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المجلة الصحية لشرق المتوسط

La Revue de Santé de la Méditerranée orientale

The World Health Organization is working to mitigate the spread and impact of COVID-19 through the equipping of frontline health workers with personal protective equipment and medical supplies, and ensuring laboratory tools are available to ramp up test and trace facilities and procedures to support health systems throughout the Region.

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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.

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Solidarity in response to COVID-19 outbreak in the Eastern Mediterranean Region

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The coronavirus disease 2019 (COVID-19) outbreak that began in Wuhan, Hubei Province, China in late 2019 has spread globally within a few months (*1*). The Director General of the World Health Organization (WHO) declared the COVID-19 outbreak to be a public health emergency of international concern (PHEIC) after the second meeting of the IHR (2005) Emergency Committee on 30 January 2020 (*2*). On 12 March 2020, the outbreak of COVID-19 was characterized as a pandemic.

The World Health Organization (WHO) has been fully engaged with the global community since identification of this emerging virus and continues to provide guidance to countries, health care workers, and the general public regarding measures to prevent and control the outbreak. Nonetheless, the outbreak has spread to most of the countries in the world within a short period. The pandemic has instigated the urgent call for international and local solidarity and collective actions in all aspects of the response. A number of countries across the world have shown the spirit of solidarity to facilitate the global response through extending support to others with financial support, donations of protective equipment and other medical supplies, sharing expertise, cross-border treatment of patients, provision of flights to repatriate citizens returning home from abroad, and facilitating the delivery of much-needed supplies. It was evident that the calls for solidarity and unity have acted as a catalyst for a strong partnership between the public and private sectors to work together closely in order to scale up the response interventions and save lives (*3*). However, more needs to be done and ensure solidarity is sustained.

As of 1 May 2020, the total number of reported confirmed cases of COVID-19 globally was 3 175 207 and 224 172 associated deaths (*4*). The number of COVID-19 cases and deaths and affected countries continues to rise. On 29 January 2020 the first cases of COVID-19 was reported from the United Arab Emirates and the WHO Regional Office for the Eastern Mediterranean (WHO/EMRO) was subsequently informed through IHR reporting mechanism (*5,6*). These initial cases all had history of travel from Wuhan City in China. The second country affected in the Region was Egypt (*5*), which reported confirmed COVID-19 cases that were found to have contacts with a confirmed case detected in China. The virus thereafter spread rapidly in the Region, but not with the explosive pattern as seen in some areas of Europe and North America. The next country in the Region to report confirmed cases was the Islamic Republic of Iran where the initial cases had history of travel to China.

To date, the largest number of confirmed cases and deaths are reported from the Islamic Republic of Iran, representing more than 48% of cases overall in the Region. All countries in the Region are now reporting COVID-19 cases, and the reported number of cases and deaths has continued to rise. As of 2 May 2020, there have been 199 139 cases in the Region and the most affected countries are: Islamic Republic of Iran (96 448 cases, 6156 deaths); Saudi Arabia (24 097 cases, 169 deaths); and Pakistan (18 114 cases, 417 deaths) (*7*).

Although overall cases and deaths reported from countries in the Region (except Islamic Republic of Iran) are fewer than those reported from some countries in Europe and North America, the risk of a sudden upsurge or next wave of infections is possible. One of the explanations for lower infection rates among countries in the Region is the timely implementation of a variety of containment and mitigation response interventions. As per the prevailing situation, most of the countries in the Region have crossed the first three stages of the transmission categories (defined by WHO) and going toward the community/local transmission of the virus. Many countries in the Region have followed WHO's clear recommendations on containment by prioritizing the expansion of testing, isolation, treatment, contact tracing and quarantining close contacts. Taking the evolving situation into consideration, countries in the Region started to move toward social distancing and other non-pharmaceutical preventive measures to minimize the human-to-human contact/transmission through travel restrictions, flight suspensions, lock downs and intensive community awareness. Nonetheless, countries with complex emergencies are still lagging behind the testing and other important public health measures.

