Ramadan Pharmaceutical Care System at the Ministry of Health Institutions, Saudi Arabia

INTRODUCTION

Islam consists of five pillars that form its foundation and which all Muslims should adhere. The Fourth Pillar of Islam is fasting in the holy month of Ramadan. All members of Islamic community should stop eating and drinking from sunrise (called Suhoor in Arabic) to sunset (called iftar in Arabic); it lasts for up to 29–30 days. All adult Muslims should fast, but it is forbidden for pre-pubescent children, pregnant and breastfeeding women and those with severe health conditions that require the frequent administration of medication. Several investigations have shown that the fasting will not affect the outcome of the disease negatively.

However, some patients may experience adverse effects if they do not follow the proper instructions provided by the medical team. A proper knowledge and perception of medications and drug therapy during the holy month of Ramadan is warranted. A pharmacist plays a potential role during the month of Ramadan in preventing drug-related problems. In addition, it is necessary to conduct an education program about medication during the holy month of Ramadan. The number of studies summarized in this review were twenty two, among which three studies were from Qatar and Turkey and two were from Saudi Arabia and USA. Most of the previous studies had a cross-sectional design. They showed that most of the pharmacists were cooperative and were willing to change and learn something new that would increase their knowledge on dealing with the patients during the month of Ramadan. As for the patients, most of them were cooperative but needed the rightful education. However, some pharmacists lack knowledge on how to deal with patients with a specific type of disease during the month of Ramadan. Some patients chose to continue with their old regimen disregarding the pharmacists note, others forgot about the advice given to them regarding medication adherence and fasting. In addition to these, there were other factors that affected the outcome of the aforementioned studies such as, age, nationality, specialty and country (Table 1). The pharmacy strategic plan was launched at the MOH in the KSA in 2012 and it was recently updated with Saudi New Vision 2030. It consisted of several pharmacy practice programs including RPC. The first program to be implemented was by the author and his colleagues. In this review, we aimed to explore the RPC at MOH in the KSA. Method of development of the project The medication safety task force committee consisted of expert people from the pharmacies of the MOH hospitals. The committee aims to set up a national RPC implementation system for pharmacies of hospitals, primary healthcare centers and dental care centers. The first author of this article headed the medication safety committee; he conducted regular periodical meetings. The committee unitized and drove the RPC system from national and international literature in addition to using the international business model, pharmacy guidelines and project management institution guidelines of a new project. The draft was sent to several reviewers of the Regional Administration of Pharmaceutical Care. The draft was corrected and revised accordingly. Then, the second draft was submitted to the reviewers again for their final comments and approval. The review process took around 6 months.
to complete the task. The General Administration of Pharmaceutical Care at the MOH sent the final document to all the hospitals for implementation. The RPC system consisted of several parts: the initial phase, planning phase, execution phase and monitoring and controlling phase.

Initial phase Assessment needs
Several countries around the world are suffering from medication errors including Arabian countries. Several healthcare societies have developed guidelines and regulations to prevent medication errors during regular and Ramadan days. It is very important to prevent medications errors during the holy month of Ramadan. In the initial phase, the following goals were planned: to prevent medications errors during Ramadan, to follow-up the medication adherence during Ramadan, to know the reasons of errors and factors associated with medications errors and to develop the procedures of medications and drug therapy during the holy month of Ramadan in the future.

SWOT analysis
In this review, we performed SWOT analysis. The strengths of this project include pharmaceutical care implementation during the holy month of Ramadan, knowledge of medications that can be used in the holy month of Ramadan and preparation of a tool to prevent mistakes of drug administration during Ramadan in the future and finally, to calculate the percentage of consumption of certain medications during Ramadan. The weaknesses of this project was annual update of drug administration during Ramadan. The opportunity points were the system fit with local and national accreditation standards; it is part of medications safety regulations. The threat to this project include changing of pharmacy administration not convened with the method.

Market Analysis
List of medications which can be administered during the holy month of Ramadan at MOH was finalized in the mid-2000s. The first booklet was released in 2005 and gets updated once in every 1 or 2 years. There was limited number of the institutions had the medications administration system during the holy month of Ramadan. Including non-MOH governmental hospitals. The RPC program was started through the General Administration of Pharmaceutical Care as part the pharmacy strategic plan in 2012–2020.

