. Seven of these 85 are regional university hospitals and they offer highly specialized care and host teaching and research. There are about 46,000 registered physicians and 106,000 registered nurses in Sweden, most of who are employed in the health care

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sector. The number of registered pharmacists in the work market is 9,800, approximately half of whom are pharmacy practitioners.[6]

Quality and efficiency of health care in Sweden is measured through a number of indicators by a system named Open Comparisons, operated and financed by the National Board of Health and Welfare [Socialstyrelsen]. The results are used to follow-up, analyze and develop health care on different levels. The target groups for this data are officials, decision makers, municipalities, regions and politicians. The indicator results are presented by municipality, region and county. The national development data over time is often presented. Certain indicators are even measured per hospital or clinic. Stakeholders may, with the help of the indicator results, study the quality of the health care system as a whole, or examine specific aspects, such as medical outcomes, patient satisfaction, accessibility, and costs, to support follow-up, development and improvements.[7,8]

PRIMARY HEALTH CARE

An overview

Primary health care accounts for about 20 percent of all expenditures on health, and about 16 percent of all physicians work in this setting.[2] There are about 1,200 primary care practices, of which 40 percent are privately owned. Team-based primary care, comprising general practitioners (GPs), nurses, midwives, childcare practitioners, pediatricians, physiotherapists, psychologists, and gynecologists, is the main form of practice. In some practices, pharmacists are included. There are, on average, four GPs in a primary care practice. GPs or district nurses are usually the first point of contact for patients, unless for minor ailments where community pharmacy practitioners often enjoy the public's trust. District nurses employed by municipalities also participate in home care and regularly make home visits, especially to the elderly; they have limited prescribing authority. People may register with any public or private provider accredited by the local regional council with most individuals registering with a practice instead of with a physician, but in some practices, it is possible to register with a specific GP. Providers (public and private) are paid a combination of fixed capitation for their registered individuals (80-95% of total payment), fee-for-service (5-18%), and often performance-related payment (0-3%) for achieving quality targets in such areas as patient satisfaction, care coordination, continuity, enrollment in national registers, and compliance with evidence-based guidelines.[5]

The National Medicine Strategy

SALAR and the Government have since 2011 jointly developed the National Medicine Strategy (NMS) together with the following stakeholders: the Medical Products Agency, the National Board of Health and Welfare, Swedish Agency for Health Technology Assessment and Assessment of Social Services, the Swedish eHealth Agency, the Health and Social Care Inspectorate, the Dental and Pharmaceutical Benefits Agency, the Public Health Agency of Sweden, the Swedish Pharmacy Association, the Swedish Pharmacists Association, the Swedish Pharmaceutical Society, the Swedish Medical Association, the Swedish Association of Health Professionals, and the research-based pharmaceutical industry. The NMS's long-term vision is "A correct medicine use to the benefit of patient and society". It aims at improving medicine use and patient safety, as well as to foster an equitable health care in Sweden. An action plan is issued annually, containing a number of assignments to the participating stakeholders, to contribute to the overall goal of an effective, safe, accessible and equitable drug use that also is both socially and environmentally sustainable. Examples of topics of previous NMS assignments related to community pharmacy are self-care with a focus on nonprescription drug use, improved patient safety in generic substitution, and development of patient-oriented quality indicators for community pharmacy practice.[9]

Changes, challenges and opportunities

Swedish primary health care faces big challenges including changes in demography, caused by a fast population growth (by 16% in the last 20 years), mostly due to a large immigration, primarily of refugees, and by an increased proportion of older people.[10] Other challenges are competence provision, the increased need to support welfare by electronic processes and communication, and given the financial conditions a need to develop and streamline health care. A further shift towards local care is a nationally agreed clear path.

Primary care is the part of health care that is best placed to address individuals' overall health care needs, including preventive measures. The Government and SALAR have reached an agreement to develop local health care. The goal of the transition is to create a good, local and coordinated health care, fostering health and health equity. Primary health care is one of four sectors, with an allocation of 2,935 million SEK to the regions, aimed at among other things improving primary care accessibility and medical continuity for patients and to contribute to a more patient-centered health care. A further goal is to enable patients and their families to become involved in care and treatment, given their conditions and needs.[11]

A current Government inquiry interim report, Good quality, local health care – a joint roadmap and vision, focuses on primary health care and how to strengthen it. It contains both legislative proposals and examples of success factors in practice to strengthen primary health care, which are intended to inspire the responsible authorities, i.e. regions and municipalities. The proposals suggested by the Inquiry form the basis for a reform of primary health care. The inquiry is to take particular account of the transfer of resources from hospital care to primary care, and the cooperation between the two and municipal health care has increased. The increased emphasis on primary health care means that this level of care needs to function effectively. GPs will take care of most of the patients' symptoms, resulting in a decreased need of specialist, emergency and hospital carer. Furthermore, there will a more in-depth inclusion of municipal services and patient participation is emphasized. Access is a challenge in primary health care today, and in the inquiry's proposals it is made clear that it has to be responsible for urgent health care. Primary care has to be organized to provide high

accessibility to the services and to meet objectives covered by its mission. Of central importance for both the quality of care and the patient's experience, as well as for the work environment of staff and the effectiveness of health care, is the continuity in the relationship between the patient and health care staff and between different professions and different health care contacts. The Inquiry proposes that the patient may be able to have access to and choose a GP, to ensure continuity and benefit of treatments. In summary, improved access, quality and continuity in primary health care are emphasized. Another proposal makes clear that research has to be conducted in primary health care.[12,13]

Another Inquiry, Digi-physical care choice, accessible primary health care based on need and continuity, is to review the patient choice systems in primary care, including an analysis of how a long-term sustainable system for 'Online Doctors' – so called digital health service providers - can be created. These systems have emerged during the past few years. According to the Inquiry the digital revolution needs to have a broad impact on health care and become a more integrated part of all health care. Digitalization creates the opportunity to remedy one of the main problems of primary care – accessibility – e.g. by being independent of geography. The Inquiry puts forward a number of proposals and makes recommendations to the regional councils through a reform package known as an integrated digi-physical choice reform. It is recommended that the regional councils require that all primary care providers ensure digi-physical care, both digital and physical accessibility. The Inquiry´s proposals are aimed at creating an integrated digi-physical patient choice, where the patient can turn to the same primary care provider regardless of whether they do so digitally or via an appointment.[14]

Neither the recent inquiries on local care and digi-physical care, nor primary care plans, include the community pharmacist as a partner. There is however an awareness of pharmaceutical competence, and the regions have employed a large number of clinical pharmacists The local care approach is in fact based on the belief that the aggregated competence of the whole health care team results in the best outcome.[12] A digi-physical care collaboration between primary care and community pharmacy would be especially beneficial in rural areas, enabling the patient to get certain health related data measured in the pharmacy and digitally sent to the patient's health care center.

REGIONAL CLINICAL PHARMACISTS

The previously mentioned regions have employed clinical pharmacists to deliver pharmaceutical health care services, mostly since the re-regulation of the Swedish pharmacy market in 2009. The majority of the 725 clinical pharmacists employed are hospital-based, but many also perform services in primary health care. Some work in primary care only. A survey was conducted through digital SurveyMonkey specifically for this article, to examine to what extent pharmacists employed by the regions deliver services in primary health care, as well as which services they provide. According to the survey, 174 clinical pharmacists nationwide are engaged in primary health care to an extent corresponding to 70 full time equivalents. The number of pharmacists varies among the regions between 1 and 35 with a median of 6. Several different primary health care services are delivered, the most common of which are patient medication reviews, conducted by pharmacists in health care centers, retirement/nursing homes and in municipal home health care in more than half of the regions. Home medication reviews have also been performed but so far to a limited extent. According to regulations by the National Board of Health and Welfare [Socialstyrelsen], all aged 75 or older with ≥5 prescribed medications are entitled to a medication review annually.[15] An MD is formally responsible, but the reviews are often undertaken by pharmacists. According to two studies, pharmacists' implementation of medication reviews has been appreciated by GPs, nurses and patients.[16,17]

Both participation of pharmacists in Pharmacy & Therapeutics Committees, or in some form of collaboration groups including primary care representatives, and follow-up, analysis and presentation of prescription statistics to GPs, exist in close to 9 out of 10 regions. In the majority of regions pharmacists are also assisting in practical medication handling and in logistics and presenting producer-neutral information and education to GPs and district nurses on new drugs or pharmacotherapeutics. To some extent this is also done with municipal home health care staff. Pharmacist participation in public procurement of drugs and financial follow-up is quite common. A joint network of clinical pharmacists in primary health care in seven regions has been established.

COMMUNITY PHARMACY

An overview

There are a total of 1,422 community pharmacies in Sweden, a 53% increase since the re-regulation of the Swedish pharmacy market in 2009, resulting in 14 pharmacies per 100,000 inhabitants an increase from the 10:100,000. Ownership of pharmacies is re-regulated, but there always has to be a pharmacist-in charge. About 97% of the country's pharmacies are operated by five community pharmacy chains, one of which is the Government-owned apoteket, the former monopolist chain of Apoteket AB (1970-2009). In one of the chains, a minor part of the pharmacies is operated as a franchise. Additionally, there are 45 independently run pharmacies, and three unmitigated e-commerce pharmacy companies, that are taking medicine orders online only. Pharmacy e-commerce accounts for 10% of the turnover and 16% of the volume of the community pharmacy market. There are also 620 so called "pharmacy representatives", usually located in general food stores, as an extension of the closest pharmacy, forwarding dispensed prescriptions. Since the re-regulation, nonprescription drugs are sold in other outlets, such as food stores and gas stations.[18]

There are 10,000 community pharmacy employees; 53% pharmacists, 23% pharmacy technicians and 24% other staff. There are two categories of pharmacists, a 3-year-long training for a BS(Pharm) degree, also named "presciptionists" in English, and a 5-year-long MS(Pharm) education. Both categories have the same rights and

obligations in community pharmacy practice, with the "prescriptionists" being the major group.

The reimbursement system is based on a Pharmacy Margin, with a combination of fixed fee and percentage. There is a reimbursement for generic substitution with an increased margin added to all generic drugs. Discounts are allowed for non-generic drugs and in reality, only used for parallel traded drugs. There is no reimbursement for primary care services.

A clinical decision support system

The use of electronic prescriptions has long been fully implemented in Sweden. A governmentally owned clinical decision support system, named Electronic Expert Support (EES), has been established, which analyses patients´ electronically stored prescriptions in the Swedish national prescription repository. It was developed following protocols for Drug Utilization Review (DUR) by Medco Health Solutions, used in various forms at community pharmacies in the US. The system has been adapted to Swedish clinical practice. The Swedish e-Health Authority's expert group is responsible for quality assurance of EES content. Its information is designed as evidence-based rules, and is constantly updated based on science and information from government agencies.

The pharmacist can use the EES while dispensing prescriptions to identify potential drug-related problems (DRPs). With EES, the electronic prescription is analyzed both individually and together with all the patient's other current prescriptions and alerts of potential DRPs and EES suggestions for resolutions of the DRPs. EES can detect DRPs including drug interactions, therapy duplications, high doses, potential contraindications, "drug gender warnings" (that is, when a drug only or usually used in women has been prescribed for a man or vice versa), and inappropriate drugs and doses for geriatric or paediatric patients. In 2018, close to 5.2 million EES-warnings were analysed.[19,20]

Primary health care services, challenges and opportunities

There are a number of primary health care services delivered by community pharmacists in Sweden, such as:

- pre-booked basic medication reviews and other patient counseling sessions in privacy, such as a 20-minute-long review of the patient's drugs, supported by the EES system
- blood pressure measurements
- blood analyses of blood sugar, HbA1c, lipids and CRP
- skin care analyses, including analyses of skin problems caused by adverse drug reactions, and counseling by a pharmacy
- birth mark control using sciascopy, to scan the birthmark; the pictures are sent to a dermatologist for clinical assessment and for notifying the patient
- inhalation check and counseling of asthma and COPD patients
- allergy consultations
- smoking cessation programs
- vaccinations, administered by nurses in cooperation with vaccination or health care centers
- dose dispensing services for nursing home patients and for patients living in their own homes
- improved adherence to prescribed drugs in patients with COPD and asthma together with Frisq – digital care plan, including the Frisq app and follow-up meeting with pharmacists.[21]

However, the number of patients receiving the services varies with both the type of service and among the different pharmacy chains but is considered to be generally low. One reason is the strong competition among the pharmacy chains after the re-regulation, resulting in a primary focus on sales of health-related products, as well as items of less related to health, such as cosmetics. Another is an emphasis on lean staff and rapid dispensing of prescriptions with minor counseling. Hence, there is usually not much time prioritization for these services, also because of a lack of remuneration and a lack of patients' willingness to pay, an argument often put forward by the pharmacy chains.