Apart from the current COVID-19 outbreak, several countries in the Region are experiencing long-standing humanitarian emergencies resulting from conflicts,

natural disasters and disease outbreaks, such as Afghanistan, Libya, Somalia, Syrian Arab Republic, and Yemen. COVID-19 adds a new layer of burden to the already weakened health systems in these countries and poses a new challenge to the health services and systems in the Region. The current burden caused by COVID-19 outbreak is exceeding the capacity of national and local health systems of the affected countries, which could jeopardize the continuity of essential health service delivery and undermine other health priorities. Moreover, the Region is home to 43% of those who need humanitarian assistance and is the source of 64% of the world's refugees (*8*). There were 12 million refugees and 13 million internally displace persons (IDPs) in the WHO Eastern Mediterranean Region as of 2018 (*9*). In the context of COVID-19 and the rapid spread of the virus, vulnerable populations living in countries with complex emergencies, especially those in besieged areas, experience volatility and/or in camp or camp-like settings, are at an increased risk.

Above all, the COVID-19 pandemic has highlighted an important principle: when it comes to public health, we are all in this together. WHO is working tirelessly to mitigate the spread and impact of the virus, assess gaps and needs, equip frontline health workers with personal protective equipment and medical supplies, ensure laboratory and testing tools are available in countries around the world, and to deliver communities and frontline responders with the latest technical guidance. If we do not unite now to prevent the spread of the virus, it will have the chance to circle back around the globe, putting all of us at risk. Thus, 'global solidarity' is needed more than ever and more countries and partners are joining this 'solidarity network' to support each other.

Solidarity in funds

A COVID-19 solidarity in funding has been rapidly formed in the Region to support its Member States in response to the COVID-19 outbreak. As of April 29, 2020, the Region has secured US$ 117 million in funding, against overall country and regional needs of US$ 476 million, with Kuwait, the World Bank and Japan accounting for the largest donations. WHO Headquarters in Geneva, Switzerland, has established a 'Solidarity Fund' with contributions from multiple donors, and the Eastern Mediterranean Region (EMR) has also benefitted from this generosity (*10*).

In line with the donors' contributions, WHO Headquarters has also developed the COVID Partners Platform, which allows for the first time all countries to be given the opportunity, in real-time, to show to the world what actions they are implementing, share their needs and plans, request international support, and track contributions towards meeting their needs (*11*).

Solidarity network

The global COVID-19 outbreak is leading to an acute and drastic shortage of essential supplies, including personal protective equipment, diagnostics and supplies and equipment for clinical management. At the request of the United Nations (UN) Secretary-General and in support of the UN Crisis Management Team, a Supply Chain Task Force has been convened at WHO Headquarters to establish the COVID-19 Supply Chain System (CSCS). The Supply Chain Task Force, co-chaired by WHO and World Food Programme (WFP), includes representation from a number of key operational organizations (WHO, WFP, United Nations Children's Fund [UNICEF], United Nations Office for the Coordination of Humanitarian Affairs [OCHA], World Bank, The Global Fund, United Nations Office for Project Services [UNOPS], United Nations Development Programme [UNDP], United Nations Population Fund [UNFPA], United Nations High Commissioner for Refugees [UNHCR], nongovernmental organizations, International Federation of the Red Cross and Red Crescent, among others) which are accountable to deliver on their agency's commitment to this critical operation and which are fully empowered to act flexibly and expediently (*12*). In addition to the CSCS, when most countries put in place travel restrictions and flight suspensions, Solidarity again plays a critical role in processing such procurement of supplies. As of 23 April, 53 shipments have been successfully dispatched to EMR countries in spite of flight restrictions, mainly from the WHO Dubai hub, along with generous support from the UAE, Saudi Arabia and Qatar for the procurement and transportation of such supplies within the Region. WHO Regional Office for the Eastern Mediterranean (WHO/EMRO) Procurement is currently processing over 185 requests across 22 offices in the Region, amounting to US$ 14 million.

