Review

Gender, age, and pharmacists' job satisfaction

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Abstract

A comprehensive literature review was conducted on the concept of job satisfaction in the pharmacist workforce field and the facets it comprises, as well as its measurement, aiming to (i) review the nature, mechanisms, and importance of job satisfaction in the context of the pharmacist workforce, (ii) survey some of the most salient facets that configure job satisfaction, and (iii) discuss validity and measurement issues pertaining to it.

Although female pharmacists generally hold less appealing jobs, earn lower wages and salaries, and are promoted less frequently than their male counterparts, they report higher levels of job satisfaction. Age has a U-shape effect on job satisfaction, with middle-age pharmacists less satisfied than both younger and older practitioners. Workload, stress, advancement opportunities, job security, autonomy, fairness in the workplace, supervisors, coworkers, flexibility, and job atmosphere are facets contributing to pharmacists' job satisfaction. Finally, discrepancy exists among researchers in measuring job satisfaction as a single global indicator or as a composite measure derived from indices of satisfaction with key aspects of a job.

Understanding the mechanisms that affect pharmacists' job satisfaction is important to employers in their pursuit to respond to practitioners' needs, decrease turnover, and increase productivity. As pharmacists' response to work-related conditions and experiences depends on gender and age, a unique set of rewards and incentives may not be universally effective. Additional research into the dynamics of the forces shaping pharmacists' perceptions, opinions, and attitudes is needed in order to design and implement policies that allocate human resources more efficiently within the various pharmacy settings.

Keywords

Pharmacists; Health Manpower; Job Satisfaction; Attitude of Health Personnel; Sex Factors; Age Factors

INTRODUCTION

Pharmacists' job-related perceptions and opinions are shaped by their experiences in the workforce. These experiences vary systematically, and are interpreted differently, by both genders and diverse age groups. They influence how much practitioners enjoy their work and affect their labor supply. Together they configure the array of advantages and disadvantages of employment opportunities known as job satisfaction.

The purpose of this article is to dwell into the concept of job satisfaction and its relevance to the pharmacist workforce. First, the nature, mechanisms, and importance of job satisfaction are reviewed. Second, some of the most salient facets configuring it are surveyed. Then issues pertaining to validity and measurement are discussed. Throughout the article frequent comparisons are made between genders and among age groups.

JOB SATISFACTION

Over the last 20 years, job satisfaction has become recognized as a proxy for pharmacists' job-related utility.[1-4] It is a comprehensive concept that measures practitioners' self-appraised well-being at work stemming from what has happened to them in a position or work setting. Workers who perceive themselves being happier with their job are said to be more satisfied.[5]

Job satisfaction affects labor market outcomes. It has been linked positively to motivation, performance, productivity, organizational commitment, and patient safety and satisfaction, and linked negatively to absenteeism, tardiness, complaints and grievances against management, theft, and job turnover.[6-13] Excessive turnover is costly to employers. Its direct costs include, among others, workers' loss of job performance and productivity; interviewing candidates; advertising and other recruitment expenses; selecting, hiring, and training the new employees; overtime wages to cover vacant positions; and management time to rearrange schedules. In addition, indirect costs include loss of social networks, increased reliance on inexperienced or overworked employees, insufficient staffing, and low morale.[14-16]

More satisfied practitioners tend to see their organization positively. They are grateful to their employer for providing a fulfilling job and are less likely to leave voluntarily, compared with less satisfied workers. They tend to invest in firm-specific human capital, which increases their organizational commitment.[17] Conversely, unfulfilled workers often express their dissatisfaction through unproductive and dysfunctional behavior. Practitioners exhibiting higher levels of satisfaction work more hours at the same wage rate than their peers reporting less satisfaction. Hence, pharmacists' contentment with their job has important implications for both performance and organizational management.

A gender incongruity, known as the paradox of the contented female worker, is related to the conceptualization of job satisfaction. Although women generally hold less appealing jobs, earn lower income, and are promoted less frequently than their male counterparts, they report higher levels of job satisfaction.[18-21] A plausible explanation for this incongruity may be that since women

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are primarily in charge of housework and childcare, they feel less pressure to succeed at work than men, who commonly are viewed as responsible for the household's financial well-being. Perhaps women who are dissatisfied with their job choose more readily than men to change employers, work fewer hours, or leave the workforce altogether to devote more time to their family, and consequently their dissatisfaction does not appear in survey results.

Another plausible explanation for this phenomenon may be that women have lower expectations than men about labor outcomes, so their goals are fulfilled more easily.[22] If female pharmacists only compare their outcomes to the outcomes of their female peers, their accomplishments may be less demanding vis-à-vis male pharmacists' accomplishments. Furthermore, insofar as job-related subjective rewards, which are distributed more equitably between the genders than objective rewards, are more appealing to women than men, women may be more inclined to compensate the forgone satisfaction of jobs that pay less income and offer fewer advancement opportunities with social aspects such as interaction with patients, good supervisors, and congenial coworkers as well as scheduling flexibility, reduced stress, and proximity to the workplace. The literature suggests that greater earnings add more to the job satisfaction of men than women.[23,24] Male and female pharmacists make job-related choices based on heterogeneous preferences over job characteristics, so the greater satisfaction of women may have its origin in special features, probably difficult to conceptualize and measure, that women value in their jobs. Policies designed to enforce equality in the gender composition of job characteristics may lead to a reduction in the job satisfaction of workers from both genders.[25]

A third explanation for the paradox of the contented female worker may be that gender disparities in job satisfaction reflect deeper differences in the occurrence of depression and despondency between the genders.[26] Women tend to respond to job inconformity by internalizing feelings of dejection rather than expressing their dissatisfaction openly. While men exteriorize more easily their job-related issues through protests, complaints, and grievances, women are more likely to transform these issues into signs of distress, especially related to work-family conflict. Thus, the greater prevalence of female than male professional work-induced depression may be a more relevant indicator of how men and women respond to disparities in income, promotion, and occupational status.

An incongruity also is apparent with age. Younger pharmacists generally are less satisfied, yet work more hours, than their older peers. This incongruity has been explained in terms of workers reducing their aspirations, and hence the satisfaction gap, as they grow older and realize that they face limited choices in the workplace.[6,27] Age has a U-shape effect on job satisfaction.[20,21,28] Initially younger workers may experience lots of satisfaction with their job because of low expectations; their limited labor market exposure does not allow them to assess accurately their working conditions. As they gain experience in their middle years, their expectations rise and their satisfaction drops as they are better able to judge their work. Beyond middle age, with a broader perspective of life and approaching retirement, older workers tend to attach less importance to professional ambitions, or maybe they acquire a growing awareness of areas within their occupation from which they derive more satisfaction.[29] Perhaps with age they adapt better to the policies and working conditions of organizations for which they have worked over several years[30], or they simply enjoy privileges such as more authority, autonomy, and occupational prestige not commonly found with younger workers.[31] An alternative explanation may be that the greater satisfaction of older workers results from a self-selection process; dissatisfied, mature workers tend to change jobs or retire while workers who remain in their jobs are the ones who experience more satisfaction.

FACETS RELATED TO JOB SATISFACTION

Multiple facets contribute to pharmacists' job satisfaction and dissatisfaction. Ten of them are analyzed here: workload, stress, advancement opportunities, job security, autonomy, fairness in the workplace, supervisors, coworkers, flexibility, and job atmosphere.

Workload

An inordinate workload is often identified as a source of dissatisfaction.[1,2,4,11,13,32,33] It has been linked to medication dispensing errors and restricts practitioners' interaction with patients[34], thus jeopardizing the effectiveness of quality control mechanisms and adequacy of patient care. Workers who experience an excessive workload report feeling anger toward their employer, resenting their coworkers, searching for another job, undergoing work-related conflicts, and suffering more health problems as a result of being overworked.[35]

In the United States and other countries, many pharmacists perceive that their workload, frequently measured as the number of prescriptions dispensed per period of time, exhibits a secular rise. They see themselves as spending more time on dispensing and administrative functions instead of counseling and other clinical activities more appealing to them.[36,37] This trend may be partly attributable to an influx of new drugs for previously untreated illnesses as well as a greater array of medications for previously treated disorders.[38] In addition, the prevalence of chronic diseases is increasing because of a continuously rising life expectancy throughout the world, which increases the demand for pharmaceutical services. Curiously, although men often are assigned a heavier workload than women, women perceive their workload to be more burdensome than do men.[39,40]

Stress

Excessive workload leads to stress[2,11,27,41], which is related to practitioners' disillusionment, low levels of organizational commitment, and excessive turnover.[42-44] Stress involves feelings of work-related tension, anxiety, frustration, and emotional imbalance. It occurs when employees encounter negative working conditions or poor workplace relationships over which they have little or no control.[45] It may be caused by role ambiguity (the absence of clear guidelines for performing tasks), role conflict (managing multiple roles), excessive regulations, job

uncertainty, absence of constructive feedback from supervisors, inadequate staff support, job policies being enforced inconsistently, and lack of power, among other factors.[46-49] In countries where they are allowed to operate, chain and mass merchandiser pharmacists generally experience more job-related stress than independent pharmacists.[50,51]

Stack[52] identifies five progressive stages of job-related stress. The first is the physical stage, characterized by illness and fatigue. The second is the social stage; negativity, blaming others for things that go wrong, missing deadlines, and working through meals occur in it. Next is the cerebral stage, during which clock watching, minor accidents, absentmindedness, and indecisiveness are observed. Then comes the emotional stage, characterized by feelings of sadness and anger, crying, yelling, being overwhelmed, and depression. Finally, in the spiritual stage workers become somber, consider making drastic changes in their lives, have difficulties relating to other people, and cool off personal relationships. Workers experiencing heavy job-related stress blame their employer for it, which erodes organizational commitment and loyalty.[44]

Burnout is the ultimate expression of stress.[6,33,53] It is caused by chronic job-related stressors and is manifested via emotional exhaustion, depersonalization, and reduced personal accomplishments that pervade employees' non-work life aspects.[54] Common symptoms include feelings of helplessness; a cynical attitude toward authority symbols; progressive apathy; and anger toward patients, supervisors, and coworkers. Pharmacists and other healthcare professionals are susceptible to burnout because they relate to patients in emotionally demanding situations that expose them to patients' problems over the long run.[55,56] Women report enduring more stress in their job than men[57] and respond by working fewer hours, getting married at an older age, and having fewer children than their male peers.[58]

Advancement opportunities

Pharmacists' perception of available advancement opportunities increases job satisfaction.[2,4,5,59] The prospect of a future promotion may provide a compensating differential for pharmacists currently willing to accept a lower-paying job. Traditionally, pharmacists have been pessimistic about the availability of advancement opportunities within their place of employment, and the limitations have been expressed by practitioners of both genders[60], although there seem to be more men than women in pharmacy management positions.

The glass ceiling is a term frequently used to describe the greater accessibility by men than women to managerial posts.[61] It refers to a metaphorical barrier preventing women from advancing in the organizational structure beyond a certain level. Yet it is not uncommon for women to show greater satisfaction than men with the promotions they receive[62], along the lines of the paradox of the contented female worker discussed above. Female pharmacists may not be as interested as their male counterparts in getting promotions that often entail increased stress and work commitments inconsistent with their household responsibilities. Thus, notwithstanding the presence of gender bias and discrimination that sometimes support glass ceilings, the more frequent promotion of men than women may be partly attributable to choice rather than a dearth of opportunities.

Job security

The perception of job security also increases pharmacists' job satisfaction.[1,9,48] A perceived risk of losing one's job, despite good performance, because of outsourcing, downsizing, relocation, or any other factor beyond practitioners' control has a deleterious impact on labor productivity, commitment, and other outcomes. Employees in organizations reducing the size of their workforce experience decreased motivation, low morale, lack of competence, and increased stress, all symptoms of what Brockner[63] calls the "survivor syndrome." They become suspicious of management, experience a drop in effectiveness to handle tasks, feel anxious about the future, and express less satisfaction. They engage in extreme risk avoidance, develop physical illnesses, and many end up resigning.[39,64,65]

Since women are more risk averse than men, they exhibit a greater level of satisfaction with job security.[20,62] Older workers also perceive a greater risk of job loss compared to younger workers[28]; this trend may reflect younger workers' relatively greater mobility, early in their careers, in search of the most suitable job for them. It also may reflect apprehension by older workers regarding their age-influenced, limited number of options available in the event of losing their job.

Autonomy

Autonomy is the ability to exercise one's judgment in conducting professional activities such as assigning priorities to pending tasks, using the necessary resources, and allocating time. Having more discretion over their work provides healthcare workers with a sense of responsibility conducive to caring more about what they do, building confidence in their abilities, generating feelings of pride, rendering a better quality output, and attaining higher levels of satisfaction.[31,66-69] Workers who think that they lack autonomy in their job feel less appreciated.[70]

The influence of autonomy on job satisfaction is stronger for female than male pharmacists[71], although it is mediated by the number of hours worked. Men who work part time experience more job autonomy than women who work part time, but for pharmacists who work at least 40 hours per week, there are no significant gender differences. Furthermore, men's perception of the importance of job autonomy declines as the number of hours worked rises, but no such trend is detected for women.[60] There is also evidence that fewer female than male physicians are satisfied with autonomy in their jobs[57,72], and community pharmacists perceive more autonomy compared to pharmacists working in hospitals and clinics.[73]

Gender differences in the perception of autonomy may be attributed to differences in how men and women interpret their actualized self. Men tend to define their selves through separation from others as part of their own identity and search for jobs that provide independence in performing tasks and allow them to experience satisfaction

through self-actualization opportunities. In contrast, women are happier in jobs that allow them to pursue care and connectedness with others within their rational self-definition because they are more likely than men to develop connected selves. Generally women are more interested in establishing interpersonal relationships, including working with others, than in pursuing self-actualization.[74]

Fairness in the workplace

Perceived disparities in how practitioners are treated account for a substantial portion of job dissatisfaction.[5,75] It is important to distinguish between unfairness and inequality. Inequality is a de facto situation partly resulting from a mismatch between labor supply, marked by heterogeneous workers, and labor demand, marked by heterogeneous employers. Presumably the better the match between the supply of and demand for labor (i.e., structures are flexible, information is free flowing, etc.), the less inequality there is in the distribution of income and benefits within a profession such as pharmacy.[76] In addition, disparities in human-capital stock and job-related preferences contribute to observed inequalities in income distribution.[77] Thus, inequality responds to the nature and intensity of organizational and workforce heterogeneity within the profession.[78]

The focus here is not on inequality but on unfairness. There are two mechanisms involved in the interpretation of fairness. One is distributive justice, which refers to perceptions regarding the distribution of decision outcomes (i.e., who gets recognition, pay raises, promotions, etc.); distributive justice prevails when outcomes are congruent with workers' expectations. The other mechanism, procedural justice, has to do with the methods used by the organization to distribute outcomes. Procedures are perceived as fair when they are bias free and applied consistently across individuals through time, when they allow for accurate representation of the opinions and arguments of affected individuals, and when corrective mechanisms are in place in the event that the wrong decision be made.[79]

Perceptions of fairness in the workplace have been linked to positive labor outcomes, which strengthen organizational commitment and trust in management. Conversely, perceived disparities in the treatment of fellow workers lead to attitudes of pessimism and excessive turnover, which are associated with feelings of lower prestige and power at work, career uncertainty, and increased work-related conflict.[80-82] Yet while managers may influence the satisfaction of their pharmacists by implementing fair procedures when allocating rewards and resources, fair procedures in the workplace do not necessarily guarantee positive outcomes, including job satisfaction; negative affectivity makes some individuals perceive conditions adversely regardless of what may be happening.[83] Self-perceived status moderates the relationship between procedural fairness and job satisfaction; the higher the self-perceived status, the stronger the positive link between both variables.[84]

Supervisors

Support from one's supervisor is another facet related to practitioners' satisfaction.[4,7,85-87] Support may be expressed in numerous ways; rendering information, creating teams and encouraging individuals to work together, setting reasonable goals, providing technical assistance and adequate facilities, and conveying feelings of empathy and emotional backing are a few examples.[43,88,89] Support from supervisors adds to pharmacists' contentment by increasing confidence and reducing anxiety. Perceptions of such support empower pharmacists[90], which fosters organizational commitment; practitioners who work in independent settings receive more support from their supervisors than those who work in hospitals or chain pharmacies, and consequently are more empowered.

Supervisors play a decisive role in fostering job environments conducive to employees' self-development. Supportive supervisors encourage workers to voice their opinions and concerns, provide positive feedback, and put in place participative strategic planning processes that contribute to organizational effectiveness.[91] They also praise deserving employees; workers who receive recognition and praise respond by increasing their productivity and satisfaction.[92]

Managers are responsible for enhancing the individual self-esteem of pharmacists under their supervision and raising organization-based self-esteem, defined as individuals' self-perceived value working with the institution.[93] This may be accomplished by taking into account workers' suggestions about improving conditions at work; providing emotional support to employees and showing genuine interest in their personal welfare; relating raises and promotions to employees' contributions to the organization; and eliminating restrictions and procedures deemed unnecessary, burdensome, or inconsequential. Workers with higher organization-based self-esteem levels perceive themselves as more important and worthwhile, and are more productive and effective, than workers with lower levels of organization-based self-esteem.

Gender plays a role in perceiving supervisors' support. Proportionately more women than men consider supervision issues important, and more women than men value workplace social support.[62] Supervisors' actions directed toward mentoring junior professionals also are perceived to be more valuable by women than by men.[19] Help and support by supervisors increase female pharmacists' job satisfaction but is not perceived as relevant by male pharmacists.[71] Moreover women supervisors who perceive themselves as holding greater responsibility and trust by their employer improve their job performance and supervise employees more closely than female supervisors who do not perceive themselves in such a way.[94]

Coworkers

Coworkers are organization members with whom pharmacists interact in performing their job and who have approximately the same level of power and authority. They are influential in the work environment[95] because they provide a dynamic communication conduit. While formal channels of communication within an institution transmit

orders and instructions from the top down and information, feedback, and suggestions from the bottom up, coworkers constitute an informal network characterized by a horizontal exchange flow. Employees prefer to communicate and discuss work-related issues with their peers rather than with supervisors; coworkers are the most common source of job-related support identified by employees.[96]

Good relations with coworkers are conducive to greater pharmacists' satisfaction.[3,5,10,41] Trust in coworkers contributes to the attainment of organizational outcomes and decreases turnover intention.[97,98] Insofar as they consider their peers' perceptions worthwhile and socially acceptable, practitioners' trust in their coworkers leads to trust their employer. These perceptions become more relevant in periods of uncertainty, when workers are not sure about what goes on at work; during such times they look toward one another for information and guidelines about how to cope with unfamiliar situations, which fosters greater awareness and mutual support.[99]

A concept applicable to relations with coworkers is the norm of reciprocity, which states that people will respond to others in the same way they are treated. When a worker feels helped and supported by his/her peers, the norm of reciprocity suggests that he/she responds by helping and supporting others. Favorable treatment carries the expectation that the debt will be repaid with similar treatment, even if the nature and timing is not clear. Pharmacists who adhere to the norm of reciprocity contribute to the stability and good will of the workgroup and the smooth functioning of the organization.[81,100,101]

Flexibility

Scheduling flexibility is another facet intimately related to the job satisfaction of pharmacists.[10,85,102,103] It is associated with fewer stressors and less burnout, and allows practitioners to accommodate nonwork-related activities valuable to them.[104] It may take different forms: working more or fewer hours per day, working different days each week, greater discretion over when or where to work, etc. Some role and practice settings such as administrative, consulting, and teaching are more suitable for flexible work arrangements than others (i.e., dispensing).

Scheduling flexibility is attractive to women, especially younger women, because it enables them to pursue household-related work and care for children and elderly family members.[18,23,105,106] It also is attractive to older pharmacists of both genders because it facilitates their transition into phased retirement as they reduce gradually the intensity of their work effort.[107] Several studies recommend that employers develop and implement programs that offer more flexibility to their employees, not only pertaining to work hours and scheduling matters but also to rewards, family issues, and matching individual competencies with job requirements.[108-110]

Job atmosphere

Also known as organizational climate, job atmosphere captures the extent to which harmony pervades operational and interpersonal relations in an institution. It gauges workers' views regarding their job environment and whether they see it as beneficial or detrimental to their well-being. The specific focus is on the organization's typical practices and behaviors that prevail in the perception of its members, especially those connected with expectations and rewards. Job atmosphere is a major contributor to pharmacists' satisfaction and dissatisfaction.[31]

Some characteristics of a healthy job atmosphere include workers looking forward to going to work, agreeing with their organization's operating values, providing extra effort and input hours when required, trusting and befriending their coworkers, acting as members of a team, feeling pride in collective achievements, and believing that their work contributes substantially to the team's success.[111] In this kind of environment new ideas are welcome and unnecessary rules are eliminated; management's thrust is on getting the best people to reach organizational goals rather than establishing self-serving lines of authority; and employees are encouraged to introduce innovations without constantly seeking approval from their supervisors, are given opportunities to participate in goal setting and planning, are recognized and rewarded for good performance, and know what is expected from them.[112] Consequently, practitioners tend to develop attitudinal commitments that lead to emotional, mental, and cognitive bonds with their employer, and these bonds are likely to be reflected in higher levels of performance and lower levels of absenteeism and turnover.[44,64,113]

Three types of commitment have been identified.[114] Continuance commitment occurs when practitioners remain with an organization because it would cost them more to leave than to stay. The second type, affective commitment, is emotional and occurs when practitioners want to remain with an organization. The third type, normative commitment, occurs when workers remain with an organization because they feel that it is the right thing to do. All three types involve a belief in, and acceptance of, the goals and values of the organization; willingness to exert considerable effort on behalf of their employer; and an explicit desire to continue doing their job.[115]

Conversely, workers' perceptions of organizational politics are detrimental to harmony in operational and interpersonal relations. Organizational politics is a term that refers to subjective assessments of self-serving work behaviors of individuals not sanctioned by authority; such perception may be fueled by uncertainty regarding organizational decisions, ambiguity of expectations, conflicting roles and procedures, and competition for scarce resources.[116] It is both divisive and narrow-minded, and usually aggravates both absenteeism and turnover.[117]

The ethical climate is an important subset of job atmosphere. It consists of perceptions shared by management and workers of what constitutes unethical behavior and how ethical transgressions should be handled.[118] Organizations perceived as having a permissive attitude toward employee deviance experience more unethical behavior issues than organizations perceived as having no tolerance toward deviance.[119,120] Two major categories of employee deviance have been identified: property deviance and production deviance.[121] Instances of property deviance include misuse of employee discounts;

taking supplies, merchandise, or information for sale or personal use; filching money; and falsifying records. Instances of production deviance include reductions in work time such as tardiness, absenteeism, abuse of sick leave, and unauthorized breaks or leaves of absence; they involve low levels of organizational commitment and lead to productivity drops.

Understanding the way pharmacists are treated, and perceived to be treated, by administrators, fellow pharmacists, technicians, other healthcare professionals, and patients is essential when configuring the workforce environment and assessing practitioners' organizational commitment. When workers are allowed to participate in the decision-making process, feel that the organization appreciates their contributions, and believe that supervisors and coworkers care about their well-being, the job atmosphere quality improves substantially.[68,122,123] Perceived support by employers fulfills workers' socioemotional needs and is interpreted by them as an indication that the organization rewards increased effort and performance.[124,125]

Women more than men tend to be affected by the job atmosphere quality.[62] Female pharmacists whose husbands are likely to earn higher levels of income than the wives of male pharmacists may feel less pressure when they downplay the importance of earnings and focus their attention primarily on working conditions, choosing jobs characterized by an absence of crises and conflicts, and good relations with supervisors and coworkers.[105,126]

VALIDITY AND MEASUREMENT ISSUES

Notwithstanding its widespread use, the concept of job satisfaction is viewed by some analysts with skepticism.[21] Critics point out that well-being measures are too subjective and may not be comparable across pharmacists; job conditions that may be adequate to some may be unacceptable to others. They contend that job satisfaction indices are ordinal measures of intangible concepts, thus providing improper representations of what needs to be measured. A fundamental issue here is whether these indices are connected to meaningful and understandable behavior.

Differences in measurement techniques are problematic. Multiple indicators have been developed, and whether they measure the same outcome is questionable.[127] The use of Likert scales provides the basis for an illustration. In studies of job satisfaction among pharmacists, analysts frequently assume that a well-constructed set of Likert questions provides interval-level scores.[128-130] Responses to job satisfaction related statements may be recorded along a five-point scale that reads as follows: 2 for "strongly agree," 1 for "agree," 0 for "neither agree nor disagree," -1 for "disagree," and -2 for "strongly disagree." Once responses are gathered, mean satisfaction scores are calculated and interpreted. The problem is that Likert response categories depict an ordinal level of measurement; the categories represent an inherent order, but the numbers assigned to the categories do not necessarily reflect the magnitude of the differences among categories.

Some critics argue that it is incorrect to assume that the intensity of feeling between "strongly disagree" and "disagree" is equivalent to the intensity of feeling between other consecutive categories in the Likert scale. This is an important issue because appropriate inferential statistics differ for ordinal and cardinal variables; using the wrong statistical technique increases the chance of reaching the wrong conclusion about the significance of empirical results.[131,132]

An alternative approach is the rating scale model, which records a pharmacist's satisfaction level on the same coordinate with measures of item difficulty utilizing a logit scale.[133] A logit scale uses the log-odds of obtaining a particular rating to estimate the level of the latent trait and item difficulty; in contrast, traditional statistical analysis treats all items as having equal values and describes data in terms of averages, percentages, and probabilities.[134]

Likert-scale data may be used as a basis for obtaining interval-level estimates on a continuum by applying a third technique, the Rasch model, which is a form of item response theory.[135] Raw scores are converted into standardized units; then the units are aligned on a ruler that measures each component of the model. This method poses the advantage of allowing hypothesis tests that reflect varying levels of an attitude or trait. Under Rasch analysis, results from a survey may be compared meaningfully only if the survey works in the same manner for everyone who responds to the questionnaire. Some analysists claim that the use of Rasch analysis in the evaluation of pharmacists' job satisfaction is superior to other approaches[136]; Rasch estimates provide more accurate scores than the traditional estimates and are more precise when mean scores are more diverse.

Then there is discrepancy among researchers regarding whether job satisfaction should be measured by a single, global indicator or be derived, as a composite measure, from various indices of satisfaction with key aspects of a job. The first choice, called a facet-free item, focuses on an aggregate satisfaction scale without reference to specific aspects that presumably influence satisfaction; the second choice, known as a facet item, combines satisfaction from different sources related to the same job.[137] Using a single, global indicator is easier and avoids methodological problems concerning allocation of weights to various facets of a job, accounting for different frames of reference, and ensuring that all pertinent areas related to job satisfaction are identified[138], but it tends to overestimate satisfaction and underestimate dissatisfaction.[139]

Recently little congruence was reported between an overall index of pharmacists' job satisfaction and several facet indices hypothesized to configure it[140]; variation in the overall index proceeded independently of variation in nearly all individual facets, which questioned the validity of deriving a composite measure of satisfaction from various indices pertaining to key facets of a job. The validity of deriving a composite measure was further challenged by the finding of significant differences between genders in the variation between several facets and overall job satisfaction.

CONCLUSIONS

This article has sought to explore the concept of job satisfaction and its relevance to the pharmacist workforce, with frequent comparisons between the genders and among age groups in job-related perceptions and opinions. Understanding the nature and magnitude of the mechanisms that make pharmacists happier at work is important to employers and managers in their quest to respond to practitioners' needs, decrease workers' turnover, and increase productivity. Male and female pharmacists, as well as pharmacists from separate age groups, respond differently to work-related conditions and experiences, so the same set of rewards and incentives may not be universally effective. Additional research is needed into the dynamics of the forces shaping pharmacists' perceptions and opinions in an effort to devise and implement specific policies that allocate human resources more efficiently within the various pharmacy settings.

CONFLICT OF INTEREST

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Original Research

Improving warfarin therapy through implementation of a hospital-based pharmacist managed clinic in Jamaica

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Abstract

Background: Pharmacist managed warfarin clinics can improve the anticoagulation status of non-valvular patients. The first of such services was implemented at the Cornwall Regional Hospital in Jamaica in 2013.

Objectives: To assess the anticoagulation control of patients on warfarin therapy over six months in the pharmacist managed warfarin clinic at Cornwall Regional Hospital.

Methods: Retrospective docket review for the period January 2014 to December 2016 was done to include data of patients attending routine clinic appointments for at least six months. Age, gender, date of visit, indication for warfarin therapy, warfarin dose and International Normalized Ratio readings were extracted. Percentage time spent in therapeutic range (TTR) was calculated by month for six months using the Rosendaal linear interpolation method. Patient anticoagulation status was categorized as poor (TTR<40%), moderate (TTR=40-64%) or good (TTR≥65%) and anticoagulation status at three months and six months was compared.

Results: For the period of assessment, 52 patients were identified; the median age was 58 years and 36 patients were males. Deep vein thrombosis was the main indication for therapy (22 of 52) and median warfarin weekly dose ranged was 15.0-130 mg. At time of recruitment most of the patients were outside the target INR range (43 of 52). Within one month, the median TTR attained was 31% [IQR 62-10]. This significantly improved by second month to 60% [IQR 82-23] (p=0.001). By month three, the proportion of patients in good, moderate and poor anticoagulant status was 19/51, 15/51 and 17/51 respectively, which at six months changed to 23/51, 12/51. 16/51 respectively; thus, although coagulation status improved from month one to three, there was no significant improvement from month three to month six (p=0.31).

Conclusions: The pharmacist managed warfarin clinic monitoring services were successful in attaining TTRs >40% and sustaining these values over six months. The services should therefore be encouraged.

Keywords

Program Evaluation; Warfarin; Anticoagulants; International Normalized Ratio; Pharmaceutical Services; Pharmacists; Retrospective Studies; Jamaica

INTRODUCTION

Warfarin remains a major choice for oral anticoagulation in non-valvular atrial fibrillation and deep vein thrombosis; however, anticoagulation status is impacted by many factors including dietary, ethnicity, genetics, age and weight.[1-4] To ensure adequate efficacy and safety with warfarin therapy, regular assessment is required to maintain an International Normalized Ratio (INR) within the recommended therapeutic range of 2.0 – 3.0, except for patients with mechanical heart valves or recurrent myocardial infarction, where the recommended range is 2.5–3.5.[5]

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Optimising the percentage of time spent in therapeutic range for INR (TTR) can reduce the risk of haemorrhagic and thromboembolic events.[6,7] Connolly *et al*.[8] reviewed TTR data from anticoagulation centres of 15 countries and reported that a TTR of at least 65% is required for optimum benefit of warfarin therapy. This threshold forms part of the guidelines supported by the United Kingdom National Institute for Health and Care Excellence and the University of Nottingham PRIMIS development group[9]; furthermore these guidelines suggest that there is no benefit from warfarin therapy when TTR <40%.[10,11]

Active monitoring through specialized anticoagulation clinics have proven beneficial in optimizing warfarin therapy and reducing the risk of complications.[12-16] In a systematic review published in 2017 of 25 randomized controlled and observational studies of 12,252 patients receiving warfarin therapy, it was shown that anticoagulation status was significantly improved in pharmacist managed outpatient care facilities, including lower bleeding and thromboembolic events.[17]

At the first pharmacist managed anticoagulation clinic established in 2013 at the Cornwall Regional Hospital in Jamaica, patients are managed for INR control once warfarin therapy is initiated by physicians at the hospital. The role of the pharmacist assigned to the clinic include making dosage adjustments to warfarin therapy as needed, as well as teach patients on appropriate dietary practices

with specific focus on vitamin K content. Possible drug interactions are also reviewed and changes actioned after consultation with assigned physician. The pharmacist initially measures INR weekly until target INR is attained and then appointments are moved to once monthly. The aim of this study was to assess the anticoagulation status achieved by this pharmacist managed clinic over a six month period of monthly monitoring.

METHODS

A retrospective review of patient records of the pharmacist managed warfarin clinic at the Cornwall Regional Hospital from the period January 2014 to December 2016 was done. The Cornwall Regional Hospital is a 400-bed capacity institution, providing many specialty services including Cardiology. The protocol was approved by the Ministry of Health Ethics Committee and the University of the West Indies Ethics Committee.

Only records of patients who were of at least 18 years old at first registration to the clinic and were on warfarin therapy for at least six months were selected. Six months was chosen as adequate to assess clinic performance based on a previous study evaluating anticoagulation clinics of the Veteran Affairs Health System in the United States of America.[18] Records were excluded if patients were younger than 18 years, had severely impaired liver and kidney function, as well as patients with bleeding disorders such as hemophilia. Data extracted from the records included patient age, gender, indication for warfarin, warfarin dose at first visit and at each monthly visit, as well as the number of missed warfarin doses per week. The missed dose information was used as a measure of compliance with warfarin therapy. INR readings were also recorded from the patient records. These readings were obtained by the pharmacist at the each visit using the Roche Diagnostic CoaguChek XS Plus system; a validated point-of-care device that consists of a CoaguChek XS Plus monitor with CoaguChek XS Plus pro-thrombin test strips and produces results within seconds from a drop (≥ 8microL) of capillary blood. The test strip consist of lyophilized reagents, thromboplastin and a peptide substrate and has an INR measuring range from 0.8 to 8.0 with 97% accuracy when compared to lab results.[19,20] INR extracted from the records included the INR reading at the first visit and INR reading by month for six months.

Data Analysis

Continuous variables were characterized by mean and standard deviation [SD] and by median and interquartile range [IQR]; categorical variables were characterized by frequencies and percentages. TTR was calculated using the Rosendaal linear interpolation method, which assumes there is a linear relationship between two consecutive INR results.[21] This method determines the proportion of time for which the INR is within therapeutic range of 2.0 - 3.0. TTR was calculated by month for a period of six months with month defined as a scheduled visit at 28 to 30 days of last clinic visit. Wilcoxon Signed Rank test was used to compare median percentage TTR between months.

Patients returning to the clinic after 30 days were considered as missing scheduled visit. Spearman's rho co-efficient was used to analyse association between number of missing visits and TTR.

Further analysis involved comparing the change in anticoagulation status of patients between month three and month six. These periods were used to compensate for missed patient visits. Where patients missed the three month or six month appointment the last TTR value was carried forward to determine anticoagulation status categorization. Patients missing two consecutive month visits were excluded from the analysis of anticoagulation status.

Using guidelines established by the University of Nottingham PRIMIS development group, patients were stratified into categories based on TTR as poor anticoagulation status (TTR<40%), moderate anticoagulation status (TTR of 40 to 64%) and good anticoagulation status (TTR≥65%). McNemar-Bowker pairwise Chi-Square test for proportions was used to compare anticoagulation status at month three and month six. For all inferential statistics done, statistical significance was considered as p values less than 0.05.

RESULTS

In total, the study identified 52 patient dockets meeting inclusion criteria and the demographics are presented in Table 1. Thirty-six (69.2 %) patients were males and the ages ranged from 23 to 90 years with a median age of 58 years. At the first visit to the clinic, the warfarin weekly doses ranged from a low of 15.0 mg to 85 mg; 9 (17.3%) patients presented with an INR within the target range; 24 (46.2%) patients were below target INR and 19 (36.5 %) patients were above target INR. The most common indication for warfarin therapy was deep vein thrombosis. During the first month the weekly dose of warfarin prescribed by the clinic range from a low of 17.5 mg to a high of 130.0 mg and varied over the five to six month period from a weekly low dose of 15.0 mg to a high of 110.0 mg. Over the six months of data collected, the records documented 30 patients as being fully compliant with dosing, while 12 patients dockets noted one to three times missing warfarin dose for the month; information documenting patient compliance was missing for 10 patients.

Of the total, 51 patients returned to the clinic within one month of the first visit with 40 (76.9%) patients attending the clinic two or more times in the first month. In terms of anticoagulation status, after one month, of the patients that were below target INR range at the first visit, 2/24 returned in good anticoagulation status, of those in target INR range, 4/9 returned in good anticoagulation status and of those above target INR range, 2/18 returned in good anticoagulation status. The mean and median TTR after one month were 36.5% (SD 30.1) and 31% [IQR 62-10], respectively (Table 1). Significant improvement in TTR was attained by the second month (54.2; SD 35.3 and 60 [IQR 82-23] respectively; p=0.001).

A total of 26 missed scheduled visits (of 312 visits; 8.3%) were recorded ranging from one patient in months one and

Table 1. Details of the 52 patients in study population

	Num. patients	Mean (SD)	Median [IQR]
Gender			
Male	36		
Female	15		
Missing data	1		
Indication			
Deep vein thrombosis (DVT)	22		
Atrial fibrillation	18		
Pulmonary embolism (PE)	5		
DVT and PE	3		
DVT and Antiphospholipid syndrome	1		
Chronic venous insufficiency	1		
External rectal vein thrombosis	1		
Cardiovascular accident	1		
Age	52	59 (16.4)	58 [72-47]
Warfarin Weekly dose/mg (range: lowest-highest)			
At first visit (Range: 15.0-85.0)		38.1 (15.4)	37.5[42.5-30.0]
Month 1[Range:17.5-130.0]		55.0 (20.4)	52.5 [63.0-40.6]
Months 2-6 [Range:15.0-110.0]		46.8 (17.4)	44.0[57.5-35.5]
INR at first visit (*Target Range 2-3*)			
Below Target	24	1.46 (0.28)	1.47 (0.51)
Within Target	9	2.32 (0.25)	2.29 (0.27)
Above Target	19	4.48 (1.54)	3.59 (1.90)
TTR%			
Month 1	51	36.5 (30.1)	31 [52-10]
Month 2	51	54.2 (35.3)	60 [82-23]
Month 3	49	53.3 (35.0)	50 [93-21.5]
Month 4	47	53.4 (37.0)	51 [100-18]
Month 5	48	53.4 (39.7)	51.5 [100-15.5]
Month 6	40	56.4 (39.6)	52.5 [100-20.5]
Total number of missed visits =26			

SD=Standard Deviation; IQR=Interquartile Range; INR=International Normalized Ratio % TTR=Percentage time spent in therapeutic range

two, three patients missing visits in month three, five patients in month four, 4 patients in month five and 12 patients in month six. No correlation was found between missed scheduled visits and median TTR by month. One patient missed two consecutive visits and was excluded from the assessment of anticoagulation status.