The 45 independently operated pharmacies are however usually less commercialized, putting a larger emphasis on counseling and patient-oriented services, enjoying a majority of patients being regular, as well as a closer collaboration with local primary health care. These pharmacies are often hubs in their neighborhoods, building long term trust in their clientele, resulting in more informal relations with both patients and local GPs and a greater knowledge about individual patients' needs. Some pharmacies apply a pharmacist-only concept that is more nonprescription drugs are put behind the counter than usually is the case in Swedish pharmacies, to ensure appropriate counseling. Local agreements are reached between the pharmacists and the GPs, both relieving health care and making patient encounters smoother. Even medications home deliveries with pharmacist counseling at the kitchen table happens.

According to a survey in 2014, 70 % of a nationally representative consumer panel of respondents 15 years of age and older (n=1000) felt that primary health care services should be performed in close proximity to or in pharmacies.[22]

"Check My Medicines" [Koll på läkemedel] operated since 2008, is a successful co-operation between the pharmacy chain of apoteket and the three main retiree organizations in Sweden. Its aim is to empower the elderly to take charge of their own medication, and to improve their use of drugs. By disseminating knowledge, creating a national dialogue and debate, Check My Medicines wants to contribute to the necessary changes which will benefit the elderly's use of drugs and their health. The project focuses on reducing the number of inappropriate medications, strengthening the monitoring systems, and developing guiding material and electronic expert systems that support both doctors and pharmacists. Furthermore, the project focuses on engaging key stakeholders, and empowering patients and their families to become actively engaged in the medical treatment in the elderly. More than 900,000 senior citizens have been educated/informed in study circles about

"medicines and elderly", and through campaigns, brochures, presentations and dialogues with their pharmacists about what they should expect from their medical treatment. They have also been empowered to ask their doctors "tough" questions. Check My Medicines has received additional funding from the Swedish Government, due to its success in empowering the elderly, and due to the good results in reducing the amount of inappropriate medications in the elderly.

A government commission by The Dental and Pharmaceutical Benefits Agency [Tandvårds- och läkemedelsförmånsverket (TLV)] has investigated a possible introduction of publicly financed patient-oriented community pharmacy services/primary health care services and is expected to conduct a pilot study, aimed at increasing adherence to prescribed drug treatment through further developed community pharmacist counseling.[23] TLV is a central government agency whose remit is to determine whether a pharmaceutical product, medical device or dental care procedure shall be subsidized by the state. It also determines retail margins for all pharmacies in Sweden, regulates the substitution of drugs at the pharmacies and supervises certain areas of the pharmaceutical market.[24]

A system of quality indicators in community pharmacy practice was developed by two Government Commissions through the Medical Products Agency [Läkemedelsverket] and tested nationwide. Examples of indicators were "Does the pharmacy have written instructions on counseling on the use of over-the-counter drugs (OTCs) in humans and animals?", "Does the pharmacy offer pre-booked counseling on medicines and their use?", and "Does the pharmacy have written work procedures for the pharmacy staff's deviation management and learning from negative events?".[25,26] A third Government Commission on quality indicators in community pharmacy practice was assigned TLV and focused among others on OTC counseling, reporting of adverse drug reactions, and continuing professional development, and may eventually be introduced in community pharmacy practice.[27]

PHARMACY ORGANIZATIONS

Views and strategies, challenges and opportunities

The Swedish Pharmacy Association [Sveriges Apoteksförening]

The Swedish Pharmacy Association [Sveriges Apoteksförening] was formed after the re-regulation of the Swedish pharmacy market in 2009. It represents nearly all pharmacies in Sweden with all pharmacy chains operating in Sweden being members. The association does not have a public strategic plan, but is a voice of its members in publicity campaigns and collaboration with health authorities and other stakeholders to achieve their goals. Among its current priorities in community pharmacy are; an increased use of the EES along with an additional effect on drug use, an expansion of pharmacists' role to impact medical treatment with pharmacist repeat prescribing, an introduction of a pharmacist-only category of drugs, and collaboration with health authorities to develop requirements and a support system for pharmacy self-care counseling.[18]

The Swedish Pharmacists Association [Sveriges Farmaceuter]

The Swedish Pharmacists Association [Sveriges Farmaceuter] is a trade union for university graduates in pharmacy, founded in 1903 with around 7,100 members. The association aims to ensure that their members have secure employment and able to develop in their professional life. As a professional association, they are experts on the competence, skills and labor market for pharmacists.[28] According to the Swedish Pharmacists Association, there are several business and professional challenges, such as pharmacists' qualifications could be better used in community pharmacy and that pharmacies could have a more prominent role in health care. Community pharmacy is perceived both by many pharmacists and the public as focusing too much on retail business. There is an apparent conflict between the retailing and professional aspects of community pharmacy. Recent pharmacy graduates are employed only for a limited time with the large pharmacy chains as they don't experience stimulating positions. Working conditions, such as salaries, hours and holidays, in community pharmacy practice are also perceived as inferior to those in other pharmaceutical related positions.

The development of patient-oriented services/primary health care services in community pharmacy in Sweden is slow, probably due to lack of collaboration among the different pharmacy chains since the re-regulation of the pharmacy market in 2009. Nor has the issue of public reimbursement been addressed until recently, by the previously mentioned TLV Government Commission. Another challenge is the rapid growth of pharmacy e-commerce in Sweden, resulting in a need for community pharmacy and its pharmacists to develop new roles. The use and handling of drug in the municipal home health care program appears to be flawed. This could be avoided by an improved role of the pharmacist linking to home health care staff.

The Swedish Pharmacists Association adopted a vision and a strategic plan in 2019 to 2025, where goals in professional issues were set. An ambition is to combine trade union and professional issues in a synergistic way. The plan contains a number of key elements, such as good working conditions enabling pharmacists to develop and use their knowledge and skills and to receive reasonable compensation. Furthermore, that the pharmacists will be recognized as playing a role for better health in society, supported by a maintenance of life-long learning. The association is envisaging the implementation of its strategic plan by advocacy work with the authorities. The association feels that there are two critical elements; (1) the maintenance of a high quality of pharmaceutical university education and continuing professional development, enabling a further demand for pharmaceutical competence; (2) a successful combination of trade union and professional issues i.e. the use of pharmaceutical knowledge and skills creating demand for pharmaceutical services demand, thereby making room for trade union successes.[29]

The Swedish Pharmaceutical Society [Apotekarsocieteten]

The Swedish Pharmaceutical Society [Apotekarsocieteten] is a non-profit organization for professionals engaged in the field of pharmaceuticals. The aim of the organization is to support research and innovation in drugs and healthcare, and to promote high professional standards through supporting education and professional development. With more than 5,300 individual members, the society is divided into 14 scientific sections, 11 regional divisions and 3 interdisciplinary interest groups. The Society accepts any member interested in drugs and is hence not a professional organization specifically for pharmacists, although pharmacists constitute a majority of its members. In its policy program, the following positions can be noted:

- Pharmacies shall be a statutory part of the health care system to enable a basis for an integrated cooperation between health care providers to the benefit of patients. The community pharmacists' competence shall be seized to achieve best patient, drug and society benefits.

- The disciplines of health economics, drug use, clinical pharmacy and communication should be invigorated in the pharmaceutical, undergraduate education

- Practical research on drug use, pharmacy practice, pharmaceutical competence use, social pharmacy and effects of drug-related interventions and health care processes should be fostered.[30]

The NEPI Foundation [Nätverket för läkemedelsepidemiologi]

The NEPI Foundation [Nätverket för läkemedelsepidemiologi] was established by the Swedish Parliament in 1993 in order to support drug information, to promote health economy, and to develop pharmacoepidemiology in Sweden. The board is appointed by the Swedish Pharmaceutical Society and the Swedish Society of Medicine. NEPI's main focus is on supporting the use of new methods to describe the use of pharmaceuticals and the effects of these pharmaceuticals on individual and public health.[31]

In a Delphi study conducted by NEPI, aimed at identifying barriers to a successful adherence and at discussing health care providers' roles, physicians, nurses, pharmacists, patients and health authority representatives (n=57) were asked to respond anonymously to a number of questions and to give free text comments. In total, 947 barriers were identified and more than 800 comments reported. One of the most common barriers listed was problems due to generic substitution, a barrier where pharmacists were considered to have a key position in alleviating the problems through appropriate counseling. An important conclusion of the study was the lack of a unified consensus on responsibilities and roles in the chain of health care, a lack that results in unnecessary excess work and difficulties to develop work models. Strikingly many respondents did not have any clear view of the role of the community pharmacist, as opposed to the perception of the role of the hospital-based regional, clinical pharmacist, a finding which indicates a profound need to elevate the position of the community pharmacist in health care.[31,32]

CONCLUDING REMARKS

There are currently extensive organizational changes occurring and proposed for in Swedish health care, focusing on a shift towards an expansion of primary health care. Prerequisites for the profound transition include a transfer of resources to primary care and an increased efficiency through both local and digi-physical care. Community pharmacy has undergone major changes after the re-regulation of the pharmacy market a decade ago and has in the view of many become too commercialized and has developed into a retail business, even if there are exceptions in the market. If the pharmacy chains would rather compete through an expansion of different, often promising, primary care services, they would both better serve the public and become more financially sustainable by attracting and keeping patients. The chances for public remuneration and/or patients' willingness to pay for the services would also increase, if the pharmacy chains were able to provide evidence of clinical, humanistic and socioeconomic gains by their services.

A big challenge is however that primary care inquires, strategic plans, and national policy documents usually do not include community pharmacy as a partner. Community pharmacy therefore has to be proactive. Community pharmacy currently faces a golden opportunity to establish a significant role in the present evolution of local and digi-physical primary care. It is crucial that community pharmacy seizes the chance of a closer collaboration with primary care and thereby contributes to a win-win situation, to the benefit of patients. Another major reason for joint efforts between primary health care and community pharmacy is the aging population of Sweden. An increase of poly-medicated patients and thereby an increased risk of drug-related problems in the population, creates a further need for pharmaceutical competence and patient counseling in community pharmacy practice. In conclusion, Swedish community pharmacy is at a decisive crossroads to choose between a continued focus on retail business or become an important link in the chain of health care.

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CONFLICT OF INTEREST

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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 Australia

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Abstract

There is evidence that the Australian Government is embracing a more integrated approach to health, with implementation of initiatives like primary health networks (PHNs) and the Government's Health Care Homes program. However, integration of community pharmacy into primary health care faces challenges, including the lack of realistic integration in PHNs, and in service and remuneration models from government. Ideally, coordinated multidisciplinary teams working collaboratively in the community setting are needed, where expanding skills are embraced rather than resisted. It appears that community pharmacy is not sufficiently represented at a local level. Current service remuneration models encourage a volume approach. While more complex services and clinical roles, with associated remuneration structures (such as, accredited pharmacists, pharmacists embedded in general practice and residential aged care facilities) promote follow up, collaboration and integration into primary health care, they potentially marginalize community pharmacies. Community pharmacists' roles have evolved and are being recognized as the medication management experts of the health care team at a less complex level with the delivery of MedChecks, clinical interventions and medication adherence services. More recently, vaccination services have greatly expanded through community pharmacy. Policy documents from professional bodies highlight the need to extend pharmacy services and enhance integration within primary care. The Pharmaceutical Society of Australia's Pharmacists in 2023 report envisages pharmacists practising to full scope, driving greater efficiencies in the health system. The Pharmacy Guild of Australia's future vision identifies community pharmacy as health hubs facilitating the provision of cost-effective and integrated health care services to patients. In 2019, the Australian Government announced the development of a Primary Health Care 10-Year Plan which will guide resource allocation for primary health care in Australia. At the same time, the Government has committed to conclude negotiations on the 7th Community Pharmacy Agreement (7CPA) with a focus on allowing pharmacists to practice to full scope and pledges to strengthen the role of primary care by better supporting pharmacists as primary health care providers. The 7CPA and the Government's 10-year plan will largely shape the practice and viability of community pharmacy. It is essential that both provide a philosophical direction and prioritize integration, remuneration and resources which recognize the professional contribution and competencies of community pharmacy and community pharmacists, the financial implications of service roles and the retention of medicines-supply roles.

