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Eastern Mediterranean Health Journal

المجلة الصحية لشرق المتوسط

La Revue de Santé de la Méditerranée orientale

The Region is passing through a critical era, marked by natural and manmade crises affecting societies and infrastructure. It is these pressing challenges that the new WHO Regional Director for the Eastern Mediterranean, Dr Ahmed Al-Mandhari, has publically sought to address through mobilization of resources and communication with Member States to improve the health and well-being of their citizens.

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IS the official health journal published by the Eastern Mediterranean Regional Office of the World Health Organization. It is a forum for the presentation and promotion of new policies and initiatives in public health and health services; and for the exchange of ideas, concepts, epidemiological data, research findings and other information, with special reference to the Eastern Mediterranean Region. It addresses all members of the health profession, medical and other health educational institutes, interested NGOs, WHO Collaborating Centres and individuals within and outside the Region.

المجلة الصحية لشرق المتوسط

هى المجلة الرسمية التى تصدر عن المكتب الإقليمى لشرق المتوسط بمنظمة الصحة العالمية. وهى منبر لتقديم السياسات والمبادرات الجديدة في الصحة العامة والخدمات الصحية والترويج لها، ولتبادل الآراء والمفاهيم والمعطيات الوبائية ونتائج الأبحاث وغير ذلك من المعلومات، وخاصة ما يتعلق منها بإقليم شرق المتوسط. وهى موجهة إلى كل أعضاء المهن الصحية، والكليات الطبية وسائر المعاهد التعليمية، وكذا المنظمات غير الحكومية المعنية، والمراكز المتعاونة مع منظمة الصحة العالمية والأفراد المهتمين بالصحة فى الإقليم وخارجه.

La Revue de Santé de la Méditerranée Orientale

EST une revue de santé officielle publiée par le Bureau régional de l'Organisation mondiale de la Santé pour la Méditerranée orientale. Elle offre une tribune pour la présentation et la promotion de nouvelles politiques et initiatives dans le domaine de la santé publique et des services de santé ainsi qu'à l'échange d'idées, de concepts, de données épidémiologiques, de résultats de recherches et d'autres informations, se rapportant plus particulièrement à la Région de la Méditerranée orientale. Elle s'adresse à tous les professionnels de la santé, aux membres des instituts médicaux et autres instituts de formation médico-sanitaire, aux ONG, Centres collaborateurs de l'OMS et personnes concernés au sein et hors de la Région.

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Working together to improve lives in the Eastern Mediterranean Region

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It was an immense honour when the World Health Organization Regional Office for the Eastern Mediterranean (WHO/EMRO) welcomed me as its new Regional Director on 1 June 2018. On this occasion, I would like to extend my sincere thanks and appreciation to the members of the WHO Executive Board during its 143rd session in Geneva, Switzerland, for giving me an opportunity to propose my agenda for change towards a stronger and healthier Region (1). I look forward to my tenure as Regional Director, and have been impressed by the support displayed by WHO/EMRO staff, the WHO Executive Board, and public health bodies further afield.

As a family physician and specialist in quality healthcare provision and management, the pressures and challenges facing the Eastern Mediterranean Region (EMR) resonate strongly with my desire to tackle these difficulties and see measurable improvement in the health of people in our Member States, and listen to their concerns. It is clear to all that the Region is passing through a critical era, marked by natural and manmade crises that have led to destruction of infrastructure and a deterioration in the health and living conditions of many people, particularly displaced populations and refugees. Thus, every effort must be made and all available resources mobilized to find appropriate solutions to these challenges.

As I take up the role of Regional Director, my immediate priority is to begin working with countries in order to bring WHO closer to its Member States. No tangible change can be made if we are far away from the areas where change is needed. The work and policies already undertaken and approved by WHO have immense applicability to the needs of the EMR; in particular the United Nation's Sustainable Developmental Goal of Universal Health Coverage (2), the International Health Regulations (2005) (3), and WHO's Thirteenth General Programme of Work 2019–2023 (4), which are among the key forces that I seek to promote in order to drive interventions during my term as Regional Director.

Further to these key forces, I have identified four priority technical areas for my agenda, which are: tackling health emergencies including disease outbreaks; improving control of communicable and noncommunicable diseases and their risk factors; strengthening health systems to achieve universal health coverage through a primary health care approach, with special emphasis on family practice; and improving maternal and child health.

However, it is important to remember that tackling degradation in public health in the Region is a collaborative effort. The Organization has a wealth of experience and expertise that has been demonstrated over decades. Together in partnership with our other United Nations agencies, developmental partners and nongovernmental organizations, no effort should be spared to strengthen coordination and collaboration mechanisms to the benefit and efficiency of operations in the Region. Ultimately my goal is to see WHO full of life, energy and enthusiasm. I would like to see staff at different levels of this Organization working together as a strong, productive team to provide the highest level of support to Member States, which turn to us for assistance in the drive to improve the lives of ordinary citizens that have found themselves desperate through no fault of their own.

I am immensely humbled by my selection as Regional Director, and look forward to working with all WHO staff and our partners in our collective effort to raise the quality of public health in the EMR. We are all aware of the steep challenges facing us, but I am confident after having witnessed the dedication and experience of EMRO staff that we can together make a noticeable difference to the lives of many.

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Association between gingivitis severity and lifestyle habits in young Saudi Arabian males

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Abstract

Background: Gingivitis is a risk factor for periodontitis, which is associated with several systemic disorders. Adolescence provides an opportunity to establish good oral health practices but there are few studies on gingivitis in adolescents.

Aims: This study assessed the association between lifestyle habits and gingivitis severity in young Saudi Arabian males.

Methods: A sample of Saudi Arabian males (n = 685) aged 13–15 years from Dammam and Khobar were included in a cross-sectional study in 2016. A questionnaire assessed socioeconomic background and daily lifestyle habits – tooth-brushing, current smoking and consumption of sugary drinks and foods. Clinical examinations recorded plaque and gingival indices on 6 index teeth. Regression analysis was used to evaluate the association of gingivitis severity with tooth-brushing and smoking adjusted for sugary drinks and foods, socioeconomic factors and dental plaque.

Results: The response rate was 96.2%. Only 38% of the respondents brushed their teeth twice daily, 10.2% smoked, and 82.8% and 68.3% consumed sugary drinks and sugary foods respectively. The prevalence of plaque and gingivitis was 87.9% and 73.9% respectively. Tooth-brushing was not significantly associated with more severe gingivitis (regression coefficient = 0.17; 95% CI: −0.16 to 0.49). Current smoking was significantly associated with more severe gingivitis only when consuming sugary drinks (regression coefficient = 0.63; 95% CI: 0.04 to 1.22).

Conclusions: Gingivitis severity was not associated with tooth-brushing but significantly increased with smoking when sugary drinks were used, indicating the effect of unhealthy lifestyle on gingival health, and the need to promote healthy lifestyle habits in this age group.

Keywords: Gingivitis; Lifestyle; Risk factors; Adolescent males; Saudi Arabia

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Introduction

Adolescence is an age where individuals adopt habits that may be carried forward well into adulthood including tooth-brushing (*1*), smoking (*2*) and dietary habits (*3*). Diseases that begin at this stage in life and continue uncontrolled may start cumulative destruction that becomes difficult to tackle later (*4*).

Gingival inflammation is reversible and occurs mostly in childhood and adolescence (*5,6*) with the prevalence decreasing as adulthood is reached (*1*). Gingivitis is a risk factor for periodontitis (*7,8*), which in turn is associated with several systemic disorders of public health importance including coronary heart diseases (*9*), diabetes (*10*), atherosclerosis (*11*), lung cancer (*12*), pancreatic cancer (*13*), psoriasis (*14*) and male infertility (*15*). Gingivitis is associated with improper oral hygiene practices related to the frequency and technique of tooth-brushing (*6*). Smoking is another risk factor for gingivitis, although the evidence is debateable with some investigators reporting that smoking increases gingival inflammation (*16*) and others that there is no relation (*17*). Some studies indicate that frequent sugar intake increases gingival inflammation (*18,19*). Gingivitis, whether self-reported (*16*) or clinically-assessed (*20*), has also been linked to socioeconomic status. For example, the prevalence of gingivitis was lower in individuals who did not live in huts or tents (informal housing structures), were more affluent (*16*), had higher parental education and family income or owned a car (*20*).

In spite of the importance of adolescence as an opportunity to establish good oral health practices, there are relatively few studies on gingivitis among adolescents. There is also little evidence to confirm or refute if factors associated with mild gingivitis are associated with the development of more advanced stages of the disease (moderate/severe gingivitis) as is the current understanding of risk factors associated with periodontal diseases (*21*). In Saudi Arabia, marked changes in lifestyle are taking place and they have public health implications because of their association with several diseases including those of the oral cavity. For example, reports indicate an increase in the consumption of sweetened beverages such as soft drinks (*22*) and fruit juices (*23*), in addition to a low prevalence of regular tooth-brushing (*24,25*) and increased prevalence of smoking among young Saudi Arabians (*26,27*). The effect

of these changing lifestyle habits on oral health needs to be studied.

The aim of the present study was to assess factors associated with the severity of gingivitis, including tooth-brushing and smoking, in a group of young Saudi Arabian males in 2 cities in the Eastern Province of Saudi Arabia. The study also examined if the effects of these habits were modified by other habits such as the daily consumption of sugary drinks and foods.

Methods

Study design

This was a cross-sectional study conducted in Dammam and Khobar in the Eastern Province of Saudi Arabia in 2016. It is part of a larger study assessing the oral health of students in middle schools.

Study sample

The target population was 13–15-year-old Saudi adolescents in middle school. Only males were included in our study on the basis that they would be more likely to smoke so that we could examine its effect on gingival health. Two public schools were selected using simple random sampling (one in Dammam and one in Khobar). All students in the 1st to 3rd grades of middle school were invited to participate if they fulfilled the following criteria: Saudi nationals; free of medical conditions that might affect their ability to brush their teeth well, such as physical or intellectual disabilities; parents consenting in writing to their participation; and participants agreeing to be clinically examined. All available, eligible students in the 2 schools at the time of the study were included.

Data collection

Data were collected using a questionnaire with 9 items, and a clinical examination was conducted by a periodontist. At the beginning of the questionnaire, there was a brief description of the study, an invitation to participate and a consent form to be signed by parents. The questionnaire had 2 sections. Section 1 asked about socioeconomic background (parents' education, university-educated or not; family residence, owned or rented; number of family members in the household; and number of bedrooms). Section 2 asked about practices related to gingival health: tooth-brushing frequency (≥ 2 times daily, once daily, several times per week, 2–3 times per month and less than that), current daily smoking (yes/no) and daily use of sugary drinks and sugary foods (yes/no). The questionnaire was in Arabic and based on one used in a previous study (*28*). It was pilot tested for clarity on a group of 20 adolescents whose results were not included in this study.

The clinical examination was conducted in daylight in a room assigned by the schools for the study team. In the examination, a mirror and a periodontal probe (UNC 15, Hu Friedy, United States of America) were used. Plaque accumulation was assessed using the plaque index of Silness and Löe (*29*). The scale of the index ranges from 0 to 3 where score 0 indicates no plaque, 1 indicates a film of plaque adhering to the gingival margin and adjacent area of the tooth detected by passing the probe on the tooth surface, 2 indicates moderate accumulation of soft deposits within the gingival pocket or the tooth and gingival margin which can be seen by the naked eye, and 3 indicates an abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin. In addition, the severity of gingivitis was assessed using the gingival index of Löe and Silness (*30*). This index assesses the change in colour and texture of gingival tissue in addition to gingival bleeding. Its scale ranges from zero, indicating normal healthy gingiva, to 3, where there is severe inflammation as indicated by marked redness, oedema, ulceration and tendency to spontaneous bleeding. Gingivitis was considered present when a score of 1 or more was recorded. The 2 indices were applied on the same set of 6 index teeth: upper right first molar, upper right lateral incisor, upper left first premolar, lower right first premolar, lower left lateral incisor and lower left first molar. On each tooth, 4 sites were evaluated: mesiobuccal, distobuccal, mesiolingual and distolingual (*31*). Examination was conducted by one examiner and intra-examiner reproducibility was established by twice examining 20 students on the same day within several hours so that the gingival condition of each participant would not be affected by oral hygiene procedures (Cronbach alpha = 0.74).

Statistical analysis

Plaque and gingival indices scores were averaged from the 4 examined sites for each of the 6 index teeth. The worst (highest) score among the 6 teeth was identified and recorded for each child. The frequency of brushing was recoded into brushing ≥ 2 times daily versus brushing < 2 times daily. The number of persons per bedroom was calculated by dividing the number of persons in the household by the number of bedrooms. Ordinal regression models were used to assess the association of the outcome (gingivitis severity ranging from gingival index score zero to score 3) with the explanatory variables – brushing ≥ 2 times daily using fluoridated toothpaste and current daily smoking. Four separate models were developed to adjust for the effect of socioeconomic factors and plaque index score (model 1), socioeconomic factors, plaque index score and daily use of sugary drinks (model 2), socioeconomic factors, plaque index score and daily use of sugary foods (model 3), and socioeconomic factors, plaque index score and daily use of sugary drinks and foods together (model 4). Goodness of fit of the 4 models for the data was assessed using pseudo R^2. Regression coefficients (beta) and 95% confidence intervals (CIs) were calculated using *SPSS*, version 20.0. Significance was set at the 5% level.

Ethical considerations

The study was conducted according to the Helsinki declaration. The study was approved by the Institutional Review Board of the University of Dammam (IRB-2015-02-187).

Results

The questionnaire was distributed to 712 boys and 685 returned it (response rate = 96.2%). The mean (standard deviation) age was 14.1 (0.3) years. Most of the participants had university-educated fathers and mothers (60.2% and 52.3% respectively, Table 1) and lived in owned houses (68.2%). The mean (standard deviation) number of family members per bedroom was 1.7 (0.9). A minority of respondents reported brushing their teeth twice daily (38%) and smoking daily (10.2%). Most participants reported daily use of sugary drinks (82.8%) and sugary foods (68.3%).

Just over a quarter of the boys (26.1%) had healthy gingiva in all 6 index teeth (score 0) and 12.1% had no plaque accumulation in any of the index teeth. Severe gingivitis (score 3 of the gingival index) was the worst condition detected in at least one tooth in 2.2% of the participants. An abundance of soft matter within the gingival pocket (score 3 of the plaque index) was recorded in at least one of the index teeth in 7.6% of the participants (Figure 1).

Table 2 shows the ordinal regression models for the association of tooth-brushing and smoking with the severity of gingivitis in the participants after controlling for the effect of different variables. Boys who reported brushing their teeth at least twice daily were more likely than those who did not brush to have more severe gingivitis although this association was not statistically significant (model 1 beta = 0.17; 95% CI: −0.16 to 0.49). Boys who were current daily smokers were also more likely than those who did not smoke to have more severe gingivitis (model 1 beta = 0.54; 95% CI: −0.04 to 1.12). This likelihood of more severe gingivitis among smokers was higher and statistically significant when daily use of sugary drinks was added alone or in combination with daily use of sugary foods (models 2 and 4 beta = 0.63; 95% CI: 0.04 to 1.22). Goodness of fit measured by pseudo R^2 indicated that models 2 and 4 had a better fit for the data.

Table 1 Socioeconomic characteristics and oral health practices of young Saudi males, Dammam and Khobar, 2016 (*n* = 685)

Socioeconomic characteristic	No. (%)
Father's education	
University educated	400 (60.2)
Less than university educated	265 (39.8)
Mother's education	
University educated	345 (52.3)
Less than university educated	315 (47.7)
Home ownership	
Owned	454 (68.2)
Rented	212 (31.8)
Number of persons per bedroom	
Mean (standard deviation)	1.7 (0.9)
Brushing teeth ≥ 2 times daily using fluoridated toothpaste	
Yes	260 (38.0)
No	425 (62.0)
Currently smoking on a daily basis	
Yes	70 (10.2)
No	613 (89.8)
Daily use of sugary drinks	
Yes	564 (82.8)
No	117 (17.2)
Daily use of sugary foods	
Yes	410 (68.3)
No	190 (31.7)

Numbers do not add up to the total sample size because of non-response on certain items.

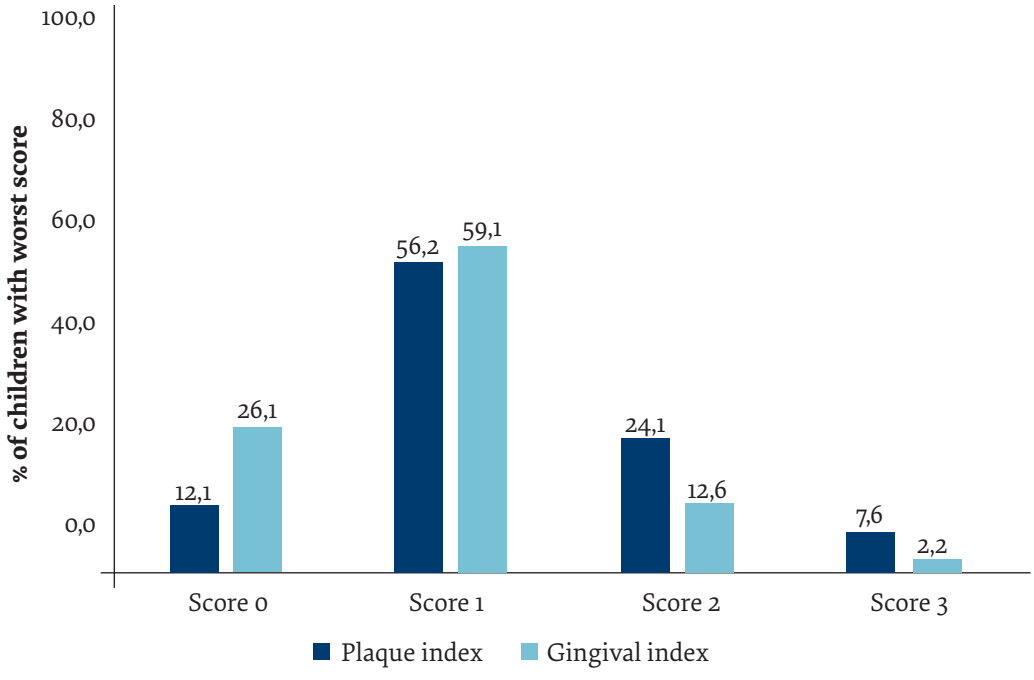
Discussion

Our study showed that when 13–15-year-old male Saudis consumed sugary drinks daily, this modified the effect of their daily smoking and increased the likelihood of greater gingivitis severity. These findings have implications for health education interventions targeting young males at this age and suggest that lifestyle habits that affect health should be comprehensively targeted. Advocates of the common risk factor approach have called for concerted efforts to tackle health problems that have common causes (*32*). Our findings provide evidence to support the merit of this recommendation.

A greater portion of the participants in our study had mild gingivitis compared to 13–15-year-old Czech children where 43% and 19.5% had mild and moderate gingivitis (*33*). The overall prevalence of gingivitis in our study (73.9%) was similar to that among Nigerian schoolchildren (71%) although a higher portion of Nigerian children had moderate/severe gingivitis (20.4%) (*34*) compared with participants in our study (14.8%). The prevalence of plaque and gingivitis in our study were very similar to that reported among 12-year-old males in Medina, Saudi Arabia (83% and 71%) (*35*).

The prevalence of twice daily tooth-brushing in our study (38%) is similar to the frequency reported among 8–12-year-old Brazilian schoolchildren (41%) (*36*). It is also in agreement with figures reported from neighbouring Gulf countries – United Arab Emirates (36%) and Oman (34%) (*37*). It was much higher than that reported in a Sudanese study of 12-year-old children in Khartoum (6.4%) (*38*). In our study, gingivitis was not significantly associated with brushing. This is in agreement with the Brazilian study, which reported no association between gingivitis and brushing once/twice daily (*36*), and another study among South African adolescents, which showed that brushing was not significantly related to gingivitis after adjusting for plaque level (*16*). This suggests that brushing was only critical for gingivitis as long as it reduced plaque accumulation. In our study, brushing twice or more daily was associated with more severe gingivitis, although the association was not statically significant. This might be attributed to reactive rather than proactive behaviour where children started to

Figure 1 Distribution by worst plaque and gingival indices scores in young Saudi males, Dammam and Khobar, 2016 (n = 685).



brush their more frequently after gingivitis occurred. This concurs with the finding of an Iranian study which reported significantly higher scores of bleeding in the posterior teeth of 15-year-old Iranians who brushed their teeth twice daily compared with those who brushed only once daily (*39*).

With regard to current smoking, 10% of our participants reported smoking. This agrees with a school-based cross-sectional study in Medina, Saudi Arabia where 11.7% of 13–15-year-old male and female students reported smoking (*40*). Another Saudi Arabian study in Riyadh reported a prevalence of 20% of ever smoking among 14-19-year-old male and female students (*26*). The higher prevalence in that study might be due to the inclusion of older students. In our study, daily smoking was associated with a greater likelihood of more severe gingivitis. Our results disagree with another study among 19-year-old individuals in Sweden where the mean gingivitis scores among never smokers and smokers were roughly the same (46% and 42% respectively) (*17*). The authors ascribed the lack of a difference to misclassification because self-reporting was used to assign smoking status. They also pointed to the relatively short period of potential exposure to smoking because of the young age of their participants. Our results are in agreement with a study among children with a mean age of 13.9 years, which reported that more current smokers than non-smokers had frequent bleeding gums (51.2% versus 33.1%) (*41*). They also agree with the South African study which reported greater odds of recent gingivitis among eighth graders who smoked regularly (odds ratio = 1.57) (*16*).

The high percentage of participants in our study who indicated daily use of sugary drinks is in agreement with recent statistics showing that Saudi Arabia ranked 9th worldwide in the use of soda drinks with 89 L purchased per capita in 2014 (*22*). Sugary drinks constituted 51% of the daily fluid intake among 12–13-year-old children in Riyadh, Saudi Arabia (*23*). The problem has been reported to be particularly prominent among males where 14–16-year-old Saudi Arabian males were reported to drink more sugar-sweetened carbonated beverages weekly and to add more sugar to hot beverages than females (*3*). In our study, sugary drinks increased the significance of the association between smoking and gingivitis severity, in agreement with other studies (*18*,*42*). Researchers ascribed this to the role of sucrose in increasing plaque mass although the mass reached a plateau after some time and gingivitis continued for a longer period afterwards (*18*). The authors commented that this could have been induced by a shift in the microbiological plaque flora rather than an increase in mass per se. The association of gingivitis with a sugary diet was attributed in another study to short chain carboxylic acids that resulted from some sugary snack particles (*19*). These products increased subgingival temperature and neutrophil emigration to the gingival crevicular fluid among those exposed to a sugary diet compared with those on a low sugar diet. Such changes induced by sugary diet are expected to add to the effects of smoking on gingival tissues, which might explain the additional risk observed in our study where neither habit on its own was a significant risk factor of increased gingivitis severity.

Table 2 Ordinal regression analyses of factors associated with the severity of gingivitis (worst score of gingival index) in young Saudi males in Dammam and Khobar, 2016

Variable	Model 1			Model 2			Model 3			Model 4		
	B (95% CI)	SE	*P*–value	B (95% CI)	SE	*P*–value	B (95% CI)	SE	*P*–value	B (95% CI)	SE	*P*-value
Brushing teeth ≥ 2 times daily with fluoridated toothpaste vs not	0.17 (–0.16 to 0.49)	0.18	0.30	0.19 (–0.14 to 0.52)	0.16	0.26	0.18 (–0.15 to 0.50)	0.19	0.29	0.20 (–0.13 to 0.53)	0.17	0.23
Currently smoking daily vs not	0.54 (–0.04 to 1.12)	0.32	0.08	0.63 (0.04 to 1.22)*	0.30	0.04*	0.55 (–0.03 to 1.12)	0.29	0.07	0.63 (0.04 to 1.22)*	0.30	0.04*
Daily use of sugary drinks vs not	–	–	–	0.30 (–0.06 to 0.66)	0.19	0.10	–	–	–	0.35 (–0.06 to 0.75)	0.21	0.09
Daily use of sugary foods vs not	–	–	–	–	–	–	0.08 (–0.27 to 0.42)	0.18	0.67	–0.07 (–0.45 to 0.32)	0.20	0.73

**Statistically significant at P < 0.05. All models are adjusted for socioeconomic variables including mother and father education, type of residence and number of persons per bedroom in addition to plaque index score.*

Model 1: includes brushing ≥ 2 times daily using fluoridated toothpaste and currently smoking daily; pseudo R^2 for goodness of fit = 0.30.

Model 2: includes variables in model 1 + daily use of sugary drinks; pseudo R^2 for goodness of fit = 0.41.

Model 3: includes variables in model 1 + daily use of sugary foods; pseudo R^2 for goodness of fit = 0.35.

Model 4: includes variables in model 1 + daily use of sugary drinks + daily use of sugary foods; pseudo R^2 for goodness of fit = 0.41.

B = regression coefficient, CI = confidence interval, SE = standard error.

Our study had some limitations related to its design. As a cross-sectional study, time sequence could not be proved; therefore proof of causality needs future longitudinal studies. The schools included could have introduced a degree of sampling bias that might have affected our conclusions. Similarly, the inclusion of only male students limits the generalizability of our findings. Further studies including randomly selected male and female students from public and private schools in different regions in the country would allow generalization to the entire population in Saudi Arabia. Our measurement of brushing focused on frequency. Future studies could add other aspects by measuring brushing time and force applied using toothbrushes with electronic sensors. We assessed gingivitis using the Löe and Silness gingival index on selected teeth (*29*). This partial recording might have affected our estimate of gingivitis prevalence or severity. However, it was previously reported that the chance of underestimating gingivitis because of partial recording is lowest among adolescents and young subjects since the sites assessed are available compared with older adults whose chances of tooth loss are higher (*43*). The prevalence of smoking might have been underestimated because it was self-reported. This might be particularly relevant in this young age group in the conservative Saudi society. However, this method has been widely used to assess smoking among different groups in other countries (*44*).

Our results can be generalized to those with similar backgrounds to the participants in our study, namely 13-15-year-old male Saudis with university-educated parents who come from the more advantaged groups of society. Other researchers have reported better gingival health among children of more educated parents (*38*). Applied to our setting, this means that the gingival condition of the general population of Saudi males of similar age might be worse than we found, which raises a concern that needs to be addressed through health education.

Our study provides evidence supporting the association of lifestyle habits with the severity of gingivitis in young Saudi males. Daily use of sugary drinks compounded the effect of daily smoking making its association with more severe gingivitis statistically significant. There is a need to promote healthy lifestyle habits in this age group using health education strategies. This is important in view of the relationship between diseases such as diabetes, cardiovascular problems and cancers and the lifestyle habits studied as well as periodontitis which is associated with gingivitis.

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Competing interests: None declared.

Association entre la sévérité de la gingivite et les habitudes de vie des jeunes garçons saoudiens

Résumé

Contexte : La gingivite est un facteur de risque de la parodontite qui est associée à plusieurs troubles systémiques. Alors que l'adolescence est une période clé pour tenter d'établir de bonnes pratiques d'hygiène buccale, il existe relativement peu d'études sur la gingivite chez l'adolescent.

Objectifs : La présente étude visait à évaluer l'association entre les habitudes de vie et la sévérité de la gingivite chez les jeunes saoudiens de sexe masculin.

Méthodes : Un échantillon de garçons saoudiens (n = 685) âgés de 13 à 15 ans originaires de Dammam et Khobar a été inclus dans une étude transversale en 2016. Un questionnaire a permis d'étudier le milieu socioéconomique et les habitudes de vie quotidiennes – brossage des dents, tabagisme et consommation de boissons et d'aliments sucrés. Des examens cliniques ont fait état de plaque dentaire et d'indices gingivaux sur six dents de référence. L'analyse de régression a été utilisée afin d'évaluer l'association entre la sévérité de la gingivite et le brossage des dents couplé au tabagisme, ajustés en fonction des boissons et des aliments sucrés, des facteurs socio-économiques et de la plaque dentaire.

Résultats : Le taux de réponse était de 96,2 %. Seuls 38 % des répondants se brossaient les dents deux fois par jour, 10,2 % fumaient, et 82,8 % et 68,3 % consommaient des boissons et des aliments sucrés respectivement. La prévalence de la plaque dentaire et de la gingivite était de 87,9 % et 73,9 % respectivement. Le brossage des dents n'était pas associé de façon significative à une gingivite plus sévère (coefficient de régression = 0,17 ; IC à 95 % : –0,16 à 0,49). Le fait de fumer était associé de façon significative à une gingivite plus sévère seulement lorsqu'il y avait également consommation de boissons sucrées (coefficient de régression = 0,63 ; IC à 95 % : 0,04 à 1,22).

Conclusions : La sévérité de la gingivite n'était pas associée au brossage des dents, mais augmentait de façon significative lorsque le tabagisme couplé à la consommation de boissons sucrées était présent, indiquant ainsi l'effet d'habitudes de vie malsaines sur la santé gingivale ainsi que la nécessité de faire la promotion de modes de vie sains au sein de ce groupe d'âge.

العلاقة بين التهاب اللثة ونمط الحياة في صفوف الشبان السعوديين

مها الطنطاوي، عادل العقل

الخلاصة

الخلفية: يمثل التهاب اللثة أحد عوامل خطر التهاب اللثة، الذي يرتبط بعدة اضطرابات نظامية. وعلى الرغم من أهمية مرحلة المراهقة باعتبارها فرصة لإرساء ممارسات جيدة لصحة الفم، صدر عدد قليل من الدراسات بشأن التهاب اللثة في صفوف المراهقين.

الأهداف: عمدت هذه الدراسة إلى تقييم الارتباط بين العادات المتصلة بنمط الحياة وشدة التهاب اللثة في صفوف الذكور في المملكة.

طرق البحث: أُدرجت عينة من الذكور السعوديين (n = ٦٨٥) في الفئة العمرية ١٣–١٥ من الدمام والخبر في المنطقة الشرقية في دراسة مقطعية أجريت عام ٢٠١٦. وأجري استبيان لتقييم الخلفية الاجتماعية والاقتصادية ونمط الحياة اليومي – تنظيف الأسنان بالفرشاة والتدخين الحالي واستهلاك المشروبات والأطعمة المحلاة. وسجلت الفحوص السريرية ترسبات ومؤشرات لثوية على ستة أسنان قياسية. واستُخدم تحليل انحدار لتقييم الارتباط بين شدة التهاب اللثة وغسل الأسنان بالفرشاة والتدخين بعد احتساب المشروبات والأطعمة المحلاة والعوامل الاقتصادية والاجتماعية والترسبات السنية.

النتائج: بلغ معدل الاستجابة ٢ , ٩٦٪. وأفاد ٣٨٪ فقط من المستجيبين بمواظبتهم على غسل أسنانهم بالفرشاة مرتين يوميا، في حين أفاد ٢ , ١٠٪ باعتيادهم التدخين، وأفاد ٨ , ٨٢٪ و٣ , ٦٨٪ باستهلاكهم المشروبات والأطعمة المحلاة على الترتيب. وبلغ معدل انتشار الترسبات السنية والتهاب اللثة ٩ , ٨٧٪ و٩ , ٧٣٪ على الترتيب. ولم يتبين أي ارتباط ذي دلالة بين غسل الأسنان بالفرشاة وازدياد حدة التهاب اللثة (معامل الانحدار = ١٧ , ٠؛ ٩٥٪ CI: –١٦ , ٠ to ٤٩ , ٠). وتبين وجود ارتباط ذي دلالة بين التدخين الحالي وازدياد حدة التهاب اللثة فقط عند استهلاك مشروبات محلاة (معامل الانحدار = ٦٣ , ٠؛ ٩٥٪ CI: ٠٤ , ٠ to ٢٢ , ١).

الاستنتاجات: لم يتبين وجود ارتباط بين حدة التهاب اللثة وغسل الأسنان بالفرشاة ولكن ازداد الارتباط بصورة ذات دلالة في حالة التدخين مع تناول مشروبات محلاة، مما يدل على أثر نمط الحياة غير الصحي على صحة اللثة والحاجة إلى التشجيع على اتباع نمط حياة صحي في هذه الفئة العمرية.

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Prevalence of and risk factors for overweight and obesity among adolescents in Morocco

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Abstract

Background: Overweight and obesity among children and adolescents is a major public health concern and their prevalence is increasing worldwide at an alarming rate in both developing and developed countries.

Aims: The objective of this study was to assess the prevalence of overweight and obesity in a representative sample of 12–18-year-old schooled adolescents in Fez, Morocco, and to investigate the possible risk factors associated with adolescent obesity.

Methods: A cross-sectional study was conducted between September 2014 and March 2015 in public secondary schools. Data were collected from a questionnaire. Weight and height were measured, and body mass index was calculated. Weight was classified according to the reference curves of WHO (2007). Data on 1818 adolescents aged 12–18 years were used.

Results: The prevalence of overweight was 7.69% and that of obesity was 3.41%. Overweight and obesity in adolescents were positively correlated to having a father (odds ratio (OR) = 1.58, *P* = 0.008) or a mother with higher education (OR = 1.56, *P* = 0.009). High family income (OR = 2.115, *P* = 0.028), motorized transport to school (adjusted OR = 1.77, *P* = 0.017), using a computer for > 4 h/day (OR: 2.56, *P* = 0.004) and frequent consumption of soda and soft drinks (OR = 1.42, *P* = 0.04) were also correlated with an increased risk for overweight and obesity.

Conclusions: This study provides useful findings that could be elaborated on and expanded in studies on overweight and obesity among adolescents in Morocco.

Keywords: Obesity, adolescents, nutrition, diet, Morocco.

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Introduction

Obesity and overweight constitute a major public health problem, and their prevalence is increasing worldwide at an alarming rate in both developing and developed countries (1). WHO has described obesity as the worst non-infectious epidemic in history (1). During the past two decades, the prevalence of overweight and obesity in many developed and developing countries has also increased rapidly in children, largely due to growing urbanization and nutrition transitions (2). The nutrition transition is generally associated with increased consumption of energy-dense foods that are low in fibre and high in sugar and of sweetened drinks as well as a decrease in physical activity and a more sedentary lifestyle (3).

Obesity is potentially serious because of its impact on the physical and psychological health of children and adolescents. It is strongly associated with numerous deleterious health issues (4). Metabolic complications associated with obesity in childhood greatly increase the risks for type 2 diabetes, hypertension, chronic inflammation and cardiovascular diseases (5). Many risk factors contribute to overweight and obesity, but they include genetic, biological, social and environmental factors, which affect weight gain through the mediators of energy intake and energy expenditure (6).

As in many other developing countries, Morocco is now facing the phenomenon of epidemiological transition (7). This has led to new health problems in the country, such as childhood overweight and obesity. The high burden of childhood obesity calls for rigorous investigations of its determinants, context-specific patterns and associated factors. The objective of this study was to assess the prevalence of overweight and obesity in a representative sample of 12–18-year-old schooled adolescents in the city of Fez, Morocco, and to investigate the possible associations with sociodemographic and lifestyle factors.

Methods

Study design and sample

Data from the Regional Academy for Education in Fez indicated that 151 974 adolescents were enrolled in secondary schools, 92% (139 812 students) of whom attended public schools and 8% (12 162 students) attended private schools. A cross-sectional study was conducted between September 2014 and March 2015.

The sample size was calculated from a sample proportion of overweight or obesity of 50%, with 95% confidence intervals (CIs) and a margin error of 0.03. The

sample proportion was assumed to be 0.50, which gave the maximum possible sample size required. The sample size was calculated from the formula:

$$n = N^*X / (X + N - 1),$$

where $X = Z_{\alpha/2}^2 * p*(1-p) / MOE^2$, $Z_{\alpha/2}$ is the critical value of the normal distribution at $\alpha/2$ (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), MOE is the margin of error, p is the sample proportion, and N is the population size (139 812 students). This method indicated that the required minimal sample size was 1060 adolescents. Additional students were included to account for missing data, and the final sample comprised 1818 adolescents randomly recruited from public secondary schools in Fez (909 boys and 909 girls aged 12–18 years) , who completed the questionnaire.

The secondary schools were selected to ensure representation of all the city districts. The city is divided into 12 districts and has a total of 95 secondary schools, and one secondary school was randomly selected from each district. Classes were then selected at each grade by a simple random method. In this way, one class was selected in each of the six grades (grades 1, 2, 3 for junior level and grades 4,5, 6 for senior level) in each secondary school. All classes were mixed (males and females), and all participants were healthy, with no physical disabilities.

Ethical permission to carry out the study was obtained from the Regional Academy for Education in Fez. Directors, teachers and students at the selected secondary schools were informed about the procedures and the purpose of the study. The field survey included anthropometric measurements and a questionnaire survey, which was administered to all participants. The questionnaires were completed anonymously to respect confidentiality.

Anthropometric measurements

Weight (kg) and height (cm) were measured, and body mass index (BMI) was calculated as weight in kilograms divided by height in metres squared (kg/m^2) for each adolescent. Corpulence was classified from the WHO reference curves (2007) for children aged 5–19 years (*8*).

Socioeconomic and lifestyle variables

The questionnaire used in this study was adapted from that of a previous study conducted in Morocco (*9*). Its validity was examined in a pilot study of 50 adolescents, which showed that it was acceptable and understandable. The questionnaire elicited information on demographic and socioeconomic variables, meal pattern, eating habits, physical activity and sedentary time.

Parents' education level was categorized into three groups. Parents who had never attended school or only primary school were considered to have a low educational level; medium level of education corresponded to secondary education (junior to senior high-school), and a high educational level corresponded to higher education and university. The monthly income of the family was used as a class variable in the following categories: low socioeconomic level, a salary < 6000 Moroccan dirhams (MAD; 1 MAD = 0.09 €) per month; medium level, a salary of 6000–10 000 MAD per month; and high socioeconomic level, a salary > 10 000 MAD per month.

The survey included questions about the frequency of practising sports and other physical activity during a typical week. Sedentary time was assessed as time spent watching television (hours per day), use of a computer (hours per day) and the mode of transport to school (walking or motoring). The questionnaire also addressed sleep duration (h/day) and dietary behaviour, such as the number and regularity of daily meals, the frequency of eating between meals and the frequency of consumption of certain types of foods per week.

Statistical analysis

The data were analysed with Epi Info, version 7.1.3.3 software. Means and percentages were used for descriptive analyses. Unpaired comparisons were performed by Student's t test (mean values). For the purpose of the analysis, the adolescents were divided into those of normal weight and those who were overweight or obese. Differences in proportions between groups were investigated with the chi-squared test. $P < 0.05$ was considered statistically significant. Logistic regression was performed to assess the association between the factors of interest and overweight, including obesity. The association between overweight or obesity and the factors considered was determined by univariate analysis. Crude odds ratios (ORs) and 95% confidence intervals (CIs) were calculated to measure the strength of associations. To elucidate the relations among several variables, we conducted a multivariate analysis by logistic regression. Factors associated with inclusion at $\alpha < 20\%$ in univariate analyses were included in the initial multivariate logistic model with additional factors reported to be associated with overweight and obesity in previous studies. The level of significance in multivariate analyses was set at $P < 0.05$.

Results

We included 1818 adolescents (909 girls and 909 boys) with mean ages of 16.03 ± 1.67 years for boys and 15.58 ± 1.68 years for girls. Table 1 shows the main anthropometric characteristics of the sample. No significant differences were found between boys and girls in age, weight, height or BMI. The distribution of corpulence according to BMI is shown in Table 2. Overall, the prevalence of underweight was 3.05%, that of overweight was 7.69%, and that of obesity was 3.41%. More boys were underweight (3.96%) than girls (2.1%), and the difference was statistically significant ($P = 0.028$). The prevalence of overweight was 8.25% for girls and 7.15% for boys, but the difference was not statistically significant ($P = 0.37$). The prevalence of obesity was higher among girls (3.96%) than boys (2.86%), but, again, the difference was not significant ($P = 0.19$).

Table 3 shows the distribution of normal, overweight and obese adolescents in relation to socioeconomic and lifestyle variables. We found a statistically significant

Table 1 Anthropometrics of the study sample

	Boys (*n* = 909)		Girls (*n* = 909)		*P*
	Mean	SD	Mean	SD	
Age (years)	16.03	1.67	15.58	1.68	> 0.05
Weight (kg)	56.34	9.80	53.37	8.90	> 0.05
Height (m)	1.66	0.09	1.60	0.07	> 0.05
BMI (kg/m²)	20.11	2.47	20.61	2.82	> 0.05

BMI, body mass index; SD, standard deviation
P for t test

Table 2 Distribution of corpulence according to BMI

Corpulence	Boys (*n* = 909)		Girls (*n* = 909)		Total (1818)		*P*
	n	%	n	%	n	%	
Underweight	36	3.96	19	2.1	55	3.03	0.028*
Normal weight	782	86.02	779	85.69	1561	85.86	0.83
Overweight	65	7.15	75	8.25	140	7.69	0.37
Obese	26	2.86	36	3.96	62	3.41	0.19
Overweight and obese	91	10.01	111	12.21	202	11.11	0.13

P for χ^2 test
** Significant*

relation between family income, reported by 1763 adolescents (55 missing values), and the weight of adolescents (P = 0.004), the prevalence of overweight and obesity increasing with increasing family income. The prevalence of overweight and obesity also increased significantly with the level of education of the father (14.69% for high and 8.91% for low education; P = 0.004) and the mother (18.42% for high and 9.33% for low; P = 0.001).