The change in anticoagulation status from month three to month six for the 51 remaining patients is displayed in Figure 1. At month three, 19 (37.3%) patients had good, 15 (29.4%) had moderate and 17 (33.3%) had poor anticoagulation status. Of those in good anticoagulation status at month three, 8/19 continued to remain in good anticoagulation status, while 7/19 presented with moderate and 4/19 deteriorated to poor anticoagulation status at month six. For patients moderate at month three, 6/15 improved to good anticoagulation status, 2/15 remained the same and 7/15 deteriorated to poor at month six. Of the seventeen patients that were in poor anticoagulation status at month three; there was improvement in TTR at month six for a greater proportion of the patients with 9/17 improved to good and 3/17 to moderate status; 5/17 remained in poor anticoagulation status. There was overall no significant improvement in the anticoagulated status of the patients from month 3 to month 6 (chi-square=3.60; degrees of freedom=3, p=0.31).

DISCUSSION

A six month assessment of the first established pharmacist managed anticoagulant clinic in Jamaica showed that overall the clinic was successful in achieving good compliance with scheduled visits. In this study, the mean TTR obtained after one month was below values established as clinically adequate; but comparable with findings from other studies showing more time requirement.[14] By the second month of therapy, the clinic was successful in maintaining monthly mean TTR in the range 53.4 % to 56.4%. The level of anticoagulation control obtained in this current setting is comparable with the meta-analysis study of Erkens, Cate, Büller and Prins, 2012, which reviewed forty randomized controlled and cohort studies of 26,064 similar patients published between January 1990 and May 2012.[22] The mean TTR calculated from this meta-analysis ranged from 56% to 75%, with the higher percentage obtained when the first month was excluded from the calculations. Similar findings were reported in the systematic review by Manzoor *et al*.[17]

Furthermore, the study of Erkens *et al*., proved that mean TTRs greater than 75 % were only observed after more than six months on warfarin. Therefore, while improvement in TTR was observed from month one to month three in the patients of this study, the absence of further improvement in patient anticoagulation status from month three to month six is consistent with the findings of Erkens *et al*.

The collection of the data for this study was limited by patients not attending scheduled visits, resulting in TTR values having to be carried forward for some patients. The measure of compliance with therapy was another limitation, as in some cases the information on missed dose was not available; furthermore patient recall over a month can be unreliable.

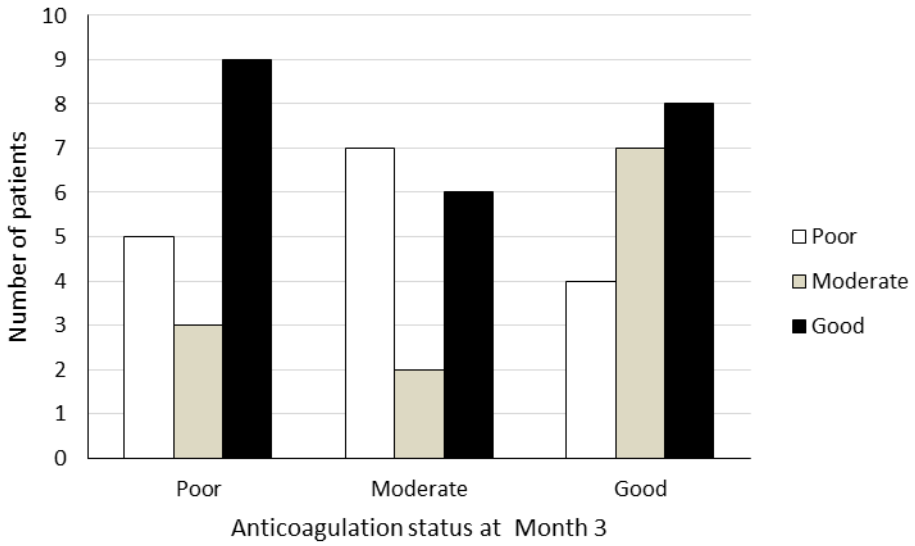

Figure 1. Change in anticoagulation status of patients on warfarin therapy from month three to month six; bars represent anticoagulation status at month six. At month three the proportions of patients in good, moderate and poor anticoagulation status were 19, 15, 17 respectively. By six months the proportions changed to 23, 12 and 16 respectively. With some patients improving and some deteriorating, the overall anticoagulation status remained the same from month three to month six (McNemar-Bowker pairwise chi-square=3.60; degrees of freedom=3; p=0.31).

CONCLUSIONS

In conclusion, the findings suggest that the monthly monitoring in this pharmacist managed clinic attained moderate to good anticoagulation status for most patients within three months and sustained for up to six months. The anticoagulation control is comparable to similar out-patient settings and such services have reported benefits to efficacy, safety and cost.[17,23,24] Therefore, this pharmacist managed warfarin clinic services has the potential to facilitate better patient outcomes and should be supported.

CONFLICT OF INTEREST

Nothing to disclose.

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Original Research

The effect of pramipexole extended release on the levodopa equivalent daily dose in Lebanese Parkinson diseased patients

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Abstract

Objective: The objective of this study is to compute the potential benefit of Pramipexole ER on total levodopa equivalent dose (LED) and Unified Parkinson Disease Rating Score (UPDRS-III) compared to mono- or combined therapy of pramipexole IR and/or carbidopa/levodopa.

Methods: This is a retrospective observational study conducted in a specialized PD (Parkinson Disease) and movement disease center in Lebanon between January and December 2017.

Results: A total of 176 patient's record was reviewed. Pramipexole ER showed a significant difference on the mean changes in LED and UPDRS-III score. After 13 weeks of initiating Pramipexole ER, the mean decrease in LED was -49.42 mg for all patients ($p < 0.001$, CI 95% [35.28-63.55]) and the mean decrease in UPDRS-III score for all patients was -6 points ($P< 0.001$).

According to the subgroup analysis, patients aged 65 years and below, the change in mean total LED from baseline (350.80 mg) was a decrease of 63.19 mg with a $p<0.001$, CI 95% [42.07-84.31]. In patients aged more than 65 years and shifted to mono or combined pramipexole ER therapy, the change in mean total LED from baseline (559.25 mg) was a decrease of 34.67 mg with a $p<0.001$ CI 95% [16.16-53.18]. In addition the results showed that in patients having an UPDRS-III score of less than or equal to 33, the change in mean total LED from baseline (436.73 mg) was a decrease of 56.76 mg ($p<0.001$; CI 95% [41.32-72.20]). However, in patients having an UPDRS-III score of more than 33 the change in mean total LED from baseline (545.06 mg) was a decrease of 2.96 mg with a p value < 0.844 CI 95% [27.32-33.15].

Conclusions: This study demonstrated the efficacy of Pramipexole ER on decreasing the total levodopa equivalent dose (LED).The role of health care professionals is to maintain the patient on the lowest effective levodopa equivalent daily dose and optimize the treatment therapy, thus decreasing the side effects that might arise from overdosing of antiparkinsonian drugs.

Keywords

Pramipexole; Levodopa; Antiparkinson Agents; Parkinson Disease; Dose-Response Relationship, Drug; Retrospective Studies; Lebanon

INTRODUCTION

Parkinson's disease (PD) is a chronic, irreversible neurodegenerative disorder, induced by massive dopamine loss and it is recognized by motor and non-motor symptoms.[1] PD available treatment is symptomatic with no proven efficacy to slow or reverse the disease progression.[2] The estimated prevalence of PD, in 2004, among Lebanese population is 0.36%.[3] Lebanese PD annual mortality rate is 0.2 per 100,000 people due to disease progression, and or medication related adverse events.[4]

Levodopa and dopamine agonists are considered essential options in early and advanced PD treatment guidelines.[5,6] Among all multiple antiparkinsonian therapies that are now available, the standardized levodopa equivalent dose (LED) is set to provide a useful tool to compare dose intensities of different medications in clinical trials. It is the dose that produces the same antiparkinsonian effect as 100 mg of immediate release levodopa.[7]

Pramipexole is a non-ergot dopamine agonist approved for the treatment of early PD. It is indicated either to delay the use of Levodopa, or as an add-on to Levodopa for patients with advanced PD experiencing Levodopa induced dyskinesia, and off periods.[8,9] Various in vivo and in vitro studies have showed that pramipexole has promising neuroprotective effects[10,11], while clinical human studies did not.[12] Pramipexole was expected to hold a significant potential in PD treatment since it is associated with lower motor complication risks, and higher reduction in Unified Parkinson Disease Rating Score (UPDRS).[13,14] UPRDS is used to follow the longitudinal course of PD and is divided into 6 sections, where section III includes a clinician-scored motor evaluation that can be used as a measure of Pramipexole efficacy on motor functioning.[14]

Pramipexole is available in two formulations; an immediate release (IR), and a once-daily extended release (ER) formula. The ER was verified to be bioequivalent to the IR formulation.[15] Furthermore the ER formulation was associated with better patient adherence to therapy, constant plasma concentration drug level, improved clinical response, and safety profile.[15,16] Several studies investigated the effect of pramipexole addition to PD patients' regimens on levodopa daily dose.[17,18] According to

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our knowledge there are no studies comparing the addition of pramipexole ER into the same patient's regimen before and after Pramipexole ER introduction.

Moreover, there is not enough information regarding the PD treatment, complication, and prognosis among the Lebanese population. Therefore, this study was undertaken to quantify the potential benefit of pramipexole ER on total LED and UPDRS-III score. The primary objective was to compare the total LED before and after introduction of pramipexole ER into the regimen for each individual PD patient.

METHODS

Study Design

This is a retrospective observational, single arm study conducted in a specialized PD and movement disease center in Lebanon between January and December 2017. Initially, total of 698 subjects' records were screened with PD. PD patients were excluded from the study if they had history of any psychiatric disorder, atypical PD symptoms, dementia, hypotension or any other clinical significant disease at any point of their lives, to make sure that the symptoms encountered are solely due to Parkinson disease. Patients were also excluded if they had received any of the following drugs; typical and atypical antipsychotics, centrally active antiemetic, amphetamine, and/or methyldopa because these medications have the ability to cause Parkinson-like side effects.

Only 176 PD patients who were shifted from their ongoing antiparkinsonian therapy (consisting of mono- or combined therapy of pramipexole IR and/or carbidopa/levodopa) to mono or combined pramipexole ER therapy were included in the study. The main reason for introducing pramipexole ER to the patients' regimens was due to the lack of efficacy of the previous regimens.

It is worth noting that pramipexole dose was increased by 0.75 mg/day every week to reach a maximum of 4.5 mg/week, whereas the levodopa/carbidopa initial dose was 25 mg-100 mg orally three times a day or 10 mg-100 mg orally 3 or 4 times a day, increased by 1 tablet every day or every other day as needed, until a dose of 8 tablets (2000 mg) was reached. When adding pramipexole ER to the regimen, the doses were adjusted according to patients' symptoms.[19]

The enrolled patients' medications were recorded and their baseline total levodopa equivalent dose (LED) was calculated before and after shifting the patient to pramipexole ER. LED was calculated based on the conversion factors in Table 1.

Table 1. Levodopa equivalent daily dose conversion factors[5]

Drug	Conversion factor
Levodopa	x 1
Entacapone	LD x 0.33
Tolcapone	LD x 0.5
Pramipexole	x 100
Ropinirole	x 20
Rotigotine	x 30
Selegiline oral	x 10
Selegiline sublingual	x 80
Rasagiline	x 100
Amantadine	x 1
Apomorphine	x 10

Outcome measures

The primary endpoint was defined as the change in LED after introducing Pramipexole ER into the regimen. The secondary endpoint was defined as the mean change from baseline to week 13 in the UPDRS-III score. A cutoff point for a minimal clinical important difference in UPDRS-III was a decrease in 2.5-5 points.[20,21] Other endpoints observed were the change in LED based on age (<65 vs. >65 years) and the severity of motor symptoms defined as mild for UPDRS-III <32, moderate 33-58, and severe >59.[22]

Data Analysis

Statistical analysis was performed using the SPSS version 20.0. Descriptive statistics were used to describe patient characteristics (frequencies and percentages for categorical variables), and mean (standard deviation) for continuous variables. Pearson chi-square test was used to study the association between different categorical variables and student-t-test for continuous variables. The LED before and after pramipexole ER introduction in the same patient was compared for statistically significant differences using the paired student-t-test. A decrease in LED was analyzed as a drug dose reduction and/or elimination from baseline PD regimens. All reported p-values were two-sided with the alpha set at a significance of 0.05.

RESULTS

Out of 176 patients 54.5% were males and 45.5% were females. The mean age of the patients ranged from 27-88 was 60 years old (SD=8.1), 56.8% were less than or equal to 65 years. Regarding the disease duration, the mean was 2.5 years (SD=2.4). The mean baseline LED was 451.5 mg and the mean baseline UPDRS-III score was 18.99 points (SD=12.7) with 86.3% of patients less or equal to 30. (Table 2)

Pramipexole ER showed a significant difference on the mean changes in LED and UPDRS-III score. After 13 weeks of initiating Pramipexole ER, the mean decrease in LED was for all patients -49.42 mg (p<0.001, 95%CI [35.28-63.55]) and the mean decrease in UPDRS-III score for all patients was -6 points (p<0.001).

Subgroup analyses

In patients aged 65 years and below, the change in mean total LED from baseline (350.80 mg) was a decrease of 63.19 mg with a p<0.001, 95%CI [42.07-84.31]. In patients

Table 2. Baseline patient characteristics

Variable	N=176
Age	Mean: 60.7 (SD=8.39)
< 65	100 (56.8)
> 65	76 (43.2)
Gender	
Male	96 (54.5)
Female	80 (45.5)
Duration of PD (y)	2.5 (2.6)
UPDRS III	18.9 (12.9)
Total Levodopa equivalent dose	451.5 mg (272.5)
Data are mean or number of subjects (%) unless otherwise indicated.	

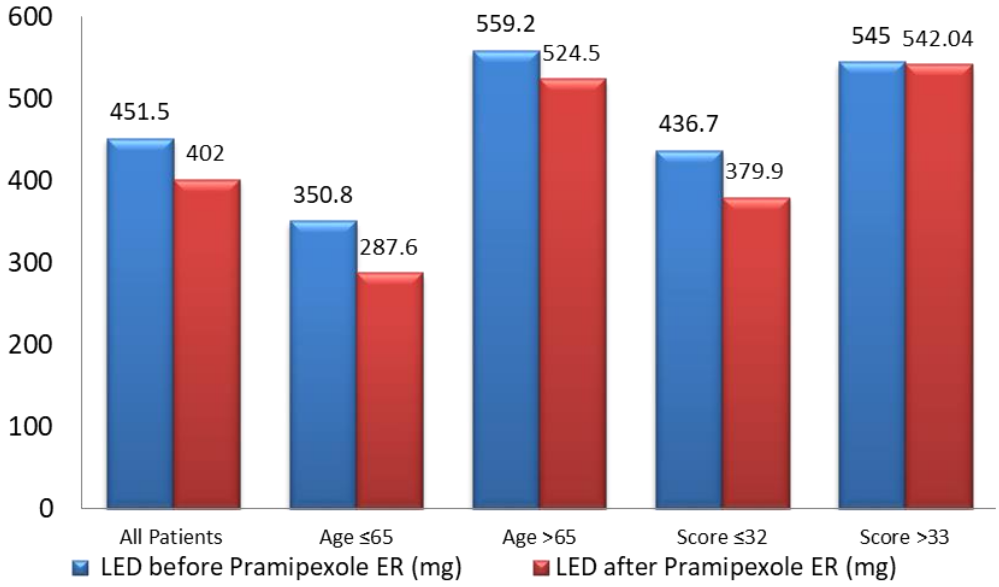

Figure 1. Change in levodopa equivalent dose.

aged more than 65 years, the change in mean total LED from baseline (559.25 mg) was a decrease of 34.67 mg with a p<0.001 CI 95% [16.16-53.18].

In patients having an UPDRS-III score of less than or equal to 33, the change in mean total LED from baseline (436.73 mg) was a decrease of 56.76 mg (p<0.001; 95%CI [41.32-72.20]). However, in patients having an UPDRS-III score of more than 33 the change in mean total LED from baseline (545.06 mg) was a decrease of 2.96 mg with a p value<0.844 95%CI [27.32-33.15] (Figure 1).

DISCUSSION

According to our knowledge there are no studies evaluating the change in total LED in the same patient before and after introduction of pramipexole ER in Lebanon. In this study, it was observed that the total LED can be significantly reduced. Either due to symptom's improvement or patient's adherence using the Pramipexole ER, PD medication's dose or agents were reduced or removed from the regimen. This result was consistent with other related studies.[23,24]

Our study showed an 8 points decrease in UPDRS-III score at 13 weeks with pramipexole ER, greater than the suggested cutoff point for efficacy. A similar study demonstrated a decrease of 6.1 points in pramipexole ER treated group.[25]

When taking age into consideration, pramipexole ER use was associated with lower LED in both groups (≤65 and ≥65 years), this indicates that pramipexole ER is an effective option in elderly patients. This correlates well with previous studies done to evaluate the efficacy of pramipexole in older patients.[26-29] A research that was conducted Pellicano et al. showed that pramipexole ER has levodopa sparing effect in patients older than 65 years16 . This theory is aligned with the standards of care in levodopa therapy among older adults with functional impairments due to the potential of worsening of the quality of life as well as greater risk of psychiatric side effects with dopamine agonists versus levodopa. However, in terms of doses, pramipexole ER decrease LED in older patients therefore further studies are required to proven the effect of dose reduction to be either beneficial or clinically insignificant and unnecessary.

With respect to the UPDRS-III score pramipexole ER was significantly correlated with lower LED total doses in patients with mild motor symptoms.

(UPDRS-III ≤33). In contrast, pramipexole ER levodopa sparing effect in patients having moderate to severe motor symptoms (UPDRS-III >33) was not significantly different. This result correlates well with other studies showing that the use of pramipexole ER was associated with lower LED in patients having mild-moderate PD[30,31] and not with severe PD, which can be explained by the need of combination therapies and higher doses to control advanced PD symptoms.

Although PD is a progressive degenerative disorder, pramipexole ER showed its ability to spare or delay the use of high levodopa doses and the absolute dependency to Levodopa, thus sparing the patient from complications that may arise from levodopa multiple daily dosing.

Limitations

Though our results were homogeneous with most previous studies, there still exist several limitations. Some of the limitations in this study are that it is retrospective and single-centered. Extra patients' visits before week 13 were not recorded. Concerning efficacy measures, we used the UPDRS-III section only, while in other trials more parts of this scoring system were used. Besides, the LED conversion factors are not universally unified and thus may affect the accuracy and reliability of our results. We couldn't study the prevalence of side effects before and after the addition of pramipexole ER and those of levodopa since data was not readily available in patient's charts. In addition, adherence to the treatment along with baseline characteristics such as co-morbidities and treatment patterns couldn't be retrieved from the available patients'

charts as well because of the retrospective nature of the study. Future studies that will address all these limitations are needed.

CONCLUSIONS

The total LED is significantly lowered when pramipexole ER is introduced to the same patient. The dose reduction is mostly prominent in patients aged less than 65 years with an UPDRS score less than 33. Furthermore, patients aged more than 65 years can also benefit from the LED reduction. This study opens new horizons on the potential role of health care professionals in maintaining the patient on the lowest effective levodopa equivalent daily dose and optimize the treatment therapy, thus decreasing the side effects that might arise from overdosing of antiparkinsonian drugs.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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Original Research

Influence of self-efficacy management on adherence to self-care activities and treatment outcome among diabetes mellitus type 2 Sudanese patients

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Abstract

Background: High level of self-efficacy and adherence to self-care activities have a positive impact on the achievement of glycemic goal among diabetic patients. In Sudan, there is a gap in knowledge related to self-efficacy management and its influence on adherence to self-care activities and overall disease control.

Objective: To identify the influence of management self-efficacy on adherence to self-care activities and treatment outcome among Sudanese patients with type 2 diabetes mellitus.

Methods: A cross-sectional study was conducted at two health care facilities in Sudan from April to May 2016. Patients with type 2 diabetes mellitus were included. Convenience sampling method was adopted. Diabetes Management Self-Efficacy Scale and the Revised Summary of Diabetes Self-care Activities were used to collect data through a face-to-face interview. Logistic regression analysis was performed. A p value <0.05 was considered to be significant. Data were processed using the software SPPS v 21.0.

Results: A total of 392 patients were included. Respondents classified with high level of self- efficacy across all domains were 191 (48.7%). Moreover, high level of education [adjusted OR 0.5 (0.3-0.7), (p=0.001)] and formal health education on diabetes [adjusted OR 2.4 (1.6-3.7), (p<0.001)], were found to be significantly associated with high level of diabetes management self-efficacy. Patients who had high level of self-efficacy to manage nutrition, physical exercise activity and medication were found more adherent to general diet, exercise activity, and medication taking, respectively. Patients with controlled disease were 87(22.2%). The only predictor of diabetes control was diabetes management self-efficacy [OR 2.1(1.3- 3.5), (p=0.002)].

Conclusions: Diabetes management self-efficacy was associated with high level of education and receiving health education. Self-efficacy was significantly associated with adherence to self-care activities and glycemic control. Substantial efforts are still needed to empower the patients with self-efficacy and improving adherence to self-care activities through appropriate interventions.

Keywords

Diabetes Mellitus, Type 2; Self Efficacy; Medication Adherence; Self Care; Healthy Lifestyle; Outcome Assessment (Health Care); Multivariate Analysis; Surveys and Questionnaires; Sudan

INTRODUCTION

Diabetes mellitus (DM) is an important public health problem with a steadily increasing rate globally. In the year 2014, an estimated number of 422 million adults were living with the disease.[1] Type 2 diabetes mellitus accounts for more than 90% of all diabetes globally.[2]

In Sudan, a recent research conducted in urban communities revealed a high rate of diabetes among adult population (19.1%) and impaired glucose tolerance (9.5%).[3] Diabetes represent a significant impact in term of adverse social effects and economic burden on Sudanese patients.[4]

Achievement of the target therapeutic goals requires regular monitoring of blood sugar, strict adherence to both lifestyle measures and medications, and continuous management to prevent complications. Therapeutic goal achievement also needs a high capability to survive with the psychosocial challenges related to living with the disease and dynamically consuming pertinent diabetes support services.[5] Multiple factors can influence glycaemic control, which can be related to the patient, the disease and the treatment.[6] Studies around different parts of the world documented high prevalence of uncontrolled diabetes with multiple factors implicated in poor blood sugar control.[7-10]

Self-care in diabetes is an evolutionary process of developing knowledge or awareness by learning to survive with the complex nature of the disease in a social context.[11] Self-care in diabetes include seven important activities, which predict the outcome of treatment, such as eating healthy diets, practicing physical exercise, monitoring of blood sugar, adherence to medications, good problem–solving skills, healthy coping skills, and risk-reduction behavior.[12] Self-management is considered as the foundation of diabetes care, and it is assumed that improving patient self-management could be through enhancement of self-efficacy.[13]

Self-efficacy concerns with the people's beliefs about their capabilities to produce designated levels of performance

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that exercise influence over events that affect their lives.[14] Self-efficacy can be simplified by the interaction between behavioral, personal, and environmental factors in health and chronic disease.[14,15] Self-efficacy has a positive influencing effect on self- management for many chronic health conditions.[15,16] High self-efficacy was found to be associated with high self-care behavior among diabetic patients, and both had a direct effect on glycosylated hemoglobin (HbA1c).[17-20] Conversely, in some studies, no significant association was documented between glucose control and self-efficacy or self-care.[21,22] Moreover, educational status, employment status, family support, positive mental attitudes and diabetes education were found to have an influence on self-efficacy.

To the best of our knowledge, no previous study was conducted in Sudan among diabetic patients to correlate self-efficacy with self-management activities and identify the role of self-efficacy on glycemic control. Therefore, this study was conducted to identify the influence of management self-efficacy on adherence to self-care activities and treatment outcome among Sudanese patients with type 2 diabetes mellitus. Secondary objectives were: to measure the level of diabetes management self-efficacy, and to determine its predictors and to determine the level of disease control and to identify its determinants.

METHODS

Design and population

A cross-sectional study was conducted at two healthcare facilities in Khartoum State in Sudan (Jabir Abu Elizz Diabetes Centre and the Outpatient Clinic in Soba Teaching Hospital) from April to May 2016. The Outpatient clinic in Soba Teaching Hospital, which is located in the Southern part of Khartoum State, provides services for approximately 40000 patients per year suffering from chronic diseases. Jabir Abu Elizz Diabetes Centre, located in the central part of Khartoum State, is the only public center for diabetes in the state. The Center provides a broad range of medical services for diabetic patients. The two healthcare facilities were selected as points for data collection due to their potentiality with respect to the number of patients.

The Patients aged over 20 years and diagnosed with type 2 diabetes mellitus, at least one year before commencement of data collection were included. Patients with cognitive impairment, inability to communicate verbally, pregnant or lactating women, and patients had severe concurrent illness that limit lifestyle change were excluded. The patients consented verbally, because the research posed no risk and did not involve procedures for which written consent is normally needed. The convenience sampling method was used, because there were no well-defined registry records in both settings. The sample size was estimated to be 384 patients by using the following equation:

$$n = \frac{(1.96)^2 pq}{(D)^2}$$

Table 1. Patients' sociodemographic data

Demographic variable	N	Percent
Gender		
Male	212	54.1
Female	180	45.9
Age in years		
<50 Years	142	36.2
>50 Years	250	63.8
Residence		
Khartoum State	279	71.2
Other states	113	28.8
Educational level		
0-9 Years	223	56.9
>9 Years	169	43.1
Marital status		
Married	342	87.2
Single	050	12.8
Financial support		
Self	286	73.0
Family	106	27.0
Employment		
Employed	161	41.1
Unemployed	231	58.9
Health insurance status		
Covered	325	82.9
Uncovered	067	17.1
Body mass index (Kg/m^2)		
Normal	142	36.2
Obese & overweight	250	63.8
Smoking status		
Smoker/Ex-smoker	97	24.8
Non-smoker	295	75.2
Duration of diabetes		
1-10 years	209	53.3
>10 years	183	46.7
Attending formal diabetes education		
Yes	195	49.7
No	197	50.3
Total	392	100

Whereas (p=Probability=0.5), (q=1-p=0.05), (D=Degree of precision=0.05, confidence level (CI)=95%).

Ethical approval for the conduction of the study was obtained from Ministry of Health – Khartoum State on 20 March 2016.

Instruments

The data was collected by the main author through face-to-face interview method using a pre-tested questionnaire. The questionnaire was developed after thoroughly searching the literature for relevant studies. Pertinent clinical parameters were extracted from the relevant patients' records. Recent HbA1c results were extracted from the patients' medical records. The second part was designed to collect data on patients' self-efficacy for the management of diabetes using the Diabetes Management Self-Efficacy Scale (DMSES), which is composed of 20 items.[23] DMSES assesses the extent to which a patient is confident that he or she can manage his/her blood glucose level (3 items), foot care (1 item), medication (2 item), diet (10 items), level of physical activity (3 items), and visiting the physician once a year for a checkup (1item). Responses were rated using a scale ranging from 0 (can't do at all) to 10 (certain to do) with high scores indicating high self-efficacy. High and low general diabetes management self-

Table 2. Determinants of diabetes management self-efficacy

Covariates	self-efficacy		Univariate analysis		Multivariable analysis	
	%	n	crude OR (95% CL)	p-value	adjusted OR (95% CL)	p-value
Gender						
Female	51.7	180	1			
Male	46.2	212	0.8 (0.5-1.2)	0.283		
Age group in year						
≤ 50	44.8	142	1			
>50	55.6	250	1.5 (1.0-2.3	0.040		
Residence						
Other states	42.5	113	1			
Khartoum	51.3	279	1.4 (0.9-2.2)	0.116		
Educational level						0.001
> 9 years	60.9	169	1		1	
0-9 years	39.5	223	0.4 (0.3-0.6)	<0.001	0.5 (0.3-0.7)	
Marital status						
Others	52.0	50	1			
Married	48.2	342	0.9 (0.5-1.6)	0.620		
Employment status						
Unemployed	47.2	231	1			
Employed	50.9	161	1.2 (0.8-1.7)	0.466		
Duration with diabetes						
> 10 years	48.1	183	1			
1-10 years	49.3	209	1.0 (0.7-1.6)	0.813		
Attending formal diabetes education						<0.001
No	36.5	197	1		1	
Yes	61.0	195	2.7 (1.8-4.1)	<0.001	2.4 (1.6-3.7)	
Diabetes complication						
No	56.9	109	1			
Yes	45.6	283	0.6 (0.4-1.0)	0.046		
Total		392				

efficacy and self-efficacy at different domains were measured as follow:

a. The patient was considered as having high level self-efficacy if scored equal or above the mean scores of all the participants.

b. Similarly, high level of self-efficacy at each domain (nutrition, physical exercise and medication) was defined as scores equal or higher than the mean score of all patients.

The third part of the data collection tool included the Revised Summary of Diabetes Self-care Activities (SDSCA).[24] In this part, the participant was requested to report the number of days in the last 7 days in which he/she performed each self-care activity. The activities include; diet, exercise, blood glucose testing, medication taking, foot care, and smoking behavior. Adherence to the activities was defined as follows:

a. Adherence to general diet, specific diet, and physical exercise domains was defined as adherence to the determined self-care activity for at least 5 days during the past week.

b. Adherence to medication was defined as full compliance during the past week. If the patient reported less than seven days adherence to medication, he/she was considered as non-adherent.

The last part of the questionnaire was designed to record glycated hemoglobin (HbA1c). Diabetes was considered controlled if HBA1c was <7% as per both study sites protocols. The questionnaire was piloted among ten patients to ensure applicability and to estimate the time frame needed for data collection. Minor changes were suggested and finally adopted in the last version.

The questionnaire was delivered to the patients in Arabic language. The Arabic version of DMSES and SDSCA were used after obtaining the permission from Elbur *et al.*[25] The translation was checked further to fit the Sudanese dialect. The research team also checked the questionnaire content validity.

The main outcome measures in the study were: 1) The influence of the level of diabetes management self-efficacy on diabetes self-care activities; and 2) The influence of the level of diabetes management self-efficacy on disease control. Two secondary outcome measures were also considered: 1) The level of diabetes management self-efficacy and its predictors; and 2) The level of disease control and its determinants.

Data analysis

Descriptive statistics were used to characterize the study sample. Percentage and means with standard deviation (SD) were used to describe the variables. Cronbach's alpha was used to examine the internal consistency of DMSES and SDSCA. Logistic regression analysis was performed to determine the most significant independent variables (demographic and clinical variables) associated with diabetes self-efficacy, management, and diabetes control as dependent variables. Crude logistic regression analysis was performed as initial steps of qualifying covariates to be included in multivariate logistic regression analysis. Covariates with p-value <0.05 were eligible for inclusion in the final model. The association between self-efficacy management and adherence to self-care activities was

Table 3. Mean number of days and adherence to diabetes self-care activities		
Diabetes self-care activities	**Days/adherence. Mean (SD)**	**Adherent**
General diet	5.1 (1.9)	253 (64.5%)
Specific diet	3.9 (1.9)	121 (30.9%)
Physical exercise	2.2 (2.3)	69 (17.6%)
Medication taking	6.1 (1.8)	272 (69.4%)
Blood glucose testing	1.7 (3.6)	0 (0%)
Foot exams	4.1 (3.0)	0 (0%)

tested by independent t test or chi-square test. P-values <0.05 were considered statistically significant. The data were processed using the software SPSS v 21.0 (SPSS Inc., Chicago IL, USA).

RESULTS

A total of 392 patients were included, with 335(85.5%) recruited from Jabir Abu Elizz Diabetes Centre and 57 (14.5%) from Soba Teaching Hospital. Male patients were 212 (54.1%) and 250 (63.8%) aged over 50 years. More than half of the participants attained an educational level between 0-9 years and 49.7% attended formal diabetes education sessions. Obese and overweight were 250 (63.8%). Table 1 showed participants characteristics.

Out of all included patients, 211(53.8%) had other concomitant disease. Patients suffered from hypertension were 140 (35.7%), and 119 (30.4%) had dyslipidemia. Regarding diabetes complications, 111(28.3%) experienced retinopathy, 236 (60.2%) neuropathy, 83(21.2%) diabetic septic foot and 12 (3.1%) nephropathy.

The internal consistency of DMSES was alpha=0.9. The mean scores of self-efficacy to manage nutrition, physical exercise and weight control and medication were 67.8 (SD 17.0), 18.6 (SD 7.3) and 18.0 (SD 3.4), respectively. The mean score of diabetes management self-efficacy across all domains was 136.8 (SD 29.7). Out of all interviewed patients, 191 (48.7%) were classified as having high self-efficacy across all domains to manage diabetes. Participants with high level of self-efficacy in nutrition management, physical exercise and weight control, and medical treatments were 188 (48.0%), 199 (50.8%) and 281(71.7%), respectively.

Table 2 shows the determinants of diabetes management self-efficacy. Multivariate analysis showed that, education over 9 years, and receiving formal health educational sessions on diabetes were significantly associated with high level of diabetes management self-efficacy.

Among the participants, 253 (64.5%), 121 (30.9%), 69 (17.6%) and 272 (69.4%) were classified as adherent to general diet, specific diet, physical exercise and treatment plan, respectively. Table 3 shows the mean number of days and the level of adherence to diabetes self-care activities.

As shown in Table 4, patients with high self-efficacy to manage nutrition, physical exercise activity and medication were found to be more adherent to general diet, exercise activity and medication taking, respectively, compared to those with low efficacy to manage these domains.

Out of all interviewees, 87 (22.2%) achieved the target therapeutic goal and considered with controlled disease. Univariate analysis showed that the only predictor of diabetes control was diabetes management self-efficacy, as shown in Table 5. The 55 patients (28.8%) who had high self-efficacy, presented more frequently the disease controlled, compared to 32 (15.9%) with low self-efficacy, [OR 2.1 (1.3- 3.5), p=0.002).

DISCUSSION

The current study is the first one of its type to investigate the influence of self-efficacy management and its influence on adherence to self-care activities and disease control among diabetic Sudanese patients. Previous studies around the world demonstrated this association, but the documentation of this association at the level of Sudanese patients might convince healthcare authorities and institutions and adopt the concept in health education aiming to change patient behavior.

Analysis of the demographic variables of the patients recruited in this study showed that approximately 30% of them were living in rural areas, where it is difficult to reach the vital services. This reflects the centralization of health services for important chronic illness like diabetes. To the best of our knowledge, there are no specialized centers to provide care for diabetic patients in other states of Sudan. This might partially explain a late diagnosis, poor diseases control, and development of complications. More than half of the respondents had education between 0-9 years, which could affect the understanding of important health education messages. Unemployed participants represented 59%, which in agreement with Von Arx *et al.*[5] study, where most of the population was unemployed because of diabetes complications. The major observed comorbid conditions were hypertension and dyslipidemia, which might increase the microvascular and macrovascular risk in patients with diabetes, but also might increase the financial burden, which inversely could affect the adherence to medication and self-care activities.[26] In our study, nearly half (48.7%) of all interviewees participated in this study were classified as having high self-efficacy across all domains to manage their diabetes, and 48.0%, 50.8% and

Table 4. Diabetes management self-efficacy and self-care management practice				
Domain	**Self-efficacy**		**Adherent**	**p-value**
	High	**Low**		
Nutrition-general diet	143 (76.1%)	110 (53.9%)	253	<0.001
Nutrition- specific diet	64 (34.0%)	57 (27.9%)	121	0.150
Physical exercise	55 (27.6%)	14 (7.3%)	69	<0.001
Medication taking	242 (74.2%)	30 (45.5%)	272	<0.001

Table 5. Determinants of diabetes control (univariate analysis)				
	Disease control		crude OR (95%CI)	p-value
	%	n		
Gender				
Female	20.6	180	1	
Male	33.6	212	1.2 (0.7-1.9)	0.472
Age group in year				
> 50	23.6	250	1	
< 50	19.7	142	0.8 (0.5-1.3)	0.375
Residence				
Other states	19.5	113	1	
Khartoum	23.3	279	1.2 ((0.7-2.1)	0.409
Educational level				
> 9 years	18.3	169	1	
0-9 years	25.1	223	1.5(0.9-2.4)	0.111
Marital status				
Others	24.0	50	1	
Married	21.9	342	0.9 (0.4-1.8)	0.742
Employment status				
Unemployed	22.1	231	1	
Employed	22.4	161	1.0 (0.6-1.6)	0.947
Duration with diabetes				
> 10 years	21.3	183	1	
1-10 years	23.0	209	1.1 (0.7-1.8)	0.694
Diabetes complication				
No	24.8	109	1	
Yes	21.2	283	0.8 (0.5-1.4)	0.447
Self-efficacy				
Low	15.9	191	1	
No	28.8	201	2.1 (1.3-3.5)	0.002
Total		392		

71.7% were classified as having a high level of self-efficacy to manage nutrition, physical exercise and weight control, and medical treatment, respectively. Comparatively, in a recent published study conducted among Saudi diabetic patients, self-efficacy was found to be moderately low.[27]

The most important predictors of high level of self-efficacy in our study were the participation in diabetic health education sessions and a high educational level (over 9 years). Both factors are deemed important for understanding of all aspects related to the disease, complications, medical management and the importance of adherence to lifestyle recommendations. Diabetes management self-efficacy was reported as the single most important determinant of the disease control and influenced by educational status.[21] Participation in diabetes education programs was also found to be a key factor in diabetes control.[28] The results of our study identified the role of self-efficacy on adherence to diabetes self-care activities across important domains of lifestyle changes. This finding was in concordance with the results of other studies conducted in China[20], India[21], and Native Americans and Alaska Natives.[29]

Our results also showed that adherence to medication was higher compared to other self-care activities (diet and exercises). In another Sudanese study also conducted in Khartoum state, the authors quoted a deficiency in knowledge about the role of adherence to both domains in the control of the disease (diet 62.3% and physical exercise 51.2%).[30]

Only 22% of the respondents attained the target therapeutic goal for the control of diabetes. This high percentage of uncontrolled diabetes justifies the prevalence of disease complications observed among the interviewees. The only predictor of diabetes control was self-efficacy for the management of the disease. In fact, several studies had linked high self-efficacy with performing diabetes self-care behaviors, which directly linked to glycemic control.[1,17,22,31-33] Self-efficacy is commonly presented as a contribute to the adjustment of the disease and good glycemic control in the long term.[20] However, the literature is not be free from controversial results, with some authors supporting that adherence to self-care management behaviors are related to poor glycemic control[9] and found no significant association between social support, self-efficacy, self-care behaviors and glycemic control.[34]

Overall, the findings of our study reflected the importance of self-efficacy as an important determinant of adherence to self-care activities and ultimately to glycemic control. Health care facilities caring for diabetic patients in Sudan should adopt educational intervention programs to increase the level of self-efficacy and to empower patients to better participate in the management of the disease. These goals could be achieved by incorporating self-efficacy in the ongoing education process and through social support.