Keywords

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

AUSTRALIAN HEALTH CARE AT A GLANCE

The Australian population was estimated to be 25.7 million in May 2020.[1] Australia is considered to have a world class health system. While Australians generally enjoy positive health outcomes, it is recognized the health system is under increasing strain from the rising rates of chronic illness and an ageing population.[2,3] The clinical and economic burden represents a major challenge for the optimal provision of healthcare.[4-6] The rapid change has resulted in major health system reform that is likely to continue over the coming years to improve patient access, enhance primary care, capitalize on technology, ensure a future-ready health workforce and deliver cost-effective health outcomes.

Australia has a mixed-model of public and private health care, based on the principle of universal access. Australia's health system is underpinned by Medicare, a universal public health insurance program which provides rebates against the cost of medical fees for Australians.[2] This is funded partly by a Medicare levy on taxable income, with any shortfall being met by the government from general revenue.[7] About 80% of general practitioner (GP) visits incur no patient out-of-pocket costs because the fee is paid directly by the government, while Australians are eligible to be treated in a public hospital without charge.[2]

Australia's health system is complex and is managed by all levels of Australian government including federal and state or territory.[8] This complexity is reflected in its funding arrangements at all levels of government. Non-government organizations and private health insurers also provide funding while individuals pay out-of-pocket expenses for a number of products and services without full (or only partial) reimbursement. Spending on health has grown by 50% (after adjusting for inflation) between 2006–2007 and 2015–2016, from AUD 113 billion to AUD 170 billion. Total health spending was AUD 185.4 billion in 2017-2018 (or AUD 7,485 per person).[9] Hospitals (40%) and primary health care (34%) accounted for three-quarters of total health spending.[9] Governments funded the majority (AUD 77.1 billion by the federal government; AUD 49.5 billion by state and territory governments) and non-government sources funded the remaining amount.[9]

The federal government is responsible for leading the development of national health policy, subsidizing primary

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health care services and providers through the Medicare Benefits Scheme (MBS), providing funds to states and territories for public hospital services, oversight of Primary Health Networks (PHNs), regulating private health insurance and funding medical research.[8,10] Importantly, the federal government funds the national universal Pharmaceutical Benefits Scheme (PBS) providing timely and affordable access to prescription medicines at Government-subsidized prices. Currently, the PBS patient co-payment is AUD 41 for general patients and AUD 6.60 for concessional patients per medicine, with thresholds in place for total patient contributions.[11] Prescription medicines below these prices are paid in full by general patients. The federal government influences the cost of the PBS by determining which pharmaceuticals to list and negotiating the price with suppliers.[8] The federal government funds community pharmacies to dispense and supply medicines under the PBS, alongside pharmacy services, an arrangement implemented through the Community Pharmacy Agreement (subject to renegotiation every five years).[8]

State and territory governments are responsible for managing public hospital and Local Hospital Network (LHN) performance.[10] The states are also responsible for funding and providing a range of community health services, including ambulance services, public dental care, and mental health care, with assistance from the federal government.[10]

COMMUNITY PHARMACY IN AUSTRALIA

The community pharmacy sector plays an important role in the Australian health care system.[12] With the average Australian visiting a community pharmacy eighteen times a year, the sector provides accessible and timely care.[13] There were 32,412 registered pharmacists in December 2019, and 5,797 community pharmacies in Australia.[14,15] Pharmacists are trained at university level, accredited by state or territory registration boards, and subject to federal and state or territory government regulations.[14] The core role of the community pharmacist is dispensing medicines. This role couples clinical review of prescriptions, and professional activities such as counselling to ensure safe and effective use of medicines.[16] The current scope of community pharmacy practice remains heavily dependent economically on the dispensing and provision of medicines.

The ownership of community pharmacy is controlled at the state level, with the number of pharmacies owned by a single pharmacist being dependent on legislation. There are also location rules (i.e., for the establishment of a new pharmacy or relocation of an existing pharmacy) to supply PBS medicines.[17]

POLICY CONTEXT IN AUSTRALIA

National Medicines Policy

Australia's National Medicines Policy (NMP), implemented 20 years ago, seeks to provide overarching policy direction around four key interlinked pillars including, timely access; medicines meeting standards of safety and efficacy; quality use of medicines (QUM); and maintaining a responsible and viable medicines industry.[18,19] In 2019, the Federal Health Minister Greg Hunt MP announced a review of Australia's NMP.[20] Recommendations for the next iteration have emphasized measuring health outcomes that are valued and relevant to patients.[20]

Medicines Safety: the 10th National Health priority area

In November 2019, health ministers agreed to make medicines safety the 10th National Health priority area.[21] The Government responded to findings of both the Interim report of the Royal Commission into Aged Care, and the Pharmaceutical Society of Australia's Medicine Safety: Take Care report.[22-24] The latter report identified 250,000 avoidable hospital admissions annually due to medication problems, and 400,000 emergency department presentations as a result of errors, inappropriate use, misadventure and drug interactions. At least half of these problems were considered preventable. Medicine misadventure costs Australia AUD 1.4 billion annually.[23]

Integrated primary health care

Integrated care is a multifaceted concept often contraposed to fragmented or episodic care, and is used synonymously with terms like coordinated care and seamless care, among others.[25,26] The Australian Government's Productivity Commission released a report identifying issues with the Australian health system including the lack of integrated care, insufficient patient-centered care, and a need to focus funding towards innovation or clinical and economic outcomes.[27] The Strategic Framework for Integrating Care report in 2018 sets a vision of integrated care in Australia.[28] The drivers of this interest in integrated care are: optimized resource investment; coordination of care across different settings; reduced duplication of services; improved health of the population and; greater health literacy and self-care.[28] Federal and state or territory governments have progressed implementation to deliver integrated care in Australia.[28] Multiple strategies are being employed including health reform and implementation of integrated service models.[29-31]

Primary health networks – primary health care organisations

A policy response was the establishment of a network of primary health care organisations, known as PHNs.[32,33] Thirty one PHNs were established across Australia, funded by AUD 900 million, replacing the 61 Medicare Locals previously operating.[34] This network was created to operate at a regional level with the authority and accountability to plan, integrate and coordinate primary health care at a local level.[35] PHNs work with primary care providers (primarily GPs), hospitals, and the broader community to:

- increase the efficiency and effectiveness of medical services for patients, particularly those at risk of poor health outcomes, and;
- improve coordination of care to ensure patients receive the right care in the right place at the right time.[36]

Each PHN conducts a local needs assessment to identify health and service needs within their regions and prioritizes activities (and funding) to address those needs.[37]

The 10-year Primary Health Care Plan

The Australian Government appointed a primary health care reform steering group in 2019 to provide independent advice for the development of the 10-year Primary Health Care Plan. The steering group consists of representatives from professions including general practice, nursing, speech pathology and physiotherapy professions, with no representation from community pharmacy.[3] The plan will guide primary health care resource allocation in Australia (AUD 104 billion into the health system from 2019–2020 and a total of AUD 435 billion over four years). It also aims to guide future primary health care reform for further integration as part of the Government's Long-Term National Health Plan.[3]

The Long-Term National Health Plan includes:

- The 2030 mental health vision;
- The 10-year Primary Health Care Plan;
- Continued improvement of private health insurance;
- The 10-year National Preventive Health Strategy, and;
- The 10-year Medical Research Future Fund investment plan.[3]

In the Government's 10-year Primary Health Care Plan, the Government committed to concluding negotiations on the next community pharmacy agreement ("The seventh agreement or 7CPA") focusing on pharmacists practicing to their full scope.[3] It also pledged to better support pharmacists in their roles as primary health care providers.[3]

INTEGRATION OF COMMUNITY PHARMACY IN THE BROADER HEALTH SYSTEM

Governments are embracing a more integrated approach to health, with implementation of primary care initiatives like PHNs and the Government's Health Care Homes program.[32,33,38] However, the integration of community pharmacy into primary health care faces challenges, including the lack of realistic integration in PHNs, and in service and remuneration models from government. Ideally, coordinated multidisciplinary teams working collaboratively in the community setting are needed, where expanding skills are embraced rather than resisted. Community pharmacists need be included in PHNs' governance, decision making and advisory structures, as it appears they are not sufficiently represented at this local level.

Recent pharmacy policy documents from professional bodies highlight the need to extend community pharmacy services and enhance integration within primary health care. The Pharmaceutical Society of Australia has developed the strategic document Pharmacists in 2023 which envisages pharmacists practising to full scope and driving greater efficiencies in the health system.[16] The report outlines eleven changes to deliver QUM by better utilizing pharmacists in the future.[16] Key themes such as pharmacists being the 'custodians' of medication safety and their role in digital health (including My Health Record, an online platform with patient health information imputed by healthcare providers across the sector), were outlined.

The Pharmacy Guild of Australia's Community Pharmacy 2025 outlines the organizations strategic vision for viability and the future of community pharmacy as an integral part of the Australian health care system. The report identifies pharmacy as health hubs facilitating the provision of cost-effective and "integrated" services to patients.[39,40] The report was informed by qualitative and quantitative market research, subject experts and a strategic advisory firm.[41]

A significant barrier to pharmacists achieving high-impact contribution as integrated members of the health team is the current state of remuneration for services. The right incentives must be provided for all health practitioners, like GPs, nurses and pharmacists to integrate services effectively, with clear responsibilities contributing to overall health outcomes. The Pharmaceutical Society recommends funding that reflects quality and complexity of pharmacist care.[16] This may be achieved through establishing practice incentive payments linked to quality measures, revising remuneration structures to account for complexity, or moving to a time-based fee structure.[16] All aspects of the pharmacist's role need to be resourced appropriately. However, there will also be specific challenges such as freeing pharmacists' time to deliver services, recording and using data to demonstrate value for the viability of community pharmacy. Without adequate funding and recognition of pharmacist's contributions to primary care, it will be difficult to ensure integration.

In the Australian Government's Response to the Review of Pharmacy Remuneration and Regulation, the government recognised the pivotal role of the community pharmacy sector.[42] The government states that it is committed to working closely with community pharmacies and other stakeholders to address the significant pressures being placed on the health care system. As highlighted in the report Bankwest Future of Business: Focus on Pharmacy, the community pharmacy sector is positioned to expand the services available and establish themselves as local healthcare centres, further reducing the demand on hospitals and other primary health care facilities.[13,43]

The Community Pharmacy Agreement

The primary driver of pharmacy policy and direction from a governmental perspective are five year agreements negotiated between the federal government and the Pharmacy Guild of Australia, with some influence and representation by the Pharmaceutical Society of Australia.[44,45] The agreement sets out the remuneration associated with dispensing prescription medications and services, which in turn, determines scope of practice and roles for community pharmacy.[46] The current agreement ("the sixth agreement or 6CPA") is due to expire on June 30th 2020. The 6CPA includes three key funding elements, namely:

- Community pharmacy remuneration;
- The Community Services Obligation funding pool;
- Community pharmacy programs.[47-50]

It was originally estimated that AUD 18.9 billion was to fund community pharmacy over five years, comprising AUD 15.5 billion from the government and AUD 3.4 billion from PBS co-payments paid by patients.[51] In addition, the 2017-

2018 budget included AUD 225 million in payments to community pharmacies over the remaining life of the sixth agreement to compensate for lower than forecast PBS prescription volumes.[52] A number of other programs have been funded throughout the life of the 6CPA.

PHARMACY PROGRAMS AND SERVICES

Australian pharmacists have long provided services to patients.[13,53-57] The 2018 Pharmacy Barometer report indicated that 19% of community pharmacy owners (one-fifth) employ a pharmacist solely dedicated to the provision of pharmacy services.[58] Services can be divided into those funded by the 6CPA, and services with other sources of funding (i.e., PHNs, or services paid for by the patient) (Table 1).

A total of up to AUD 1.26 billion in funding was available for pharmacy programs and services under the 6CPA.[50] This consisted of:

- AUD 613 million for the continuation of a number of programs and services from the 5CPA;
- AUD 50 million for a new pharmacy trial program (PTP); and
- up to AUD 600 million for new and expanded community pharmacy programs.

The 6CPA encompasses a number of areas of practice including: Medication adherence programs, Medication management programs, and other trial programs.