The frequency of overweight and obesity further increased with the number of hours per day spent watching television, although the relation was not significant (P = 0.32). Time spent using a computer was, however, statistically significantly related to the prevalence of overweight and obesity, the prevalence being higher in adolescents who spent more than 4 h/day using a computer than in those who spent < 1 h/day (or a few times a week) (P = 0.003). No significant association was found between the daily duration of sleep and risk for overweight or obesity (P = 0.75).

We found no statistically significant relation between the prevalence of overweight and obesity and practice of sport at school (P = 0.56), although the prevalence of overweight was lower among adolescents who practised physical activity outside school every week (P = 0.02). The prevalence of overweight and obesity was higher among adolescents who went to school in motor vehicles than among those who walked to school (P = 0.001).

The eating habits of normal and overweight adolescents are shown in Table 4. No statistically significant associations were found between adolescents who were overweight and and those of normal weight who ate breakfast regularly (P = 0.87), ate lunch regularly (P = 0.46), ate dinner regularly (P = 0.14) or ate between meals (P = 0.88). A statistically significant relation was seen between the prevalence of overweight and the frequency of consumption of soda and soft drinks (P = 0.03).

Similarly, in the multivariate logistic regression analysis (Table 5), overweight and obesity in adolescents were significantly associated with higher education of both the father (adjusted OR = 1.58; 95% CI, 1.13–2.21; P = 0.008) and the mother (adjusted OR = 1.56; 95% CI, 1.11–2.18; P = 0.009); family income (2.12, 1.08–4.14; P = 0.028); transport to school in a motor vehicle (1.77, 1.10–2.82; P = 0.017); use of a computer for > 4 h/day (2.56, 95% CI, 1.33–4.93; P = 0.004); and drinking soda and soft drinks three or more times a week (1.42, 1.01–1.98; P = 0.04).

Discussion

In this study, the prevalence of overweight was 7.29% and that of obesity was 3.41%. This result is consistent with those of surveys in other Moroccan cities (*10*,*11*). The prevalence of overweight and obesity among schoolchildren aged 7–14 years in Rabat were 5.1% and 3.7%, respectively (*10*), and Kaoutar et al. (2013) in Marrakech reported a prevalence of overweight and obesity of 9.1% in a sample of 1407 schooled adolescents aged 12–18 years (*11*). Studies in other countries of the Maghreb found similar or higher rates. In Tunisia, the prevalence of overweight and obesity among adolescents aged 15–19 years was estimated to be 15% and 2.6%, respectively (*12*). In Algeria, the prevalence was higher, one study showing a prevalence of 5.26% for overweight and 18.64% for obesity among children aged 6–12 years (*13*). The differences between countries of the Maghreb might be due to differences in period, gender, the targeted age groups and methods (*14*, *15*).

Table 3 Numbers and percentages of normal and overweight or obese adolescents according to socioeconomic and lifestyle variables

	Normal weight		Overweight or obese		Total		*P*
	n	%	*n*	%	N	%	
Gender							
Boys	782	89.57	91	10.43	873	100	0.18
Girls	779	87.52	111	12.48	890	100	
Total	1561	88.54	202	11.46	1763	100	
Average family income (MAD/month)							
Low (≤ 6000)	1402	89.07	172	10.93	1574	100	0.004*
Medium (6000–10 000)	85	83.33	17	16.67	102	100	
High (≥ 10 000)	42	76.36	13	23.64	55	100	
Not reported	32	100	0	0	32	100	
Total	1561	88.54	202	11.46	1763	100	
Father's education level							
Low	859	91.09	84	8.91	943	100	0.004*
Medium	458	85.77	76	14.23	534	100	
High	244	85.31	42	14.69	286	100	
Total	1561	88.54	202	11.46	1763	100	
Mother's education level							
Low	1127	90.66	116	9.34	1243	100	0.001*
Medium	341	83.99	65	16.01	406	100	
High	93	81.58	21	18.42	114	100	
Total	1561	88.54	202	11.46	1763	100	
Television viewing (h/day)							
≤ 1	511	90.45	54	9.55	565	100	0.32
1–2	665	88.21	89	11.80	754	100	
2–4	235	87.36	34	12.64	269	100	
≥ 4	150	85.71	25	14.29	175	100	
Total	1561	88.54	202	11.46	1763	100	
Use of computer (h/day)							
A few times a week	167	91.98	15	8.02	182	100	0.003*
≤ 1	556	92.52	47	7.48	603	100	
1–2	455	87.19	68	12.81	523	100	
2–4	226	86.18	38	13.82	264	100	
≥ 4	157	82.74	34	17.26	191	100	
Total	1561	88.54	202	11.46	1763	100	
Sleep duration (h/day)							
< 8	574	89.31	71	10.69	645	100	0.75
9–10	376	87.93	53	12.07	429	100	
> 10	611	89.09	78	10.91	689	100	
Total	1561	88.54	202	11.46	1763	100	
Practise sports at school							
Yes	1523	88.82	198	11.18	1721	100	0.56
No	38	91.49	4	8.51	42	100	
Total	1561	88.54	202	11.46	1763	100	
Practice of sport outside school							
Yes	524	90.97	52	9.03	576	100	0.02*
No	1037	87.36	150	12.64	1187	100	
Total	1561	88.54	202	11.46	1763	100	
Mode of transport to school							
Walking	1431	89.32	171	10.68	1602	100	0.001*
Motor vehicle	130	80.74	31	19.26	161	100	
Total	1561	88.54	202	11.46	1763	100	

MAD, Moroccan dirham
P for χ^2 test
**Significant*

Table 4 Numbers and percentages of normal and overweight or obese adolescents according to dietary behaviour

Dietary behaviour	Normal weight		Overweight or obese		Total		*P*
	n	%	*n*	%	*n*	%	
Eat breakfast regularly each day							
Yes	1141	88.66	146	11.34	476	100	0.87
No	420	88.24	56	11.76	1287	100	
Total	1561	88.54	202	11.46	1763	100	
Eat lunch regularly each day							
Yes	1511	88.67	193	11.33	1704	100	0.46
No	50	8.75	9	15.25	59	100	
Total	1561	88.54	202	11.46	1763	100	
Eat dinner regularly each day							
Yes	1021	87.71	143	12.29	1164	100	0.14
No	540	90.15	59	9.85	599	100	
Total	1561	88.54	202	11.46	1763	100	
Eat between meals							
Yes	940	88.68	120	11.32	1060	100	0.88
No	621	88.34	82	11.66	703	100	
Total	1561	88.54	202	11.46	1763	100	
Fruit consumption (days/week)							
< 3	829	86.99	124	12.94	953	100	0,06
≥ 3	732	90.37	78	10.04	810	100	
Total	1561	88.54	202	11.46	1763	100	
Vegetable consumption (days/week)							
< 3	277	85.76	46	14.24	323	100	0.12
≥ 3	1284	89.17	156	10.83	1440	100	
Total	1561	88.54	202	11.46	1763	100	
Milk and dairy product consumption (days/week)							
< 3	917	89.73	105	10.27	1022	100	0.07
≥ 3	644	86.91	97	13.09	741	100	
Total	1561	88.54	202	11.46	1763	100	
Soda and soft drink consumption (days/week)							
< 3	1202	89.51	141	10.49	1343	100	0.03*
≥ 3	359	85.47	61	14.53	420	100	
Total	1561	88.54	202	11.46	1763	100	
Sweets and chocolate consumption (days/week)							
< 3	1310	88.87	164	11.13	1474	100	0.37
≥ 3	251	86.85	38	13.15	289	100	
Total	1561	88.54	202	11.46	1763	100	
Cake, pastry, biscuit consumption (days/week)							
< 3	1313	89.38	156	10.62	1469	100	0.07
≥ 3	248	84.36	46	15.64	294	100	
Total	1561	88.54	202	11.46	1763	100	

Elsewhere, the prevalence of overweight and obesity also varies considerably. In studies conducted in Middle East countries, the rates of overweight were higher than in our study. For instance, the prevalence of overweight and obesity among Kuwaiti elementary schoolchildren was 20.2% and 16.8%, respectively (*16*). The prevalence of overweight is much higher in developed countries. In the United Kingdom, for example, the prevalence was 23.6% among boys and 27.9% among girls (*17*), and, in the USA, the prevalence was estimated to be 35.3% for boys and 34.1% for girls (*18*). These results are difficult to compare because of the differences in the reference

Table 5 Results of logistic regression: adjusted odds ratios (aORs) and 95% confidence intervals (95% CIs) for the risk of overweight (including obesity) in relation to selected factors

Risk factor	Category	Reference	aOR	95% CI	*P*
Gender	**Boy**	**Girl**	**0.922**	**0.683–1.246**	**0.607**
Education of father	Medium	Low	1.285	0.846–1.952	0.283
	High		1.576*	1.125–2.208	0.008
Education of mother	Medium	Low	1.553	0.908–2.654	0.107
	High		1.556*	0.112–2.179	0.009
Average family income (MAD/month)	6000–10 000	≤ 6000	1.374	0.784–2.406	0.266
	≥ 10 000		2.115*	1.081–4.138	0.028
Computer use (h/day)	≤ 1	A few times a week	0.925	0.501–1.708	0.804
	1–2		1.527	0.843–2.766	0.162
	2–4		1.729	0.913–3.276	0.092
	≥ 4		2.561*	1.331–4.931	0.004
Practise sport outside school	Yes	No	0.682	0.458–1.016	0.064
Mode of transport to school	Motor vehicle	Walking	1.765*	1.104–2.821	0.017
Television viewing (h/day)	1–2	≤ 1	1.255	0.878–0.795	0.211
	2–4		1.363	0.864–0.152	0.182
	≥ 4		1.569	0.943–2.607	0.082
Sleep duration (h/day)	9–10	< 8	1.034	0.735–1.454	0.847
	> 10		1.145	0.784–1.673	0.428
Regular breakfast intake per day	Yes	No	0.919	0.675–1.284	0.622
Eat between meals every day	Yes	No	1.072	0.789–1.457	0.653
Soda and soft drinks intake (days/week)	≥ 3	< 3	1.415*	1.014–1.975	0.041

MAD, Moroccan dirham

**P: significance*

[a]OR: odds ratio adjusted in multivariate regression model for each independent factors

values used to classify weight, sample size, age group and sociodemographic and genetic factors.

We found a significant relation between family income and overweight in adolescents, the prevalence of overweight and obesity increasing with higher family income. A similar finding was reported in a study of Moroccan adults, in which family income, used as a determinant of socioeconomic status, was strongly associated with overweight and obesity (*19*), and the study in Tunisia indicated a link between living in household of a high socioeconomic level and overweight among adolescents (*12*). The literature is, however, contradictory, with some studies reporting that obesity is more prevalent among people of low socioeconomic status (*20*) and others showing the opposite (*21,22*). Studies in developed countries in particular indicate excess weight among children in families of lower socioeconomic status (*23*), while in studies in developing countries excess weight is found predominantly among children and adolescents in families of higher socioeconomic status (*24*). Several explanations have been proposed. The low prevalence of obesity in groups of low socioeconomic status in developing countries is related to food scarcity, patterns of high energy expenditure and the greater capacity of the elite to obtain adequate food supplies (*25*). The inverse correlations reported in some studies may be due to the benefits of economic growth, notably better access to food and high energy expenditure by poorer social groups, difficulty in acquiring more expensive, less energy-dense foods and a trend towards less leisure time and fewer opportunities for exercise (*26*).

Another important risk factor of adolescents for overweight and obesity was having parents with a high educational level, in accordance with other studies (*22, 27–29*); however, studies in developed countries found that obesity was more strongly related to lower parental education (*30,31*). Our finding is related to the association between high parental educational level and occupation and consequently to higher socioeconomic status; therefore, their children have access to high-energy foods, such as fast foods, increasing their risk for obesity.

Watching television daily for ≥ 4 h was not associated with overweight or obesity in our study, although a previous study found a significant positive correlation with the risk of adolescents for overweight (*32*). We did find a statistically significant correlation between the prevalence of overweight and obesity and the number of hours spent using a computer, consistent with the findings of studies in Brazil and Portugal (*33,34*). Media use may reduce energy expenditure by replacing physical activity and also increase snacking, which is further encouraged by advertisements for energy-dense foods (*35*).

Practising sports at school was not significantly associated with overweight and obesity; however, the majority of the participants participated in school sports,

so the association would be difficult to identify. In our sample, practising sports outside schools was also not significantly associated with overweight and obesity. Other studies have shown the opposite. For instance, a study in Saudi Arabia showed that intense physical activity was inversely associated with adolescent obesity (*36*), and a strong negative association was reported between vigorous physical activity and total and central body fat in Spanish adolescents (*37*). Inadequate physical activity has been hypothesized to be an important contributing factor to the development of childhood obesity. A review of the influence of physical activity on adiposity among 5–18-year-olds showed that adiposity was reduced and aerobic capacity increased with more time spent in intense physical activity (*38*). Our finding that the mode of transport to school was associated with overweight and obesity is similar to those of other studies (*33*,*39*). Walking has been shown to be beneficial to health and weight control, while motorized vehicle use is associated with overweight and other disorders (*40*).

Overweight and obesity were significantly associated with a high frequency of drinking soda and soft drinks, in line with previous studies. For instance, the consumption of carbonated soft drinks was associated with obesity in Mexican–American children (*41*), and BMI was positively correlated with consumption of sugar-sweetened carbonated beverages in boys in Saudi Arabia (*42*).

Our findings should be interpreted in the light of the potential limitations of the study. The risk factors for overweight and obesity were identified from self-reported data, which could be biased by socially desirable reporting, even though students were encouraged to be honest by assuring them that their responses were anonymous and confidential. Furthermore, the results reflect only the situation of adolescents attending public high schools in a city. It would be important also to study private high schools, in which most of the students belong to upper socioeconomic classes.

Conclusion

This study provides useful findings that could be elaborated and expanded in future studies on overweight and obesity among adolescents in Morocco. Primary prevention of obesity should be a national public health priority in our country. Initiatives to combat overweight and obesity among children and adolescents must include monitoring of nutritional status at both the individual and the collective level, and strategies for the prevention, diagnosis and early treatment of overweight and obesity should be introduced before the problem spreads more widely.

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Prévalence et facteurs de risque du surpoids et de l'obésité parmi les adolescents au Maroc

Résumé

Contexte : Le surpoids et l'obésité chez l'enfant et l'adolescent représentent une préoccupation de santé publique majeure et leur prévalence est en augmentation de manière alarmante dans les pays industrialisés et les pays en développement.

Objectif : La présente étude avait pour objectif d'évaluer la prévalence du surpoids et de l'obésité dans un échantillon représentatif d'adolescents scolarisés âgés de 12 à 18 ans à Fès, au Maroc, et d'examiner les facteurs de risque potentiels associés à l'obésité des adolescents.

Méthodes : Une étude transversale a été menée entre septembre 2014 et mars 2015 dans des établissements d'enseignement secondaire publics. Des données ont été collectées au moyen d'un questionnaire. Le poids et la taille ont été mesurés, et l'indice de masse corporelle a été calculé. Le poids a été classé selon les courbes de référence de l'OMS (2007). Les données relatives à 1818 adolescents âgés de 12 à 18 ans ont été utilisées.

Résultats : La prévalence du surpoids était de 7,69 % et celle de l'obésité de 3,41 %. Le surpoids et l'obésité chez les adolescents avaient une corrélation positive avec le niveau d'éducation supérieur du père (odds ratio (OR) = 1,58, p = 0,008) ou de la mère (OR = 1,56, p = 0,009). Un revenu familial élevé (OR = 2,115, p = 0,028), un transport scolaire motorisé (OR ajusté = 1,77, p = 0,017), l'utilisation d'un ordinateur plus de quatre heures par jour (OR = 2,56, p = 0,004) et la consommation régulière de sodas et de boissons gazeuses (OR = 1,42, p = 0,04) étaient également corrélés à une augmentation du risque de surpoids et d'obésité.

Conclusion : La présente étude a fourni des résultats utiles qui pourront être approfondis et étendus à d'autres études sur le surpoids et l'obésité parmi les adolescents au Maroc.

انتشار فرط الوزن والسِمنة وعوامل الخطر المسببة لهما بين المراهقين في المغرب

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الخلاصة

الخلفية: يشكل فرط الوزن والسمنة بين الأطفال والمراهقين شاغلاً رئيسياً من شواغل الصحة العامة ويتزايد انتشاره في جميع أنحاء العالم بمعدل ينذر بالخطر في كل من البلدان النامية والمتقدمة.

الهدف: كان الهدف من هذه الدراسة هو تقييم مدى انتشار فرط الوزن والسمنة في عينة تمثّل المراهقين في المدارس الذين تتراوح أعمارهم بين ١٢ و١٨ سنة في مدينة فاس بالمغرب، واستقصاء عوامل الخطر المحتملة المرتبطة بالسمنة لدى المراهقين.

طرق البحث: أجريَت دراسة مقطعية بين أيلول/ سبتمبر ٢٠١٤ وآذار/ مارس ٢٠١٥ في المدارس الثانوية العامة، وجُمِعَت البيانات عن طريق استبيان. وقيس الوزن والطول، وحُسِب مؤشر كتلة الجسم. وصُنِّفَ الوزن بحسب المنحنيات المرجعية لمنظمة الصحة العَالمية (٢٠٠٧). وحُلِلَت بيانات ١٨١٨ مراهقاً تتراوح أعمارهم بين ١٢ و١٨ سنة.

النتائج: بلغ معدل انتشار فرط الوزن ٦٩ ,٧٪ ومعدل انتشار السمنة ٤١ ,٣٪. وارتبطت زيادة الوزن والسمنة لدى المراهقين ارتباطاً إيجابياً بوجود أب متعلم تعليماً عاليًا (نسبة الأرجحية = ٥٨ ,١، P= ٠٠٨ ,٠) أو أم متعلمة تعليماً عاليًا (نسبة الأرجحية = ٥٦ ,١، P=٠٠٩ ,٠). وارتبط أيضًا بزيادة خطر الإصابة بفرط الوزن والسمنة كل من دخل الأسرة المرتفع (نسبة الأرجحية = ١١٥ ,٢، P= ٠٢٨ ,٠)، والذهاب بالمركبات إلى المدرسة (نسبة الأرجحية المصححة = ٧٧ ,١، P=٠١٧ ,٠)، والجلوس على الكمبيوتر لأكثر من ٤ ساعات يوميًا (نسبة الأرجحية= ٥٦ ,٢، P=٠٠٤ ,٠)، وكثرة استهلاك الصودا والمشروبات الغازية (نسبة الأرجحية= ٤٢ ,١، P=٠٤ ,٠).

الاستنتاجات: تقدم هذه الدراسة نتائج مفيدة يمكن التعمق فيها وتوسيع نطاقها في الدراسات المتعلقة بفرط الوزن والسمنة بين المراهقين في المغرب.

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Quality of care provided to children with cerebral palsy, Alexandria, Egypt

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Abstract

Background: Assessing the quality of care has become increasingly important to health care providers, regulators and purchasers of care.

Aims: This study assessed the quality of care provided to children with cerebral palsy attending Alexandria University Children's Hospital, Egypt.

Methods: Paediatric neurology residents (n = 15) who provided care to children with cerebral palsy at the hospital completed a structured checklist assessing their compliance with generic care standards. The medical records of 84 children with cerebral palsy who received care at the hospital were reviewed using the same checklist. Another checklist was completed by the head of the paediatric neurology unit, medical director of the hospital, head of physical medicine and head nurse to assess adherence to process and service improvement standards. Face-to-face interviews were conducted with the caregivers/parents of the children using a client satisfaction questionnaire.

Results: Based on what was reported by health care providers, most did not adhere to the recommended practices in the care of children with cerebral palsy. Review of the medical records also showed a lack of compliance with standards. The mean total satisfaction percentage score of parents/caregivers was 55.43% (SD 18.16). Satisfaction was particularly low for waiting time, waiting area and availability of required facilities for their child's care.

Conclusions: There is a wide gap between the actual care provided to children with cerebral palsy and the recommended standards. Moreover, the documentation system in the hospital is poor. A quality improvement plan is needed for the provision of care to children with cerebral palsy.

Keywords: Cerebral palsy, Child care, Standard of care, Hospitals, Egypt

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Introduction

Cerebral palsy is the most common cause of motor disability in childhood (*1,2*). It accounts for 60% of severe motor disabilities in school-aged children (*3*). The prevalence of cerebral palsy is around 1.5–3 per 1 000 live births in both developed and developing countries (*4–6*). Differences in prevalence may be due to differences in the characteristics of the populations studied or may also be the result of variations in identifying cerebral palsy cases because of inconsistency in the definition and classification of the condition. A study in Egypt reported a prevalence of 2.04 per 1 000 live births among children in Al-Karga District, New Valley Governorate (*7*). Another study in Al-Quseir City, Red Sea Governorate reported a prevalence in children of 3.06 per 1 000 live births (*8*).

Assessment of children with cerebral palsy is best performed by a multidisciplinary team. Management aims at minimizing disability, improving quality of life and encouraging participation in society (*9*).

The demands of caring for a child with cerebral palsy are considerable, and parents have to deal with the continuously changing needs of their child. Disabilities associated with cerebral palsy affect children's independence and hence the lives of their caregivers. Caring for a child with cerebral palsy can negatively affect parent's physical and psychological health, social relationships, and financial situation. However, the quality and type of care given to children with cerebral palsy are likely to affect the resultant disability, and the quality of their lives and that of their families (*10,11*).

Measuring the quality of care has become increasingly important to health care providers, administrators, managers and policy-makers. Data from assessment of quality of care should be applied to improve the delivery of care and patient outcome (*12,13*). Explicit methods of measuring quality of care should be based on reliable, valid and standardized tools. Quality measures are usually categorized into structure, process and outcome measures. Structure and process measures are based mainly on the availability of standards of care and/or quality indicators (*13*).

The present study was conducted to assess the quality of care provided to children with cerebral palsy attending the Alexandria University Children's Hospital, Egypt.

Methods

Study design and setting

This was a cross-sectional study conducted at Alexandria University Children's Hospital, Egypt within its affiliated Paediatric Neurology Outpatient Clinic and Physical Medicine and Rehabilitation Clinic. The hospital provides care for children with cerebral palsy, including management of acute conditions, inpatient services, rehabilitation and follow-up care. The field work was carried out between 1 February and 30 April 2014.

Participants

The study included the following participants.

- Fifteen paediatric neurology residents working at Alexandria University Children's Hospital for more than 1 year and directly involved in the care of children with cerebral palsy.
- The Head of the Paediatric Neurology Unit, Medical Director of the Hospital, Head of Physical Medicine and Head Nurse of the Paediatric Neurology Department at Alexandria University Children's Hospital.
- Parents/caregivers of all children with cerebral palsy attending Alexandria University Children's Hospital during the period 1 February to 30 April 2014 (88 children).

Data collection

Health Care Improvement Scotland developed standards for care of children and young people who are experiencing difficulties that could be related to their mental health, known as integrated care pathways (ICPs) for mental health (14). The standards have 3 elements: process standards, generic care standards and service improvement standards (21 standards).

Process standards (9 standards) outline the infrastructure that must be in place in order to provide high quality care, the key tasks to be undertaken and who is responsible. Generic care standards (10 standards) describe the interactions and interventions that must be offered to anyone who accesses specialized child and adolescent mental health services. Service improvement standards (2 standards) ensure that ICPs are being implemented and actively used for data capture and variance analysis, leading to service improvements. Each standard includes a number of criteria to be fulfilled (14).

We developed a structured checklist of statements included in the process and service improvement standards in the ICPs that were relevant to the service provided to children with cerebral palsy in Egypt and best fit the culture, resources, and economic and administrative situation in Egypt. The checklist consisted of 19 statements with 3 possible answers (not met, partially met or fully met). It was completed by the Head of Paediatric Neurology Unit, Medical Director of the Hospital, Head of Physical Medicine and the Head Nurse of the Paediatric Neurology Department to assess the degree of adherence to process and service improvement standards.

A second checklist was designed based on the criteria of generic care standards in the ICPs. It included 33 statements divided into 4 domains, which related to standards of: care assessment (16 items), care planning (8 items), care delivery (5 items) and outcome (4 items). Each statement had 2 options, usually done or rarely done. This checklist was completed by the 15 paediatric neurology residents; none declined to participate.

The medical records of all children with cerebral palsy who regularly attended the paediatric neurology outpatient clinic (n = 84) were reviewed to assess their completeness according to the generic care standard using the same checklist filled by the paediatric neurology residents. Each item was marked as recorded or not recorded in the medical records.

Face-to-face interviews were held with the parents/caregivers of 88 children with cerebral palsy (the 84 whose records were reviewed and 4 other children who had no medical records at the clinic as they had just started coming to the clinic). None declined to participate. Education, marital status and working status of the caregivers were recorded. They were asked a general question about their overall satisfaction with the services provided at the hospital for their children. In addition, a structured client satisfaction questionnaire, consisting of 8 items, was used to assess their degree of satisfaction with specific aspects of the services: waiting time, waiting area, availability of facilities, number of days the services are available, cost of services, time allowed to discuss problems with care providers and the adequacy of the explanation received.

Data analysis

Data were coded and entered in Microsoft *Excel*. Descriptive statistical were mainly used. Numbers and percentages were used for conformity with generic care standards as reported by the residents and as documented in the medical records reviewed.

Range, mean and standard deviation (SD) for the total score for conformity to generic care standards was calculated twice – as reported by the residents and as documented in the medical records reviewed. Items that were not done or not recorded were scored zero and those that were always done or recorded were scored 1.

Parents' satisfaction was analysed using number and percentage as well as by calculating the total raw and percentage score for every parent (by giving a score of 0 for unsatisfied, 1 for uncertain and 2 for satisfied), and then calculating the mean satisfaction percentage score. The question about their overall satisfaction with the services provided at the hospital for their children was not included in the calculation of the total satisfaction score. Analysis of variance and Student t-test were used to examine the relationship between the mean satisfaction percentage score and caregiver characteristics, after testing for normality (Shapiro–Wilk test) and homogeneity of variances. A P-value ≤ 5 was considered statistically significant.

Ethical considerations

Approval for this study was obtained from the Research Ethics Committee of the Alexandria Faculty of Medicine. Verbal and written consent was obtained from all participants in the study after explaining the aim and procedures of the study. Complete confidentiality was ensured: the data were collected only by the researchers and no one else had access to them.

Results

Conformity to process and service improvement standards

Table 1 shows the conformity to process and service improvement standards as rated by the Head of the Paediatric Neurology Unit, Medical Director of the Hospital, Head of Physical Medicine and the Head Nurse in the

Table 1 Conformity to process and service improvement standards for care provided to children with cerebral palsy (CP) as reported by senior hospital managers

Not met	Partially met	Fully met
There are systems in the hospitals to record diagnostic and/or assessment information which allow for the recording of multiple values.	A named strategic lead and integrated pathway coordinator are present in the hospital for implementing a multiagency and multidisciplinary plan.	The relationship between local governance arrangement and integrated care pathways for CP children in hospital can be demonstrated.
The multi-agency and multi-disciplinary care team reviews individual and grouped variances.	Multiagency and multidisciplinary work forces (including advocacy services and voluntary organizations) are involved in the care pathway development process.	There is a local plan which includes details of how the hospital will deliver care for the children with CP who are accessing services for the first time or who are currently accessing services.
A survey of care providers for children with CP is conducted at least annually and the survey results acted upon.	Children with CP and their parents/carers are involved in the care pathway development process.	There is a secure system in place that allows for the recording of, and access to, information in the child's care record.
A survey of children with CP and their parents/carers about care they have received is conducted at least annually and the survey acted upon.	System is in place for awareness-raising, promotion and education sessions about the care pathway.	
	A process mapping exercise is carried out for : Identification of current patterns of service delivery and available resources Evaluation of the journey of care of children with CP Establishment of the strengths and weakness of current service provision Identification of demands on the service. Identification of gaps in services.	
	A local plan which includes timescales for the children with CP is developed and agreed	
	There are systems in place to monitor and demonstrate that the training and supervision needs of care providers for children with CP are acted upon and actively promoted	
	There are systems in place to ensure that these training and supervision needs and requirements are incorporated into the hospital development plans.	
	There are systems in place to record the number of children with CP accessing the hospital services.	
	Information is recorded and transferred in accordance with current recommendations on consent, confidentially and record-keeping standards.	
	There are systems in place for recording, collating, analysing, reporting and acting upon variances for children with CP.	
	The local management team reviews grouped variance to identify areas where service re-design can improve service delivery.	

neurology department. The majority of process and service improvement standards were not fully met (either totally unmet or only partially met) except for 3 standards: presence of a local plan with details of how the organization will deliver care for the children with cerebral palsy who are accessing services for the first time or who are currently accessing services; availability of a secure system that allows the recording of and access to information in the child's care record; and demonstrated relationship between local governance arrangements and ICP for children with cerebral palsy in hospital.

Standards that were totally unmet at the hospital included: lack of a system to monitor care providers of children with cerebral palsy and demonstrate that their training and supervision needs are acted upon and actively promoted; lack of an annual survey of children with cerebral palsy and their parents/carers about care they have received.

Conformity to generic care standards as reported by health care providers

Table 2 shows the reported adherence to the generic care standards of the 15 health care providers (residents) who were directly involved in the care of children with cerebral palsy at Alexandria University Children's Hospital.

Care assessment standards. During the initial assessment, developmental history is taken by most of the providers (80%), and 73% take a history of past and current interventions. Two thirds of the care providers reported that they usually assess the child for the presence of other associated co-morbidities. A schedule of routine visits for the child was reported by 73% of the providers. The majority of the providers reported that information on how the diagnosis of cerebral palsy was reached was not recorded and there was no cooperation with other agencies in the process of care. Only 33% of the care providers said they explained the diagnosis of cerebral palsy to the parents and none of them provided educational, social and lifestyle information and guidance to the parents.

Care planning standards. Two thirds of the providers reported that they recorded the timing of the child's reviews and 53% of them reported that the child's care plan was planned and agreed with parents/caregivers. Only 33% reported that the child care plan was based on multidisciplinary assessment, and its specific goals were identified. None of the providers recorded the child's care plan or his/her treatments and interventions in the child health record.

Care delivery standards. Regarding care delivery, particularly for children admitted as inpatients, 33% documented the reasons for admission in the child's follow-up record and 13% recorded the aim of the admission. Only 7% of the health care providers recorded the plan for discharge and length of inpatient stay.

Care outcome standards. Less than a half of the providers (47%) said they identified and recorded what had improved or what had got worse in the child's condition, and what aspects of the plan had been changed. All the care providers rarely recorded whether the planned outcomes were achieved or not.

Conformity to generic care standards as found in health care records

Our review of the health care records of 84 children with cerebral palsy to assess their conformity to the generic care standards are shown in Table 2.

Care assessment standards. In nearly all records, the diagnosis of cerebral palsy was documented. The majority of records (87%) included data on associated co-morbidities, and the developmental history of the child was noted in 63% of the records. On the other hand information on how the diagnosis of cerebral palsy was reached and the current and past interventions were documented in only 21% and 19% of the records respectively. Information given to the parents about cerebral palsy, and guidance and advice to them were noted in 20% of the records. The records do not include any system to record parents' disagreement with the child's care plan. No consent form signed by parents for the care and treatment was present.

Care planning standards. The timing of reviews was clear in only 44% of the records, while the specific goals of the care were identified in 98% of records. The child's care plan was documented in 59% of records.

Care delivery standards. The decision-making process, including when to start, review, maintain or end medications, and their side-effects were noted in 2% of the records. Few records contained data about the reasons and aims of inpatient admission (2%) and none had information about the actual length of stay. The plan for discharge was identified in 34% of the records.

Outcome standards. Only 20% of the records contained information about whether the planned outcome have been achieved or not. In addition, 33% and 1%of the records respectively documented what had improved and what had become worse in the child's conditions. The aspects of the child care that had been changed were identified in only 7%of the records.

Conformity scores

Table 3 shows the scores for conformity to the standards in the 4 care areas as reported by the health care providers and found in our review of the children's health records.

As reported by the health care providers, scores for care assessment standards ranged from 2 to 10 with a mean of 6.53 (SD 2.95). For care planning standards, out of 8 points, the mean score was 2.0 (SD 1.36). Scores ranged from 0 to 3 in both care delivery and outcome standards with a mean of 1.27 (SD 0.88) and 1.40 (SD 1.35) respectively.

Based on the review of the children's records, scores for care assessment standards ranged from 2 to 10 with a mean of 4.71 (SD 2.13). For care planning standards, the mean score was 2.52 (SD 1.61). Scores ranged from 0 to 3 for both care delivery and outcome standards with means of 0.45 (SD 0.59) and 0.89 (SD 1.13) respectively.

Table 2 Conformity to generic care standards as reported by health care providers and found in the review of the health care records of the children with cerebral palsy

Standards of care	Reported as usually done (*n* = 15) No. (%)	Recorded in the child's health file (*n* = 84) No. (%)
Care assessment standards		
History is taken on personal, family and social circumstances	7 (47)	24 (29)
Developmental history is taken	12 (80)	53 (63)
History of current and past interventions (including outcomes, adverse reactions, side-effects) is taken	11 (73)	16 (19.0)
A consent form is signed by parents/caregiver for care and treatment	1 (7)	0 (0)
The needs of the child and parents/caregivers are recorded	7 (47)	9 (11)
Additional vulnerabilities and co-morbidities are assessed and recorded	10 (67)	72 (86)
Educational, vocational status is recorded	4 (27)	7 (8)
Time for completion of holistic assessment is recorded	6 (40)	12 (14)
Schedule of routine visits is recorded	11 (73)	84 (100)
The diagnosis of cerebral palsy and other diagnoses is recorded	8 (53)	82 (98)
Information on how the diagnosis of cerebral palsy was reached is recorded	5 (33)	18 (21)
Diagnosis of cerebral palsy is explained to the parents	5 (33)	2 (2)
Appropriate information about cerebral palsy is given to the parents in writing	4 (27)	0 (0)
There is cooperation with other partner agencies	0	0
The care plan of the child is structured	7 (47)	8 (10)
Information and guidance (including educational, social and lifestyle advice) are provided to the parents	0 (0)	17 (20)
Care planning standards		
Appropriate advice is provided to parents about available voluntary organizations and advocacy services	1 (7)	9 (11)
The child care plan is planned and agreed with parents/care givers	8 (53)	18 (21)
The timings of review	10 (67)	37 (44)
The other agencies are involved in child's care and support and information is shared with them	1 (7)	6 (7)
The child care plan is based on multidisciplinary assessment of strengths of the rehabilitation process, needs and past experiences	5 (33)	11 (13)
The care plan of the child is clear	0 (0)	49 (59)
The child care plan identifies the specific goals of the child in relation to his/her condition	5 (33)	82 (98)
The child's tasks, treatments and interventions are identified in the care plan of the child	0 (0)	50 (60)
Care delivery standards		
When to initiate, review or end medication and recording of their side-effects	10 (67)	2 (2)
Reasons for inpatient admission are recorded	5 (33)	2 (2)
Aims of admission are recorded	2 (13)	0 (0)
Expected and actual length of inpatient stay are recorded	1 (7)	0 (0)
Plan for discharge is recorded	1 (7)	29 (34)
Outcome standards		
What has improved in the child's condition is recorded	7 (46)	28 (33)
What has become worse in the child's condition is recorded	7 (47)	1 (1)
Achievement of the planned outcomes is recorded	0 (0)	17 (20)
Aspects of the plan that have been changed are recorded	7 (47)	6 (7)

Table 3 Scores for conformity to standards in the 4 areas of care in the generic care standards

Area of care	Reported by health care providers		Review of records	
	Range of scores	Mean score (SD)	Range of scores	Mean score (SD)
Care assessment standards (16 items)	2–10	6.53 (2.95)	2–10	4.71 (2.13)
Care planning standards (8 items)	0–4	2.0 (1.36)	0–7	2.52 (1.61)
Care delivery standards (5 items)	0–3	1.27 (0.88)	0–3	0.45 (0.59)
Outcome standards(4 items)	0–3	1.40 (1.35)	0–3	0.89 (1.13)

SD = standard deviation.

Satisfaction of parents/caregivers with the care provided

All interviewed caregivers were mothers. Table 4 shows the satisfaction of the mothers with the care provided. Only 37% said they were satisfied with the services provided at the hospital for their children; 2% were unsatisfied and 61% were uncertain. Satisfaction was particularly low for waiting time, waiting area and availability of required facilities for their child's care. About two thirds of the mothers (64%) were satisfied with the cost of services. Only 28% were satisfied with the amount of explanation received about their child. The total satisfaction percentage score ranged from 0 to 94% with a mean of 55.4% (SD 18.2%) and a median of 55.7%.

Table 5 shows the mean satisfaction percentage score of the mothers in relation to their sociodemographic characteristics (education, marital status and working status). No statistically significant associations between the score and sociodemographic characteristic were found.

Discussion

Children with developmental disabilities are likely to experience unmet service needs, which will affect them and their families (*15,16*). Integrated care plans across all agencies involved in caring for children with cerebral palsy are essential in providing high quality care. A plan should contain general principles of care agreed by all members in the decision-making team and adapted to fit the local context taking into consideration differences in culture, educational levels of parents/caregivers, availability of trained health care providers and local resources (*17*).

In our study, from the perspective of head managers in the hospital involved in the care of children with cerebral palsy, the hospital lacked a named strategic lead and a coordinator for implementing a multiagency and multidisciplinary plan. Moreover, a lack of multiagency and multidisciplinary work forces involved in the care pathway development process was also reported.

At the centre of the decision-making team are the parents of the child with cerebral palsy and the child/young person him/herself. No decision about any aspect of care should be made without full involvement of the child/young person and their family in the decision-making process (*18*). In our study, the respondents reported that children with cerebral palsy and their parents/carer were not involved in the care pathway development process. Moreover, no surveys were conducted of the children and their family members to assess their satisfaction with the care they received and identify their expectations and their concerns.

Based on the skills and competencies required to meet the operational objectives of managing a child with a chronic disability, periodic assessment of training needs of health care providers should be conducted. The training plan should be based on the gap between the current capabilities of the health workers and the required capabilities to achieve the objectives of care (*19*). Among the standards reported as totally or partially unmet at the hospital was the lack of a system to monitor the training and supervision needs of care providers for children with cerebral palsy and demonstrate that

Table 4 Satisfaction of caregivers with the care provided to their child with cerebral palsy (*n* = 88)

Care item	Not satisfied	Uncertain	Satisfied
	No. (%)	No. (%)	No. (%)
Waiting time	25 (27)	50 (58)	13 (15)
Waiting area	56 (63)	27 (31)	5 (6)
Availability of facilities needed for your child	22 (23)	55 (64)	11 (13)
Number of days where services are available to you	3 (2)	54 (62)	31 (36)
Cost of services	5 (5)	27 (31)	56 (64)
Doctor listens carefully to what you say	8 (8)	48 (55)	32 (37)
Enough time to discuss problems	13 (14)	46 (53)	29 (33)
Adequate explanation about your child	12 (13)	52 (60)	24 (28)

Table 5 Satisfaction percentage score of caregiver according to sociodemographic characteristics (*n* = 88)

Characteristic	No.	Caregivers' satisfaction percentage score		*P*-value[a]
		Min–Max	Mean (SD)	
Level of education				0.133
Illiterate/read and write	39	27.78–94.44	59.40 (17.39)	
Primary school	20	16.67–83.33	56.39 (20.25)	
Secondary school	22	27.78–77.78	50.76 (13.64)	
University	7	0.0–83.33	45.24 (24.73)	
Marital status				0.859
Married	80	0.0–94.44	55.76 (18.30)	
Divorced	4	38.89–72.22	51.39 (14.61)	
Widowed	4	33.33–83.33	52.78 (22.45)	
Working status				0.136
Housewife	80	0.0–94.44	54.51 (18.20)	
Employed	8	44.44–88.89	64.58 (15.97)	

[a] *P < 0.05 was considered statistically significant.*
SD = standard deviation.

they are acted upon and actively promoted. In addition, there is no system to ensure that these training and supervision needs and requirements are incorporated into the hospital development plans.

A report by the care quality commission in the United Kingdom in 2012 described the experiences of stakeholders and administrative staff about how services are provided to children with disabilities and their families (*20*). They reported generally negative experiences, particularly concerning coordination of services, their involvement in decisions and in the delivery of care, and the general quality of care provided. Moreover, they considered that health care action plans were inconsistent, so people using services had different experiences depending on the service they got.