Limitations

Our study presented some limitations. First, the study was conducted in two settings in one state, so the results cannot be generalized to all diabetic patients at the national level. Second, the study adopted convenience sampling. And third, the self-report method was used to collect data on adherence to self-care management activities, which imply the obtained results may suffer from any bias.

CONCLUSIONS

The level of self-efficacy and adherence to self-care management were high in about half of the respondents, and there was a significant association between self-efficacy and adherence to self-care activities and level of glycemic control. Educational level and formal diabetes education were found to be significantly associated with high level of diabetes management self-efficacy. Enhancing self-efficacy and adherence to self-care activities through continuous patient education must be taken in consideration in diabetes management plan.

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CONFLICT OF INTEREST

None to be declared.

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Original Research

Health promotion of bowel cancer and breast cancer screening in community pharmacies: Pharmacists' perceptions of their role, knowledge and confidence.

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Abstract

Objectives: To identify community pharmacists' perceptions of their role, knowledge and confidence in relation to bowel cancer and breast cancer screening health promotion.

Methods: This was a mixed-methods study with community pharmacists and key informants in the Metro South Health (MSH) region of Brisbane, Queensland, Australia. In Part 1, quantitative data was collected from community pharmacists via an electronic survey. In Part 2, qualitative data was collected from community pharmacists and key informants via in-depth interviews. This paper reports the findings of community pharmacists' perceptions of their role, knowledge and confidence to promote bowel cancer and breast cancer screening in community pharmacies.

Results: A total of 27 community pharmacists (13 males, 14 females) completed the survey. Most (71%) either 'agreed' or 'strongly agreed' discussing health advice, such as cancer screening, with their consumers was valuable and integral to their broader role. An average of 60% described their confidence as 'average' or 'good' when discussing bowel and breast cancer screening and prevention with consumers. In eight knowledge questions about bowel and breast cancer and cancer screening, an average of 82% of community pharmacists responded with correct answers (range 52% to 100%). Community pharmacists were consistently more confident and knowledgeable about bowel cancer services than breast cancer services. Five (5) community pharmacists participated in in-depth interviews. The interview findings supported the quantitative findings. Most community pharmacists described their confidence to promote bowel cancer and breast cancer screening as moderate, and consistently reflected they felt more knowledgeable and confident about bowel cancer topics than breast cancer topics.

Conclusions: Overall, this research supports the feasibility of promoting bowel cancer screening in community pharmacies. It suggests further training is warranted for community pharmacists to increase their knowledge of breast cancer and their confidence in promoting breast cancer referral and screening services. It highlights the important role community pharmacists have in increasing engagement in the national bowel cancer and breast cancer screening programs, and in potentially decreasing the mortality rates of these cancers.

Keywords

Intestinal Neoplasms; Breast Neoplasms; Early Detection of Cancer; Mass Screening; Community Pharmacy Services; Health Knowledge, Attitudes, Practice; Attitude of Health Personnel; Health Promotion; Pharmacies; Pharmacists; Qualitative Research; Australia

INTRODUCTION

Cancer is the leading cause of disease burden in Australia.[1] Bowel cancer and breast cancer are among the most common cancers estimated to account for 12.4% and 13.0% of all new cancers diagnosed in Australia in 2017.[2,3] Bowel cancer and breast cancer are associated with a significant risk of mortality estimated to account for 8.6% and 6.5% of all age-standardised cancer-related mortality in Australia in 2017.[4]

In Australia, the national screening programs for bowel cancer and breast cancer are operated by the federal government's National Bowel Cancer Screening and BreastScreen Australia programs in partnership with state and territory governments. The programs aim to deliver "an organised, systematic and integrated process of testing for signs of cancer or pre-cancerous conditions in asymptomatic populations" to enable earlier detection and improved survivability.[1] The programs are provided free-of-cost every 2 years to populations where evidence suggests screening is most effective at reducing cancer-related morbidity and mortality.[1] For bowel screening, immunochemical faecal occult blood tests are offered to people aged 50 to 74 years.[1,5] For breast screening, a mammogram is recommended to women aged 50 to 74 years.[1,6] Women over 40 years of age are also eligible.

Research suggests Australia's national bowel cancer and breast cancer screening programs are highly effective. A major evaluation of the BreastScreen Australia program showed the program reduces breast cancer mortality by up to 28%.[7] Participants in the National Bowel Cancer Screening Program found to have bowel cancer are likely to have less-advanced cancer than non-participants at the time of diagnosis and a greater chance of survival.[8] The National Bowel Cancer Screening and BreastScreen Australia programs are well accepted by consumers,

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accessible and cost-effective.[7-9] Despite this, participation is moderate. In the two-year period, 2014 to 2015, 39% of eligible people completed a screening test for bowel cancer, and 54% of women in the target age group (50 to 74 years) completed a screening test (mammogram) for breast cancer.[1] It is therefore important to find novel ways of promoting and improving participation in bowel cancer and breast cancer screening.

Community pharmacies are one setting where cancer screening may be effectively promoted. In Australia, under the Quality Care Pharmacy Program, community pharmacies are required to deliver health promotion activities. There are more than 5300 community pharmacies in Australia, and this number is increasing.[10] Pharmacies are the most visited healthcare service in Australia; 94% of Australian adults use a pharmacy each year. This accounts for 300 million patient visits annually.[10] An estimated 3.9 million consumers attend a pharmacy each year specifically to ask for health advice.[10] Pharmacies may be effective at engaging hard-to-reach groups, including lower-socioeconomic groups, who may be at increased risk of cancer but less likely to participate in screening.

Most pharmacies in Australia are actively involved in some form of health promotion. For example, national health promotion programs for alcohol awareness, sexual health, smoking cessation, weight loss and continence care.[11] Recent research demonstrates the effectiveness and acceptability of health promotion programs in Australian pharmacies for screening for alcohol consumption[12], cardiovascular disease[13], chlamydia[14], diabetes[15,16] and hypertension.[17]

There is available research about health promotion for cancer and cancer screening in pharmacies. Studies by Jiwa *et al*.[18-20] suggest pharmacists in Australia have an important role in the promotion of screening for bowel cancer. A systematic review, which included two studies by Jiwa *et al*.[18,20] and nine other studies from international settings concluded pharmacies have "significant potential" for the delivery of health promotion for the early detection of cancer, including promotion of screening for bowel and breast cancer.[21]

Australia's pharmacies are involved in the national cancer screening programs, in particular, for bowel cancer. Community pharmacies can promote the national bowel cancer screening program by selling screening kits to those who fall outside the program's eligibility criteria for free testing.[22] Recently, there has been a small pilot project involving the promotion of breast cancer screening services in community pharmacies.[23] However, involvement in these programs is at the discretion of individual pharmacies. This lack of consistency in service provision, and the potential for confusion among consumers, is problematic.

Overall, there is paucity of research – generally, and from Australia specifically – about key stakeholders' perceptions of the feasibility of promoting bowel cancer and breast cancer screening in community pharmacies. Subsequently, there is a lack of evidence to inform programs for promoting cancer screening in pharmacies. This mixed-methods study with community pharmacists and key informants in the Metro South Health (MSH) region of Brisbane, Australia seeks to address this gap in knowledge. This paper reports findings related to community pharmacists' perceptions of their role, knowledge and confidence in relation to bowel cancer and breast cancer screening health promotion. Other findings are reported elsewhere.

METHODS

This mixed-methods study was conducted in two parts. In Part 1, quantitative data was collected from pharmacists via an electronic survey. In Part 2, qualitative data was collected from community pharmacists and key informants via in-depth interviews. This paper reports on data collected from community pharmacists in Part 1 and Part 2.

Part 1 of this study was an electronic survey (see online Appendix). The survey was advertised to all pharmacists registered with the Queensland branch of the Pharmacy Guild of Australia via (1) group emails (including one initial and one follow-up email) and (2) posts on a social media channel. Community pharmacists were requested to complete the survey via an electronic link to the web host. The survey was open for 3 months between July and September 2016.

The survey consisted of multiple-choice questions. The survey began with demographic questions and asked community pharmacists about (1) perceptions of their health promotion role, (2) confidence in their health promotion role and (3) knowledge about bowel cancer and breast cancer. These questions were answered using Likert scales (e.g. 1=strongly agree to 5=strongly disagree, 1=poor confidence to 5=excellent confidence, etc.) and drop-down menus (e.g. true – false – unsure, etc.). Knowledge questions related to the key risk reduction, screening and early detection messages of the National Bowel Cancer Screening Program and BreastScreen Australia Program. The survey was delivered by email to all pharmacies registered with the Pharmacy Guild of Australia's Queensland branch (approximately 255 pharmacies, or 85% of all pharmacies in the MSH region).

Part 2 of the study involved in-depth interviews with community pharmacists and key informants from the MSH region of Brisbane. This paper reports the findings from community pharmacists only. Other findings are reported elsewhere. A purposeful sample of community pharmacists was recruited through an expression of interest at the end of the survey. The only criteria required to participate in an in-depth interview was the identification as a community pharmacist. Sampling was not based on answers to the electronic survey. All survey respondents were community pharmacists. Those who were interested in participating in an in-depth interview provided contact details. Other community pharmacists were purposefully recruited through the researchers' professional networks. All community pharmacists were provided with additional information by telephone or email. If a community pharmacist wished to proceed, a convenient time and date were arranged. All interviews were conducted face-to-face by the same experienced qualitative researcher in a public

space such as a café or the participant's pharmacy. Written informed consent was obtained from participants prior to commencement. The interviews lasted 45 to 90 minutes and were audio-recorded and transcribed with the participants' consent.

Interviews built on the electronic survey to add a rich and contextualised understanding to the quantitative data. The interviews included questions exploring pharmacists' perceptions of their role, confidence and knowledge in relation to health promotion generally, and the promotion of cancer screening specifically. The interviews investigated topics related to health promotion and cancer screening raised by the participants during the discussions.

To participate in the survey or an interview for the data reported in this paper, participants were: (1) currently registered as a pharmacist with the Pharmacy Board of Australia, (2) practicing as a community pharmacist (and not as a hospital, clinical or online pharmacist), and (3) practicing in the MSH region. MSH is a health catchment of Brisbane with approximately 1 million people, which is 23% of the Queensland population.[24] This catchment was selected because improving the provision of health services is a priority for the project's funders.

Quantitative data was analysed in Microsoft Excel®. The analysis involved counts and proportions. The data were tabulated and represented graphically.

Qualitative data was analysed thematically in two phases: (1) deductively to answer the research question posed for study (What are pharmacists' current knowledge, self-efficacy and capacity in discussing and promoting bowel cancer and breast cancer screening with their consumers?), and (2) inductively to examine the contextual data related to the research topic. The data analysis was undertaken following the iterative process outlined by Green and Thorogood.[25] The interviews were transcribed and read and re-read to develop familiarisation with the data. Next, significant statements in the transcripts – 128 in total – were identified and allocated a code. These statements were grouped with other similarly-coded statements to form themes – distinct, significant concepts related to the research topic. A detailed data analysis log was maintained.

The data analysis was undertaken iteratively over several months until the data settled. One researcher transcribed each in-depth interview. This researcher led the analysis of the in-depth interview transcripts with the support of two other researchers. An inter-rater reliability check was conducted with a random sample of 33 statements (approximately 25% of the data) selected from across all transcripts. The authors achieved 91% agreement about the theme to which each statement belonged and discussed the remaining 9% of statements until a consensus was reached. For this paper, the authors were in total (100%) agreement about the statements selected as evidence for each theme.

This research was undertaken collaboratively by practitioners and researchers from MSH (BreastScreen Queensland Brisbane Southside Service and National Bowel Cancer Screening Program) and the Queensland University of Technology's School of Public Health and Social Work.

Table 1. Demographic information for pharmacists (n=27) who completed the electronic survey.

Gender		
Male	48%	(n=13)
Female	52%	(n=14)
Age		
20-29 years	48%	(n=13)
30-39 years	15%	(n=4)
40-49 years	15%	(n=4)
50-59 years	18%	(n=5)
60-69 years	4%	(n=1)
>70 years		
Qualification		
Non-tertiary qualification	4%	(n=1)
Undergraduate degree	89%	(n=24)
Postgraduate qualification	15%	(n=4)
No response	7%	(n=2)
Length of time practicing as a pharmacist		
<1 year	11%	(n=3)
1-5 years	33%	(n=9)
6-10 years	11%	(n=3)
11-15 years	7%	(n=2)
21-25 years	19%	(n=5)
>25 years	19%	(n=5)

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RESULTS

The electronic survey was completed by 27 pharmacists (13 males, 14 females). See Table 1. Almost half (48%) of the respondents were aged 20-29 years and most (89%) had an undergraduate degree. Community pharmacists had been practicing for <1 year (11%), 1-5 years (33%), 6-15 years (18%), or over 21 years (38%). Five community pharmacists participated in an in-depth interview. This paper presents the findings from three themes, which emerged from this data: (1) pharmacists' perceptions of their health promotion role, (2) pharmacists' descriptions of their current health promotion role and (3) pharmacists' knowledge and confidence in their health promotion role. These themes relate to community pharmacists' perceptions of their health promotion role generally, and to their role in promoting bowel cancer and breast cancer screening specifically.

THEME 1: Community pharmacists' perceptions of their health promotion roles: "That's what they're there for".

According to the survey, most community pharmacists (71%, n=19) either 'agreed' or 'strongly agreed' discussing health advice, such as cancer screening, with their consumers was a part of their role. However, eighteen percent (18%, n=5) of community pharmacists indicated a 'neutral' response to this question. The same number of community pharmacists (71%, n=19) either 'agreed' or 'strongly agreed' discussing health advice with their consumers was a valuable part of their role. Fifteen percent (15%, n=4) of community pharmacists indicated a 'neutral' response to this question. See Figure 1.

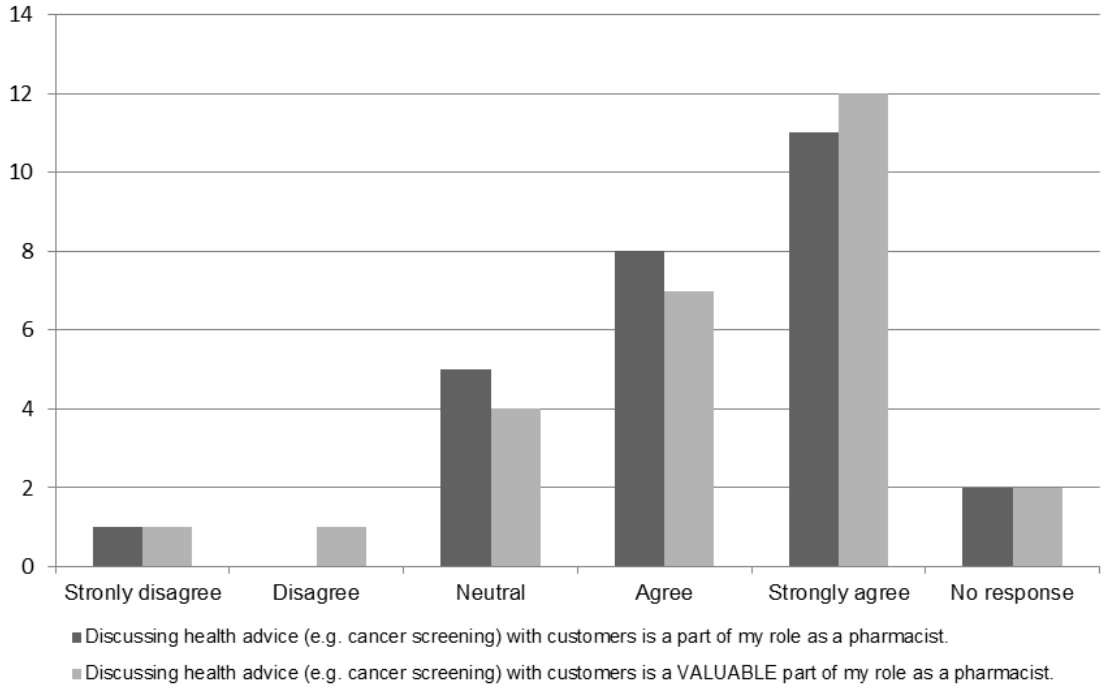

Figure 1. Pharmacists' responses to survey questions about their role discussing health advice with their consumers.

In the interviews, community pharmacists reflected on their health promotion role. Community pharmacists described health promotion as integral to their job. One community pharmacist stated:

> I think they're [pharmacists] – that's what they're there for… They're there to promote – or they're there to do health promotion. That's what they are there to do. (P:I08)

This community pharmacist went on to explain:

> [Y]our community pharmacy is not somewhere you should just be going to get your prescription dispensed. You know, it's somewhere you should be going as part of your overall health status… [Y]ou should be going to get advice… (P:I08)

Community pharmacists considered the promotion of bowel cancer and breast cancer screening to be consistent with their current health promotion role. They described the promotion of cancer screening as fitting seamlessly with this role. For these reasons, most community pharmacists regard pharmacies as suitable places for the promotion of cancer screening:

> I think it [the pharmacy] is an ideal place… [A] primary level type of space to approach people who are already in the pharmacy who are interested in their health, first of all. And who, you know, may be curious and open to those type of suggestions. (P:I07).

Community pharmacists reflected on of the importance of their health promotion role – both generally, and in relation to the promotion of bowel cancer and breast cancer screening specifically. For example, community pharmacists reflected on their potential role in the prevention or early detection of cancer:

> You will pick up … a certain percentage [of people] that have no idea that they may have breast cancer or bowel cancer, so it's certainly does work… If they have time with a pharmacist or a trained pharmacy staff, they will get positive outcomes from that, and if you get it early enough, you may prevent a long-term hospital stay. (P:I07)

Community pharmacists identified limitations in their current health promotion role. Community pharmacists felt they were not approaching problems at the population-level because their interactions with consumers are individual and often in an acute or post-diagnosis phase. This idea is reflected in the following quote.

> [W]e're dealing with each individual person as they come in, but we're not globally going out there and going, yes, this is what everyone should do… [T]he thing is, you're so caught up doing other things that … you don't really get a chance to do the sort of a broader scale – And the thing is, you actually want to be talking to the people that don't have these problems yet, it's prevention that you're wanting, whereas I think that's the problem… – how do we reach those people in a bigger scale? (P:I08)

Another limitation community pharmacists perceive about their current health promotion role is that consumers do not recognise or take advantage of this role. One community pharmacist stated:

> [W]e could play a huge role in that [the promotion of cancer screening in pharmacies]… [T]hey [clients] don't always come and ask, come to us, [be]cause they don't think … they can come to us for that. But rather, I think there's a huge role for that. (P: I04)

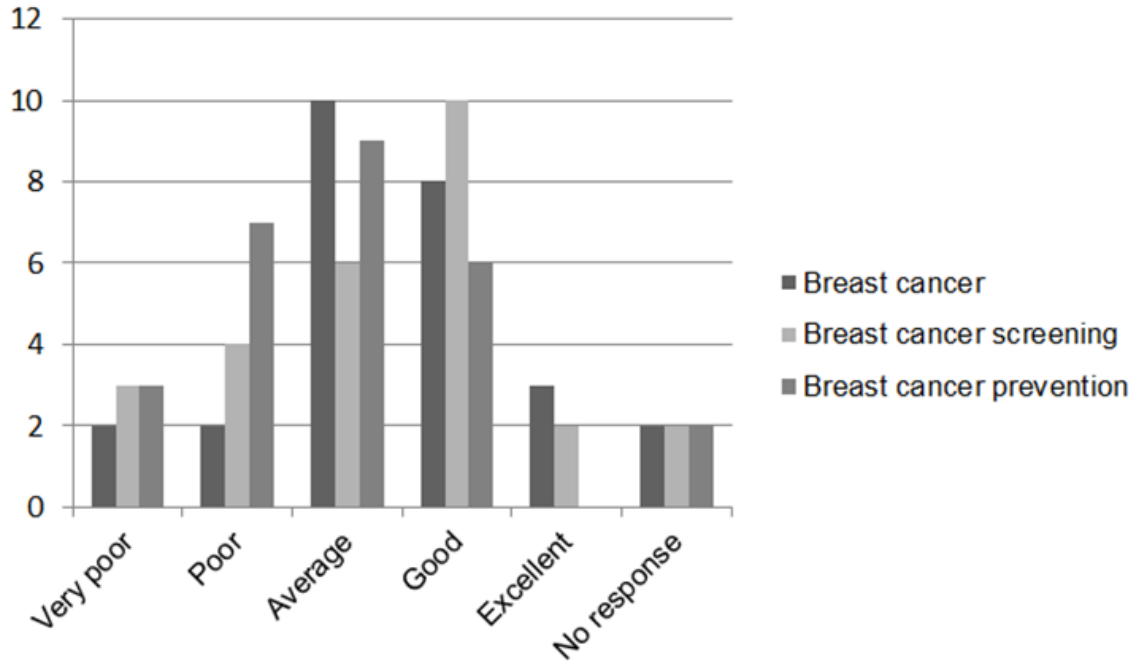

Figure 2. Pharmacists' responses to survey questions about their confidence discussing breast cancer topics with their consumers.

In summary, this theme presents community pharmacists perceptions about their health promotion role in community pharmacies. Community pharmacists feel health promotion is an important and relevant aspect of their role because it aligns with the broader holistic health care approach. In particular, community pharmacists consider breast cancer and bowel cancer screening consistent with early detection and prevention philosophies underpinning primary health care. However, they feel their role is limited by individualised consumer care and consumer understanding.

THEME 2: Community pharmacists' descriptions of their current health promotion roles: "Talking about it was just sort of second nature".

In the interviews, community pharmacists reflected about their current health promotion role. They describe this role as one which centres around the provision of basic health information and simple screening for common conditions such as skin cancer, hypertension and diabetes. One community pharmacist stated:

> So, if you were concerned about that spot, for example, so we would take a picture, that goes … directly to the specialist, dermatologist, and the patient will get a report within twenty-four to forty-eight hours. And we've had many cases where they've had to then go to have that looked at by the specialist, next step up. So there's the – that service that we actually already offer… (P:I04)

Another community pharmacist gave the following example:

> [A]t the moment we might do blood pressure testing for cardiovascular risk. We look at, in the diabetes risk assessment … waist measurement and other sorts of risk factors questionnaires, things like that, that would grade someone's risk of getting those diseases and then having basically a referral process to the [general practitioner]. (P:I05)

More particularly, community pharmacists reflected about their role in relation to the promotion of bowel cancer screening because it is currently part of their practice

> I mean, we do bowel screening [promotion] now, and we were historically always involved in the Rotary bowel screen. So, talking about it was just sort of second nature around that time of year. But we've also had the bowel screen kits in store… (P:I01)

A second community pharmacist explained:

> [B]owel cancer we do have … test kits from – so, we do actually sell that. Do we sell a lot of it? No, but we do sell an odd bit, and that's why I tell the rest of my staff that – look, you need to know how it works, so we've actually even got a demonstration kit. (P:I04)

No community pharmacists described a current role in the promotion of breast cancer screening. Some expressed confusion about how they might promote breast cancer screening in future. This was underpinned by community pharmacists' perceptions about a lack of resources to support their promotion of breast cancer screening in pharmacies. One community pharmacists explained:

> So, what am I providing? … Because, generally when I provide screening, I have a physical role at some point in that process, so whether it's checking their blood pressure, whether it's checking their sugar levels, whether it's just doing a … risk assessment… I don't know how you'd do that with breast cancer. (P:I01)

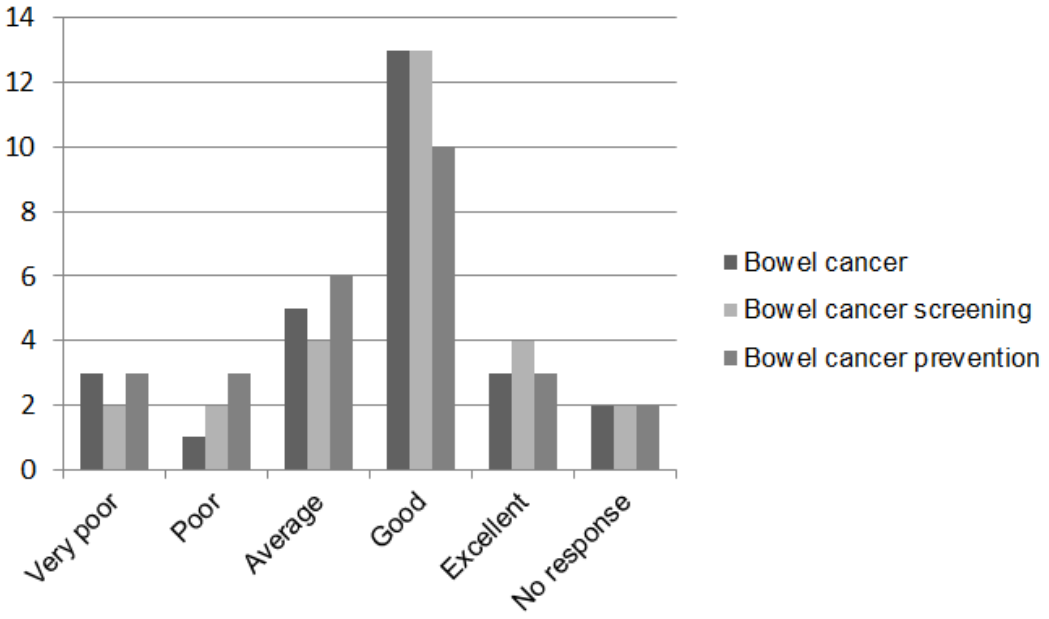

Figure 3. Pharmacists' responses to survey questions about their confidence discussing bowel cancer topics with their consumers.

Overall, this theme presents community pharmacists descriptions of their health promotion role in community pharmacies. Community pharmacists describe health promotion as providing basic health information including cancer screening. They understand and accept the process for bowel cancer screening because it is currently part of their practice. However, they are uncertain about breast cancer screening because it is not currently part of their role and foresee resourcing issues.

THEME 3: Community pharmacists' knowledge and confidence in their health promotion roles: "We're may be less confident in that area".

In the survey, most community pharmacists described their confidence as 'average' or 'good' when discussing breast cancer (67%, n=18), breast cancer screening (60%, n=16) and breast cancer prevention (56%, n=15). See Figure 2. Many community pharmacists described their confidence as 'average' or 'good' when discussing bowel cancer (67%, n=18), bowel cancer screening (63%, n=17) and bowel cancer prevention (60%, n=16). See Figure 3. Community pharmacists were more likely to describe their confidence as 'excellent' in relation to the bowel cancer topics and as 'very poor' in relation to the breast cancer topics.

The quantitative findings were supported by the community pharmacists in the interviews. Most community pharmacists described their confidence to promote bowel cancer and breast cancer screening as moderate. This was because they were uncertain about bowel cancer and breast cancer topics, and about the process of promoting bowel cancer and breast cancer screening. For example, one community pharmacist revealed the following:

> I would say my confidence would be moderate at the moment… I would think that I personally would need more education, obviously of the process [of the promotion of cancer screening] and what was going to be offered, and then the referral process as well, and other questions that might come up [from consumers]. (P:I03)

The community pharmacists consistently reflected they felt more knowledgeable and confident in relation to bowel cancer topics than breast cancer topics. This was because, as seen in Theme 2, community pharmacists perceive they have a current health promotion role in relation to bowel cancer screening, but not in relation to breast cancer screening:

> Bowel screening [promotion] we do, we're very good at it. Breast [screening promotion] is… We're may be less confident in that area. (P:I01)

Despite reporting only moderate confidence in discussing breast cancer and bowel cancer with their consumers, the survey demonstrated community pharmacists' knowledge about bowel cancer and breast cancer topics is acceptable. In the eight knowledge questions about cancer and cancer screening, an average of 82% responded with a correct answer (range: 52% (n=11 [Question 8]) and 100% (n=21 [Question 3])). Again, community pharmacists were more likely to report correct answers in relation to bowel cancer topics than they were in relation to breast cancer topics. See Figure 4.

In summary, this theme presents community pharmacists knowledge and confidence in their health promotion roles. Community pharmacists feel more knowledgeable and confident about promoting bowel cancer screening because it is currently part of their practice. They feel less confident about promoting breast cancer screening because they feel unsure about current and relevant knowledge, the screening process, and referral systems. However, according to the electronic survey, most community pharmacists have acceptable knowledge of breast and bowel cancer topics.

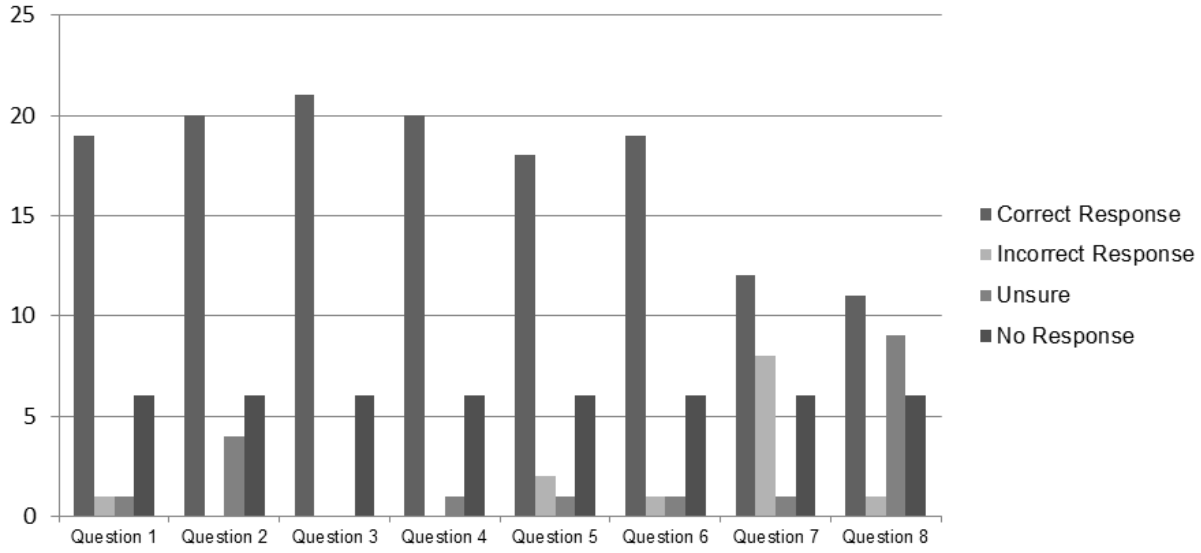

Figure 4. Pharmacists' responses to survey questions about their knowledge of bowel and breast cancer topics.
Question 1: Overweight and obesity increase the risk of both breast and bowel cancer. [TRUE]
Question 2: Drinking alcohol above recommended guidelines increases the risk of cancer. [TRUE]
Question 3: Smoking tobacco increases the risk of cancer. [TRUE]
Question 4: A healthy diet reduces the risk of cancer. [TRUE]
Question 5: People over 50 years of age should be screened for bowel cancer every 2 years. [TRUE]
Question 6: Only people who have symptoms should be screened for bowel cancer. [FALSE]
Question 7: Most breast cancers occur in women over 50 years of age. [TRUE]
Question 8: A breastscreen (mammogram) can detect breast cancer before a lump can be felt. [TRUE]

DISCUSSION

The community pharmacists who participated in this study perceive their role in health promotion, including in the promotion of bowel cancer and breast cancer screening, to be valuable and integral to their broader role. This is consistent with the literature. Pharmacists perceive this role to be important because they recognise the need for increased cancer screening, feel they can influence consumers to engage in screening and believe consumers appreciate this service.[26-29] Pharmacists consider the promotion of cancer screening to add value to their role, and to increase consumers' confidence in them as health professionals.[30]

In Australia, community pharmacists are familiar with the concept of health promotion. All the community pharmacists who participated in this research could cite at least one example of a health promotion activity they conduct(ed) in their pharmacy, often in relation to the prevention or early detection of common chronic conditions. These activities were undertaken routinely and as part of broader health promotion events such as 'awareness months'. Under the Quality Care Pharmacy Program[31], such health promotion activities are a requirement for pharmacies in Australia.

Many of the community pharmacists described a current role in the promotion of bowel cancer screening – in the sale of bowel screening kits, and educating consumers about the correct use of these kits. The literature agrees pharmacists in Australia have a key role in the promotion of bowel cancer screening because more than three consumers per week present to each community pharmacy in Australia with the mild gastrointestinal symptoms, which may be indicative of malignant disease.[18,32] Most of the community pharmacists in this study described having bowel screening kits available in-store if requested by a consumer rather than actively promoting the sale of kits. A more active approach to the promotion of bowel screening kits could be an important aspect of pharmacists' role. The literature suggests pharmacists participate in basic assessment and referral for people presenting with gastrointestinal symptoms.[18-20,32]

All the community pharmacists in this study perceived themselves as having a role in the promotion of bowel cancer screening but none of the community pharmacists identified a current role in the promotion of breast cancer screening. In international studies, most pharmacists report they do not, or do not frequently or consistently, engage in activities such as responding to inquiries about symptoms, providing advice and educational materials about screening, assessing or enabling self-assessment of risk-factors or referring to screening to promote breast cancer screening.[27-29] When reflecting on a potential future role in promoting breast cancer screening, the community pharmacists in this study were unsure what this would involve except for consumer requests for referral to screening providers.

International literature suggests pharmacists' current role in the promotion of breast cancer screening centres on education – for example, teaching clinical breast examination and explaining mammography schedules, etc.[27,33] In this research, community pharmacists' uncertainty about their role in the promotion of breast screening was underpinned by the lack of educational resources associated with the BreastScreen Australia program. The literature agrees the lack of consumer resources is the most significant barrier to the promotion of

breast cancer screening in community pharmacies.[27] Most pharmacists agree they would be more likely to provide breast cancer health promotion if they have access to consumer education materials about breast cancer.[29,34] Resources to promote breast cancer screening are an important consideration.

Most of the community pharmacists participating in this study perceived their role in the promotion of bowel and breast cancer screening to be one of information provision. The broader literature suggests pharmacists may have a role in screening for bowel and breast cancer risk using basic assessment tools like those used for identifying risk for chronic health conditions.[32,33] There is some Australian research about pharmacists' perceptions of using assessment tools in the promotion of bowel cancer screening[18,20] but there is limited evidence about breast cancer screening tools for community pharmacists.

The community pharmacists participating in this study identified two limitations they perceive in their current health promotion role: (1) their role focuses on individual consumer rather than a population approach, and (2) the community are unaware of their health promotion role. These are interrelated concepts because a population approach is an added challenge to pharmacists' health promotion role identified in other research about the promotion of cancer screening in pharmacies.[27] These limitations highlight the importance of activities to raise awareness of pharmacists' health promotion roles, if a program for promoting cancer screening in pharmacies is to be effective.

The findings of this research suggest community pharmacists' knowledge in relation to bowel cancer and breast cancer topics is relatively good despite their perception. This is a novel finding. In the literature searches conducted for this paper, only one previous study from Australia measured pharmacists' knowledge and this was according to indicators for referral for bowel cancer screening. The findings indicate pharmacists' knowledge to be variable, with pharmacists correctly identifying consumers to be referred for screening between 30% and 70% of the time.[19] International literature finds pharmacists' knowledge in relation to breast cancer and screening to be poor to moderate, however pharmacists are generally enthusiastic to improve their knowledge.[27-29,34]

Despite relatively good knowledge, the community pharmacists in this study report their confidence in discussing cancer and cancer screening to be moderate. The literature agrees discussing cancer in pharmacy settings is perceived by pharmacists as an anxiety-provoking experience because the discussion requires advanced communication skills, and there could be a significant negative impact on consumers if these skills are not applied effectively.[35] In this study, the community pharmacists were unsure about promoting cancer screening – and, in particular, breast cancer screening – to consumers, which underpinned their lack of confidence. Community pharmacists' confidence was directly related to their knowledge. Many community pharmacists expressed concern they lacked the knowledge about cancer and screening necessary to respond to the questions asked by consumers. As pharmacists' confidence in their ability to perform a behaviour, such as health promotion, is crucial in predicting whether they will do so[26], these issues must be addressed to increase pharmacists' self-efficacy and willingness to promote cancer screening.