Medication adherence programs

Dose administration aids: (a well-sealed that allows individual medicine doses to be organized according to the prescribed dose schedule).[59] Incentives are divided among the number of claiming pharmacies on a pro rata basis for the activity documented. In 2016, the average claim amount earned by pharmacies, per dose administration aid, was AUD 3.84.[60]

Staged supply (medicines provided by the community pharmacy in instalments to patients). The service is of particular value to patients with a mental illness, drug dependency, or who are unable to manage their medicines safely (eg. people living in accommodation where there is the possibility of theft or lack of refrigeration). Pharmacies may claim payments for up to 15 patients per month. For the provision of the first staged supply, a pharmacy may claim a fee of AUD 8.12 per patient. For each subsequent supply during the same week period, the pharmacy may claim a fee of AUD 4.12 per patient.

Clinical interventions (a documented clinical activity contributing to improved medicines utilization, QUM, or reduced adverse outcomes). Reimbursement is based on the number of interventions within a defined period of time per pharmacy. Payment is subject to a cap of 3.5% of prescription volume for individual pharmacies.[61] Incentives are divided among the number of claiming pharmacies on a pro rata basis for the activity documented. In 2016, the average amount remunerated per intervention was AUD 3.40.[60]

Medication management programs

MedsCheck and Diabetes MedsCheck: (an in-pharmacy medicines review service between the patient and community pharmacist to improve QUM and patient outcomes). A diabetes MedsCheck builds on the format of a MedsCheck service focusing specifically on patient's with type 2 diabetes. Pharmacies are subject to a combined service cap of twenty MedsChecks or diabetes MedsChecks per month. The community pharmacy is remunerated a fee of AUD 66.53 per patient for a MedsCheck, or AUD 99.79 for a diabetes MedsCheck.[62]

Home Medicines Reviews (HMR): (a medicine review provided by an accredited pharmacist in the patient's home, following referral by a medical practitioner). Following interview with the patient, the accredited pharmacist produces a report detailing recommendations to assist the referrer and patient in developing a medication management plan. Only accredited pharmacists who have undertaken additional training and assessment are authorized to provide medicine review services. To maintain accreditation status, pharmacists must complete 20 additional continuing professional development (CPD) credits annually (in addition to the 40 CPD credits required for general registration).[63]

Changes announced in April 2020 are the most significant since the program's inception, providing a unique opportunity for accredited pharmacists to have a greater role in the health system. Pathways available for HMRs have been broadened to include referrals from medical practitioners other than GPs. Pharmacists may also initiate up to two remunerated follow-up services within nine months of the initial interview.[64] Pharmacies and accredited pharmacists are subject to a cap of 30 HMRs per month. A fee of AUD 222.77 per patient may be claimed for the initial HMR service (interview and report), while an additional AUD 111.39 and AUD 55.70 may be claimed for the provision of first and second follow-up services, respectively.[64]

Residential Medication Management Reviews (RMMR) and QUM: (to enhance the QUM in residential aged care facilities). An RMMR is a service provided to a permanent resident of a residential aged care facility by an accredited pharmacist. It involves a comprehensive assessment to identify and resolve medicine-related problems. The QUM service is a separate service provided by a registered or accredited pharmacist focusing on improving practices and procedures as they relate to quality and safe use of medicines in a residential care facility.[65]

The above services form the core of the remuneration associated with the delivery of services funded by the federal government. Most, if not all, of this funding is claimed by community pharmacies indicating that most are taking advantage of this remuneration. However, this still forms a relatively small percentage of the total revenue for a community pharmacy.

Table 1. Pharmacy programs and services

Services funded under the 6CPA	• Medication management programs
	  ○ MedsCheck and Diabetes MedsCheck
	  ○ Home Medicine Reviews
	  ○ Residential Medication Management Reviews and Quality Use of Medicines
	• Medication adherence programs
	  ○ Clinical Interventions
	  ○ Dose administation aids
	  ○ Staged Supply

Other funded programs under the 6CPA	• Trial programs
	  ○ Community Pharmacy in Health Care Homes trial
	  ○ Take Home Naloxone pilot trial
	  ○ Pharmacy Trial Programs
	  ▪ Pharmacy Diabetes Screening trial
	  ▪ Indigenous Medication Review Service feasibility (IMeRSe) trial
	  ▪ Getting Asthma Under Control (PTP-ARC) trial
	  ▪ Integrating practice pharmacists into Aboriginal Community Controlled Health Services (the IPAC project)
	  ▪ Reducing Medicine Induced Deterioration and Adverse Reactions (ReMInDAR) trial
	  ▪ Early detection and management of cardiovascular disease risk factors (CVD) trial
	  ▪ Chronic Pain MedsCheck trial
	  ▪ Mental Health service (PharMIbridge) trial
	• Other programs
	  ○ eHealth programs
	  ▪ Electronic Prescription Fee
	  ○ Rural support programs
	  ▪ Rural Pharmacy Workforce Program
	  ▪ Rural Pharmacy Maintenance Allowance
	  ○ Aboriginal and Torres Strait Islander (ATSI) specific programs
	  ▪ Quality Use of Medicines Maximized for ATSI People (QUMAX)
	  ▪ S100 Pharmacy Support Allowance
	  ▪ ATSI Workforce Program (Pharmacy Assistant Traineeship Scheme and Pharmacy Scholarships Scheme)

Services with other sources of remuneration (ie. through PHNs or the Workforce Incentive Program)	• General practice pharmacists

Unremunerated services or a fee paid by patients	• Immunisation services
	• Chronic disease management support
	  ○ Blood pressure monitoring
	  ○ Cholesterol monitoring
	  ○ Blood glucose monitoring
	  ○ Inhaler technique checks
	  ○ INR recording
	  ○ HbA1c monitoring
	• Health checks to support early detection
	  ○ COPD screening
	  ○ Australian Type 2 Diabetes risk assessment (AUSDRISK™)
	  ○ Obstructive sleep apnoea screening
	• Health promotion services
	  ○ Weight management
	  ○ Smoking cessation
	• Emergency contraception
	• Wound care services
	• Compounding services
	• Staged supply services
	• Mental health support services
	• Needle and syringe exchange services
	• Opioid substitution therapy services
	• Return of unwanred medicines
	• Baby progress recording
	• Breastfeeding advice and support

Future services	• Minor ailment service • Pharmacist prescribing ○ Urinary tract infection prescribing trial • Continued dispensing

Additional programs

Community Pharmacy in Health Care Homes trial: (an initiative funded to support the incorporation of medication management programs within Health Care Homes). A Health Care Home is a general practice (or Aboriginal Community Controlled Health Service) that coordinates care for patients with chronic and complex conditions.[38] Pharmacies involved in the trial work in conjunction with the Health Care Home team by delivering patient-centred medication management services until the trial concludes on June 30th 2021. Community pharmacy's role in Health Care Homes is to conduct an initial medication reconciliation of a patient's medicines, and develop a Medication Management Plan. The plan includes (1) goals of medication therapy (i.e., proposed plan of action), (2) person responsible for the identified goal (eg. patient, pharmacist, or GP), (3) identification of medication adherence and management services (e.g., blood pressure monitoring, blood glucose monitoring, dose administration aids, or development of an asthma action plan), (4) reconciled medication list, and (5) proposed review date. Each patient is assigned to a complexity tier and pharmacies are remunerated accordingly (Table 2).[66,67] However, there appears to be no publicly available data on the uptake of the program.

Take Home Naloxone pilot trial: Under this trial, naloxone is available to people at risk of overdose, which includes illicit drug users and people who use prescription opioids, or their carers/ family at no-charge. No prescription is required. The Australian government has invested AUD 10 million in the pilot, running between December 1st 2019 and February 28th 2021. Payments are made for each individual supply of naloxone ranging from AUD 41.34 to AUD 48.42 (excluding GST) depending on the product supplied.[68]

Pharmacy Trial Programs

As aforementioned, AUD 50 million was allocated to support PTP programs under the 6CPA. The PTP was introduced to trial new or expanded community pharmacy programs with the aim of improving clinical outcomes for patients and extending the role of community pharmacists.[69,70] As follows:

Pharmacy Diabetes Screening trial: The trial aimed to compare clinical and cost effectiveness of three different pharmacy-based diabetes screening interventions (including AUSDRISK™ assessment) for early detection, education and referral.[71,72]

Indigenous Medication Review Service feasibility (IMeRSe) trial: The trial aimed to optimize patient's medication management via a culturally responsive service for Indigenous Australians, delivered by community pharmacists integrated with Aboriginal Community Controlled Health Services.[73]

Getting Asthma Under Control (PTP-ARC) trial: The trial aimed to improve clinical outcomes for populations at risk of uncontrolled asthma. The intervention targeted three factors associated with uncontrolled asthma including adherence, suboptimal inhaler technique or uncontrolled allergic rhinitis.[74]

Integrating practice pharmacists into Aboriginal Community Controlled Health Services (the IPAC project): The trial aimed to evaluate the impact of pharmacists in Aboriginal health settings providing medication management services to ATSI people. Ten full time equivalent pharmacists integrated into Aboriginal Community Controlled Health Service sites were conducting patient-related and practice-related activities.[75]

Reducing Medicine Induced Deterioration and Adverse Reactions (ReMInDAR) trial: The trial aimed to determine the effectiveness of a pharmacist service in reducing medicine-induced deterioration, frailty and adverse reactions in older people living in aged-care facilities.[76]

Early detection and management of cardiovascular disease risk factors (CVD) trial: The trial aimed to evaluate health checks to detect, diagnose and enable early intervention of cardiovascular disease. The service was delivered by community pharmacists in collaboration with general practice and other providers to ensure individuals with elevated risk status were offered appropriate treatment to reduce their overall risk and improve quality of care.[77]

Chronic Pain MedsCheck trial: The trial aimed to assist patients taking medication for ongoing chronic pain. The service involved a consultation with a pharmacist to review pain medication use and develop an action plan, incorporating education, self-management and/or referral where required.[78]

Bridging the Gap between Physical and Mental Illness in Community Pharmacy (PharMIbridge) trial: The primary focus of this AUD 5 million trial is on medication adherence and improving quality of life for mental health patients.[79] The trial, planned to start later this year (2020), will involve 35 pharmacies across three states and territories.[80]

Services with other sources of remuneration

General practice pharmacists': In recent years there has been an increase in pharmacists working in general practice in Australia, with evidence showing that pharmacists provide valuable support to the general practice team.[81]

Table 2. Payments for the provision of Health Care Homes medication management services for community pharmacies

Tier Category	Total per patient capped payment trial period	Inclusions
Tier 1 (Multiple chronic conditions)	AUD 418.75	Initial Medication Management Plan; three follow up reviews; health outcome data collection.
Tier 2 (Multimorbidity and moderate needs)	AUD 1,372.75	Initial Medication Management Plan; three follow up reviews; health outcome data collection; supporting services (flexible category).
Tier 3 (High risk chronic and complex needs)	AUD 1,642.75	Initial Medication Management Plan; three follow up reviews; health outcome data collection; supporting services (flexible category).