High standards for documentation and management of health care records are consistent with current best practice requirements in any health care organization. A system should be in place to audit health care records and report results. Facility/service managers are responsible for ensuring that requirements of this policy are disseminated and implemented in their hospital, department or service. Moreover they must ensure that health care personnel within their facility or service have timely access to paper-based and electronic health care records. The health care record is a documented account of a patient/client's: history of illness; health care plan/s; health investigations and evaluations; diagnosis; care; treatment; progress; and health outcome for each health service intervention or interaction. It serves as a basis for planning care and for communicating patients' conditions and treatments with other health care providers (*21*).

The senior managers in our study reported that, although there is a secure system that allows information to be recorded in and accessed from the child's care record, the system lacks child diagnostic and assessment information that allows any changes to be detected. Moreover, our review of the child health records showed that most items on our checklist were not recorded, including medical and developmental histories, how the diagnosis was reached, structured care plan, medication decisions, specific goals of care, admission information and outcome measures. This finding is in contrast to the results of a study in California (*22*) that reviewed the service system delivered to children and young people with special needs and reported the health records were considered adequate. Nevertheless, they recommended that all families be able to receive a copy of the health record of their children whenever needed.

One of the basic measures of quality improvement in health care is to monitor the process of care and identify any deviation from the recommended care. Reasons for deviations should be specified and discussed, action taken and recorded, and the outcome documented and fed back to front-line staff (*14*). In our hospital, weakness in the documentation system, lack of record-keeping standards, and the absence of systems for recording, collating, analysing, reporting and acting upon changes are major barriers to quality improvement in the care of the children with cerebral palsy.

The responses of the 15 health care providers directly involved in the care of children with cerebral palsy showed that the standard of care was poor as indicated by the small number of providers who reported adherence to the recommended generic care standards of care. Specific areas that showed poor adherence were: recording a structured care plan; including the family in the decision-making process; giving enough information to the family about the diagnosis, plan of care and the anticipated outcome; and recording details of admissions to the hospital and the outcome of child care.

Parental involvement in the process of child rehabilitation is very important for both parents and

professionals, and raises the level of parental satisfaction with the delivered care (*23*). Two community-based studies of family-centred services in Australia used the Measure of Processes of Care for Service Providers to assess the perceptions of parents/carers of the services provided (*24,25*). The families rated "respectful and supportive care" highest and "providing general information" lowest.

Another study in Finland, which assessed the child health care from the perspective of both health care providers and users, indicated that providing written information about the child's condition, therapies and progression, and information about family group supports and community voluntary organizations that offer services were rated by both families and service providers as being poorly delivered (*26*). In a study in Switzerland, parents reported the overall level of care as fair to moderate but provision of information was the lowest rated area (*27*).

Parent/caregiver satisfaction with the care provided to their children is one of the outcome measures commonly used to assess the quality of health care (*28*). In our study, the mothers' satisfaction was very low for the waiting time and waiting areas as well as the availability of required facilities for their child's care. Moreover, they were dissatisfied with the amount of explanation they received about their child. The fact that there was no significant association between the mothers' characteristics and their satisfaction with the care provided indicates a sub-optimal level of care from the perspective of all caregivers regardless of their background. In a study in Iceland, parents reported the overall therapy services as respectful, supportive and coordinated (*29*). Nevertheless, they felt that the information they received from professionals was insufficient. Similarly, a study in the Netherlands reported that parents of children with cerebral palsy did not feel adequately informed, especially about services for their children and family (*30*).

Similar to our study, 2 studies conducted in public hospitals and outpatient health care services reported low levels of patient satisfaction with care received with regard to attitudes towards professionals, quality of the surrounding atmosphere (including waiting areas), waiting time before being seen by a professional and quality of administrative services (*31*). They compared these services with those provided by the private sector and found better patient satisfaction in the private sector. They attributed this to the lower burden on professionals in the private sector, the availability of more facilities and more organized administrative services.

Conclusions

Our study shows that there is a wide gap between the actual provision of care for children with cerebral palsy and the recommended standards for the process of care of such children. Most mothers were not satisfied with several aspects of care provided to their children. Moreover, the documentation system in the hospital is poor.

A quality improvement plan is needed for care provision of children with cerebral palsy and their families, which includes continuous monitoring to identify variations in care and their causes, and to take action to address any problems. Periodic assessment of training needs of health care providers is important and the findings should be acted upon. Furthermore, a specific documentation system is urgently needed as part of the care pathways for children with cerebral palsy.

The family is the primary support for their child; it is therefore very important for health care providers to work in collaboration with families and to find ways to increase their participation in the care and rehabilitation plan of their child. As effective communication and information is key to quality standards for health and social care, strategies are needed to allow professionals enough time to listen carefully to the families' needs and to respond to their enquiries.

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Qualité des soins apportés aux enfants atteints de paralysie cérébrale, Alexandrie (Égypte)

Résumé

Contexte : Évaluer la qualité des soins est devenu de plus en plus important pour les prestataires de soins de santé, les autorités de réglementation et les acheteurs de soins.

Objectifs : La présente étude a évalué la qualité des soins fournis aux enfants atteints de paralysie cérébrale pris en charge à l'hôpital universitaire pour enfants d'Alexandrie (Égypte).

Méthodes : Le personnel médical résident du département de neuropédiatrie (n = 15) responsable de la prise en charge des enfants atteints de paralysie cérébrale a rempli une liste de contrôle structurée visant à mesurer leur observance des normes de soins génériques. Les dossiers médicaux de 84 enfants atteints de paralysie cérébrale traités dans cet hôpital ont été examinés à l'aide de la même liste de contrôle. Une autre liste de contrôle a été remplie par le responsable de l'unité de neuropédiatrie, par le directeur médical de l'hôpital, par le responsable de la médecine physique et l'infirmière en chef

afin d'évaluer l'observance des procédures et des normes d'amélioration des services. Des entretiens en face-à-face ont été conduits avec les soignants et les parents des enfants à l'aide d'un questionnaire de satisfaction clients.

Résultats : Sur la base de ce qui a été rapporté par les prestataires de soins de santé, la plupart ne se conformaient pas aux pratiques recommandées pour les soins apportés aux enfants atteints de paralysie cérébrale. L'examen des dossiers médicaux a également démontré le non-respect des normes. Le score de satisfaction total moyen des parents/soignants était de 55,43 % (ET 18,16). La satisfaction était particulièrement basse eu égard au temps d'attente, aux salles d'attente et à la disponibilité d'établissements compétents pour la prise en charge de leurs enfants.

Conclusions : Il existe un écart important entre les soins fournis actuellement aux enfants atteints de paralysie cérébrale et les normes recommandées. De plus, le système de documentation de l'hôpital n'est pas performant. Un plan d'amélioration de la qualité est requis pour la prestation de soins apportés aux enfants atteints de paralysie cérébrale.

جودة الرعاية المقدمة إلى الأطفال الذين يعانون من الشلل الدماغي، الإسكندرية، مصر

منى خليل، هبة الوشاحي، هيام عبد الغني، طارق عمر، سامية أحمد

الخلاصة

الخلفية: تزايدت أهمية تقييم جودة الرعاية بالنسبة لمقدمي الرعاية الصحية والجهات التنظيمية ومشتري هذه الرعاية.

الأهداف: هدفت هذه الدراسة إلى تقييم جودة الرعاية المقدمة إلى الأطفال المصابين بالشلل الدماغي في مستشفى الأطفال بجامعة الإسكندرية، مصر.

طرق البحث: قام الأطباء المقيمون في قسم أعصاب الأطفال (n = ١٥) الذين يقدمون الرعاية الصحية إلى الأطفال المصابين بالشلل الدماغي في المستشفى باستيفاء قائمة مراجعة منظمة لتقييم امتثالهم لمعايير الرعاية العامة. واستُعرضت السجلات الطبية لما مجموعه ٨٤ طفلا مصابا بالشلل الدماغي ممن تلقوا العلاج في المستشفى باستخدام نفس قائمة المراجعة. وقام رئيس وحدة طب أعصاب الأطفال والمدير الطبي للمستشفى ورئيس قسم العلاج الطبيعي ورئيسة الحكيمات باستيفاء قائمة أخرى لتقييم الامتثال لمعايير تحسين العملية والخدمات. وأجريت مقابلات مباشرة مع مقدمي الرعاية/ أولياء أمور الأطفال باستخدام استبيان لرضاء العميل.

النتائج: استنادا إلى ما أفاد به مقدمو الرعاية الصحية، تبين أن معظمهم لم يلتزم بالممارسات الموصى بها في رعاية الأطفال المصابين بالشلل الدماغي. كما أظهر استعراض للسجلات الطبية عدم الالتزام بالمعايير. وبلغ متوسط نسبة الرضا الإجمالية لأولياء الأمور/ مقدمي الرعاية ٤٣ , ٥٥٪ (بانحراف معياري مقداره ١٦ , ١٨). وجاء مستوى الرضا عن وقت الانتظار ومكان الانتظار وتوفر المرافق اللازمة لرعاية أطفالهم متدنيا للغاية.

الاستنتاجات: توجد فجوة واسعة بين الرعاية الفعلية المقدمة إلى الأطفال المصابين بالشلل الدماغي والمعايير الموصى بها. هذا بخلاف ضعف نظام التوثيق في المستشفى. ويلزم وضع خطة لتحسين جودة الرعاية المقدمة إلى الأطفال المصابين بالشلل الدماغي.

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Nutritional intake and its association with educational achievement in high-school students in Islamic Republic of Iran

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Abstract

Background: Inadequate food intake can affect learning and memory. Studies on the nutrient intake of adolescents in Sabzevar are lacking.

Aims: This study assessed the nutrient intake of high-school students in Sabzevar and its association with academic attainment.

Methods: This cross-sectional study was conducted on 800 of 8 000 high-school students in Sabzevar. Stratified sampling was used. Demographic data and academic information were collected and the parents of the students completed a food frequency questionnaire which included 189 food items. The students' weight and height were measured using standard methods. Each food was coded using Nutritionist IV software and mean values of nutrients (13 vitamins/minerals, 4 food types and total energy) were calculated.

Results: The mean body mass index of female and male students was 20. 3 (SD 2.7) kg/m2 and 19.5 (SD 3.2) kg/m2 respectively. The intakes of energy, vitamins A, C, D, folic acid, calcium, iron and zinc were significantly lower than the dietary reference intake ($P < 0.05$). A statistically significant correlation was seen between iron intake and academic scores in female students ($P < 0.05$) but not for any other nutrient.

Conclusions: The intake of most nutrients in high-school students in Sabzevar was lower than the dietary reference intake. Nutrition education and nutritional support strategies are recommended to improve the nutritional status of these students.

Keywords: Adolescent; Students; Nutritional status; Recommended dietary allowances, Iran

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Introduction

Adolescents have received considerable research attention in the past decade mainly because of the sheer size of this population *(1)*. About 85% of adolescents live in developing countries and account for about one third of the national populations those countries *(2)*. Nearly 70% of children and adolescents suffering from malnutrition live in Asia *(3)*. The increasing incidence of childhood obesity and the socioeconomic and public health burden it causes is a real threat for developing countries *(4)*. Inappropriate nutritional habits and unhealthy lifestyles are important health risk factors in this vulnerable group and may eventually lead to chronic diseases in adulthood *(5,6)*. Obesity during childhood and adulthood is a fast emerging problem in the Islamic Republic of Iran and the highest prevalence of obesity is observed among teenagers; it is reported that 12.2% of adolescents are overweight and 3.9% obese *(7)*. Other studies have also shown the increasing prevalence of overweight and obesity in children and adolescents in the country *(8,9)*. Another Iranian study has shown that a lack of adequate food is associated with impaired concentration and learning, and academic misconduct *(10)*.

Studies suggest that learning and memory are influenced by diet, not only during childhood but also in adolescence. For example, omega-3 fatty acids reduce the ageing-related reduction in the memory *(11)*. In an Iranian study, temporary starvation or attendance without eating breakfast and fasting affected precision, concentration and academic ability *(12)*. On the other hand, Swedish students eating fish high in omega-3 fatty acids were more likely to have good school grades *(13)*.

There is a lack of information about the nutrition and nutrient intake of adolescent students in Sabzevar. Therefore, we aimed to assess the nutritional intake of high-school students and its association with academic attainment.

Methods

Study design and sample

This cross-sectional study was conducted in Sabzevar, Islamic Republic of Iran . The sample included 800 high-

schools students aged 14 to 18 years in Sabzevar. The sample was selected from the 8 000 high-school students in Sabzevar, 10% of the high-school population in Sabzevar.

The Department of Education of gave permission for the study and helped with coordination. All 50 high schools in Sabzevar were identified and listed (30 girls' and 20 boys' schools) and 25 schools (15 girls' and 10 boys' schools) were selected by a stratified sampling method based on a random method. In each school, participants of each class (first to fourth grades of high school) were selected using stratified sampling according to size. For example, from a class of 40, 10 students were selected and from a class of 30, 7 were selected. The study was explained to the students and their parents' written consent was obtained. No students declined to participate and all responded to questionnaire.

Study tool and data collection

Data were collected in a questionnaire which had two parts. The first recorded information about demographic factors (weight, height, age, sex), and the student's scores in school subjects (mathematics, physics, chemistry and biology) and overall grade point average (GPA). The mean subject and GPA scores were taken from the students' academic records. Weight was measured in light clothing and without shoes using a precision digital scale (Seca) to the nearest 100 g, and height was measured with a tape measure to the nearest 1 cm. Body mass index (BMI) was calculated (weight/metre^2; kg/m^2).

The second part was a quantitative food frequency questionnaire to measure dietary intake. The content validity of the instrument was determined by calculating the content validity ratio coefficient and content validity index *(14)*. The questionnaire was given to a panel of experts in the field of nutrition and health. They were asked to rate each item as: necessary, useful but unnecessary, unnecessary. After the validity and reliability process, 189 foods were included. The content validity index value was 0.85, which represents an acceptable validity of the instrument. Internal consistency of the questionnaire was evaluated with Cronbach alpha (0.91).

Before the study began, training was given to parents on how to complete the food frequency questionnaire and measure food and beverage intake. Participants determined how many times they ate the food and how much they ate each time in the past month. The amounts for each food were converted to grams using household measures guidelines *(15)*. Foods were coded according to Nutritionist IV and the students' diets were analysed using Nutritionist IV software (N Squared Computing, California, USA). The mean food intake of the students was compared with the daily references intake values *(16)*.

Statistical analysis

SPSS, version 16 was used for data analysis. Data for nutrient intake are presented as mean and standard deviation (SD). The Pearson correlation test was used to compare nutrient intake and GPA scores and the t-test was used to compare the food data with standard values for both sexes. $P < 0.05$ was considered statistically significant

Table 1 Comparison of energy and nutrient intake of male high-school students with the dietary reference intake (DRI)

Nutrient	Mean (SD)	DRI	P-value
Energy (Kcal/d)	2160(675.7)	2400	0.001
Protein (g/d)	55.5(25.21)	52	0.16
Carbohydrates (g/d)	308.38(90.3)	130	0.0001
Fat (g/d)	34.10 (68.5)	25–30%	0.07
Fibre (g/d)	5.23 (4.25)	38	0.0001
Vitamin A (IU/d)	920.1 (875.2)	3000	0.0001
Vitamin D (IU/d)	150.15 (90.85)	200	0.0001
Vitamin E (mg/d)	6.35 (6.45)	15	0.0001
Vitamin C (mg/d)	30.5 (42.3)	75	0.0001
Vitamin B1 (mg/d)	1.0 (0.5)	1.2	0.12
Vitamin B2 (mg/d)	1.1 (0.6)	1.3	0.14
Vitamin B3(mg/d)	14.7 (6.9)	16	0.21
Vitamin B6 (mg/d)	1.2 (0.7)	1.3	0.75
Vitamin B9 (folate (µg/d)	228 (125.72)	400	0.0001
Vitamin B12 (µg/d)	2.6 (1.6)	2.4	0.18
Calcium (mg/d)	345.5 (575.15)	1300	0.0001
Iron (mg/d)	17.3 (8.5)	11	0.01
Zinc (mg/d)	4.5 (8.0)	11	0.01

SD = standard deviation; d = day.

Ethical considerations

The study was approved by the Ethics Committee of Sabzevar University of Medical Sciences.

Results

Of the 800 students included in this study, 500 were girls and 300 boys. The mean BMI of the girls was 20.3 (SD 2.7) kg/m² and of the boys was 19.5 (SD 3.2) kg/m². Based on BMI, 10.7% of the girls and 15.5% of the boys were underweight (BMI < 18.5 kg/m²), 13.2% of the girls and 9% of the boys were overweight (BMI: 25–29.9 kg/m²) and 3% of the boys were obese (BMI ≥ 30 kg/m²); none of the girls was obese.

The mean intake of energy and nutrients of the boys and girls is shown in Tables 1 and 2 respectively. Compared with the recommended daily values, the energy and nutrient intake of the students was significantly lower for vitamins A, D and C, folic acid and calcium ($P = 0.0001$), and iron and zinc ($P = 0.01$). A statistically significant association was found between iron intake and average grades in the academic subjects and GPA score of the girls ($P = 0.0001$) but not the boys ($P = 0.001$).

The energy and nutrient intake of boys compared with girls is shown in Table 3. Energy and zinc intake was significantly lower in the girls than the boys, while vitamin A was significantly higher in girls than boys.

Discussion

Our study showed that intake of nutrients, including energy, vitamin A, C, D, folic acid, calcium, iron and zinc in the students was lower than the recommended daily amounts of food. Our results are consistent with another Iranian study on 396 teenage girls in Kerman that showed energy, fat, vitamin A and calcium intake was insufficient *(17)*. Similarly, a study in Poland reported that the daily intake of calcium, iron, zinc and copper in adolescent aged 16 to 19 years was low *(18)*. Also, in the United States, the National Growth and Health Study data showed that the majority of girls had inadequate intakes of calcium, magnesium, potassium, and vitamins D and E *(19)*. Vitamin C deficiency has also been reported among students *(20,21)*, which is consistent with the findings of our study. A lack of nutrients appears to be common in adolescents and the students in our study were no exception.

In our study, energy and zinc intake of girls was significantly lower than boys but vitamin A intake was significantly which may indicate a lower intake of meat and higher intake of vegetables in girls.

Our findings also showed a significant relationship between iron intake and academic subject/GPA scores in girls. Our result is consistent with a study on high-school girls in Gonabad *(22)* which showed that 16 weeks of iron supplementation significantly increased the average learning score (speed and accuracy) in the experimental group compared with the control group of students, suggesting iron deficiency among girls has an adverse effect on learning. A meta-analysis of randomized controlled trials that assessed the effects of micronutrient-fortified foods on cognitive function found that the micronutrient intake of iron, zinc, iodine, vitamin A had a beneficial effect on short-term memory and working memory performance in children aged 5–15 years *(23)*. In a study of children aged 6–16 years (5 365 children), high levels of serum folate were associated with

Table 2 Comparison of energy and nutrient intake of female high-school students with the dietary reference intake (DRI)

Nutrient	Mean (SD)	DRI	*P*-value
Energy (kcal/d)	1920 (565.15)	2200	0.001
Protein (g/d)	50.1 (20.3)	46	0.06
Carbohydrates (g/d)	308.38 (90.3)	130	0.0001
Fat (g/d)	30.3 (60.8)	25–30%	0.15
Fibre (g/d)	5.25 (4.10)	26	0.0001
Vitamin A (Iu/d)	1100.1 (955.2)	2300	0.0001
Vitamin D (Iu/d)	110.5 (80.85)	200	0.0001
Vitamin E (mg/d)	5.45 (4.35)	15	0.0001
Vitamin C (mg/d)	30.5 (42.3)	65	0.0001
Vitamin B1 (mg/d)	0.9 (0.5)	1	0.15
Vitamin B2 (mg/d)	1.0 (0.3)	1	0.98
Vitamin B3(mg/d)	13.2 (1.2)	14	0.17
Vitamin B6 (mg/d)	1.12 (0.63)	1.2	0.21
Vitamin B9 (folate) (µg/d)	284.22(140.10)	400	0.0001
Vitamin B12 (µg/d)	2.5 (1.5)	2.4	0.83
Calcium (mg/d)	345.5 (575.15)	1300	0.0001
Iron (mg/d)	9.5 (15.5)	15	0.01
Zinc (mg/d)	3.2 (6.0)	9	0.01

SD = standard deviation; d = day.

Table 3 **Comparison of energy and nutrient intake in male and female high-school students**

Nutrient	Males	Females	*P*-value
	Mean (SD)	Mean (SD)	
Energy (kcal/d)	2160(675.7)	1920 (565.15)	0.0001
Protein (g/d)	55.5(25.21)	50.1 (20.3)	0.18
Carbohydrates (g/d)	308.38(90.3)	308.38 (90.3)	0.68
Fat (g/d)	34.10 (68.5)	30.3 (60.8)	0.49
Fibre (g/d)	5.23 (4.25)	5.25 (4.10)	0.39
Vitamin A (IU/d)	920.1 (875.2)	1100.1 (955.2)	0.001
Vitamin D (IU/d)	150.15 (90.85)	110.5 (80.85)	0.05
Vitamin E (mg/d)	6.35 (6.45)	5.45 (4.35)	0.11
Vitamin C (mg/d)	30.5 (42.3)	30.5 (42.3)	0.66
Vitamin B1 (mg/d)	1.0 (0.5)	0.9 (0.5)	0.56
Vitamin B2 (mg/d)	1.1 (0.6)	1.0 (0.3)	0.09
Vitamin B3(mg/d)	14.7 (6.9)	13.2 (1.2)	0.16
Vitamin B6 (mg/d)	1.2 (0.7)	1.12 (0.63)	0.23
Vitamin B9 (folate) (µg/d)	228 (125.72)	284.22(140.10)	0.06
Vitamin B12 (µg/d)	2.6 (1.6)	2.5 (1.5)	0.67
Calcium (mg/d)	345.5 (575.15)	345.5 (575.15)	0.71
Iron (mg/d)	17.3 (8.5)	9.5 (15.5)	0.07
Zinc (mg/d)	4.5 (8.0)	3.2 (6.0)	0.0001

SD = standard deviation; d = day.

a better learning score and better test scores, while serum levels of vitamin B12 did not show such a relationship *(24)*. A study in 2013 also found that the omega-3 fatty acid, docosahexaenoic acid, affected behaviour, memory and brain activity because of its effect on brain development *(25)*. In addition, studies have shown that the lack of an adequate supply of nutrients and malnutrition impaired concentration and learning and was associated with poor academic performance *(9,26)*, and a study in Malaysia also reported that nutritional status and parents' education are factors that could improve academic performance of children *(27)*.

However, in an Iranian study in Kashan, no statistically significant relationship was seen between malnutrition and mathematics, science and spelling scores in elementary school students *(28)*. Overall, the results of such studies, suggest that adequate nutritional support in school can promote children's growth and educational achievement.

Conclusion

The findings of our study show that the intake of many nutrients in high-school students in Sabzevar is lower than the recommended daily intake. Considering the important role of nutrition in the health and academic performance of students, nutrition education and nutritional support strategies are recommended to raise awareness and improve the nutritional and academic status of students. These could include the provision of snacks in schools and supplementation nutrition such as iron. A clinical trial to better evaluate the relationship between nutrient intake and individual student achievement should be conducted. Future studies should replicate our analysis in other young populations and further investigate how health-related behaviour influences cognitive and academic outcomes.

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Apport nutritionnel et résultats scolaires chez des élèves du secondaire en République islamique d'Iran

Résumé

Contexte : Un apport alimentaire insuffisant peut influencer négativement les processus d'apprentissage et de mémorisation. Il n'existe pas d'études sur l'apport nutritionnel des adolescents à Sabzevar.

Objectifs : L'étude a évalué l'apport nutritionnel d'élèves du secondaire à Sabzevar, ainsi que son association avec les résultats scolaires.

Méthodes : La présente étude transversale a été menée auprès de 800 élèves du secondaire sur 8000 à Sabzevar. La méthode d'échantillonnage stratifié a été appliquée. Des données démographiques et des informations académiques ont été recueillies, et les parents des élèves ont rempli un questionnaire de fréquence de consommation qui incluait 189 produits alimentaires. Le poids et la taille des élèves ont été mesurés à l'aide de méthodes standardisées. Chaque aliment a reçu un code attribué par le logiciel de nutrition Nutritionist IV et les valeurs moyennes des nutriments (13 vitamines/minéraux, quatre types d'aliments et l'énergie totale) ont été calculées.

Résultats : L'indice de masse corporelle moyen des élèves de sexe féminin et masculin était de 20,3 kg/m2 (ET 2,7) et 19,5 kg/m2 (ET 3,2) respectivement. Les apports en énergie, en vitamines A, C et D, en acide folique, en calcium, en fer et en zinc étaient significativement moins élevés que les apports nutritionnels conseillés ($p < 0,05$). Une corrélation statistiquement significative a été observée entre l'apport en fer et les résultats scolaires des élèves de sexe féminin ($p < 0,05$) , ce qui n'était pas le cas pour les autres nutriments.

Conclusions : Pour la plupart des nutriments, les apports étaient plus bas que les apports nutritionnels conseillés chez les élèves du secondaire de Sabzevar. Une éducation nutritionnelle et des stratégies d'appui dans ce domaine sont recommandées afin d'améliorer l'état nutritionnel de ces élèves.

المدخول الغذائي وارتباطه بالتحصيل التعليمي في صفوف طلاب المدارس العليا في جمهورية إيران الإسلامية

أكرم كوشكي، مريم محمدي، محمود ريوندي

الخلاصة

الخلفية: يمكن أن يؤثر التناول غير الكافي للطعام على التعلّم والذاكرة. وثمة نقص في الدراسات المتعلقة بالمدخول الغذائي للمراهقين في سابزيفار.

الأهداف: عمدت هذه الدراسة إلى تقييم المدخول الغذائي لطلاب المدارس الثانوية في سابزيفار وارتباطه بالتحصيل الأكاديمي.

طرق البحث: أُجريت هذه الدراسة على ٨٠٠ من أصل ٨٠٠٠ طالب في محافظة سابزيفار. واستُخدم أسلوب اختيار العينة العشوائي. فتم جمع بيانات سكانية وأكاديمية واستكمل الطلاب استبيانا عن وتيرة تناول الغذاء شمل ١٨٩ صنفا غذائيا. وقيس وزنهم وطولهم باستخدم أساليب معيارية. وتم ترميز كل صنف غذائي باستخدام برمجية Nutritionist IV، واحتسبت القيمة المتوسطة للعناصر الغذائية (١٣ مواد فيتامينية/ معدنية، و٤ أنواع غذائية، وإجمالي الطاقة).

النتائج: بلغ متوسط مؤشر كتلة الجسم للطالبات والطلاب ٣, ٢٠ كجم/ م٢ (بانحراف معياري مقداره ٧, ٢) و٥, ١٩ كجم/ م٢ (بانحراف معياري مقداره ٢, ٣) على الترتيب. وتبين أن حصص مواد الطاقة، وفيتامينات ألف وجيم ودال، وحمض الفوليك، والكالسيوم، والحديد، والزنك أقل بكثير من المدخول الغذائي المرجعي (P < ٠, ٠٥). وشوهد ارتباط ذو دلالة إحصائية بين حصة الحديد والدرجات الأكاديمية في صفوف الطالبات (P < ٠, ٠٥) ولكن ليس في أي مغذيات أخرى.

الاستنتاجات: تبين انخفاض مدخول معظم المغذيات في صفوف طلاب المدارس العليا في محافظة سابزيفار مقارنة بالمدخول الغذائي المرجعي. ويوصى بوضع استراتيجيات للتثقيف والدعم التغذويين من أجل تحسين الحالة التغذوية لهؤلاء الطلاب.

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Knowledge, awareness and acceptability of anti-HPV vaccine in the Arab states of the Middle East and North Africa Region: a systematic review

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Abstract

Background: Rapid changes in lifestyle induced by globalization have brought about changes in sexual behaviour, especially among younger generations. These changes may lead to considerable consequences on the prevalence of sexually transmitted disease, including human papillomavirus (HPV) infection.

Aims: The objective of this study is to provide a systematic review of peer-reviewed literature on human papillomavirus (HPV) vaccine awareness and acceptability in the Arab states of the Middle East and North Africa region**.**

Methods: A systematic search was conducted across 2 electronic databases: PubMed and EMBASE, to identify studies related to HPV vaccination awareness and acceptability in the region between January 2010 and April 2017.

Results: Eighteen studies from 9 countries were identified. The analysis showed low to moderate HPV infection knowledge and anti-HPV vaccine awareness. Nevertheless, most studies reported moderate to high anti-HPV vaccine acceptability among subpopulations. Broad gaps in knowledge and willingness were highlighted regarding HPV vaccine acceptability.

Conclusions: An examination of the region collectively offers an insight into the willingness of the general population and healthcare providers to receive more information about the virus and prevention of infection through vaccination. This review suggests that the vaccine acceptability would be high once cost concerns are resolved.

Keywords: HPV, awareness, vaccine, Middle East, North Africa.

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Introduction

The Arab world stretches from Morocco to Saudi Arabia, and is characterized by societies sharing relatively comparable cultures and religious conservatism. This implies more conservative sexual behaviours than in other cultures (*1*). Given this particular cultural context, the prevalence of sexually transmitted infections [including human papillomavirus (HPV)] has previously been reported to be low in this region compared to rest of the world (*2*). That said, given the rapid changes in lifestyle induced by globalization, sexual behaviour, especially among younger generations, is changing: practices are much more liberal than what was accepted during previous decades. These changes may induce considerable consequences on the prevalence of sexually transmitted diseases, even in this region (*1*).

The incidence of cervical cancer has been reported as 6.4 per 100 000 in the North Africa region and 3.4 per 100 000 in the Greater Middle East (*3,4*). Although difficult to evaluate precisely because of the absence of cancer registries, cervical cancer rates are estimated to be lower in this region than in the rest of the world. This partly explains the delay seen in establishing national cervical cancer prevention programmes in this region (*5*).

Despite the inaccurate incidence estimates, cervical cancer is the second most common cancer among women in Algeria and Morocco (after breast cancer) and the third most common in Tunisia, Oman and United Arab Emirates (*3*). In the extended Middle East and North Africa (MENA) region (excluding Pakistan), cervical cancer is ranked as the fourth most common cancer, with 7949 new cases estimated in 2008 (4.4% of all cancers in the region) (*5*).

Based on these statistics, and despite the relatively low incidence, cervical cancer is still a public health issue in the Arab states. Because of the proven causal link between HPV infection and the development of cervical cancer, the introduction of an effective and safe anti-HPV vaccine is an excellent opportunity to eradicate this devastating preventable disease as well as other HPV-related diseases in the Arab MENA states, as elsewhere in the world (*6*).

In June 2006, the first vaccine against HPV was approved by the Food and Drug Administration of the United States of America for the primary prevention of cervical cancer. Today, 2 prophylactic vaccines against HPV are currently registered: bivalent Cervarix (GlaxoSmithKline, Belgium) and quadrivalent Gardasil (Merck and Co., Inc., United States of America) (*7*). Both vaccines are well tolerated with good profiles for efficacy

in preventing HPV infection (*6*). The vaccine against HPV has gained rapidly in popularity in many countries and it has been licensed in over 150 countries around the world (*8*).

Despite the availability of the vaccine, national programmes implementing HPV vaccination are very rare in the Arab states: only 1 country (United Arab Emirates) has effectively introduced the vaccine through a national programme and very few others have planned to introduce it in the near future (*8*).

Several factors have influenced the slow introduction of the anti-HPV vaccination in the region: financial constraints, poor infrastructure for adolescent vaccine delivery, competition with high-priority vaccines and the lack of reliable data on the burden of HPV diseases (*8–10*). However, the main obstacle to an effective introduction of the anti-HPV vaccine is still the low political will that is often justified by cultural and religious sensitivities, which could limit the success of such vaccination programmes (*11*).

The experience of the United Arab Emirates also revealed a high overall absorption of the vaccine in the first year of introduction (77%). This then declined to 59% in 2010/2011, probably because of the unfounded media campaign fueling the controversy surrounding the possible adverse effects of the vaccine (*8*).

In this study, we aimed to assess the knowledge and awareness of HPV infection and anti-HPV vaccine, the acceptability of the vaccine and the willingness to receive or recommend the vaccine in the Arab states of the MENA region through a systematic review of the peer-reviewed literature. We chose to restrict our search to only the Arab states of the region to enhance the generalizability of our results to all countries of this region with similar cultural and religious background.

Methods

Identification of studies

Studies assessing the knowledge and acceptability of anti-HPV vaccine in Arab states of the MENA region were identified by searching for studies in 2 databases (PubMed and Embase) published between 1 January 2010 and 10 April 2017.

The search was conducted using the key term "HPV vaccine" in addition to all terms describing the geographic and cultural area of interest (keywords were: Algeria, Bahrain, Egypt, Iraq, Jordan, Libya, Kuwait, Lebanon, Mauritania, Morocco, Oman, Qatar, Saudi Arabia, Sudan, Syria, Tunisia, United Arab Emirates and Yemen).

Inclusion criteria

All the included studies met the following criteria:

- conducted in at least 1 of the Arab states of the MENA region,
- had considered at least 1 of the themes: <list2>
  - HPV infection knowledge,
  - HPV–cervical causal association knowledge,
  - anti-HPV vaccine awareness
  - willingness to receive the vaccine or to get daughter vaccinated.

Search strategy

All literature relating to HPV vaccination in the Arab states of the MENA region was sought and the search consisted of database-specific vocabulary and use of Boolean operators for: HPV vaccine AND (Sudan OR Mauritania OR Morocco OR Algeria OR Tunisia OR Libya OR Egypt OR Lebanon OR Syria OR Iraq OR Jordan OR Bahrain OR Qatar OR Saudi Arabia OR Yemen OR Kuwait OR United Arab Emirates OR Oman). Date restriction was employed for the period 01 January 2010–10 April 2017 to exclude old studies published during the first years of commercialization of the HPV vaccine. A language restriction was employed to capture only publications in English and French, the 2 main languages of scientific publications in the region of interest. The complete search strategy is presented in Figure 1.

Study selection

The search was narrowed to identify studies that involved the examination of HPV vaccine acceptability and knowledge or attitudes related to HPV vaccines in the Arab states of the MENA region.

No limit was placed on the types of study participants, all subpopulations were considered: women, parents, males, healthcare professionals and students. No limit was placed on study design, however, included articles were required to report original data (i.e. not reviews, editorials or commentary).

Titles and abstracts of all articles returned from the initial search were screened and those which were irrelevant (irrelevant geographic area, literature reviews, HPV prevalence, HPV genotype distribution, case studies, cost–effectiveness studies, etc.) were excluded (n = 67 articles). The remaining articles were given full-text review and further exclusions were made if they did not meet the inclusion criteria. The articles were examined by 2 reviewers to confirm that inclusion criteria were satisfied and to reach consensus when necessary.

Overall, most of the studies had been properly conducted except 2 papers issued by the same author and based on the same data, but reporting nonconcordant results for the same assessed outcomes. The full-text screening led to the exclusion of 13 more articles for noneligibility (10 eligibility criteria unmet, 2 articles based on the same study with nonconcordant results and 1 nonaccessible article). A total of 18 studies were retained (Figure 1).

Data abstraction and analysis

A systematic review of publications of interest was performed summarizing the main results; these were subsequently treated as primary data.

A data abstraction form was created after a preliminary scan of the relevant literature and data abstraction

was conducted by one of the reviewers involved in the selection of studies. Abstracted data were oganized by key information such as study population, sample size and main conclusions on the levels of HPV and HPV vaccine knowledge, awareness and willingness to receive or to recommend the vaccine.

Awareness, knowledge and acceptability levels were divided into 4 categories: HPV knowledge, association between HPV and cervical cancer awareness, HPV-vaccine awareness and willingness to get vaccinated or to vaccinate daughters.

Factors influencing HPV knowledge and anti-HPV-vaccine acceptability were reported to provide a qualitative overview for a better understanding of the improvement opportunities of the acceptability of anti-HPV vaccination.

Results

Overview of the reviewed studies

The 18 studies reviewed involved 9 Arab states of the MENA region: 6 studies were conducted on healthcare clinicians or students; 3 involved parents; 7 involved women of different age groups; 1 involved adolescents and young adults and 1 involved a group of young men (Table 1).

Knowledge and awareness of the HPV infection

Nine of the selected studies examined HPV infection knowledge by asking if (yes or no) participants had already heard about HPV infection and/or were satisfied with the information they had received.

Prevalence varied between 4.2% and 97.0% depending on the country and subpopulation. It was highest among the subgroup healthcare professionals (97.0%) and lowest among the subgroup of parents (ranging between 4.2% and 18.0%). Knowledge of HPV infection ranged between 31.0% and 65.0% among women, 20.0% among adolescents and 31.0% among males (Table 2).

Knowledge and awareness of the causal link HPV infection–cervical cancer

Ten of the reviewed studies had examined the HPV–cervical cancer association awareness. Prevalence varied be-

Figure 1 Data flow diagram of the complete search strategy

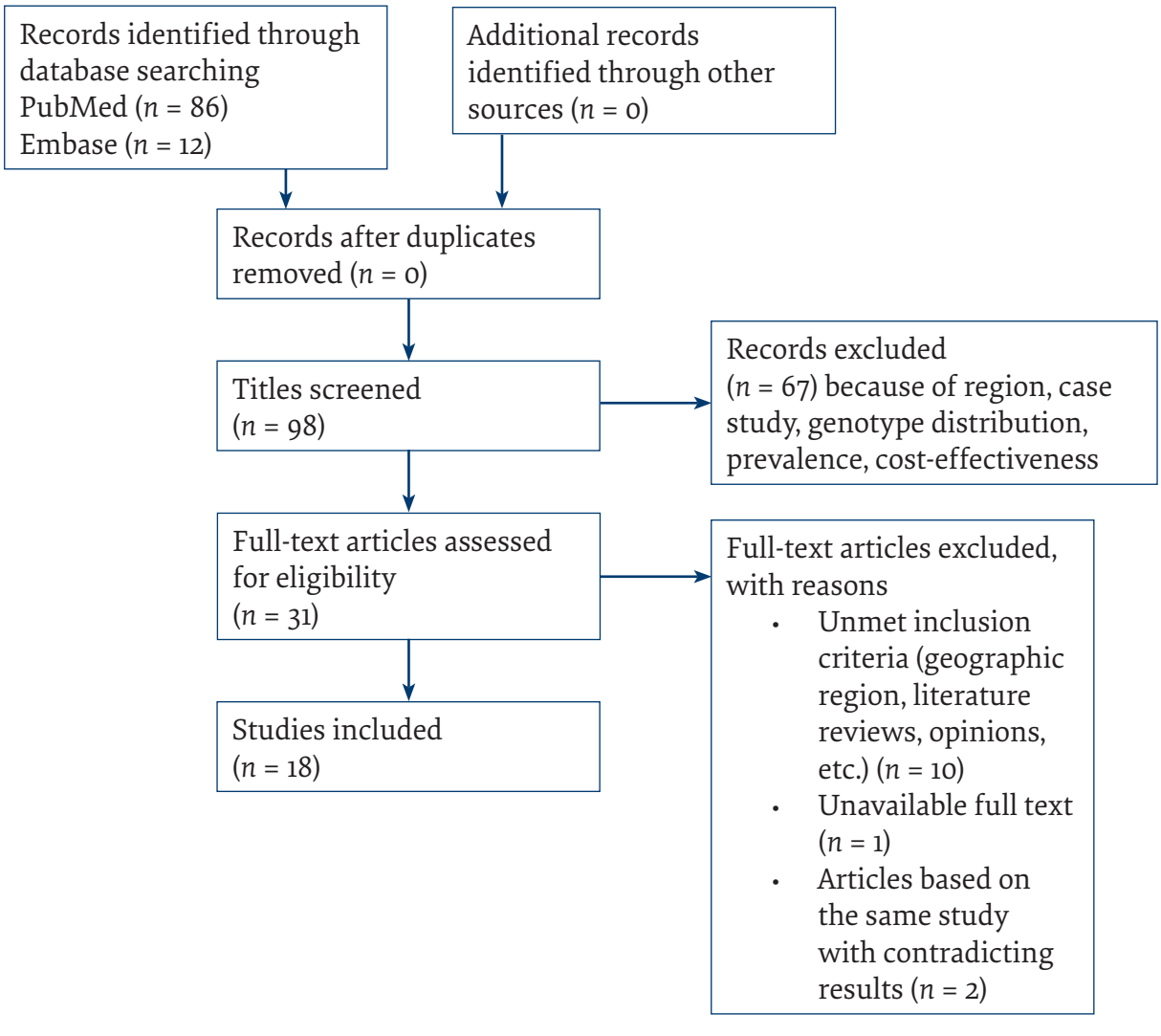

Table 1 Descriptive summary of the studies retained in the review

Category	No.	Reference
Total no. of studies	18	–
Total no. of countries	9	–
Bahrain	1	19
Egypt	1	20
Jordan	1	21
Lebanon	1	13
Morroco	4	14,22–24
Saudi Arabia	5	25–29
Syrian Arab Republic	1	30
Sudan	1	31
United Arab Emirates	3	12,15,16
Demographics of studies		
Women	7	13,16,19,20,25,26,31,
Parents	3	14,23,30
Men	1	15
Healthcare clinicians & students	6	12,21,22,27–29
Adolescents and young adults	1	24
Knowledge and awareness of HPV	9	
Reported prevalence > 80%	1	12
Reported prevalence 30–80%	5	15,16,19,20,26
Reported prevalence < 30%	4	14,23,24,29
Awareness of causal link HPV infection–cervical cancer	10	
Reported prevalence > 80%	3	12,13,22
Reported prevalence 30–80%	4	25,27,28,31
Reported prevalence < 30%	3	
Knowledge and awareness of anti-HPV vaccine	9	
Reported prevalence > 80%	1	12
Reported prevalence 30–80%	6	13,22,26,28–31
Reported prevalence < 30%	2	14,21
Acceptability of anti-HPV vaccine	11	
Reported prevalence > 80%	4	16,19,20,25
Reported prevalence 30–80%	6	12,14,15,23,26,29
Reported prevalence < 30%	1	24

HPV = human papillomavirus.

tween 8.4% and 95.1% depending on the country and subpopulation. Prevalence was highest among the subgroup females, ranging between 27.4% and 81.9%, and lowest among the subgroup of parents (8.4%). Among healthcare professionals and students, the prevalence ranged between 45.0% and 95.1% (Table 2)

Anti-HPV vaccine awareness

Nine of the selected studies examined anti-HPV vaccine awareness. Prevalence varied between 14.2% and 97.0%. The highest prevalence was found among the subgroup healthcare professionals and students ranging between 27.2% and 97.0%. The lowest prevalence was found among the subgroup parents ranging from 14.2% to 34.2%. Among females, the prevalence ranged between 32.3% and 63.5% (Table 2).