The finding that pharmacists' confidence in promoting health is variable is supported by the broader literature. A systematic review concluded pharmacists' confidence in providing health promotion services generally is "mixed".[26] Pharmacists' confidence in relation to promoting breast cancer screening is inconsistent.[27,29,34] However, with training, one study found Australian pharmacists were both confident and effective at promoting screening for bowel cancer, including in undertaking relatively complex tasks such as assessing 'alarm symptoms' and referring to screening.[18-20,32]

Overall, community pharmacists were consistently more confident and knowledgeable in relation to bowel cancer topics than breast cancer topics. The main reason for this finding is because community pharmacists in Australia are already engaged in the bowel cancer screening program, but less engaged with the breast cancer screening program. These are important findings to inform the education of community pharmacists in promoting cancer screening in community pharmacies, which is essential if such a health promotion program is to be effective.

Strengths and limitations

There are some limitations to this research. Firstly, the purposeful sample may have self-selection bias. Secondly, the self-report survey and interviews might have reporting and / or social desirability bias. Thirdly, a small sample from one region limits generalisability but the findings may be useful in understanding similar sample groups.

CONCLUSIONS

This paper presents the findings about promoting bowel cancer and breast cancer screening in community pharmacies in Australia. Specifically, it presents findings related to community pharmacists' perceptions of their role, knowledge and confidence in relation to cancer screening promotion. Community pharmacists perceive their role in health promotion, including in the promotion of bowel cancer and breast cancer screening, to be valuable and integral to their broader role. Community pharmacists have moderate levels of knowledge and confidence necessary to perform this role. Overall, this research supports the feasibility of promoting bowel cancer screening in community pharmacies. It suggests further training is warranted for community pharmacists to increase their knowledge of breast cancer and their confidence in promoting breast cancer referral and screening services. It highlights the important role community pharmacists have in increasing engagement in the national bowel cancer and breast cancer screening programs, and in potentially decreasing mortality rates of these cancers.

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CONFLICT OF INTEREST

None.

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Original Research

Evaluation of students' attitudes towards pharmacist–physician collaboration in Brazil

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Abstract

Objective. To measure undergraduate pharmacy and medical students' collaborative attitudes regarding Pharmacist–Physician collaboration.

Methods. A cross-sectional descriptive study was conducted from September 2016 to February 2017 in Northeast Brazil. Pharmacy and medical students from the first and the last year of courses were invited to complete Portuguese version of Scale of Attitudes Toward Pharmacist-Physician Collaboration (SATP^{2}C). Descriptive and comparative analyses were performed using IBM SPSS (22 version). Differences were considered significant when p<0.05.

Results. Three hundred seventy students completed the SATP^{2}C. Overall, the students had positive attitudes towards physician-pharmacist collaboration. There was no significant correlation between age and score (p=0.79). Women showed a more positive collaborative attitude than men (53.1, SD=6.8 vs. 55.1, SD=6.3). Pharmacy students had a higher score than medical students (57.5, SD=4.7, vs. 51.1, SD=6.4). The first-year medical students had a higher score than last-year medical students (52.3, SD=6.0 vs. 49.5, SD=6.6; p<0.007). There was no significant difference in the attitudes between the first and last year pharmacy students (p<0.007).

Conclusions. Pharmacy and medical students showed positive attitudes towards physician-pharmacist collaboration. However, pharmacy students presented more collaborative attitudes than medical ones. Additionally, the first-year medical students had more collaborative attitudes than last-year medical students. Studies should be conducted to provide recommendations to improve interprofessional education efforts to further enhance the positive attitudes toward physician-pharmacist collaboration.

Keywords

Intersectoral Collaboration; Interprofessional Relations; Attitude of Health Personnel; Professional Practice; Education, Pharmacy; Education, Medical; Pharmacists; Physicians; Surveys and Questionnaires; Brazil

INTRODUCTION

Interprofessional collaboration is to work together cooperatively, share responsibilities to solve problems, and make decisions for patients, respecting the different qualities and abilities of different health and social care professionals.[1-4] This practice have shown a positive impact on patient care, health services and system improvement.[4-8] That is why several studies highlight the need for collaborative practice between different health care professionals, including physicians and pharmacists.[4,9-13]

Interprofessional collaboration should be encouraged during undergraduation to be effective.[12] The government and universities of some countries, such as Canada, Sweden, the United Kingdom, and Italy, have been promoting the development of interprofessional care.[10] Although there are incentives to work in collaboration, if professionals are not training already in undergraduation level to work together, they are going to have some difficulty.[14] Therefore, some courses of study aim to develop competencies and strategies within interprofessional education.[14,15] According to Centre for the Advancement of Interprofessional Education, interprofessional education is defined as occasions when two or more professions learn with, from and about each other to improve collaboration and the quality of care.[16] This practice may develop and/or improve the students' ability to work together and thereby contribute to the improvement of patient care.[16,17]

Randomized studies show that the involvement of the pharmacist in patient care can provide clinical benefits. A systematic review and meta-analysis of nineteen randomized trials showed a significant reductions in systolic/diastolic blood pressure (−8.1 mmHg [95%CI, −10.2 to −5.9] / −3.8 mmHg [95%CI,−5.3 to −2.3]) with pharmaceutical care compared with usual care.[18] Importantly, the pharmaceutical interventions are most effective when done in collaboration with other health professionals.[19]

In Brazil, the predominant health education model is uniprofessional, however, interprofessional education has been growing in the last years.[20] Since 2002, National Curricular Guidelines for health courses require professionals capable of working in collaboration and interprofessionally, reinforcing the necessity of

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interprofessional education.[21] In addition, in recent years, the pharmacists clinical role has been expanding, for a patient-centered practice model.[22-24] This scenario requires the pharmacists interact with other health professionals, such as physicians, to achieve the best patient outcomes.

In this sense, collaborative attitudes, as well as evaluation of them, must be encouraged on undergraduation level to improve the quality of services offered in the future. Some countries have investigated attitudes of medical and pharmacy students towards physician pharmacist collaboration[12,25], however no study has measured it in Brazil. In this sense an instrument has been translated, adapted and validated by Cunha[26] as the "Attitudes Scale on Medical-Pharmaceutical Collaboration" and can be used to compare the differences between groups in collaborative medical-pharmaceutical attitudes and research on the clinical outcomes of the collaboration between professionals. Therefore, this study aimed to measure undergraduate pharmacy and medical students' collaborative attitudes regarding Pharmacist–Physician collaboration.

METHODS

Design

A cross-sectional descriptive study was carried out from September 2016 to February 2017 in Sergipe State, Northeast Brazil, to evaluate the collaborative attitudes between pharmacy and medical students.

Participants

Pharmacy and medical students from the first and the last year of courses composed the sample, in order to verify if there is difference between the collaborative attitudes of students who were starting and finishing their respective courses. These students were enrolled at the two largest higher education institutions in the state of Sergipe, Brazil. One is private and the other is public, with two campuses located in two different cities. The students were chosen by convenience, being that all students who were present in the universities during researchers' visit of were invited to participate in the study. A population number of the students was provided by higher education institutions. The sample was calculated for a finite population of 763 students, adopting a confidence level of 95% ($p<0.05$) and a margin of error of 5%, totalizing 256 students. Students (1) of both genders (2) who were enrolled in the first or last year of the pharmacy or medical course in one of the two universities and (3) who agreed to participate in the project were included.

Data collection

The pharmacy and medical students were invited to complete the Portuguese version of the Scale of Attitudes Toward Pharmacist–Physician Collaboration (SATP^{2}C).[26] This scale was originally developed by Hojat and Gonnella[20] and was translated and validated to Brazil by Cunha et al.[26], showing adequate psychometric properties. This scale includes 16 Likert-type items on a 4-point scale (1=strongly disagree; 2=disagree; 3=agree; 4=strongly agree). All items are directly scored except for the 9th, which is a reverse scored item (1=strongly agree; 2=agree; 3=disagree; 4=strongly disagree). The respondent can score between 16 and 64. A high score means more positive attitude about the relationship between physicians and pharmacists.[13,27]

The instrument was applied in two forms: in person or online. In both cases, all participants were instructed before the application and could give up at any time. In in-person application, three researchers (FOP, KSSR, DCAA) were at the two universities and asked the students to answer the scale. In online application, the students who did not respond in person were asked to answer the scale in an online version through Google Forms (Google Inc, Mountain View, CA, USA). Besides instrument data, students also provided socio-demographic (gender, age) and academic data (higher education institution/campus, course, year of course).

Data analysis

Data from the survey instrument were coded and entered into IBM SPSS (22 version) software, and digitation was performed by one of the researchers (FOP). The Kolmogorov-Smirnov test was used to check the normality assumption; the Mann-Whitney Rank Sum test was used for difference between groups; and the Spearman Rank Order was used for correlation of age and total score. Results were expressed as mean and standard deviation (SD). Differences were considered significant when the p-value <0.05.

Ethical considerations

This research was approved by the Ethics Committee on Research Involving Human Beings from the Federal University of Sergipe (62433616.8.0000.5546).

RESULTS

Three hundred seventy students composed the sample. The mean age was 22.7 (SD=4.8). Socio-demographic aspects are shown in Table 1.

Overall, the students presented positive attitudes towards collaboration, with a mean total attitude score higher than 3 (Table 2). The mean score of each item for each course is shown in Table 2 and ranged from a low of 2.8 (for the item "Pharmacists are qualified to assess and respond to patients' drug treatment needs") from medical students to a high of 3.8 (for the item "A physician should be viewed as a collaborator and colleague with a pharmacist rather than his/her superior") from pharmacy students.

There was no significant correlation between age and score ($p=0.79$). Women revealed a more positive collaborative

Table 1. Sample's Sociodemographic Aspects

	n	%
Gender		
Male	102	28
Female	207	56
Non informed	61	16
Course		
Pharmacy	207	56
Medicine	163	44
Year of course		
First	216	58
Last	154	42

Table 2. Pharmacy and medical students' mean score of each item from scale of Attitudes Toward Pharmacist-Physician Collaboration

Sentence M (SD)	Pharmacy Student	Medical Student	Total Score
A physician should be viewed as a collaborator and colleague with a pharmacist rather than his/her superior	3.8 (0.4)	3.6 (0.6)	3.7 (0.5)
Pharmacists are qualified to assess and respond to patients' drug treatment needs	3.5 (0.6)	2.8 (0.8)	3.2 (0.8)
During their education, pharmacy and medical students should be involved in teamwork in order to understand their respective roles	3.6 (0.5)	3.6 (0.5)	3.6 (0.5)
Pharmacists can contribute to decisions regarding drug interactions that can affect the patients	3.8 (0.4)	3.2 (0.7)	3.5 (0.6)
Pharmacists should be accountable to patients for the drug they provide	3.4 (0.6)	2.8 (0.8)	3.1 (0.8)
There are many overlapping areas of responsibility between pharmacists and physicians in drug treatment of the patients	3.3 (0.6)	3.3 (0.6)	3.3 (0.6)
Pharmacist have special expertise in counseling patients on drug treatment	3.5 (0.6)	2.8 (0.8)	3.2 (0.8)
Both pharmacists and physicians should contribute to decisions regarding the type and dosage of medicine given to the patients	3.5 (0.7)	2.8 (0.9)	3.2 (0.8)
The primary function of the pharmacist is to fill the physician's prescription without question.	3.7 (0.5)	3.1 (0.6)	3.4 (0.7)
Pharmacists should be involved in making drug policy decisions concerning the hospital/pharmacy services upon which their work depends	3.6 (0.5)	3.3 (0.6)	3.5 (0.6)
Pharmacists as well as physicians should have responsibility for monitoring the effects of drugs on the patients	3.5 (0.6)	3.0 (0.8)	3.3 (0.7)
Pharmacists should clarify a physician's order when they feel that it might have the potential for detrimental effects on the patient	3.7 (0.6)	3.1 (0.8)	3.4 (0.8)
Physicians and pharmacists should be educated to establish collaborative relationships	3.8 (0.4)	3.7 (0.5)	3.7 (0.5)
Physicians should consult pharmacists for helping patients with adverse reaction or refractory to drug treatment	3.6 (0.5)	3.2 (0.7)	3.4 (0.6)
Physicians should be made aware that pharmacists can help in providing the right drug treatment	3.8 (0.5)	3.3 (0.6)	3.6 (0.6)
Interprofessional relationships between physicians and pharmacists should be included in their professional education programs	3.6 (0.6)	3.4 (0.6)	3.5 (0.6)

attitude than men (55.1; SD=6.3 vs. 53.1; SD=6.8; p=0.019), and pharmacy students seemed more likely to have collaborative attitudes (57.5; SD=4.7) than medical students (51.1; SD=6.4, p=0.001). First-year medical students revealed a more positive collaborative attitude than those in their last year (Table 3). In contrast, there were no significant differences in the collaborative attitudes between first year and last year pharmacy students. Regarding mean score for each course in first and last year, medical students showed significant difference (first year=52.3, last year=49.5, p=0.007) while there was no significant difference for pharmacy students (first year=57.1, last year=58.2, p=0.129).

DISCUSSION

Interprofessional collaboration is a widely acknowledged subject. Government, health care decision-makers, and health professionals have been discussing the need for collaborative work to prevent drug-related problems, improve patient safety, optimize team members' skills, and enhance the quality of the health care delivery system.[3-5,28] In this sense, positive collaborative attitudes between pharmacists and physicians are fundamental.[29] In this context, this study evaluated pharmacy and medical students' collaborative attitudes toward pharmacist-physician collaboration in one state of Brazil.

In this study, pharmacy students had more collaborative attitudes than medical ones. Similar results were found by Winkle *et al*., in which first-year pharmacy students' score was significantly higher than that of first year medical students [mean (SD) total attitude score of 56.6 (7.2) vs. 52.0 (6.1)].[12] Another study carried out in Kuwait by Katoue et al. corroborates these findings that pharmacy students expressed more positive attitudes towards interdisciplinary collaboration than medical students [mean (SD) total attitude score of 56.2 (4.9) vs. 44.6 (6.2)].[25] At the beginning of their academic programs, the mean scores for pharmacy and medical students were 60 and 56 (p<0.0001), respectively, which have averages greater than our findings. This could be due to pharmacists' work process that has been changing to assume an active role in patients' health.[4] This new endeavor is also reflected in students' behavior. Similarly, other studies showed a less collaborative attitude from physicians, which may infer that physicians have a common self-perception of being the dominant authority in patient care.[26,30] In this sense, interventions are necessary to encourage medical students to work collaboratively.

This study showed striking differences in scores between pharmacy and medical students and an apparent lack of opinion regarding pharmacist's role by medical students. This may be due to the fact that, in Brazil, patient-centered approach by pharmacists is still recent.[31] In addition, only in 2017 the National Guidelines for Undergraduate education

Table 3. Group differences on the Scale of Attitudes Toward Pharmacist–Physician Collaboration.

	n	M (SD)	*p* value
Gender			0.019[a]
Male	102	53.1 (6.8)	
Female	207	55.1 (6.3)	
Course			0.001[a]
Pharmacy	207	57.5 (4.7)	
Medicine	163	51.1 (6.4)	
Year of course			0.46
First	216	55.0 (5.9)	
Last	154	54.2 (7.0)	

[a] Mann-Whitney Rank Sum test was used for difference between groups, defined as p<0.05

in Pharmacy were updated and it stated that 50% of training hours should be spent in teaching health care.[32] Then, the fact that pharmacist's role is still not well established in Brazil as well as medical students are not aware of this new direction of Pharmacy profession, may explain the low scores. Thus, introducing interprofessional collaboration practices during undergraduation is important to promote better understanding of healthcare team's roles.

A significant difference was observed between genders in this study. Women demonstrated a more positive collaborative attitude. In contrast, Wang *et al.*[15] evaluated the attitudes towards physician-pharmacist collaboration using the SATP^{2}C and found men more prone to a collaborative attitude. According to these authors, this finding may be related to local culture: in China, open-mindedness is a strong characteristic of masculinity. Hojat and Gonnella[27] did not find gender differences in their study. Similarly, Hansson *et al*.[33] investigated differences in attitudes towards collaboration between doctors and nurses among medical students and found a significant difference between male and female students, implying a more positive attitude among female students. This finding is consistent with previous studies and may be associated with women's social and communication skills and maternal attitudes.[33-35] Hojat *et al*.[36] investigated attitudes toward physician-nurse collaboration in the United States and Mexico across genders and noted female physicians did not express more positive attitudes toward physician–nurse collaboration than males. This may indicate that these data may be multifactorial; therefore, future studies should investigate this issue.

The first-year medical students had a higher score than last-year medical students, which may be associated with the emphasis on specialization and profession-specific education that does not stimulate interprofessional collaboration.[37-39] In addition, Hojat *et al*.[34] highlight that physicians see themselves at the top of hierarchical patient care, possessing a greater power position, so they are less likely to demonstrate collaborative attitudes.[12,40] When medical students get in touch with those physicians (in medical institutions and hospitals), they seem to be more influenced by their peers than by some interprofessional collaborative discipline.[33]

This study had some limitations. Brazil is a continental country with cultural and regional differences, and in this sense the sample size did not allow greater generalization, as it included respondents from only one state of Brazil. The time of instrument application could also have influenced the acquired data due to differences in the higher education institutions' calendars; some respondents participated in the research after finishing the period, whereas others participated after starting the period. Another observation was the low rate of return of medical students' participation in the online version of the instrument. Other limitation refers to the cross-sectional nature of study, since it presents the collaborative attitudes of medical and pharmacy students at one point of time and may not reflect these attitudes over time. Another possible limitation is respondents' bias as they could have provided socially desirable responses. Finally, our finds showed the impact that higher education course cause in the student, modeling its attitudes among graduation. For that, other studies should have been conducted in order to improve the health professional formation, making him/her more prepared for collaborative work.

CONCLUSIONS

This study succeeded in measuring undergraduate pharmacy and medical students' collaborative attitudes in one state of Brazil, showing that pharmacy students are more likely to demonstrate collaborative attitudes. It was also verified that first-year medical students demonstrated more collaborative attitudes than last-year medical ones.

Besides, the current study provides basement for discuss and improve undergraduate health courses leading students to develop collaborative attitudes between different professionals. This change in students' attitudes towards interprofessional collaboration has the potential to reflect the health care delivery in the future.

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CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest to disclose.

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Original Research

A retrospective analysis of prescription medications as it correlates to falls for older adults

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Abstract

Objectives: To determine the correlation between falls and two medication factors: the class of medications and potentially inappropriate medications (PIMs) prescribed to community-dwelling older adults aged 55 and older.

Methods: Retrospective, cross-sectional study. Home health patients residing in a Texas/Mexico border community and reporting at least one fall within the past month. Medication use, medication classification, and potentially inappropriate medications (PIM) recorded by level of falls; non-fallers and recurrent fallers.

Results: Of 99 participants, 13.1% reported falling once and 86.9% reported two or more falls. Participant's average number of medications used was 10.51 (SD 5.75) with 93.9% having four or more prescribed medications. Average number of PIMs prescribed per participant was 1.42 (SD 1.51) with at least one PIM prescribed to 65.6% of participants. Twenty three out of 83 identified classes of prescribed medications met criteria for the study's analyses but resulted in no significant association to falls when comparing NF to RF. Agents acting on the renin-angiotensin system and lipid modifying agents were the most frequently prescribed medication classes (N=55, 55.6%). Ibuprofen was the PIM most frequently prescribed (n=13, 13.1%). The correlation between use of a prescribed PIM and number of falls was not statistically significant (p=0.128).

Conclusions: There was no correlation between classes of medication and level of falls. Recurrent fallers were more likely to have been prescribed a PIM than non-fallers (not significant). Although the analyses conducted for this study did not result in statistical significance, the high prevalence of polypharmacy and prescribed PIMs observed in these participants warrants a thorough review of medications to reduce fall risks among older adults.

Keywords

Inappropriate Prescribing; Potentially Inappropriate Medication List; Accidental Falls; Aged; Middle Aged; Medical Audit; Cross-Sectional Studies; Texas

INTRODUCTION

Falls among older adults are commonly assumed to be a natural part of the ageing process. While older age may increase the risk of falls, environmental components, health-related risks that can impair balance such as vertigo, and certain medications are other factors that contribute to falls in older adults.[1] Polypharmacy, the use of four or more prescribed medications, has also been associated with an increased risk of falls.[2,3] However, medication use is often overlooked by healthcare professionals.[4] This is relevant given that the number of older adults is increasing in the United States (U.S.) and given that polypharmacy is an increasing trend among older adults.

In a 2008 study conducted by the American Society of Consultant Pharmacist Foundation, 75% of older adults took one or more prescription medications and 25% took five or more drugs regularly.[5] Additionally, the number of medications prescribed tends to increase as adults grow older.[6]

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Beyond the number of medications that an elderly patient is taking, it is important to consider the appropriateness of drug therapy, given that polypharmacy also increases the risk of adverse effects. These adverse effects may be due to physiological changes associated with the ageing process such as decreased drug metabolism or reduced renal function. Adverse effects may also result from medication nonadherence; either by choice or because of memory loss. Regardless of the reasons that may contribute to adverse effects, these adverse effects can result in mechanisms that increase the likely hood of falling such as dizziness, orthostatic hypotension, sedation, and confusion.[1,7] Therefore, it is important to consider not only the number of medications prescribed but the associated risks and benefits associated with the medications prescribed.

The American Geriatrics Society developed and updated a set of criteria by which to guide the prescribing of certain medications associated with potentially adverse events in older adults.[8] The Beers criteria include a list of Potentially Inappropriate Medications (PIMs) to be avoided in older adults as well as drugs for which dose should be adjusted based on kidney function and based on known drug to drug interactions.[8] The Beers criteria were developed using a rigorous systematic review process to identify and grade the level of evidence available. The evidence was also evaluated by a panel of 13 experts in geriatric care and pharmacotherapy to determine needed exceptions to the listed recommendations based on clinical relevance.[8] A study examining the point-prevalence of the use of PIMs in

Medicare beneficiaries aged 65 years or older in the United States in 2012 demonstrated that approximately one-third of these patients were using PIMs.[9]

Of particular interest to this study is that specific types of prescription medications have been associated with an increased risk of falling including psychotropic, ototoxic, antibiotic, antihypertensive, cardiac, and analgesic drugs.[10-12] Woollcott *et al*.[10] conducted a meta-analysis of studies examining the association of nine medication classes with falls among older adults. They concluded that four classes of medications were associated with falls: antidepressants [Bayesian OR=1.68, CI (1.47 – 1.91)], benzodiazepines [1.57 (1.43 – 1.72)], sedatives/ hypnotics [1.47 (1.35 – 1.62)], and neuroleptics/ antipsychotics [1.59 (1.37 – 1.83)].[10]

Despite the prevalence of polypharmacy and the use of PIMs in older adults and more than 10 years of research examining medications and the risk of falls[13-14], there is still a gap in the literature regarding the association of falls to specific medications or polypharmacy interactions.[10] This lack of evidence warrants further analysis of prescribed medications and their association to falls. Therefore, there are two objectives to this study: to analyze the correlation between classes of medications and fall occurrences among older adults; and to analyze the correlation between PIMs prescribed and fall occurrences for community-dwelling older adults.

METHODS

Study Design

This study was an analysis of data from a previously published study of falls among community dwelling older adults.[15] Original data collection was approved by the Institutional Review Board (IRB) of the University of Texas at El Paso. Specific data analyzed for this study were number and types of prescribed medications (classified by Beers criteria as PIMs) and number of falls reported by community dwelling older adults.

Participants

Participants in the original study were 99 home health patients who resided in a Texas/Mexico border community and who had reported at least one fall within the past month.[15] Participant's age ranged from 55-96. Please refer to Lawson & Gonzalez[15] for specific exclusionary criteria.

Medications

A comprehensive medication history was recorded for all participants including name, dose, and frequency. Data regarding medications prescribed were recorded from home health agency chart reviews (nursing intake) and patient interviews. The World Health Organization (WHO) Collaborating Center for Drug Statistics Methodology was used to determine the classification of medications.[16] Only medications that could be classified according to the WHO were analyzed and therefore herbal medications were excluded. Since the conception and completion of this study, the 2012 American Geriatrics Society Beers Criteria[8] was the prominent guideline used to screen for PIMs. The 2012 version of the Beers criteria was therefore used to identify all potentially inappropriate medications observed in each participant's medication history. Polypharmacy was defined as the use of four or more medications.

Number of Falls

A fall was defined as an unexpected event in which a person comes to rest on the ground, floor, or at a lower level. Participants were asked to report the number of falls they experienced in the past month after the meaning of a fall was explained. If there was a discrepancy between number of falls reported by participants and that recorded in their medical record, participants were contacted a second time to determine that they understood clearly what constituted a fall. The number of falls reported after clarification was the number recorded for that participant. For statistical analyses, participants were categorized as non-fallers if they reported only one fall and as recurrent fallers if they reported two or more falls.[17]

Statistical Analysis

Differences in medication use between non-fallers and recurrent fallers were analyzed using a two-tailed Fisher's exact test in R version 3.1.1. Analyses of medication use by level of faller were conducted for the classification of medication[16] as well as by PIMs.[18] A classification of medication was not included in the analyses if that class of

Table 1. Participant characteristics and the prevalence of potentially inappropriate medication use according to the 2012 Beers Criteria

N (%) [SD]	Participants N=99	PIMs N=141
Gender		
Females	68 (68.7%)	1.27 [1.28]
Males	31 (31.3%)	1.77 [1.91]
Ethnicity		
Mexican	18 (18.2%)	0.83 [0.99]
Mexican-American	60 (60.1%)	1.38 [1.25]
Other	21 (21.2%)	2.05 [2.25]
Age, y		
55-75, y	34 (34.3%)	1.59 [1.56]
76-85,	43 (49.5%)	1.47 [1.62]
86-95, y	21 (21.2%)	1.10 [1.22]
>95, y	1 (1.0%)	1.00 [0.00]
Number of drugs used per participant	10.51 [5.75]	1.42 [1.51]
<4	6 (6.1%)	89 (89.9 %)
≥4	93 (93.9%)	10 (10.1 %)
Number of participants with PIMs	65 (65.6 %)	
Potentially inappropriate medication (PIMs)		

Table 2. Frequency of Patients Prescribed a Category of Medication for Total Study Population and by "Falls" Group

Drug Class[a]	Number Prescribed (%) *N* = 99	Recurrent Faller[b] *N* = 86	Non- Faller[c] *N* = 13	FET[d] *p* value
Renin-angiotensin system acting agents	55 (55.6%)	45	10	0.136
Lipid modifying agents	55 (55.6 %)	49	6	0.555
Antithrombotic agents	47 (47.5 %)	41	6	1.000
Beta blocking agents	43 (43.4%)	38	5	0.771
Vitamins	40 (40.4 %)	34	6	0.764
Diuretics	39 (39.4%)	31	8	0.126
Peptic ulcer & gastroesophageal reflux	39 (39.4 %)	34	5	1.000
Opium alkaloids and derivatives	32 (32.3 %)	30	2	0.213
Calcium channel blockers	31 (31.3%)	27	4	1.000
Blood glucose lowering drugs (excluding insulins)	30 (30.3 %)	27	3	0.749
Other analgesics and antipyretics	29 (29.3 %)	28	1	0.101
Anti-epileptics	25 (25.3 %)	23	2	0.507
Mineral supplements	25 (25.3 %)	22	3	1.000
Anti-inflammatory, anti-rheumatic, non-steroids	24 (24.2 %)	21	3	1.000
Thyroid preparations	24 (24.2 %)	20	4	0.510
Drugs for constipation	23 (23.2 %)	21	2	0.727
Anti-anemic preparations	20 (20.2 %)	17	3	0.722
Psychoanaleptics-antidepressants	17 (17.2 %)	15	2	1.000
Antihistamines for systemic use	16 (16.2 %)	14	2	1.000
Insulins and analogues	15 (15.2 %)	11	4	0.107
Other drugs for obstructive airway diseases, inhalants	14 (14.1 %)	13	1	0.686
Selective beta-2-adrenoreceptor agonists	14 (14.1 %)	13	1	0.686
Drugs used in benign prostatic hypertrophy	11 (11.1 %)	11	0	0.350

[a] Drugs are classified according to the World Health Organization Collaborating Center for Drug Statistics Methodology.[15] [b] Recurrent fallers reported two or more falls in past month. [c] Non-fallers reported one fall in last month. [d] Fishers two-tailed exact test.

medication was prescribed to fewer than ten participants. An analysis was also not conducted for any specific PIMs if it was prescribed to fewer than four participants. Significance at $p<0.05$ was assumed.

RESULTS

Of the 99 participants, 13 (13.1%) were classified as non-fallers (reported only one fall) and 86 (86.9%) were classified as recurrent fallers (reported two or more falls). The study population was primarily female (68.7%) and Mexican-American (60.1%). See Table 1 for participant characteristics.

Ninety-three (93.9%) participants had four or more prescribed medications with an average of 10.51 (SD 5.75) medications used by study participants. Additionally, 65 (65.6%) of participants had at least one PIM prescribed with the average of 1.42 (SD 1.51) PIMs prescribed to study participants.

Of the 83 identified classes of prescribed medications only 23 met the criteria to be included in this study's analyses. Of the 23 medication classes analyzed, there was no significant association to increased number of falls when comparing non-fallers to recurrent fallers (see Table 2). Agents acting on the renin-angiotensin system and lipid modifying agents were equally the two most often prescribed classes of medications (n=55, 55.6%).

Potentially Inappropriate Medications prescribed to at least four participants are listed in Table 3. Ibuprofen was the PIMs most often prescribed (n=13, 13.1%). The difference between the group of participants that were prescribed and not prescribed a PIM to the number of falls was not significant (p = 0.128). See Table 4.

DISCUSSION

Polypharmacy and the use of PIMS were highly prevalent in the study population. Most participants (94%) were prescribed four or more medications with an average of more than ten medications prescribed. This study may provide further evidence that polypharmacy is associated with falls; however a group of older adults who had never fallen was not available for comparison. All participants in the present study had reported at least one fall in the past month. It is also important to consider that all participants were home health patients because of medical complications and therefore more likely to be receiving more medications than they were before receiving home health services. However, data were not available to analyze whether PIMs were present before a reported fall or only present at the time of data collection. Patients were asked to provide a list of their current medications, but were not asked how long they had been prescribed each medication. It is also important to note that a fall was never

Table 3. Frequency of Potentially Inappropriate Medications (PIM)[a] Prescribed to Study Participants

Medication Prescribed	Frequency[b] (%)
Ibuprofen	13 (13.1 %)
Gabapentin	11 (11.1 %)
Sertraline	9 (9.1 %)
Alprazolam	5 (5.1 %)
Ranitidine	5 (5.1 %)
Zolpidem	5 (5.1 %)
Clonazepam	4 (4.0%)
Darifenacin	4 (4.0%)
Glyburide	4 (4.0%)
Promethazine	4 (4.0%)
Terazosin	4 (4.0%)

[a] PIM Classified According to the 2012 Beer's Criteria. [b] Number of participants who were prescribed a PIM are not independent cases (i.e. one person may have more than one prescribed PIM).

Table 4. Relationship Between Participants Prescribed a PIM[a] and Participants Not Prescribed a PIM by "Falls" Group

PIMs Prescribed	Recurrent Faller[b] *N* = 86	Non- Faller[c] *N* = 13	FET[d] *p* value
Prescribed PIM	59 (90.8%)	6 (9.2 %)	0.128
Not Prescribed PIM	27 (79.4 %)	7 (20.6 %)	

[a] PIM = Potentially inappropriate medication classified according to the 2012 Beers criteria.[17] [b] Recurrent fallers -reported two or more falls in past month. [c] Non-fallers reported one fall in last month. [d] Fishers two-tailed exact test.

the reason for the referral for home health services for study participants.

Another impetus for this study was to analyze the association between drug class and fall occurrences among older adults. In this study, the four classes of medications prescribed the most were agents acting on the renin-angiotensin system (55.6%), lipid modifying agents (55.6%), antithrombotic agents (47.5%) and beta blocking agents (43.4%). Similar to the Gurwitz *et al*. study of an ambulatory adult population, cardiovascular medications were amongst the most frequently prescribed medications.[19] The relevance of this is that falls are one of the adverse effects of taking cardiovascular medications. However, only a small percentage of participants in Gurwitz *et al*.[19] study reported a fall. Although previous researchers have correlated specific medications to fall occurrences[13,14,20-22], an association between falls and class of medications was not supported in this study despite the extensive analysis of drug class.

There was also no support for an association between potentially inappropriate medications (PIMs) prescribed and fall occurrences for the 99 community dwelling older adults in this study. The majority of participants in this study had at least one prescribed PIM (65.6%). From a population-based study of community dwelling adults over the age of 65, Davidoff *et al*. (2015) reported that 42.6% of adults in general had at least one medication that met the broad definition of a potentially inappropriate medication using the 2012 Beers criteria. Therefore participants in the present study had a higher overall use of PIMS than that reported from the 2006-2010 Medical Expenditure Panel Survey used in the Davidoff *et al*.[23] analysis.

The most prevalent PIM prescribed to study participants was ibuprofen (13.1%). Similarly, nonsteroidal anti-inflammatory drugs (NSAIDs) were the most commonly prescribed PIMs reported by Davidoff *et al*.[23] The effects exerted by NSAIDs on the central nervous system can include sedation, drowsiness, somnolence, dizziness, lightheadedness, or hypotension, thereby increasing the risk for falls.[24-26] However, in a systematic review, nine of the 13 studies showed no statistically significant increased risk of falls with NSAID use in the elderly.[27] Furthermore, there is limited evidence of a causal relationship between use of specific NSAIDs and falls.[24] Other frequently used PIMs reported for study participants included gabapentin, sertraline, and alprazolam. These medications are identified as PIMs due to the high risk of adverse drug events including a high risk of falls and fractures.[8]

Although more participants in the recurrent faller group were prescribed a PIM compared to those in the non-faller group, the difference was not statistically significant in this study. However, study limitations need to be considered. One analysis not undertaken in this study was the drug interactions between medication classes rather than just the use of any one specific PIM. Therefore, certain combinations of medications would make it more likely that a patient would be at increased risk of falling. For example, benzodiazepines taken in combination with other medications have been reported to result in falls but not when taken without other medications.[28,29] In one study, 71.2% (790/1110) of participants that experienced an injury were using a benzodiazepine in combination with other drugs versus only 4.3% (320/7522) of participants that experienced an injury who were using a benzodiazepine with no other drug use. The most frequently prescribed benzodiazepines to the present study participants were alprazolam and clonazepam. Additionally, patients were not asked about herbal medications they may have been taking and therefore not considered in this study. It is not known if ingredients in herbal medications interact with prescribed medications that could contribute to the increased risk of falls.

Another limitation to this study was that participants were already receiving home health intervention due to an identified medical crisis. It is possible that adjustments had already been made to medication regimens as a result of the home health interventions and that medications that may have contributed to the fall were removed from the patient's record by the time that data collection was conducted. Finally, blood pressure control in patients on antihypertensive medications and timing of medication administration and falls was not assessed. As a result, it is not possible to make any conclusions regarding falls and blood pressure control in this sample of patients in which the use of antihypertensive, specifically agents acting on the renin-angiotensin system was common.

As stated previously, adverse drug interactions have been correlated with falls in earlier studies of community dwelling older adults.[19] Therefore, preventive strategies to decrease the risk of falls in this patient demographic should be implemented and patients should be monitored during their course of care. For example, the results of the present study confirmed that the use of antihypertensive medications (agents acting on the renin-angiotensin system and beta blocking agents) is very common in older adults. Monitoring a patient's blood pressure response to these medications is critical for ensuring that hypotension does not contribute to the potential for falls. This is especially important when doses are changed or additional medications that affect blood pressure are added to a medication regimen.

Assessing the presence of side effects to medications is also extremely important. It should not be assumed that a patient will report these side effects to their provider without specific probing. A study by Steinman *et al*.[30] demonstrated that 31% of patients living in outpatient

settings did not report adverse symptoms or side effects to their physicians. Patients need to be educated on symptoms of orthostasis and adverse drug effects for all medications including antihypertensive medications that may cause falls.[30] Furthermore, the use of PIMs in older adults is a common phenomenon. It is essential for healthcare providers to identify PIMs when reviewing medication regimens of older adults in order to inform prescribers to consider the use of alternative medications that could reduce the risk of falls to this vulnerable population. Due to polypharmacy and increase risk for falls, medication reconciliation and comprehensive medication review are essential to help prevent and reduce the risk for falls. Many coalitions and governmental agencies have developed toolkits that help to identify patients who are at a risk for falls. These tool kits can be incorporated into primary care settings to identify patients at risk and modifiable risk factors and offer effective interventions to prevent falls.

By the time of completion of the study, an updated version of the Beers criteria has been published. The updated criteria contain some new changes that were not previously outlined in the 2012 Beers criteria. This may necessitate an additional follow-up study using the updated criteria. The main updates of the 2015 Beers Criteria were drug-drug interactions, renal-dose adjustments, and new medication/classes of medications that should be avoided in geriatric patients.