Several PHNs provide or have provided funding to embed non-dispensing pharmacists in general practice in defined regions.[82-84] In February 2020, the Workforce Incentive Program funding stream commenced providing general practices with financial support to employ nurses, Aboriginal and Torres Strait Islander practitioners, allied health professionals, and pharmacists in rural and remote areas. Pharmacists are included in this list for the first time, which means the opportunity exists for general practices to use this funding to support the employment of pharmacists.[81,85]

General practice pharmacists perform a range of clinical and administrative duties related to their expertise in medication use and safety.[86] The services provided by pharmacists in general practice varies between practices, but generally includes:

- Patient-focused activities including resolving medicines use and safety problems, medicines education, medicines reconciliation or improving relationships with other providers including community pharmacists;
- Staff-focused activities including practice staff education sessions and answering medication information queries;
- Practice-based activities including Drug Utilisation Reviews (criteria-based evaluation of drug use to help ensure medicines are used appropriately at the individual patient level) and advice on prescribing according to evidence-based guidelines.[82]

General practice pharmacists provide an opportunity to improve collaborative working relationships between GPs and community pharmacists and provide a link to existing community pharmacy services.[87]

Unremunerated services or a service fee paid by patients

Vaccination services: (community pharmacists deliver a range of vaccinations, primarily influenza, depending on state and territory-based legislation). Community pharmacists have rapidly adopted broader roles in providing immunization services since 2014, in all states and territories since 2016, leading to increased vaccination rates.[88,89] A pharmacist with general registration may administer vaccinations after completing an approved course of training, cardiopulmonary resuscitation, and first aid including anaphylaxis training, and are permitted under state or territory legislation.[88,90]

In all jurisdictions across Australia, trained pharmacists can legally administer vaccinations, but the range of vaccinations and the allowable age of patients varies by jurisdiction. Each state and territory have differing vaccination legislation, regulations and training requirements. For example, under New South Wales regulation and authorization, pharmacists can administer diphtheria-tetanus-pertussis (whooping cough) (dTpa) and measles-mumps-rubella (MMR) vaccines to people aged 16 years and over and privately funded influenza vaccines to people aged 10 years and over.[91] The Queensland Government in February 2020 lowered the age that approved pharmacists to administer the influenza vaccine to people aged 10 years and above, and expanded the range of vaccines (available to persons 16 years and above) to include: dTpa, dTpa in combination with inactivated poliovirus, poliomyelitis, MMR, cholera, hepatitis A, haemophilus influenzae type B, meningococcal ACWY and pneumococcal vaccine.[92]

Currently, trained pharmacists in Victoria, Western Australia and the Australian Capital Territory (but not all states and territories) can administer government-funded vaccines to eligible persons under the National Immunisation Program (NIP).[92,93] The NIP provides vaccines to eligible people at no charge to the patient. The influenza vaccine is available free-of charge under the NIP for people in at risk groups (ie. all people aged 6 months to 5 years (this cohort is newly eligible in 2020), Aboriginal and Torres Strait Islander people aged 6 months and over, people aged 65 years and over, pregnant women, and people aged six months and over with medical conditions that increase risk of influenza complications).[94] There have been calls for a nationally consistent approach and to extend the NIP to allow pharmacists in all states and territories to administer vaccinations under the program.[95,96] With wide public acceptance, and the fact that some consumers are willing to pay for the service even if eligible to receive a vaccination at no cost at their general practice, underpins the need to have these vaccinations easily accessible to ensure greater uptake through all community pharmacies.

Future services

Minor ailment service: Non-prescription medicines are divided into two scheduling categories in Australia: Schedule 2 medicines ("pharmacy medicines") provided under supervision of a pharmacist and Schedule 3 medicines ("pharmacist only medicines") handed out by the pharmacist directly. A trial undertaken in 2018 evaluated a community pharmacist delivered minor ailment service to triage, manage and appropriately refer patients to GPs through agreed pathways. The rationale of the trial was to support community pharmacy integration, standardize practice, and increase the quality and safe use of nonprescription medicines.[57,97,98]

Pharmacist prescribing: Pharmacist prescribing of Schedule 4 and 8 medicines ("prescription only medicines") is not currently permitted. Health professionals who have prescribing rights in Australia, other than medical doctors, include dentists, optometrists, midwives and nurse practitioners.[99] There has been much discussion about expanding prescribing rights to pharmacists. In a position statement released by the Pharmacy Board of Australia in 2019, the Pharmacy Board concluded that under Australian law there are no regulatory barriers to collaborative prescribing which is undertaken alongside medical professionals, or under structured arrangements where pharmacists have limited authorization to prescribe under a guideline or standing order.[100,101] Legislative, regulatory and practice changes are required to allow pharmacists to collaboratively prescribe within health teams under these models. Autonomous prescribing would require additional regulation and would need to be signed off by state and federal governments.[101]

Urinary tract infection prescribing trial: Community pharmacists in Queensland will be involved in a urinary tract infection (UTI) prescribing trial, expected to launch mid-2020.[102] The aim of the trial is for community

pharmacists to provide optimal care to women with uncomplicated UTIs.[102] The rationale of the service is to improve access to care and reduce visits to emergency departments and other health providers.[102]

Continued dispensing: More recently, the Australian Government approved a number of temporary dispensing changes in response to the widespread bushfires and the COVID-19 pandemic.[103] Under strict conditions, pharmacists are able to supply PBS medicines to patients in emergency situations.[104] A patient may receive one supply of their usual medicine without a prescription in a 12-month period at the usual PBS consumer co-payment.[103] Continued dispensing arrangements are in place until June 30th 2020.[103]

FUTURE DIRECTIONS FOR COMMUNITY PHARMACY

Future directions for community pharmacy and pharmacists will be influenced both by economic and professional factors.[46] The national agreement is thought to be a blueprint for professional services and sets out the remunerated roles for community pharmacy. Thus, the next agreement (7CPA) and the Government's 10-year Primary Health Care plan will become the determinant of sustainability for the profession.[46] It is clear that the next five years will be critical to lay the foundation for change that is needed to support further integration of community pharmacy into primary care. Policy and funding support must be included for services that complement and expand integrated models and promote access to services led by or are conducted in collaboration with pharmacists. Generally, more complex services and clinical roles and their associated remuneration structures (such as, accredited pharmacists, pharmacists embedded in general practice and residential aged care facilities) promote integration into primary care and follow up. However, this has the potential to marginalize community pharmacies. Nevertheless, community pharmacists' roles have evolved and pharmacists are being recognized as the medication experts of the health team. Vaccination services have greatly expanded through community pharmacies and are considered to be highly successful, reflecting the reach and accessibility of the pharmacy network. The challenge for the future in Australia will be determining which professional services are envisaged by payers to be delivered via the community pharmacy structure, and which services will be delivered by other types of pharmacists, not linked nor employed by community pharmacies. Interestingly, there is endorsement from consumer associations such as Consumers Health Forum of Australia. Leanne Wells, Chief Executive of the Consumers Health Forum of Australia in 'The future of pharmacy is in the primary care sector' highlights the need for care to be better coordinated and delivered by a cohesive team comprising a GP, nurse and a pharmacist at a minimum with appropriate care from others as needed.[105] In addition, the 2018 Pharmacy Barometer survey of 361 Australian pharmacists showed that community pharmacists reported 'very good' working relationships with GPs, and the majority identified that their opinion and expertise is well respected.[58]

CONFLICT OF INTEREST

None declared.

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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 Spain

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Abstract

From a political and governance perspective Spain is a decentralized country with 17 states [*comunidades autónomas*] resulting in a governmental structure similar to a federal state. The various state regional health services organizational and management structures are focused on caring for acute illnesses and are dominated by hospitals and technology. In a review by the Interstate Council, a body for intercommunication and cooperation between the state health care services and national government, there is a move to improve health care through an integrative approach between specialized care and primary care at the state level. Community pharmacy does not appear to have a major role in this review. Primary health care is becoming more important and leading the change to improve the roles of the health care teams. Primary care pharmacists as the rest of public health professionals are employed by the respective states and are considered public servants. Total health care expenditure is 9.0% of its GDP with the public health sector accounting for the 71% and the private sector 29% of this expenditure. Community pharmacy contracts with each state health administration for the supply and dispensing of medicines and a very limited number of services. There are approximately 22,000 community pharmacies and 52,000 community pharmacists for a population of 47 million people. All community pharmacies are privately owned with only pharmacists owning a single pharmacy. Pharmacy chain stores are not legally permitted. Community pharmacy practice is based on dispensing of medications and dealing with consumer minor symptoms and requests for nonprescription medications although extensive philosophical deep debates on the conceptual and practical development of new clinical services have resulted in national consensually agreed classifications, definitions and protocolized services. There are a few remunerated services in Spain and these are funded at state, provincial or municipal level. There are no health services approved or funded at a national level. Although the profession promulgates a patient orientated community pharmacy it appears to be reluctant to advocate for a change in the remuneration model. The profession as a whole should reflect on the role of community pharmacy and advocate for a change to practice that is patient orientated alongside the maintenance of its stance on being a medication supplier. The future strategic position of community pharmacy in Spain as a primary health care partner with government would then be enhanced.

Keywords

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

INTRODUCTION

From a political and governance perspective Spain is a highly decentralized country organized around 50 provinces in 17 States [*Comunidades Autónomas*], and two Autonomous cities, resulting in a governmental structure similar to a federal state. Spain has a population of 47 million people with its gross domestic product (GDP) in 2019 of EUR 1,244,757million (EUR 26440 per capita). The Spanish health care system is organized through a public National Health System (NHS) model financed through general taxes. Health care is provided through a network of hospitals and primary care health centers offering a broad portfolio of services with no-copayments except for medicines.[1] Expenditure in public health care is 6.4% of its GDP with the public health sector accounting for the 71% and the private sector 29% of this expenditure. The private sector is increasing, with almost 20% of the population having private insurance.[1]

In 2018 total health care expenditures according to Health Ministry was EUR 105,000 million/year (9.0% GDP and EUR 255/pp) distributed in public health care costs of EUR 74,000 million/year (6.4% of the GDP and EUR 1594/pp) and private care costs of EUR 31,000 million/year (2.6% of the GDP and EUR 662/pp). Expenditures in the public health care was distributed in hospital care (63%), primary care (14%), community pharmacy (17%) and others (6%). The cost of prescription medicines in community pharmacy, financed by the government public health system, was EUR 12,000 million.[2]

The Interstate Council [*Consejo Interterritorial*] is a body for intercommunication and cooperation between the state health care services and national government with objective of ensuring cohesion of the system and guaranteeing citizens' rights in the whole country.[3] Each state has its own health ministry [*consejería de salud*] and these are linked to the national Ministry of Health.

The responsibility for health matters is fundamentally transferred from the National government to the states. The National government retains the responsibility of registering medications and setting the price of medications and defining common set of health services to which all the population is entitled. These health services are defined in the Common Services Portfolio of the National Health System [*Cartera Común de Servicios del Sistema Nacional de Salud*] which is subdivided into three sections. One of them, Supplementary Common Portfolio [*Cartera Común Suplementaria*], includes the dispensing of

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medicines. Importantly there are no pharmaceutical services incorporated in any of the lists.[4]

Primary health care

The Spanish National Health System, due to its decentralized structure and management, faces challenges. The system is structurally focused to care for acute illnesses and thus is dominated by hospitals and technology. However, there is generally acceptance that there is need to evolve due to changes in social need, such as aging, polypharmacy patient, frailty and vulnerability of the population. Defragmentation of the healthcare delivery has led to the development of 17 separate and different regional health services.[5] However, there is a move to improve health care through an integrative approach between specialized care and primary care at the states level. The common objective is to work towards a new management model, more horizontal and organized around patients with chronic illnesses.[1] The system currently suffers from 17 different approaches using different terminologies.[6]

In 2018, the Interstate Council commenced a consultative process to design a "Community and Primary Care Strategic Framework".[7] State representatives, health care professionals, patients and users were invited to participate with the aim of improving health care and advance the strengthening and leadership of primary health care. The Ministry of Health has agreed with the Interstate Council proposal to progress towards a more integrated, equitable and efficient primary care.[8] There is a sense that primary health care progressively needs to take the lead, assuming a greater importance in the health care system.

According to the report, primary care has disproportionately suffered from the impact of the 2008 economic crisis and austerity politics, negatively affecting the approximately 13,000 primary care health centers. Primary health care is organized in various ways within states using different terminology and management structures although there is a commonly, smaller geographical areas usually called basic health zones [*zonas básicas de salud*].[9] Health centers are where basic–primary health care is provided through "primary health care teams", composed of family physicians, pediatricians, gynecologists, nurses, primary care pharmacists, assistants and support administrative personnel. All heath care professionals are employed by the respective states and are considered public servants.

There are around 750 primary care pharmacists, although they are not always located in health centers and not widespread. Their role is to improve safety, effectiveness and efficiency in the use of medicines and medical devices both at an individual or population level. Primary care pharmacists hold a strategic position being able to coordinate and guaranteeing pharmacotherapy continuity along the system and direct patient care activities are included in their job profiles.[10] However, the direct patient services for these primary care pharmacists is very limited and only occurs in few locations. In the short term, primary care pharmacists are expected to coordinate the development of multidisciplinary protocols to guarantee pharmacotherapy continuity including medication reconciliation in care transitions. Currently, there is limited collaboration between primary care pharmacists and community pharmacy and there is no policy guiding this collaboration and it tends to be episodic and sporadic. Primary care pharmacists could extend this coordination with the establishment of collaboration protocols between primary care teams and community pharmacy for medication reconciliation, pharmacotherapy optimization, improvement of medication safety and effectiveness, adherence improvement and reduction of inappropriate use of medicines. The potential for extensive collaboration has not been explored strategically nor operationally.