Planning phase Scope of the project
The RPC system is a part of pharmacy strategic planning. It includes the list of medications which can be utilized during the holy month of Ramadan, the therapeutics interchange system of medication during fasting in Ramadan, the medications that require dose correction and adjustment during Ramadan and prevention of drug-related and pharmaceutical care-related issues during Ramadan.

Vision, Mission and Goals
The vision was to implement the RPC program with best clinical and economic outcomes at MOH institutions, KSA. The mission is to provide best system of RPC at all healthcare institutions at MOH institutions, KSA. The main objectives of the RPC program was to provide best system of medication therapy during Ramadan, know the medication interchange during Ramadan and to prevent medications errors during the holy month of Ramadan.

Project description
All the pharmacists and healthcare providers should follow this policy.

- The updated list should be distributed to all the healthcare providers before at least 1 month before Ramadan
- The pharmacist should check with all healthcare teams for switching medication before or during Ramadan
- An annual educational talk should be delivered to the healthcare teams
- The caregiver should notify his/her supervisor or department director or head as soon as the discovery of medication error happens during Ramadan and if the occurrence is severe, take immediate action
- The immediate supervisor or employer must be notified to assess the outcome and to take action
- The patients should be monitored for the occurrence of drug-related problems
- All drug-related problems during Ramadan should be documented
- Immediate supervisor or employer should sign the reporting document and forward it to the pharmacy department.
- The following information must be documented by the MSO or by the pharmacist or by the pharmacy technician and the forwarded to the MSO
- The MSO at the pharmacy department should document his/her suggestions to prevent recurrence of medication error based on his/her assessment of the action taken, document that and sign the drug-related problems form.
- The MSO is responsible to send the completed form (and enter the data in the electronic form on the MOH website) to the General Administration of Pharmaceutical Care, National Drug Information Center, Medication Safety Department via fax or email; if MSO need to contact the authorized pharmacist he/she should contact through telephone number.
- The MSO is responsible to keep all the original completed reporting forms in a confidential manner. He must not respond to any requests from any employees asking for photocopying the forms to prevent its misuse
- The MSO is responsible to aggregate the data of all the drug-related problems and prepare an annual Medication Error Summary Report for Ramadan
- The MSO is responsible to submit the annual report to:
  - Quality Department
  - PTC Committee
  - Patient Safety Committee
  - Medication Safety Committee
- Note: In addition, the MSO is responsible to submit the report of independent case (considered as sentinel event) to them.
- An investigation of the medication errors, their causes and contributing factors should be performed and documented by the MSO in coordination with the affected department(s)/assigned team or perform RCA investigation if the case is considered as sentinel event
- Necessary action(s) should be taken with follow-up actions as necessary to decrease reoccurrence and to prevent their occurrence.

Planning cost management
This project required financial assistance for the education and training of staff and outsourcing of electronic database for instance, Survey Monkey system, in order to measure the economic indications for all pharmacy staff during the RPC implementations.
Table 1: Summarized studies of medications therapy during the holy month of Ramadan.