Anti-HPV vaccine acceptability

Eleven of the selected studies examined anti-HPV vaccine acceptability by asking whether participants would accept to receive the vaccine or to get their daughters vaccinated. Prevalence varied between 20.4% and 99.0%. The highest prevalence was among the subgroup females, ranging between 46.0% and 99.0%. The lowest prevalence was among the subgroup adolescents and ranged between 20.4% and 62.0%. The acceptability prevalence was around 46.0% among males and it ranged between 50% and 74% among healthcare professionals and students (Table 2).

Factors associated with the acceptability of anti-HPV vaccine

Several studies discussed factors possibly influencing vaccine acceptability. The main barriers to acceptability of the vaccine included:

- cultural barriers, reported especially by nurses who found it difficult to address the issue of vaccination with parents (*12*),
- high costs (*13,14*).

In terms of factors improving the acceptability of the vaccine, the following were reported:

a high socioeconomic level generally (*14*),

clear recommendations from the authorities or medical professionals about the effectiveness and safety of the vaccine (implying better information) (*14*),

the desire to become protected again HPV and to protect a partner (*15*).

Strategies for introduction of anti-HPV vaccine

Among the 18 studies retained in this review, 3 were conducted in the United Arab Emirates, the only country that had already introduced a national programme of HPV vaccination. In 2008, the Health Authority of Abu Dhabi (the capital of the United Arab Emirates) introduced the free anti-HPV vaccine for schoolgirls, whether or not they were natives of the United Arab Emirates; becoming the first country in the MENA region to organize a national cervical cancer immunization programme (*12,15,16*).

Regarding the 8 other countries included in this review, they had all previously introduced at least 1 of the 2 available vaccines, but none had issued clear recommendations about the vaccine or planned for a national immunization programme except Morocco (*8*). In fact, since 2011, a programme of national immunization was proposed for all girls aged 11 years by Moroccan authorities. However, this programme is still in its pilot phase.

Most of the studies covering cervical cancer awareness and screening interventions highlighted the

Table 2 Overview of knowledge and awareness of human papillomavirus (HPV) infection and anti-HPV vaccine, and acceptability and willingness related to anti-HPV vaccine in the Arab states of the Middle East and North Africa (MENA) region (*continued*)

Study	Country	Publication year	Subgroup	N Population	Response rate (%)	Knowledge of HPV infection (%)	Awareness of HPV- cervical cancer link (%)	Awareness of anti-HPV vaccination (%)	Acceptability of anti-HPV (%) (%) vaccination	Current cervical cancer awareness, knowledge and screening intervention
					Females					
Moosa (19)	Bahrain	2014	Women	571	99.0	31.3	NA	NA	91.3	HPV vaccines are already licensed HPV vaccine not been included in the national immunization programme Baseline data on HPV epidemiology and distribution of HPV types in Bahrain are lacking
Shaltout (20)	Egypt	2014	Women older than 18 years	490	90.4	33.2	NA	NA	99.0	HPV vaccines are already licensed HPV vaccine not been included in the national immunization programme Baseline epidemiological data are lacking No nationwide policy for HPV prevention is implemented
Al-nuaimi (16)	Emirates	2011	Secondary school girls (grade 11 and 12)	334	99.4	65.0	NA	NA	83.0	HPV vaccine is included in the national immunization programme for girls entering grade 11 Need for an educational programme for both parents and girls on HPV vaccine
Dany (13)	Lebanon	2015	College female students	215	42.0	NA	81.9	63.5	NA	HPV vaccines are already licensed HPV vaccine not been included in the national immunization programme Need to learn about the behavioural perceptions towards HPV vaccination as a first step to develop a health policy Need to launch educational programmes that offer guidance to adolescents to increase their awareness of the risks associated with HPV infection
Al-Obaid (25)	Saudi Arabia	2014	Women	417	76.0	NA	32.2	NA	89.9	HPV vaccine not been included in the national immunization programme The epidemiology of HPV amongst women in Saudi Arabia is not fully understood
Hussain (26)	Saudi Arabia	2016	Young women	325	NA	34.5	27.4	32.3	64.3	HPV vaccines are already licensed HPV vaccine not been included in the national immunization programme
Almobarak (31)	Sudan	2016	Women between 14 and 58 years old	500	NA	NA	46.4	39.2	NA	HPV vaccines are already licensed HPV vaccine not been included in the national immunization programme Cervical cancer screening programme coverage is still incomplete due to lack of infrastructures and trained healthcare professionals, poor health care access and lack of awareness

Table 2 Overview of knowledge and awareness of human papillomavirus (HPV) infection and anti-HPV vaccine, and acceptability and willingness related to anti-HPV vaccine in the Arab states of the Middle East and North Africa (MENA) region (*continued*)

Study	Country	Publication year	Subgroup	N Population	Response rate (%)	Knowledge of HPV infection (%)	Awareness of HPV- cervical cancer link (%)	Awareness of anti-HPV vaccination (%)	Acceptability of anti-HPV (%) (%) vaccination	Current cervical cancer awareness, knowledge and screening intervention
				Males						
Ortashi (15)	Emirates	2013	Male university students	356	71.0	31.0	25.0	NA	46.0	HPV vaccine is included in the national immunization programme for girls entering grade 11 An awareness and training campaign among health care providers was organized by the Health Authority of Abu Dhabi, and an extensive media campaign was also run; people were reached through the media and at work places
				Healthcare clinicians and students						
Ortashi (12)	Emirates	2012	School nurses	125	100.0	97.0	80.0	97.0	74.0	HPV vaccine is included in the national immunization programme for girls entering grade 11 An awareness and training campaign among health care providers was organized by the Health Authority of Abu Dhabi and an extensive media campaign was also run. People were reached through the media and at work places
Obeidat (21)	Jordan	2012	Female health care workers	187 female health care workers: (53 physicians, 92 nurses/ midwives, 42 others)	NA	NA	NA	26.0	NA	HPV vaccines are already licensed HPV vaccine not been included in the national immunization programme The uptake of cervical cancer screening is poor and is not nationally organized Need to develop educationalprogrammes that will target these women
Berraho (22)	Morocco	2013	Primary care physicians	87	77.7	NA	95.1	76.	NA	HPV vaccines are already licensed The initiation of a National Cancer Control Plan, have started in 2010 to implement organized screening programmes using for cervical cancer detection Adding HPV vaccine to the national immunization programme is not yet confirmed
Al-Darwish (27)	Saudi Arabia	2014	Medical school students	188	96.8	NA	Females: 53.2 Males: 45	Females: 27.2 Males: 38.7	NA	HPV vaccines are already licensed HPV vaccine not been included in the national immunization programme

Table 2 Overview of knowledge and awareness of human papillomavirus (HPV) infection and anti-HPV vaccine, and acceptability and willingness related to anti-HPV vaccine in the Arab states of the Middle East and North Africa (MENA) region (*continued*)

Study	Country	Publication year	Subgroup	N Population	Response rate (%)	Knowledge of HPV infection (%)	Awareness of HPV- cervical cancer link (%)	Awareness of anti-HPV vaccination (%)	Acceptability of anti-HPV (%) (%) vaccination	Current cervical cancer awareness, knowledge and screening intervention
Sait (*29*)	Saudi Arabia	2011	Physicians	200	80.0	NA	NA	48.5	50.0	HPV vaccines are already licensed HPV vaccine not been included in the national immunization programme Need for improvement in medicalteaching for medical students and continuing education of the doctors regarding cervical cancer prevention and screening
Shaikh (*28*)	Saudi Arabia	2014	Female university students (healthcare)	1258	89.9	NA	59.6	NA	NA	HPV vaccines are already licensed HPV vaccine not been included in the national immunization programme Most female cancer awareness campaigns are mainly focused on breast cancer
					Parents					
Moualif (*14*)	Morocco	2013	Parents	852	NA	Mothers: 4.2 Fathers: 6.6	NA	Mothers: 14.2 fathers: 14.8	Mothers: 32 fathers: 45	HPV vaccines are already licensed The initiation of a National Cancer Control Plan started in 2010 to implement organized screening programmes using for cervical cancer detection Adding HPV vaccine to the national immunization programme still a future perspective
Selmouni (*23*)	Morocco	2015	Parents of girls aged 12–15 years	653 mothers; 659 fathers	98.0	Mothers: 9 Fathers: 6.6	NA	NA	Mothers: 76.8 Fathers: 68.9	HPV vaccines are already licensed The initiation of a National Cancer Control Plan started in 2010 to implement organized screening programmes for cervical cancer detection Adding HPV vaccine to the national immunization programme still a future perspective
Alsaad (*30*)	Syria	2012	Mothers with daughters in sixth grade classes	345	86.0	18.0	8.4	34.2	NA	HPV vaccines are already licensed HPV vaccine not been included in the national immunization programme Need for health education and promotion campaign on the connection between HPV infection and cervical cancer

Table 2 Overview of knowledge and awareness of human papillomavirus (HPV) infection and anti-HPV vaccine, and acceptability and willingness related to anti-HPV vaccine in the Arab states of the Middle East and North Africa (MENA) region (*concluded*)

Study	Country	Publication year	Subgroup	N Population	Response rate (%)	Knowledge of HPV infection (%)	Awareness of HPV- cervical cancer link (%)	Awareness of anti-HPV vaccination (%)	Acceptability of anti-HPV (%) (%) vaccination	Current cervical cancer awareness, knowledge and screening intervention
Adolescents and young adults										
Zouheir (*24*)	Morocco	2015	Adolescents and young adults	1044 subjects: 688 (12–16 years) 356 (18–30 years)	82.0	20.0	NA	NA	Females: 20.4 Males: 62.0	HPV vaccines are already licensed The initiation of a national cancer control plan started in 2010 to implement organized screening programmes for cervical cancer detection Adding HPV vaccine to the national immunization programme still a future posibility

NA = not available.

lack of baseline epidemiological data, the lack of organized cervical cancer screening and the need to launch educational programmes for all subpopulations. Studies conducted in the United Arab Emirates are the only ones reporting cervical cancer awareness intervention such as training campaigns among health care providers and extensive media campaign for the population at large.

Discussion

This review revealed low to moderate knowledge of HPV infection and anti-HPV vaccine awareness; nevertheless, it showed moderate to elevated levels of anti-HPV vaccine acceptability among the various demographic groups studied.

What is interesting in our findings is that despite the lack of knowledge about HPV, its causal relationship with cervical cancer and the availability of the vaccine, a strong interest in learning more about the vaccine was identified along with a strong willingness to become vaccinated or to get daughters vaccinated.

These results convey a real opportunity for education and awareness strategies about HPV and cervical cancer. In addition, the cultural barrier that seems to be the main justification for the lack of political will to engage in national cervical cancer prevention seems unfounded.

Based on our findings, information on and public sensitization to HPV, its seriousness, potential complications, challenges and the assurance of effectiveness of the vaccine would improve the acceptability of such a vaccine (*11*). In addition, studies conducted in the only country that already has a national programme showed that the cultural barrier was mentioned by only 18% of participants, demonstrating that this reason is not among the principal barriers (*15*).

These results revealed an opportunity for countries wishing to set up a vaccination programme, and where cervical cancer is considered a public health problem. Our findings indicate that education strategies and interventions aimed at increasing awareness and knowledge about HPV and the anti-HPV vaccine would be in accordance with public expectations and would optimize the acceptability of the vaccine.

In addition, qualitative insights provided by this review showed that the factors influencing acceptability are often related to public trust issues such as concerns about side-effects and safety (*17*).

Training and education would also need to be provided for health care professionals, especially health care students, since this subgroup reported average anti-HPV acceptability. Recognizing the major importance of these current and future clinicians in terms of cervical cancer awareness and screening enhancement among the population, these efforts would be a priority in terms of cervical cancer education.

Providing scientifically correct information in a proactive manner, through specific training for health professionals or through a community-based outreach, is the only effective way for health authorities to reassure

people and ensure good vaccine acceptability (*18*).

To our knowledge, this review is the first study focusing on anti-HPV vaccine acceptability in the MENA region. One of its strengths is the inclusion of both quantitative and qualitative research studies, which increased the depth and explanatory nature of our findings.

This review focused on different subgroups of the population and did not exclude any category from the analysis. Thus, we enhanced the generalizability of the trends recorded for each subgroup throughout the geographic area of interest. The restriction on language and religion of the enrolled countries was also aimed at enhancing the external generalizability of the results.

One of the limitation of this study is a potential misclassification of demographic data based on the origin of the participants (rural versus urban) since this detail was not always clearly stated in the studies we reviewed. Additionally, not all the studies are consistent regarding their methodologies in the sense that not all the questions of interest were systematically discussed. For example, while some studies assessed level of knowledge and awareness of cervical cancer and HPV, others did not. The same was found for willingness to vaccinate and acceptability of the HPV vaccine. Some studies discussed all themes. This indicates a need for more standardized methods for collecting data in order to provide better insight. Finally, there is a possibility that we missed some eligible studies not identified in the search, or studies that were not published (publication bias).

Conclusions

To the best of our knowledge, this is the first systematic review of the potential willingness in regard to the introduction of the anti-HPV vaccine in this part of the MENA region. An examination of this area collectively offers an insight into the willingness of the population and the medical staff to receive more information about the virus and its prevention through vaccination. It also revealed the lack of clear recommendations and serious strategies towards anti-HPV vaccine from most of the health authorities of the region.

Knowing the elevated levels of acceptability and willingness to receive the anti-HPV vaccine in the Arab states of the MENA region, health authorities should benefit from this opportunity to provide more information and education for health workers, women/girls, young people and parents on HPV infection and how to acquire effective protection.

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Connaissance, sensibilisation et acceptabilité en matière de vaccin contre le papillomavirus humain dans les États arabes de la Région du Moyen-Orient et de l'Afrique du nord : analyse systématique

Résumé

Contexte : Les changements de modes de vie rapides induits par la mondialisation ont entraîné des changements de comportements sexuels, en particulier chez les jeunes générations. Ces changements peuvent avoir des conséquences considérables sur la prévalence des maladies sexuellement transmissibles, dont l'infection par le papillomavirus humain (VPH).

Objectif : La présente étude avait pour objectif de procéder à une analyse systématique des publications revues par des pairs portant sur la sensibilisation au vaccin contre le papillomavirus humain (VPH) et son acceptabilité dans les États arabes de la Région du Moyen-Orient et de l'Afrique du Nord.

Méthodes : Une recherche systématique a été effectuée dans deux bases de données électroniques (PubMed et EMBASE) afin d'identifier les études sur la sensibilisation à la vaccination contre le VPH et son acceptabilité dans la région, qui ont été produites entre janvier 2010 et avril 2017.

Résultats : Dix-huit études, menées dans neuf pays, ont été identifiées. L'analyse a montré une connaissance de l'infection par le papillomavirus humain et une sensibilisation au vaccin contre le VPH allant de faibles à modérées. Néanmoins, la plupart des études ont rapporté une acceptabilité du vaccin contre le VPH comprise entre modérée et élevée parmi les sous-populations. D'importants écarts de connaissance du vaccin contre le VPH et de disposition à l'accepter ont été mis en évidence.

Conclusion : Un examen dans la région dans son ensemble offre un aperçu de la disposition de la population générale et des prestataires de soins de santé à bénéficier de davantage d'informations sur le virus et d'une prévention de l'infection grâce à la vaccination. Cette étude suggère que l'acceptabilité des vaccins sera élevée une fois que la question des coûts sera résolue.

معرفة اللقاحات المضادة لفيروس الورم الحليمي البشري والوعي بها وتقبّلها في الدول العربية لإقليم الشرق الأوسط وشمال أفريقيا: استعراض منهجي

رحاب قمعون

الخلاصة

الخلفية: أدت التغيرات السريعة في نمط الحياة التي أفرزتها العولمة إلى حدوث تغييرات في السلوك الجنسي لا سيَّما في أوساط الأجيال الشابة. ويمكن أن تؤدي هذه التغييرات إلى آثار هائلة على مستوى انتشار الأمراض المنقولة جنسياً، ومنها عدوى فيروس الورم الحليمي البشري.

الأهداف: هدفت هذه الدراسة إلى تقديم استعراض منهجي للدراسات السابقة المحكّمة حول الوعي بلقاحات فيروس الورم الحليمي البشري وتقبّلها في الدول العربية التابعة لإقليم الشرق الأوسط وشمال أفريقيا.

طرق البحث: أجري بحث منهجي في قاعدتي بيانات إلكترونيتين، وهما قاعدة بيانات PubMed وقاعدة بيانات EMBASE، لتحديد الدراسات المتعلقة بالوعي بلقاحات الورم الحليمي البشري وتقبّلها في الإقليم في الفترة ما بين يناير ٢٠١٠ وأبريل ٢٠١٧.

النتائج: تم تحديد ١٨ دراسة من ٩ بلدان. وأظهر التحليل مستوى معرفة منخفض إلى متوسط بعدوى فيروس الورم الحليمي البشري ومستوى وعي منخفض إلى متوسط باللقاحات المضادة له. غير أن معظم الدراسات أفادت بأن مستوى تقبل استخدام اللقاحات المضادة للفيروس يتراوح ما بين متوسط إلى مرتفع في أوساط مجموعات السكان الفرعية. وأبرز وجود فجوات واسعة في مستوى المعرفة والاستعداد لتقبل استخدام اللقاحات المضادة لفيروس الورم الحليمي البشري.

الاستنتاجات: توفر دراسة الإقليم على نحو جماعي نظرة معمقة حول استعداد عموم السكان ومقدمي الرعاية الصحية لتلقي مزيد من المعلومات بشأن الفيروس والوقاية من العدوى باستخدام اللقاحات المضادة. ويشير هذا الاستعراض إلى أن مستوى تقبل اللقاحات سيرتفع بمجرد التصدي للاهتمامات المرتبطة بتكلفته.

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The most important risk factors affecting mental health during pregnancy: a systematic review

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Abstract

Background: Pregnant women comprise a vulnerable population owing to the changes they experience in various stages that affect their mental health. Mental health problems affects nearly one-fifth of pregnant women during the prenatal and postpartum periods. Millennium Development Goals 4 and 5 focus on maternal and child health and specify that overall health cannot be reached without mental health.

Aims: The aim of this comprehensive systematic review was to evaluate research evidence on the determinants of antenatal mental health disorders among Iranian women.

Methods: Using a systematic literature review of observational studies in English and Farsi we focused on Iranian women being evaluated for the determinants of antenatal mental health problems. PubMed, Scopus, ISI Web of Science, Scientific Information Databases (SID), Global Medical Article Limberly, Iranian Biomedical Journal and the Iranian Journal Database were independently searched to identify articles published during 2000–2016.

Results: Thirty-one studies met the inclusion criteria and the results showed a significant relationship between antenatal mental health risks and variables such as lack of social support, marital status, domestic violence, unintended pregnancy and socioeconomic status. The paucity of high quality research evidence limited proper evidenced-based planning and generating results deemed essential to address antenatal mental health issues for Iranian pregnant women.

Conclusions: Our results showed that socioeconomic status and marital quality are the most important risk factors for disturbing mental health among Iranian pregnant women.

Keywords: mental health, pregnancy, postpartum, risk factors

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Introduction

Mental health is a major health issue worldwide and an important factor in social mobility and efficacy (*1*) and pregnancy is a unique maternal experience with significant psychological, physiological and biochemical effects on women (*2*). Pregnant women are vulnerable because of changes they experience in the stages of pregnancy that may affect their mental health (*3–5*). Mental health problems affects nearly one-fifth of pregnant women during the prenatal and postpartum periods, which could last up to a year (*6*), and may lead to poor health for the mother, father and infant (*7,8*).

While some women overcome their mental health problems, many develop a chronic state (*9*). An international call to action by the World Health Organization (WHO) entitled "No health without mental health" has emphasized the importance of mental health issues and the major burden these have on resource-constrained countries with a limited health care budget (*10*).

A 2007 study showed that mental problems account for 7.4% of the global burden of disease measured (*11*). For this reason, mental health needs to be considered a single target in the Sustainable Development Goals (*12*). Furthermore, Millennium Development Goals 4 and 5 give a greater focus on maternal and child health and indicate that overall health cannot be attained without mental health (*13*). Maternal mental health requires a clear definition for each of the related factors to assist healthcare providers develop effective preventive care programmes. Determining the related factors associated with mental health is necessary to reach Goals 4 and 5 and this review examines the factors contributing to antenatal mental health issues among Iranian women.

Methods

Sources

In this systematic review, all the existing published studies on the determinants for antenatal mental health problems among Iranian women were collected following the Preferred Reporting Items for Systematic Reviews guidelines (*14*). Articles in Farsi and English from 2000 to February, 2016 were retrieved from the Scientific Information Databases, Global Medical Discovery (GMD), Iranian Biomedical Journal (Iran Medex), and Iranian Journal Database (Magiran), and international databases such as PubMed/

Medline, Scopus, and ISI Web of Science. Relevant article and report references were found through electronic search and reviewed manually (Table 1).

Method of selection

The research team discussed and agreed on the data extraction process and the use of standard forms. Retrieved articles were studied and evaluated by the authors independently by having the first researcher extract data and a second researcher evaluate for revision. In the case of any disagreement, the opinion of a third person was sought and considered. The information from all the studies (including authors, title, year of publication, type of study, sampling method and sample size, subjects' age and prevalence) was examined and any risk for bias reduced by indicating "insufficient information." Data summary forms helped identify and select relevant studies after systematic review. A summary of the study design characteristics is given in Table 2.

Quality assessment of articles

The quality of articles were blindly assessed by 2 independent experts using the Mirza and Jenkins checklist and in case of any disagreement a third reviewer would evaluate the articles for a final decision with consideration for the opinion of other 2 reviewers. The article evaluation checklist for selected studies included: precision and clarity of study goals, adequate sample size, representative sample with justification, clarity of inclusion and exclusion criteria, reliability and validity of mental health measurement tools, response rate for questionnaires completed and excluded samples, adequate explanation of data, and appropriate statistical analysis (*15*). The quality assessment assigned a score of 1 for "acceptable" and 0 for "unacceptable", with a maximum score of 9.

To ensure the accuracy of the extracted scores, another reviewer examined the process. Authors independently assessed, appraised, discussed and reached their final consensus on the scores.

Studies published during 2000–2016 which focused on predictive factors or showed a relationship between mental health and pregnancy were included. Those studies with pregnancy as their main inclusion criteria and some of the Iranian studies which only evaluated the effect of pregnancy on mental health after delivery were excluded.

Results

Compilation and interpretation of data

From a total of 1255 reviewed articles for related subjects, titles and abstracts, the researchers selected 30 for in-depth evaluation and quality assessment (Table 3). Articles which used descriptive–analytical methodology, cohort studies and a cross-sectional approach were included. Researchers reviewed study results in order to implement content analysis and form categories.

Studies without a discussion on the contributing factors to mental health in pregnancy (1140 articles) or those, which only discussed mental health after delivery (84 articles) were excluded. The total number of women included in all the reviewed studies was 10 465, with a mean of 267 (standard deviation 304.8).

Tools

Various assessment tools were used to evaluate mental health. For instance, 6 (19.4%) used the General Health Questionnaire (GHQ-28); 12 (38.7%) used The Beck Depression Inventory; 4 (12.9%) used the Edinburgh Postnatal Depression Scale; 3 (9.7%) used the Symptom Checklist 90 (SCL-90); 2 (6.5%) used the Depression Anxiety Stress Scale (DASS-21); 1 (3.2%) used the Spielberger State-Trait Anxiety Inventory; 2 (6.5%) used the Pregnancy Related Anxiety Questionnaire; and 1 (3.2%) used the Pregnancy Stress Rating Scale.

Maternal mental health-related factors during pregnancy

The results of the 30 articles included in this review are shown in Table 4.

Six articles discussed the relationship between social support (family, friends and spouse) and mental health during pregnancy; 2 of these studied social support in general and coming from any source with a significant effect on mental health (*16,17*). Two others found a strong negative association between the level of husband's emotional support and the level of depression in pregnant women (*18,19*). Also, Rabieipoor et al. reported that women

Table 1 Details of the search strategy

Database	Search terms	Yield
PubMed	"Mental health" AND "Depressive disorder" OR "Depression" AND "Anxiety" AND "Pregnancy" AND "Iran"	160
Elsevier	"Mental health" AND "Depressive disorder" OR "Depression" AND "Anxiety" AND "Pregnancy" AND "Iran"	547
Scopus	"Mental health" + "Depressive disorder" + "Depression" + "Anxiety" + "Pregnancy" + "Iran"	48
Scientific Information Databases (SID)	Mental health + Depression + Anxiety + Pregnancy + Iran	34
Iranian Biomedical Journal (Iran Medex)	Mental health + Depression + Anxiety + Pregnancy + Iran	165
Iranian Journal Database (Magiran)	Mental health + Depression + Anxiety + Pregnancy + Iran	128
Global Medical Discovery (GMD)	Mental health + Depression + Anxiety + Pregnancy + Iran	173

Table 2 Design characteristics and rank score of studies included in the systematic review (*n* = 31)

Study	Clear study aims	Adequate sample size	Representative sample	Clear inclusion & exclusion criteria	Measure of mental health valid and reliable	Response rate reported and losses given	Adequate description of data	Appropriate statistical analysis	Appropriate informed consent procedure	Total score
Asltoghiri et al.	1	1	1	0	1	1	0	1	1	7
Abdollahzade Rafi et al.	1	1	1	1	1	1	0	1	1	8
Shahmiri et al.	1	1	1	0	1	1	0	1	0	6
Pazandeh et al.	1	1	1	1	1	1	1	1	0	7
Omidvar et al.	1	1	1	0	1	1	1	1	0	7
Mossalanejad et al.	1	1	1	0	1	1	1	1	0	7
Ghasemi et al.	1	1	1	1	1	1	1	1	1	9
Salmalian et al.	1	1	1	1	1	0	1	1	0	7
Sadeghi et al.	1	0	1	0	1	1	1	1	0	6
Nazari et al.	1	1	1	0	1	1	0	1	1	7
Babanazari et al.	1	1	1	1	1	1	1	1	1	9
Garrusi et al.	1	1	1	1	1	1	0	1	0	7
Parsaie Rad et al.	1	0	1	1	1	1	1	0	1	7
Forouzandeh et al.	1	1	1	1	1	0	1	1	1	8
Mortazavi et al.	1	1	1	1	1	1	1	1	0	8
Moshki et al.	1	1	1	1	1	1	1	1	0	8
Kheirabadi et al.	1	1	1	1	1	1	0	1	1	8
Shishegar et al.	1	1	1	1	1	1	0	1	1	8
Abbaszadeh et al.	1	1	1	1	1	1	1	1	0	8
Baghi et al.	1	0	1	1	1	1	1	1	0	7
Rabeipour et al.	1	1	1	1	1	1	1	1	0	8
Rezaee et al.	1	1	1	1	1	1	0	1	1	8
Hosaynisazi et al.	1	1	1	1	1	1	1	0	1	8
Hosseini Nasab et al.	1	0	1	1	1	1	0	1	1	8
Zareipour et al.	1	1	0	1	1	1	1	0	0	6
Enayati et al.	1	0	1	1	1	1	0	0	1	6
Zarei et al.	1	0	1	1	1	1	1	1	1	8
Amanat et al.	1	0	1	1	1	1	1	1	1	8
Bondad et al.	1	1	1	1	1	1	0	1	1	8
Lalooei et al.	1	1	1	1	1	1	1	0	1	8
Modabernia et al.	1	0	1	1	1	1	1	0	1	7

In the overall assessments, the mean quality assessment score for the selected studies was 7.48 out of 9.

whose husbands participated in prenatal care had better mental health (*20*). However 1 study found no significant relationship between level of social support and mental health (*21*).

Eight studies discussed the relationship between marital quality (marital communication and marital satisfaction) and mental health during pregnancy; 3 of these revealed that women who were more satisfied regarding marital communication had a lower level of depression (*18,22,23*). One study showed that women in conflict with their husbands had more depression (*24*). Three of the studies revealed that women who reported lower marital satisfaction experienced greater anxiety and depression (*18,25,26*).

Fifteen articles discussed unintended pregnancy and mental health, with 5 reporting no significant relationship (*20,21,24–26*) and 7 studies reported more mental problems among women who had unwanted pregnancy (*17,27–32*).

Stress could be measured in different ways in different studies. Our review examined articles that addressed

Table 3 Characteristics of studies included in the systematic review (*n* = 31)

Study	Study type	Setting	Sample size	Mean maternal age (years)	Gestational age at screening	Assessment instrument
Asltoghiri et al. 2011	Prospective descriptive-analytical	Hamedan	161	26.4	28–30w 38–40w	BDI
Abdollahzade Rafi et al. 2008	Correlational	Shiraz	95	26.2	Third trimester	EPDS, SSQ, PSA
Shahmiri et al. 2006	Descriptive–analytical	Zanjan	300	26.2	3 trimesters	SDS
Pazandeh et al. 2002	Cross-sectional	Tehran	580	25.5	3 trimesters	BDI
Omidvar et al. 2007	Descriptive–analytical	Babol	191	25.4	3 trimesters	BDI
Mossalanejad et al. 2007	Cross-sectional	Jahrom	214	–	3 trimesters	SCL-90-R
Ghasemi et al. 2003	Cross-sectional	Tehran	1452	25.3	3 trimesters	SCL-90-R
Salmalian et al. 2007	Cross-sectional	Babol	263	25.6	Third trimester	BDI
Sadeghi et al. 2014	Longitudinal	Bandar Abbas	71	28.2	29–32w 33–36w 37–42w	STAI
Nazari et al. 2014	Descriptive–analytical	Khorramabad	280	26.7	3 trimesters	GHQ
Babanazari et al. 2008	Descriptive cross-sectional	Rasht	286	25.7	3 trimesters	PRAQ, GRIMS
Garrusi et al. 2014	Cross-sectional		255	29.1	3 trimesters	BDI
Parsaie Rad et al. 2010	Cross-sectional, analytical	Ahvaz	70	24.8	36–40w	PSQI, BDI
Forouzandeh et al. 2002	Descriptive–analytical	Shahrekord	267	24.9	3–4m 6–7m & 9	GHQ-28
Mortazavi et al. 2013	Longitudinal	Shahroud	358	24.32	Third trimesters	GHQ-28
Moshki et al. 2015	Cross-sectional	Gonabad	208	25.32	3 trimesters	EPDS
Kheirabadi et al. 2010	Prospective cohort	Isfahan	1291	–	3 trimesters	EPDS
Shishehgar et al. 2014	Cross-sectional	Shahriar	210	27	3 trimesters	PSQ
Abbaszadeh et al. 2013	Case–control	Kashan	465	25.32	3 trimesters	BDI
Baghi et al. 2013	Cross-sectional	Saqqez	140	27.40	Second and third trimester	EPDS
Rabeipour et al. 2015	Descriptive–correlational	Urmia	275	27.25	3 trimesters	GHQ-28
Rezaee et al. 2014	Cross-sectional	Babol	142	24.38	3 trimesters	DASS-21
Hosaynisazi et al. 2005	Cross-sectional	Tehran	180	26.40	3 trimesters	BDI
Zareipour et al. 2012	Cross-sectional	Kuhdasht	250	25.5	3 trimesters	GHQ-28
Enayati et al. 2008	Cross-sectional	Ahvaz	150	–	3 trimesters	SCL-90-R
Zarei et al. 2012	Cross-sectional	Tehran	267	29.5	3 trimesters	DASS-42
Ahmadzadeh et al. 2007	Descriptive–analytical	Isfahan	600	26.0	3 trimesters	BDI
Bondad et al. 2002	Descriptive–analytical	Mashad	320	24.5	3 trimesters	BDI
Lalooei et al. 2007	Cross-sectional	Tehran	400	26.4	3 trimesters	BDI
Modabernia et al. 2009	Cross-sectional	Rasht	415	–	3 trimesters	BDI

– = not known. SCL-90-R = Symptom Checklist-90-Revised. PTDS = Post-Traumatic Stress Disorder Diagnostic Scale. HSCL-25 = Hopkins Symptoms Checklist. BDI = Beck Depression Inventory-II. EDS = Edinburgh Postnatal Depression Scale. SSQ = Social Support Questionnaire. PSA = Pregnancy-Specific Anxiety. SDS = Zung Self-Rating Depression Scale. SCL-90-R = Symptom Checklist-90-Revised. STAI State-Trait Anxiety Inventory. PRAQ = Pregnancy Related Anxiety Questionnaire. GRIMS Golombok-Rust Inventory of Marital Status. PSQI = Pittsburgh Sleep Quality Index. PSQ = Pregnancy Stress Questionnaire. GHQ = General Health Questionnaire DASS21 = Depression Anxiety Stress Scale.

important aspect of stress-provoking life events. There were 3 studies reporting a direct and significant correlation between negative life events and depression (*23,24,27*), including pregnancy.

Four studies reported a direct and moderate correlation between sleep quality, breathing interruption during sleep and poor mental health. Pregnant women are among those who suffer from interrupted and poor quality of sleep, affecting their mental health (*33–36*).

Three articles studied the relationship between sex of the fetus and mother's mental health in pregnancy and reported conflicting results: 2 studies found no significant relationship (*20,37*) and 1 indicated that the level of anxiety among mothers was related to undesirable sex of the fetus (*28*).

Twelve articles discussed the relationship between

Table 4 Factors associated with mental health in studies included in the systematic review (*n* = 31)

Study	Dependent variable	Results	
		Observed association, positive or negative	No association
Asltoghiri et al. 2011	Depression	Sleep problems (positive)	
Abdollahzade Rafi et al. 2008	Depression	Social support level (negative)	
	Anxiety		Social support
Shahmiri et al. 2006	Depression	Quality of marital communication (negative) Being employed (negative) Poor socioeconomic status (positive) Parity (positive)	Maternal age Woman's education level
Pazandeh et al. 2002	Depression	Social support level Woman's educational level (negative) A history of premenstrual syndrome (positive) Having medical disorders (positive) Unwanted pregnancy (positive) Separation from parents before age 15 years (positive) Parity (positive)	Socioeconomic status Being employed Maternal age
Omidvar et al. 2007	Depression	The age difference between couples (positive) Marital dissatisfaction (positive) Quality of marital communication (negative) Stressful events (positive) Woman's education level (negative) Being employed (negative)	Parity Unwanted pregnancy
Mossalanejad et al. 2008	Mental health	Marital satisfaction (positive) Parity (negative)	Unwanted pregnancy
Ghasemi et al. 2003	Mental health	History of infertility History of abortion Woman's educational level (positive)	Economic status
Salmalian et al. 2007	Depression	History of abortion (positive) Unwanted pregnancy (positive) Pregnancy complications (positive) Maternal age (positive) Disturbing events (positive) Socioeconomic level (negative) Husband's education level (positive) Parity (positive) History of poor pregnancy outcomes (positive)	Employment of women Living in extended family History of depression
Sadeghi et al. 2014	Anxiety	Being employed (negative)	Maternal age, Woman's education level History of abortion Sex of fetus
Nazari et al. 2014	Mental health	Unwanted pregnancy (negative)	Woman's education level Economic status
	Anxiety	Undesirable sex of fetus (positive)	
	Depression		Sex of fetus
Babanazari et al. 2008	Anxiety	Marital satisfaction level (negative) Woman's education level (negative)	Unwanted pregnancy Socioeconomic status
Garrusi et al. 2014	Depression	Perceived poor body image (positive)	
Parsaie Rad et al. 2010	Depression	Sleep problems (positive)	
Forouzandeh et al. 2002	Mental health	Marital satisfaction (positive) Quality of marital communication (positive) Marital dissatisfaction (negative) Unwanted pregnancy (negative) Having medical disorders (negative) Stressful events (negative) History of mental health problems (negative) Being employed (positive)	Woman's education level Parity Unwanted pregnancy History of infertility Economic status
Mortazavi et al. 2013	Mental health	Poor economic status (negative) Parity (negative)	
Moshki et al. 2015	Depression	Social support (negative)	

Table 4 Factors associated with mental health in studies included in the systematic review (*n* = 31)

Study	Dependent variable	Results	
		Observed association, positive or negative	No association
Kheirabadi et al. 2010	Depression	History of depression (positive) Unplanned pregnancy (positive) Being a housewife (positive) Parity (positive)	
Shishegar et al. 2014	Stress	Job level of husband (positive)	Woman's education level Socioeconomic status
Abbaszadeh et al. 2013	Depression	Quality of life (negative)	Maternal age Parity Economic status Social support Unwanted pregnancy
Baghi et al. 2013	Depression	Sleep problems (positive)	
Rabeipour et al. 2015	Mental health	Parity (negative) Husbands participation level (positive) Maternal age (negative)	Unwanted pregnancy Sex of the fetus Socioeconomic status Woman's education level Woman's employment status
Rezaee et al. 2013	Depression	Woman's education level (negative)	Economic status Body mass index Parity
	Anxiety	Pregnancy complications (positive)	Maternal age Woman's education level Economic status
Hosaynisazi et al. 2005	Depression	Employment of pregnant woman (negative) Quality of marital communication (negative) Living in expanded family (positive) Husband's job level (negative) Unplanned pregnancy (positive) Woman's education level (negative) Husband's education level (negative) Husband's emotional support (negative) Domestic violence (positive) Parity (positive)	Maternal age History of infertility
Zareipour et al. 2012	Mental health	Unwanted pregnancy (negative) Maternal age (negative) Parity (negative) Poor socioeconomic status (negative) Woman's education level (positive)	Husband's education level Employment status of woman Living in expanded family Husband's job type History of abortion
Enayati et al. 2008	Mental health	Unwanted pregnancy (negative)	
Zarei et al. 2012	Anxiety	History of infertility (positive)	
Ahmadzadeh et al. 2007	Depression	Unwanted pregnancy (positive)	History of abortion Woman's education level Being an employed
Bondad et al. 2002	Depression	Sleep problems (positive)	
Lalooei et al. 2007	Depression	History of abortion (positive) Maternal age (positive) History of depression (positive)	
Modabernia et al. 2009	Depression	Woman's education level (negative) Being employed (negative) Parity (positive)	Maternal age Socioeconomic status

parity or number of children and maternal mental health and reported conflicting results: 7 articles found a positive and significant relationship (*17,29,22,25,27,29,30*) and another 5 studies showed no significant relationship (*2,23,24,37,38*).

Nine studies evaluated the relationship between obstetric history and complications and maternal mental health during pregnancy and reported contradictory results. Regarding infertility, 2 of 4 articles reported

that poor mental health status was related to a history of infertility (*39,40*). Regarding abortion, study results were contradictory with 3 reports of a significant relationship between a history of abortion and mental health (*27,39,41*) and 3 studies finding no significant relationship (*32,27,40*). Also, Salmalian et al. and Rezaei et al. reported that depression level among pregnant women was positively related to complications of pregnancy (*27,38*).

Three articles reported a positive and significant relationship between maternal depression during pregnancy and a history of mental problems (*23,29,42*).

Demographic factors

Regarding maternal age, 4 studies showed that mental problem among pregnant women had a significant positive relationship with maternal age (*22,27,30,41*), while another 6 articles reported no significant relationship (*17,18,21,37,38,42*). Omidvar et al. focused on maternal age difference with husband as a possible contributing factor and found that younger pregnant women with elderly husbands had more mental health problems (*24*).

The relationship between mental health and socioeconomic factors, including women's education level, economic status, and employment status, were evaluated in many studies: 2 showed that pregnant women with poor economic status experienced more depression (*18,22*), but 8 did not find any such relationship (*17,20,23,26,28,38,39,43*)

Studies on a woman's employment status and mental health during pregnancy generated conflicting results, where 5 studies showed no significant relationship between women's mental health and their employment status (*17,20,27,30,37*), and 4 studies found more mental problem among employed pregnant women (*18,22,23,29*). Two studies reported a strong relationship between husband's job and maternal mental health (*18,27*).