Spanish community pharmacy

To practice as a pharmacist there is a need to complete a five-year university degree resulting in the award of Master of Pharmacy (MECES Level 3) meeting European Union regulations.[11] In addition, to work as a pharmacist dealing with patients in any setting, it is compulsory to register in a Province Pharmacists' Association [*Colegio Provincial de Farmacéuticos*]. These Provincial Pharmacists' Associations are members of a national professional association called General Council of Province Pharmacists' Associations [*Consejo General de Colegios Oficiales de Farmacéuticos*] which tends to act as the major professional organization dealing with central government.[12]

There are a number of other organizations which represents pharmacy owners [*Federación Empresarial de Farmacéuticos Españoles*] or employees (Unions and a new technicians Federation is under way).There is also the Spanish Family and Community Pharmacy Society (SEFAC), a scientific society which is enthusiastically involved in promoting clinical activities in community pharmacies and has achieved a good relationship with family physicians associations.

There are approximately 22,000 community pharmacies in Spain with an average of 2,117 people per pharmacy the lowest ratio in the European Union after Greece.[13,14] All community pharmacies are privately owned with only pharmacists owning a single community pharmacy, although more than one pharmacist may jointly own a pharmacy. Pharmacy chain stores are not legally permitted. The establishment of new pharmacies is controlled by the state governments based on two criteria: population per pharmacy and distance from another existing pharmacy. The minimum population allowed for opening a new pharmacy range from 700 to 2,500 in states. The minimum distance between the new pharmacy and an existing one ranges from 150 to 250 meters.[15] In 2018, there were more than 74,000 registered pharmacists of whom approximately 52,000 work in community pharmacy.[13] There is an average of 2.4 pharmacists per pharmacy. The technician workforce is estimated to be around 31,000.[16]

In 2019, the average turnover of a community pharmacy was EUR 911,740, coming 71% from medicines and 29% from consumer health products. The average net margin before taxes for a community pharmacy was around 10%.[17] The staff pharmacists' salary is usually between EUR 25,000 and EUR 35,000 per year.[18] Community pharmacy national medication sales in 2019 were estimated to be EUR 15,636 million corresponding to 1,359 million units. Consumer

Table 1. Classification of Community Pharmacy services [*servicios asistenciales*] in community pharmacy agreed by Foro AF-FC

Pharmaceutical Care Services	Community health related services
Dispensing	Health promotion
Minor ailments	Health education
Reconciliation	Health prevention including screening
Adherence	Measurement of clinical parameters
Home first-aid kit	Nutritional advice/counselling
Compounding	Syringe-exchange program
Medication review	Smoking cessation
Medication information service	

health products accounted for EUR 6,068.6 million corresponding to 557.5 million units. Medications are exclusively sold in community pharmacies.

Community pharmacies are reimbursed by government at a margin of about 28% of the pharmacy fixed retail price. The price of medications is fixed by the national government making it common to all states. This is one of the primary responsibilities of the national Government.

COMMUNITY PHARMACY SERVICES

A national Law 16 passed in 1997 covers specific matters related to community pharmacy and is in addition to Common Services Portfolio of the National Health System.[19] The main service in Law 16 covers the distribution and supply of medicines. This law also makes it compulsory for all Spanish pharmacies to provide patient counseling services, medication review with follow-up (detecting, preventing, solving negative outcomes of pharmacotherapy), compounding, and pharmacovigilance (adverse drug reaction reporting system). However, despite this law community pharmacy practice is much the same as prior to the law being enacted, with an emphasis and focus on dispensing of medications and dealing with consumer minor symptoms and requests for nonprescription medications.

An important advance in defining direct patient services was made in Spain with the publication of a national "Consensus on Pharmacy Services". This statement came from an expert panel which met in 2001 under the guidance of the Ministry of Health.[20] The consensus identified and defined three main services to be provided: dispensing, minor ailments scheme, and medication review with follow up. Dispensing was defined to include the provision of the medication with advice to ensure patient knowledge and adherence with treatment. Minor ailments service covered assisting the patient to choose the appropriate nonprescription medication for minor ailment and, if necessary, referral to the physician. Medication review with follow up covered monitoring a patient's pharmacotherapy to identify, detect, and prevent negative clinical outcomes. To follow up on these definitions a national group called Pharmaceutical Care Forum was established with the support of the Ministry of Health in 2004. This group confirmed the previous consensus, and went onto developing service protocols for these three services. It counted with the participation of different partners, and published a new Consensus on Pharmaceutical Care.[21] In 2009, following the completion of the work, a Pharmaceutical Care Forum in Community Pharmacy [Foro AF-FC] was established with the following participants in: General Council of Province Pharmacists' Associations, the Spanish Family and Community Pharmacy Society, the postgraduate pharmacy practice group of the University of Granada and the Spanish Pharmaceutical Care Foundation. From 2012 to 2018, the Clinical Pharmacy and Pharmacotherapeutic Unit at the University of Barcelona and since 2018, representatives of the Spanish Pharmacy Deans Conference. This Forum has updated definitions and described, classified and developed various services and protocols for community pharmacy services (Table 1).[22,23]

In summary, the above-mentioned process has meant the pharmacy profession has had extensive philosophical deep debates on the conceptual and practical development of new clinical services resulting in national consensually agreed classifications, definitions and protocolized services. However, the practical application to usual day practice has been limited with only the passionate, enthusiastic and motivated pharmacists taking up the mantle of providing services. Even in this group, it has been to a limited number of patients and intermittingly, probably attributed to the lack of remuneration.

In addition to the above-mentioned process, research has been conducted by various Spanish research groups showing that some pharmacy services can achieve positive outcomes measured by the ECHO model. Medication review with follow up service using the Dáder Method has been the most studied service.[24-26] The conSIGUE Program, promoted by General Council of Province Pharmacists' Associations, has studied the impact and implementation of MRF service.[27] The impact and implementation of Adherence services in community pharmacy, also promoted by the General Council, had been investigated and continues under research.[28,29] SEFAC is also promoting research, having participated in an international project and undertaken research such as INDICA+PRO evaluating the impact and the implementation of a minor ailment service co-designed with GPs.[30,31]

Remunerated services at a state level

There are a few remunerated services in Spain and these are funded at a states, provincial or municipal level. For all these services or programs, a form of accreditation by providers is required.

Methadone supply is quite a common service having started in the Basque country in 1995, Cataluña and Aragon (1998) and extended to other 7 states. Remuneration ranges from EUR 54 to 67 per patient/month. In the Basque country there are 890 methadone patients.

HIV testing which started in the Basque Country in 2009 and has been subsequently implemented in Cataluña, Baleares islands, Cantabria and Castilla y León. Patients pay EUR 5, except for Cataluña where the patient pays EUR 10,

community pharmacy receiving from the administration a payment between EUR 10 and 18 per test. In addition, since 2014 in the Basque country a syphilis test is performed to men who have had sex with men. To date 24,602 HIV tests had been performed (since 2009), 2,284 syphilis tests since 2011.[32]

In Cataluña, remunerated services include colorectal cancer screening (EUR 1 per test and EUR 10 monthly practice allowance).[33] Patient group educational program on use of medications are also remunerated. Although a sentinel pharmacy pharmacovigilance program is undertaken in Madrid, Castilla Leon, and Asturias with no payment, in Cataluña it is remunerated with approximately 100 participant pharmacies receiving a practice allowance of EUR 1,000 per year.

In the Basque country there are other drug addiction related programs such as state financed anti-HIV kit (containing a new syringe, a preservative, a small towel, sterile water and a small container to prepare the mixture). From 1997 to 2017, 4.66 million kits have been sold at a pharmacy charge to the patients of EUR 1. Additionally, there is also a syringe exchange program, paid by the state at no cost to the patient. In one of the provinces of the Basque country there were 18,046 syringe exchanges during 2018.[34]

Dose administration aids (DAA), preparation of multicompartment compliance aids, are very common in Spain although, in general, pharmacies do not charge or charge a token amount (around EUR 10 per month). There are some examples of agreements for DAA services between town councils and local pharmacies.[35] The first such program was a social-health program, remunerated at EUR 31.63 patient/month, in the Basque country. Eligible patients are part of a municipal social services program. The service is provided by community pharmacies and is paid by the state health ministry.[36]

In Valencia there is a "directly observed treatment" service, mainly for tuberculosis treatments, which consists of patients taking their medications in the presence of the pharmacist who certifies the action.[37] This service is being reimbursed at EUR 56.06 patients per month), covering all observed treatments requested by physicians.

Most Spanish pharmacies subscribe to a drug-waste collection system (SIGRE) in response to European Directive 94/62 governing container management.[38] This service is also free, financed by pharmaceutical companies and use the wholesalers to manage logistics of discarded medicines. In 2019, 102.84 g per person and year were recycled what means an increase of 16.12% since 2015.[39]

Professional organization strategic plans

There are no detailed strategic plans from the professional organizations. Although general statements of the future of the profession are made by professional organizations and there is an apparent national, state and local consensus that the future of community pharmacy and pharmacist lies in patient orientated services. The development of a strategic plan for community pharmacy 2020-2030 had been announced by the General Council to be presented in 2020; however, no information is yet available.

Since 2019 the General Council of Province Pharmacists' Associations, has had a promoting and marketing campaign using new branding for the profession "We are Pharmacists, We are Patient Carers, We are Socially Orientated, We are Digital" [*Somos Farmacéuticos, Somos Asistenciales, Somos Sociales, Somos Digitales*]. A significant amount of resources is being devoted to the development and use of technology concentrating mostly of the projects around a Nodofarma project. Nodofarma is an electronic platform whose an objective is to facilitate the transformation of the community pharmacy profession. The platform, which is an attempt to link the 22,000 community pharmacies, is composed of a series of interconnected services. Programs such as SEVeM (Spanish branch of EMVO) to identify and avoid dispensing counterfeit medicines, CISMED to analyze in real time medication shortages, validation of private prescriptions both paper and electronically produced, and Nodofarma Asistencial (a networking system to help pharmacists implement the nationally agreed professional services). Some Province Pharmacists' Associations have their own platforms (i.e. Seville, Valencia) that are envisaged to be integrated or interoperable with Nodofarma in a near future.

Concurrently the Spanish Community and Family Pharmacists Association (SEFAC), has developed and offers its members a service practicing oriented platform called SEFAC-eXPERT which provide community pharmacists with information technology based service programs and protocols. Interestingly at the moment, there is no coordination between these two major organizations around those projects and there appears to be a competitive approach.

CHALLENGES TO THE INTEGRATION OF COMMUNITY PHARMACY

Perspective from the pharmacy organizations

Despite much debate over the last 10 years with respect to the implementation and universality of patient-oriented services from community pharmacy, it is reasonable to conclude that most of the barriers remain unresolved and the implementation of services has not been established in a universal way in community pharmacy.[40] Critically there is lack of payment for services which with a number of other factors is essential. Significantly, there appears to be a lack of advocacy from the majority of the leadership for changes to the current remuneration system and this continuous to be a critical factor delaying the implementation of services. It is acknowledged that implementation and sustainability of services requires profitability, with this issue not seeming to be a priority for professional leaders. Nevertheless, the discourse of professional pharmacy organizational leaders has changed and at present, they are publicly promoting and defending a more clinical and patient oriented practice through service implementation. This discourse, however, is not being followed by a change in usual practice by ordinary community pharmacists.

There is a perception that practicing community pharmacists may not yet have a clear understanding of the required practice change when researchers and strategists talk about a shift from a product to a patient-oriented

practice. The political climate of professional pharmacy organizations, associated with the facilitation for the provision of services, is limited to having a consensus on national priority services and to providing excellent technology to provide the services. Research has shown that service implementation needs well defined services, and implementation programs that entails implementation indicators and the support of practice change facilitators with remuneration to succeed and be sustainable.[27,29,31,41,42,43] Most of the General Council of Province Pharmacists' Associations and other pharmacy organizations efforts to change the current practice of community pharmacy are based on strategies that support research, educational actions and technology but not the critical element of remuneration that might be the catalyst for the change of practice.

Perspective from the health authorities

Community pharmacy is seen as an external element to the system, a private actor and external contractor in a system controlled and managed by public authorities. The external contractual relationship of community pharmacy, in a health care system, that most other health care professionals in primary care are employees of the states leads to a perception that community pharmacists are mainly product providers. Nevertheless, there is a recognition that pharmacists are health care professionals, well distributed around the country and with a great potential. Governments, at different levels, when developing policies appear to only have limited consideration of the value-add of community pharmacy services. At the same time, some administrators and health care professionals embedded in the health care system are influenced and focus on the commercial elements of community pharmacy. They may not be aware or reject the potential role of community pharmacy in optimizing healthcare outcomes for individual patients and the population. It appears that in a competitive environment for resources, the economic arguments associated with community pharmacy services are rejected.