<table>
<thead>
<tr>
<th>No</th>
<th>Author</th>
<th>Year of publication</th>
<th>Country</th>
<th>No of participants</th>
<th>Study design</th>
<th>Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M. Aslam and A. Assad</td>
<td>1986</td>
<td>Kuwait</td>
<td>325</td>
<td>cross-sectional</td>
<td>The report recommends a greater awareness amongst the prescribers of the problems which can occur in this way and better counseling of patients so that they understand the potential hazards of non-compliance and the importance of the prescribed regimen for their treatment.</td>
<td>The study about demand of knowable and education about medication during Ramadan</td>
</tr>
<tr>
<td>2</td>
<td>Ural, E et al.</td>
<td>2008</td>
<td>Turkey</td>
<td>45, 24 hr. ambulatory monitoring during and 1 month after</td>
<td>Prospective study</td>
<td>Ramadan fasting is safe even for patients with moderate to severe hypertension, unless they have uncontrolled hypertension.</td>
<td>The study about safety of fasting during Ramadan</td>
</tr>
<tr>
<td>3</td>
<td>Boobes, Y et al.</td>
<td>2009</td>
<td>Saudi Arabia</td>
<td>22, 2 months</td>
<td>Prospective study</td>
<td>It is safe for renal transplant recipients of more than one year and having stable graft function to fast during the month of Ramadan; however caution is advised for moderate to severe impaired renal function.</td>
<td>The study about safety of fasting during Ramadan</td>
</tr>
<tr>
<td>4</td>
<td>Pekdemir, Murat et al.</td>
<td>2010</td>
<td>Turkey</td>
<td>2079</td>
<td>Cohort study</td>
<td>Results show that during Ramadan, the clinical features of patients admitted to the ED and the number of ED admissions for specific ailments did not change significantly</td>
<td>The study about safety of fasting during Ramadan</td>
</tr>
<tr>
<td>5</td>
<td>Pinelli, Nicole R Jaber, Linda A</td>
<td>2011</td>
<td>USA</td>
<td>27</td>
<td>Observational study</td>
<td>Lack of patient education prior to Ramadan may contribute to the suboptimal practices reported.</td>
<td>The study about demand of knowable and education about medication during Ramadan</td>
</tr>
<tr>
<td>6</td>
<td>Gabori, B et al.</td>
<td>2011</td>
<td>Marseille, France</td>
<td>202, 3 months</td>
<td>Cross-sectional study</td>
<td>Systemic advice on treatment adjustment needs to be given with hypoglycemic agents</td>
<td>The study about demand of knowable and education about medication during Ramadan</td>
</tr>
<tr>
<td>7</td>
<td>Wilbu, K et al.</td>
<td>2012</td>
<td>Qatar</td>
<td>500</td>
<td>Cross-sectional</td>
<td>Qatar pharmacists frequently interact with diabetes patients, but application of recommended medical guidelines for care and medication dosing for fasting patients is not optimal. Despite barriers limiting enhanced participation in diabetes patient management during Ramadan, Pharmacists are interested in developing in these services.</td>
<td>The study about demand of knowable and education about medication during Ramadan</td>
</tr>
<tr>
<td>8</td>
<td>Ahmedani, M. Y. MY et al.</td>
<td>2012</td>
<td>Pakistan</td>
<td>110</td>
<td>Prospective study</td>
<td>With active glucose monitoring, alteration of drug dosage and timing, dietary counseling and patient education, the majority of the patients did not have any serious acute complications of diabetes during Ramadan.</td>
<td>The study about safety of fasting during Ramadan</td>
</tr>
<tr>
<td>Study</td>
<td>Authors</td>
<td>Year</td>
<td>Country</td>
<td>Sample Size</td>
<td>Study Method</td>
<td>Main Findings</td>
<td>Study Focus</td>
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<tr>
<td>9</td>
<td>Shirin Sadeghpour Parnaz et al.</td>
<td>2012</td>
<td>Multinational</td>
<td>23 studies</td>
<td>Systemic review</td>
<td>Fasting is generally safe for healthy individuals, but might be hazardous to patients with various GI disease and may increase the risk of complications in this group.</td>
<td>The study about Safety of fasting during Ramadan</td>
</tr>
<tr>
<td>10</td>
<td>Mygin, Anna et al.</td>
<td>2013</td>
<td>Pakistan's in Denmark</td>
<td>168</td>
<td>Semi-structured interviews and medication reviews analysis</td>
<td>This patient-centered approach to counselling on medicines may facilitate better medicine use and thus better clinical health outcomes among patients that choose to fast.</td>
<td>The study about impact of education during Ramadan</td>
</tr>
<tr>
<td>11</td>
<td>Peeters, B et al.</td>
<td>2013</td>
<td>Belgium</td>
<td>52 patients</td>
<td>Observational study</td>
<td>This pilot study found a low prevalence of Ramadan fasting among Turkish migrants with diabetes in Belgium. We also found that provision of advice by healthcare providers could be improved. Larger scale studies are warranted to confirm these findings.</td>
<td>The study about impact of education during Ramadan</td>
</tr>
<tr>
<td>12</td>
<td>Salim, I et al.</td>
<td>2013</td>
<td>Qatar</td>
<td>36 studies</td>
<td>Systemic review</td>
<td>Ramadan fasting is not associated with any change in incidence of acute cardiac illness and the majority of cardiac patients can fast without any difficulty. Improvement in lipid profile, especially 30% to 40% increment in HDL, as reported in some studies, appear promising. Diabetic patients should be carefully monitored during Ramadan fasting.</td>
<td>The study about Safety of fasting during Ramadan</td>
</tr>
<tr>
<td>13</td>
<td>Chentl, F et al.</td>
<td>2013</td>
<td>Algeria</td>
<td>977</td>
<td>Observational study</td>
<td>Patient suffers from metabolic complications during Ramadan and forget the recommendations that the healthcare had provided them.</td>
<td>The study about demand of Knowable and education about medication during Ramadan</td>
</tr>
<tr>
<td>14</td>
<td>Jaber, D et al.</td>
<td>2014</td>
<td>Jordan</td>
<td>381 Physicians</td>
<td>Self-administered questionnaire</td>
<td>Most physicians' attitudes and practices were in line with religious opinion in regard to which routes of drug administration can nullify fasting, indicating that physicians have adequate knowledge in this area.</td>
<td>The study about demand of Knowable and education about medication during Ramadan</td>
</tr>
</tbody>
</table>