There were 13 studies exploring the relationship between a woman's education level and their spouses and maternal mental health levels during pregnancy. Six of these reported a moderate negative relationship between mothers' educational level and their mental health (*17,18,27,30,39,44*) while 7 found no significant relationship (*20,22,23,28,37,38,43*). Also, a significant positive relationship was found between husband's education level and maternal mental health (*18,27*), contradicted in 1 report (*30*).

Two studies reported that the type of family arrangement had no significant relationship with maternal mental health during pregnancy (*27,30*), but Hosaynisazi et al. reported that mental problems in pregnant women who lived in the extended family had poorer level of mental health (*18*).

Only 1 study focused on the relationship between domestic violence and women's mental health during pregnancy, and reported a significant and adverse relationship between husband's physical and sexual violence toward his pregnant spouse and her mental health (*18*).

Additional factors with inconsistent findings

Researchers found significant maternal mental problems positively related to maternal body mass index (*38*), history of premenstrual syndrome, and being separated from parents before the age of 15 (*17*). Regarding desirable body image and mental health during pregnancy, 1 study showed that women who had a positive outlook in regard to their body image had lower level of depression (*45*).

Discussion

There have been many systematic reviews about factors affecting mental health problems during pregnancy and afterward throughout the world, but the present study is the first systematic review that has been conducted in the Islamic Republic of Iran.

In general, previous studies have shown that antenatal mental problems were not directly related to economic status in low- to moderate-income countries (*46*), but other risk factors such as cultural practices had reciprocal effects on each other and contributed to severe mental disorders (*47,48*). For instance, a study from Pakistan reported that financial problems and illiteracy had a direct relationship with anxiety and depression, while family support reduced mental health problems in pregnancy (*15*). In 2010, another systematic review indicated that life stresses, history of depression, lack of social support, domestic violence, unintended pregnancy and poor communication were associated with antenatal depression (*49*).

This systemic review found a list of contributing factors for antenatal mental health problems, including lack of social support, type of relationship with husband, marital satisfaction, unintended pregnancy, stressful life events and domestic violence. According to Iranian published research, the quality of the relationship with the husband and marital satisfaction were associated with mental health issues, similar to results from high-income countries: women whose husbands welcomed their pregnancy experienced more emotional support and a better state of mental health (*13*). This is consistent with findings of Iranian studies, which reported a healthier mental state for pregnant women who had their husband's acceptance and support during pregnancy (*30,40*). Our review identified marital quality as the strongest antenatal anxiety-related factor, and this was directly associated with mental problems during pregnancy, clearly demonstrating the important role of husbands in enhancing or aggravating anxiety during pregnancy. A poor marital relationship was the most consistent variable in predicting anxiety during pregnancy and one of the most important factors for managing emotional upheavals by recruiting the husband's support to reach a desired outcome. Marital discord resulted in a lack of maternal attachment to the fetus and family unit: pregnant women experienced a high level of anxiety and expressed disgust toward pregnancy.

The conflicting findings on unwanted pregnancy and mental health indicated that unintended pregnancy by itself did not affect mental health, but when combined with poor socioeconomic status or lack of social support and pregnancy acceptance, women exhibit mental problems. Other research has emphasized the effect of socioeconomic status on mental health in association with unintended

pregnancy; in contrast, the husband's emotional support during pregnancy was associated with improved mental health (*50*).

We found that economic burdens during pregnancy affected mental health and more educated and employed women who received adequate health services tended to have a healthier mental state. In fact, more educated and employed women in low-income countries showed lower risk for mental health problems during pregnancy (*13*). Therefore, employment and financial independence increased women's participation in social activities and improved their mental health coping skills.

The results of this systemic review demonstrate that mental health in pregnancy is significantly affected by social issues, support systems, and communication within the family dynamic. These contributing factors can be modified from the social perspective through public education and policy changes to improve antenatal mental health.

The lack of reporting statistical values, including odds ratio and risk ratio, is the most important limitation of this systematic review. Therefore, we could not estimate the effect size of each mental health-related factor. Nevertheless, our results showed that socioeconomic status and marital quality are the most important risk factors for disturbing mental health among Iranian pregnant women. Our findings could be used as a guide to educate and train clinicians to recognize the risk factors and screen women at every prenatal visit and monitor for mental health concerns.

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Facteurs de risque les plus importants affectant la santé mentale pendant la grossesse : analyse systématique

Résumé

Contexte : Les femmes enceintes constituent une population vulnérable du fait des changements dont elles font l'expérience à différentes étapes qui affectent leur santé mentale. Les troubles de santé mentale touchent près d'un cinquième des femmes enceintes durant les périodes prénatale et postpartum. Les objectifs du Millénaire pour le développement n° 4 et 5 se concentrent sur la santé de la mère et de l'enfant, et spécifient que la santé en général ne peut être atteinte si la santé mentale n'est pas assurée.

Objectif : La présente étude systématique détaillée avait pour objectif d'évaluer les données issues de la recherche menée sur les déterminants des troubles de santé mentale pendant la grossesse parmi les femmes iraniennes.

Méthodes : À l'aide d'un examen systématique de la littérature portant sur les études d'observation en anglais et en farsi, nous nous sommes concentrés sur l'évaluation des déterminants des problèmes de santé mentale pendant la grossesse chez les femmes iraniennes. Des recherches indépendantes ont été menées dans PubMed, Scopus, Web of Science, Scientific Information Database (SID), Global Medical Article Limberly, Iranian Biomedical Journal et Iranian Journal Database afin d'identifier les articles publiés entre 2000 et 2016.

Résultats : Trente et une études répondaient aux critères d'inclusion, et les résultats obtenus démontraient un lien significatif entre les risques de santé mentale pendant la grossesse et des variables telles que le manque de soutien social, le statut marital, la violence domestique, une grossesse non désirée et le statut socio-économique. Le manque de données de recherche de qualité constituait un frein à la planification reposant sur des bases factuelles, ainsi qu'à la génération de résultats jugés essentiels pour le traitement des problèmes de santé mentale pendant la grossesse chez les femmes iraniennes.

Conclusions : Nos résultats ont montré que le statut socio-économique et la qualité de la vie conjugale étaient les facteurs de risque les plus à même de perturber l'état de santé mentale des femmes enceintes iraniennes.

عوامل الخطر المهمة المؤثرة على الصحة النفسية أثناء الحمل: استعراض منهجي

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الخلاصة

الخلفية: تشكّل النساء الحوامل إحدى الفئات السكانية المعرضة للخطر بسبب التغيرات التي تشهدنها خلال مراحل الحمل المختلفة والتي تؤثر على صحتهن النفسية. فتؤثر مشكلات الصحة النفسية على نحو خُمس النساء الحوامل خلال مرحلتي الحمل والنفاس. ويركّز الهدفان ٤ و٥ من الأهداف الإنمائية للألفية على صحة الأم والطفل ويشيران إلى أن الصحة العامة لا يمكن تحقيقها دون الصحة النفسية.

الأهداف: هدف هذا الاستعراض المنهجي الشامل إلى تقييم البراهين البحثية المتعلقة بمحددات الاضطرابات النفسية أثناء الحمل في أوساط النساء الإيرانيات.

طرق البحث: ركّزنا على النساء الإيرانيات اللاتي يجري تقييم محددات مشكلات الصحة النفسية لديهن أثناء الحمل وذلك باستخدام استعراض

منهجي للدراسات القائمة على الملاحظة باللغتين الإنجليزية والفارسية. وتم البحث بشكل منفصل في قواعد البيانات PubMed وScopus وشبكة العلوم ISI وقاعدة بيانات المعلومات العلمية (SID) ومجلة (Global Medical Article Limberly) ومجلة البيولوجيا الطبية الإيرانية وقاعدة بيانات المجلات العلمية الإيرانية، وذلك لتحديد المقالات التي نشرت خلال الفترة ٢٠٠٠–٢٠١٦.

النتائج: استوفت ٣١ دراسة معايير الإدراج وأظهرت النتائج علاقة دالة بين مخاطر الصحة النفسية أثناء الحمل ومتغيرات مثل نقص الدعم الاجتماعي والوضع العائلي والعنف الأسري والحمل غير المقصود والحالة الاقتصادية الاجتماعية. وأدت ندرة البراهين البحثية عالية الجودة إلى الحد من التخطيط السليم القائم على البراهين وتحقيق نتائج عُدّت أساسية للتصدي لمشكلات الصحة النفسية للنساء الحوامل الإيرانيات.

الاستنتاجات: أظهرت نتائج الدراسة أن الحالة الاقتصادية الاجتماعية وجودة العلاقة الزوجية هما أهم عاملين من عوامل الخطر للإصابة باضطراب الصحة النفسية لدى النساء الحوامل الإيرانيات.

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Effects of iron supplementation and nutrition education on haemoglobin, ferritin and oxidative stress in iron-deficient female adolescents in Palestine: randomized control trial

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Abstract

Background: Iron deficiency and iron-deficiency anaemia are associated with oxidative stress, but their role is largely unclear. Information is scarce on the effects of iron supplementation on biomarkers of oxidative stress in humans.

Aims: This study evaluated the effectiveness of iron supplementation and nutrition education on improving the levels of haemoglobin and ferritin, and decreasing oxidative stress among iron-deficient female adolescents in Gaza, Palestine.

Methods: A total 131 iron-deficient female adolescents were recruited and allocated randomly into 3 different groups. The iron supplementation group (A) received 200 mg of ferrous fumarate weekly during the 3-month intervention, the iron supplementation with nutrition education group (B) received iron supplements with nutrition education sessions, and the control group (C) did not receive any intervention. The levels of haemoglobin, ferritin and malonyl dialdehyde were measured at baseline, after 3 months (at which point the intervention was stopped), and then 3 months later. Trial registration number: ACTRN12618000960257.

Results: Haemoglobin levels increased significantly after supplementation in both groups A and B. At the follow-up stage (3 months after stopping the intervention), iron and haemoglobin levels in group B continued to increase and malonyl dialdehyde decreased. In Group A, haemoglobin, ferritin and malonyl dialdehyde levels decreased after 3 months of stopping the intervention. No changes were seen in Group C.

Conclusions: A nutrition programme should be adopted and integrated into comprehensive intervention programmes to target iron-deficiency anaemia among female adolescents in Palestine.

Keywords: Adolescent; female; anaemia, iron deficiency; oxidative stress; dietary supplements, Gaza

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Introduction

Iron deficiency is the most common form of nutritional disorder worldwide, affecting more than 2 billion people globally (*1*). Iron deficiency is not the only cause of anaemia but where anaemia is prevalent, iron deficiency is the most common cause (*2*). Most adolescents suffer from iron deficiency and its adverse health effects (*2*). In Gaza, Palestine, the prevalence of anaemia was reported as 33.3% (*3*), while the prevalence of iron deficiency was 23.6% among adolescents (*4*). Adolescents of today are the adult population of tomorrow and therefore their health and wellbeing are important (*5*).

Pregnancy increases the risk of iron deficiency and the approach to iron-deficiency anaemia in pregnancy has changed recently, from providing nutritional supplements during pregnancy to taking steps earlier to ensure that women, especially adolescents, have adequate iron stores before conception (*6*).

Previous studies have found that knowledge is one of the first steps to changing behaviour. Nutrition knowledge is therefore an essential basis for good dietary habits (*7,8*). Conversely, a lack of knowledge is a risk factor for malnutrition (*9*). Nutrition education programmes are needed to increase awareness in female adolescents about anaemia (*10*). Moreover, health education has proven to be very effective and has resulted in a substantial improvement in iron levels and nutrition knowledge (*11,12*).

Oxidative stress is defined as an imbalance between the oxidation and anti-oxidation systems, resulting in the excessive production of reactive oxygen species (*13,14*). Reactive oxygen species of erythrocytes is one of the principal causes of anaemia (*15*). Red blood cells are subjected to continuous oxidative stress during their lifetime. They are particularly susceptible to oxidative damage from high content of unsaturated fatty acid chains in the lipid bilayer combined with high oxygen

levels (16).

As far as we know, no studies have been carried out to assess the effects of ferrous fumarate supplementation on the biomarkers of oxidative stress in female adolescents with iron deficiency and iron deficiency anaemia. Therefore, the aim of this study was to evaluate the effects of iron supplementation and nutritional education on haemoglobin (Hb) and ferritin levels and oxidative stress in female adolescents (aged 15–19 years) with iron deficiency and iron-deficiency anaemia in Gaza, Palestine.

Methods

Study design and setting

This randomized control trial was conducted in Gaza, Palestine on female adolescents aged 15–19 years with iron deficiency and iron-deficiency anaemia (mild and moderate). The study was conducted from 25 October 2015 to 25 April 2016.

Sample size and selection

The sample size was calculated based on the formula for 2 means:

$$n = [(Z\alpha/2 + Z\beta)^2 \times 2(\sigma^2)]/(\mu_1 - \mu_2)^2$$

Where:

μ_1 = mean change in Hb after 3 months from iron supplements = 1.23 g/dL (17).

μ_2 = expected mean change in Hb after 3 months from iron supplements = 2 g/dL

σ = standard deviation = 1.195

$Z\alpha/2$: at 5% level of significance = 1.96

$Z\beta$: for a power of 80% = 0.84.

The calculation gave 38 respondents in each group. However, assuming a 15% drop-out from the trial, the number of participants was increased to 45 per group.

Eligibility

Participants were eligible for inclusion in the trial if they were unmarried and not pregnant. Participants were excluded if they: had severe anaemia (Hb < 8 g/dL); were suffering from acute or chronic infections that could affect their Hb and ferritin levels at the time of the blood sampling; had anaemia other than iron-deficiency anaemia; were underweight; were on medication; or were diagnosed with thalassemia trait.

Group allocation and intervention

This intervention programme was part of a 2-phase study in which anaemia and iron deficiency status were assessed among female adolescents attending secondary schools in Gaza (first phase).

In the first phase, a sample of female adolescents aged 15–19 years was selected from secondary schools in Gaza. As there are 5 governorates in Gaza, 1 school was selected from each governorate out of a total of 145 schools. Schools were listed by governorate and 1 was randomly selected from each governorate. Similarly classes were selected randomly from grades 10, 11 and 12 in the selected schools, 1 or 2 class(es) from each grade according to the population of the governorate. All the girls in the selected classes (330 girls) were assessed for iron deficiency and iron-deficiency anaemia. Preliminary screening for iron deficiency and iron-deficiency anaemia (Hb < 12 g/dL and ferritin < 15 µg/L) was done through vein blood samples. The girls were also interviewed in school by a female research assistant about their socioeconomic status and to determine if they met the eligibility criteria.

A total of 177 girls (54%) had iron deficiency or iron-deficiency anaemia. Of these, 43 did not meet the eligibility criteria and were excluded. Therefore 135 students with iron deficiency or iron-deficiency anaemia were invited to participate in the second phase of the study. None was taking taking any supplements. Those who agreed (n = 131) were randomized into 3 groups (Figure 1).

- Group A (iron supplementation) included 45 participants who received 200 mg of ferrous fumarate once weekly for 3 months; this was given by the researchers during school hours.
- Group B (iron supplementation with nutrition education) included 44 participants who received iron supplements (ferrous fumarate) once weekly and 9 nutritional education sessions (1.5 hours/session) for 3 months.
- Group C (controls) included 42 participants who did not receive any intervention throughout the study period.

The purpose of the nutrition education was to teach the participants about the importance of good nutrition, with an emphasis on iron deficiency and iron-deficiency anaemia. The nutrition education intervention consisted of lectures, posters, videos, booklets, and brochures. Nutrition lectures were delivered by the researchers using simple methods and vocabulary to present topics on nutrition in Arabic such as food groups, the food pyramid, a balanced diet, iron absorption enhancers and inhibitors, good sources of iron, and ways to improve the absorption of iron from foods.

After 3 months of the intervention, the supplementation and education sessions were stopped for Groups A and B, and the groups were followed up after a further 3 months.

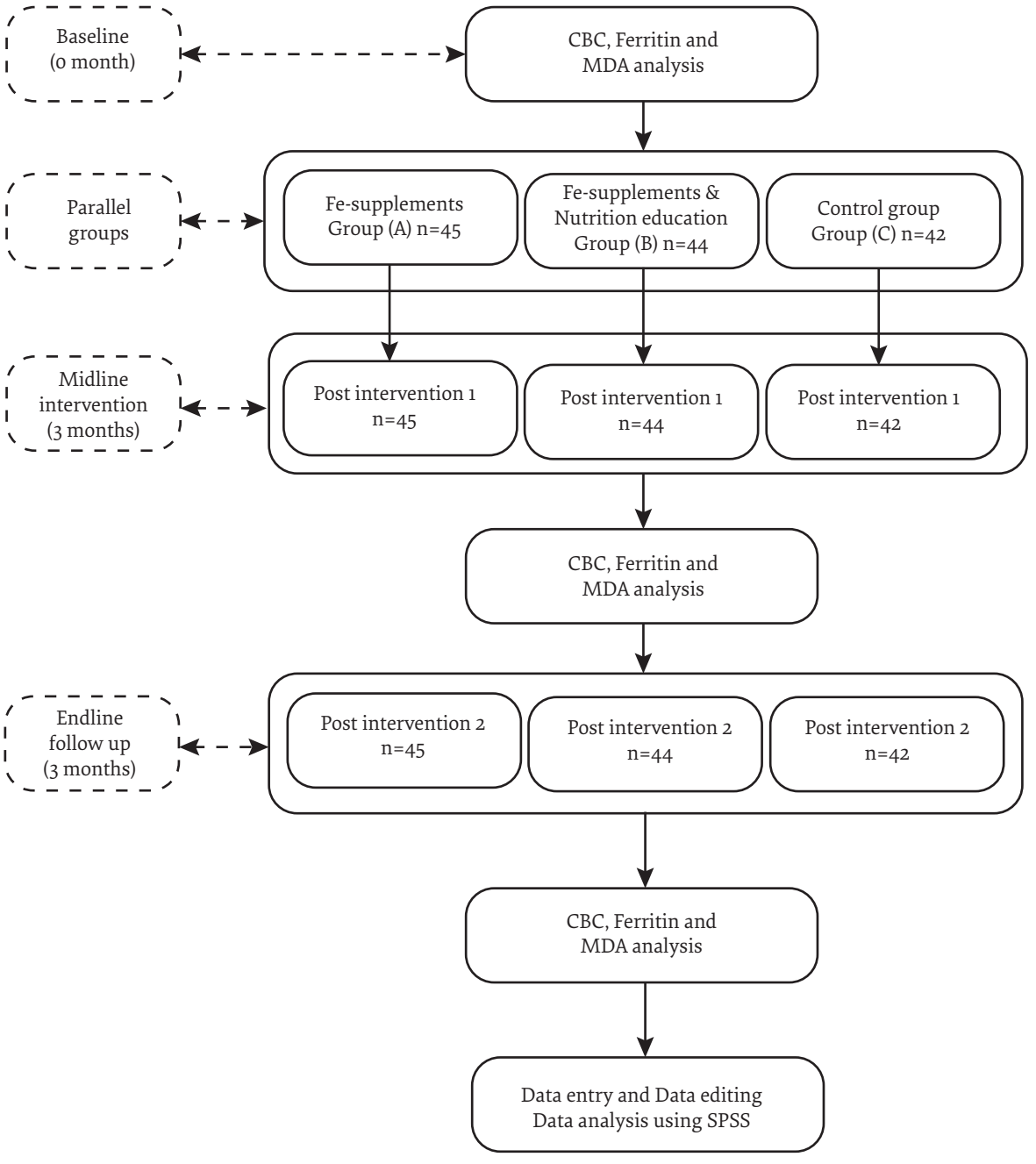
After the study was completed, the intervention was offered to the girls in the control group; they were given a packet of iron supplement tablets (20 tablets) and 2 sessions of nutrition education.

Measurements

Three blood assessments were done: at baseline (25 October 2015), after 3 months (first post-intervention, 25 January 2016), and after 6 months of baseline (second post-intervention (25 April 2016).

Complete blood count, serum ferritin and malonyl dialdehyde (MDA) levels were measured. About 5 mL of

Figure 1 Flow diagram of the progress of the groups through the stages of the study, at baseline, and after 3 and 6 months of the intervention (CBC = complete blood count, MDA = malonyl dialdehyde, Fe = Iron)



venous blood were drawn (0.5 mL in EDTA tubes and 3 mL in serum evacuated tubes) from each participant. All the samples were placed in tube racks and packed in an appropriate ice container (4 °C) and sent to a laboratory accredited by the Palestinian Ministry of Health. The samples were analysed on the same day. Blood samples were coded so assessors were unaware of the group a blood sample was from.

Anaemia was assessed by measuring Hb concentration in the complete blood count analysis (Horiba ABX Micros ES 60, France). Iron status was assessed by measuring the serum ferritin levels (Chemistry Autoanalyzer, Model: BS-120, Mindray Bio-Medical Electronic Co. Ltd, China) in duplicate, and recording the average results. An MDA adduct competitive ELISA kit (OxiSelect™, Cell Biolabs, Canada) was used to measure MDA levels.

Body weight of each participant was measured by using a calibrated scale (Seca model 750 1017009, Germany. Students were weighed barefooted to the nearest 0.5 kg. Standing height also was measured without shoes to the nearest 0.5 cm with a stadiometer (Seca body meter 206, Germany), with the shoulders in a relaxed position and the arms hanging freely. The body mass index (BMI) for age was be calculated using the Anthro Plus program of

the Centers for Disease Control and Prevention (version 7.1.5.2). Duplicate measurements of weight and height of the students were taken and the mean of value was determined.

Statistical analysis

All analyses were conducted using *SPSS*, version 22. Repeated measures analysis of variance (one-way repeated measures ANOVA) was used to evaluate changes in all the continuous variables (Hb, ferritin and MDA) over the study period. Repeated measures ANOVA measured the changes between the groups, within the group, and time and group interactions. A *P*-value < 0.05 was considered statistically significant.

Ethical considerations

Before data collection, written permission to carry out the study was obtained from the Helsinki Committee in Palestine and the Ministry of Education in Palestine (reference number PHRC/HC/3^/14). After reviewing the study protocol, the Human Ethics Committee of Universiti Kebangsaan Malaysia gave its ethical approval (reference number UKM1.5.3.5/244/NN-025-2015).

In keeping with social and cultural norms, a female interviewer was hired. Written consent was obtained from all the respondents if they were aged ≥18 years or from their parents if they were under 18 years. It was explained that they were free to withdraw from the study at any time.

Trial registration

This trial is registered under ACTRN number: ACTRN12618000960257.

Results

Descriptive results of the study sample

Table 1 describes the baseline sociodemographic characteristics of the participants (age, region, educational grade), BMI, and blood analysis. Ferritin and MDA levels in group B were slightly higher than in the other 2 groups but no statistically significant differences were found. Thus, no adjustments were made in the outcome analysis on the basis of any of the variables.

Effect of nutrition education and supplementation on Hb, ferritin and MDA status

The main objective of the trial was to determine the effectiveness of iron supplementation and nutrition education on the levels of Hb, ferritin and MDA in female adolescents aged 15–19 years. The effect of the intervention was assessed using the 2 dimensions of repeated measure ANOVA; firstly, the within group effect to determine whether there was a difference in the blood parameters (Hb, ferritin and MDA), and secondly, to assess the interaction of treatment and time together.

Table 2 shows that the difference in the mean Hb concentration was statistically significant between within the same group at different intervals ($P < 0.001$). A post-hoc test using the Bonferroni correction showed that there was a statistically significant difference between all the timelines. The mean ferritin concentration also differed significantly between the timelines ($P < 0.001$). A post-hoc test using the Bonferroni correction showed that there was a statistically significant difference between the baseline and midline, and the baseline and end-line, but there was no statistically significant difference between the midline and end-line. There was a statistically significant difference between the 3 timelines in MDA concentrations also ($P < 0.001$). The Bonferroni test showed that the differences were statistically significant between the baseline and midline, and the midline and end-line, but not between the baseline and end-line.

The results of the mean ferritin concentration were statistically significant between the groups at midline and end-line (post-intervention and post-intervention 2) ($P < 0.001$).

Figures 2, 3 and 4 explain the differences in the effect of nutrition education intervention between the 3 groups after 6 months. The trend in the plot showed the adjusted mean levels (estimated marginal mean) of Hb, ferritin and MDA for zero months (baseline), 3 months (intervention period) and 6 months (follow-up without intervention). The mean Hb, ferritin and MDA levels

Table 1 Characteristics and blood measurements of the groups at baseline (randomization)

Variable	Group A (*n* = 45)	Group B (*n* = 44)	Group C (*n* = 42)	Test value	*P*-value
Age (years) [mean (SD)]	16.11 (0.89)	16.37 (0.78)	16.51 (0.89)	2.422[a]	0.09
Grade (10th, 11th, 12th) [No.]	18, 12, 15	16, 10, 18	9, 15, 18	4.452[b]	0.34
Region (NG, GC, MG, KH, RF) [No.]	10, 10, 10, 9, 6	4, 15, 14, 6, 5	12, 10, 10, 7, 3	7.915[b]	0.44
Body mass index (kg/m²) [mean (SD)]	21.74 (3.88)	22.63 (3.57)	22.49 (4.13)	20.405[a]	0.50
Haemoglobin (g/dL) [mean (SD)]	11.52 (0.96)	11.45 (1.18)	11.73 (0.89)	0.800[a]	0.41
Ferritin (µg/dL) [median (IQR)]	8.60 (4.0)	10.50 (4.5)	9.50 (6.0)	1.471[b]	0.47
Malonyl dialdehyde (Pmol/mL) [median (IQR)]	83.0 (43.0)	92.0 (31.0)	83.50 (63.0)	1.076[b]	0.58

[a]*One-way ANOVA F-test.* [b]*Kruskal–Wallis chi-squared test.*

NG: North Gaza, GC: Gaza City, MG: Middle Governorate, KH: Khanyounis, RF: Rafah.

SD = standard deviation, IQR = interquartile range.

Table 2 Changes in haemoglobin, ferritin and malonyl dialdehyde levels at different intervention times

Blood analysis	Intervention groups			Mixed repeated-measure ANOVA	
	Group A (n = 45)	Group B (n = 44)	Group C (n = 42)	Time effect	Interaction effect
	Mean (SD)	Mean (SD)	Mean (SD)	ηp^2 (P-value)	ηp^2 (P-value)
Haemoglobin (g/dL)				0.373 (< 0.001)*	0.177 (< 0.001)*
Baseline	11.52 (0.96)	11.45 (1.18)	11.73 (0.89)		
Midline	12.46 (0.64)	12.09 (1.02)	11.98 (0.93)		
End-line	12.04 (0.67)	12.17 (0.94)	11.74 (0.84)		
Ferritin (µg/L)				0.511 (< 0.001)*	0.331 (< 0.001)*
Baseline	9.92 (3.16)	9.19 (2.92)	9.70 (3.48)		
Midline	15.92 (5.43)	14.75 (3.69)	10.13 (5.25)		
End-line	13.94 (4.61)	15.73 (3.99)	10.14 (4.14)		
Malonyl dialdehyde (Pmol/L)				0.437 (< 0.001)*	0.186 (< 0.001)*
Baseline	90.14 (47.88)	91.5 (27.33)	96.23 (40.81)		
Midline	129.8 (61.89)	116.7 (35.33)	112.0 (39.79)		
End-line	91.2 (43.60)	78.64 (25.62)	107 (39.96)		

**Significant at P < 0.05.*

ηp = partial eta, SD = standard deviation.

were almost equal for the 3 groups at the baseline. After 3 months of the intervention, the mean Hb, ferritin, and MDA levels increased in the 2 intervention groups but there were no changes in the control group. After 6 months of the baseline, the Hb and ferritin levels still increased in the nutrition education group, while the MDA level decreased in the same group. On the other hand, for the group that received iron supplementation alone, there was a decrease in the Hb and ferritin levels at the follow-up stage.

Discussion

This study evaluated the effects of an iron supplementation and nutrition education intervention on Hb, serum ferritin and MDA levels as indicators of oxidative stress among female adolescents with iron deficiency and iron-deficiency anaemia in Gaza, Palestine.

After 3 months of the intervention, mean Hb concentration had increased significantly in groups A and B. This finding is consistent with the results of studies in Malaysia and Ghana in 2012 (*17,18*).

The results of our study showed that weekly iron supplementation (200 mg of ferrous fumarate) led to an increase in Hb levels from a mean of 11.52 (SD 0.96) g/dL to 12.46 (SD 0.64) g/dL after 3 months. This result is consistent with that of previous studies. For example, a study in India found an increase in mean Hb levels from 10.51 (SD 0.35) g/dL to 12.49 (SD 0.65) g/dL after 3 months of weekly iron supplementation with folic acid among

Figure 2 Mean ferritin levels of the groups pre- and post-intervention

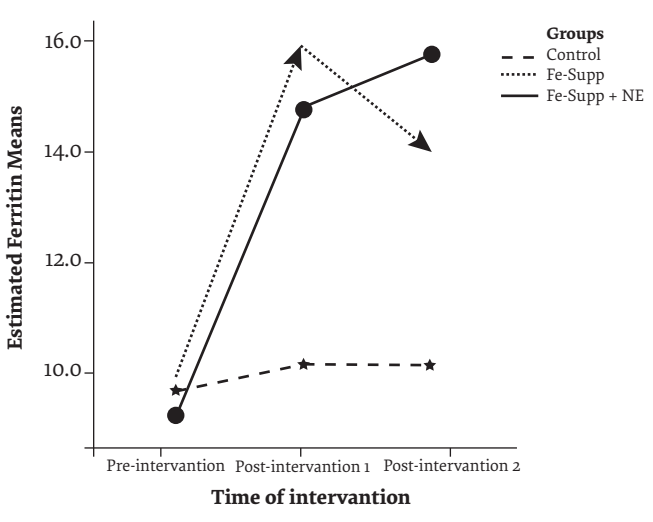


Figure 3 Mean haemoglobin levels of the groups pre- and post-intervention

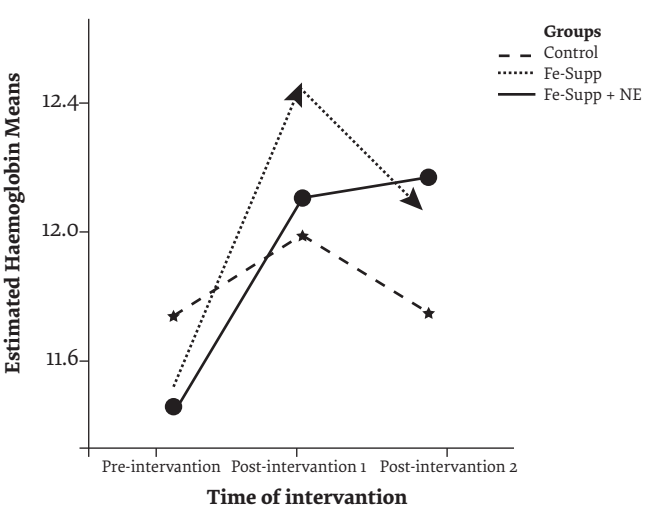
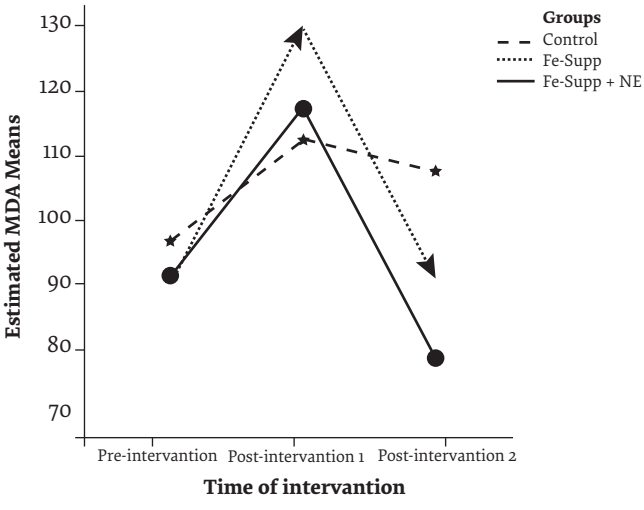


Figure 4 Mean malonyl dialdehyde levels of the groups pre- and post-intervention



female adolescents (*19*). Another study in India found the mean Hb level among female adolescents with anaemia increased from 10.80 g/dL to 12.65 g/dL after 3 months of once weekly iron supplementation (*20*). Similarly, the study in Ghana among students with anaemia aged 6–11 years reported an increase in mean Hb levels from 11.38 (SD 0.15) g/dL to 11.63 (0.13) g/dL after 10 weeks of a 5-day weekly iron supplementation (65 mg of ferrous fumarate) (*17*). A study in Peru also reported an increase in mean Hb levels with twice-weekly iron supplementation (60 mg of ferrous sulfate)—from 11.39 (SD 0.05) g/dL to 12.07 (SD 0.01) g/dL—among female adolescents with anaemia aged 12–18 years after 4 months (*21*).

No significant differences in Hb levels were seen between groups A, B and C (P = 0.57) before the intervention. At 3 months, a significant increase in the Hb levels was seen in groups A and B but not the control group. At 6 months, Hb levels in group A decreased, but in group B, Hb levels continued to increase, though at a lower rate, until the end of the study. These results are consistent with the results of a study conducted among adolescents in Malaysia (*17*). The improvement in the Hb levels in the participants in the iron supplementation group was most likely due to the iron supplementation, while the improved Hb levels in the participants in the iron supplementation with nutrition education group were most likely because of modifications to their dietary habits, which depended on a positive attitude and good practices.

The effect of the iron supplementation on iron levels was assessed using the mean ferritin concentration. There was a significant increase in the mean ferritin level in Groups A and B. This finding is consistent with the findings of the studies by Opoku and Menendez et al. (*18*,*22*). In our study, mean ferritin levels after 3 months of iron supplementation in group A changed from 9.9 (SD 3.16) µg/L to 19.92 (SD 5.43) µg/L. This change was higher than the change in a study in Malaysia where ferritin levels increased from 34.3 (SD 2.49) µg/L to 37.5 (SD 2.49) µg/L among female adolescents aged 12–17 years with anaemia but not iron deficiency following weekly iron supplementation for 3 months (*23*). This difference in the amount of increase may be because the Malaysian study targeted non-iron-deficient female adolescents. In addition, according to the results of our study, the change in the ferritin levels after the iron supplementation was lower than the study by Opoku, in which an increase in the ferritin levels was reported from a mean of 14.17 (SD 0.64) µg/L to 40.38 (SD 4.95) µg/L following 5-day a week iron supplementation for 10 weeks among students aged 6–11 years with iron-deficiency anaemia (*18*). This difference may have been due to the age differences between the studied samples.

Information is scarce on the effects of iron supplementation on the biomarkers of oxidative stress in humans (*24*). The lack of epidemiological data on oxidative damage in healthy human populations is a serious gap in the distribution, correlation and causative factors of oxidative damage (*25*). Iron deficiency and iron-deficiency anaemia are associated with oxidative stress, but their role in initiating stress is largely unclear. Also, oxidative stress induced by iron deficiency and iron-deficiency anaemia may also be caused by an inadequate supply of oxygen to tissues, resulting in increased concentrations of inflammatory mediators that activate leukocytes (*26*,*27*). There are inconsistencies in the results of these studies. Previous studies reported that MDA levels increased significantly in iron-deficiency anaemia (*28*–*30*).

In iron-deficiency anaemia, oxidative stress increases with the generation of free radicals, while therapeutic doses of iron supplements increase oxidative stress and antioxidant supplementation reduces oxidative stress. This increase and reduction in oxidative stress was studied among adults (*31*). Unlike in adults, oxidative stress in iron-deficiency anaemia is not aggravated by iron supplementation among children aged 10 months to 16 years (*31*). Tiwari et al. concluded that iron supplementation is effective in improving Hb levels but at the cost of increased oxidative stress among women with anaemia (*29*). An increase in MDA levels has been reported after 13 weeks of iron supplementation (*32*). An increase was also found in women after only 4 weeks of iron supplementation (*33*). The MDA level correlated with the serum ferritin level, suggesting that the iron status, having been modified by iron supplementation, increased the biomarker of lipid peroxidation (MDA).

In contrast, the findings of our study differ from other studies that reported iron supplementation for 6 weeks or 12 weeks caused a decrease in MDA levels (*24*,*30*), while another study reported no significant effects on lipid peroxidation and iron-deficiency anaemia after iron supplementation (*33*). These different findings might be explained by the different study designs, sample sizes, biomarkers, the consideration of certain covariates in some studies, and the health status of the participants. The use of various dosages of iron supplements and

the duration of the supplementation are other possible reasons (*24*).

In our study, at week 13 of iron supplementation, the MDA biomarker was 44% higher than at the baseline. This finding is consistent with that of previous studies, which reported that an increase in the level of oxidative stress was induced by iron supplementation with ferrous fumarate or ferrous sulfate (*26*,*32*). In a 70-day study of iron-deficient non-anaemic women who were given ferrous sulfate (98.0 mg Fe/day) for 8 weeks, there was a marked increase in the plasma MDA level. At week 6 of the supplementation, the MDA indicator was more than 40% higher than at baseline (*26*,*32*).

A limitation of this study is that we did not include an intervention a group that only received nutritional education to compare with the other groups.

Conclusions

Interventions and strategies are needed to control anaemia and iron deficiency in Palestinian adolescent girls. The implementation of nutrition education programmes, including about iron-deficiency anaemia, in Palestinian secondary schools is recommended. The Palestinian Ministry of Health, in conjunction with the Ministry of Education, should carry out assessments of anaemia and iron deficiency.

The school-based nutrition education programme was associated with improvements in the Hb and iron status, and knowledge, attitudes and practices among female adolescents in Gaza. This findings highlights the importance of nutrition education. Given that iron supplementation helps adjust iron deficiency temporarily, a combination of supplementation and education is recommended to correct iron deficiency, and maintain Hb within the normal range. Our findings are supported by several studies showing nutritional education is an effective tool in improving haematocrit, Hb, serum ferritin levels and anaemia status among adolescents (*34*,*35*). Future studies are needed to determine whether nutrition education alone would be sufficient to increase Hb and ferritin among iron-deficient female adolescents.

Oxidative stress increases with iron deficiency and iron-deficiency anaemia. However, doses of ferrous fumarate for 3 months can increase the oxidative status by increasing MDA levels. The goal should be to correct anaemia without increasing the oxidative stress. Therefore, further studies are needed in this regard.

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Effets de la supplémentation en fer et de l'éducation nutritionnelle sur l'hémoglobine, la ferritine et le stress oxydatif chez des adolescentes carencées en fer (Palestine) : essai contrôlé randomisé

Résumé

Contexte : Les carences en fer et l'anémie ferriprive sont associées au stress oxydatif, mais leur rôle reste grandement méconnu. Les informations portant sur les effets de la supplémentation en fer sur les biomarqueurs du stress oxydatif chez l'homme sont peu nombreuses.

Objectifs : La présente étude a évalué l'efficacité de la supplémentation en fer et de l'éducation nutritionnelle sur l'amélioration des taux d'hémoglobine et de ferritine, ainsi que sur la réduction du stress oxydatif chez les adolescentes carencées en fer à Gaza (Palestine).

Méthodes : Au total, 131 adolescentes carencées en fer ont été recrutées et réparties de façon aléatoire en trois groupes distincts. Le groupe de supplémentation en fer (A) a reçu 200 mg de fumarate de fer sur une base hebdomadaire au cours d'une intervention de trois mois. Le groupe de supplémentation en fer avec éducation nutritionnelle (B) a reçu des suppléments en fer et a assisté à des sessions d'éducation nutritionnelle. Le groupe témoin (C) n'a bénéficié d'aucune intervention. Les taux d'hémoglobine, de ferritine et de malonyl–dialdéhyde ont été mesurés au début, après trois mois (stade auquel l'intervention a été interrompue) et ensuite trois mois plus tard. (Numéro d'enregistrement de l'essai : ACTRN12618000960257).

Résultats : Les taux d'hémoglobine des groupes A et B augmentaient significativement après une supplémentation. À l'étape de suivi (trois mois après l'arrêt de l'intervention), les taux de fer et d'hémoglobine du groupe B continuaient d'augmenter et les taux de malonyl–dialdéhyde diminuaient. Dans le groupe A, les taux d'hémoglobine, de ferritine et de malonyl–dialdéhyde diminuaient trois mois après l'arrêt de l'intervention. Aucun changement n'a été observé dans le groupe C.

Conclusions : Un programme de nutrition devrait être adopté et intégré aux programmes d'intervention globaux de façon à cibler l'anémie ferriprive chez les adolescentes en Palestine.