A final limitation of the present study is that all participants had experienced at least one fall. Although people who had experienced only one fall could be classified as non-fallers, it did not change the fact that there were not an equivalent number of participants in either group. Additionally, the original study was conducted with the intent of examining a population of patients who reported falling in the past month.[15] Therefore, medication use for participants who were medically stable and who had never fallen was not possible.

CONCLUSIONS

The findings in this study did not confirm results from previous studies demonstrating correlations with certain medication classes and fall risks among older adults. Limitations in the ability to consider the effects of potential drug interactions and pharmacodynamic effects of medications on these older adult patients may have contributed to the lack of correlation noted between classes of medications and falls. Although the subjects experiencing recurrent falls were more likely to have been prescribed a PIM, this finding was also not statistically significant in this investigation. However, consideration of the potential for falls associated with medication use in older adults is still warranted due to the high prevalence of polypharmacy in this demographic group and the negative sequelae of falls. Future investigations should take into consideration the effects of interactions medications may play in putting older adults at risk for falls.

CONFLICT OF INTEREST

None.

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Original Research

Evaluation of medication adherence among Lebanese diabetic patients

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Abstract

Background: Diabetes type 2 is considered one of the main public health concerns. Lack of adherence to treatment leads to poor therapeutic outcome, poor glycemic control, and high risk for developing diabetes complications.

Objectives: The aim of this study is to evaluate adherence to oral antidiabetic medication in Diabetes type 2 Lebanese patients, and to evaluate factors leading to low adherence.

Methods: A cross-sectional study was conducted in outpatients endocrinology clinics of two hospitals and four private clinics located in Beirut-Lebanon. Data was collected using a well-structured questionnaire by trained pharmacists. Adherence level was measured by the Lebanese Medication Adherence Scale (LMAS-14). Bivariate and multivariate analyses were conducted using SPSS version 20.

Results: Overall, 245 patients were included in the study with the majority being females (54.3%) and obese (47.8%). Only 29% of the participants had controlled glycemia (HbA1c <7%) with 31.8% of subjects had high adherence to their medication compared to 68.2% with low adherence. Increased working hours/day was associated with a decrease in adherence to oral antidiabetic medication (OR=0.31; 95% CI 0.11:0.88; p=0.029). Other factors significantly associated with decreased adherence to treatment were forgetfulness, high drug costs, complex treatment regimens, experiencing side effects, and perception of treatment inefficacy. Postponing physician office visits also decreased the probability of being adherent to oral antidiabetic medication (OR=0.36; 95% CI 0.15:0.86; p=0.022). Skipping or doubling the dose in case of hypo/hyperglycemia and the sensation of treatment burden also decreased medication adherence (OR=0.09; 95% CI 0.02:0.34; p=0.001, and OR=0.04; 95% CI 0.01:0.13; p<0.001 respectively).

Conclusions: Adherence to oral antidiabetic medication is low for Lebanese patients, which leads to a poor glycemic control and increases the diabetes complications. Intervention programs including patient education strategies are essential to improve medication adherence.

Keywords

Medication Adherence; Treatment Adherence and Compliance; Diabetes Mellitus, Type 2; Risk Factors; Multivariate Analysis; Cross-Sectional Studies; Lebanon

INTRODUCTION

Diabetes type 2 (DM2) is considered one of the main public health concerns, and its prevalence is increasing at an alarming rate worldwide.[1] According to the International Diabetes Federation's latest report, the global prevalence of diabetes is estimated to be 8.8%[2], and predicted to increase by 54% worldwide between 2010 and 2030.[3] The World Health Organization (WHO) estimates that Diabetes will be the seventh leading cause of death by 2030.[2]

The American Diabetic Association (ADA) considers glycemic control as an important strategy for managing DM2.[4] Glycosylated hemoglobin (HbA1c) is the most reliable method and the main target to control glycemia and prevent complications.[5] The treatment target set by ADA for HbA1c is less than 7%.[4] A high value of HbA1c (7% or over) indicates a poor diabetes control, leading to severe complications such as cardiovascular disease, neuropathy, retinopathy, nephropathy, and lower limb amputations.[6,7]

A study done in the United States found that 12.9% of diabetic patients had poor glycemic control and did not achieve the control target HbA1c[8] compared to a larger number of diabetic patients in Saudi Arabia, Lebanon, Jordan, and Libya (32.1%, 31.8%, 30%, and 20.2% respectively).[9-12]

The WHO defines adherence as the extent to which a patient's behavior in medication intake, diet follow up, and performing lifestyle changes, agrees with health care provider recommendations.[13] In developed countries, WHO estimates adherence to long-term therapy for chronic diseases to be around 50%.[13] Adherence to diabetes treatment is very variable and may range from 1.4 to 88%.[14] A great progress has been made in the treatment of DM2 with the development of new therapeutic classes. However, a lack of adherence to treatment leads to a poor therapeutic outcome, a poor glycemic control, a high risk for developing diabetes complications, and an increased hospitalization and death rates.[15-17] In a study conducted

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on diabetic patients in Malaysia, 53% of patients were found to have low adherence[18] and 72% of patients had poor glycemic control.[19] Nevertheless, several studies have shown a positive association between adherence and glycemic control.[20,21]

Numerous factors influence treatment adherence, including demographic characteristics, socioeconomic status, duration of disease, class of drug prescribed, presence of comorbidities, polypharmacy, patient-healthcare provider relationship, occurrence of adverse events, perception of inefficacy, drug cost, forgetfulness, and presence of psychological factors, specifically depression.[22]

In Lebanon, there is a shortage of studies evaluating adherence to antidiabetic medication. Therefore, the main objective of this study is to evaluate adherence to oral antidiabetic medication for DM2 Lebanese patients, and to evaluate factors leading to low adherence.

METHODS

Study design

An observational cross-sectional study was conducted in outpatient endocrinology clinics of two tertiary care hospitals and four private endocrinology clinics located in Beirut, Lebanon between April 1st, 2017 and July 30th, 2017.

The sample size in this cross-sectional study was calculated using the following formula[23]:

$n = Z^2 * p(1-p)/d^2$

where Z is the standard normal variate (Z=1.96 when confidence interval is 95%), p is the expected proportion of outcome in the population (based on other studies), and d is the precision.[23]

Based on a study done on Lebanese patients with chronic diseases, 17% were highly adherent[24], so a minimal sample size of 217 patients was necessary.

Lebanese adult outpatients (>18 years), diagnosed with DM2 by an endocrinologist and have been taking at least one oral antidiabetic medication (biguanides, sulfonylureas, meglitinides, thiazolidinediones, dipeptidyl peptidase 4 inhibitors, alpha-glucosidase inhibitors and sodium-glucose co-transporter 2 inhibitors) for at least 6 months were included in this study. Excluded subjects were patients less than 18 years of age, patients with diabetes type 1, patients on insulin therapy only, pregnant women, and patients with memory disorders or intellectual disability.

Data collection

Data was collected using a well-structured questionnaire which was developed based on a literature review. The questionnaire was presented in Arabic language to facilitate its comprehension and was filled by trained pharmacists. It was tested on 20 patients to evaluate their understanding of the questions and to do the necessary modifications. These patients were not included in the final sample.

The questionnaire contained data about sociodemographic characteristics, lifestyle information such as physical activity defined by at least 30 minutes of moderate-intensity exercise on most days of the week[25], health status, patient disease status, medication-related characteristics, medication adherence using a Lebanese Medication Adherence Scale (LMAS-14), patient's relationship with the healthcare providers, and information about the patient's attitudes, behaviors, knowledge, and motivation towards his illness and treatment.

The clinics were visited by patients coming from different Lebanese regions. For each patient visiting the clinics included in the study, interviewers checked the patient's file to confirm the diagnosis of DM2 and to check the inclusion criteria. An oral consent was obtained from each patient to participate in the study. Accurate data on the patient's medical and medication history was recorded from the patient's file. The value of HbA1c of each patient was taken from the recent lab test performed within less than 1 month, brought in with the patient. A controlled HbA1c in DM2 patients is defined as being below 7%.[5] Patients were asked about past medication history and over-the-counter (OTC) drugs containing sugar such as cough syrups and some vitamins. Certain acute hyperglycemic medications such as glucocorticoids, and some chronic drugs such as thiazide diuretics, and atypical antipsychotics were also recorded.[5]

The LMAS-14

Adherence to oral antidiabetic medication was evaluated using the fourteen-item LMAS-14. This instrument is a new Lebanese scale to measure medication adherence by considering socio-economic and cultural factors related to the Lebanese culture. It was validated by Lebanese hypertensive patients and can be used to assess adherence to treatment in chronic diseases.[26] The LMAS-14 contains 14 Likert scale questions with four answers each (coded from zero (less adherence) to three (high adherence)). Score can range from zero (lowest adherence) to 42 (highest adherence). LMAS assesses occupational factors including forgetfulness during busy periods (intensive work or travel), if the patient was invited to lunch or dinner, if some food items were prohibited during treatment period because of possible food-medication interaction, and delay in buying a new pills box when the old one is over. It also assesses psychological factors including experiencing any secondary effects or feeling clinically better or worse with a change in behavior when the laboratory exams are improved. Annoyance factors are also included in LMAS-14 such as frustration from taking a lot of pills, boredom of chronic treatment, and experience of some side effects. Finally, economical factors are assessed in LMAS-14 including health insurance coverage of medication cost, and expensive medication.

Each patient's score was calculated to assess adherence to medication. Patients were classified into adherent or non-adherent using a cut-off point of 38 as in previous studies. Sensitivity and specificity of LMAS-14 were respectively 82.9% and 36.9%.[26]

Data analysis

All data were analyzed using SPSS version 20. Bivariate and multivariate analyses (logistic regression) were done. A confidence interval of 95% and a p-value <0.05 were

Table 1. Description of the study population (N=245)

Variables	n (%)
Sex	
Females	133 (54.3)
Body mass index (BMI) [1]	
Underweight (BMI<18.5 kg/m^2)	1 (0.4)
Normal weight (BMI≥18.5 kg/m^2)	36 (14.7)
Overweight (BMI≥25 kg/m^2)	91 (37.1)
Obese (BMI≥30 kg/m^2)	117 (47.8)
Education level	
Illiterate	87 (35.5)
Elementary	74 (30.2)
Intermediate/ Secondary	56 (22.9)
University	28 (11.4)
Occupation	
Unemployed	120 (49)
Employed/Self-employed	111 (45.3)
Retired	14 (5.7)
Working hours/ day	
0	134 (54.7)
<8h	13 (5.3)
>8h	98 (40)
Medical Insurance	177 (72.2)
Smoking	
Yes	96 (39.2)
No	124 (50.6)
Ex-smoker	25 (10.2)
Physical activity	85 (34.7)
Recommendation of diet by physician	237 (96.7)
Follow-up of diet	
No/Sometimes	195 (79.6)
Yes	50 (20.4)
Family history of diabetes	160 (65.3)
Intake of chronic hyperglycemic medication	41 (16.7)
Intake of acute hyperglycemic medication (OTC)	80 (32.7)
HbA1c (%)	
Uncontrolled (≥7%)	174 (71)
Controlled (<7%)	71 (29)
Type of Comorbidities	
Hypertension	151 (61.6)
Dyslipidemia	147 (60)
Respiratory diseases (Asthma or COPD[2])	9 (3.7)
Congestive heart failure/Angina/ Arythmia	40 (16.3)
Kidney disease	19 (7.8)
Hepatic disease	3 (1.2)
Gastrointestinal disease	11 (4.5)
Other Comorbidities (uricemia, anemia, osteoporososis, thyroid/nervous disease…)	101 (41.2)
Pharmacological class of oral antidiabetic medication	
Biguanides	216 (88.2)
Sulfonylureas	126 (51.4)
DPP-4 inhibitors	96 (39.2)
Thiazolidinediones	14 (5.7)
SGLT2 inhibitors	11 (4.5)
Meglitinides	8 (3.3)
Alpha-glucosidase inhibitors	2 (0.8)
Combination	91 (37.1)

[1] World Health Organization (WHO). Global Database on Body Mass Index.
[2] COPD: Chronic Obstructive Pulmonary Disease

considered to get a statistically significant result. The dependent variable for logistic regression was the dichotomized adherence score (based on a cut-off point=38). Only variables having p-value<0.2 in the bivariate analysis were included in the multivariate analysis.

RESULTS

A total of 245 patients who met the inclusion criteria were included in this study, with an average age of 59.32 years (SD=10.77). More than half of the patients (54.3%) were females. Age difference was not significant between males (60.59 years; SD 11.22) and females (58.25 years; SD 10.304) with a p-value=0.09. The majority of the patients were either overweight (37.1%) or obese (47.8%). Most of the patients were illiterate (35.5%) and unemployed (49%). Around half of the population (50.6%) was nonsmokers. Only 34.7% were physically active and 20.4% followed the diet recommended by their physician properly. One hundred sixty patients (65.3%) had a family history of diabetes. The mean duration of diabetes was 9.03 years (SD 8.01) and was accompanied with comorbidities in 86.5% of the cases. The most common comorbidity was hypertension (61.6%) followed by dyslipidemia (60%). Almost 63% of patients regularly measured their HbA1c. The mean HbA1c was 7.90% (SD 1.63). Good glycemic control (HbA1c<7) was achieved in only 29% of participants. The total number of medications taken per day by the patients was 5.21 (SD 2.76). The most common class of oral antidiabetics taken was biguanides (88.2%) followed by sulfonylureas (51.4%) (Table 1).

After classification of LMAS-14 score into two classes, 31.8% of patients had a high adherence (score≥38) and 68.2% had low adherence (score<38) following dichotomization using a cut-off point 38.

Bivariate analysis

Among socio-demographic factors, only working hours/day had a significant influence on medication adherence (p=0.001).

Concerning lifestyle characteristics, among patients who follow up the diet recommended by their physician, most of them were adherent to their oral antidiabetic medication (30.8%) while 15.6% were non-adherent (p=0.006). Moreover, among patients who do not consume beverages containing sugar, 85.9% of them were adherent (p=0.01).

Among patients who had an uncontrolled HbA1c level, 75.4% of the patients were non-adherent to their oral antidiabetic medication (p=0.025). Concerning patient's health status, the presence of comorbidities had no significant effect on medication adherence. However, the presence of respiratory disease (Asthma or Chronic Obstructive Pulmonary Disease) was associated with a decrease in medication adherence (p=0.041) (7.8% were non-adherent while 1.3% were adherent).

Taking sulfonylureas was also a significant factor (p=0.026) affecting adherence. From the patients who knew the names of their antidiabetic drugs, 52.6% were adherent while 37.7% were not (p=0.029), and among patients who did not understand their treatment regimen, 20.5% were adherent while 34.1% were not (p=0.03). Among patients who postponed their physician office visits, 53.9% were non-adherent while 29.5% were adherent (p<0.001), and finally among patients who visited their physicians annually or every few years, 32.9% and 14.4% were non-adherent, while 23.1% and 5.1% were adherent (p=0.026), respectively.

Table 2. Factors associated with adherence score using a dichotomized scale

Variables	n (%) Non-adherent (<38)	n (%) Adherent (≥38)	p-value
Working hours/ day			0.001
0	97 (58.1)	37 (47.4)	
< 8h	3 (1.8)	10 (12.8)	
> 8h	67 (40.1)	31 (39.7)	
Follow up of diet			0.006
No/ Sometimes	141 (84.4)	54 (69.2)	
Yes	26 (15.6)	24 (30.8)	
Consumption of beverages with sugar			0.010
No	118 (70.7)	67 (85.9)	
Yes	49 (29.3)	11 (14.1)	
HbA1c			0.025
Uncontrolled (≥ 7%)	126 (75.4)	48 (61.5)	
Controlled (< 7%)	41 (24.6)	30 (38.5)	
Respiratory disease (Asthma or COPD)			0.041
No	154 (92.2)	77 (98.7)	
Yes	13 (7.8)	1 (1.3)	
Sulfonylureas			0.026
No	73 (43.7)	46 (59)	
Yes	94 (56.3)	32 (41)	
Knowledge of the drugs' names by the patient			0.029
Some of them/ No	104 (62.3)	37 (47.4)	
Yes	63 (37.7)	41 (52.6)	
The patient understood his treatment regimen			0.030
No	57 (34.1)	16 (20.5)	
Yes	110 (65.9)	62 (79.5)	
Postponing physician office visits			< 0.001
No	77 (46.1)	55 (70.5)	
Yes	90 (53.9)	23 (29.5)	
Frequency of physician office visits			0.026
Every month	15 (9)	8 (10.3)	
Every 3 to 6 months	73 (43.7)	48 (61.5)	
Every year	55 (32.9)	18 (23.1)	
Every few years (> 2 years)	24 (14.4)	4 (5.1)	
Experience of side effects			0.002
No	94 (56.3)	60 (76.9)	
Yes	73 (43.7)	18 (23.1)	
In case of hypo/hyperglycemia, patient skips/doubles the dose			< 0.001
No	115 (68.9)	72 (92.3)	
Yes	52 (31.1)	6 (7.7)	
In fasting states, patient skips taking his medication			0.012
No	136 (81.4)	73 (93.6)	
Yes/ Sometimes	31 (18.6)	5 (6.4)	
Following healthcare provider instructions			< 0.001
No/ Sometimes	73 (43.7)	16 (20.5)	
Yes	94 (56.3)	62 (79.5)	
Main reason for discontinuing treatment			< 0.001
Forgetfulness	55 (32.9)	5 (6.4)	
High cost	41 (24.6)	11 (14.1)	
Complexity of treatment regimen	11 (6.6)	3 (3.8)	
Experience of unwanted side effects	22 (13.2)	1 (1.3)	
Perception of inefficacy	10 (6)	1 (1.3)	
No discontinuation of treatment	28 (16.8)	57 (73.1)	
The patient feels his treatment is inconvenient and a burden			< 0.001
No	71 (42.5)	70 (89.7)	
Yes	96 (57.5)	8 (10.3)	
Number of comorbidities	Mean = 2.072	Mean = 1.705	0.047
Total number of medications/ day	Mean = 5.503	Mean = 4.590	0.016
Number of antidiabetic medication / day	Mean = 1.898	Mean = 1.667	0.041

Experiencing side effects lead patients to be less adherent (p=0.002). Among the patients who had experienced side effects, 43.7% were non-adherent while 23.1% were adherent. On the other hand, stopping medication in case of hypo/hyperglycemia and fasting were also significant factors for non-adherence, p<0.001 and p=0.012, respectively. Moreover, forgetfulness, high drug cost, complex treatment regimens, and perception of treatment inefficacy had a significant association with poor medication adherence (p<0.001) (Table 2).

Multivariate analysis

Results of logistic regression showed that increased working hours/day was associated with a decrease in

Table 3. Results of the binary logistic regression using the dichotomized LMAS as the dependent variable

Variables		Adjusted Odds Ratio (Exp-beta)	95% Confidence Interval	p-value
Working hours/ day	<8h vs 0h	1.537	0.548; 4.310	0.414
	>8h vs 0h	0.307	0.106; 0.884	0.029
Main reason for discontinuing treatment (Reference group: not discontinuing)	Forgetfulness	0.023	0.006; 0.084	<0.001
	High cost	0.202	0.067; 0.608	0.004
	Complexity of treatment regimen	0.065	0.012; 0.359	0.002
	Experience of unwanted side effects	0.022	0.002; 0.214	0.001
	Perception of inefficacy	0.072	0.007; 0.786	0.031
Postponing physician office visits		0.358	0.149; 0.860	0.022
Follow-up of diet		2.555	0.986 ; 6.618	0.053
In case of hypo/hyperglycemia, the patient skips/doubles the dose		0.087	0.022 ; 0.344	0.001
The patient feels his treatment is inconvenient and a burden		0.042	0.014; 0.125	<0.001

Dependent variable: dichotomized LMAS. Omnibus test p-value<0.001/Hosmer–Lemeshow test p-value=0.831. Nagelkerke R^2=0.654/Overall predicted percentage = 85.3%.
Variables excluded from the model: Age, Gender, BMI, Physical activity, Consumption of beverages with sugar, Controlled/Uncontrolled HbA1C, Number of comorbidities, Presence of COPD/Asthma, Taking sulfonylureas, Intake of acute hyperglycemic medication (OTC), Knowledge of the drugs' names by the patient, Frequency of physician office visits, The patient understood his treatment regimen, Experience of side effects, Presence of diabetes complications, Number of antidiabetic medication/day, Number of medications/day, Skipping doses in fasting states, Following healthcare provider instructions.

adherence to oral antidiabetic medication (OR=0.31; 95%CI 0.11:0.88; p=0.029). Forgetfulness, high drug cost, complex treatment regimens, experiencing side effects, and perception of inefficacy were significantly associated with a decrease in the level of adherence (p<0.001, p=0.004, p=0.002, p=0.001, and p=0.031 respectively). Postponing physician office visits significantly decreased the probability of being adherent to oral antidiabetic medication (OR=0.36; 95%CI 0.15:0.86; p=0.022). Skipping or doubling the dose in case of hypo/hyperglycemia, and sensation of treatment burden were also significantly associated with a decrease in the level of adherence (OR=0.09; 95%CI 0.02:0.034; p=0.001, and OR=0.04; 95%CI 0.01:0.13; p<0.001 respectively) (Table 3).

DISCUSSION

Adherence to oral antidiabetic medication was 31.8% among Lebanese DM2 patients. The adherence rate was similar to studies conducted in China[27] and Korea[28], greater than that reported in Iraq (29.8%)[29], and lower than reports from of other countries, such as Ethiopia (45.9%)[22], United States (47.3%)[30] and India (60%).[31] Cultural diversity between countries could explain the difference in adherence levels between different populations. Yet, this difference could also be due to the variation of the methodologies and the different measurement scales used to evaluate adherence.[32]

Among the socio-demographic factors, the findings showed that adherence rates were similar in both genders, which was consistent with the results obtained in Malaysia and India.[18,31] Age also had no association with adherence to treatment. However some studies have found an association between age and non-adherence. In a Malaysian study, older age was associated with an increased medication adherence.[18] This study also found a significant association between working hours/day and medication adherence. When the working hours increase (>8h), the probability of being adherent to oral antidiabetic medication decrease. Being at work for a long period of time may prevent the patient from taking his treatment regularly and attending to his health care professional as recommended.[33]

Lack of follow up to recommended diet and consumption of beverages containing sugar were also increased among non-adherent patients. Other studies have also found that non-adherence to oral antidiabetic medication also comprised non-adherence to the non-pharmacologic guidelines.[34] Following non-pharmacologic recommendations is crucial in achieving the target HbA1C. This includes a proper diet (low in saturated fat, sodium and carbohydrates, and high in fiber contents), weight loss, and exercise.[34]

Among Lebanese DM2 patients, only 29% had achieved the target HbA1c (<7%).This is much lower than that in the United States (87.1%).[8] In this study, patients who had good glycemic control had better adherence to oral antidiabetic drugs compared to those who had poor glycemic control. This coincides with studies done in China[27], Ethiopia[35], and Libya[36] where an inverse association between medication adherence and glycemic control (represented by the value of HbA1C) was reported.[35-37]

The duration of diabetes after diagnosis was not found to be associated with adherence among Lebanese DM2 patients. Nevertheless a study conducted in China showed that newly diagnosed patients had a lower adherence to their therapy.[27] Newly diagnosed patients may still not be aware of the consequences of missing their treatment and the complications associated with poor glycemic control. Contrariwise, a study done in the United Arab Emirates showed that patients with a longer duration of diabetes were more likely to be non-adherent to their treatment.[38] It is suggested that newly diagnosed patients may be more committed to their treatment, but they soon adapt to the disease burden due to the chronic nature of disease.[38]

The presence of comorbidities was not associated with medication adherence. However, the presence of asthma or COPD was found to reduce adherence in diabetic patients. This can be explained by the use of corticosteroids or long-term beta agonists in the control of these diseases, which may lead to corticosteroids-induced hyperglycemia.

Furthermore, it is suggested that decreased quality of life in the presence of these diseases may decrease motivation to treatment and thus adherence.

Medication related factors, including regimen complexity and multiple daily dosing, were also factors affecting medication adherence. Patients taking more than two drugs were less adherent to treatment.[39] This is similar to the results obtained on diabetic patients in Nigeria, Ghana, and Hungaria, where adherence rates decreased as the pill burden increased.[39-41] Combination therapy reduces pill burden and dosing frequency, and is a good strategy to improve drug adherence.[40,42]

Among the different classes of oral hypoglycemics, only sulfonylureas were associated with decreased adherence. Sulfonylureas are particularly associated with an increased risk of hypoglycemia which is perceived as life-threatening by patients.[43] A study conducted in Sweden showed symptomatic hypoglycemia in patients treated by sulfonylureas was associated with non-adherence.[44] Hypoglycemia can negatively affect the quality of life for diabetic patients, and decrease their adherence to treatment.[44]

In this study, it was revealed that patients who experienced side effects to their medication were less adherent to the treatment regimen. This result is in agreement with the findings in United States which reported that side effects of medication is a main factor for low adherence to antidiabetic medication.[30]

As for factors related to the patient-provider relationship, patients who visited their physician more frequently and did not postpone their office visits were more adherent to their medication as they were more interested in improving their health status. The physician's communication skills and a good relationship between patients and their healthcare providers are two factors that greatly improve adherence.[13,45,46] Communication between physician and patient promotes the patient's knowledge about his treatment and illness condition and thus improves medication adherence.[47]

Forgetfulness and high cost of drugs were two factors leading to low medication adherence when the motivation or intention exists. This is similar to the findings of several studies in Canada and Nigeria.[47,48] Several actions are suggested to decrease patient forgetfulness such as getting help from a family member, using pill boxes, putting medication in a place where the patient performs daily activity, and setting medication alarms. Concerning high drug costs, physicians may prescribe generic drugs at lower prices for less fortunate patients.[32] Also a governmental plan should be launched to provide free access to medical services and chronic medications.

No association was found between adherence and education level, similar to studies from Ethiopia, India and Nigeria.[22,31,39] This may be due to the fact that the majority of the population were elderly and had poor knowledge concerning their disease or treatment. Low understanding of treatment regimen among diabetic patients was significantly associated with low medication adherence. This is similar to another study which demonstrated a significant association between medication adherence and patient's knowledge.[18] To that end, patient education by the health care professional on medication regimen and behavior towards the disease is essential in order to improve adherence and to achieve a controlled level of HbA1c. Health care professionals should be approachable, listen to their patients' concerns, inform their patients about the course of the disease and how to manage side effects. A shared decision making model is reccomended.[47]

This study is the first study in Lebanon to assess medication adherence among diabetic patients. Numerous factors were found to negatively affect adherence, leading to poor treatment outcomes. However, this study presents several limitations. Self-reporting was used to evaluate adherence so a recall bias may have occurred and patients may have elicited only socially accepted responses. Due to these possibilities it is suggested that adherence was overestimated. Also, being a cross-sectional study, a causal relationship between medication adherence and the various behaviors of the patient is difficult to establish.

CONCLUSIONS

Several factors influence adherence levels in Lebanese DM2 patients including drug discontinuation when fasting and not respecting physician's instructions. This reflects the fact that some patients have their own perceptions which affect their treatment decisions. This issue can be solved by improving patient education and reinforcing the continuity of care by emphasizing patient-physician relationships.

Moreover, forgetfulness, high cost of drugs, complexity of treatment regimen, side effects, and perception of inefficacy are factors that decrease adherence. Resolving these problems involves decreasing the number and the frequency of therapy. Health care providers should also give more attention to medication side effects in chronic diseases that require long-term treatment.

In the absence of any medical insurance or government program for social support, the cost of medications imposes a great burden for many patients. This highlights the need for better social security programs and governmental support to decrease the economic burden of medication and therefore to avoid diabetes complications.

A study on a larger patient size and conducted all over Lebanon is needed to provide stronger evidence about the factors affecting adherence, and to perform better intervention programs.

CONFLICT OF INTEREST

There is no conflict of interest.

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Original Research

Swedish patients' trust in the bioequivalence of interchangeable generics. What factors are important for low trust?

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Abstract

Background: Generic substitution (GS), is a cost-containment strategy meant to contain pharmaceutical expenditure without compromising health objectives. In order to shape GS into a policy that is both efficient and safe it is crucial to understand which factors are most important for patients' trust in GS.

Objective: To assess Swedish patients' level of trust in the bioequivalence of cheap and expensive generic medicines, and the association between trust and various factors.

Methods: A cross-sectional study was conducted. Questionnaires were handed out at 12 community pharmacies in Sweden, selected through stratified sampling, between March and April 2015. The questionnaire included seven socio-demographic questions in addition to 18 items divided into three sections: the 'views on generic medicine'-scale, information on and prior experiences of GS, financial aspects and change of color/name. Odds Ratios (ORs) were estimated applying adjusted logistic regression analyses with trust in the bioequivalence of generic medicines used as outcome variable and various factors as predictors.

Results: A total of 719 patients participated (response rate 85.7%). The results show that 70.7% of the respondents' trust that cheap and expensive interchangeable generic medicines are equal. Of the respondents 36.0% considered the change in appearance and 40.8% the change in names to complicate adherence. Lower trust in the bioequivalence of generic medicines were associated with being female (aOR=1.82, 95%CI 1.20:2.75, p<0.01), patients perceiving that changes in product name and appearance make adherence more complicated (aOR=2.18, 95%CI 1.48:3.19, p<0.001), disagreeing in that GS saves money for me (the customer) (aOR=2.68, 95%CI 1.58:4.55, p<0.001) or that GS saves money for society (aOR=3.21, 95%CI 1.46:7.08, p<0.01).

Conclusions: Seven out of ten respondents had trust in the bioequivalence of generic medicines, and one in three considered GS to complicate adherence. Four factors were associated with lower trust in GS, i.e. female gender, agreeing that changes in product name and appearance complicates adherence, disagreeing in that GS saves money for me or disagreeing in that GS saves money for the society. Low trust in GS needs to be addressed, not least in the communication between health professionals and patients.

Keywords

Drugs, Generic; Drug Substitution; Health Knowledge, Attitudes, Practice; Patient Preference; Multivariate Analysis; Surveys and Questionnaires; Sweden

INTRODUCTION

Generic substitution (GS), the substitution of prescribed medicines for cheaper generic alternatives, is a cost-containment strategy meant to contain pharmaceutical expenditure without compromising health objectives.[1] GS means that patients are offered a cheaper generic medicine with the same amount of active substance, same formula, with bioequivalence demonstrated in appropriate studies (thereby exchangeable) instead of the prescribed product.[2] It is implemented in a wide range of countries and the number of off-patent medicines entering the market is increasing.[1,3] GS was introduced in Sweden in 2002 and has been effective, lowering the cost of pharmaceuticals for patients and the government by billions (SEK) every year and giving Sweden among the lowest prices on off-patent medicines in all of Europe.[4]

A high substitution rate is a desirable goal for policymakers as well as taxpayers to encourage competition on the pharmaceutical market and lower the cost of medicines. However, it is only a desirable goal if patients accept GS and trust the generics they purchase from the pharmacy. Patients' experiences with GS are mixed. Nordic and international studies have reported that GS is well accepted by a majority of patients.[5,6] Nevertheless, patients report that GS confuses and worries them, possibly resulting in mix-ups, double medication and non-adherence thereby posing a risk to patient safety.[7-11] Some patients (range 8-34%) also report reduced effect of treatment or new side effects from GS.[5,12] Trust in the bioequivalence of generics

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has been proven important to receive the full benefit of a treatment.[13] Hence, patients' perceptions of the received product and trust in the bioequivalence of interchangeable generic and brand medicines can be crucial for adherence, effect and side effects.[13-15]

A systematic review from 2018 identified seven domains influencing generic use in the United States (patient-related; formulary management and cost containment; Medicare and Medicaid polices; promotional activities; educational initiatives; technological; and physician-related factors). Patient-related factors were the most studied and discussed domain in the identified litterature[16], implying its large role in understanding GS. Level of education, gender, prior experience with GS and income has been shown to influence patients' acceptance of GS.[5,16-21] Recommendations, information and the perceptions of physicians and pharmacists have also been found important to patients' experience and acceptance.[7,16,22-24] By including all those factors previously identified in one study, this study provides a broader knowledge base regarding patients' trust in the bioequivalence of generic medicines. This could benefit decision makers and professionals involved with the development and improvement of the current system for GS. The aim of this study was to assess Swedish patients' level of trust in the bioequivalence of cheap and expensive generic medicines, and the association between trust and various factors.

METHODS

Study design and context

This was a cross- sectional study with data collected through a structured questionnaire.[25]

The Swedish healthcare system is tax funded, and the degree of reimbursement for pharmaceuticals increases with patients' expenses for prescription medicines included in the pharmaceutical benefits scheme.[26] The patient pays a maximum of 2200 SEK within a period of 12 months for pharmaceuticals included in the pharmaceutical benefits scheme. All costs in excess are subsidized by the government until the end of the 12-month period. Based on clinical data from the manufacturing pharmaceutical company, the Swedish Medical Product Agency decides which pharmaceuticals with the same amount of active substance and same formula are to be considered bioequivalent and thereby interchangeable.[27,28] All Swedish pharmacies must provide patients with the cheapest interchangeable product, which once a month is appointed by the Dental and Pharmaceutical Benefits Agency and referred to as "the preferred product of the month". The prescriber or the pharmacist can oppose the substitution, for instance, on medical grounds.[1] The patient can also choose the prescribed product or an alternative generic instead of the generic with the lowest price, but will then have to pay the price difference out of pocket.

Sample selection

A stratified random sampling method was used.[25] All 290 municipalities in Sweden were divided into ten strata based on average yearly income (per household), which has been shown previously to influence patient preferences regarding generic substitution.[21] One municipality in each stratum was selected with the aim of representativity with regard to geography, size (number of inhabitants) and percentage of people born outside Sweden.[29] In the two strata with the highest number of inhabitants (representing more than 20% of the population), two municipalities were selected from each, resulting in 12 municipalities in total. One pharmacy was selected in each municipality with the aim of heterogeneity in regard to placement/surrounding and pharmacy owner. Proportionate sampling was used to decide the number of questionnaires for each stratum, so that the number of questionnaires per strata would reflect the total number of individuals in each strata and hence the population.[25] Questionnaires were hence handed out at 12 pharmacies in 12 different municipalities located in the northern, middle and southern part of Sweden. Inclusion criteria were that participants should have previously or currently use prescribed medicines, at some point have been offered a generic substitution and speak Swedish.

Questionnaire development

A questionnaire was developed based on previously identified factors relevant to patients' acceptance of and trust in generic substitution.[5,17,18,20,21] The questionnaire included 18 items divided into three sections, in addition to seven questions about socio-demographics. Section 1 consisted of the 'views on generic medicine'- scale with four items developed in Danish by Rathe *et al*. and one question regarding acceptance of GS.[30] The 'views on generic medicine'-scale consists of questions about the equivalence between cheaper and more expensive generics in regards to safety, side-effects and effect. The Danish questions were translated to Swedish by the Swedish and Danish authors (one author is fluent in both Swedish and Danish) and checked by experts in the field. The two languages are closely related and very similar in regard to the four items in the scale. All items were answered on a 5-point Likert response scale (strongly agree=5, agree=4, neutral=3, disagree=2, strongly disagree=1). The response to the four items-'views on generic medicine'- scale resulted in a trust index value from 1 to 5, which measured to what degree the patients considered interchangeable generics with different price (expensive/cheap) equal regarding safety, side-effects and effect. From here on described as trust in equality. In this paper, the scale was reversed so that a high score equals a high level of trust (max=5) and a low score a low level of trust (min=1), in the interests of simplifying understanding of the results. An average trust score was calculated of the 4 items (range 1 to 5) and dichotomized (low trust ≤3, and high trust>3) and applied as the outcome variable.

Section 2 consisted of eight items concerning information regarding GS from physicians and pharmacists, as well as patients' prior experiences with GS. Section 3 included five items regarding the financial aspect of GS and difficulties with changes in color/name. All items were answered on a 5-point Likert response scale. Two different scales were used: 'Strongly agree, agree, don't agree or disagree' and 'always, often, sometimes (half of the time), seldom, never'. The questions regarding socio-demography

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included: age, gender, education level, native language, income, and number of medicines taken daily.

The questionnaire was initially tested for content validity by three researchers with wide experience in quantitative and qualitative method design. Subsequently, 20 cognitive interviews with concurrent and retrospective 'thinking aloud' and probing were carried out with medicine users focusing on comprehensiveness and relevance of the questions as well as the appearance of the questionnaire.[31] The questions and response scales were adapted accordingly. All pilot respondents were shown the new version of the questionnaire and approved the changes. Last, the feasibility of the data collecting procedure and comprehensibility of the final questionnaire was piloted at two different community pharmacies. A total of 41 questionnaires were handed out over two days to pharmacy customers who met inclusion criteria. Minor modifications were made to the layout and order of questions post pilot.

Data collection

All pharmacy owners and pharmacy managers at the 12 pharmacies contacted regarding data collection at or near the pharmacy agreed to participate. Pharmacy customers were approached consecutively inside or next to the entrance of the selected pharmacies. The concept of generic substitution was clarified for all customers, and their informed consent requested before the questionnaire was handed out. Some customers (n=160) requested that data collectors read the questions to them, for example due to poor eyesight. Gender and approximate age were registered for customers declining participation. Data were collected during March and April 2015. The days and times for data collection were varied to include all types of customers. Data were therefore collected during all opening hours on weekdays as well as weekends.

Statistical analysis

In the analysis the following independent variables were used: gender, age, education level, income, native language, number of pharmaceuticals per day, acceptance of GS, information received, prior experiences with changes in effect/side effects, difficulties with adherence due to name and appearance changes and financial aspects. Moreover the two items regarding confusion because of changes in name or appearance were combined into one dichotomized item predicting overall confusion. All variables were initially analyzed descriptively. Socio-economic characteristics and the answers to section 2-3 are presented descriptively and stratified according to level of trust.