As complementary to this Solidarity in the CSCS, the WHO Clinical Unit continues to convene clinicians around the globe, twice weekly by teleconference (COVID-19 Clinical Network) to share knowledge and experiences from clinicians caring for COVID-19 patients and highlight operational challenges and technical questions. There are over 30 countries represented on this teleconference. This has highlighted the need to better support health systems become ready for a surge in cases, and the Clinical Unit and the CSCS have developed a Clinical Concept of Operations intended to guide countries with surge decision-making, and tools to accelerate the availability of oxygen and biomedical equipment (*13*).

Solidarity trial

The Solidarity Trial is an international clinical trial to help find an effective treatment for COVID-19, launched by WHO and partners (*14*). The Solidarity Trial will compare four treatment options against standard of care, to assess their relative effectiveness against COVID-19. By enrolling patients in multiple countries, the Solidarity Trial aims to rapidly discover whether any of the drugs slow disease progression and/or improve survival. The greater the number of participating countries, the faster results will be generated. WHO is facilitating access to thousands of treatment courses for the trial through donations from a number of manufacturers. In line with

the call for Solidarity participation, 12 countries in the Region have enrolled or are in the process of enrollment. By working together, we will hopefully be able to accelerate the identification of effective therapeutics against COVID-19.

While some countries in other regions are beginning to see rates of infection flatten and relatively fewer deaths than witnessed previously, without 'national unity' and 'global solidarity', we may yet see the most brutal impacts of the virus. The time for global Solidarity is imperative and is the only way to get through this unprecedented COVID-19 outbreak. We again call for "Solidarity" to slow the spread of the virus and to protect innocent citizens, including the world's most vulnerable populations living in settings with weak health care systems.

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What works where in prevention of Covid-19: The case of Somalia

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The outbreak of coronavirus disease 2019 (COVID-19) has posed significant challenge to the countries with the best health systems in the world (1). As governments scramble to contain and/or prepare for outbreaks of the COVID-19 virus, there is increasing concern about the potential impact of the coronavirus epidemic in countries with weak health systems (2). The World Health Organization (WHO) encourages governments to improve preparation for and response to COVID-19, such as legislation and policy, coordination, surveillance, response preparation, risk communication, human resources, and laboratory capacities (2). So far, most of the COVID-19 cases are in countries with a decent health system, including China, South Korea, Italy, and the United States of America. The preventive measures that have stabilized the epidemic in China may also work in other strong economies and countries with solid health systems. However, how countries with weak health systems such as Somalia will cope, remains unclear.

Somalia is a country affected by complex emergencies resulting from prolonged conflict, climate change, outbreaks of communicable diseases and a dysfunctional health system. Less than 30% of the Somali population have access to health services (3). The national health system is fragmented, and the absence of unified health system governance has affected the capacity of national authorities to implement coordinated interventions. Nonetheless, the COVID-19 epidemic requires a well-coordinated preparation and response - a capacity that Somalia lacks. The WHO Somali office is the sole trusted partner that can initiate a coordinated plan throughout the country to prevent and contain the epidemic. However, the security situation in the country may limit the presence of WHO experts in the field, and the absence of epidemiologists and highly trained public health professionals may affect the success of WHO efforts.

The country's health system has no capacity to make early case detections, isolate and care for patients, and trace contacts. As a result, the sole alternative for the country is to develop effective preventive measures to mitigate the epidemic. Most countries rely on measures including social distancing, closure of schools, cancelling big social gatherings and improved hygiene (2). These measures depend largely on how individuals respond to the advice on prevention and this is highly unlikely to work in Somalia for several reasons. People in Somalia are not familiar with the notion 'health prevention'; they only seek health advices when they become ill (4). In addition, advice such as stay at home, or self-quarantine, will be an economic burden too heavy to bear for the majority of the population that depend their livelihood on daily paid jobs. Regarding cancellation of social events, mosques are where the biggest social gatherings occur several times a day. Cancelling such events and or advising against it may provide an opportunity for terror groups to exploit and use it against the government. This is exacerbated by prevalent religious fatalism; a belief that one's fate is predetermined and if they were to be infected by COVID-19, it was meant to happen regardless of their efforts. Prominent religious leaders, who consistently preach that COVID-19 is a punishment only for the unbelievers, enforce this perception. Those religious leaders have supreme power in shaping the mindset of the Somali community and the Somali government has little power and resources to enforce preventive actions or to challenge the misinformation created by religious leaders. Moreover, there are no research institutions in the country, nor human resources for research that help policy-makers decide the context specific mitigation activities.