أثر مكمّلات الحديد و التثقيف التغذوي على مستويات الهيموجلوبين والفيريتين والإجهاد التأكسدي لدى المراهقات اللائي تعانين من نقص الحديد في فلسطين: تجربة ضابطة عشوائية

مروان جلمبو، نوريما كريم، إيهاب نصر، رازينة شاريف

الخلاصة

الخلفية: يرتبط نقص الحديد وفقر الدم الناجم عن نقص الحديد بالإجهاد التأكسدي، إلا أن دور كل منها يظل غير واضح بدرجة كبيرة. ولا تتوفر سوى معلومات شحيحة بشأن آثار مكمّلات الحديد على العلامات البيولوجية للإجهاد التأكسدي في البشر.

الأهداف: عمدت هذه الدراسة إلى تقييم فعالية مكمّلات الحديد والتثقيف التغذوي على تحسن مستويات الهيموجلوبين والفيريتين، وتضاؤل مستوى الإجهاد التأكسدي في صفوف المراهقات اللائي تعانين من نقص الحديد في قطاع غزة بفلسطين.

طرق البحث: ضمت هذه الدراسة ١٣١ مراهقة ممن تعانين من نقص الحديد، تم توزيعهن بشكل عشوائي على ٣ مجموعات مختلفة. فتلقّت مجموعة مكمّلات الحديد (المجموعة ألف) ٢٠٠ ملليجرام من فومارات الحديد أسبوعيا خلال فترة التدخل الممتدة لثلاثة أشهر، وتلقت مجموعة مكمّلات الحديد والتثقيف التغذوي (المجموعة باء) مكمّلات للحديد مع عقد جلسات للتثقيف التغذوي، ولم تتلق المجموعة الضابطة (المجموعة جيم) أي تدخلات. وقيست مستويات الهيموجلوبين والفيريتين وثنائي ألدهيد المالون مقابل خط الأساس، أي بعد ثلاثة أشهر (وهي وقت توقف التدخل)، ثم بعد ثلاثة أشهر أخرى.

النتائج: ارتفعت مستويات الهيموجلوبين ارتفاعا دالا بعد استخدام المكمّلات في كلتا المجموعتين ألف وباء. وفي مرحلة المتابعة (بعد ثلاثة أشهر من وقف التدخل)، استمرت مستويات الحديد والهيموجلوبين في المجموعة باء في الارتفاع وانخفض مستوى ثنائي ألدهيد المالون. وفي المجموعة ألف، انخفضت مستويات الهيموجلوبين والفيريتين وثنائي ألدهيد المالون بعد ثلاثة أشهر من إيقاف التدخل. ولم تشاهد أي تغييرات في المجموعة جيم.

الاستنتاجات: ينبغي اعتماد برنامج للتغذية وإدماجه في برامج التدخل الشاملة لاستهداف فقر الدم الناجم عن نقص الحديد في صفوف المراهقات في فلسطين.

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Syrian pharmacovigilance system: a survey of pharmacists' knowledge, attitudes and practices

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Abstract

Background: The Syrian pharmacovigilance (PV) system consists of a PV unit responsible for all related activities at the national level. Pharmacists' participation in the system can play a major role in its efficiency. To date, little is known about the position or the contribution of Syrian pharmacists within the programme.

Aims: To describe Syrian pharmacists' knowledge, attitudes, practices and perceived barriers to reporting of adverse drug reactions (ADR), and to evaluate the sociodemographic effects within Damascus and rural Damascus.

Methods: We used a self-administered, cross-sectional, questionnaire-based survey conducted on a random sample of 656 registered pharmacists in 2 Syrian governorates.

Results: The response rate was 77%. Fifty-five percent of pharmacists had an acceptable level of knowledge about PV. Only 10.8% stated that they had reported an ADR at least once during their years of practice. Although 29.6% claimed they had reported ADRs to the Ministry of Health, 83.1% admitted that they did not know where or how they could get the official reporting forms.

Conclusions: Pharmacists who participated in the survey demonstrated limited knowledge towards PV and the Syrian PV system, and had relatively mixed attitudes towards reporting. Although they acknowledged the importance of ADR reporting, the current level of participation is low. The reasons for under-reporting were uncertainty of the fate of the reports, how they would be addressed, the complexity of the forms and the modest publicity of the PV programme.

Keywords: pharmacovigilance, adverse drug reactions, pharmacists, survey, Syria

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Introduction

Spontaneous reporting of adverse drug reactions (ADRs) of medicines is a crucial component of any national pharmacovigilance (PV) system and a vital tool required for improving and maintaining the appropriate use of medications (*1*). The World Health Organization (WHO) defines PV as "the science and activities related to the detection, assessment, understanding, and prevention of adverse reactions or any other drug-related problems" (*2*). An ADR is commonly defined as "a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man" (*2,3*). The term "adverse drug reaction" needs to be distinguished from the term "adverse drug event" (ADE). Although other definitions exist (*4–6*) an ADE is defined as an adverse outcome that occurs while a patient is taking a drug, but is not or not necessarily attributable to it (*3*). Some ADEs are caused by errors classified as medication errors; these errors are usually more common than ADEs, but only a small percentage cause ADEs (*4*).

Pharmacists play an important role in ensuring drug safety; they focus almost exclusively on drugs during their professional education (*5*). With the recent shift in pharmaceutical education toward a patient-centred focus, reporting ADRs is becoming one of the core duties of pharmacists. Sound clinical judgment of any medication error' ADE or ADR; detailed information about the patient's past and current medical history; and insight into the effects of the drugs are required to make a correlation between the event and the drug involved (*5,6*)

In June 2012, the Syrian Arab Republic was admitted as an associate member of the WHO programme for international drug monitoring, and is currently awaiting full membership while compatibility between the national and international reporting formats is being established (*7*). The Syrian pharmacovigilance system (SPS) was established in 2011. It consists of a PV unit responsible for all related activities on the national level, and is linked to public hospitals, health programmes and local manufacturers, and internationally to the Uppsala Monitoring Centre (*8*). The PV unit has created an official online ADR reporting form, assigned PV officers in government hospitals, asked all working pharmaceutical companies in Syria to commission PV officers and initiated several training programmes (*8,9*). Pharmacists' participation in the SPS can play a major role in the success of the programme. A survey to record the status of PV in 13 Middle Eastern countries concluded that the focus of policies was on detection and prevention of counterfeit

medicines (*10*). The survey called for the exploitation of technology to enhance the ease of reporting of ADRs and related data management. Although officials from the Syrian Arab Republic were invited to participate, they did not respond, and the survey did not provide any data from this country. Surveys of 2 neighbouring countries, Jordan and Turkey, showed insufficient knowledge about the concept of PV and spontaneous reporting of ADRs (*11,12*).

To date, little is known about the position or the contribution of Syrian pharmacists toward the instated SPS and ADRs reporting programme. Our objective was to describe Syrian pharmacists' knowledge, attitudes, practices and perceived barriers to ADR reporting and to evaluate the sociodemographic effect between the city and the countryside around Damascus.

Methods

Study design

This study was approved by the Institutional Research Committee, Taibah University, Saudi Arabia. It took place between December 2013 and July 2014. The study was a self-administered, cross-sectional, questionnaire-based survey conducted on a random sample of registered pharmacists in 2 Syrian governorates, the Syrian capital Damascus and the countryside around Damascus.

Participants

We identified our sample using a multi-step randomized (using a random number generator) and cluster (governorate) technique producing a sample of 857 pharmacists [city: 304 of a possible 1278 registered in the city (24%); countryside: 553 of a possible 2140 registered in the countryside (26%)] with good-standing active licenses with the Syrian Syndicate of Pharmacists and practising in community or hospital settings. This method was used to divide the studied area (cluster) into smaller, more targeted clusters to create a more representative sample of the population that includes adequate representation of both governorates (clusters). The purpose of applying the cluster model is to examine the effect of sociodemographics in each governorate. In this case both clusters of this population were identified and pharmacists in these each of these clusters were surveyed (*13*).

Survey instrument

A comprehensive search was performed to retrieve appropriate articles/studies in PubMed, Ovid SP, Embassy, IPA, Ensco Medline, and Science Direct. The search approach engaged the keywords and/or the MeSH terms "pharmacovigilance", "adverse drug reactions," "pharmacists," and "reporting" combined with any alternative such as "adverse drug events," "Middle East," "Syria," "Arab countries," "knowledge" and "attitude." A self-administered questionnaire was designed after assessment of appropriate literature and surveys formerly utilized in analogous studies, which includes demographic information, respondent's comprehension in reference to PV concepts, the SPS, ADR reporting, their reporting practices, and the factors they perceive to be important as motivators or barriers to reporting (*9,10,12–16*). A professional group of experts consisting of 3 administrative and social pharmacy professors, 1 clinical pharmacist and 1 psychologist critically studied, validated and approved the questionnaire for content. This survey was pilot tested on 12 pharmacists not participating in this study.

The semistructured questionnaire had a total of 19 items, divided into 5 main sections. The first section included 3 items, demographic, professional, and direct patient care involvement of the participating pharmacists.

The second section consisted of 5 questions to assess the knowledge of the respondents on some selected basic terminologies of PV. These questions included general definitions and specific differences among various PV concepts. Answers to these questions were graded with a score of 1 for each correct answer and 0 for each incorrect answer, with a maximum possible score of 5; the average and the median scores were estimated. The third section consisted of 8 statements to assess pharmacists' knowledge of the current reporting system, their attitude, and their behaviour concerning the reporting of ADRs. The responses to the questions in this section were listed in a 3-point Likert scale ranging from agree to neutral to disagree. The fourth section included 2 items about respondents' perceived barriers and motivators to reporting ADRs. These questions were also listed in a 3-point Likert scale as described for section 3. The fifth and final section was a general open-ended question for the respondents to make suggestions to increase the level of pharmacists' participation in reporting ADRs. Questionnaires with > 80% of unresolved answers were not included in the study analysis.

Data collection

The investigators visited the pharmacists at their practice sites to invite them to participate in an anonymous survey delivered by hand. No additional assistance or explanation was provided by the team on answering the questions. The survey included consent to participate in the study on a separate front sheet. Time to complete the survey was determined by the respondents, as well as the business volume when the survey was handed to them. The interviewing team was instructed to ensure the completeness of all survey questions by the participating pharmacists.

Data analysis

The results were statistically analysed using *SPSS* (version 17). The Pearson Chi-squared test was used to calculate *P*-values for categorical variables; < 0.05 was considered statistically significant. Descriptive analyses were used to describe the collected data. Qualitative analysis was used to categorize pharmacists' comments into categories. Agreement was reached on classification of statements into themes after negotiation among the investigators relating to interpretation of the comments and consistency.

Results

Demographics

The 857 pharmacists visited by our team returned 656 (77%) valid surveys (city: 217, countryside: 439). The rest of the pharmacists declined to participate, kept the survey promising to fill it at a later time but lost it or failed to return it the next day, or returned incomplete surveys. The first section of the survey showed statistically significant differences between the 2 governorates in age, number of years experience and education level (Table 1). The majority of the respondents were female (64.5%) and most practised in privately owned independent pharmacies (96%). The time range spent on direct patient contact varied, with the largest number (41.5%) acknowledging direct patient contact ranging between 5 and 10 min for each patient interaction. Pharmacists practising in the countryside governorate spent more time with direct contact per patient in comparison with their counterparts in the city (P = 0.026).

Knowledge of selected basic pharmacovigilance concepts

The survey contained a group of multiple choice questions to assess the pharmacists' knowledge regarding selected basic PV-related concepts (Table 2). A 60% score was considered acceptable. Although most respondents (72%) identified the term ADR correctly according to the WHO definition (2), only 12% could make the distinction among the concepts of medication errors, ADEs and ADRs. The

Table 1 Sociodemographic characteristic of the responding Syrian pharmacists (*n* = 656), 2013–2014

Parameter	City (*n* = 217) No. (%)	Countryside (*n* = 439) No. (%)	Total (*n* = 656) No. (%)	*P*-value [a]
Age (years)				
20–29	24 (11.1)	158 (35.9)	182 (27.7)	
30–39	38 (17.5)	83 (19)	121 (18.4)	
40–49	57 (26.3)	103 (23.5)	160 (24.4)	0.013
50–59	62 (28.6)	56 (12.7)	118 (18.1)	
≥ 60	36 (16.5)	39 (8.9)	75 (11.4)	
Sex				
Female	137 (63.1)	286 (65.1)	423 (64.5)	0.736
Highest pharmacy degree				
Bachelor	149 (68.7)	313 (71.3)	462 (70.4)	
Masters	29 (13.4)	47 (10.7)	76 (11.6)	0.042
PhD/Pharm D	14 (6.4)	7 (1.6)	21 (3.2)	
Not reportedb	25 (11.5)	72 (16.4)	97 (14.8)	
Professional				
Practice setting				
Community	194 (89.4)	436 (99.3)	630 (96)	0.033
Hospital (inpatient)	11 (5.1)	2 (0.46)	13 (2)	
Hospital (outpatient)	12 (5.5)	1 (0.23)	13 (2)	
Experience (years)				
< 2c	0 (0)	212 (48.3)	212 (32.3)	
2–5	28 (12.9)	118 (26.9)	146 (22.3)	
6–10	67 (30.9)	57 (13)	124 (18.9)	0.027
11–15	88 (40.6)	23 (5.2)	111 (16.9)	
> 15	34 (15.6)	29 (6.6)	63 (9.6)	
Average time spent in direct contact with patient for each prescription (min)				
< 5	126 (58.1)	92 (21)	218 (33.2)	
5–9	61 (28.1)	211 (48.1)	272 (41.5)	0.026
10–15	26 (12)	81 (18.5)	107 (16.3)	
> 15	4 (1.8)	55 (12.4)	59 (9)	

[a] *Chi-squared test.*

[b] *Although unanswered, the minimum required for licensure in Syria is to obtain a bachelor degree.*

[c] *In Syria, pharmacists cannot practice in the city without a minimum 2 years experience in the countryside.*

term PV was correctly defined by less than 26% of the respondents. Pharmacists practising in the countryside provided more correct answers to the questions compared with their peers practising in the city (P = 0.003). The total number of pharmacists with an acceptable level of knowledge (score 3/5 or more) was 361 (55%). The total median score for the questions in this section was a poor score of 2 (interquartile range 2) out of a possible maximum score of 5. The average score was 2.06 (standard deviation 1.18). We did not run a test for normal distribution of the data.

Knowledge of the Syrian pharmacovigilance system, attitude and practice

A total of 504 pharmacists (city: 116; countryside: 388) did not know about the SPS provided by the Ministry of Health (Table 3). Those who were aware of the system said they had acquired this knowledge from other pharmacists (57.8%) or through formal publications by the Ministry of Health (53.9%). Only 71 pharmacists (10.8%) (city: 25; countryside: 46) stated that they had reported an ADR at least once during their years of practice, not necessarily to the Ministry of Health. Although 21 of them (29.6%) claimed that they reported these ADRs to Ministry of Health using the proper submission process, 59 (83.1%) admitted that they did not know where or how they could get the official reporting forms.

There was no significant difference (P > 0.05) between the 2 governorates in terms of utilization of the reporting system (data not shown). Almost 40% of the respondents believed that reporting is a professional duty of all pharmacists. Most stated that it is a shared responsibility with the pharmaceutical industry (78.1%) (Table 3). Approximately 18.3% suggested that the reporting process can help improve pharmacists' knowledge about available medications in the market. No significant differences in attitudes were observed among respondents in terms of age, sex, experience, governorate and practice setting (P > 0.05).

Perceived barriers and motivators

Factors that encouraged pharmacists to utilize the reporting system were ranked by the participating pharmacists (Table 4). The factors with the most "agree" responses were ranked top. These factors were similar in both groups of participating pharmacists. The level of seriousness of the ADR to the patient (death, life-threatening, hospitalization, disability, function, or organ impairment, congenital anomaly) topped the motivating factors for pharmacists to report ADRs (49.7%) followed by the severity of the ADR reported (47.6%), and the fact that the ADR being reported is for a newly available drug (32.9%). A newer ADR of an existing drug and the frequency of the ADR were among the factors ranked top by fewer respondents, at 27.6% and 10.4%, respectively. Several barriers to reporting were reported (Table 5). Poor availability of forms was perceived as a top barrier by 70.2% of the pharmacists who provided valid responses, 54.3% did not report because they do not have the time, 44.4% did not report because they do not know how to report ADRs, and 38.1% found the reporting system too complex. About 31% of our respondents feared that the ADR might be wrongfully reported. Legal accountability, complacency and lack of clinical training were ranked the least important factors by our pharmacists.

Pharmacists' comments on the level of participation in the Syrian pharmacovigilance system

The survey contained 1 open-ended question, in which the pharmacists were asked to provide comments on the PV system in the country. Comments were provided by only 41 pharmacists (city 13; countryside 28) and were categorized under 3 major themes.

- Disappointment with the system [n = 19 (city 4; countryside 15)] including statements such as:
- "Reporting will not result in effective follow-up from the responsible authorities."
- "Reporting is a waste of time and effort."
- "Reports will not reach listening ears."
- Reports of a complicated reporting process (n = 13; city 7; countryside 6) with statements such as:
  - "It is too complicated."
  - "We were not trained to do it."
  - "I feel like I am taking an exam when I fill this form."
- Poor engagement of pharmacists in the patient's therapeutic plan (n = 9; city 2; countryside 7) with statements such as:
  - "Patients usually report these to their physicians."
  - "We cannot be sure of the relationship of the reaction to the drug because we do not know the full history of the patient."
  - "We do not have the tools to know about patients' current and past medications."

Discussion

Knowledge of the Syrian pharmacovigilance system and selected basic concepts

Knowledge and attitude of pharmacists on ADR reporting could greatly influence their practice and thereby contribute to patient safety. The assessment of these parameters will help in identifying the interventions needed to be taken by different parties to ensure the success of the national PV programme. This is the first study of its kind in the Syrian Arab Republic that sought to assess the knowledge, attitude and practice of pharmacists concerning the national SPS.

Data reported from neighbouring countries indicate poor knowledge of PV concepts among pharmacists. In Jordan (*11*), only 25.5% defined PV correctly while 69.7% defined ADR correctly, and only 17.2% of the Turkish community pharmacists interviewed had

Table 2 Syrian pharmacists' knowledge of basic concepts of pharmacovigilance, 2013–2014

Question	Correct answer No./total valid answers (%)			Incorrect answer No./total valid answers (%)		
	City	Country	Total	City	Country	Total
What is an ADR? Harmful effects which occur when a drug is used in the usual dose. Unexpected responses to a drug when it is used at a higher dose. Harmful effects which occur when the patient is taking a drug but it is not necessarily related to the drug. None of the above.	148/215 (68.2)	322/438 (73.5)	471/653 (72.1) *P* = 0.435	67/215 (31.2)	116/438 (26.5)	182/653 (27.9)
Which statement regarding ADRs is correct? ADRs are always preventable. ADRs are preventable to some extent. ADRs are not preventable at all. ADRs refer only to the serious harmful effects of drugs.	152/217 (70)	371/439 (84.5)	523/656 (79.7) *P* = 0.727	65/217 (30)	68/419 (15.5)	133/656 (20.3)
What is pharmacovigilance? The skills required by each practising pharmacist to provide a patient-centred pharmaceutical care. The science and activities related to the detection, assessment, understanding, and prevention of adverse reactions or any other drug-related problems. The monitoring activities conducted by the government to assure the availability and accessibility of pharmaceutical preparations. The scientific discipline that identifies, measures, and compares the costs and consequences of drug therapy to healthcare systems and society.	14/212 (6.6)	159/431 (36.9)	173/643 (26.9) *P* = 0.003	198/212 (93.4)	280/431 (63.8)	470/643 (73.1)
The difference between ADR and ADE is: An ADE is a special type of ADR in which a causative relationship between the drug and the reaction can be shown. An ADE is an adverse outcome that occurs while a patient is taking a drug, but is not necessarily attributable to it, while the ADR is a necessarily attributed to the drug provided. An ADE is an expected outcome that occurs while the patient is taking a drug, while the ADR is always an unexpected outcome of the drugs. There is no difference between the terms.	19/215 (8.8)	54/434 (12.4)	73/649 (11.2) *P* = 0.664	196/215 (91.2)	380/434 (87.6)	576/649 (88.8)
How is medication errors related to adverse drug reactions and adverse drug events? Not related. ADRs can be caused by medication errors. ADEs can be caused by medication errors. Both ADRs and ADEs can be caused by medication errors.	18/215 (8.4)	58/434 (13.4)	76/649 (11.7) *P* = 0.532	197/215 (91.6)	376/434 (86.6)	573/649 (88.3)

ADR = adverse drug reaction.

any knowledge about PV (*12*). Another study found pharmacists' knowledge in regard to drug safety in the Palestinian territories to be very limited (*17*). Our results found Syrian pharmacists' knowledge to be comparable to their peers in the region (*11,12,16*). Most pharmacists still lack the ability to identify the PV concept, or to differentiate between the terms associated with it; this knowledge gap may limit their ability to identify ADEs or ADRs for reporting purposes (*14*). At the same time, the poor level of knowledge observed can negatively impact the accuracy and the validity of the whole reporting system. We believe that the low reporting rate in our sample may be related to the retail setting environment in Syrian pharmacies, where minimum interaction takes place between pharmacist and patient, unfamiliarity with the terms, the ambiguity of the reporting process and requirements, and the limited access to reporting forms, as suggested in previous studies (*11,12,17,18*). Although pharmacists practising in the countryside were significantly younger, with less experience in terms of years, a significantly higher number of them expressed adequate knowledge of SPS. Those with a Master's degree were more familiar with the concept of PV. There was no significant difference between the 2 groups on the level of utilization of the reporting system. A poor overall knowledge on the Ministry of Health reporting system for ADRs was observed (23.2%). This is a serious indicator of the ineffectiveness of the activities set up by

Table 3 Questions of knowledge of reporting system, attitude, and practice among Syrian pharmacists, 2013–2014

Statement	Level of agreement, No. (%)		
	Agree	Neutral	Disagree
I am familiar with the Syrian pharmacovigilance system (SPS) administered by the Ministry of Health	128 (19.5)	24 (3.7)	504 (76.8)
I learned about SPS through: [a]			
Professional meeting	14 (10.9)	11 (8.6)	103 (80.5)
Official ministry publication	69 (53.9)	7 (5.5)	52 (40.6)
A continuing education session	2 (1.6)	4 (3.1)	122 (95.3)
Pharmaceutical company publication	6 (4.6)	37 (28.9)	85 (66.5)
Other pharmacists	74 (57.8)	8 (6.3)	46 (35.9)
I know about the online form to report adverse drug reactions available from the Ministry of Health website	107 (16.3)	27 (4.1)	522 (79.6)
I have used the online form to report and adverse drug reaction at least once during my practice	71 (10.8)	22 (3.4)	563 (85.8)
I have used the online form to report an adverse drug reaction to: [b]			
The Ministry of Health	21 (29.6)	0 (0)	50 (70.4)
Pharmaceutical company over the phone	6 (8.5)	2 (2.8)	63 (88.7)
A company representative in person	26 (36.6)	0 (0.0)	45 (63.4)
The company distributor	2 (2.8)	12 (16.9)	57 (80.3)
Reporting adverse drug reactions is pharmacist's professional duty	247 (37.6)	127 (19.3)	282 (42.9)
Besides pharmacists, reporting adverse drug reactions is the responsibility of:			
Prescriber	141 (21.5)	442 (67.4)	73 (11.1)
Patient	87 (13.3)	372 (56.7)	197 (30)
Allied health professional	51 (7.7)	106 (16.2)	499 (76.1)
Drug company	512 (78.1)	82 (12.5)	62 (9.4)
The primary goal of adverse drug reactions reporting is (Please pick only one):			
Patient safety		449 (68)	
Transparency of exchanging clinical knowledge among healthcare practitioners		73 (11)	
Comprehensive understanding of the drug actions		95 (15)	
Improving patient's adherence to medication		33 (5)	
Other		6 (1)	

[a] *Numbers and percentages are calculated out of the 128 participants who stated they were familiar with the pharmacovigilance system. Percentages may add up to more than 100 since some pharmacists claimed they reported to more than one entity.*

[b] *Numbers and percentages are calculated out of the 71 participants who stated they had used the online form. Percentages may add to more than 100 since some pharmacists claimed they reported to more than one entity.*

the Ministry of Health in raising awareness about the programme. Nevertheless, it is better than the findings from some studies in Turkey (17.2%) and Saudi Arabia (13.2%) (*12,18*) and comparable to results from a Jordanian study (26%) (*11*).

Attitude and practice

Our results demonstrated mixed attitudes among pharmacists towards reporting. It was encouraging to note that respondents mostly demonstrated a good understanding of the purpose of reporting and a fair proportion (38%) considered reporting of ADRs to be a professional responsibility. This is still much lower than results reported from neighbouring countries, where 97% of the pharmacists interviewed in a Saudi Arabian study considered the reporting of ADRs to be an integral part of pharmaceutical care, and in Turkey, where 89% of the pharmacists believed that the role of the pharmacist in the reporting of ADRs was essential (*12,18*).

However, lower reporting rates were seen in some neighbouring countries. Only 4% of the pharmacists surveyed in a Saudi Arabian study claimed that they had submitted an ADR report to the Ministry of Health and 6.3% claimed that they had submitted a report to the pharmaceutical company (*18*). Less than 20% of the pharmacists in Jordan reported at least one ADR during the years of their practice (*11*). In Turkey, 65% of the pharmacists surveyed stated that patients reported an ADR to them during the previous 12 months, however, only 21% reported these ADRs to the organizations concerned (*12*).

Attitudes are modifiable factors (*11,14,16*), and structured continuing education programmes and adequate promotion programmes can help improve the

Table 4 Ranking of factors that encouraged Syrian pharmacists (*n* = 656) to utilize the reporting system, 2013–2014

Factor	Ranking (%)			Not ranked
	Top	Middle	Least	
Incidence of the ADR	10.4	45.9	36.3	7.5
New ADR of an older drug	27.6	49.9	13.3	9.3
Severity of the reactiona	47.6	23.2	14.9	14.3
Level of seriousness to the patient	49.7	24.5	10.4	15.4
ADR of a newly available drug	32.9	37.2	21.5	8.4

ADR = adverse drug reaction.

low reporting rates seen among pharmacists in Syria. The majority of our respondents were community pharmacists (96.3%); other studies have found hospital pharmacists to use the reporting system more frequently than community pharmacists (*11*).

Perceived barriers and motivators

We identified several factors that discourage pharmacists from reporting ADRs. In the city, time constraints were the number one barrier. Lack of knowledge on the reporting process and concern that these ADRs might be wrongfully reported were ranked highest in the countryside. Some of these factors were observed in other studies in the region. Similar to studies conducted among pharmacists in Jordan, Turkey and Saudi Arabia (*11,12,18*), our pharmacists reported limited availability of forms as the principal barrier at around 70%. Other barriers cited were lack of knowledge on how to report, time constraints and fear of wrongfully reporting an ADR. Contrary to other reports (*9,10,12,13,16*), our pharmacists did not see a lack of clinical training, complacency or legal accountability as barriers to utilizing the reporting system.

As in Jordan (*11*), our respondents ranked the level of seriousness of the reaction as the top motivator,. A new ADR was ranked top by 27.6% of our respondents (87.9% in Jordan), and if the ADR concerned a new drug, it was ranked top by 33% of our respondents (57% in Jordan). While the severity of the reaction was ranked top by 47.6% of our study respondents, the study in Jordan discussed the "unusual" nature of the reaction and this was perceived as a barrier by 97.6% of the pharmacists (*11*).

Comments on the level of participation in the pharmacovigilance system

Analysis of the pharmacists' comments showed uncertainty concerning the fate and the handling of the submitted reports, in particular they suspected the transparency with which their reports were addressed. It is obvious that the Ministry of Health needs to provide a clear explanation of the correct handling and processing of these reports. Although these points are listed on the programme website (*10*), PV awareness programmes and feedback pathways need to be established by the Ministry of Health and promoted more frequently among practising pharmacists in all settings. The submission process involved faxing or emailing the form; a direct online submission method with a receipt acknowledgement would provide a suitable solution to this problem. Comments also showed that pharmacists were disappointed with the complexity of the form itself and the submission process. We noted that the available form did not come with any guide or any explanation of the steps taken by the Ministry of Health following the reporting process. Although these steps were explained in Ministry of Health educational programmes, these programmes are limited and could not reach out to an adequate number of pharmacists. Finally, pharmacists felt that their level of engagement in the patient's therapeutic plan was minimal. This was shown to be a huge barrier for pharmacists to deliver clinical services, even in western countries (*19*). Pharmacists had difficulties identifying and dealing with different drug-related problems, including ADRs or ADEs,

Table 5 Ranking of factors that discouraged Syrian pharmacists (*n* = 656) from utilizing the reporting system, 2013–2014

Factor	Ranking (%)			Not ranked
	Top	Middle	Least	
System complexity	38.1	26.4	33.7	1.8
Availability of forms	70.2	11.4	15.8	2.6
Complacency	9.6	12.1	67.2	11.1
Legal accountability	129	9.9	71.1	6.1
Lack of clinical training	7.4	8.1	82.3	2.2
ADRs may be wrongfully reported	31.2	21.5	42.1	5.2
Lack of knowledge of the process	44.4	18.4	32.6	4.6
Time constraints	54.3	22.3	21.3	2.1

ADR = adverse drug reaction.

because they did not have full access to the patient's past and current medical situation.

Our study did have some limitations. Most respondents did not have a reliable internet access in their practice and this limited their access to the online reporting system. This barrier was not discussed in our study. Most pharmacists interviewed practised in the community, which may have contributed to the modest levels of knowledge and utilization obtained. Many pharmacists left some of the questions unanswered, or provided the same rank in their answers to many of the questions, which may have lead to some bias in the answers to these questions. Additionally, the number of pharmacists who left comments was very low.

Furthermore, since the system is in the early stages of implementing the reporting of ADRs, many pharmacists may face different barriers trying to use the system for the first time in the future. Further research adopting a work environment approach to examining barriers and motivators in reporting ADRs is required.

Lessons learnt

Most pharmacists surveyed did not achieve the 60% acceptable score in the knowledge of PV terminology and ADR reporting. There is an urgent need for educational programmes to raise awareness regarding the national PV system in the country, and to emphasize the role of pharmacists in ensuring drug safety and their responsibility to report ADRs. The role of pharmacists in the reporting of ADRs may differ from one jurisdiction to another, but their professional responsibility to report must always be an integral part of their professional duties.

Conclusions

Pharmacists who participated in the survey demonstrated limited knowledge towards PV and SPS, but relatively mixed attitudes towards reporting. Although they acknowledged the importance of ADR reporting, the current level of participation is low. The reasons for under-reporting were the uncertainty of the fate of the reports, the modality used to address these reports, the complexity of the forms and the modest publicity of the programme.

Finally, pharmacists felt they were not effectively engaged in the patient's therapeutic plan to identify the causal relation between the drug and the reaction. A future study covering all Syrian governorates would generate more-valuable data to support the findings of our study.

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Le système de pharmacovigilance syrien : étude des connaissances, des attitudes et des pratiques des pharmaciens

Résumé

Contexte : Le système de pharmacovigilance syrien est constitué d'une unité de pharmacovigilance responsable de toutes les activités associées au niveau national. La participation des pharmaciens au système contribue de façon décisive à son efficacité. À ce jour, peu d'informations sont disponibles sur la position des pharmaciens syriens à l'égard de ce programme ou sur leur contribution.

Objectif : Décrire les connaissances, les attitudes, les pratiques et les facteurs de frein perçus des pharmaciens syriens en matière de déclaration des réactions indésirables aux médicaments, ainsi qu'évaluer les conséquences socio-démographiques observées dans Damas et Damas rural.

Méthodes : Une étude transversale reposant sur un questionnaire auto-administré a été conduite sur un échantillon aléatoire composé de 656 pharmaciens agréés dans deux gouvernorats syriens.

Résultats : Le taux de réponse était de 77 %. Cinquante-cinq pour cent des pharmaciens avaient un niveau de connaissance du système de pharmacovigilance acceptable. Seuls 10,8 % ont déclaré avoir rapporté un réaction indésirable au moins une fois au cours de leurs années d'exercice. Bien que 29,6 % aient affirmé avoir notifié des réactions indésirables aux médicaments auprès du ministère de la Santé, 83,1 % ont admis qu'ils ignoraient où et comment se procurer les formulaires de déclaration officiels.

Conclusion : Les pharmaciens ayant participé à l'étude avaient une connaissance limitée de la pharmacovigilance et du système de pharmacovigilance syrien, et avaient des attitudes relativement mitigées vis-à-vis de la déclaration. Bien qu'ils aient reconnu l'importance de la déclaration des réactions indésirables aux médicaments, le niveau de participation actuel reste faible. Les raisons de la sous-déclaration étaient le fait de ne pas savoir ce qu'il adviendrait de ces déclarations, la façon dont celles-ci seraient traitées, la complexité des formulaires et la faible publicité autour du programme de pharmacovigilance.

نظام التيقظ الدوائي السوري: مسح لمعلومات الصيادلة واتجاهاتهم وممارساتهم

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الخلاصة

الخلفية: يتألف النظام السوري للتيقظ الدوائي من وحدة مسؤولة عن جميع الأنشطة ذات الصلة بهذا الموضوع على المستوى الوطني. وتلعب مشاركة الصيادلة في النظام دورًا رئيسيًا في نجاحه. ولا يُعرف، حتى الآن، سوى القليل عن موقف الصيادلة السوريين أو مساهمتهم داخل البرنامج.

الأهداف: هدفت الدراسة إلى وصف معلومات الصيادلة السوريين واتجاهاتهم وممارساتهم والحواجز المتصورة أمام إبلاغهم عن التفاعلات الدوائية الضارة، وتقييم الأثر الاجتماعي السكاني بين المدينة والريف المحيط بدمشق.

طرق البحث: أجرينا مسحًا مقطعياً معتمدًا على استبيان ذاتي لعينة عشوائية مكونة من ٦٥٦ صيدليًا مسجلًا في محافظتين سوريتين.

النتائج: بلغ معدل الاستجابة ٧٧٪. كان ٥٥٪ من الصيادلة مقبولاً من حيث المعلومات بشأن التيقظ الدوائي. وقد ذكر ٨ , ١٠ ٪ فقط منهم أنهم أبلغوا عن تفاعلات دوائية ضارة مرة واحدة على الأقل خلال سنوات ممارستهم. وعلى الرغم من زعم ٦ , ٢٩ ٪ منهم أنهم أبلغوا وزارة الصحة عن تفاعلات دوائية ضارة، لكن ١ , ٨٣٪ أقروا بأنهم لا يعرفون أين أو كيف يمكنهم الحصول على استمارات التبليغ الرسمية.

الاستنتاجات: أظهر الصيادلة الذين شاركوا في المسح محدودية معرفتهم بالتيقظ الدوائي وبالنظام السوري للتيقظ الدوائي، ولكن كان لديهم مواقف مختلطة نسبيًا تجاه التبليغ. وبرغم اعترافهم بأهمية التبليغ عن التفاعلات الدوائية الضارة، فإن مستوى مشاركتهم الحالي منخفض. وكانت

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Quality of life and family function of parents of children with attention deficit hyperactivity disorder

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Abstract

Background: Attention deficit hyperactivity disorder (ADHD) is a common paediatric neurodevelopmental disorder, with serious impacts on individuals, families and communities. It is associated with cognitive, behavioural, emotional, social and developmental disturbances and impaired academic achievement.

Aims: To describe quality of life (QOL) of parents of ADHD children and family function. To determine the relationship between QOL, family function and sociodemographic characteristics.

Methods: This was a cross-sectional study of 125 parents of children with any type of ADHD who were selected by systematic random sampling. The study was conducted between May and December 2015 in the Outpatient Family Medicine Clinic at Suez Canal University Hospital. The World Health Organization Quality of Life-Brief (WHOQOL-BREF) and Adaptability, Participation, Growth, Affection, Resolution (APGAR) questionnaires were used for data collection.

Results: Median physical, psychological and social domain scores were 12, and mean environmental domain score was 11.9. The median scores of perception of health and QOL of the parents were 3.0. Most of the families (79.2%) were dysfunctional. Statistically significant relationships were found between all domains and education; physical scores of QOL and gender, employment and income; psychological scores of QOL and residence; environmental scores of QOL and age, income and marital status. Dysfunctional families were likely to be affected by age, gender, physical and psychological domain scores of QOL of parents.

Conclusions: Parents of children with ADHD had average QOL. Most parents had dysfunctional families. Future family intervention studies are recommended.

Keywords: attention deficit hyperactivity disorder, children, family function, parents, quality of life.

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Introduction

Attention deficit hyperactivity disorder (ADHD) is one of the most common neurodevelopmental disorders in children and adolescents. Symptoms of ADHD are associated with disturbances in cognitive, behavioural, emotional, social and developmental function and impaired academic achievements (*1*). ADHD is a heterogeneous disorder with genetic factors and deficits in brain structure and neuronal functioning and connectivity (*2,3*).

According to the definition of ADHD in the Diagnostic and Statistical Manual of Mental Disorders 4th Edition (DSM-IV), the prevalence in 22 Arab countries was 1.3–16%. In 2 studies in Egypt, prevalence ranged from 6.5% among primary school children in grades 3–5 aged 8–10 years to 7.5% among children aged 4–12 years (*4*). The prevalence of ADHD based on DSM-V among children aged 6–14 years in Fayoum City, Egypt reached 20.5%. In western countries, the prevalence ranged from 7.3% in Italy to 10.6% in France and the United States of America (*5*).

The World Health Organization (WHO) defines quality of life (QOL) assesses individuals' perception of their position in life in the context of the culture and value systems in which they live, and in relation to their concerns, standards, goals and expectations (*6*). Assessment of QOL is important in medical practice to improve the doctor–patient relationship and assess the effectiveness and relative merits of different treatments, as well as in health service evaluation, research and policy-making (*7*). Parents of children with ADHD report lower levels of QOL compared to parents of healthy children (*8*).

Family function is defined in the 5 components of the APGAR scale: Adaptability: sharing of resources, and the degree of satisfaction with the received attention; Participation: refers to family communication and joint decision-making on problem solving; Growth: achieves emotional growth owing to the freedom to change roles within the family; Affection: the individual's satisfaction regarding intimate relationships between family members and family interactions; and Resolution: sharing of time and satisfaction with the commitments that family members establish. Family functioning is seriously affected by children with ADHD, especially in families with simultaneous childhood and parental ADHD (*9*). Dysfunctional families have less than optimal functioning in areas of relationships, communication,

organization and problem solving (*10*).

ADHD is a major clinical and public health problem because its consequences for society are enormous in terms of financial cost, stress on families, impact on academic and vocational activities, and negative effect on self-esteem. It is a common neurodevelopmental disorder with a high degree of associated behavioural problems. It has a negative impact on QOL of parents and on family function.

We have not found any data on QOL or family function among parents of children with ADHD in Egypt or other Arab countries. Evaluation of the QOL of parents with children with ADHD and their family function could facilitate future supportive interventions. The aims of the present study were to describe QOL of parents of ADHD children and family function; and to determine the relationship between QOL and family function and sociodemographic characteristics.

Methods

Study design

This was a cross-sectional study that was conducted between May and December 2015 at the Child Psychiatry Clinic at Suez Canal University Hospital, Ismailia City, Egypt. The Clinic has a registry of children aged 6–14 years diagnosed with ADHD. Parents of children with ADHD were recruited during their follow-up visits to the Clinic and then they were referred to the Family Practice Clinic where data were collected.

Study participants

We included parents of children with any type of ADHD (inattention, hyperactivity or their combination) for > 1 year based on the diagnostic criteria of DSM-IV. The children were diagnosed by a psychiatrist at the Child Psychiatry Clinic and were undergoing treatment. The following were excluded: parents of > 1 child with ADHD, as this would have caused cumulative effects on QOL; parents of children diagnosed within the past year; and parents who had children with intellectual problems, pervasive developmental disorder, conduct disorder, oppositional defiant disorder or substance abuse.

Sampling and sample size

We recruited a systematic randomized sample from the clinic registry, which contains 280 children with ADHD who are being followed up in the clinic. Two hundred and fifty children fulfilled the inclusion and exclusion criteria. A sample of 112 parents was calculated based on the formula (*11*): $n = \left\{\frac{z\sigma}{E}\right\}^2$

Z = 1.96, where σ = the estimates of standard deviation (SD) of QOL among parents with children with ADHD (σ = 2.7) (*8*); and E = the margin of error (E = 0.5), and we allowed for 10% drop out, so the total sample included 125 parents. The largest SD was selected to ensure an adequate sample size. The records included telephone numbers and addresses of parents, and they were called and invited for interview and follow-up in the clinic.

Questionnaires

We used 3 structured questionnaires. They were self-administered, but if the parent was illiterate, the questionnaire was administered by S.S. Azazy.

Questionnaire I

Questionnaire I collected sociodemographic characteristics: gender, age, marital status, education, employment status, residence and perceived satisfaction with income.