Crude and adjusted logistic regression analyses were performed. The crude association between low trust as the outcome variable and each of the independent variables

Table 1. The characteristics of the study population and their average trust in the bioequivalence of cheap and expensive interchangeable generic medicines. The data are displayed for each level of the studied variables for all respondents and stratified into low (trust≤3) and high (trust>3) trust.

Variable	n (%)	**Trust value** (all respondents)			
		median	**mean (SD)**	**Low trust n (%)**	**High trust n (%)**
Gender					
Male	294 (40.9)	4.0	3.9 (0.9)	63 (21.4)	231 (78.6)
Female	425 (59.1)	3.8	3.6 (1.1)	148 (34.8)	277 (65.2)
Age					
18-35	36 (5.0)	4.0	4.0 (0.7)	4 (11.1)	32 (88.9)
36-50	103 (14.3)	4.0	3.8 (1.0)	31 (30.1)	72 (69.9)
51-65	207 (28.8)	3.8	3.7 (1.0)	63 (30.4)	144 (69.6)
66-80	321 (44.7)	3.8	3.7 (1.0)	103 (32.1)	218 (67.9)
81+	52 (7.2)	3.8	3.8 (0.9)	10 (19.2)	42 (80.8)
Education level					
Elementary school	144 (20)	3.5	3.5 (1.1)	56 (38.9)	88 (61.1)
High school	232 (32.3)	4.0	3.8 (1.0)	62 (26.7)	170 (73.3)
University	341 (47.4)	4.0	3.8 (0.9)	92 (27.0)	249 (73.0)
Missing	2 (0.3)	3.1	3.1 (1.6)	1 (50.0)	1 (50.0)
Income (monthly before tax)					
<10 000 SEK	71 (9.9)	3.8	3.5 (1.2)	26 (36.6)	45 (63.4)
10 000-19 999	247 (34.4)	3.8	3.7 (1.0)	75 (30.4)	172 (69.6)
20 000-29 999	135 (18.8)	4.0	3.8 (1.0)	34 (25.2)	101 (74.8)
30 000-39 999	105 (14.6)	4.0	3.9 (0.9)	22 (21.0)	83 (79.0)
40 000+	93 (9.5)	4.3	3.9 (0.9)	23 (24.7)	70 (75.3)
Missing	68 (9.5)	3.4	3.4 (1.2)	31 (45.6)	37 (54.4)
Native language					
Swedish	699 (93.0)	3.8	3.8 (1.0)	195 (27.9)	474 (67.8)
Other	45 (6.3)	3.8	3.5 (1.0)	15 (33.3)	30 (66.7)
Missing	5 (0.7)	3.5	3.3 (1.4)	1 (20.0)	4 (80.0)
Number of pharmaceuticals (daily)					
None	101 (14.0)	4.0	3.6 (1.1)	35 (34.7)	66 (65.3)
1 to 2	261 (36.3)	3.8	3.8 (0.9)	66 (25.3)	195 (74.7)
3 to 4	200 (27.8)	3.8	3.7 (1.0)	63 (16.5)	137 (68.5)
5+	157 (21.8)	3.8	3.7 (1.1)	47 (30.0)	110 (70.0)
Total	719 (100.0)	3.8	3.7 (1.0)	211 (29.3)	508 (70.7)

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was assessed through crude odds ratios (OR) with 95% confidence intervals (CI) applying univariable logistic regression. For the multivariable analysis the four items regarding 'prior experiences' were excluded due to a risk of overlap with questions in the trust index. The multivariable model was fitted by first including variables based on above univariate/crude analysis. Initially, variables with p-values <0.15 were included. In the next steps one by one, variables having a p-value >0.05 and implying a change less then <20 % in the beta coefficients by removal of the other variables in the remaining model were removed.[32] The fit of the model was tested with Hosmer and Lemeshow Test.[32]

RESULTS

A total of 849 pharmacy customers who met the inclusion criteria were invited to fill out the questionnaire; 719 agreed to participate, resulting in a response rate of 84.7%. The population characteristics and the median and average trust values are presented in Table 1. The majority of the participants were women (59.1%), the most common age group was 66-80 years old (44.7%) and most common education level was university or equivalent (47.4%). Half of the study population was currently using three or more medicines per day.

Patients trust in GS (range 1 to 5) was on average 3.8 (median) or 3.7 (mean, SD 1.0), see Table 1. The average

Table 2. Overview of the answers to questionnaire items and average trust in the bioequivalence of cheap and expensive exchangeable generic medicines. Data are displayed for each level of the studied variables for all respondents and stratified on low (trust≤ 3) and high (trust>3) trust.

Variable		Trust value (all respondents)		
	n (%)	Median (mean)	Low trust n (%)	High trust n (%)
Acceptance of generic substitution (GS)				
Sometimes/often/always Yes to GS	584 (81.2)	4.0 (4.0)	112 (19.2)	472 (80.8)
Seldom/never Yes	126 (17.5)	2.8 (2.7)	94 (74.6)	32 (25.4)
Missing values	9 (1.3)	3.0 (3.4)	5 (55.6)	4(44.4)
Previous experiences				
Have experienced better effect	132 (18.4)	3.4 (3.4)	58 (43.9)	74 (56.1)
Never experienced better effect	522 (72.6)	4.0 (3.9)	119 (22.8)	403 (77.2)
Missing values	65 (9.0)	3.0 (3.2)	34 (52.3)	31 (47.7)
Have experienced less effect	213 (29.6)	3.0 (3.0)	126 (59.2)	87 (40.8)
Never experienced less effect	440 (61.2)	4.3 (4.2)	50 (11.4)	390 (88.6)
Missing values	66 (9.2)	3.0 (3.2)	35 (53.0)	31 (47.0)
Have experienced fewer side-effects	102 (14.2)	4.0 (3.9)	56 (54.9)	46 (45.1)
Never experiences fewer side-effects	546 (75.9)	3.0 (3.1)	119 (21.8)	427 (78.2)
Missing values	71 (9.9)	3.0 (3.2)	36 (50.7)	35 (49.3)
Have experienced more side-effects	159 (22.1)	3.0 (2.9)	103 (64.8)	56 (35.2)
Never experiences more side-effects	490 (68.2)	4.3 (4.1)	69 (14.1)	421 (85.9)
Missing	70 (9.7)	3.0 (3.2)	39 (55.7)	31 (44.3)
Information				
Have received info from physician	467 (65.0)	4.0 (3.7)	125 (26.8)	342 (73.2)
Have never received info from physician	252 (35.0)	3.8 (3.7)	86 (34.1)	166 (65.9)
Have received info from Pharm	713 (99.2)	3.8 (3.7)	209 (29.3)	504 (70.7)
Have never received info from Pharm	6 (0.8)	3.50 (3.5)	2 (33.3)	4 (66.7)
Have received info from physician and Pharm	465 (64.7)	4.0 (3.8)	124 (26.7)	341 (73.3)
Never received info from physician or Pharm	4 (0.6)	3.6 (3.6)	1 (25.0)	3 (75.0)
Confusion				
Change in appearance complicates adherence				
Strongly agree/agree	259 (36.0)	3.5 (3.6)	97 (37.5)	162 (62.5)
Neutral/disagree/strongly disagree	458 (63.7)	4.0 (3.8)	112 (24.5)	346 (75.5)
Missing values	2 (0.3)	2.1 (2.1)	2 (100.0)	0
Change in names complicates adherence				
Strongly agree/agree	293 (40.8)	3.5 (3.5)	115 (39.2)	178 (60.8)
Neutral/disagree/strongly disagree	424 (59.0)	4.0 (3.9)	94 (22.2)	330 (77.8)
Missing values	2 (0.3)	2.1 (2.1)	2 (100.0)	0
Financial aspects				
GS saves money for me (the customer)				
Strongly agree/agree/neutral	623 (86.6)	4.0 (3.8)	159 (25.5)	464 (74.5)
Disagree/strongly disagree	95 (13.2)	3.0 (3.1)	52 (54.7)	43 (45.3)
Missing values	1 (0.2)	4.8 (4.8)	0	1 (100)
GS saves money for society				
Strongly agree/agree/neutral	671 (93.3)	4.0 (3.8)	179 (26.7)	492 (73.3)
Disagree/strongly disagree	47 (6.5)	2.5 (2.8)	32 (68.1)	15 (31.9)
Missing	1 (0.2)	5.0 (5.0)	0	1 (100.0)
The pharmacy profits from GS				
Strongly agree/agree	116 (16.1)	3.3 (3.4)	50 (43.1)	66 (56.9)
Neutral/disagree/strongly disagree	602 (83.7)	4.0 (3.8)	161 (26.7)	441 (73.3)
Missing	1 (0.2)	5.0 (5.0)	0	1 (100.0)

Pharm=Pharmacist; GS= Generic substitution

trust value was lower among women than among men. Moreover, trust decreased with increased age and number of pharmaceuticals. Patients with a lower education level and patients with lower income had a lower level of trust on average, see Table 1. When the total sample was stratified into groups of low and high trust, 70.7% of the respondents had high trust in the equivalence. A majority (82.1%) of the respondents sometimes, often or always accepts generic substitution, see Table 2. The trust average (mean) among this group was 4.0 (SD 0.9) compared to 2.8 (SD 0.8) among those who seldom or never accept substitution. A majority (53.1%) of the patients with low trust in bioequivalence still accepted substitution sometimes, often or always.

In Table 2 findings concerning information regarding GS from physicians and pharmacists and patients' prior experiences with GS are presented. Nearly one-third (29.6%) of the respondents had experienced less effect after substitution, and 22.1% more side effects. However, 18.4% had experienced a better effect and 14.2% fewer side effects. Almost all patients (99.2%) had received information about GS from a pharmacist at some point, while 65.0% had received information from a physician. Slightly more than one-third of the patients considered the change in appearance (36.0%) or name (40.8%) to complicate adherence. Patients with a greater number of medicines were overrepresented in the group that found GS to complicate adherence. When asked if generic substitution saves money for society 6.5% disagreed or strongly disagreed. Regarding savings on a personal level 13.2% disagreed or strongly disagreed, see Table 2.

The multiple logistic regression (Table 3) showed that women had lower trust than men (ORadjusted=1.82, 95%CI 1.20:2.75, p<0.01), and that patients who considered GS to complicate adherence had a lower trust in the bioequivalence compared to patients who did not (ORadjusted=2.18, 95%CI 1.48:3.19, p<0.001). Patients disagreeing in that GS saves money for me (the customer) (ORadjusted=2.68, 95%CI 1.58:4.55, p<0.001) or that GS saves money for society (ORadjusted=3.21, 95%CI 1.46:7.08, p<0.01) had lower trust, as presented in Table 3. The Hosmer and Lemeshow Test support fit of the model (p=0.92). For the crude analysis, see Online Appendix.

DISCUSSION

The aim of this study was to assess Swedish patients' level of trust in the bioequivalence of cheap and expensive generic medicines, and the association between trust and various factors. Overall, the results show that a majority (70.7%) of the respondents' trust that cheap and expensive interchangeable generic medicines are equal in regard to quality, effect and side-effects and that 81.2% of the respondents sometimes/often or always accepted GS. A vast majority of the respondents does believe that today's system saves money for the individual and society. Out of the studied variables, female gender and opinions that changes in name and appearance make adherence more complicated, disagreeing in that GS saves money for me (the customer) or that GS saves money for society were seen to significantly increase the odds of low trust in the bioequivalence. We found no association for level of education, prior experience with GS (excluded in our adjusted analysis due to overlap with the outcome variable) and income, which earlier has been shown to influence patients' acceptance of GS.[5,16-20] However, level of education and income were important mediators in our final model.

This study implies that the majority of Swedish patients (70.7%) trust in the bioequivalence of interchangeable generics, however almost one third of the patients have a low level of trust. Nevertheless, a majority (53.1%) of the patients with a low level of trust in the equality still accepted generic substitution. A Finnish questionnaire study found that 80.9% of patients held the opinion that cheaper generics are equally effective and in Denmark a corresponding figure was 90.4%.[30,33] This result indicates that Swedish patients have a lower level of trust in the bioequivalence of cheaper generics than patients in

Table 3. The result from the univariate and multivariate logistic regression analyses presented as odds ratios (OR) for low trust in the bioequivalence of cheap and expensive interchangeable generics with 95% confidence intervals (95%CI). *p<0.05 **p<0.01 ***p<0.001. (n=648)

Variable	Crude OR (95%CI)	Adjusted OR[1] (95%CI) n=648
Gender		
Male (ref)	1	1
Female	1.96 (1.39:2.76)***	1.82 (1.20:2.75)**
Confusion		
Change in appearance/name complicates adherence		
Neutral/disagree/strongly disagree on item 3A+3B (ref)	1	1
Agree/strongly agree on item 3A+3B	1.98 (1.43:2.75)***	2.18 (1.48:3.19)***
Financial aspects		
GS saves money for me (the customer)		
Strongly agree/agree/neutral (ref)	1	1
Disagree/strongly disagree	3.53 (2.27:5.50)***	2.68 (1.58:4.55)***
GS saves money for society		
Strongly agree/agree/neutral (ref)	1	1
Disagree/strongly disagree	5.86 (3.10:11.08)***	3.21 (1.46:7.08)**

[1]A backward elimination stepwise selection model was performed. Only the variables included in the final model are presented. The final model is adjusted for education level, monthly income, age, numbers of medication, and information from the physician. Individuals were excluded from regression analyses if data was missing on covariates. The final adjusted model included 648 patients.
GS= Generic substitution

Denmark and Finland. The system for substitution varies between the three countries; Denmark appoint new products with the lowest price every fortnight compared to every month in Sweden, and every three months in Finland. Hence, no conclusion can be drawn regarding the influence of the duration of price period on patients' trust in bioequivalence.

Another variable previously shown to positively influence patients trust in GS is the pharmaceutical counselling at the pharmacy.[7,22-24] Pharmacists have an important role to play in securing the patients' confidence in generics and consequently adherence to generics. As our results show, several factors impact the trust level, such as gender and opinions that changes in name and appearance make adherence more complicated, disagreeing in that GS saves money for me (the customer) or that GS saves money for society. Pharmacists should be aware of these factors when counselling patients. Potentially the 'views on generic medicine'-scale could be used by pharmacists in the counselling session to identify patients with low trust in the bioequivalence of cheaper generics. Pharmacists need to be both knowledgeable about generics and transfer this information to patients. In addition, they need to use counselling skills, such as listening, and explore the individual patient's opinion about generics.

No comparative communication study between the Nordic countries exist, but in all the countries there are studies showing a need for increased counselling.[34-38] As an example a Swedish study found that little or no medical information is given in the interaction with the patient during dispensing at the pharmacy.38 Still in Swedish pharmacies, no more time was spent on medical information when GS occurred even though Swedish pharmacists had identified GS as a complicating factor for adherence.[39,40] Nevertheless, both in the Finnish and the Danish legislation it is explicit in the legal texts, that information about generics has to be given both in writing (on the label) and orally.[41] There is also a specific requirement that Finnish pharmacists must ensure that the patient is aware of the fact that the generic is replacing the previous brand. This is not the case for the Swedish legislation. To further explore the impact of counselling on trust, a Nordic comparative study is warranted.

The results also showed that about 30% have experienced less effect compared to about 20% who had experienced a better effect from their medication after a substitution. In addition, almost 25% of patients reporting more side effects compared to 14% of participants reporting fewer side effects. This is in line with previous studies reporting changes in effect and/or side effects after substitution.[5,7,8,12] However, to the best of our knowledge no one has previously studied occurrence of better effect and fewer side effects after GS.

Over one third of patients considered GS to complicate adherence, this was also associated with lower trust in the bioequivalence. Lower adherence due to changes in medicine appearances after GS has previously been shown by Kesselheim *et al*.[11,42] Requirements regarding equal appearance for all generics that are to be substituted could prevent unintentional interruption in medication use and mix ups. In Sweden there are no requirements regarding appearance in order for approval of bioequivalence (except for differences in size) and substitution.[43] Hence, GS can result in differences in e.g. color of the medicine. In this way, current legislation does not support patients' use of medicine in this regard, thereby potentially causing GS to complicate adherence. This could compromise the outcome of the treatment and hence needs to be addressed, also in the communication between health professionals and patients.

In this study, females have lower trust in GS compared to men, which is also reported elsewhere.[6,17-20] Women often view themselves as more sensitive to medicines compared to men.[44,45] This might have consequences for their trust in GS, making them more sensitive to side effects and effects/no-effects of generics. They also have slightly different health behavior compared to males. For example, females tend to use more medicines compared to men.[46] They also seek more information about medicines.[47,48] Depending on what information they seek and find this could either make them more reluctant or more positive to GS.

To conclude, although rigid requirements exist regarding the demonstration of bioequivalence in order to be eligible for GS[27,28,49], many patients still distrust that cheap and expensive generics are equal in regard to quality, effect and side-effects. With this study design, it is not possible to determine the direction of the causality between low level of trust and experienced differences. Still distrust in equality are noteworthy as patients' perceptions of received product and trust in the bioequivalence of generics and brand medicines has been found to be crucial for adherence, received effect and side effects.[13-15] This suggests that it is this important for health professionals and authorities to be aware of low trust among some patients as well as adherence challenges after GS. Health care professionals need to keep this in mind when communicating with patients, in order to provide the support needed to prevent non-adherence and feelings of insecurity among patients. Also, physicians or pharmacists have the option to refuse GS for patients in risk of mix-ups. It can however affect the cost of the prescribed medicine for the patient and availability since the pharmacy might not have all generics in stock. Further, many refusals of substitution could not only result in a direct increase of costs for the patient, but could also affect prices generally due to a reduced market share for the preferred product of the month. Guided by the result from this study authorities and policy makers should reflect on whether the requirements for substitution are sufficient, as changes in colors and names can complicate patient adherence. With limited resources available, the best choice for the individual patient and for society must always be weighed in order to achieve a fair and cost-efficient healthcare system that does not compromise health objectives.

The method used had two primary strengths. First, since questionnaires were handed out by a data collector according to a predetermined procedure, all respondents received the same information and were able to ask questions if any uncertainties arose with regard to

questions.[50] Second, there was a high response rate (84.7%). However, some limitations need to be mentioned. The labor-intensive method of having data collectors hand out the questionnaires kept the number of pharmacies where data were collected quite low (n=12) which could have affected the representability. While the gender distribution in the study population was similar to the population medicine users in Sweden[51], there was an underrepresentation of young medicine users and people in the lowest income level[29,47], and an overrepresentation of people with a university degree or equivalent.29 Customers who declined participation most often gave lack of time as a reason, but some stated that they did not like questionnaires in general. The customers who declined to participate represented the study population as well as the population of medicine users with regard to gender distribution and estimated age. The 'views on generic medicines' scale has been used for Danish patients prior to this study. When changing the dichotomization as originally presented in Rathe *et al.*, including index 3 (neither trust nor distrust) into the 'high trust' group, 80% of the respondents in this study trusted in GS compared with 90% of Danish patients.[30] Further the translation process can have resulted in divergence from the original language. As all participants were explained the concept of generic medicines and the word bioequivalence was not used, the internal validity was secured. A cross-sectional design also limits the ability to draw any casual interference of the identified relationships. Here a longitudinal design is warranted.

CONCLUSIONS

Seven out of ten respondents trusted the bioequivalence of generic medicines, and one in three considered GS to complicate adherence. In addition, four factors were associated with lower trust in GS i.e. female gender, agreeing with changes in product name and appearance complicates adherence, disagreeing in that GS saves money for me and disagreeing in that GS saves money for the society. Low trust in GS needs to be addressed, not least in the communication between health professionals and patients. More than one in three respondents considered the changes in name or appearance to complicate their adherence, and about one-third had experienced a change in effect and number of side effects after a substitution. This could compromise the outcome of the treatment. It is important that health professionals are attentive to, prevent and address nonadherence, especially after GS.

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CONFLICT OF INTEREST

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Original Research

Frequency of occurrence of medication discrepancies and associated risk factors in cases of acute hospital admission

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Abstract

Background: Medication discrepancies are a common occurrence following hospital admission and carry the potential for causing harm. However, little is known about the potential risk factors involved in medication discrepancies.

Objective: The objective of this study was to determine how frequently medication discrepancies occur and their associated risk factors, in patients hospitalized via the emergency department of the Spaarne Gasthuis Hospital, located in The Netherlands.

Methods: This retrospective observational study examines 832 hospital admissions which took place between April 1st and June 30th, 2015. Medication reconciliation was performed within 24 hours of admission and medication discrepancies were registered. The primary outcome recorded in the study was the proportion of patients experiencing one or more medication discrepancies, as verified by the physician. As a secondary outcome, the association between these discrepancies and pre-specified variables was analyzed using univariate and multivariate logistic regression.

Results: At least one medication discrepancy was found to have occurred with 97 of the 832 patients (11.7%), the most common discrepancies involving incorrect drug dose (44.9%) and omission of medication (36.4%). In the univariate analysis, age (OR=1.03 [95% CI 1.02:1.04] p<0.001) and number of pre-admission medications taken (OR=1.13 [95%CI 1.09:1.17] p<0.001) were revealed to be significantly associated with the risk of medication discrepancies. Sex, type of medical specialty, and surgical versus non-surgical specialty were found not to be significantly associated with discrepancies. In the multivariate analysis, both the number of pre-admission medications (OR=1.10 [95%CI 1.06:1.15] p<0.001) and age (OR=1.02 [95%CI 1.01:1.03] p=0.004) were independently associated with the risk of medication discrepancy.

Conclusions: Of the total number of patients, 11.7% experienced one or more medication discrepancies following admission to the hospital. Elderly patients taking multiple drugs were found to be particularly at risk.

Keywords

Medication Reconciliation; Medication Errors; Documentation; Hospitalization; Patient Admission; Multivariate Analysis; Retrospective Studies; Netherlands

INTRODUCTION

Up to two-thirds of all hospitalized patients will experience one or more discrepancies (differences) between the patient's medication history as determined at the point of hospital admission, and the medication prescribed during hospitalization.[1] Medication discrepancies occur most frequently at the point of hospital admission and discharge.[2,3] Between 11 and 59% of medication discrepancies are potentially harmful.[1] This constitutes a major public health burden, and one which is largely preventable.[2,4]

In the hospital setting, it is often not feasible for pharmacy professionals to perform medication reconciliation for all patients at the point of admission and discharge. To optimize quality of healthcare, it is important to identify the patient group most likely to incur medication discrepancies. Medication reconciliation for patient groups at particular risk should ideally be performed by pharmacy professionals.[5-7] In the Netherlands, this task is most often performed by pharmacy technicians who work under the supervision and responsibility of a pharmacist. The review by Hias *et al*. examined the risk factors for medication discrepancy and identified a correlation between patient characteristics and medication discrepancies at the point of admission.[8] However, the studies reviewed mostly involved a small number of patients. These researchers also showed that the potential risk factors identified varied between different studies.[8] The number of pre-admission drugs

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taken was the most frequently identified risk factor for discrepancies in general, whereas age was the most frequently identified risk factor for potentially harmful discrepancies.[8] Other risk factors, such as gender, type of care before admission, number of comorbidities and type of care received prior to admission, were all associated with medication discrepancies - significantly in some studies, and non-significantly in others.[8]

Contradictory results imply that the potential risk factors for the occurrence of medication discrepancies are still not fully elucidated. Since no conclusive outcome can be found in the literature, more research is needed to identify the risk factors in this area. The aim of this study, therefore, is to determine the frequency with which medication discrepancies occur, and the associated risk factors in patients hospitalized through the emergency department of the Spaarne Gasthuis Hospital in The Netherlands. This admission group was selected, because the urgency of the patients' situation lends itself to greater risks regarding this issue.

METHODS

Study design and population

For this retrospective observational study, data were obtained from the Spaarne Gasthuis Hospital located in Haarlem, The Netherlands. Patients were included in the study if they visited the emergency department and were subsequently admitted to the hospital between April 1st and June 30th, 2015. A further inclusion criterion was the performing of medication reconciliation by the pharmacy technician, following the treating physician entering the prescribed medication on the hospital information system Epic (Verona, WI, USA). Medication reconciliation was performed within 24 hours of admission. Available sources were reviewed in order to obtain the best possible medication history. The available medication history, as stored in the hospital information system, in cases where the patient had been previously hospitalized. The availability of medication records from the community pharmacy was also checked; in The Netherlands, medication dispensed by pharmacies is registered electronically, and this information is accessible to other healthcare professionals if the patient has granted permission for this. With these lists of medication as the starting point, semi-structured interviews with each of the patients and/or caregivers were performed, and for each drug the drug name, dosage, frequency, and route were checked. If discrepancies were identified, these were communicated to the treating physician. For patients who were re-hospitalized in the study period, only the first hospitalization was included. Patients who used no medication before admission were excluded from the study.

This study is a retrospective observational study, and as such does not the need for approval by a Medical Ethics Committee, according to the Dutch Medical Research Involving Human Subjects Act. All patients received usual care and data were gathered retrospectively and processed anonymously, according to privacy legislation.

Data collection and monitoring

The data were collected from the hospital information system using SAP Crystal Reports (Walldorf, Germany). The extracted data were converted to Microsoft Excel version 2010 (Redmond, WA, USA). For every admission, medications prescribed prior to admission, medications prescribed on hospital admission, age, sex, and the medical specialty treating the patient, were extracted. Medications were classified according to the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) methodology.[9] The integrity of the data was sample-wise checked by a clinical pharmacist.

Outcome measures

The primary outcome assessed by the study was the proportion of patients experiencing one or more medication discrepancies. Medication discrepancy is defined as an inconsistency between the actual medication as detailed in Epic and the best possible medication history based on the medication reconciliation. Any inconsistency was discussed with the attending physician. Cases where the physician did not accept the proposal of the pharmacy technician and therefore did not change the prescribed medication were not included as a medication discrepancy, as the physician may have changed or stopped the medication intentionally. Four types of discrepancy were distinguished in this study: omission of medication, differing drug dose (including differing frequency of administration), restarting stopped medication, and incorrect drug (including different drug routes).

The following potential risk factors were assessed: age, sex, type of medical specialty, surgical specialty versus non-surgical, and number of drugs taken prior to admission. The secondary outcome assessed by the study was the type of medication involved in the medication discrepancy classified using the first level (anatomical main group) of the WHO ATC group, as well as the frequency of medication discrepancies as cited by this group.[9]

Data Analysis

IBM SPSS Statistics for Windows version 24 (IBM Corp, Armonk, NY) was used for the statistical analyses. Descriptive analysis was used to analyze the frequency of medication discrepancies. Univariate binary logistic regression was conducted to determine which pre-specified variables were significantly associated with the occurrence of medication discrepancies. All potential predictors with a p-value <0.05 were entered into the multivariate logistic regression analysis, adjusting for potential confounders. A p value below 0.05 was regarded as statistically significant and 95% confidence intervals are reported.

RESULTS

During the study period, a total of 999 medication reconciliations were performed, all occurring within 24 hours of hospital admission. Sixty-three medication reconciliation interviews were excluded on account of the patients being re-hospitalized within the study period. A further 104 patients were excluded because they did not

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Table 1. Baseline characteristics (n = 832)	
Sex,	n (%)
Male	387 (46.5)
Age in years, mean (SD[a])	63.5 (23.5)
Age categories,	n (%)
≤18	60 (7.2)
19-45	94 (11.3)
46-65	198 (23.8)
66-75	157 (18.9)
76-85	204 (24.5)
>85	119 (14.3)
Medical specialty	no (%)
Gastroenterology	88 (10.6)
Geriatrics	116 (13.9)
Internal	203 (24.4)
Neurology	63 (7.6)
Pediatrics	45 (5.4)
Pulmonology	101 (12.1)
Surgical	187 (22.5)
Other[b]	29 (3.5)
Num. medications prior to admission, mean (SD)	6.9 (4.9)
minimum	1
maximum	26

[a] SD = standard deviation
[b] Others; includes urology, gynecology, dental specialisms, cardiology, otorhinolaryngology

use medication before admission. Thus, 832 patients were included in the analyses (Table 1).

In 97 of the 832 patients, at least one medication discrepancy was detected (11.7%). A total of 176 medication discrepancies were identified in these 97 patients, which gives a frequency of 0.21 discrepancies per admission and 1.8 discrepancies per admission with at least one medication discrepancy. The prescribing of an incorrect drug dose was found to be the most common discrepancy type, followed by the omission of medication (Table 2). Drugs most frequently involved in medication discrepancies pertained to the ATC groups 'Systemic hormonal preparations', 'Cardiovascular system' and 'Sensory organs' (Table 3).

The univariate logistic regression analysis showed that age (OR=1.03 [95%CI 1.02:1.04] p<0.001) was significantly associated with the risk of medication discrepancy (table 4). Patients younger than 18 years had the lowest risk and the risk increased in patients of 66 years and above. Furthermore, a significant association between the number

Table 2. Type of medication discrepancy (n=176)	
Type of discrepancy	**N (%)**
Omission of medication	64 (36.4)
Differing drug dose	79 (44.9)
Restarting stopped medication	14 (8.0)
Incorrect drug	19 (10.8)

of medications taken prior to admission (OR=1.13 [95%CI 1.09:1.17] p<0.001) and the risk of medication discrepancies, was found. In patients using less than seven medications, the frequency of one or more medication discrepancies at admission was 0.05, while in patients using seven or more medications the frequency was 0.24. No significant association was found with sex and medical specialty. In the multivariate analysis, the number of pre-admission medications taken (OR=1.10 [95%CI 1.06:1.15] p<0.001) and age (OR=1.02 [95%CI 1.01:1.03] p=0.004) were statistically significantly associated with the frequency of medication discrepancy.

DISCUSSION

In approximately one in nine acutely admitted patients at least one medication discrepancy was identified during medication reconciliation. Independent risk factors for medication discrepancy were identified as age and the number of pre-admission medications taken. The prescribing of an incorrect drug dose was the most common discrepancy, followed by the omission of medication. In our study, medication discrepancies were excluded if the physician did not change the discrepancy following notification.

A study by Allende Bandrés *et al*. differentiated medication discrepancy justified by a pharmacist and found a frequency of 1.8 medication discrepancies per admission with at least one medication discrepancy, which is in line with the current study's findings.[10] Cornu *et al*. identified 279 medication discrepancies which were accepted in 163 patients (giving a frequency of 1.7, as compared to 1.8 in the current study).[11] The study also revealed a frequency of 1.4 medication discrepancies per admission, which is higher than the current study's findings, of a frequency of 0.21. However, there are substantial differences in methodology between the current study and that of Cornu *et al.* – for example, in the latter study, only patients aged 65 years and older were included. The average age in the study

Table 3. Number of prescribed medications and discrepancies per ATC-group.

ATC-code	Number of prescribed medications	Number of discrepancies (n=176)	Discrepancies per ATC-group (%)
A: Alimentary tract and metabolism	1373	45	3.3
B: Blood and blood forming organs	532	4	0.8
C: Cardiovascular system	1284	51	4.0
D: Dermatologicals	130	5	3.8
G: Genito-urinary system and sex hormones	109	4	3.7
H: Systemic hormonal preparations[a]	170	9	5.3
J: Anti-infective for systemic use	130	1	0.8
L: Antineoplastic and immunomodulating agents	55	0	0.0
M: Musculo-skeletal system	210	4	1.9
N: Nervous system	944	25	2.6
R: Respiratory system	534	17	3.2
S: Sensory organs	110	10	9.1
Others	44	1	2.3

[a] excluding sex hormones and insulin's

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Table 4. Univariate and multivariate analyses: possible risk factors for medication discrepancies.

Variable	All admissions (n=832)	Discrepancies/admission (n=97) (%)[a]	Odds ratio [95%CI]	Adjusted Odds ratio [95%CI]
Sex				-
Female	445	51 (11.5)	1 (ref)	
Male	387	46 (11.9)	1.04 [0.68:1.59]	
Age, years (SD)	63.5 (23.5)	74.0 (14.3)	1.03 [1.02:1.04] *	1.02 [1.01:1.03] *
Age categories, in years				-
≤18	60	1 (1.7)	0.51 [0.05:5.06]	
19-45	94	3 (3.2)	1 (ref)	
46-65	198	13 (6.6)	2.13 [0.59:7.67]	
66-75	157	29 (18.5)	6.87 [2.03:23.25] *	
76-85	204	34 (16.7)	6.07 [1.81:20.30] *	
>86	119	17 (14.3)	5.06 [1.44:17.81] *	
Number of medications taken prior to admission (SD)	6.9 (4.9)	9.9 (4.1)	1.13 [1.09:1.17] *	1.10 [1.06:1.15] *
Type of medical specialty, no				-
Non-surgical	620	74 (11.9)	1 (ref)	
Surgical	212	23 (10.8)	0.90 [0.55:1.48]	
Medical specialty				-
Gastroenterology	88	8 (9.1)	0.56 [0.24:1.26]	
Geriatrics	116	16 (13.8)	0.89 [0.46:1.70]	
Internal	203	31 (15.3)	1 (ref)	
Neurology	63	5 (7.9)	0.48 [0.18:1.29]	
Pediatrics	45	1 (2.2)	0.13 [0.02:0.95] *	
Pulmonology	101	12 (11.9)	0.75 [0.37:1.53]	
Surgical	187	22 (11.8)	0.74 [0.41:1.33]	
Other[b]	29	2 (6.9)	0.41 [0.09:1.82]	

[a] percentage of the number of admissions; b 'Other' includes urology, gynecology, dental specialisms, cardiology, otorhinolaryngology.
* statistically significant at p<0.05

population assessed by Cornu *et al*. was therefore older than in the current study (83.7 versus 63.5 years) and the study population used more medications prior to admission (7.2 versus 6.9). Since the current study found an association between increasing age and higher numbers of pre-admission medications, and the occurrence of medication discrepancies, it can be assumed that those particular risk factors contributed to the relatively high frequency of discrepancies reported by Cornu *et al*.

To the best of the author´s knowledge, this is the first study to assess the frequency of occurrence of medication discrepancies according to WHO ATC group. Patients using medications from the ATC groups 'Systemic hormonal preparations', 'Cardiovascular system' and 'Sensory organs' were found to be at greater risk. Four previous studies have divided up medication discrepancies according to drug class.[8] The most common discrepancy that was found in the current study was incorrect drug dose. This is not consistent with earlier studies, in which omissions constituted the most common discrepancy found.[1] This difference in findings may be explained by differences in methodology. Omitting to prescribe a drug might be intentional, while in the current study only medication discrepancies that were accepted by the physician were included.

The number of pre-admission medications taken was the most frequently identified risk factor for medication discrepancy in the review conducted by Hias *et al*.[8] The odds ratio for each additional medication varied from 1.09 to 1.47 in these studies, compared with 1.13 in the current study.[8] Age was also investigated as a risk factor, but the literature revealed no conclusive outcome.[8] Studies inferred that increasing age is associated with the frequency of medication discrepancy did not always adjust for potential confounders such as underlying diseases.[1,2,10,11] The results detailed are similar to those of the current study. Hias *et al*. showed that 5 out of 24 studies found an association between sex and the frequency of medication discrepancies.[8] Our results showed no association between sex and the number of medication discrepancy, in line with other studies.[8]

Our study has both strengths and limitations. Firstly, this study is noteworthy in that, to the best of our knowledge, it is the largest study to date examining the risk factors for medication discrepancy in acutely admitted patients. Secondly, this study excluded discrepancies that were not accepted by the physician following notification. Thirdly, this study analyzed the medication discrepancies with reference to ATC grouping in order to assess whether some medications were more often involved in discrepancies than others. A potential limitation of the study is that we did not include medication discrepancies that remained unchanged by the physician after notification. It was assumed that, in such cases, the discrepancies were intentional rather than being in error. It is possible that this resulted in a lower frequency of medication discrepancies in our study, compared to earlier studies. Secondly, this study did not differentiate between discrepancies that were not clinically relevant and those that were. Thirdly, this study was performed in just one hospital, potentially limiting the generalizability of the results.

This study suggests the importance of performing medication reconciliation. It confirms that patient age and the number of preadmission medications taken are independent risk factors for medication discrepancy in acutely admitted patients and identifies various drug groups as being particularly susceptible. It is recommended that medication reconciliation to be conducted prior to

prescription, to mitigate the possibility of medication errors. Future research might examine how to better differentiate between accepted and not accepted medication discrepancies and determine the clinical relevance of this issue.

CONCLUSIONS

To conclude, approximately one in nine patients acutely admitted to the hospital were found to have experienced one or more medication discrepancies. Patients using medications from the ATC groups ´Systemic hormonal preparations', 'Cardiovascular system' and 'Sensory organs' were most at risk in this regard. Both increasing age and a higher number of pre-admission medications were found to be potential risk factors for medication discrepancies during admission. It is suggested that consideration should be given to deploying pharmacy professionals in the performing of the medication reconciliation for these high-risk patients, in order to reduce the occurrence of medication discrepancy following hospital admission.

CONFLICT OF INTEREST

None of the authors have any conflict of interest to declare.

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Original Research

Pharmacists' immunization experiences, beliefs, and attitudes in New Brunswick, Canada

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Abstract

Background: The expansion of pharmacist scope of practice to include provision of immunizations has occurred or is being considered in various countries. There are limited data evaluating the experiences of Canadian pharmacists in their role as immunizers.

Objective: To describe the experiences of pharmacists in the Canadian province of New Brunswick as immunizers, including vaccines administered and perceived barriers and facilitators to providing immunizations.