There were factors that affected the study such as age, nationality, specialty and country.
<table>
<thead>
<tr>
<th>No.</th>
<th>Authors</th>
<th>Year</th>
<th>Location</th>
<th>Sample Size</th>
<th>Study Type</th>
<th>Results/Findings</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>Lai, Y F et al.</td>
<td>2014</td>
<td>Singapore</td>
<td>32</td>
<td>Prospective study</td>
<td>Fasting significantly increases the mean INR of medically stable patients taking warfarin and the likelihood of having an INR above therapeutic targets. For patients maintained at the higher end of INR target ranges or at increased risk of bleeding, closer monitoring or dosage adjustment may be necessary during fasting.</td>
<td>The study about the problems during Ramadan</td>
</tr>
<tr>
<td>16</td>
<td>Aydin, O et al.</td>
<td>2014</td>
<td>Turkey</td>
<td>300</td>
<td>Cross-sectional study</td>
<td>Results showed that in a Muslim population, the patients with asthma and COPD do not feel their diseases to be an inhibitory factor for fasting during Ramadan.</td>
<td>The study about Safety of fasting during Ramadan. Several factors might affect the adherence to treatment in patients with asthma and COPD.</td>
</tr>
<tr>
<td>17</td>
<td>Wilbur, K Al Tawengi, K Remoden, F</td>
<td>2014</td>
<td>Qatar</td>
<td>500 healthcare providers in 3 months</td>
<td>Cross-sectional descriptive study</td>
<td>Qatar pharmacists face several practical barriers to guiding diabetes patient self-management during Ramadan, but are motivated to assume a greater role in such care. Educational programs are necessary to improve pharmacist knowledge in the provision of accurate patient advice.</td>
<td>The study about demand of Knowable and education about medication during Ramadan. Pharmacists are motivated to assume a greater role in diabetic patients during Ramadan. Some pharmacists lack knowledge on how to manage diabetic patients during the month of Ramadan.</td>
</tr>
<tr>
<td>18</td>
<td>Mikhael, Ehab Muder Jasim, Ali Lateef</td>
<td>2014</td>
<td>Iraq</td>
<td>34</td>
<td>Observational study</td>
<td>Physicians fail to take patient fasting status into consideration when prescribing antibiotics for their fasting patients. Antibiotics with a twice-daily regimen are not suitable and best be avoided for fasting patients in Iraq during Ramadan—especially if it occurs during summer months—to avoid treatment failure and provoking bacterial resistance.</td>
<td>The study about the problems during Ramadan.</td>
</tr>
<tr>
<td>19</td>
<td>Ibrahim, Osama H Mohamed</td>
<td>2015</td>
<td>UAE</td>
<td>115 healthcare providers in 3 months</td>
<td>Observational study</td>
<td>Pharmacists are more qualified to adjust and manage medication regimens than what they are presently performing.</td>
<td>The study about the impact of the pharmacist and his role in Ramadan. Estimate the awareness of pharmacist’s role in providing pharmaceutical care during Ramadan.</td>
</tr>
<tr>
<td>20</td>
<td>Alomi YA, Zahran R</td>
<td>2015</td>
<td>Saudi Arabia</td>
<td>88 healthcare providers in 2 months</td>
<td>Cross-sectional study</td>
<td>The 50% Self-Assessment core elements of Drug Therapy use During the Holy Month of Ramadan Program in Saudi Arabia NOT existed. One third of responders does not know the core elements of the drug therapy during Ramadan</td>
<td>The study about demand of Knowable and education about medication during Ramadan. The study first done in Saudi Arabia, reflected the practice during the holy month of Ramadan. However, the study had a few number of responders</td>
</tr>
<tr>
<td>21</td>
<td>Amin, Mohamed E.K. Chewning, Betty</td>
<td>2016</td>
<td>Egypt</td>
<td>298 Pharmacists</td>
<td>Cross-sectional study</td>
<td>This study identifies variability among community pharmacists’ knowledge of diabetes management during Ramadan. It also shows willingness among the majority of pharmacists to learn more about the topic.</td>
<td>The study about demand of Knowable and education about medication during Ramadan. Eighty percent of the responding pharmacists reported the MRA (medication regimen adjustment) conversion for chronic conditions started either 1-3 days before, or during the first week of Ramadan</td>
</tr>
<tr>
<td>22</td>
<td>Lou, Alina et al.</td>
<td>2016</td>
<td>USA</td>
<td>37</td>
<td>Cross-sectional study</td>
<td>Most women chose not to fast during pregnancy.</td>
<td>The study about the problems during Ramadan. 23 women believed that fasting was harmful to themselves.</td>
</tr>
</tbody>
</table>
Execution phase