Questionnaire II

Questionnaire II was an Arabic version of World Health Organization Quality of Life-Brief (WHOQOL-BREF). This is the short version of WHOQOL-100 and is recommended for use with time constraints or to minimize the burden on the respondents. It included 26 items; 24 of which covered 4 QOL domains: physical health (7 items), psychological health (6 items), social relationships (3 items) and environment (8 items). Two other items measured overall QOL and general health (*12*). Items were rated on a 5-point Likert scale (low score of 1 to a high score of 5) with 3 negatively phrased items in Questions 3, 4 and 26. SPSS version 20 was used to calculate the mean of each domain score, which was multiplied by 4 to create scores within a range of 4–20, so as to be directly comparable with scores derived from the WHOQOL-100, which were transformed to a 0–100 scale using the formula (score – 4) × (100/16). High scores indicated high QOL (*7*). The scores were checked and analysed by a statistician. Validity and reliability of the Questionnaire II in an Arab general population were tested and confirmed. The questionnaire was validated using construct validity. Test–retest reliability and internal consistency for the full questionnaire and all domains were conducted with 30 parents and repeated after 2 weeks with Cronbach's $\alpha \geq 0.7$, as in a previous study (*13*).

Questionnaire III

Questionnaire III was an Arabic version of the APGAR scale. It was used to assess perceived family function, with the 5 components: adaptability, participation, growth, affection and resolution. There were 3 possible answers (almost never, sometimes and almost always) for each of the 5 questions, with scores varying between 0 and 2. The total score ranged between 0 and 10 and families were characterized as functional (7–10) or dysfunctional (≤ 6). A dysfunctional family could also be classified as moderately (4–6) or severely (≤ 3) dysfunctional (*14*). The APGAR questionnaire was previously translated, face validated (*15*) and tested for internal consistency and test–retest reliability (Cronbach's α = 0.7). The scoring was checked and analysed by a statistician.

Outcome variables

Four domains of WHOQOL-BREF instrument (physical, psychological, social and environmental) and family function (functional and dysfunctional).

Ethical consideration

The study was approved by the Ethics Committee of the Faculty of Medicine, Suez Canal University. It was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. The research protocol was registered at the University on 14 April 2015. All parents who agreed to participate gave signed informed consent prior to their inclusion in the study. The questionnaires were anonymous and confidentiality of data was preserved.

Statistical analysis

The data were entered and analysed by small STATA version 12 (statistics and data) and SPSS version 20. Data were tested for normality using the Shapiro–Wilk test. Categorical data were presented in frequencies and percentages. Continuous normally distributed data were presented as mean (SD). Continuous not normally distributed and ordinal data were presented as median and interquartile range. Nonparametric tests were used Wilcoxon rank-sum (Mann–Whitney test) for the relationship between 2 categorical variables and continuous non-normally distributed variables; Kruskal–Wallis test with post hoc multiple comparison using Mann–Whitney tests) for the relationship between 3 categorical variables and continuous non-normally distributed variables; χ^2 test to analyse the relationship between categorical variables; and Fisher's exact test in cases of expected cells < 5. Binomial logistic regression was used to test the effects of sociodemographic variables and 4 domains of WHOQOL-BREF on the likelihood that participants had dysfunctional families. Tests were two-tailed and $P < 0.05$ was considered significant and $P < 0.017$ for multiple comparisons.

Results

The study included 125 parents with children with ADHD, with a 100% response rate. The mean age of the parents was 35.1 years (range 19–57 years). Most of the participants 95 (76%) were aged < 40 years. Nearly two thirds of the sample were mothers 80 (64%) and had received secondary education 77 (61.6%). More than half of the participants were employed (n = 71; 56.8%) and most of them (n = 98; 78.4%) had sufficient income. The majority of the sample lived in urban areas (n = 106; 84.8%) and 122 (97.6%) were married and 3 (2.4%) were divorced.

WHOQOL-BREF

The median scores of physical, psychological and social scores of the participants were 12.0 and the mean score of their environmental domain was 11.9. The median scores of perception of health and QOL of the parents were 3.0 (Table 1).

There was a significant relationship between physical domain of QOL and gender, employment status, income and educational status (Table 2). Women had lower scores than men; unemployed parents had lower scores than employed parents; parents with insufficient income had lower scores than those with sufficient income; and parents who received primary/preparatory education had the highest score. Post hoc comparison revealed that parents with primary or preparatory education had significantly higher scores than illiterate parents (z = 2.50 P = 0.016), and they had higher scores than those with secondary and higher education (z = 3.98, $P < 0.001$).

There was a significant relationship between the psychological domain of QOL and residence and educational status (Table 2). The scores of parents who lived in urban areas were lower than those who lived in rural areas, and the participants who received primary/preparatory education had the highest scores. Post hoc multiple comparison revealed that illiterate parents had significantly lower scores than those with primary/preparatory education (z = 3.60, $P < 0.001$), and they had lower scores than those with secondary and higher education (z = 2.99, $P = 0.003$). Parents with secondary and higher education had lower scores than those with primary and preparatory education (z = 3.70, $P < 0.001$).

There was a significant relationship between the social domain of QOL and educational status (Table 2). The median scores for parents who received secondary/high education were near to the median scores for those who were illiterate, but lower than the scores for those who received primary/preparatory. Post hoc comparison revealed that illiterate parents had significantly lower scores than those who had received primary and

Table 1 QOL of the study sample

	WHOQOL-BREF raw scores		WHOQOL-BREF transformed scores (4–20)		WHOQOL-BREF transformed scores (0–100)	
QOL	Mean (SD) **	Median (IQR)	Mean (SD) **	Median (IQR)	Mean (SD) **	Median (IQR)
Physical domain*	22.1 (4.41)	21.0 (19.0–24.0)	12.6 (2.52)	12.0 (10.9– 13.7)	53.8 (15.8)	50.0 (42.9–60.7)
Psychological domain*	17.9 (4.53)	18.0 (16.0–21.0)	11.9 (3.03)	12.0 (10.7–14.0)	49.5 (18.9)	50.0 (41.7–62.5)
Social domain*	9.29 (2.55)	9.0 (8.0–10.0)	12.4 (3.40)	12.0 (10.7–13.3)	52.5 (21.2)	50.0 (41.7–58.3)
Environmental domain**	23.8 (5.18)	24.0 (20.0–27.0)	11.9 (2.59)	12.0 (10.0– 13.5)	49.0 (16.2)	50.0 (37.5–59.4)
Perception of health (Q1)	2.99 (0.87)	3.0 (2.0–4.0)	2.99 (0.87)	3.0 (2.0–4.0)	2.99 (0.87)	3.0 (2.0–4.0)
Perception of QOL (Q2)	3.18 (1.04)	3.0 (2.0–4.0)	3.18 (1.04)	3.0 (2.0–4.0)	3.18 (1.04)	3.0 (2.0–4.0)

***Normally distributed, *not normally distributed data.*

IQR = interquartile range; Q1 and Q2 = ordinal variables; QOL = quality of life; SD= standard deviation; WHOQOL-BREF = World Health Organization Quality of Life-Brief.

Table 2 Relationship of sociodemographic characteristics and all domains of QOL (WHOQOL-BREF transformed scores 4–20)

Variable	Physical domain	Psychological domain	Social domain	Environmental domain
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)
Age (years)				
< 40	12.0 (10.9–14.9)	12.0 (10.8–14.8)	12.0 (10.7–14.7)	12.5 (10.0–14.0)
≥ 40	12.0 (11.7–13.7)	12.0 (11.3–13.3)	12.0 (10.7–13.3)	11.0 (10.0–11.5)
z	0.372	0.035	0.8	3.40
P	0.708	0.972	0.424	0.001*
Gender				
Female	11.7 (10.3–12.6)	12.0 (10.7–14.7)	12.0 (10.7–14.7)	11.8 (10.0–14.0)
Male	13.7(12.0–14.6)	12.0 (11.3–13.7)	12.0 (9.33–13.3)	12.0 (10.8–12.8)
z	3.93	0.116	1.08	0.023
P	< 0.001*	0.908	0.279	0.981
Employment status				
Employed	12.6 (12.0–13.7)	12.0 (11.3–14.0)	13.3 (10.7–14.7)	12.0(10.0–13.5)
Unemployed	11.4 (10.3–13.1)	11.3 (09.3–12.7)	10.7 (10.7–13.3)	9.00 (11.0–14.0)
z	2.71	1.8	1.81	1.31
P	0.007*	0.071	0.070	0.188
Income				
Sufficient	12.0 (11.4–14.3)	12.0 (10.7–14.7)	12.7 (10.7–14.7)	12.5 (10.5–13.5)
Insufficient	10.9 (10.3–12.0)	11.3 (10.0–12.7)	10.7 (10.7–12.0)	10.0 (8.50–11.5)
z	2.32	1.69	1.71	3.36
P	0.021*	0.091	0.086	0.001*
Residence				
Rural	13.1 (12.0–15.4)	12.7 (12.7–14.7)	13.3 (10.7–17.3)	11.0 (11.0–14.0)
Urban	12.0 (10.7–13.7)	11.3 (10.7–13.5)	12.0 (10.7–13.3	12.0 (10.0–13.5)
z	1.93	2.65	1.78	0.207
P	0.054	0.008*	0.075	0.836
Marital status				
Married	12.0 (10.7–13.7)	12.0 (10.7–14.0)	12.0 (10.7–13.7)	12.0 (10.0–13.5)
Divorced	10.9 (10.9–10.9)	11.3 (11.3–11.3)	10.7 (10.7–10.7)	8.0 (8.0–8.0)
z	1.50	0.704	1.30	2.67
P	0.125	0.503	0.211	0.002*
Educational status				
Illiterate/read and write1	12.6 (9.1–13.7)1<2**	9.33 (4.0–11.3)1<2,3**	10.7 (4.0– 12.0)1<2,3**	9.0 (8.0–9.0)1<2,3**
Primary/preparatory education2	17.7(12.1– 17.7)2>1,3**	16.7(12.7– 16.7)2>1,3**	13.3(12.0– 18.3)2>1,3**	14.0(11.0–15.5)2>1,3**
Secondary and high education3	12.0 (10.9–13.7)3<2**	12.0 (10.7 – 14.0)3<2**	12.0 (10.7 – 14.7)3<2**	12.0 (10.0–13.5)3<2**
H	15.9	22.7	10.0	19.0
P	0.001*	< 0.001*	0.007*	< 0.001*

**Statistically significant difference (P < 0.05); **Statistically significant difference for multiple comparison (P < 0.017).*

z = 2-sample Wilcoxon rank-sum test (Mann–Whitney test).

H = Kruskal–Wallis test.

[1,2,3]Post hoc analysis using Mann–Whitney tests.

IQR = interquartile range; QOL = quality of life; WHOQOL-BREF = World Health Organization Quality of Life-Brief.

preparatory education (z = 3.13, *P* = 0.001) and lower scores than those with secondary and higher education (z = 2.25, *P* = 0.025). Parents who had received primary and preparatory education had higher scores than those with secondary and higher education (z = 2.03, *P* = 0.042).

There was a significant relationship between the environmental domain of QOL and age, income, marital status and educational status (Table 2). The scores of parents aged ≥ 40 years were lower than those of parents aged < 40 years. The scores of parents with insufficient income were lower than those of parents with sufficient income. Divorced parents had lower scores than married

parents. Parents who received primary/preparatory education had the highest scores. Post hoc comparison revealed that illiterate parents had significantly lower scores than those who had received primary and preparatory education ($z = 3.78$, $P < 0.001$), and lower scores than those who had received secondary and higher education ($z = 3.69$, $P = 0.001$). Parents who had received secondary and higher education had lower scores than those who had received a primary or preparatory education ($z = 2.19$, $P = 0.028$).

Family function

Ninety-nine (79.2%) parents reported dysfunctional families [32 (25.6%) severe and 67 (53.6%) mild] and 26 (20.8%) reported functional families. There was a significant relationship between family function and age and area of residence (Table 3). Significantly more parents of dysfunctional families were aged < 40 years. Significantly more dysfunctional families lived in urban areas. There was no significant relationship between family function and gender, educational status, employment status, income sufficiency or marital status.

There was a significant relationship between family function and the psychological domain of QOL (Table 4). The score of the psychological domain of QOL was significantly higher in functional families. There was no significant relationship between family function and the physical, social and environmental domains of QOL.

Age, gender and psychological score of QOL were significant independent negative predictors of dysfunctional families (Table 5). Social and environmental scores were nonsignificant negative predictors of dysfunctional families. Conversely, physical score of QOL was a significant independent positive predictor of a dysfunctional family. Employment status, income insufficiency and rural residence were nonsignificant positive predictors of dysfunctional families. The variables in the regression model predicted 47.5% of variability in dysfunctional families' scores as indicated by the Nagelkerke R^2.

Discussion

Four domains of WHOQOL-BREF, physical, psychological, social and environmental, were studied and their median scores were average. Also the perception of health and QOL of the parents was also around the middle

Table 3 Relationship between family function and sociodemographic characteristics

Variable	Family function				$\chi 2$	*P*-value
	Functional (n = 26)		Dysfunctional (n = 99)			
	No.	%	No.	%		
Age (years)						
< 40	11	42.3	84	84.9	20.4	0.001*
≥ 40	15	57.7	15	15.1		
Gender						
Female	16	61.5	64	64.7	0.09	0.7
Male	10	38.5	35	35.3		
Educational status						
Illiterate/read and write	3	11.5	5	5.05	Fisher's exact	0.6
Primary/preparatory education	3	11.5	9	9.09		
Secondary school education	15	57.7	62	62.6		
High education	5	19.3	23	23.2		
Employment status						
Employed	13	50	58	58.6	0.6	0.4
Unemployed	13	50	41	41.4		
Income						
Perceived as sufficient	20	76.9	78	78.8	0.04	0.8
Perceived as insufficient	6	23.1	21	21.2		
Residence						
Rural	10	38.5	9	9.09	13.8	0.001*
Urban	16	61.5	90	90.9		
Marital status						
Married	26	100	96	96.9	Fisher's exact	0.4
Divorced	0	0	3	3.03		

**Statistically significant difference (P -value < 0.05).*

Table 4 Relationship between family function and domains of quality of life

Variable		Family function		Wilcoxon rank-sum test	*P*
		Functional (*n* = 26)	Dysfunctional (*n* = 99)		
Physical	Median (IQR)	12.0 (10.9–13.7)	12.0 (10.9–14.3)	z = 0.11	0.9
Psychological	Median (IQR)	12.7 (11.3–14.8)	12.0 (10.0–14.0)	z = 2.2	0.03*
Social	Median (IQR)	12.0 (10.67–14.0)	12.0 (10.7–13.3)	z = 0.75	0.5
Environmental	Median (IQR)	11.3 (11.0–13.0)	12.0 (10.0–13.5)	z = 0.38	0.7

**Statistically significant difference (P < 0.05).*

z = 2-sample Wilcoxon rank-sum test (Mann–Whitney test).

IQR = interquartile range.

scores. Most of the participants had dysfunctional families based on APGAR scale.

All the scores of the WHOQOL-BREF domains were lower than in a comparative study by Xiang et al. in Hong Kong (*8*), which compared QOL of 77 parents of children with ADHD with QOL of the general population. Although the children in the current study were under treatment, QOL of their parents was lower than in the study by Kim et al. in Korea (*16*). They studied 75 children with ADHD and their parents to assess parental QOL and depressive mood following methylphenidate treatment of their children. The decrease in parental depression scores from baseline to 8 weeks was significantly associated with increases in the domain scores of WHOQOL-BREF. The lower QOL of parents in the current compared with previous studies could be related to differences in socioeconomic status, selection criteria of the participants, or treatment method or compliance. We found partial agreement with other studies that used different tools for assessment of QOL, such as the case–control study by Hadi et al. in the Islamic Republic of Iran (*17*), in which 100 mothers of children with ADHD scored lower than the control group for most of the dimensions of the Health-Related Quality of Life Scale.

All 4 domain scores of WHOQOL-BREF in the current study were significantly higher in parents who had received primary/preparatory education compared with other levels of education. Significantly lower physical domain scores were found among mothers, unemployed parents and those with insufficient income, compared with fathers, employed parents and those with sufficient income. Psychological domain scores of the parents were lower among those who lived in urban rather than rural areas, which could have been due to other stressful situations in urban areas. Environmental domain scores were lower among parents aged ≥ 40 years, those with insufficient income and divorced parents, compared with parents aged < 40 years, those with sufficient income and married parents. Most of these relationships could be explained by the lower socioeconomic status of the parents in ≥ 1 of the studied categorical variables.

It was found that 79.2% of families in the current study were dysfunctional. This was consistent with another study that assessed the family function of 47 Norwegian fathers and 217 mothers of children with ADHD using the Family Assessment Device (FAD) (*18*). This study found that parents with a child with ADHD had poorer family function compared to others who did not have a child with ADHD. Our results of family dysfunction are congruent with another study that used the FAD questionnaire (*10*).

Table 5 Binary logistic regression of family dysfunction, sociodemographic and domains of quality of life

	B	Wald	*P*	OR	95% CI for OR	
					Lower	Upper
Age	−0.080	5.37	0.021*	0.923	0.862	0.988
Gender (females)	−2.66	4.89	0.027*	0.070	0.007	0.739
Employment status (unemployed)	1.38	2.02	0.155	3.979	0.592	26.7
Income (insufficient)	0.592	0.502	0.478	1.807	0.352	9.28
Residence (rural)	1.59	2.60	0.107	4.882	0.710	33.6
Physical scores	0.882	14.9	< 0.001*	2.415	1.54	3.78
Psychological scores	−0.802	7.785	0.005*	0.449	0.255	0.788
Social scores	−0.096	0.487	0.485	0.909	0.694	1.19
Environmental scores	−0.139	0.445	0.505	0.871	0.579	1.31
Constant	4.67	2.529	0.112	106.475		

**Statistically significant difference (P < 0.05).*

χ^2 (9) = 45.4, P < 0.001; Model summary: −2 log likelihood = 82.5; Cox & Snell R^2 = 0.304; Nagelkerke R^2 = 0.475.

CI = confidence interval; OR = odds ratio.

It suggested that parents of children with ADHD have difficulty with family cohesiveness and organization. Our results agree partially with a study in the Islamic Republic of Iran that assessed marital satisfaction among 200 parents of children with ADHD and 200 controls using the Evaluation and Nurturing Relationship Issues, Communication and Happiness (ENRICH) questionnaire (*19*). It showed that parents of children with ADHD had a lower level of marital satisfaction. Our results are also similar to another Iranian study (*20*) that used the FAD questionnaire and Chulalongkorn Family Inventory on 30 families of children with ADHD and 30 control families. The families of children with ADHD were less healthy in function than the controls were. One explanation is that parents of children with ADHD have problems with child interaction and experience emotional stress, distress and exhaustion. When the child does not respond to ordinary parental requests, stress can rise sharply, which can affect family function. We found that fathers were less likely to report dysfunctional families than mothers were. Increasing age and psychological scores of QOL were associated with a reduced likelihood of dysfunctional families. Increased scores for the physical domain of QOL were associated with increased likelihood of dysfunctional families. Our results are congruent with the study by Moen et al. (*18*), who also found that increasing age was associated with better family function, although gender was not a predictor. However, Foley concluded that socioeconomic status is not protective against family dysfunction (*10*). The difference between these studies could be related to the different predictors studied and family function questionnaires used.

Strength and limitations

This study could be one of the first to investigate parental QOL and family function of children with ADHD in Egypt. Inferential statistics and discussion were based on WHOQOL transformed 4–20 scores to facilitate comparison with other studies. Most studies have used the FAD questionnaire for assessment of family function, which is not exactly comparable with APGAR score. We did not assess the different treatment methods among the children in our study. Outcome variables were not compared with controls and could have been affected by factors other than sociodemographic characteristics, such as disease characteristics. The results cannot be generalized to other parents of children with ADHD because the study was hospital based and only represents parents of children who sought advice or treatment.

Conclusion

Parents of children with ADHD had average QOL and the majority of them perceived family dysfunction despite all their children receiving treatment. There was a significant relationship between some sociodemographic characteristics and each of the 4 domains of QOL. There was increased likelihood of having dysfunctional families that were reported by mothers and increasing physical scores of QOL, while there was a reduction in likelihood of having dysfunctional families with increasing age and better psychological scores of QOL. Assessment of QOL and family function is recommended in future supportive interventions in families of children with ADHD.

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Qualité de vie et fonctionnement familial des parents d'enfants souffrant d'un trouble de déficit de l'attention avec hyperactivité

Résumé

Contexte : Le trouble de déficit de l'attention avec hyperactivité (TDHA) constitue un trouble neuro-développemental courant de l'enfant ayant une grave incidence sur les individus, les familles et les communautés. Il est associé à des troubles cognitifs, comportementaux, émotionnels, sociaux et développementaux, ainsi qu'à une baisse des résultats scolaires.

Objectifs : Fournir une description de la qualité de vie des parents d'enfants atteints d'un TDHA, ainsi que de leur fonctionnement familial. Déterminer la relation entre la qualité de vie, le fonctionnement familial et les caractéristiques socio-démographiques.

Méthodes : Il s'agissait d'une étude transversale menée auprès de 125 parents d'enfants souffrant de différents types de TDHA, sélectionnés par échantillonnage aléatoire systématique. L'étude a été conduite entre mai et décembre 2015 dans la clinique de consultations externes en médecine familiale du centre hospitalier universitaire du Canal de Suez. Le questionnaire de l'OMS sur la qualité de vie dans sa version abrégée et le score d'Apgar (apparence, pouls, grimace, activité, respiration) ont été utilisés pour recueillir les données.

Résultats : Les scores médians concernant les domaines physique, psychologique et social étaient de 12, et le score moyen du domaine environnemental était de 11,9. Les scores médians de la perception de la santé et de la qualité de vie de ces

parents étaient de 3,0. La plupart des familles (79,2 %) étaient dysfonctionnelles. Des liens statistiquement significatifs ont été trouvés entre tous les domaines et l'éducation ; entre les scores de la qualité de vie portant sur la condition physique et le sexe, l'emploi et les revenus ; entre les scores de la qualité de vie portant sur l'état psychologique et le lieu d'habitation ; et entre les scores de la qualité de vie liés à l'environnement et l'âge, les revenus et la situation maritale. Les familles dysfonctionnelles étaient susceptibles d'être affectées par les scores de la qualité de vie des domaines portant sur l'âge, le sexe, et la condition physique et psychologique des parents.

Conclusion : Les parents d'enfants atteints d'un TDHA avaient une qualité de vie moyenne. La plupart des parents venaient de familles dysfonctionnelles. Des études portant sur les interventions familiales sont recommandées à l'avenir.

جودة الحياة والوظيفة العائلية لآباء الأطفال المصابين باضطراب قصور الانتباه وفرط الحركة

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الخلاصة

الخلفية: إن اضطراب قصور الانتباه وفرط الحركة هو اضطراب عصبي نموي شائع بين الأطفال، وله آثار خطيرة على الأفراد والأسر والمجتمعات. وهو يرتبط بالاضطرابات الإدراكية والسلوكية والعاطفية والاجتماعية والنموية وضعف الأداء الأكاديمي.

الأهداف: وصف جودة الحياة والوظيفة العائلية لآباء الأطفال المصابين بقصور الانتباه وفرط الحركة. وتحديد العلاقة بين جودة الحياة والوظيفة العائلية، والخصائص الاجتماعية السكانية.

طرق البحث: ضمت هذه الدراسة المقطعية ١٢٥ من الآباء لأطفال مصابين بأي نوع من أنواع اضطراب قصور الانتباه وفرط الحركة، وقد اختيروا عن طريق عينة عشوائية منتظمة. وأجريَت الدراسة بين شهري مايو/ أيار وديسمبر/ كانون الأول ٢٠١٥ في العيادة الخارجية لطب الأسرة في مستشفى جامعة قناة السويس. واستخدم لجمع البيانات استبيانات منظمة الصحة العالمية لجودة الحياة والتكيف، والمشاركة، والنمو، والمودة، والقرار.

النتائج: بلغ وسيط المقياس في المجالات البدنية والنفسية والاجتماعية ١٢، ومتوسط المقياس للمجال البيئي ٩ , ١١. وبلغ وسيط مقياس الإدراك بالصحة وجودة الحياة للآباء ٠ , ٣. وكان لدى معظم الأسر (٢ , ٧٩٪) اختلال وظيفي. وقد وجدت علاقات ذات دلالة إحصائية بين جميع المجالات والتعليم؛ والمقاييس البدنية لجودة الحياة ونوع الجنس والعمل والدخل؛ والمقاييس النفسية لجودة الحياة والسكن؛ والمقاييس البيئية لجودة الحياة والعمر والدخل والحالة الزواجية. وقد تأثرت الأسر التي لديها اختلال وظيفي بالعمر ونوع الجنس ومقاييس المجال البدني والنفسي لجودة الحياة لدى الآباء.

الاستنتاجات: آباء الأطفال المصابين بقصور الانتباه وفرط الحركة كان لديهم جودة حياة متوسطة. وكان لدى معظم الآباء اختلال وظيفي عائلي. ويوصَى بدراسات مستقبلية للتدخلات العائلية.

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Joint evaluation of marketing authorization files of inactivated polio vaccines in countries of the Eastern Mediterranean Region

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Abstract

Background: In 2012, the World Health Assembly declared ending polio a "programmatic emergency for global public health". In response, the Global Polio Eradication Initiative developed "The Polio Eradication and Endgame Strategic Plan 2013–2018" to address the eradication of all types of poliomyelitis.

Aims: The World Health Organization invited selected countries in the Eastern Mediterranean Region to take part in a joint evaluation of the marketing authorization files of candidate standalone inactivated poliovirus vaccines (IPVs), aimed to facilitate the evaluation process and expedite the timelines for registration.

Methods: This report describes the planning, organization and execution of the joint meeting among 6 countries of Eastern Mediterranean Region.

Results: Participants prepared a joint list of questions and concerns which was shared and discussed with the respective manufacturers on the last day of the review. Manufacturer provided answers to the questions. The questions that could not be responded to immediately by the manufacturer remained to be addressed after the meeting directly between the manufacturer and the national regulatory authoritys. A final joint evaluation report was prepared before the end of the meeting by the participating countries.

Conclusions: The report focuses on the benefits of the exercise and highlights its shortcomings as a sole strategy to secure the timely registration of the vaccine in target countries. We discuss additional aspects to be addressed to effectively accelerate registration, and hence access to priority vaccines.

Keywords: poliomyelitis, inactivated vaccines, marketing authorization, Eastern Mediterranean

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Introduction

On 26 May 2012, the World Health Assembly declared ending polio a "programmatic emergency for global public health". In response to this declaration, the Global Polio Eradication Initiative developed "The Polio Eradication and Endgame Strategic Plan 2013–2018". This plan addresses the eradication of poliomyelitis, whether caused by wild poliovirus or circulating vaccine-derived poliovirus (cVDPV). It includes the sequential removal of Sabin poliovirus strains from trivalent oral polio vaccine (tOPV) starting with Sabin type 2. The type 2 poliovirus has been prioritized for removal because wild virus type 2 had been eradicated in 1999 and Sabin type 2 is currently the cause of the majority of vaccine-related paralytic cases. In addition, given the potential of Sabin viruses to mutate and assume the characteristics of wild poliovirus, all live polioviruses will have to be removed from human populations (*1–3*).

The withdrawal of the type 2 tOPV from routine immunization programmes in all countries, preceded by the introduction of at least 1 dose of inactivated poliovirus vaccine has been endorsed by the Strategic Advisory Group of Experts on Immunization, the main technical oversight committee of the World Health Organization (WHO) on vaccination (*2*).

The introduction of 1 dose of IPV into the routine immunization schedule administered concomitantly with the second or third dose of diphtheria, tetanus and pertussis (DTP)-containing vaccines; should take place at least 6 months before the introduction of bivalent OPV (bOPV) planned in April 2016. Immunization with OPV alone for the prevention of poliomyelitis no is longer recommended by WHO (*4*).

The registration of standalone IPV became a high priority for national immunization programmes. All countries where a registration was needed, were requested through a joint letter by the Director-General of the WHO, the Executive Director of UNICEF and the Chief Executive Officer of Gavi, the Vaccine Alliance, addressed to the ministers of health to assign it a high priority. In order to enable the smooth introduction of IPV and use of bOPV, the appropriate IPV presentations should have ideally been registered by the end of 2014 and bOPV by the end of 2015 at the latest.

The WHO recommends that countries importing vaccines that are prequalified by WHO and are supplied through United Nations (UN) procuring agencies grant a marketing authorization to such products. The process followed to grant the marketing authorization may rely on the marketing authorization granted by the national regulatory authority (NRA) in the producing country and/or on the WHO prequalification (*5,6*).

There are several IPVs and bOPVs from different producers prequalified by WHO. These products have been registered in the country of origin by a "functional" NRA in accordance with assessment performed using WHO established indicators (*7,8*), and have subsequently undergone an extensive review by the WHO prequalification programme. This prequalification programme provides an independent opinion on the quality, safety and efficacy of vaccines supplied by UN agencies; ensures the efficacy in the target population, including in co-administration with other vaccines used by national immunization programmes; and assesses the programmatic suitability of the vaccine (*9–11*). In this context, WHO sent communications to the NRAs of countries worldwide requesting them to consider relying on the evaluations performed by the producing country NRA and that performed by the WHO prequalification (through access to their evaluation reports) in order to save resources and time in the process of granting a marketing authorization/ registration of these prequalified products.

Therefore, WHO invited countries in the Eastern Mediterranean Region to take part in a joint evaluation of the files of standalone IPVs for approval for marketing authorization. The meeting was aimed at assisting countries with the review/evaluation of IPV marketing authorization files and hence to facilitate the overall timelines required for granting the marketing authorization, so that the process would be completed by the end of 2014 in all countries of the Region. It was also intended to foster collaboration and exchange of technical information between countries in the Region.

Preparations and conduct of the meeting

The global production capacity of IPV is insufficient to secure simultaneous introduction of 1 dose of IPV in all countries of the world. Therefore, the polio global eradication initiative established prioritization criteria for the introduction of IPV and grouped countries in tiers as described below and shown in Table 1.

- Tier 1: Wild polio virus (WPV) endemic countries or countries that have reported a circulating vaccine-derived poliovirus type 2 (cVDPV2) since 2000.
- Tier 2: Countries that have reported a circulating vaccine-derived poliovirus type 1 or type 3 (cVDPV1/ cVDPV3) since 2000 or large/medium sized countries with 3 doses of diphtheria, tetanus, pertussis vaccine (DTP3) coverage < 80% in 2011, 2012 and 2013.
- Tier 3: Large/medium countries adjacent to Tier 1 countries that have reported wild polio virus since 2003, or bordering countries with a current persistent cVDPV2 outbreak (if not already in Tier 1/Tier 2) or countries that experienced a wild polio virus importation since 2011.
- Tier 4: All other OPV-only using countries.

For the countries which had already introduced IPV in their national immunization programmes, the tier concept was not applicable (no tier). Tier 1 countries were assigned the highest priority and Tier 4 countries the lowest.

Countries were also grouped into 3 main categories or regulatory tracks based on the regulatory pathway that they follow for medicines registration, including vaccines:

- *Countries that conduct a full evaluation process independently of whether the vaccine is prequalified or not.* This pathway implies a complete review of the manufacturer's dossier for quality, safety and efficacy, review of samples (sometimes also testing) and inspection of manufacturing sites for approval and granting of the marketing authorization.
- *Countries that follow a facilitated evaluation procedure based on the fact that the vaccine is prequalified.* This pathway implies that the NRA may use a facilitated review procedure based on reliance on the review done by the WHO prequalification programme in order to save resources and avoid duplication of work (*12,13*).
- *Countries that accept using a prequalified vaccine based on the prequalification status without any additional review (PQ vaccine).*

A few countries in the Region have provisions applicable to special situations (special approval, acceptance of marketing authorization granted in the United States of America or the European Union) (Table 1). All countries in all regions of the world were contacted to report to WHO whether they had one or more IPV vaccines registered and whether they had provisions to allow the use of alternative regulatory pathways to accelerate registration of IPV. Between 75% and 80% of countries answered the request. Countries that did not provide information on status of registration of IPV and/ or pathway applied were not contacted further.

Countries worldwide were mapped according to their tier and regulatory pathway followed, and from this matrix, those that had not registered any standalone IPV or had only 1 brand of IPV registered were selected for this joint evaluation meeting.

Seven countries were identified in the Eastern Mediterranean Region with no IPV or only 1 brand of IPV registered, all of which reported to follow regulatory track 1 for registration of IPV. These were Egypt, Islamic Republic of Iran, Jordan, Morocco, Pakistan, Saudi Arabia and Tunisia. (Saudi Arabia was selected as representing all other Gulf Cooperation Council countries). These countries were offered the opportunity to participate in

Table 1 Inactivated poliovirus vaccine (IPV) licencing status in countries in the Eastern Mediterranean Region by October 2014

Country	Tier	Immunization schedule	Regulatory pathway	Mfg A	Mfg B	Standalone IPV
Bahrain	No tier	Sequential	No information available	NA	NA	NA
Jordan	No tier	Sequential	Full registration	1	0	1
Kuwait	No tier	Sequential	Special approval for emergency situations	1	0	1
Lebanon	No tier	Sequential	Full registration	NA	NA	NA
Oman	No tier	Sequential	Special approval for emergency situations	0	0	0
Qatar	No tier	Sequential	Full registration	NA	NA	NA
Saudi Arabia	No tier	Sequential	Full registration	1	0	1
Syrian Arab Republic	No tier	Sequential	Full registration	1	0	1
United Arab Emirates	No tier	Sequential	Full registration	1	0	1
Libya	4	IPV	Vaccines registered by USFDA or EU can be used in country	1	0	1
Afghanistan	1	OPV	PQ_vaccine	NA	NA	NA
Pakistan	1	OPV	Full registration	1	0	1
Somalia	1	OPV	PQ_vaccine	NA	NA	NA
Yemen	1	OPV	PQ_vaccine	NA	NA	NA
Iraq	2	OPV	PQ_vaccine	NA	NA	NA
Egypt	3	OPV	Full registration	1	0	1
Sudan	3	OPV	Expedited review procedure	NA	NA	NA
Iran (Islamic Republic of)	3	OPV	Full registration	1	0	1
Djibouti	4	OPV	PQ_vaccine	NA	NA	NA
Morocco	4	OPV	Full registration	0	0	0
Tunisia	4	OPV	Full registration	0	0	0

Mfg = manufacturer.
Sequential = sequential immunization, first with OPV followed by 1 dose of IPV
NA = not available.
USFDA = United States of America Food and Drug Administration.
EU = European Union.
OPV = oral polio vaccine.
PQ = prequalified vaccine.

a WHO-organized meeting for the joint evaluation of the marketing authorization files from 2 IPV manufacturers (manufacturers A and B). Three communications were sent to the heads of national regulatory agencies to inform them about the polio endgame strategy and about the proposal for facilitated evaluation of the products. A first letter signed by the heads of UNICEF, Gavi, the Vaccine Alliance, and WHO was sent in 2013 to the ministers of health of countries worldwide, an information note issued by WHO on 16 April 2014 by the Assistant Director-General, Health Systems and Innovation, and the Assistant Director-General, Polio and Emergencies was sent to the heads of the national regulatory agencies in target countries worldwide. A third letter from WHO, signed by the Coordinator of the Regulatory Systems Strengthening team was sent to the heads of national regulatory agencies in the 7 target countries in the Eastern Mediterranean Region providing background information on the polio endgame strategy, terms of reference for participation in the joint evaluation meeting, declaration of interests and confidentiality agreements.

The terms of reference described the roles and responsibilities of each of the parties involved, i.e. the NRA, the manufacturers and WHO. Commitments by manufacturers included the timely submission of the marketing authorization files to the NRAs that would participate in the meeting. The NRAs in turn committed to using the joint evaluation reports as the basis for approval of the vaccines by the end of 2014, and WHO committed to organizing the meeting and to following up until completion of the objective.

Six countries responded to the invitation letters, agreed to the terms of reference and signed the confidentiality agreements and the declaration of interests. All, with the exception of Pakistan took part in the meeting.

The confidentiality agreement signed by nominated participants was valid for interactions during and after the review. In addition, the participants confirmed that they had the authority to protect non-public information, including confidential commercial information, provided to them during the meeting and that they would take all practicable steps to protect such non-public information from disclosure unless authorized by the owner in writing.

The joint review meeting was conducted in Morocco in October 2014 to facilitate the registration of 2 IPV products (from manufacturers A and B) with support from NRAs from the producing countries. The meeting lasted 5 days in total, with two and a half days dedicated to review each product file and other relevant documents.

Six countries participated in the joint evaluation. Countries which did not have any IPV registered took part in the evaluation of both products (Jordan and Morocco), while those in which only 1 of the products was already registered took part in only 1 of the 2 joint product evaluations performed (Egypt, Islamic Republic of Iran, Saudi Arabia and Tunisia).

This joint evaluation meeting was limited to marketing authorization applications of inactivated poliovirus vaccines submitted to the NRAs of countries where the joint evaluation process would be legally accepted for issuance of a marketing authorization. The approval of the IPV vaccines would be based on the information shared during the joint evaluation meeting and the information provided in the assessment reports from the vaccine-producing country NRAs (for the dossier, good manufacturing practice (GMP) inspections and test results). No further testing or inspections would be conducted by the countries before granting the marketing authorization. However, the decision whether or not to register the candidate vaccines remained the prerogative and responsibility of each of the participating authorities.

Participants received the applications and the marketing authorization dossiers in common technical document format, except for additional specific locally required information (e.g. labelling). Three countries, Egypt, Islamic Republic of Iran and Saudi Arabia did not receive the files from manufacturer B through the official channel in time. The participants who received the files within the expected timeframe (1 month before the meeting) reviewed them in advance and shared their findings, questions and concerns during the joint evaluation process. Those who did not receive them in advance through the official submission channels received a copy of the files from WHO with permission from the manufacturers. These were used to advance the review process and facilitate participation in the meeting discussions, but did not represent an official submission, which had to be provided after the meeting.

The meeting brought together representatives from the participating NRAs in the Eastern Mediterranean Region, representatives from the vaccine-producing countries' NRAs, a consultant from the Medicines Control Council of South Africa invited to assist the regulators, and representatives from WHO secretariat as organizers and facilitators.

All the information reviewed and questions raised were reflected in a report produced by the meeting participants, "the joint evaluation report". This common report was presented to representatives of the 2 manufacturing companies. A face-to-face meeting was held with manufacturer A on the last day of the review of their file and a teleconference discussion was held with manufacturer B on the last day of the joint evaluation of their file.

The participants agreed that the timeline for sending the joint evaluation report containing the list of questions to the manufacturers (applicants) would not exceed 2 weeks after the joint evaluation meeting. Official responses from the manufacturers were to be provided within 2 weeks of receipt of the report, and the final decision for marketing authorization would be taken before the end of 2014. The participants decided that in order to perform the oversight of newly introduced IPV vaccines, the sharing of information between the participating NRAs might extend beyond the granting of a marketing authorization to include collaboration for post-marketing monitoring of changes and product performance.

The type of information shared under a confidentiality agreement between participating NRAs, facilitators from the NRAs in the vaccine-producing countries, WHO, and the manufacturers included:

- full dossiers from both companies for the 10-dose presentation of manufacturer A and the 1- and 5-dose presentations from manufacturer B of standalone IPV and additional information required for approval of the variation for the 5-dose presentation of manufacturer B;
- information contained in the marketing authorization applications and applications to vary a marketing authorization received by any participants which could be of interest to the other participants;
- test results shared by the NRAs of the producing countries;
- assessment reports made by the participants and presentations made during the meeting;
- the final list of questions resulting from the review by all participants;
- post-marketing surveillance data of significant public health interest to other participants;
- outcome of GMP inspections conducted by the NRAs of the 2 manufacturing countries;
- the manufacturers' immediate responses to questions.

Results

The representative from the NRA from vaccine-producing country A presented a summary of the production process and quality control, the assessment report of the quality part of the common technical document, and the lot release and test results reports of the previous 3 years. The GMP reports were discussed via teleconference by the GMP inspectors who had conducted the inspections on behalf of the NRAs of the manufacturing country (producing country NRAs). The review of the non-clinical, clinical and post-marketing surveillance data was

presented by the expert consultant from South Africa. Each participating country made a presentation of their independent review performed ahead of the meeting and provided their main findings and observations and points for further clarification.

After review of each part, participants prepared the joint list of questions and concerns which was shared and discussed with the respective manufacturers on the last day of the review. Each manufacturer provided as many answers to the questions as possible. The questions that could not be responded to immediately by the manufacturer remained to be addressed after the meeting directly between the manufacturer and the NRAs. A final joint evaluation report was prepared before the end of the meeting by the participating countries.

The second half of the week was dedicated to the product of manufacturer B. A similar process as that applied to manufacturer A was followed.

Countries followed up with manufacturers after the meeting on a bilateral basis with respect to the official path for submissions, the responses to pending questions, issue of final reports and granting of marketing authorization.

Post-meeting information gathered by WHO from the participating countries shows that the approval of the IPV vaccines subject to the joint review in the relevant countries of the Eastern Mediterranean Region has been achieved as shown below.