Methods: An anonymous, self-administered, web-based questionnaire was offered via email by the New Brunswick Pharmacists' Association to all its members. The survey tool was adapted, with permission, from a tool previously used by the American Pharmacists Association and validated using content validity and test-retest reproducibility. Pharmacist reported immunization activities and perceived facilitators and barriers to providing immunization services were assessed.

Results: Responses from 168 (response rate of 26%) were evaluable. Approximately 90% of respondents worked in community practice full time, 65% were female and 44% were practicing for 20 or more years. Greater than 75% reported administering: hepatitis A and B, influenza, and zoster vaccines. The majority of respondents felt fully accepted (agreed or strongly agreed) as immunization providers by patients, local physicians, and the provincial health department (97%, 70%, and 78%, respectively). Most commonly reported barriers were: lack of a universally funded influenza immunization program, insufficient staffing and space, and concerns around reimbursement for services.

Conclusions: Pharmacists in New Brunswick, Canada are actively participating in the provision of a variety of immunizations and felt fully supported by patients and other healthcare providers. Barriers identified may provide insight to other jurisdictions considering expanding the role of pharmacists as immunizers.

Keywords

Pharmacists; Immunization Programs; Vaccination; Public Health; Professional Practice; Attitude of Health Personnel; Health Knowledge, Attitudes, Practice; Surveys and Questionnaires; Canada

INTRODUCTION

Immunization is a cornerstone of public health through the prevention of infectious diseases and their complications.[1,2] Prior to the introduction of vaccines, common infectious diseases were the leading cause of mortality worldwide.[3,4] It is estimated that between 2 and 3 million deaths are prevented each year because of immunization.[1] Despite this, vaccine-preventable diseases remain a global public health concern, with most jurisdictions falling below their immunization coverage goals.[5-7]

Several strategies have been suggested to enhance vaccination coverage, including the use of non-traditional vaccine providers (i.e. providers other than family physicians and public health nurses).[8,9] Pharmacists, as accessible and trusted health care professionals, are in an ideal setting to fulfill multiple roles (such as educator, facilitator or immunizer) in the fight against vaccine-preventable disease.[10,11] Recommendations to receive immunizations by a pharmacist have been shown to have a positive impact on a person's decision to be immunized.[12]

While pharmacists have functioned as immunizers in the United States since 1996, the scope of pharmacy practice in Canada began to expand to include administration of drugs, including immunizations, more recently, starting in 2007 in Alberta.[13-15] Legislation in New Brunswick (NB), Canada enabled pharmacists, with appropriate training and a permit, to begin immunizing in 2009 (initiation in practice in 2010), making it the first province in the Maritime provinces of Canada to permit pharmacists to immunize, joining pharmacists in Alberta and British Columbia (2009).[16,17] Legislation in New Brunswick allowed for the administration of most vaccines (including yellow fever with appropriate training) and injectable medications to those 5 years of age and older; however, remuneration for services were only reimbursed by the provincial government for the provision of influenza vaccines to those meeting specific criteria (e.g. over 65 years of age). The inclusion of pharmacist immunizers in the US has shown benefits, supporting the expanded scope of pharmacy practice to include immunization.[18-20] Studies have demonstrated increased influenza vaccination coverage

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rates in states allowing pharmacists to immunize versus those that did not, although some of the studies had methodological concerns.[21,22] American pharmacists initially focused on provision of seasonal influenza vaccinations, gradually addressing other vaccination needs with time and experience. [23,24]

While American pharmacists have had successes as immunizers, they have also faced challenges. Although most licensed US pharmacists are trained to administer vaccines, they face numerous barriers such as time, space and concerns about liability and reimbursement.[23,25,26] Conversely, several facilitating factors have been identified as important, including support from management, year-round immunization programs to maintain competencies, and increasing the number of immunizers in a practice site.[27]

As immunization administration is more recent for Canadian pharmacists, limited data is available on their perspective on their experiences, and there is no data from any of the Maritime provinces, where pharmacists are thought to fill gaps due to shortages of primary care providers.[28-31] The aim of the study was to determine which vaccines pharmacists in New Brunswick, Canada are providing, and to identify barriers and facilitators associated with immunizing to inform continuing education and practice policy.

METHODS

Study Design and Participants

A web-based self-administered survey, was adapted (with permission) from a survey tool previously used by the American Pharmacists Association incorporating input from Canadian experts in the field and stakeholders using the principles of Dillman.[32,33] Content validity testing was completed by four reviewers, with expertise in immunization, using a rating worksheet with a four-point content validity index. Questions rated as 1 (not relevant) or 2 (major revisions) were removed and those rated 3 (relevant, minor revision required) or 4 (relevant and succinct) were kept. Test-retest reliability was assessed by five pharmacists completing the survey on two separate occasions, with a correlation co-efficient calculated to compare the two sets of responses. The correlation co-efficient was >0.80, which was determined sufficient to consider the responses as consistent.

The web-based questionnaire was sent via email to NB pharmacists via the New Brunswick Pharmacists' Association (NBPA) between April and June 2014. The email contained a detailed information letter and direct link to the web-based survey. Eligible participants had to be licensed pharmacists in NB working either full- or part-time in a clinical pharmacy setting (community pharmacy, ambulatory clinic or hospital). Two reminder letters were sent via email by NBPA at weekly intervals to improve the survey response rate. All surveys were completed via Opinio software.[34] The final survey took approximately 30 minutes to complete, though participants had the option to save their progress and complete the survey later. All contact with pharmacists was directly via NBPA. Survey participants remained anonymous, and no personal identifiers were collected.

This study was approved by the Research Ethics Board of the Capital District Health Authority (File #CDHA-RS/2014-035 approved May 14, 2013). All research was performed in accordance with relevant guidelines and regulations.

Survey

The survey consisted of a total of 41 questions within the following five domains: 1) demographic information, including primary practice setting and years of practice; 2) immunization training status, confidence in providing immunizations, personal immunization status, and attitudes towards vaccine safety and importance; 3) immunization services offered by their practice site, vaccines provided, and perceptions of barriers to provision of immunization services; 4) immunization services provided by the individual pharmacist; and 5) reimbursement and perception of acceptance as an immunization provider.

Likert scales were a 5-point scale that ranged from Strongly Disagree to Strongly Agree for agreement with statement questions and for frequency of activity questions, the options were "Never", "Rarely", "Sometimes", Often", and "Always". A copy of the survey may be obtained by contacting the corresponding author.

Data analysis

Survey data was analyzed using descriptive statistics to identify the general respondent characteristics and frequency of responses. Comparison of continuous variables was done using parametric and non-parametric methods as appropriate based on distribution of the data. Chi-square was used for comparison of categorical variables. All analyses were completed using Excel 2013 version (Microsoft Corporation).

Responses to open-ended questions were read and re-read in order to become familiar with the content. Codes were assigned to segments of the data that were relevant to the research question. An inductive coding process was used that informed development of common themes.

RESULTS

The overall survey response rate was 28% (180/635); however only 168 (26%) were evaluable. Table 1 outlines the demographic information of the respondents. The majority (86%, 132/154) reported having received all required adult immunizations and 93% (144/154) reported receipt of the annual influenza vaccine. Of those that responded "yes"; most stated that they received the influenza vaccine to protect their patients, themselves and society. Reasons for responding "no" included personal choice, lack of accessibility, and that they were healthy.

Approximately 93% of respondents indicated that they had completed an injection training program with over 90% of those who completed a program responding that they felt "confident" or "very confident" in providing immunizations based on the training they acquired. When respondents were asked to provide suggestions for additional content that should be included in the online modules and the live

Table 1. Comparison of survey sample demographics to Canadian Institute for Health Information (CIHI) human resources data for pharmacists in New Brunswick in 2013.[35]

Characteristic	Study result	NB Pharmacist population
Number of Pharmacists	168 evaluable	813 (635 members of NBPA at the time of the survey)
Gender		
Male	34.7%	33.7%
Female	65.3%	66.3%
Age[a]		
<30	17.3%	18.6%
30-39	28.6%	28.5%
40-49	28.6%	27.6%
50-59	19.6%	20%
60+	5.9%	5.4%
Years Practicing[b]		
0-9	35.2%	37%
10-19	20.8%	26.3%
>20	44%	36.6%
Primary Position		
Staff pharmacist	52.8%	65.4%
Owner/Manager	39.6%	28%
Practice Setting (community)	89.9%	75.1%

[a]CIHI data provided in bands
[b]Note, slight differences in ranges of years, CIHI data provided 0 to 10 years and 11 to 20, and <20, this survey was survey was 0 to 9 years and 10 to 19 years, and 20 years or more

day training, the most common responses were for more information on the management of adverse events following immunization, as well as additional information on providing immunizations to special populations (e.g. immunocompromised individuals and travelers), and further reinforcement of general administration practices, such as selecting needle gauge and length for patients of various sizes and ages.

Over 93% of respondents indicated that they currently administer vaccines in their practice with nearly 80% of them providing immunizations "often" or "always". Most patients immunized by pharmacists were adults 18 years of age and older with respondents indicating less than 20% (on average) of vaccines administered were to those less than 18 years of age. Approximately 27% of respondents were immunizing for 1 year or less, 49% for 1 to 3 years and 25% for over 3 years. The number and type of vaccines administered in the last year varied between respondents (Table 2 and Table 3). Of the estimated 15,000 vaccines administered based on self-reporting by respondents since they began immunizing, seven adverse events were reported, 6 were vasovagal and 1 was suspected anaphylaxis. All were managed appropriately based on the written responses.

The majority of respondents (>80%) were comfortable or very comfortable initiating conversations with patients about receiving influenza, herpes zoster, hepatitis A or hepatitis B vaccines but less comfortable discussing other vaccines, including pneumococcal, tetanus and meningococcal. The reasons most often cited for why they were uncomfortable were: lack of knowledge of the vaccine, reimbursement concerns, being unsure if it is a required vaccine, and being unsure about safety in different patient populations.

Most respondents felt fully accepted as immunization providers by patients, with about 97% reporting agreement or strong agreement, as well as most reporting frequent request for vaccine information or advice (Table 4). Seventy percent or more agreed or strongly agreed that they had been fully accepted as an immunization provider by local physicians and health departments. Referrals from other providers were reported by many respondents, with 85% indicating referrals from physicians, 43% reported referrals from nurses, and 32% indicated referrals from public health.

Survey respondents were asked to identify barriers they perceived to providing immunization services from a list of possible barriers, in which they could check all that they felt applied, as well as the option to write-in additional barriers, which are presented in Table 5. Four key barriers identified through quantitative (Figure 4) and qualitative responses (not shown) were: 1) concern about reimbursement, 2) lack of a universal influenza program (reimbursement concerns), 3) insufficient staffing and 4) lack of space for vaccine administrations within the pharmacy.

Comparisons of immunizers versus non-immunizers were not possible due to very few respondents identifying as non-immunizers. Comparisons were made between respondents in practice less than 10 years versus those

Table 2. Cumulative number of vaccines provided per pharmacist in the last year

Number of vaccines	%
<50	11%
50-100	25%
101-150	22%
151-200	9%
>200	33%

Table 3. Number of respondents currently administering various vaccines

Vaccine	Num. Administering / respondents
Hepatitis A	115 / 117
Influenza	117 / 120
Hepatitis B	114 / 117
Herpes zoster	91 / 120
Human papillomavirus	62 / 120
Travel vaccines	43 / 116
Pneumococcal	31 / 117
Tetanus (Td, Tdap)	21 / 113
Meningococcal	16 / 116

Table 4. Frequency of patient/parent requests for vaccine information or advice

Frequency	%
Daily	18%
Weekly	19%
Monthly	23%
Rarely	10%
30% did not respond to this question?	

greater than 10 years. Those practicing less than 10 years were less likely to have concerns about staffing as a barrier (27% versus 45%, p=0.03) and were also more likely to have been immunizing for longer than 24 months (78% versus 49%, p=0.003).

When asked what was needed to expand immunization services in their practice, respondents' answers were classified according to four categories: scope of practice; logistics; promotion; and training. Regarding scope of practice, many open-ended responses related to the issue that pharmacists should be able to administer all vaccines that are recommended in the publicly funded programs, not just influenza (at least for those individuals 5 years of age and older) and that they should be able to provide them through provincial funding like physicians, who administer most vaccines within the publicly funded systems, and public health, who focus their immunization services to areas where there is a shortage of primary care providers. Some also conveyed that travel vaccines, including yellow fever should also be provided in pharmacies. When discussing logistics, many spoke of the need to have adequate staffing, space, refrigerators and other supplies and equipment, and access to health and vaccine records. Adequate reimbursement was also a major issue raised by respondents. This included providing publicly funded vaccines free of charge and providing an administration fee for those vaccines so that the cost to the consumer would be no different in a pharmacy than in a physician's office. Lack of public awareness was considered an issue with the suggestion that more promotion to the public about the availability of vaccines in pharmacies and the capabilities of the pharmacists be a priority. Promotion to physicians of the benefits of pharmacists providing vaccines and the likelihood that this would not compete with physicians' practices was also considered to be valuable. Continued and ongoing training of pharmacists was felt to be important including both vaccine information, but also practical issues including needle size, gauge, and landmarking. A centrally maintained information website by pharmacists for pharmacists was also thought to be useful. Training of pharmacy technicians was also seen by many as an essential step since they are critical to the proper patient flow and they are not currently involved in vaccine training.

DISCUSSION

This study explored immunization-related activities and perceived barriers to providing immunization services of pharmacists in New Brunswick, Canada within the first five years of legislative changes allowing them to immunize. Most respondents were administering immunizations, providing a variety of vaccines, with the most common being influenza, hepatitis A and hepatitis B, mainly to adults

Table 5. Reported barriers to providing immunizations in respondents' practices

Barrier	%
Reimbursement concerns	66
Lack of universal influenza vaccination	44
Insufficient staffing	42
Lack of space for administration	23
Record keeping	11
Lack of support from physicians	11
Lack of space for vaccination storage	10
Time for certification	10
Managing adverse effects	9
Liability concerns	9
Cost of certification	7
Unable to recognize adverse effects	6
Lack of support from management	5
Note: total number of responses greater than N, as respondents could choose all that applied	

18 years of age and older. Most felt accepted as immunizers by patients and other providers, but identified several barriers, with reimbursement concerns, lack of staff and space restrictions as the most frequently cited obstacles to providing or expanding immunization services. Reported barriers were similar between survey responses and open-ended questions. These data are consistent with those reported by others, where lack of reimbursement by third party payers for vaccines administered in the pharmacy setting was identified as an important challenge in the provision of immunization services.[26,36-38] This includes the lack of a publicly funded universal influenza immunization program and lack of access to other publicly funded vaccines for adults, such as pneumococcal polysaccharide vaccine. Likewise, lack of staff or time and space restrictions were found to be common concerns.[26,36-38]

Seasonal influenza vaccine for high risk individuals is the only vaccine for which NB pharmacists are reimbursed within the publicly funded immunization program, so it is not surprising that this was the most frequently administered vaccine.[39] Respondents also reported frequent administration of vaccines outside of the publicly funded program (Hepatitis A and B, either as a single vaccine or in combination), likely administered for travel and would be paid out of pocket or by private insurance. Likewise, herpes zoster, also privately funded, was common. Unlike many US jurisdictions, pneumococcal vaccine was not a commonly administered vaccine, probably due to lack of reimbursement through the publicly funded system.[37]

Like another Canadian study, we found that the majority of respondents have received all required adult immunizations and the annual influenza vaccine.[40] High immunization coverage in pharmacists offers protection to patients and if they are supporters of immunization for themselves, it is more likely that they will be strong advocates for immunizing their patients.[41-43]

The majority of respondents felt that they have been fully accepted as immunizers by patients and other providers, which was further supported by how often they indicated they received referrals from other providers. Similar results were seen in a national survey of the public and healthcare providers on the potential role of pharmacists as

immunizers.[44,45] Despite these positive responses, several concerns were identified around the lack of awareness of the role pharmacists can take in provision of immunizations by various groups, including the public and physicians. Despite some successes, a public relations campaign and targeted efforts with other healthcare providers may be required for full acceptance of pharmacists as immunizers.

Interestingly those practicing less than 10 years, had less concerns about staffing and were immunizing longer than their counterparts in practice greater than 10 years. It is not known whether newer practitioners were more interested in embracing expanded scope of practice or if they felt more pressure to obtain immunization training to obtain and maintain professional employment. This was observed in a recent qualitative study, in which respondents felt compelled to become certified and provide immunizations for employment.[46]

Many concerns have been raised by other providers about the potential issues around pharmacist management of adverse events following immunization.[47,48] The responses to this study offer further support for the capabilities of pharmacists in this area, as very few identified management of adverse events as a potential barrier, although many did note interest in having more training provided around management of adverse events, and for those that had a patient experience a reaction following immunization, managed it appropriately.

The barriers most frequently identified to providing immunizations were concerns around reimbursement (including, lack of a universally funded influenza vaccination program), insufficient staff and lack of space in the pharmacy. Unfortunately, due to current funding models and limitations within healthcare budgets, these barriers are unlikely to be resolved quickly. Of note, these barriers were also identified in other jurisdictions, adding further support to the barriers identified in this study having applicability across jurisdictions.[28,49]

Strengths of this study included the development and testing of the questionnaire, which included permitted use of questions from a previously used questionnaire that were adapted for the jurisdiction, discussion with stakeholders on information that would be valuable, and content validity testing, and test-retest reliability prior to deployment. In addition, this study provides the perspective of pharmacists who were newly immunizing in a country with universal health coverage that may provide insight to other similar jurisdictions looking to add this to pharmacist scope of practice.

Although the response rate was lower than anticipated, it was over 20% and our sample appears representative of the pharmacist population in NB with respect to gender and age distribution at the time of the survey.[35] The distribution of number of years practicing is similar between our respondents and CIHI data, despite differences in the ranges available (e.g. 0 to 9 years versus 0 to 10 years).[35] Differences were seen in the primary position with our study having more respondents who identified as owners or managers compared to the CIHI data for the province. We also had more respondents indicate a community practice setting than the CIHI results. This may be due to the fax reminder sent to pharmacies about the survey from the New Brunswick Pharmacists' Association. The reminders were focused on community pharmacies and it is possible that more managers and owners were responsible for reviewing faxes received and subsequently more likely to respond. In addition, staff pharmacists may not have had time to fill out the questionnaire during their shift and may not have been willing to do it during off hours. We also anticipated more responses from community pharmacists, as immunizing by pharmacists is primarily completed in the community setting in NB. It is possible that managers and owners may perform different immunizing behaviours and have different concerns (such as reimbursement) than staff pharmacists; however, we are unable to determine what these differences may be. Our response rate however was higher than others recently completed (~18-19%) with pharmacists in Canada around scope of practice or immunization status.[29,40] An additional limitation was the number of surveys without sufficient responses to be evaluable. As this was the first study of its kind in Canada, it was long, to ensure it captured the breadth and depth of pertinent areas of immunization practice. Despite the length and number of incomplete questionnaires, a sufficient number were evaluable to allow a response rate greater than 25%.

CONCLUSIONS

Pharmacists in New Brunswick, Canada are actively participating in the provision of a variety of immunizations, beyond influenza vaccines, including hepatitis A and B, and herpes zoster. They felt strongly supported by patients and other healthcare providers. The main barriers identified included the lack of a universally funded influenza immunization program, insufficient staffing and space, and concerns around reimbursement for services. The results of this study may provide insight to other jurisdictions considering expanding the role of pharmacists as immunizers. Future work will include development of strategies to overcome identified barriers, in consultation with stakeholders, and evaluation of implementation of strategies. Additionally a replication study may be completed to assess changes in practice over time.

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CONFLICT OF INTEREST

All authors declare that they have no competing interests in relation to this project.

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Original Research

Assessment of diarrhea treatment and counseling in community pharmacies in Baghdad, Iraq: A simulated patient study

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Abstract

Background: Because community pharmacists are the most accessible healthcare professionals, they are often involved in managing minor ailments within the community setting.

Objective: This study evaluated the community pharmacists' history taking practice, medicine dispensing and advice in response to acute diarrhea.

Methods: Authors conducted a simulated-patient study in 75 community pharmacies in Baghdad, Iraq from February to May 2015. The female simulated-patient complained of acute diarrhea that had lasted for one day and requested for medicine to treat her condition. After exiting each pharmacy, she then assessed the practices of the community pharmacists through the use of a specially designed checklist adopted with modifications from relevant guidelines. For history taking, a maximum total of eight was the highest obtainable score. Data collected was quantitatively analyzed and Mann-Whitney, Chi-square or Fishers exact tests were used at an alpha level of 0.05.

Results: All of the 75 pharmacies visited were managed by professionally qualified pharmacists. The most common questions asked during history taking were number of diarrheal episodes (n=62; 82.7%); duration of symptoms (n=59; 78.7%) and presence of other diseases and if any drug had been taken (n=58; 77.3%). Female pharmacists had a higher total mean score (6.45, SD=1.33) for history taking when compared to their male counterparts (4.34, SD=2.13); p <0.001. Medicine combination of diphenoxylate HCl 2.5mg + atropine sulphate 0.025mg (n=34; 27.9%) was most frequently dispensed while the least was oral rehydration salt (n=1; 0.8%). Around 20% (n=15) of pharmacists dispensed antimicrobial agents. Over half (n=46; 61.3%) of pharmacists indicated the frequency of use on the medicine packet. Conversely, less than half (n=33; 44.0%) gave any advice on food and fluid intake.

Conclusions: Majority of the community pharmacists asked at least four questions while taking patient history and was very likely to recommend antidiarrheal medicines as first line treatment options. The authors recommend the development of a minimum standard of practice as well as enhanced training for Iraqi community pharmacists.

Keywords

Diarrhea; Counseling; Nonprescription Drugs; Community Pharmacy Services; Pharmacies; Professional Practice; Patient Simulation; Iraq

INTRODUCTION

Community pharmacists are the most accessible health professionals.[1] They provide primary healthcare services to communities, and are important sources of advice, medication and treatment for minor ailments both in high and low-to middle income countries.[1,2] They can be a valuable resource for health advice.[2] Minor ailments are 'common or self-limiting or uncomplicated conditions which can be diagnosed and managed without medical intervention'.[3,4] In the UK, 18% of general practice workload is estimated to relates minor ailments, with a financial burden of GBP 2 billion annually.[5] Currently, minor ailment services exist in many regions and countries such as UK[6], Canada[7], Australia[8], and New Zealand.[9] Quality of pharmacy services represents optimum patient care to meet patient's needs. There must be a minimum standard of practice in community pharmacy setting. The International Pharmaceutical Federation (FIP) has recommended set of areas and domains e.g. supply of non-prescription medicines for self-care, and interaction with patients as minimum requirements for practice.[10] It is important to ensure that the right patient receives the appropriate medicine in the correct dose and form.[11]

In a country like Iraq, the instability across the country (followed the war of 2003) plus funding shortfalls have affected the quality of healthcare service delivery.[12] Further, physicians in Baghdad were being killed at a rate of 47.6 per 1,000 professionals; with nearly 5,400 physicians were leaving the country annually[12] and the healthcare system is undergoing a major crisis.[13] The medical brain drain has impacted health care delivery. In Iraq the health infrastructure is not fully restored even after much rebuilding in the recent past.[14] There are plans for a realignment of the health care system with the primary health case as the foundation. As of April 2011, 20,066 pharmacists were registered in the Syndicate of Iraqi Pharmacists (SIP), a professional organization whose purview encompasses 18 provinces, or governorates.[15] Thus, the role of other healthcare professionals e.g. community pharmacists for managing health like minor ailments in poor resource settings become very important. There is a need to avoid burdening the focal health system.

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Most of community pharmacies in Iraq are located within the big cities. The total number of community pharmacies in Baghdad (8465), Babylon (1227), Ninawa (1143), and Najaf (1044) exceeds the number of pharmacies in all other Iraqi cities combined[15] and as on 2013 Baghdad had a total of 6220 pharmacists.[16]

There is evidence to suggest that members of the Iraqi public frequently use community pharmacies to access healthcare services.[17,18] A study by Ibrahim *et al*.[17] found that 70% of respondents visited community pharmacies once or more per month, and over half of them rated community pharmacists as their first contact in case of any drug-related problem. In another study, Seston *et al*. who explored the attitude and beliefs of community pharmacists in managing acute diarrhea in adults witnessed ambiguity in the treatment of acute diarrhea in community pharmacy, particularly in relation to attitudes to oral rehydration and anti-motility drugs.[19] Many of the pharmacists dispensed antimotility more than oral rehydration salt (ORS) even though the recommendation is to treat with ORS. There is insufficient data on how community pharmacists in Iraq manage common medical conditions. Thus, this study aimed at evaluating the practices of Iraqi community pharmacists when managing symptoms of acute diarrhea in adults, with specific focus on their patient's history taking, medication dispensing, and advice giving practices.

METHODS

Study design

A cross-sectional survey using the simulated-patient (SP) method (or mystery patient/shopper) was used in this study. This method is simple and provides real behavior and practice from the client's perspective.[1,18,20] This research approach is also simple but robust method for assessing the community pharmacists' dispensing practices. A standardized scenario of acute diarrhea is defined as an episode of diarrhea lasting 14 days or less[21,22] and scoring system was used in each pharmacy.

Ethical approval was obtained from the Ministry of Health and Syndicate of Iraqi Pharmacists (Approval No: 881). Due to the nature of the study, the study participants were not informed about the study priori. The information obtained was recorded, kept and reported anonymously. The findings were presented as aggregate.

The study targeted community pharmacists. It was conducted in 75 community pharmacies located in Baghdad, the capital of Iraq from February to May 2015. The total number of community pharmacies in Baghdad is 8465 and it has 6220 pharmacists. Due to the safety and security factors, and accessibility to different locations, only 75 pharmacies were able to be selected conveniently within the specified study period.

Data collection

The data collection checklist was developed by the principal researcher from the American College of Gastroenterology Clinical Guidelines and the World Health Organization (WHO) manual for diarrhea treatment[22,23], and consisted of two parts. Part one contained eight items required when taking a complete patient history from a patient with diarrhea. Questions asked in this section include duration of the diarrhea and number of episodes daily, whether vomiting or blood was present and pre-illness practices (please explain what "pre-illness practices" and "presence of diseases and drug taken" mean). Answers to these questions could be either "yes" or "no". The second part of the checklist contained five open ended questions, and collected information about dispensed medicines and their costs, written instructions provided, and any other advice given by the pharmacist.

A middle-age female pharmacist posed as the simulated patient, and visited the selected community pharmacies during the day time. She complained of suddenly occurring diarrhea that had lasted for one day, accompanied by abdominal cramps. She then requested for any antidiarrheal medicine. Immediately after each visit (outside the visited pharmacy), she used the evaluation checklist to assess the pharmacist's practices. She filled the checklist form alone. All the visits were performed by the same person.

Data analysis

Quantitative analysis was done for the collected data. The qualitative information was analyzed using content analysis approach. Mean and standard deviation were used to present continuous variables, whereas frequencies and percentages were used for discrete/categorical variables. Cost of dispensed medicines was reported in US dollars, using an exchange rate of 1 USD equal to 1.164 Iraqi Dinar (IQD). For the history taking items, a score of "zero" was assigned to the option "No", and "1" to the "Yes" option for each of the eight questions. Thus, higher scores denoted better history taking practices, and the maximum total score any pharmacist could attain for history taking was eight. Comparisons of continuous variables (history taking scores) between groups were done using the independent Mann-Whitney test. For categorical variables like gender and type of pharmacy, differences between groups were compared using Chi-square or Fishers exact tests as appropriate. SPSS (SPSS Inc., Chicago, Illinois) software version 17 was used for all data analyses. Alpha values of less than 0.05 were considered statistically significant.

RESULTS

All of the 75 pharmacies visited were managed by pharmacists, and more than half (n=42, 56.0%) of the pharmacists in-charge of the outlets were male. Majority of visited pharmacies (n=60, 80.0%) operated on a part-time basis (working hours from 4 to 9 pm); while the rest operated as full-time pharmacies (working hours from 10 am to 9 pm).

All pharmacists asked the SP at least one question about their diarrhea history before dispensing medicine(s). The most frequent questions asked during history taking were number of episodes of watery stool (n=62; 82.7%) and duration of diarrhea (n=59; 78.7%). While, presence of fever or other problems (n=35; 46.7%) and whether blood was present in stool (n=32; 42.7%) were the least asked (Table 1). When the total score obtained from history taking was compared with regards to the attending

Table 1. Diarrhea history taking practices of the community pharmacists

Items of history taken		Male n (%)	Female n (%)	p-value (Chi-square)
1. Duration of diarrhea				0.004
	Yes	28 (37.3)	31 (41.3)	
	No	14 (18.7)	2 (2.7) [a]	
2. Number of watery stool/day				0.021
	Yes	31 (41.3)	31 (41.3)	
	No	11 (14.3)	2 (2.7) a	
3. Presence of blood in the stool				0.000
	Yes	8 (10.7)	24 (32.0)	
	No	34 (45.3)	9 (12.0)	
4. Presence and number of vomiting				0.404
	Yes	27 (36.0)	23 (30.7)	
	No	15 (20.0)	10 (13.3)	
5. Presence of fever, cough, or other problems				
	Yes	8 (10.7)	27 (36.0)	0.000
	No	34 (45.3)	6 (8.0)	
6. Pre-illness practice				0.253
	Yes	25 (33.3)	23 (30.7)	
	No	17 (22.7)	10 (13.3)	
7. Amount of fluid taken				0.535
	Yes	30 (40.0)	23 (30.7)	
	No	12 (16.0)	10 (13.3)	
8. Presence of diseases and drug taken				0.002
	Yes	27 (36.0)	31 (41.3)	
	No	15 (20.0)	2 (2.7) [a]	

[a] Fisher's Exact Test.

pharmacist's gender; female pharmacists got a higher mean score (6.45; SD=1.33) than male pharmacists (4.34; SD=2.13), and this difference was statistically significant (Mann-Whitney test, p<0.001). This gender variability in history taking practices can also be seen in table one, where Chi-square/Fishers' Exact tests showed that significant differences (p<0.05) existed between male and female pharmacists with regards to most of the items used to assess history taking practices. On the other hand, there were no significant differences in the history taking practices and total scores between the two types of pharmacies (part-time and fulltime) visited during the study.

Because the SP requested medication, a wide variety of medicines were dispensed for her. All 75 pharmacies dispensed at least one medicine (Table 2). There were a total of 122 items/medicines dispensed by the 75 community pharmacists (around 2 medicines per pharmacy, range: 1-3 medicines). Around half (n=34; 45%) of the pharmacists dispensed 2 medicines. Commonly dispensed medicines included the tablet/capsule dosage forms. The pharmacists dispensed antidiarrheal, antimotility, antispasmodic, antimicrobial, antipyretic, antiemetic, and mineral supplement. Costs of these medications ranged from $0.20 to $1.38. Most pharmacists (n=34; 45%) dispensed antidiarrheal, followed by antimotility (n=25; 33%) and the least was mineral supplement (n=1; 1.3%). The dispensed medicines were diphenoxylate HCl 2.5mg + atropine sulphate 0.025mg (n=34; 27.9%), loperamide 2mg (n=25; 20.5%), hyoscine-N-butylbromide 10mg (n=18; 14.8%), metronidazole 200mg (n=10; 8.2%), furazolidone 50mg (n=5; 4.1%), acetaminophen (18.0%; n=22), domperidone 10mg (n=7; 5.7%), and oral rehydration salt (n=1; 0.8%). Around 20% (n=15) of pharmacists dispensed antimicrobial agents.

With regards to the actual dispensing practices of the pharmacists, more than two thirds (n=46; 61.3%) of them provided written information on the packets of the medicines they dispensed about frequency of usage and dose to be taken. Less than half (n=33; 44.0%) provided information on food and fluid intake. In addition, only thirteen pharmacists (17.3%) asked the SP to go for a laboratory test, and only two (2.7%) advised the SP to consult a physician.

DISCUSSION

According to Barr and Smith[24], diarrheal illnesses account for 2.5 million deaths per year worldwide. In a countries at war and in crisis, inadequate access to clean drinking water, poor hygiene and sanitation are among the major drivers of the increased prevalence of diarrhea in these areas.[25,26] Because pharmacists can be seen and consulted without appointments, they are a good source of primary healthcare services especially in poor resource setting countries.[1] Thus, community pharmacists can play a useful role in the prevention and treatment of diarrhea and its often encountered complication-dehydration.[27] In this study, the SP method was used to study client-provider interaction and assess the quality of care delivered by the pharmacists.

Normally acute diarrhea is caused by virus (i.e. viral gastroenteritis) and is self-limited. In most cases, laboratory screenings are not necessary.[28] Riaz *et al*. recommended to carefully select patients for initially laboratory work up for stool culture based on their clinical presentation.[29]

To take a complete patient history from patients presenting with acute diarrhea, a wide range of questions need to be asked.[22,23] These would usually include onset of symptoms and duration, presence of other illnesses or symptoms, severity and frequency of diarrhea, in addition to the type of stool (e.g. watery, bloody, purulent or mucus-filled). Patients should also be investigated for fever, vomiting, dehydration, urine output dizziness and thirst. However, in

Table 2. Medicines dispensed to the simulated patient

Medicines (Generic name)	Pharmacological use	Pharmacies n (%)	Medicines dispensed n (%)
Diphenoxylate HCL 2.5 + Atropine Sulphate 0.025mg	Antidiarrheal	20 (26.8)	20 (16.5)
Loperamide 2mg + Paracetamol	Antimotility + Antipyretic	9 (12.0)	18 (14.9)
Loperamide 2mg	Antimotility	7 (9.3)	7 (5.8)
(Diphenoxylate HCL 2.5 + Atropine Sulphate 0.025mg) + Hyoscine-N-ButylBromide 10mg	Antidiarrheal + Antispasmodic	6 (8.0)	12 (9.9)
(Diphenoxylate HCL 2.5 + Atropine Sulphate 0.025mg) + Paracetamol	Antidiarrheal + Antipyretic	5 (6.7)	10 (8.2)
Metronidazole 200mg	Antimicrobial	4 (5.3)	4 (3.3)
Loperamide 2mg + Hyoscine-N-ButylBromide 10mg	Antimotility + Antispasmodic	4 (5.3)	8 (6.6)
Furazolidone 50mg	Antimicrobial	3 (4.0)	3 (2.4)
Loperamide 2mg + Domperidone 10mg	Antimotility + Antidopaminergic/Antiemetic	2 (2.7)	4 (3.3)
Metronidazole 200mg + Domperidone 10mg	Antimicrobial + Antidopaminergic/Antiemetic	2 (2.7)	4 (3.3)
Metronidazole 200mg + Hyoscine-N-ButylBromide 10mg	Antimicrobial + Antispasmodic	2 (2.7)	4 (3.3)
Furazolidone 50mg + Paracetamol	Antimicrobial + Antipyretic	2 (2.7)	4 (3.3)
Loperamide 2mg + Hyoscine-N-ButylBromide 10mg + Paracetamol	Antimotility + Antispasmodic +Antipyretic	2 (2.7)	6 (4.6)
Hyoscine-N-ButylBromide 10mg	Antispasmodic	1 (1.3)	1 (0.9)
Oral rehydration salt	Mineral supplement	1 (1.3)	1 (0.9)
(Diphenoxylate HCL 2.5 + Atropine Sulphate 0.025mg) + Domperidone 10mg	Antidiarrheal + Antidopaminergic/Antiemetic	1 (1.3)	2 (1.6)
Metronidazole 200mg + Paracetamol	Antimicrobial + Antipyretic	1 (1.3)	2 (1.6)
Metronidazole 200mg + Paracetamol+ Hyoscine-N-ButylBromide 10mg	Antimicrobial + Antipyretic + Antispasmodic	1 (1.3)	3 (2.4)
Loperamide 2mg + Paracetamol + Domperidone 10mg	Antimotility + Antipyretic + Antidopaminergic/Antiemetic	1 (1.3)	3 (2.4)
(Diphenoxylate HCL 2.5 + Atropine Sulphate 0.025mg) + Domperidone 10mg + Hyoscine-N-ButylBromide 10mg	Antidiarrheal + Antidopaminergic/Antiemetic + Antispasmodic	1 (1.3)	3 (2.4)
(Diphenoxylate HCL 2.5 + Atropine Sulphate 0.025mg) + Hyoscine-N-ButylBromide 10mg + Paracetamol	Antidiarrheal + Antispasmodic + Antipyretic	1 (1.3)	3 (2.4)
	Total	75 (100)	122 (100)

most cases of non-severe illnesses, it is not necessary to determine the exact cause of diarrhea.[30] Most of the questions asked during history taking by the pharmacists in this study covered at least half of the items on the study checklist, suggesting that the practice among the community pharmacists in this study were somewhat satisfactory. Most of the pharmacists asked patients about the eight items in history taking. Female pharmacists in this study also had better total history taking scores than their male counterparts. While there is some evidence that feminine characteristics such as communication and empathy are beneficial in patient care[31], other studies have also reported no differences between the genders in thinking and clinical reasoning when supplying medication.[32] As recommended in the best practice, most frequent questions asked during the history taking were number of watery stool; duration of diarrhea, presence of diseases and drug taken, amount of fluid taken, presence and number of vomiting, and pre-illness practice.