Management team
The management team responsible for the follow-up of the RPC project was from the GAPC or local pharmacy administration and medication safety committee. The central committee was designed through the General Administration of Pharmaceutical Care at MOH. The committee consisted of representatives from each region specialized in medication safety with an emphasis on the RPC system. Another regional committee was established for each region with representatives from each hospital and group of primary healthcare center. Each hospital or group of primary healthcare center established local medications safety committee. The local committee consisted of medication safety pharmacist, physicians, nurses, quality management, risk management and any invited member. All committees will have a monthly meeting to discuss the RPC system and documentation, analysis of medication errors and prevention of medication errors during the holy month of Ramadan.\textsuperscript{35}

Education and training
The project requires regular educational courses to be conducted regarding the RPC system through the General Administration of Pharmaceutical Care at MOH and through the Regional Administration Pharmaceutical Care for the staff of pharmacy administration, hospital and primary healthcare centers.

Risk Management
There are six types of risks to this project: budget risks, scope risks, personal risks, schedule risk, technical risks and quality risks. This project might be exposed to budget, personal, schedule and quality risks. The budget risk is related to non-availability of funds for education and training, to update medication list and to interchange during Ramadan through RPC. This project might be exposed to personal risks such as unavailability and shortage of human resources with high workload. In addition to this, the pharmacy staff might not have received education and training about the project. Schedule risk constitutes the program not starting during Ramadan or during fasting by patient. Quality risks related to nonqualified pharmacists being available and non-trained pharmacist in the quality pharmacy tools. Other technical risks include non-availability of electronic system of medication list or interchange drugs through the RPC implementation and documentation with friendly use.

Monitoring and controlling phase

Project Quality Management
The process of quality management during project management is one of the essential tools used to follow-up the implementation of the project and measure the impact of the project. Several quality tools were used, for instance, the adherence of the RPC, the clinical outcome and the cost avoidance impact of the drug-related problems during Ramadan, in addition to taking care of patient satisfaction of the RPC system at MOH institution in KSA.\textsuperscript{22,28}

Closing of the project
The RPC system at MOH institutions is an essential tool to choose the best drug therapy during the holy month of Ramadan and prevent drug-related problems in the KSA. The system should continue with the corporate committee of medications safety and other related committees. The annual report of RPC should be done. Education and training courses for healthcare providers should be conducted regularly. Further expanded related cost avoidance of drug related problem during Ramadan in the future. Annual celebrating with the involving members of the project is recommended.

ACKNOWLEDGEMENT
None.

CONFLICT OF INTEREST
The authors declare that there are no conflicts of interest.

ABBREVIATIONS
MOH: Ministry of Health; KSA: Kingdom of Saudi Arabia; USA: United State of America; RPC: Ramadan Pharmaceutical Care; SWOT: Strengths, Weaknesses, Opportunities and Threats; MSO: Medication Safety Officer; RCA: root cause analysis; PTC: pharmacy therapeutic committee.

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REFERENCES

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