Perspective from the other health care professionals

In the recent past, there have been some controversies around nursing profession and community pharmacist practicing pharmaceutical care. The nursing profession was advocating that certain roles around medication such as medication reviews and adherence would be best delivered by them. However, at present interprofessional relationships have improved and there are good interactions and collaboration between pharmaceutical organizations, such as the General Council of Province Pharmacists' Associations, SEFAC and some medical scientific associations. From a corporative point of view there are good relationships with the General Councils of medical practitioners and dentists with a number of agreements including dealing with electronic private prescriptions. The relationship with some GPs associations is excellent and there is a yearly conference between SEFAC and the Spanish Society of Primary Care Physicians (SEMERGEN).[44] As an example, a statement in collaboration with the Spanish Society of General and Family Physicians (SEMG) and SEMERGEN entitled "COVID-19. Problems and solutions in Primary Care and Community Pharmacy" has been released.[45]

Perspective from the patients

Patients in Spain report being very satisfied and comfortable with the current pharmacy service as their expectations and needs are being apparently met. Patients are generally unaware of the need for professional services so their current expectations are fully met.

Future

The future integration of community pharmacy in the Spanish healthcare system can be said to be dependent on several critical factors. These factors include:

• The development of the strategic review of primary care in Strategic Framework for Primary and Community Care [*Marco estratégico para la Atención Primaria y Comunitaria*] provides an opportunity for community pharmacy to be integrated in primary care. The integration of community pharmacy in the system needs to be an element of the strategic direction for primary care.

• The enhancement of the role of primary care pharmacists in the collaboration and coordination of community pharmacists. Integration with the rest of the health care team would be essential.

• The inclusion of community pharmacy services in the Common Services Portfolio would ensure that these services are provided to population in all states

• Following the discourse on the importance of patient orientated services from community pharmacy by pharmacy political leaders at the state level should be focused on the value add and the need to implement remunerated services.

• The profession at all levels commences advocating for the remuneration of community pharmacy services.

• The enhancement of the positive relationship between Spanish General Council and SEFAC with primary care medical practitioners' associations.

Although a number of these factors are external to the profession, the major emphasis should be on ensuring that the profession as whole reflects on the role of community pharmacy and advocates for a change to a practice that is patient orientated alongside the maintenance of its stance on being a medication supplier. The future strategic position of community pharmacy in Spain as a primary health care partner with government would then be enhanced.

CONFLICT OF INTEREST

None declared.

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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 Lebanon

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Abstract

Within a crippling economic context and a rapidly evolving healthcare system, pharmacists in Lebanon are striving to promote their role in primary care. Community pharmacists, although held in high esteem by the population, are not recognised as primary health care providers by concerned authorities. They are perceived as medication sellers. The role of the pharmacist in primary health care networks, established by the Ministry of Public Health (MOPH) to serve most vulnerable populations, is limited to medication delivery. The practice of the pharmacy profession in Lebanon has been regulated in 1950 by the Lebanese Pharmacists Association [Order of Pharmacists of Lebanon] (OPL). In 2016, the OPL published its mission, vision, and objectives, aiming to protect the pharmacists' rights by enforcing rules and procedures, raise the profession's level through continuous education, and ensure patients' appropriate access to medications and pharmacist's counseling for safe medication use. Since then, based on the identified challenges, the OPL has suggested several programs, inspired by the World Health Organization and the International Pharmaceutical Federation guidelines, as part of a strategic plan to develop the pharmacy profession and support patient safety. These programs included the application of principles of good governance, the provision of paid services, developing pharmacists' core and advanced competencies, generation of accreditation standards for both community pharmacy and pharmacy education, suggesting new laws and decrees, continuing education consolidation and professional development. There was an emphasis on all decisions to be evidence assessment-based. However, OPL faces a major internal political challenge: its governing body, which is reelected every three years, holds absolute powers in changing strategies for the three-year mandate, without program continuation beyond each mandate. Within this context, we recommend the implementation of a strategic plan to integrate pharmacy in primary health centers, promoting the public health aspect of the profession and taking into account of critical health issues and the changing demographics and epidemiological transition of the Lebanese population. Unless the proposed blueprint in this paper is adopted, the profession is unfortunately condemned to disappear in the current political, economic and health-related Lebanese context.

Keywords

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

BACKGROUND

Lebanon, a developing Middle Eastern country situated to the Eastern side of the Mediterranean Sea, is currently undergoing demographic changes. In 2012, the Lebanese population was estimated at 4.5 million and by 2017 had reached 6.5 million. This increase was related to the inflow of Syrian refugees upon the declaration of war in 2012.[1] According to the World Bank, 24% of the population is below 15 years of age, and 8% above 65 years of age, which indicates that almost half of the population is active, with an age dependency ratio of 47%.[2]

The country is also facing public health challenges: the fight against non-communicable diseases (85% of the burden of disease), the lack of health promotion across the life cycle, and the establishment of health preparedness and surveillance systems.[3] Although Lebanon is an upper-middle-income country, the healthcare system is struggling due to several events the country has endured. The civil war (between 1975 and 1990), the Syrian interference (1991-2005), the Israeli war and its consequences. The Syrian refugees' influx has led to an unprecedented economic crisis.[4] Coupled with mismanagement at the political level, instability and financial crises were followed in December 2019 by the COVID-19 pandemic, which added to the collapse of the Lebanese economy.[5]

Within a struggling and rapidly evolving healthcare system, the pharmacists are striving to promote their role in the community and the hospitals; the clinical aspect of the profession still needs to be established. On another hand, collaboration with the pharmaceutical industry has a legal framework that is limited to trade and product sales, while regulations related to ongoing marketing and research activities are missing. To date, pharmaceutical products managed by pharmacists are considered goods for the median to high socioeconomic levels populations, while the poorest categories acquire their medications through institutions where non-pharmacists manage medications procurement, storage, distribution and administration, mainly through charity and a public network of primary healthcare centers (mainly dispensaries).

PRIMARY HEALTHCARE IN LEBANON

According to 2016 WHO data, the total Lebanese population estimated at 6 million spends 6.4% of the GDP on health – 47.6% from public funds, 36.4% from out-of-pocket payment, and the rest (16%) from private insurance companies. Importantly 5.2% of households experience catastrophic health expenditure.[2,6] The Lebanese healthcare system relies primarily on the private sector that

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represents 80% of hospitals and 68% of primary health centers (PHC) owned by non-governmental organizations, religious instances, and political parties. Thirty two percent of PHC are owned by the government. The public sector serves the lower socioeconomic status vulnerable populations and refugees, through its hospitals and primary healthcare network.[7] It is noteworthy that during the COVID-19 crisis and as of February 2020, the public sector was more involved in patient screening and treatment, with the objective of implementing a long-term expansion strategy, such as the provision of public hospitals with modern equipment, the restructuring of their human resources and the renovation of their buildings. However, public health coverage for all the Lebanese population is far from being achieved. Despite the presence of the social security fund, private insurance companies, and some additional private/public funds, a substantial percentage of the population is only entitled to secondary and tertiary care Ministry of Public Health (MOPH) coverage.[2] Thus, health coverage for the poorest is not always possible, given the economic difficulties that have been drowning the country in debt. The government covers the healthcare cost of non-insured populations in private institutions, thus playing the role of a third-party payer and currently owes the private health sector institutions millions of dollars.[8]

In line with WHO, the Lebanese the Ministry of Public Health (MOPH) defines PHC as "the essential health care, made available in a comprehensive way for individuals and families in the community, to access with affordable costs. Primary health care is considered the core of the health system, and is based on the principles of justice, equality, and rational use of resources".[8] Nevertheless, the reality differs from that axiom, given the Lebanese healthcare system is oriented towards curative care. MOPH only allocates 5% of its budget to preventive PHC services: The government supports a national network of PHC centers to provide reduced-cost consultations and free chronic medications and vaccines to beneficiaries all over Lebanon.[7,9,10] Six hundred dispensaries related to the private sector (NGOs, religious and political instances) and a network of 226 public PHC centers, PHC centers do not report standardized national indicators, but plans are underway to establish those indicators. Indicators of success are only available for the 17 public owned centers accredited in 2011 by the Canadian accreditation agency.[8,11]

The PHC strategy of the MOPH includes several programs: communicable diseases, immunization, mother and child health, nutrition, environmental health, non-communicable diseases, health awareness, and essential medication. Each program has its administration, strategy, and objectives. Moreover, the MOPH implements health promotion at schools and plans towards a whole social and health program in collaboration with the Ministry of Education and Higher Education, the Ministry of Social Affairs, the Ministry of Interior, and the United Nations Development Program.[12] The most striking challenge reported by the government is the unprecedented burden of the refugees on the PHC network. The low-income category of the Lebanese population represents 44% of primary care beneficiaries, while the rest are Syrian refugees and other nationalities (56%).[2] The overcrowded centers and the increase in waiting times for consultation resulted a drop in the number of Lebanese population subjects attending these centers. Consequently, the World Bank launched in July 2015 the Emergency Primary Healthcare Restoration Project (EPHRP), to re-establish the ratio of Lebanese versus other nationalities visiting the PHC centers: The projects aim to deliver a package of essential healthcare services to 150,000 vulnerable Lebanese in 75 selected PHC centers.[13]

Role of the pharmacist in the PHC in Lebanon

Pharmacists in Lebanon play an important role in the provision of primary care in the community.[14] Nevertheless, the income of community pharmacists is linked to the products' price and not to the service they provide, which does not serve the image they wish to portray to policy makers and MOPH leaders. In parallel to this unfortunate image of "medication seller" in the community and hospital settings, some pharmacists have managerial positions in the public sector and play a major role in the regulatory aspects of medication approval and importation conducted by the MOPH. However, the role of these managers in the PHC strategy is minor because they work in a different department. The MOPH restricts the role of pharmacists in PHC to medication supply and mandates the use of generic medications in the centers to alleviate the high cost of pharmaceuticals on households, government, and insurers. In addition, the essential medications program related to PHC, only involves pharmacists working in the public sector who constitute 2% of Lebanese pharmacists.

Nevertheless, according to the Lebanese general population, community pharmacists play an important role in primary care.[14] A study including 1070 participants demonstrated that the majority (85%) believed that community pharmacists were responsible for their health security and medication safety, while only 30% thought that the role of community pharmacists was limited to dispensing medications. Important only 33.4% trusted the services provided by PHC centers/dispensaries as 65% of participants thought that PHC personnel lack appropriate qualifications. When asked about the quality of medications, 68% of respondents showed trust in medications available in community pharmacies, compared with 34.4% in medications from dispensaries in PHC.[15] They are counseling patients about their chronic and infectious diseases, medication-related matters and nutrition, flu vaccination, treatment of a minor ailment with over-the-counter medications, and are providing services to patients such as monitoring blood pressure and glycemia.[16] Although these services are not required by the law, patients' expectations in Lebanon are high in this regard, and counseling is given at the discretion of the pharmacist, with much variability in practice, depending on the patient insistence, the pharmacist time and willingness.[14]

STRATEGIC STATEMENTS FOR THE PHARMACY ORGANIZATION IN LEBANON

The regulation of the pharmacy profession started in Lebanon in parallel with pharmacy academic teaching 17, and the implementation of several laws were deemed necessary following the increasing number of pharmacy graduates over the years, whose numbers and quality was

only controlled by academic institutions. In 1950, the Lebanese Pharmacists Association [Order of Pharmacists of Lebanon] (OPL) – the only official pharmacists' association in Lebanon – was established, and it was not until 1994 that a second law (367/94) addressed the practice of the pharmacy profession in the country (rules for registration and practice).[17] To practice the profession of pharmacy in Lebanon, registration at the OPL is mandatory. However, the OPL does not differentiate between different pharmacy specialties.