In this study, more than two thirds of the pharmacists provided written information about frequency of usage and dose to be taken, less than half provided information on food and fluid intake, and less than one-fifth asked the SP to go for a laboratory test, and only two advised the SP to consult a physician. Patients were recommended to avoid dairy products. It is noted that acute diarrhea do not seek medical attention, as most patients are able to manage their illness[33] The overall quality of counselling is below expectation and similar to some studies. In a recent study in Germany and Qatar, where the authors reported poor quality counselling for acute diarrhea.[34,35] The German study showed that information about dosage was the most commonly provided, while the least common information given was about side effects. Good advice is helpful for the patients but there is a need for improvement among community pharmacists in Germany.[34] The study in Qatar also highlighted the fact that the counselling practices were below expectation. A study in Turkey, noted that all pharmacy care providers, pharmacists and pharmacy technicians provided consultation to the SP in the study but made little enquiry about the medical history and background characteristics of the patients.[36]

For mild to moderate diarrheal cases, treatment options for patients may include antisecretory or antimotility agents like loperamide.[21] In this study, loperamide alone or in combination was the most dispensed medicine. They were also provided with loperamide or loperamide-simethicone combination. The antisecretory drug bismuth subsalicylate is a safe alternative in patients with fever and inflammatory diarrhea. But, this was not the condition experienced by the SP in this study. While, *et al*. discovered probiotics and other medicines alone or in combination to be commonly recommended by pharmacists and pharmacy technicians.[36] According to Leemans, there is no evidence to support the prescribing of probiotics for adults with acute diarrhea.[37] In another study in Trinidad, they used hypothetical case

presentation to the community pharmacists.[38] They found that the pharmacists prefer antimotility agents as a first choice therapy alone or with ORS for adults, followed by cotrimoxazole. Interestingly however, antibiotics (alone or in combination) were not widely recommended treatment options in this study, as they were dispensed in only around 20% of cases. This is contrast to the study by Ibrahim *et al*. that have shown that antibiotics are often widely used (44%) in the management of diarrhea.[35] Although it should be noted that antibiotic therapy is usually not required for most patients with diarrhea, because the illness is usually self-limiting.[33] For people in resource-poor countries who have diarrhea, oral rehydration salts are widely known to be a useful first line and cost effective measure to treat and/ prevent dehydration.[24,29] Only one pharmacist in our study recommended and dispensed a pack of oral rehydration salt to the SP. This is not surprising as other study has also reported similarly low rates of ORS use in the management of adult diarrhea.[35]

This study has few limitations that include small sample size and the fact that only community pharmacies in one Iraqi city were visited, thus limiting the generalizability of the results. It may be useful for future studies to have larger sample sizes and randomly select community pharmacies across the entire country. Future research may also try to assess and explain whether female pharmacists provide better quality care than male pharmacists, by using more robust methods. A likely reason why the female pharmacists in this study seemed to do better at history taking from the SP, may be due to bias by accidently introduced by using a female SP for this scenario. Especially in this country, where Islam is predominant, there are cultural or religious norms that govern interactions between men and women. These norms would very likely have come in to play, especially in this diarrhea scenario, as diarrhea is associated with some degree of embarrassment. Therefore, while the female pharmacists would easily relate with the SP (as she was a female like them), male pharmacists may not have been so comfortable with her, and would have found it difficult to appropriately question her.

The study findings suggest the need for improving community pharmacy practice standards attainable through continuing pharmacy education programs. Findings of this research also suggest the need for more in-depth researches in order to quantify the exact dispensing practice among community pharmacies.

CONCLUSIONS

Findings from this study suggest that majority of the community pharmacists asked at least four questions while taking patient history and were very likely to recommend antidiarrheal medicines like loperamide and diphenoxylate as first line treatment options. Even though less than half of them provided the SP any advice on food and water intake, and antibiotic dispensing was fairly low. It can thus be inferred that their patient history taking and health advice providing skills can still be improved upon. Consequently, we recommend the development of a minimum standard of practice as well as enhanced training (e.g. mandatory continuing education programs) on the proper management of minor ailments like diarrhea for Iraqi community pharmacists.

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CONFLICT OF INTEREST

None to declare.

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Original Research

Development and validation of a scale to measure the quality of patient medication counseling using Rasch model

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Abstract

Objective: The purpose of this study is to develop and validate the psychometric properties of a scale for measuring the quality of patient medication counseling by using the Rasch model.

Methods: In this study, the scale was developed based on the literature review. It consisted of 31 items across five subscales: introduction, problem identification, content, behavior, and conclusion. A convenient sample of community pharmacists was recruited from four major cities in Vietnam: Hanoi, Da Nang, Ho Chi Minh, and Can Tho. Data collection was conducted from June 10 to October 30, 2017. A Rasch analysis for polytomous data was performed to assess the suitability of the item and the reliability of the scale.

Results: The research results showed that all items had a positive point-measure correlation coefficient between 0.47 and 0.77. All items had infit and outfit values in the optimal range between 0.5 and 1.5 except for D_5, but its value was within acceptable range. Differential item function analysis indicated that all items had no DIF, except for items B_4 and E_4 containing moderate magnitude of DIF. Response category statistics found that there was a gradual increase in difficulty level from category 1 to 5 and no presence of reversal. Infit and outfit statistics of these categories were also considered good, with their values close to 1. The test result of the item characteristic curve and the person-item map showed that there were some overlapping items. Their appearance, however, might play an important role in measuring different aspects of construct. The overall scale reliability index (0.97) was high and the overall scale separation index (6.11) was good.

Conclusions: The developed scale satisfied the requirements of the Rasch model. The scale is a useful tool that could be used to measure the quality of patient medication counseling among community pharmacists.

Keywords

Counseling; Community Pharmacy Services; Validation Studies as Topic; Psychometrics; Reproducibility of Results; Surveys and Questionnaires; Vietnam

INTRODUCTION

Community pharmacists are the last professionals to meet patients before medication use is initiated.[1] They play an important role by counseling patients[2] about proper medication use and pharmaceutical care optimization[3], with the ultimate goal of improving patients' therapeutic outcomes.[4] Like community pharmacies in many other developing countries, pharmacies in Vietnam are usually the community's first destination for advice on health-related issues. In recent years, the number of drugstores in Vietnam has increased rapidly. From 40,000 retail drug stores in 2011[5], this number increased by 1.4 times and reached 54,250 in 2015.[6] As a result, a network of community pharmacies is distributed throughout the country, including in remote areas. However, the majority of these drug stores is under private ownership and has not been strictly regulated by the national health system.[7] Although an international quality standard for good pharmacy practice (GPP) has been promulgated by the Ministry of Health[8], the patient-centered medication counseling practices at community pharmacies in Vietnam have not been highly efficient.

An instrument for evaluating medication counseling appears to be necessary for pharmacy managers, policy makers, and educators to measure the effectiveness of community pharmacists' patient care practices. A number of instruments could be used to assess the quality of medication counseling.[9-11] Abdel-Tawab *et al*. developed a framework of medicine-related consultation, containing 46 consultation behavior-related items of community pharmacists.[9] Puumalainen *et al*. built an instrument with 35 items for assessing pharmacists' medication counseling.[11] However, these scales were developed for research purposes in Western countries. The evaluation of the effectiveness of medication counseling required in the Vietnamese context may be very different.

The study of the scale's psychometric properties by the validity and reliability test is very significant to protect the propriety of the questionnaire from deficiency.[12] In recent years, research in a variety of fields, including health research, that uses the Rasch model to evaluate psychometric properties of the scale has had rapidly increasing popularity.[13] Most previous scales related to this study topic are still validated through item analysis using classical test theory. A Rasch model had not been applied to assess the scale of patient medication counseling until recently.

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To date, there is no validated instrument that measures the quality of patient medication counseling among community pharmacists in Vietnam. The aim of this study is to develop and validate such an instrument by exploring the validity and reliability of the scale items based on the application of a Rasch analysis model.

METHODS

Study design and sample

The convenient sampling method was used for the study. Four investigators recruited participants from each city — Hanoi, Da Nang, Ho Chi Minh, and Can Tho. Community pharmacists who were taking a pharmacy continuing training course at the medical and pharmacy schools of these cities were invited to participate in the study. They were then required to complete self-administered printed questionnaires. Finally, a total of 560 questionnaires were delivered by hand to community pharmacists in Hanoi (130), Da Nang (120), Ho Chi Minh City (160), and Can Tho (150). Any questionnaires with missing answers would be excluded from the data analysis. The cross-sectional study was conducted from June 10 to October 30, 2017.

This study was part of a research project that explored the viewpoints of community pharmacists in Vietnam on pharmaceutical care practice. The principles of conducting research were applied, including protection of privacy, autonomy for study participants, and causation of least harm to them. Moreover, any specific personal information of participants was not collected in the current study, so it did not require approval of research ethics.

Instrument

The study scale was developed based on three previously published medication consultation models: the Calgary-Cambridge guide developed by Kurtz *et al*.[14], the United States Pharmacopeia Medication Counselling Behavior Guidelines redeveloped and then validated by Puumalainen *et al*.[11], and the Medication-Related Consultation Framework developed by Abdel-Tawab *et al*.[9] From these models, subscales and their corresponding items were collected to suit the context of current pharmaceutical care in Vietnam. Finally, five subscales consisting of 31 items relevant to activities and behaviors of medication consultation were selected on the scale (Table 1), which was structured as follows: subscale A—Introduction (n=6 items), subscale B—Problem identification (n=6 items), subscale C—Content (n=7 items), subscale D—Behavior (n=6 items), and subscale E—Conclusion (n=6 items). All items were rated by pharmacists on a five-point Likert scale ranging from 1 (not done) to 5 (excellent).

The study scale was originally developed in English. The process of translation was carried out according to WHO guidelines.[15] A native Vietnamese-speaking expert performed a Vietnamese translation (shown in online appendix), which was evaluated by a university lecturer of Pharmacy to adapt the terminology used in pharmacy practice. To avoid cultural bias, the questionnaire was then translated back into English by a native English-speaking expert (see online appendix). The back-translation was validated by an English fluency lecturer. The original and back-translated versions were compared by two evaluators based on semantic, cultural, and conceptual considerations for translation segments.[16] The results indicated that both evaluators confirmed the high similarity between the two versions. Additionally, a pilot study with 30 pharmacy students was conducted to test the difference in their average scores between the original and back-translated versions by using the Wilcoxon test. The result showed that there was no significant difference in average scores between the two versions (Z= -0.370, p=0.711). Therefore, the Vietnamese translation was considered appropriate for the present study. Finally, the Vietnamese translation was tested on 30 pharmacy students in Can Tho University of Medicine and Pharmacy to detect ambiguities. As a result, all items of the translation were clear and easy to understand, and there was no change to the translation. The study used the Vietnamese version to collect data.

Rasch analysis

The item response theory (IRT) was first introduced in the 1950s by Frederic Lord.[17] IRT is a latent trait theory including mathematical models applied to reveal psychometric properties of construct. The Rasch model is most commonly used in IRT models and its theoretical basis is a description of the relationship between the level of a person's ability and of item difficulty.[18] In this study, the person' ability is understood as pharmacist's capability in medication counseling. The higher the ability score of pharmacist, the higher the effectiveness of medication counseling. The analysis of collected data was conducted using jMetrik software version 4.0.6 based on the Rasch rating scale model. The user manual for this software is provided in Meyer's official guide, "Applied Measurement with jMetrik".[19] Additionally, a simple score was calculated based on the average of the individual item scores, with higher scores representing more effective medication counseling by the pharmacist, and its values were ranged from 1 to 5.

Item validity

To assess the items' validity in fitting the Rasch model, a series of tests, consisting of item polarity, item fit statistics, item characteristic curve, differential item functioning, response category statistics, and the person-item map, were examined in this study.

Item polarity was evaluated by using the point–measure correlation coefficient (PTMEA CORR). PTMEA CORR value should display a high and positive item value (0.3–0.8) that indicates the items are working in the same direction to measure a single basic construct.[20] Conversely, a negative or zero value shows that the relationship between item responses is in conflict with the construct.[21] An item which is outside the interval from 0.3 to 0.8, would be recommended for removal.

Two basic statistics that are commonly recommended for item fit assessment are the item infit and outfit mean-square fit statistics. They describe the degree to which an item functions as intended.[22] In other words, they present how accurately or predictably an item fits the model.[23] Infit statistics is inlier-sensitive fit statistics, which reflect responses for items that are close to the person's ability level.[24] Outfit statistics is outlier-sensitive fit statistics,

Table 1. The originally questionnaire "Measure the quality of patient medication counseling".

Item	Item content	1	2	3	4	5
	A—Introduction					
1	Greets patient.					
2	Introduces self to patient.					
3	Confirm the patient's identity.					
4	Discuss the purpose and structure of the consultation.					
5	Demonstrates respect and interest.					
6	Pays attention to comfort and privacy.					
	B—Problem identification					
1	Identifies reason(s) for visit.					
2	Identifies the issues that the patient wishes to address.					
3	Checks & confirms patient's problem(s) and further problems.					
4	Assesses any actual and/or potential concerns.					
5	Obtains pertinent initial medication history related information.					
6	Explores social history.					
	C—Content					
1	Discusses the name and indication of the medication.					
2	Gives advice on how & when to take medication, length of treatment.					
3	Explains how long it will take for the drug to show an effect.					
4	Discusses storage recommendations, ancillary instructions.					
5	Explains likely risks of side effects of options and manage the side effects of the drug if they do occur.					
6	Discusses significant drug interactions.					
7	Refers appropriately to other healthcare professional(s).					
	D—Behavior					
1	Listens actively & allows patient to complete statements without interruption.					
2	Avoids or explains jargon.					
3	Demonstrates empathy with and supports patient.					
4	Shares thinking with the patient to encourage patient's involvement.					
5	Manages time effectively.					
6	Displays effective nonverbal behaviors.					
	E—Conclusion					
1	Helps patient to plan follow-up and next steps.					
2	Explains what to do if patient has difficulties to follow plan.					
3	Summarizes session briefly and clarifies plan of care.					
4	Verifies patient's understanding, via feedback.					
5	Checks that patient agrees & is comfortable with the plan.					
6	Provides an opportunity for final concerns or questions.					
1-Not Done, 2-Poor, 3-Unsatisfactory, 4-Satisfactory, 5-Excellent						

which reflect unexpected responses for items far from the person's ability level.[24] The mean-square (MNSQ) value ranged from zero to positive infinity. An item is considered consistent with the Rasch measurement when MNSQ reaches the expected value of 1 and must always be positive.[19] Values far greater than 1 indicate that the data had too much variation (noise), and values very close to zero indicate it is too consistent.[19] The MNSQ optimal value of each item must be located within 0.5–1.5.[19] According to Wright and Linacre, values of less than 0.5 or 1.5–2.0 do not bring efficiency to building measurements, but do not decline.[25] Therefore, any individual item with MNSQ more than 2.0 will be suggested for removal from the present study.

Table 2. Demographic characteristics of community pharmacists in this study (n = 422)

Characteristics	Frequency (%)
Gender	
Male	134 (31.8)
Female	288 (68.2)
Age group (years)	
25 or less	85 (20.1)
26–35	193 (45.7)
36–45	100 (23.7)
46–55	24 (5.7)
56–60	11 (2.6)
>60	9 (2.1)
Pharmacy education	
Bachelor of pharmacy [a]	136 (32.2)
Lower level of Bachelor's degree [b]	286 (67.8)
Pharmacy experience (year)	
1 or less	57 (13.5)
2–5	183 (43.4)
6–10	101 (23.9)
11–20	53 (12.6)
21–30	21 (5.0)
>30	7 (1.7)

[a] Bachelor of pharmacy (5-year program); [b] Lower level of Bachelor's degree consisting of college diploma in pharmacy (3-year program) and secondary diploma in pharmacy (2-year program).

Item characteristic curve (ICC) describes the relationship between the person's ability and probability of a correct response.[26] The inflection point is characteristic of each curve, with its perpendicular projection on the vertical axis showing probability of a correct answer and on the horizontal axis reflecting the person's ability. Moreover, ICC also reflects the item difficulty, and its difficulty gradually increases from left to right of the plot.[19] An easier item is represented by the curve closer to the left side of the plot because probability of a correct response is higher for a lower-ability person.[26]

Table 3. Average score, difficulty, fit statistics and item correlation

Subscale	Item	Average score	Difficulty	Std. Error	Infit MNSQ	Outfit MNSQ	PTMEA CORR.
A	1	3.86	-0.60	0.07	1.23	1.19	0.68
	2	2.77	1.40	0.06	1.38	1.36	0.47
	3	3.39	0.33	0.07	0.94	0.93	0.55
	4	3.52	0.09	0.07	0.65	0.66	0.68
	5	4.00	-0.89	0.07	0.71	0.74	0.69
	6	3.74	-0.34	0.07	1.05	1.13	0.53
B	1	3.59	-0.03	0.08	1.08	1.05	0.74
	2	3.69	-0.32	0.09	0.70	0.71	0.77
	3	3.41	0.50	0.08	1.06	1.07	0.64
	4	3.28	0.86	0.08	1.11	1.16	0.67
	5	3.82	-0.72	0.09	0.94	0.90	0.73
	6	3.68	-0.28	0.09	1.11	1.13	0.71
C	1	3.39	0.45	0.08	1.17	1.17	0.61
	2	3.77	-0.58	0.08	0.85	0.82	0.72
	3	3.54	0.06	0.08	0.74	0.77	0.69
	4	3.63	-0.20	0.08	0.86	0.92	0.69
	5	3.61	-0.13	0.08	0.81	0.81	0.63
	6	3.57	-0.02	0.08	1.14	1.13	0.62
	7	3.40	0.42	0.08	1.37	1.37	0.49
D	1	3.78	-0.26	0.07	0.86	0.86	0.69
	2	3.86	-0.44	0.07	0.68	0.71	0.68
	3	3.86	-0.44	0.07	0.56	0.56	0.74
	4	3.49	0.35	0.07	0.88	0.88	0.67
	5	3.27	0.79	0.07	1.80	1.79	0.47
	6	3.66	0.00	0.07	1.14	1.14	0.52
E	1	3.57	0.07	0.09	1.11	1.09	0.77
	2	3.42	0.58	0.09	0.98	0.99	0.76
	3	3.66	-0.27	0.09	1.09	1.11	0.71
	4	3.58	0.01	0.09	0.87	0.86	0.72
	5	3.58	0.01	0.09	0.85	0.84	0.69
	6	3.70	-0.41	0.09	1.04	1.02	0.67

Differential item functioning (DIF) is also used to evaluate the fit for each item based on a comparison of differences in proportion of correct responses between two groups of participants with equal ability. The probability of correct responses is not influenced itself by the participants' gender. Therefore, DIF analysis by gender grouping with reference group (female) vs. local group (male) was conducted to assess the characteristics of each item in this study. The process measures DIF used in the following statistics: the Mantel chi-square statistic (Mantel), Standardized Liu-Agresti Cummulative Common Log-Odds Ratio (LOR Z), and Liu-Agresti Cumulative Common Log-Odds Ratio (L-A LOR). For the Mantel statistic, items with values above 3.84 (indicating a Type I error rate ≤0.05) were considered as presence of DIF.[27] LOR Z values outside of the range from -1.96 to 1.96 represent evidence of DIF.[28] L-A LOR values are used to classify the size of the DIF: items with L-A LOR <0.53 are classified as class "A" because of the negligible amount of DIF, items with value between 0.53 and 0.74 belong to class "B" with moderate DIF, and items with a value of more 0.74 belong to class "C", containing high DIF.[29] Items with class "C" will be excluded from the study. DIF analysis for polytomous items in the current study was estimated in DIFAS software version 5.0.

For a subscale, response category statistics were conducted by combining all the items that belonged to that subscale into a single group. Categories statistics in each subscale required a gradual increase in difficulty level from category 1 (not done) to 5 (excellent) and no presence of reversal.[19] Besides, the fit of these categories was considered good if categories' infit and outfit values were close to 1.[19]

The person-item map displays distribution of items on the right of the map and distribution of persons on the left. The top represents the hardest items and participants with most ability. In contrast, the bottom represents the easiest items and participants with least ability. On the person-item map, items are considered ideal when their distribution is sufficient to cover the distribution of a person. In the current study, the person-item map is generated by using BIGSTEPS software version 2.82.

Reliability

The reliability for person and scale was examined by reliability and separation index. A reliability value above 0.80 is considered as good reliability, while a value between 0.67 and 0.80 is fair, and one less than 0.67 is poor.[30] A separation index value greater than 3 is considered good.[31] Separation index indicates the statistically distinct measurement level of an item's difficulty or a person's ability.[32] Strata is an converted index from separation index, and reflects the actual number of distinct levels that can be separated by calculating: Strata=(4G+1)/3, where G – separation index.[33] Additionally, Cronbach's alpha was also used to examine the reliability of the scale with an accepted value of more than 0.7.[34]

RESULTS

There were 422 completed questionnaires with all the answers, with a response rate of 75.4%. Psychometric properties of the study scale were considered on this dataset. Nearly 70% of the respondents were female

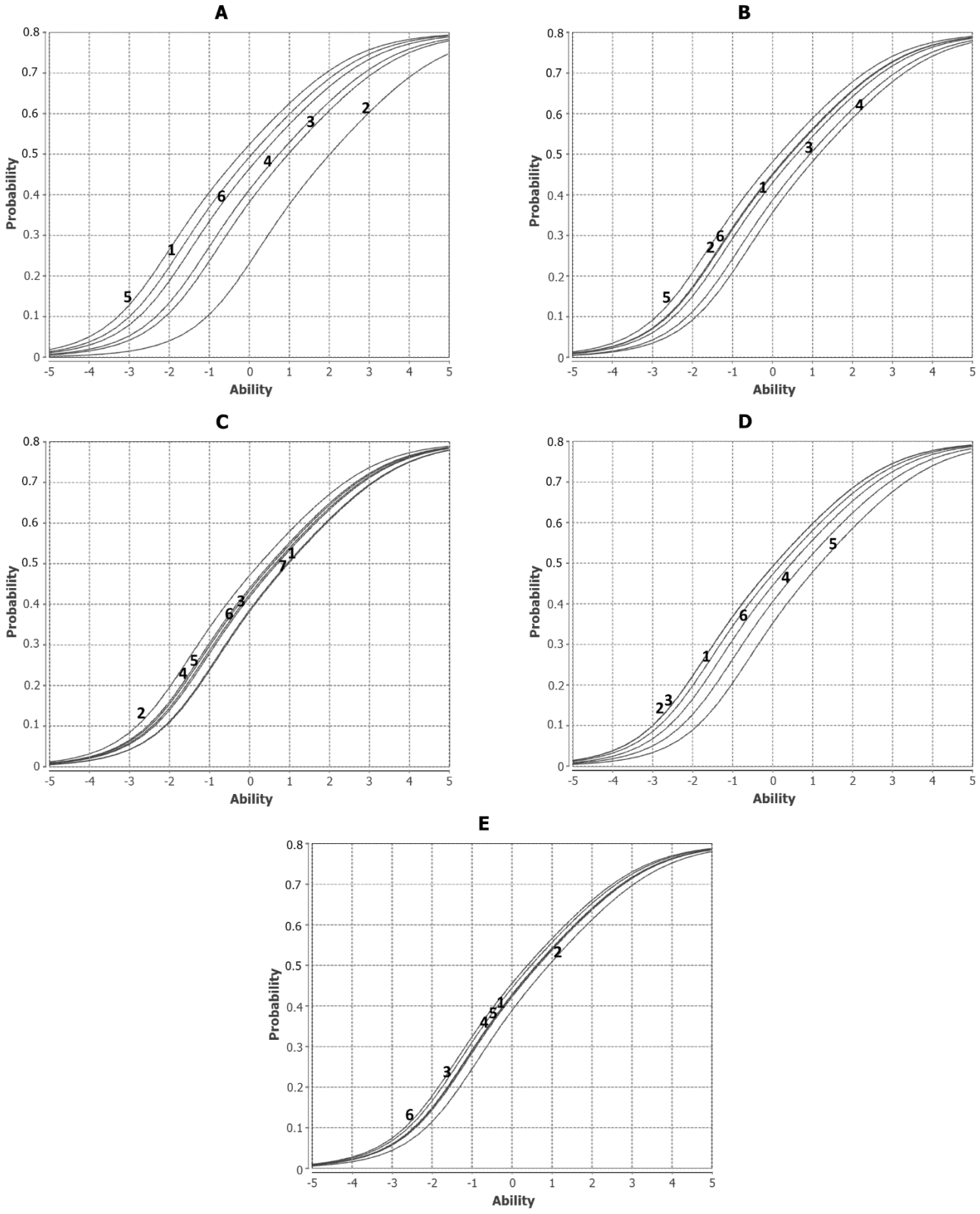

Figure 1. Item characteristic curve for sub-scales.

pharmacists with a lower level of a Bachelor's degree[35]; most of the respondents were in the age range of 26–35 years (45.7%) and had a pharmacy experience range of 2–5 years (43.4%). A description of the participants' demographic characteristics is shown in Table 2.

As shown in Table 3, all items of each subscale had positive PTMEA CORR values between 0.47 and 0.77. Hence, it can be concluded that all items of each subscale worked together to measure the proposed construct. The results of individual items tests showed that the infit and outfit

Table 4. Differential item functioning between reference group (male) and focal group (female)

Item	Male Mean (SD)	Female Mean (SD)	Mantel	LOR Z	L-A LOR	DIF classification
A_1	3.80 (1.22)	3.90 (1.09)	1.66	1.225	0.31	A
A_2	2.92 (1.33)	2.69 (1.24)	2.32	-1.498	-0.36	A
A_3	3.43 (1.11)	3.37 (1.06)	0.77	-0.878	-0.21	A
A_4	3.53 (1.04)	3.51 (0.96)	0.01	0.095	0.02	A
A_5	3.98 (0.96)	4.00 (0.88)	0.00	0.059	0.02	A
A_6	3.75 (1.05)	3.74 (0.97)	0.17	-0.414	-0.10	A
B_1	3.54 (1.09)	3.62 (1.02)	0.05	0.234	0.06	A
B_2	3.59 (0.98)	3.73 (0.88)	2.10	1.381	0.36	A
B_3	3.37 (0.95)	3.43 (0.97)	0.05	0.220	0.05	A
B_4	3.35 (0.97)	3.25 (0.97)	6.46	-2.584	-0.63	B
B_5	3.75 (1.04)	3.84 (0.92)	1.06	1.024	0.26	A
B_6	3.62 (1.03)	3.70 (0.98)	0.24	0.504	0.12	A
C_1	3.40 (1.06)	3.39 (0.99)	0.02	-0.154	-0.03	A
C_2	3.74 (0.89)	3.78 (0.87)	1.20	1.160	0.28	A
C_3	3.54 (0.86)	3.54 (0.86)	0.13	-0.366	-0.09	A
C_4	3.69 (0.93)	3.61 (0.86)	1.17	-1.101	-0.27	A
C_5	3.61 (0.89)	3.61 (0.85)	0.03	-0.165	-0.04	A
C_6	3.54 (0.97)	3.58 (0.93)	0.21	0.446	0.11	A
C_7	3.40 (1.02)	3.41 (1.01)	0.04	0.217	0.05	A
D_1	3.75 (1.09)	3.79 (1.12)	2.54	1.529	0.37	A
D_2	3.81 (1.04)	3.89 (1.02)	3.53	1.772	0.43	A
D_3	3.82 (0.98)	3.88 (0.94)	1.55	1.212	0.31	A
D_4	3.51 (0.94)	3.48 (0.93)	0.70	-0.894	-0.21	A
D_5	3.33 (1.11)	3.24 (1.10)	0.61	-0.803	-0.19	A
D_6	3.63 (1.09)	3.67 (1.10)	0.39	0.627	0.14	A
E_1	3.57 (1.05)	3.56 (1.02)	0.02	0.134	0.04	A
E_2	3.47 (1.01)	3.40 (1.01)	0.33	-0.573	-0.15	A
E_3	3.69 (0.95)	3.65 (0.89)	0.53	-0.737	-0.18	A
E_4	3.66 (0.94)	3.55 (0.87)	6.22	-2.547	-0.70	B
E_5	3.60 (0.93)	3.57 (0.95)	0.00	0.008	0.00	A
E_6	3.66 (0.93)	3.72 (0.92)	3.31	1.650	0.43	A

MNSQ values were within the optimal range between 0.5 and 1.5 for all subscales, except for the item D_5 as shown in Table 3. However, it was not within the removal limits proposed by Wright and Linacre[25] and, therefore, would be retained.

To evaluate subscale A, it was shown that a person with an ability score of -1 obtained the probability of a correct response of 0.4 to answer item A_5 (see curve 5 of subscale A on Figure 1). Curve A_2 yields a probability score of 0.45 for an ability score of 1.5. Therefore, it could be seen that A_5 was easier than A_2. In addition, the distance between the curves of subscale A had the most complete and clearest separation, reflecting a good difference in difficulty of items in this scale. Difference in difficulty level of items in scale E was the worst because the curves were close together and even curves 1, 4, and 5 seemed to overlap. Similarly, items B_2, B_6, C_7, C_1, D_2, and D_3 had a poor distinction in difficulty level. However, overlapping items could play a different role in measuring the variety of aspects in each subscale.

DIF analysis (Table 4) with reference group (female) vs. focal group (male) showed that all items in the scale had no DIF except for B_4 and E_4. Their Mantel value was greater than the critical criterion of 3.84, the LOR Z value was less than -1.96, and the magnitude of DIF was moderate (class B). However, they were within acceptable limits of the present study.

Of the subscales displayed in Table 5, subscale E — consisting of six items — had the widest range of thresholds from a low of −3.73 to a high of 4.85 and no presence of reversal. Subscale A contained items with the narrowest range of thresholds from a low of −1.56 to a high of 2.44. Categories statistics in each subscale found a reasonable distribution and the difficulty level was gradually increased from category 1 to 5. In other words, it was harder for examinees to obtain a score threshold of 5 rather than of 4, 3, 2, or 1. Additionally, the categories of all subscales had good infit and outfit statistics, with values close to 1.[19]

The person-item map in Figure 2 showed that distribution of persons had a good spread in the range with an ability score from -2.5 to 4. However, distribution of the items had a much more compact spread in range with a difficulty score from -1 to 1.5, and there were several cases where multiple items were located in the same position on the measurement. Therefore, it could be seen that the items had limited coverage on the distribution of persons. Some gaps were found between items A_2 and B_4, as well as the upper position of A_2 and the lower of A_5. Moreover, the mean of person's ability (M=1) (reflected by point M on the vertical axis) was higher than the mean of item difficulty (M=0), which indicates that a majority of pharmacists had good practice skills in medication counseling. Although some overlapping items were discovered, their appearance may play an important role in the measurement of different subscales or different aspects of a subscale.

The results showed that reliability of the scale and person were very high, with an item reliability value of 0.97 for the overall scale, within the range of 0.94–0.99 for five

Table 5. Response Category statistics of items for each subscale

Subscale	Category	Threshold	SE	Infit MNSQ	Outfit MNSQ
A	1	-	-	-	-
	2	-1.56	0.10	0.68	0.69
	3	-1.32	0.07	0.95	0.91
	4	0.45	0.05	0.82	0.91
	5	2.44	0.06	1.00	1.00
B	1	-	-	-	-
	2	-3.15	0.15	1.06	1.11
	3	-1.73	0.08	0.93	0.92
	4	0.82	0.06	0.86	0.87
	5	4.06	0.07	1.02	1.00
C	1	-	-	-	-
	2	-3.05	0.14	1.04	1.06
	3	-1.57	0.07	0.90	0.88
	4	0.81	0.05	0.91	0.92
	5	3.81	0.07	1.09	1.07
D	1	-	-	-	-
	2	-2.35	0.13	1.17	1.20
	3	-1.12	0.08	0.74	0.70
	4	0.93	0.05	0.84	0.88
	5	2.54	0.06	0.89	0.91
E	1	-	-	-	-
	2	-3.73	0.15	0.97	0.99
	3	-2.23	0.09	0.90	0.89
	4	1.11	0.06	0.90	0.90
	5	4.85	0.08	1.12	1.08

subscales, and 0.96 for person's ability (shown in Table 6). This suggested that individual items had a high level of internal consistency in construct. Additionally, the item separation values of the overall scale (6.11), of five subscales (range of 3.99–11.83), and of person's ability (4.78) are well in accordance with those proposed by Fisher, who stated that a separation index above 3 is good.[31] Based on the results of the strata index calculation, the scale's difficulty could be separated approximately into eight distinct levels; person's ability was separated approximately into seven. Further, the study also found a high Cronbach's alpha coefficient (0.96).

DISCUSSION

In this study, the psychometric properties of the scale were

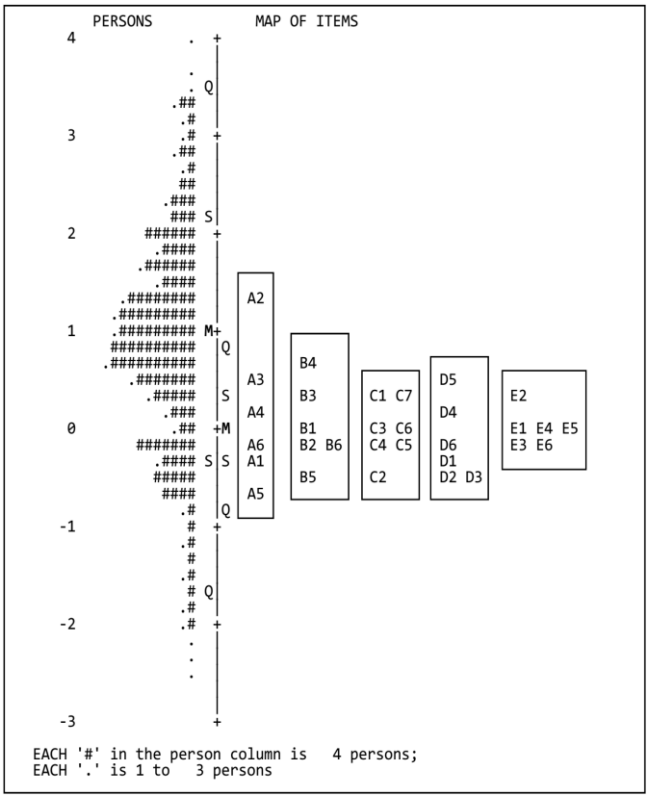

Figure 2. The person-item map

Table 6. Reliability and separation index

Index	Subscale					Overall scale	Person
	A	B	C	D	E		
Reliability	0.99	0.97	0.94	0.98	0.96	0.97	0.96
Separation	11.83	5.72	3.99	6.89	4.85	6.11	4.78
Strata	16.11	7.96	5.65	9.52	6.80	8.48	6.71
Cronbach's alpha	0.83	0.89	0.87	0.84	0.91	0.96	–

explored by using a Rasch model. Through the implementation of a series of item analysis tests, all items of the scale were seen to be in line with the Rasch model. In addition, the scale had a high reliability and high separation index. Therefore, the scale may be useful to measure patient medication counseling by community pharmacists in Vietnam.

Although the scale generally satisfied the criteria of the Rasch model, some items should be improved to further increase its efficiency. The test results of the ICC (see Figure 1) showed that the item's difficulty needed to be improved to make a distinct separation between the curves. In future study, items of subscales B, C, D, and E that had overlapping curves will be prioritized for betterment. Although items B_4 and E_4 with moderate DIF did not affect the measurement of the construct, their improvement was required to further increase the power of the tool. Additionally, the analysis of the person-item map illustrated that the item's difficulty should be increased because the average score of item's difficulty was less than the average score of the current pharmacist's capacity. Besides, for each subscale, overlapping items at the same location on the vertical axis should adjust to allow sufficient coverage of the distribution of the item on the distribution of persons as well as fill gaps on the measurement. The presence of overlapping items might be one of the reasons to explain the high reliability of the overall scale in the present study. A similar study on evaluation, the Brazilian-Portuguese version of the "Medication Counseling Behavior Guidelines" — without application of Rasch analysis — by Santos *et al.*, also found that the overall scale had high reliability with the Cronbach's alpha coefficient of 0.99.[36]

A similar topic study using the Rasch analysis was done by Schatz *et al.*[37] However, the study only determined the person's ability scores, item's difficulty, and scale's reliability without evaluating the suitability of items with other basic item analysis paradigms in the Rasch model. In addition, the study focused only on drug information related to a prescription containing hydrochlorothiazide advised by the pharmacist. Other aspects of the medication consultation process were not assessed in their study.

The sample size used in this study was considered compatible with the Rasch model. According to Chen *et al.*, a sample size greater than 250 was required to maintain the stability and robustness of item parameters in Rasch analysis for polytomous items.[38] In addition, the large number of pharmacists with a lower level of Bachelor's degree (67.8%) in the current study might have been appropriate for research purposes, because this number was roughly equivalent to the overall rate in Vietnam (72.8%).[39]

This study has shown some limitations. The convenient sampling method applied to the current study might lead to a lack of population representation among pharmacists in Vietnam. In addition, pharmacists in other cities and remote areas were not included in the sample. Besides, the study only performed a DIF analysis to understand the difference in proportion of correct responses between male and female pharmacists, so a future DIF analysis would be needed to compare groups with geographical differences to increase the validity of the scale.

In future study, we hope to improve the scale to better serve the measurement of medication counseling among pharmacists in Vietnam. Some overlapping items would be improved by replacing them with new ones or deleting them for the purpose of increasing item difficulty. Then, the scale would be re-evaluated by using the Rasch model as well as other item analysis paradigms of IRT. Further, a random sample of pharmacists collected from different locations, including rural areas, would be selected to ensure population representation.

CONCLUSIONS

In this study, a scale for measuring the quality of patient medication counseling was developed and validated by applying the Rasch model. The study results showed that the developed scale had satisfactory psychometric properties. The scale is a useful instrument for measuring patient medication counseling among community pharmacists in Vietnam. The success of this model application in the present study led to the creation of a more efficient scale with enhanced quality. The authors hope that the availability of this scale will promote pharmacy research in the area of patient medication counseling.

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CONFLICT OF INTEREST

No conflict of interest associated with this work.

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