- Egypt registered product B in 2015.
- Jordan and Morocco registered product A in the first quarter of 2015 while the approval of product B was delayed until there was full compliance with the information required in module 1.
- Tunisia provided a special approval to product B in 2014 based on emergency provisions.
- Saudi Arabia dropped the registration of product B since they prefer to use product A, which is available in combination.
- The Islamic Republic of Iran registered product B in the first quarter of 2015.

Discussion

The organization of this joint review meeting for licensure of IPV was communicated 8 months in advance to ministries of health and heads of NRAs in each of the countries, with regular follow-up communications thereafter until the meeting took place in October 2014. Responses from countries were required in order to proceed with sharing the terms of reference: NRAs had to agree and accept the terms of reference in order to be invited to participate in the joint review. The terms of reference indicated clearly the need to use the reports produced during the review as the basis for licensure without further requirements. Participants in the meeting were the scientific reviewers from each of the countries, however they had not been appropriately briefed on the objectives and expected outcomes of the exercise nor on the commitments taken by their heads of agencies to secure participation. Despite the thorough and systematic process being followed, the information did not cascade from management in the national regulatory agencies to the technical staff that participated in the meeting.

Manufacturers agreed to submit the same files at least 1 month before the meeting to all participating countries so that reviewers in the countries would have time to go through the data before the meeting. This condition was not met in all cases and participants from 3 countries (Egypt, Islamic Republic of Iran and Saudi Arabia) received advanced copies of the files from manufacturer B through WHO with permission from manufacturers so that they would still have the opportunity to review the files prior to the meeting despite not having received the official submission. However, the submission by the manufacturers through the regular channels (i.e. their respective local agents) remained the requirement to officially start the registration process.

The experience from this joint evaluation showed that the technical staff participating in the meeting, appreciated and benefited from the information and guidance received from the producing country NRAs. In addition to the observations and questions raised by the 6 participating countries from the Eastern Mediterranean Region, the inputs from regulators from the NRAs in the producing countries enriched the discussion. Their presence at the meeting and the sharing with participating NRAs of their assessment reports, test results and GMP inspection reports helped to address GMP related and other questions that would have normally taken time to be addressed to the satisfaction of the NRAs. Participation of manufacturers in the meeting was very useful and accelerated the process of addressing the questions and concerns expressed by participating NRAs. In this particular instance, the evaluation process was different from the regular full review pathway in that duplication of inspections and unnecessary testing at the time of registration of the vaccine were avoided. However, the dossier was reviewed in full by all participating countries with additional support provided by the NRAs in the manufacturing countries. The meeting achieved the overall objective of avoiding duplication of inspections and testing of samples, and thus helped in shortening the timeframes for registration. Furthermore, many of the questions raised in the joint report were immediately addressed by the manufacturers, thus reducing the number of pending items to a minimum.

Besides these achievements, which are not minor, the meeting also helped to identify aspects that remain to be addressed. One important issue is the diversity of country-specific requirements in terms of content, language and format. Although the common technical document dossier was specifically designed to harmonize requirements between regulators worldwide, Module 1, which contains the administrative and legal information, is not harmonized and is subject to a diversity of formats with variable content, including different legal documents in different languages sometimes required to

be notarized, and mock-up labels and inserts with specific country requirements, including translation to the local language. Such heterogeneity in format and contents of module 1 of the common technical document dossier has to be tackled by manufacturers on a country-by-country basis and takes significant resources and time.

Another aspect highlighted during the organization of the meeting was that internal communication within the NRAs was not equal to the needs and failed to cascade the information from the heads of the NRAs to the scientific staff that participated in the meeting.

Furthermore, the majority of NRAs across the world require manufacturers to establish in their respective country a national agent who is responsible of all communications between the NRA and the manufacturer. These national agents are responsible for submitting the application forms, as well as the files and providing responses to questions, and translations to the local language if needed, etc. It is not easy for manufacturers to find adequate, responsive agents in many countries. In the specific case of this joint review meeting, lack of responsiveness from some of the agents and difficulties in complying with the specific country requirements of Module 1 delayed some of the submissions beyond the proposed timeframes.

In recent years, WHO has organized several joint review meetings to assist countries with either the scientific review of clinical trial applications or the review of marketing authorization dossiers for different vaccines. The joint reviews conducted in the context of licensure of MenAfriVac in countries of the meningitis belt in Africa is just 1 example of such activities (*12*). These activities have provided the opportunity for countries to further strengthen their technical understanding of the products and the quality, pre-clinical and clinical issues to be considered, depending on the vaccine type and epidemiology of the disease. Joint evaluations also contribute to building trust and fostering collaboration between regulators, opening the door to networking and to mutual reliance. As relevant as these activities may be, they are not sufficient to streamline, align requirements and improve the efficiency of registration procedures in countries.

The WHO proposes to expedite the registration of IPV and of other vaccines required for emergency use, such as pandemic influenza or Ebola virus vaccines, based on a waiver of the regular marketing authorization procedure in favour of a procedure based on reliance on the producing country NRA approval and/or WHO prequalification. However, the regulatory frameworks in countries are in many cases not sufficiently flexible to accommodate such special circumstances.

Further guidance by WHO on good regulatory practices and best registration practices seem necessary to assist countries to follow defined and transparent procedures to introduce provisions in their regulatory frameworks to allow for flexibilities such as reliance on work performed by other stringent regulators, or reliance on WHO prequalification. WHO is currently developing guidance on good regulatory practices; a second draft for comments is posted on the WHO website (*13*). Furthermore, work on alignment of country-specific requirements as required in Module 1 of the common technical document seems urgently needed.

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Évaluation conjointe des dossiers d'autorisation de mise sur le marché des vaccins antipoliomyélitiques inactivés dans des pays de la Région de la Méditerranée orientale

Résumé

Contexte : En 2012, l'Assemblée mondiale de la Santé a déclaré que l'éradication de la poliomyélite constituait une « urgence programmatique pour la santé publique mondiale ». En réponse à cela, l'Initiative pour l'éradication de la poliomyélite a mis au point le « Plan stratégique pour l'éradication de la poliomyélite et la phase finale 2013-2018 » afin d'éradiquer tous les types de poliomyélite.

Objectif : L'Organisation mondiale de la Santé a invité certains pays de la Région de la Méditerranée orientale à prendre part à une évaluation conjointe des dossiers d'autorisation de mise sur le marché des vaccins antipoliomyélitiques inactivés candidats dans leur formulation simple. Ce processus visait à faciliter les procédures d'évaluation et à accélérer les délais d'enregistrement.

Méthodes : Le présent rapport fait la description de la planification, de l'organisation et de l'exécution de l'évaluation conjointe dans six pays de la Région de la Méditerranée orientale.

Résultats : Les participants ont préparé une liste commune de questions et de préoccupations qui a été distribuée et discutée avec les fabricants respectifs au cours du dernier jour de l'examen. Les fabricants ont répondu aux questions. Les questions auxquelles les fabricants n'ont pas pu apporter de réponses immédiatement ont été traitées après la réunion directement entre les fabricants et les autorités nationales de réglementation. Un rapport final d'évaluation conjointe a été préparé avant la fin de la réunion par les pays participants.

Conclusions : Le rapport se concentre sur les bénéfices de l'exercice et souligne ses lacunes en tant que stratégie unique pour garantir l'enregistrement en temps voulu du vaccin dans les pays cibles. Nous avons également discuté d'autres aspects à traiter de façon à accélérer l'enregistrement effectivement, et par là même l'accès aux vaccins prioritaires.

تقييم مشترك لملفات تراخيص التسويق الخاصة بلقاحات شلل الأطفال المعطلة في بلدان إقليم شرق المتوسط

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الخلاصة

الخلفية: أعلنت جمعية الصحة العالمية في عام ٢٠١٢ أن القضاء على شلل الأطفال يمثل «عملية برمجية ملحة بالنسبة للصحة العامة العالمية». واستجابة لذلك، صممت المبادرة العالمية للقضاء على شلل الأطفال «الخطة الاستراتيجية للقضاء على شلل الأطفال والشوط الأخير من استئصاله ٢٠١٣–٢٠١٨» للتصدي لشلل الأطفال بجميع أنواعه.

الأهداف: دعت منظمة الصحة العالمية مجموعة مختارة من البلدان في إقليم شرق المتوسط للمشاركة في عملية تقييم مشترك لملفات تراخيص التسويق الخاصة باللقاحات المرشحة المعطلة المستقلة لفيروس شلل الأطفال، بهدف تيسير عملية التقييم وتسريع الوقت المستغرق في عملية التسجيل.

طرق البحث: يتناول هذا التقرير التخطيط لعقد اجتماع مشترك بين ٦ بلدان من إقليم شرق المتوسط وتنظيمه وتنفيذه.

النتائج: أعد المشاركون قائمة مشتركة بالأسئلة والاهتمامات التي تم الإعراب عنها ومناقشتها مع جهات التصنيع المعنية في اليوم الأخير من الاستعراض. وقدم المصنعون ردودا على تلك الأسئلة. وأفاد المصنِّعون بأن الأسئلة التي لم تتسن الإجابة عليها بشكل آني سيتم تناولها بعد الاجتماع بين المصنِّعين وهيئات التنظيم الوطنية بشكل مباشر. واضطلعت البلدان المشاركة بإعداد تقرير التقييم المشترك الأخير قبل نهاية الاجتماع.

الاستنتاجات: يركز التقرير على فوائد هذه العملية ويسلط الضوء على أوجه القصور فيها باعتبارها استراتيجية وحيدة لضمان تسجيل اللقاحات في الوقت المناسب في البلدان المستهدفة. وقد ناقشنا الجوانب الإضافية التي ينبغي تناولها من أجل تسريع عملية التسجيل على نحو فعال، ومن ثم الوصول إلى اللقاحات ذات الأولوية.

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Blood transfusion and hepatitis: what does it take to prevent new infections?

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Viral hepatitis is a global public health problem affecting millions. Yet, the burden of disease as a consequence of infection with hepatitis B and C viruses is preventable. An estimated 240 million people are chronically infected with hepatitis B virus, and between 130 and 150 million people globally have chronic hepatitis C infection *(1,2)*. Together, they cause the deaths of about 1 million people every year, the overwhelming majority as a result of the consequences of chronic infection: cirrhosis and primary liver cancer *(3,4)*.

Death and disability from hepatitis B or C infections are preventable through prevention of new infections and treatment of chronic hepatitis. The hepatitis B vaccine provides protection against infection and its complications *(5)*. Treatment for hepatitis B and C is improving in terms of efficacy, duration and cost. Most people with hepatitis C can be cured with direct-acting antiviral medicines *(6–8)*.

The 63rd (2010) and 67th (2014) Sessions of the World Health Assembly recognized the serious burden of viral hepatitis on global health, and called for Member States of the World Health Organization to develop and implement national strategies for preventing, diagnosing, and treating viral hepatitis. These resolutions highlight the importance of ensuring safety of blood and blood products as one of the key strategies for prevention *(9,10)*. Furthermore, in 2016, the World Health Assembly adopted the first global hepatitis strategy, which introduced the first-ever global targets for viral hepatitis. These include a 30% reduction in new cases of hepatitis B and C by 2020 and a 10% reduction in mortality. Blood safety is one of the key approaches to reducing new cases of hepatitis B and C *(11)*.

The use of unsafe blood and blood products is one of the ways hepatitis B and C infections are transmitted. For example, the overall risks of becoming infected with hepatitis B and C viruses from a blood transfusion in sub-Saharan Africa were estimated to be 4.3 and 2.5 infections per 1 000 units respectively *(12)*. A study in Pakistan also estimated the residual risk of transmission of hepatitis B and C infections was 62.5 and 4.4 per million first-time blood donors respectively *(13)*.

Several studies have reported a high prevalence of hepatitis B and C infections in the blood donor populations in the Eastern Mediterranean Region, thus increasing the risk of transmission through blood transfusion. The prevalence of hepatitis B surface antigen is reported to be 1.5% to 4.3% in blood donors in Egypt and the prevalence of hepatitis C antibody to be 2.7% to 3.8% *(14,15)*. In Pakistan, 2.2% and 4.2% of blood donors are reported to be positive for hepatitis B surface antigen and hepatitis C antibodies respectively *(16)*. The burden of hepatitis infection in the Region among blood donors is not limited to Egypt and Pakistan. A study from Kuwait published 13 years ago showed a prevalence as high as 5.4% for hepatitis C antibodies and 3.5% for hepatitis B surface antigen in non-Kuwaiti Arab first-time blood donors. This study also indicated a higher prevalence of these markers in replacement and/or directed donors as compared to the prevalence in voluntary, unpaid blood donors *(17)*.

About 7 million units of blood are donated annually in the Region. Only 51% of these donations are collected from voluntary unpaid blood donors from low-risk populations. All countries of the Region report that donations are screened for hepatitis B and C viruses using enzyme-linked immunoassays. Some countries perform a nucleic acid amplification test, in addition to conventional enzyme-linked immunoassays. However, quality of testing is a concern: only 13 of the 22 countries in the Region participate in a national external quality assessment scheme for transfusion-transmitted infection marker testing *(18)*. There are many countries where rapid diagnostic tests are still in use which are a potential hazard for transfusion-transmitted infections *(19)*. Effective pre-donation counselling, collection of blood from voluntary unpaid and regular blood donors from low-risk populations, and quality assured testing enhance blood safety, even in countries with a very high prevalence of transfusion-transmitted infections *(20)*.

In January 2016, the global development community committed to the 2030 agenda for sustainable development goals (SDGs) with new targets, including combating hepatitis *(21)*. The increasing global attention on the SDGs and the set targets provide an opportunity to highlight the importance of blood safety in combating

hepatitis infections. In addition, in order to implement the global hepatitis strategy, a regional action plan has been endorsed by Member States of the Eastern Mediterranean Region. The action plan prioritizes evidence-based effective interventions, including hepatitis B vaccination, blood and injection safety, harm reduction for injecting drug users and hepatitis B and C diagnosis and treatment, and has set regional targets *(22)*.

However, success in achieving these targets depends on the commitment of governments and other partners, particularly in countries with high rates of hepatitis infection, to take real action to improve blood safety as part of a comprehensive approach to reduce the burden of hepatitis. It also demands immediate and determined action by all involved to strengthen collaboration between hepatitis prevention and control programmes and blood transfusion services to: promote blood collection from voluntary, unpaid, regular donors from low-risk populations; ensure quality assured testing; reduce unnecessary transfusions; and provide counselling, care and treatment for those blood donors with hepatitis infections *(23)*.

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Strengthening community support, resilience programmes and interventions in infectious diseases of poverty

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Abstract

Background: There is an urgent need to promote innovative partnerships, community leadership and commitment toward strengthening coherent and sustainable community support, resilience programmes, engagement and social mobilization for resiliency.

Aims: This paper aims to strengthen coherent, scalable and sustainable community participation, resilience policies and innovative programmes to accelerate elimination and eradication of infectious diseases of poverty.

Methods: An unstructured and retrospective review approach was used to determine and to define full papers, reviewed publications, and grey literature on the topics of community resilience, infectious diseases of poverty elimination and eradication, and the global health security agenda.

Results: Little is documented on individual and community responsibility cooperation in elimination of infectious diseases of poverty through surveillance and resilience, eradication programmes and interventions. Hence, it is essential to develop joint ownership of community infectious diseases, or emerging outbreaks projects, that can play an important role in research and policy decisions, and advance new cultural and psychobehavioural public health directions. Such an enabling environment is imperative to improve accessibility and availability to essential medical and pharmaceutical commodities in the supply chain management.

Conclusions: It is essential to strengthen effective community-based access to drugs and vaccine coverage and effectiveness procurement systems. This is required to improve access to and uptake of care service delivery and management, monitoring and evaluation of integrated and cost-effective programmes, Sustainable Development Goals, and upholding global health security.

Keywords: Community programmes, community resilience, disease eradication, infectious diseases, poverty

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Introduction

Infectious diseases of poverty still afflict millions of people with serious disabilities and deformities, killing almost 1.1 million people, and exact an enormous public health burden and cost on the developing world (*1*). Formal eradication campaigns were initiated for malaria in 1960–1976, dracunculiasis and leprosy in 1991, and polio, onchocerciasis and lymphatic filariasis in 1988, 1997 and 2000 respectively (*2,3*). Subregional campaigns in Africa have eliminated measles and are also underway for elimination of onchocerciasis and Chagas' disease. Smallpox and measles elimination and eradication programmes have yielded valuable lessons that have since been applied to other infectious diseases; mainly value-added, evidence-based information and integrated surveillance and response to garner resources and capability for concerted and coherent national and global partnerships, frameworks and actions plans (*1,4*). The programmes have also shown that eradication can be achieved with cost-effective, all-inclusive, community-based programmes and interventions to prevent and interrupt mosquito vector transmission and spread of insecticide/drug resistance in advancing malaria, schistosomiasis, TB/HIV and polio elimination and ultimate eradication. Moreover, the programmes have improved strategies for promoting sustainable community engagement and risk communication that are needed to promote participation of vulnerable communities and community health workers. The programmes have also increased access to and uptake of national healthcare delivery programmes and medical resources, including scaling up national immunization coverage and effectiveness, and increasing supply chain management and quality health outcomes (*2,5*). Implementation of effective strategies and sustainable development programmes in communities and national governments is required to improve infectious diseases elimination, poverty alleviation and response to the threat of emerging pandemics. Also, promoting understanding of local culture, behaviour and practice is needed to guide community empowerment and cohesive systems for enhanced health data sharing and con-

stant risk communication to tackle the vicious cycle of poverty and health system inequalities (*6*,*7*). For example, the lymphatic filariasis and onchocerciasis control programmes for West Africa have been ongoing for >17 years and are likely to reach their elimination targets according to the World Health Organization (WHO) (*8*). However, WHO is still on risk mapping and stratification of most infectious diseases of poverty (including neglected tropical diseases [NTDs] and NCDs) prevalence for the 19 African countries in the most recent sustained control to elimination programmes. The Roll Back Malaria initiative in 2008, followed by The Global Fund to Fight AIDS, Tuberculosis and Malaria, have significantly reduced public health burden in some African countries, thus providing hope of elimination. For example, scaling up proven, integrated national malaria control, elimination and eradication programmes and interventions, mainly artemisinin combination therapy, insecticide-treated bednets and insecticide residual spraying is crucial for acceleration of evidence-based national programmes in Africa and elsewhere (*7*,*9*–*11*). However, malaria alone still kills almost 1 million children each year – the majority in the least developed countries, mainly in sub-Saharan Africa (*12*,*13*). Although antiretroviral therapy can manage human immunodeficiency virus (HIV) infection by prolonging and improving quality of life, an estimated 33 million people are living with HIV today, with a further 2.7 million new infections occurring annually due to social and cultural practices, and behavioural and economic challenges (*12*–*14*).

It is vital to assess how changes in community roles and positive behavioural changes can identify new expectations and targets, while building important skills, knowledge and best practices in diseases elimination and eradication. Development of in-depth operational research in vulnerable communities is core to sustained partnerships and resource mobilization, as well as promoting community resiliency building (15). Understanding the spatial and geographical heterogeneity of pathogens and mosquito vectors, the different extent and nature of disease, and the effectiveness of national programmes in different communities is needed to generate evidence-based community elimination programmes. There is also a need to establish, through robust political leadership and financial commitment, coherent and sustainable community-based programmes for elimination and eradication of infectious diseases of poverty and emerging epidemics, based on equity and inclusiveness, coverage and operational challenges (*16*, *17*). Other contextual control measures include social and behavioural characteristics, intervention coverage, mass drug administration, intermittent preventive chemotherapy or vaccine acceptance and coverage, and populations' connectedness (*16*–*19*). Yet, most endemic communities are readily embarking on programmes to end the scourge of infectious diseases (*17*,*19*,*20*). Strengthening and improving primary healthcare delivery systems to reduce morbidity to a level at which it is no longer considered a major public health problem, and eradication of infectious diseases, involve reducing worldwide incidence to zero, thereby obviating the need for further evidence-based active surveillance, monitoring and quality management systems, and effective elimination measures. Public health medicine has enjoyed periodic major successes in the control of infectious diseases as result of multilateral partnerships, leadership, and commitment towards elimination (*21*). For example, achieving polio eradication in most affected countries in Africa requires mobilization of sufficient resources to improve mass/targeted vaccination commitment and surveillance campaigns; strengthening cold supply chain and vaccination coverage rates; timely communication and reporting; and increased incentivizing of community health workers at all levels (*22*).

This paper aims to strengthen coherent, scalable and sustainable community support and resilience policies and innovative programmes to accelerate eradication of infectious diseases of poverty, eliminate the threat of emerging pandemics, and improve global health security.

Strengthening community engagement and participation in sustainable health services delivery innovations

There is an urgent need for effective support, community social mobilization and awareness outreach for resiliency, community-based partnership, programmes or projects ownership, shared responsibility and participation in elimination (*23*). Increasing government funding allocation and financial resource commitment, inclusiveness and social equality is core to boosting citizenry resilience and empowerment strategies, and tackling the persistent drawbacks and challenges facing infectious diseases elimination and eradication in Africa and elsewhere (*23*,*24*). There is also a need for technical assistance and active community participation in decision-making policy to provide equitable service delivery and immunization programmes coverage to have an impact in all affected and remote settings. Community social and economic capacity building in full participation and project ownership can play an important role in positive rethinking and upholding new cultural and psychobehavioural directions (*16*,*23*).

There is a need for robust and practical community-based support and resilient surveillance and response systems that highlight the importance of an effective and sustained partnership with local community, nongovernmental organizations, schools and faith-based groups. As such, scaling up access to and use of reliable and low-cost mobile health and social media technologies is core to increase adherence to bednets ownership and drug prescription, combating drug/insecticide resistance, and best practices in infectious disease elimination and eventual eradication (*24*–*26*). Thus, evidence supporting policy uptake of concerted and coordinated community-based programmes and interventions is core to achieving elimination of infectious diseases of poverty in developing countries mainly in Africa, Latin America and Asia-Pacific regions.

Developing contextual research needs for defining priorities, improving care management and integrated vector management approaches, and potential outbreak preparedness is needed through more sensitive early detection and surveillance methods of salient hotspots, reservoirs and asymptomatic cases, and building rapid response and best practice capabilities. It also relies on maintaining safety and quality standards of national programmes in all rural and remote settings, performance and effectiveness metrics in understanding the benefits and limitations (*2*,*27*). Furthermore, improving quality healthcare services delivery and integration of health systems innovations is vital in tackling communicable diseases and emerging pandemics threats, and furthering regional/global elimination and eradication programmes.

Developing and implementing improved community risk mapping and empowerment effectiveness initiatives

Implementation of evidence-based and effective community-based programmes and interventions allows communities to be engaged and participate, gain new knowledge and confidence, and achieve self-care satisfaction Enabling these competencies and skills, coupled with technical assistance and policy guidelines, are important in improving delivery of quality care services and health systems to strengthen eradication of infectious diseases and elimination of pandemic threats (*28*,*29*). Building the capacity to respond resiliently, adequately, timeously and firmly to challenges within the communities (*30*). Importantly, political leadership and policy decisions necessitate cost–benefit analysis of insourcing and outsourcing community-based resources and health commodities mobilization. As well as financial allocation analysis and forecasting simulations in disease elimination and eventual eradication. Hence, comprehensive and sustainable community-based, national programmes for malaria, HIV, tuberculosis, neglected tropical diseases, and emerging pandemic threats require implementation of social resiliency and quality care programmes, including national health insurance schemes to scale up and improve access to universal health coverage, livelihood and well-being.

Strengthening acceptable and effective intervention packages requires multidisciplinary and intersectorial linkage

Advancing local, regional and global systems approaches, cooperation and coordination are needed to improve national surveillance and response to infectious diseases and emerging pandemics threats and existing burdens (*31*,*32*). There is also a need for improved sanitation and access to potable drinking water, effective environment and waste management programmes, in addition to community resilience and incentives to reduce and eliminate poverty-associated diseases, and maternal and childhood morbidity and mortality (*33*).

Galvanizing collaborative support between new local and international (private–public) organizations and philanthropic bodies is necessary for continuous outcomes-based public health programmes, social mobilization, and ownership and resiliency interventions in elimination and eradication (*34*). Some vulnerable communities or countries will need more support than others, especially as their local health priorities include disease eradication and pandemic preparedness (*30*,*31*). For example, it might be best for developing and developed countries to vaccinate above the level of herd immunity to eliminate a disease.

Social resiliency and social equality can lead to the benefits of lower infection rates and associated treatment costs, increasing health care access and risk reduction strategies in order to improve livelihood and productivity in countries that are prone to infectious diseases and pandemic threats (*3*,*7*,*25*,*30*,*35*).

Integration of outcome-based and sustainable social equality and community surveillance projects

Integration of outcome-based and sustainable social equality and community surveillance projects is crucial for prevention of disease recurrence, rapid preparedness and establishment of early warning signals of epidemics. This requires a combination of routine and active case surveillance, monitoring and evaluation, especially during disease elimination, and certification of eradication campaigns and various integrated interventions (*21*,*32*). Such integrated surveillance and response in elimination serves multiple purposes: prediction of and finding remaining cases of circulating infection; measuring and mapping uptake of vaccine or drugs; detecting emergence and spread of antimicrobial and insecticide resistance; and identifying populations at risk in remote settings in Africa, Latin America and Asia–Pacific region (*2*,*25*,*30*,*34*). Also, identifying the remaining pockets of susceptible individuals and hotspots is essential for focused elimination and eradication efforts (*31*). Communities can become less engaged as disease incidence declines, and consequently less involved in control activities, or start actively refusing vaccination. Once elimination and eradication have been achieved, returns on investment, health and economic benefits are potentially infinite (*4*,*10*,*35*).

Addressing communication gaps and drawbacks in infectious disease elimination and eradication

Fostering effective and sustained dialogue in infectious disease elimination requires cooperation and partnership, with ample investment and good governance among all stakeholders including governments, policymakers, communities and households. Hence, increased joint

leadership and advocacy are crucial for robust community-based outbreak preparedness and awareness campaigns, improved national vector control interventions, and technical assistance implementation at all levels. Communication gaps can be addressed through contextual and outcomes-based programmes, and service delivery can be provided and maintained by broadcasting the right messages and simple information or precautions for community empowerment, along with lessons learnt and success stories to support quality risk communication strategies (*1*,*2*,*23*).

Exploring outcomes of community-based models of care delivery that leverage increased acceptance, access to and use of mobile health and digital technology is needed. This should rely on the value of products to patients/populations end-users applications and frameworks for measuring quality and cost-effectiveness of healthcare interventions (i.e., mass drug treatments, immunization, preparedness and surge capacity, etc.) to those in need in remote and low-resource settings (*3*,*4*,*17*,*20*,*35*).

Conclusion

Successful control, elimination and eradication of infectious diseases of poverty rely on coherent, multifaceted community-based health programmes, innovations and actions plans, while upholding previous lessons learned. Hence, effective long-term stable, sustainable, integrated and coordinated community-based models and approaches should strengthen successful implementation of communities support and resilience programmes and ownership, and continuous health education, vigilance and preparedness for prevention against disease recurrence, sporadic outbreaks and importation of pathogens. Application of cutting edge science and technological innovations in understanding and improving community knowledge, cultural and behavioural attitudes, and practices in globalization and epidemiological transition are constituents in attaining the Sustainable Development Goals, healthier communities and global health security.

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Renforcement du soutien communautaire, des programmes de résilience et des interventions en matière de maladies infectieuses de la pauvreté

Résumé

Contexte : Il existe un besoin urgent de promouvoir des partenariats innovants, le leadership et l'engagement communautaires pour renforcer, de façon cohérente et durable, le soutien communautaire, les programmes de résilience, l'engagement et la mobilisation sociale afin de permettre la résilience.

Objectifs : La présente étude vise à renforcer la participation communautaire, les politiques de résilience et les programmes innovants de façon cohérente, progressive et durable dans le but d'accélérer l'élimination et l'éradication des maladies infectieuses de la pauvreté.

Méthodes : Une analyse non structurée et rétrospective a été menée afin d'identifier et de sélectionner les articles complets, les publications revues et la littérature grise portant sur la résilience communautaire, l'élimination et l'éradication des maladies infectieuses de la pauvreté, ainsi que sur le programme mondial de sécurité sanitaire.

Résultats : Il existe peu de recherche documentée sur la responsabilité individuelle et collective de coopérer en vue de l'élimination des maladies infectieuses de la pauvreté grâce à la surveillance et la résilience, et aux programmes et interventions d'éradication. Il est donc essentiel de développer une responsabilité commune vis-à-vis de la prise en charge des maladies infectieuses ou des programmes concernant les flambées émergentes, qui puisse jouer un rôle important dans la recherche et les décisions politiques, ainsi que de faire progresser les nouvelles orientations culturelles et psycho-comportementales en matière de santé publique. Un tel environnement favorable est impératif pour améliorer l'accès aux produits médicaux et pharmaceutiques essentiels, ainsi que leur disponibilité dans la gestion de la chaîne d'approvisionnement.

Conclusions : Il est crucial d'améliorer l'accès communautaire aux médicaments et à la couverture vaccinale et de renforcer les systèmes d'achat de façon efficace. Ceci est nécessaire pour améliorer l'accès et le recours aux prestations de services de santé, la gestion, le suivi et l'évaluation de programmes intégrés et ayant un bon rapport coût-efficacité, les Objectifs de développement durable, ainsi que pour préserver la sécurité sanitaire mondiale.

تعزيز البرامج والتدخلات المتّسقة والمستدامة في مجال الدعم المجتمعي والقدرة على التصدّي للأمراض المعدية للفقر: للقضاء عليها واستئصالها

إرنست تامبو، جين ينكيو نغوغانغ، زياو-نينغ، جهو إكسياو-نونغ

الخلاصة

الخلفية: توجد حاجة ملحة لتعزيز الشراكات المبتكرة والقيادة المجتمعية والالتزام بتعزيز البرامج المتسقة والمستدامة لدعم المجتمع والقدرة على التصدي والمشاركة والتعبئة الاجتماعية لهذا التصدّي.

الهدف: تهدف هذه الورقة إلى تعزيز سياسات المشاركة المجتمعية والقدرة على التصدّي المتسقة والقابلة للتطوير والمستدامة والبرامج المبتكرة للتعجيل بالقضاء على الأمراض المعدية للفقر واستئصالها.

طرق البحث: استُخْدِم نهج غير منظم للمراجعة بأثر رجعي لتحديد وتعريف كامل الأوراق المنشورة التي روجعت والأوراق غير المنشورة بشأن قدرة المجتمعات على التصدّي والمشاركة في القضاء على الأمراض المعدية للفقر واستئصالها وتعزيز جدول أعمال الأمن الصحي العالمي.

النتائج: لم يوثق سوى القليل حول المسؤولية والمشاركة الفردية والمجتمعية في القضاء على الأمراض المعدية مجتمعية المنشأ للفقر وترصدها والقدرة على التصدّي لها، والبرامج والتدخلات بشأن استئصالها والقضاء عليها. ومن ثَمَّ فمن الضروري تطوير الملكية المشتركة للمجتمع بشأن المشاريع المعنية بالأمراض المعدية أو الفاشيات الناشئة التي يمكن أن تلعب دوراً مهماً في إعادة التفكير في البحوث والقرارات السياسية والنهوض بالتوجهات الثقافية والاتجاهات النفسية السلوكية الجديدة للصحة العامة. وهذه البيئة التمكينية ضرورية لتحسين الوصول إلى إدارة سلسلة التوريد للسلع الطبية والصيدلانية الأساسية وتوافرها.

الاستنتاجات: هناك حاجة إلى تعزيز الوصول إلى خدمة الرعاية المجتمعية واستيعابها إلى أنظمة التغطية بالأدوية واللقاحات والحصول عليها، وتعزيز فعالية أنظمة الشراء لتحسين تقديم خدمات الرعاية وإدارتها، ورصد وتقييم البرامج المتكاملة والفعالة من حيث التكلفة لبلوغ مستوى صحي أعلى للسكان، ولبلوغ أهداف التنمية المستدامة، ودعم الأمن الصحي العالمي.

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Meeting of the Eastern Mediterranean Regional Technical Advisory Group on immunization[1]

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In May 2012, the Sixty-fifth World Health Assembly endorsed the Global Vaccine Action Plan (GVAP) in resolution WHA65.17 (*1*) as the operational framework for implementation of the Decade of Vaccines 2011–2020 (*1*). An Eastern Mediterranean vaccine action plan 2016–2020 was subsequently developed and endorsed in October 2015 by the 62nd Regional Committee for the Eastern Mediterranean in resolution EM/RC62/R.1 (*2*) as a framework for implementation of GVAP in Member States of the Region. The regional vaccine action plan defines strategic objectives and priority actions for immunization programmes from 2016 to 2020 and beyond (*3*). It takes into account the specific needs of Member States in the Region and the challenges facing these countries.

To follow up on implementation of the EMVAP, the World Health Organization Regional Office for the Eastern Mediterranean (WHO/EMRO) organized the first meeting of the reconstituted Regional Technical Advisory Group (RTAG) on Immunization in Muscat, Oman, 14 December 2017 (*4*). The meeting was attended by 10 of the 12 members of the RTAG, as well as staff from WHO/EMRO, WHO headquarters, UNICEF headquarters and regional offices, the GAVI Secretariat, and the Centers for Disease Control and Prevention (CDC).

The objectives of the meeting were to:

- discuss the terms of reference and operating procedures of the reconstituted RTAG; and
- review regional progress, challenges and constraints facing the achievement of the goals of the Eastern Mediterranean Vaccine Action Plan (EMVAP) and provide advice on the way forward.

Dr Rana Hajjeh, Director, Department of Communicable Diseases Prevention and Control, WHO/EMRO, in her opening remarks, welcomed members of the RTAG and thanked them for their willingness to support immunization programmes in the Region through their membership of RTAG. Dr Ziad Memish, Director of the Research Department, Prince Mohammed Bin Abdulaziz Hospital, Riyadh, Saudi Arabia, was appointed as Chairman of RTAG.

Summary of discussions

The RTAG felt that the current structure of WHO's regional vaccine-preventable diseases and immunization (VPI) programme is adequate, but that staff numbers are insufficient to cover the various areas of work and the increasing demand by countries for technical support (in particular those facing acute and or protracted emergencies). Exploring other mechanisms to increase human resource capacity at WHO such as the use of fellowship programmes, junior professional officers and secondments is needed.

Routine immunization coverage in the Region shows continued success in 14 out of the 22 countries. However, achieving the EMVAP coverage target remains a challenge in other countries, particularly those facing various degrees of humanitarian emergency. The large number of unvaccinated children in the Region is of great concern. There is a need to map who and where they are, and why they are not reached. A strategic plan for countries with a high number of unvaccinated children, based on the mapping exercise and adopting a focused approach, is required, along with the allocation of the necessary funds.

There is a need to raise the visibility of measles in order to increase political commitment. Countries need to assess population immunity, predict and early detect outbreaks, and address immunity gaps to mitigate outbreaks, such as applying cohort analyses and reviving and using the measles strategic planning tool. Rubella vaccination should be introduced more widely in the Region, where suitable, and the opportunity of measles elimination used to eliminate rubella as well.

There is a need to address the introduction of new vaccines according to their respective disease burden. Accordingly, pneumococcal conjugate vaccine (PCV) should come first, followed by rotavirus vaccine, then human papillomavirus (HPV) vaccine. National Immunization Technical Advisory Groups (NITAG) will need to be well informed in order to take the appropriate decision on this for each country.

The polio transition process involves careful analysis of the risks and opportunities associated with ramping down or transitioning the assets, functions and knowledge of the polio programme at all levels. Four countries in the Region are considered priority: Afghanistan, Pakistan, Somalia and Sudan. The Regional Steering Committee on Polio Transition decided in 2017 to add Iraq, Syrian Arab Republic and Yemen to the list of priority transition

[1] This report is extracted from the Summary report on the Meeting of the Eastern Mediterranean Regional Technical Advisory Group (RTAG) on Immunization, Muscat, Oman, 14 December 2017 (http://applications.emro.who.int/docs/IC_Meet_Rep_2018_EN_17034.pdf?ua=1).

countries in the Region due to ongoing conflicts causing refugee migrations and internally displaced persons.

The Global Polio Eradication Initiative (GPEI) will begin to be phased out 6–12 months after certification of interruption of wild poliovirus transmission, impacting the size and availability of polio assets. There is concern about the development of this change, especially in the field. Afghanistan and Pakistan will not be affected by polio transition in the immediate future, as they remain endemic for polio. Huge resources were invested in polio eradication and there is concern about the loss of polio infrastructure. Resources need to be mobilized to maintain and adapt this infrastructure for the elimination/eradication of other diseases (such as measles), and to sustain the eradication of polio.

The RTAG noted the following achievements in the Region with appreciation.

- The maintenance of high coverage for all antigens provided by national immunization programmes in 14 countries of the Region (Bahrain, Egypt, Islamic Republic of Iran, Jordan, Kuwait, Libya, Morocco, Oman, Palestine, Qatar, Saudi Arabia, Sudan, Tunisia and United Arab Emirates). However, there are concerns about the quality of immunization data and the validity of coverage estimates for Libya.
- The maintenance of immunization programme functions under extremely challenging situations, including active conflict, in some areas in countries experiencing humanitarian emergencies (Iraq, Libya, Syrian Arab Republic and Yemen). The Region has gained much experience and developed best practices in delivering immunization in areas of armed conflict and in the various phases and types of humanitarian crisis.
- The progress towards measles and rubella control/elimination in the Region, with the achievement of a very low incidence of endemic measles virus transmission (<1/million population) in seven countries in 2017 (Bahrain, Egypt, Islamic Republic of Iran, Jordan, Morocco, Palestine and Tunisia).
- • The remarkable progress made towards polio eradication in the Region, particularly in Afghanistan and Pakistan, the two remaining endemic countries, and the commencing of planning for polio transition in the Region.

Recommendations

To RTAG:

1. Revise the terms of reference of the RTAG to include addressing vaccine-preventable diseases control and immunization during acute and protracted humanitarian emergency situations.
2. Establish a RTAG website with an interactive component open for questions and answers.
3. Include the engagement of NITAGs as an agenda item at the next RTAG meeting.
4. Establish RTAG working groups on the following: meeting EMVAP immunization coverage targets; conflicts and complex emergency situations; and new vaccines introduction.

To EMVAP:

1. WHO should develop a comprehensive advocacy and resource mobilization strategy for implementation of EMVAP-related activities.
2. WHO should develop a business case to demonstrate the vaccine-preventable diseases burden in terms of morbidity and mortality, the economic benefits of achieving EMVAP goals, and the cost of implementing the related activities.
3. RTAG should utilize any opportunity with governments and partners to raise the visibility of EMVAP goals and promote commitment.

Routine immunization:

1. WHO should take immediate action to work with countries and partners to map the unvaccinated children in each country to identify who and where they are, and why they are not being reached.
2. WHO should develop a concrete strategic plan for countries with a high number of unvaccinated children to reach the unreached. It should adopt a focused approach and include the allocation of the required funds.
3. If possible, WHO should support Pakistan in forming and leading a multi-partner taskforce, learning from the polio experience, and focusing on addressing the gaps in routine immunization.

Measles and rubella control and elimination:

1. WHO should maintain the measles elimination target of 2020 and verify elimination in countries that meet the criteria for verification.
2. WHO should establish progress milestones on the path to elimination for countries facing high endemicity/outbreaks of measles. By 2020, attain at least 90% measles-containing vaccine first-dose (MCV1) immunization coverage in Djibouti, Pakistan, Sudan, and Syrian Arab Republic; and at least 80% MCV1 coverage in Afghanistan, Somalia and Yemen.
3. Bahrain, Jordan, Oman and Palestine are to submit for measles (and rubella, if applicable) elimination verification at the earliest opportunity and no later than end 2018.
4. Egypt, Kuwait, Islamic Republic of Iran, Libya, Morocco, Saudi Arabia and Tunisia should begin preparation of documentation for verification of measles (and rubella, if applicable) elimination, completing the documentation by 2019.
5. Countries that have not yet introduced rubella-containing vaccine (RCV) and potentially meet the criteria for introduction (Afghanistan, Djibouti, Pakistan

and Sudan), should introduce RCV into their national programmes by 2020.

Polio transition:

1. WHO should identify mechanisms and responsible focal points for coordination between the VPI programme and the GPEI, and provide clear milestones for monitoring progress.
2. WHO should systematically identify and leverage synergies between the immunization programme and ongoing polio eradication activities before the commencement of polio transition.

Introduction of new and underutilized vaccines:

1. Countries that have not yet done so, should add the following new vaccines to their immunization programme schedule in order of priority as determined by NITAG: pneumococcal conjugate vaccine, rotavirus vaccine, chicken pox vaccine, hepatitis A vaccine, and human papillomavirus vaccine.
2. Countries where hepatitis B immunization has not been implemented at birth, should take the necessary steps to introduce this as soon as is feasible.
3. Countries that have not introduced HPV vaccination should initiate efforts to quantify the HPV-related burden of disease, enhance advocacy for HPV vaccination, and raise public and physician awareness and education.
4. Countries should plan to establish an adolescent vaccination platform where this is absent. This is necessary for implementation of the pre-teenage tetanus/diphtheria/pertussis booster and the introduction of HPV vaccine.

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