In 2016, the OPL published its mission, vision, and objectives. The aim was to protect the pharmacists' rights by enforcing rules and procedures, raise the profession's level through continuous education, and ensure patients' appropriate access to medications and pharmacist's counseling for safe medication use.[18] The OPL pursues a new vision of implementing the Nine Star Pharmacist role in Lebanon for the pharmacy profession, based on the WHO/FIP.[19] It collaborates with many stakeholders, the Ministry of Public Health (MOPH), the Ministry of Education and Higher Education (MEHE) and universities, to achieve these goals. However, the OPL faces a major internal political challenge: its governing body, that holds almost absolute powers in changing strategies, is reelected every three years based on a program and priorities for the short term 3-year mandate, without system continuation beyond each mandate. This does not always serve OPL's mission and vision, particularly if the successive mandates do not share a common vision for the profession or have the same priorities.

Community pharmacy in Lebanon

According to the latest available OPL list (December 2017), a total of 3,762 community pharmacists (employers and employees) practice in 3,157 pharmacies across the Lebanese territory. National laws and regulations allow each registered pharmacist to own one community pharmacy. Pharmacies are the only for-profit organization allowed to sell prescription and non-prescription drugs. The ratio of pharmacies in Lebanon per 10,000 inhabitants is 66.06, a high number compared to the worldwide mean, with unbalanced distribution across geographical governorates [Mohafazat] with the highest concentration being in Mount Lebanon and lowest in Beirut.[20] This distribution of community pharmacies is regulated by law with the opening of a new community pharmacy being dependent on: (1) a minimal distance of 300 meters is mandatory between two pharmacies as per the OPL Decree No. 2622 regardless of the population density; (2) the pharmacist should be the sole owner of the pharmacy without any partners, and should not have any other source of income, except for part-time academic teaching; (3) a licensed/registered pharmacist must be present at all times in the pharmacy during opening hours according to both OPL and MOPH laws.

Despite the presence of a strict legal framework, community pharmacists suffer from a substantial decrease in quality of life, which is the natural consequence of daily challenges they are facing, a gradually decaying national economy, high workload in some locations, medications pricing fixed by the government and financial difficulties preventing them from hiring assistants, in addition to demanding patients who expect the pharmacist to play the role of a primary healthcare professional.[14,20,21]

Pricing of medications

Pharmacy profit is directly linked to the total medications' sales, applied for both prescription and non-prescription medications. The remuneration model consists of a fixed percentage of the selling price is allocated to the pharmacist and a small fixed amount (less than half a US dollar per medication). The selling price of all medications in community pharmacies in Lebanon is set by MOPH regulation. MOPH updated the pricing strategies in 2006, and 2014, decreasing dramatically the selling price of most medications, and consequently a fall in the net pharmacy profit.[3] In 2006, the MOPH reviewed the 23% fixed percentage of profit allocated to pharmacists and divided medications in four pricing categories (A, B, C, and D) according to the FOB (Free on Board) importation price or equivalent in CIF (Cost, Insurance, and Freight), while allocating a different percentage of profit for each category. Moreover, medications with FOB over 100 USD, previously categorized as A, were classified as category D, and their profit margin decreased significantly. In 2014, MOPH updated the category D to include only the medications with prices ranging from 100 to 300 USD FOB and added a new category E to include medications with prices above 300 USD FOB with a fixed profit of 86 USD, irrespective of the fees and taxes the community pharmacies have to pay 22. Since this margin of profit is insufficient to cover for community pharmacies' expenses and taxes, the majority stopped selling this category of medications.[23] The margin of profit directly impacted (overall 18.4% in 2017) is projected to hit 9.9 % by 2047, according to the OPL estimates.

It should be noted that pharmacists are not compensated for the counseling services they provide at the community pharmacies.

Current challenges of community pharmacy in Lebanon

Based on the above-mentioned key points, community pharmacy in Lebanon has several challenges to overcome:

- The increasing number of graduated pharmacists and over-crowding of community pharmacies in some regions, resulting in unethical competition and practices to attract customers and increase market share.
- The lack of recognition of specialized pharmacists at the OPL and the MOPH levels, which does not encourage new graduates to pursue further studies and ultimately provide higher-level service.
- Financial difficulties and impossibility to hire assistant pharmacists leading to lower service quality, overwhelming of pharmacists, and subsequent burnout.

OPL agenda

In December 2015, based on the challenges and difficulties, the OPL-suggested several programs as part of a strategic plan to develop the pharmacy profession and support patient safety. These programs were inspired by the World Health Organization (WHO) and the International Pharmaceutical Federation (FIP) guidelines and are part of both pharmacist- and patient-related professional and

clinical governance principles. They included the application of principles of good governance, the provision of paid services, developing pharmacists' core and advanced competencies, generation of accreditation standards for both community pharmacy and pharmacy education, suggesting new laws and decrees, and continuing education consolidation and professional development. There was an emphasis on all decisions being research and assessment based.[17]

Application of the principles of good governance

In 2015 the OPL adopted various forms of governance national, general, political, corporate, clinical, and educational. It was the modern approach for the OPL board and scientific committee to apply its strategy and reach its goals.

Educational Governance includes all processes and structures related to the performance, effectiveness or responsibility of educational activities and programs with reporting to a program board, learning needs analysis, risk assessment, peer review, and educational analysis. In cooperation with academics, the OPL is focusing on certain educational topics directly related to the pharmacy field. The key consideration of pharmacists is the university curriculum due to its immediate effects on technical competencies and clinical governance. By suggesting new legislation, coupled with clinical competencies for graduates and for preceptors, the objective is for health care practitioners to increase the efficiency of their graduate and postgraduate programs, and establish strong levels of patient treatment.[24,25] Continuing professional growth, auditing (laws, accountability, and transparency), risk assessment, evidence-based practice, research, and development are part of the process.

Remunerating of services

The OPL started to implement the transition in pharmacist roles by introducing electronic systems such as the electronic patient profile with medication therapy planning, pharmacovigilance and medication safety system and the forum for medication shortage.[26,27] A memorandum of understanding is currently under development to be signed between the different parties involved such as OPL, MOPH, and third-party payers. These electronic networks are anticipated to enhance patient care delivery.[28] The OPL is also negotiating with the authorities concerned, MOPH in particular, to update the payment process of the community pharmacist (fees per service, in addition to the small profit per medication), similarly to developed countries.[29]

Developing pharmacists' core and advanced competencies

In Lebanon, there is a clear oversupply of pharmacists, especially those with no specialization (no post graduate qualifications). Working in conjunction with academic institutions and concerned authorities, there are efforts to curb the rapid growth of graduates' numbers and pharmacy students' enrollment are being made.[30] In parallel, discussions are underway to adjust the graduate pharmacist profile to include international accepted competencies for improved employability.[31] The OPL has developed and disseminated the structure of core competencies for entry-level pharmacists, as proposed by the FIP, the WHO and other organizations.[32,33] Specialized competencies for professional pharmacists are also being developed. These changes will require the academic syllabi to be tailored to international requirements and local needs, and are expected to enhance the graduate experience in the learning environment, leading to the graduation of practice-ready pharmacists.[34]

Accreditation standards

The OPL is working to create and implement accreditation standards for community pharmacies to guarantee the quality of services given, and others specifics for academic institutions to boost the pharmacist's education.[35,36]

New laws and decrees suggestions

The OPL has recommended additional legislation by parliament to cover prescription procedures in hospital and community settings. The introduction of standard operating procedures and prescribing instructions for both the prescriber and the pharmacist have been submitted to the relevant authorities and are consideration..

Continuing education consolidation and professional development

Currently, the OPL is promoting the compulsory continuing education legislation (number 190, November 2011) and is seeking to enroll pharmacists from all specialties in continuing education.[37-39] Converting continuing general education sessions into relevant continuous professional development is ongoing. The OPL organizes special sessions for hospital pharmacists to support pharmacists' in the ongoing hospital accreditation endeavor.[40-42] Sessions, geared towards the acquisition of soft skills, are offered for community pharmacists, particularly in the areas of communication, management, and leadership.[43,44] In addition to the scientific dimension, there is a focus on the public safety element of community pharmacy (patient awareness and promotion, dental treatment, vaccine, and fighting antibiotic resistance).[45-47]

INTEGRATION OF COMMUNITY PHARMACY IN PRIMARY HEALTH CARE SYSTEM

Currently there is little or no integration of community pharmacy in the Lebanese primary health care system and the MOPH program. Community pharmacy faces many challenges. To overcome these challenges a bold agenda is required with the OPL board prepared to accept and promote strategies which will enhance the profession (Table 1).

To integrate community pharmacy and community pharmacist role in the MOPH PHC program, the following key issues need to be considered and included in the strategy of the upcoming OPL board:

- Establish a clear strategic plan with clear steps for the integration of PHC and community pharmacy. It would be necessary to generate appropriate policies and procedures to include: a legal framework, the preparation and implementation of bold and innovative practice programs, such as participation of community pharmacists in smoking cessation, nutritional advice,

Table 1. Suggested Strategic Plan 2021-2024

Objective	Activity	Where do we stand	Difficulty
1-Improve pharmacy education	Implement core competencies	Ask universities to implement competencies	+
	Implement researcher and preceptor competencies	Suggest available documents to universities	+
	Implement the Pharmacy Accreditation	Collaborate with the MEHE and universities (project ready to implement)	++
2- Decrease non-specialized graduates' number	Apply post graduate training (general and special training and competencies; ready to implement)	Collaborate with the MOPH to have the appropriate legal framework Implement in collaboration with stakeholders	+++
	Improve colloquium examination	Collaborate with universities and MEHE	++
	Push for laws to decrease graduates numbers (numerus clausus)	Collaborate with Parliamentary commission for education (change the existing text)	+++
3- Improve community practice	Improve the pricing process to include services	Negotiate fees with the MOPH	+++
	Apply GPP standards for the community to prove the pharmacists' worth	Collaborate with the MOPH to form a Quality and Accreditation committee	++
4- Improve patient health and services	Implement patient profile related to medications	Collaborate with insurance and NSSF	+++
	Implement medication safety project	Collaborate with MOPH through the Pharmacovigilance and PHC programs	++
	Promote the public health aspect of pharmacy		
5-Improve medications quality and supply	Implement medication shortage platform	Collaborate with MOPH	++
	Guarantee the generics quality	Collaborate with the industry and MOPH to classify generics and improve their quality	+++
	Promote multi-sectorial collaboration	Collaborate with national and international industries and other institutions	+
6- Promote the OPL status and expand the pharmacist role	Promote the OPL image on the national and international levels	Collaboration with other healthcare professional orders, organizations and relevant ministries	++
	Expand the pharmacist role (Nine Star Pharmacist) in all sectors	Clinical pharmacy implementation (changing the text of the law within parliament)	+++
		Promote new CE/CPD activities	+

MOPH: Ministry of Public Health; MEHE: Ministry of Education and Higher Education; GPP: Good Pharmacy Practice; NSSF: National Security and Social Funds; CE/CPD: Continuing Education / Continuing Professional Development; OPL: Order of Pharmacists of Lebanon; PHC: Primary Health Care

vaccination, medication safety, and prescribing medications for specific minor ailments. Enhance education and certification to ensure that community pharmacist conduct these roles and provide to a high quality.

- Take into consideration critical issues in health, such as the distribution of chronic versus infectious diseases in Lebanon and mother and baby health problems. Specific certificates can be delivered in collaboration with the OPL, academia and the MOPH for:
  - special populations, such as pediatrics, geriatrics, cancer patients and mothers
  - special types of diseases such as infectious diseases and decrease in antibiotic resistance, chronic diseases management (prevention, management, and medication adherence)
  - specific medication related issues such as medication reconciliation, medication errors, side effects
- Take into account the epidemiological transition in Lebanon: aging of the population, and its associated increase in comorbidities and polypharmacy related problems. Management would be facilitated by the implementation of the previously suggested patient profile, linking community pharmacies and third-party payers, and helping the pharmacist in the management of complex cases.
- Include and elaborate the public health aspect of the profession in the undergraduate, graduate, and continuous education of pharmacists: focus on hygiene, breastfeeding, vaccines, smoking cessation, healthy diet, physical activity and other preventive measures. In addition, medication-related correct use (decreasing errors, misuse, or abuse), adherence, safety and interactions issues, and disposal processes are important points to tackle. Specific postgraduate and continuing education programs can be tailored to this aspect of the profession.

In conclusion, adopting the blueprint suggested in this paper is necessary, because the profession is unfortunately condemned to disappear in the current political and health Lebanese context. The potential opportunity for pharmacists to actively collaborate with local and international authorities, promoting patients' health as a core stakeholder of the MOPH PHC program, provides an opportunity for a better future.

CONFLICT OF INTEREST

None.

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None.

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