In the midst of this swiftly evolving crisis and the current development in Kenya and Ethiopia, which have confirmed COVID-19 cases, certain contextual and culturally sensitive preventive measures may help Somalia and other similar settings prepare and effectively respond to the epidemic. Extensive information campaign about the preventive actions with risk communication has pivotal importance. To reinforce the guidelines given by the health authorities, the campaign should be delivered through mosques, and social and public media with clear presence of religious leaders in information provision. If the campaign is led by religious leaders it will have strong potential to encourage people to follow the preventive instructions for self-isolation, cancelling big events including religious gatherings, and also to adhere to hygiene practices as instructed. However, the correct information should be provided to religious leaders prior to their involvement in the awareness campaign. Hygienic kits should be supplied in large scale and should be made available in markets, schools and religious sites. WHO and other international actors may help surveillance, early case detection and isolation of infected individuals and management of the very sick, using WHO guidelines. There are large

internally displaced populations (IDPs) in the country, living in camps with high population density, which is often coupled with unsanitary conditions. Mobilizing IDPs' community leaders and health providers to spread awareness on basic hygiene is critical to prevent the epidemic from this vulnerable group.

The existence of early warning surveillance systems, strong community-based surveillance under the polio programme, functioning federal and state health authorities offer an opportunity to an effective and successful national response. As the Somali federal government leads the national response to COVID-19, regional authorities and the private health establishments should continue to work with the federal authorities and other health agencies (WHO, UNICEF and others) to ensure a collaborative response. To unite the country towards the prevention of the epidemic, the Federal Ministry of Health (MoH) should take an apolitical role to avoid power struggles and rifts with the regional health ministries, which may otherwise impede the coordination efforts. Finally, political commitment is an essential component of the COVID-19 response. Therefore, to contain the epidemic, the highest level of political commitment and good leadership is needed more than ever in Somalia today.

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Virtual social networks and mental health intervention for medical staff during the COVID-19 outbreak in the Islamic Republic of Iran

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Previous experiences from other crises have confirmed that timely mental health intervention is critical for medical staff caring for patients, in this case those affected by COVID-19 (*1*). Negative emotions and stress can originate from fear of infection, isolated working conditions, fear of transmission to family or friends, and increased workload. Social contacts potentially increase the risk of contamination and should be restricted, resulting in people losing the benefits of social interaction. Behaviours that were considered potentially 'pathological' by mental health care providers during any other crisis are now being tolerated in the current COVID19 situation. Thus, decreased levels of self-confidence in health care providers in all of disciplines and higher stress levels are apparent (*2*). Consequently, such frontline medical staff want help. However, the ensuing overload of information is not always reproductive and can lead to higher levels of anxiety.

Medical professionals working in the Islamic Republic of Iran are facing even more challenges compared to their colleagues in other countries when it comes to social support (*3*). First, there have been several tragic events that have happened recently in the country (natural disasters, passenger aircraft crash) as well as continuing international political tensions. Second, American economic sanctions continue to affect the availability of essential medicines and equipment. Third, cultural and religious gatherings in the Islamic Republic of Iran might increase the risk of the spread of communicable diseases.

Given this background, finding a replacement for social contact is paramount. While there is still a long way to establish tele-medicine in the Islamic Republic of Iran, social networking remains popular in the country (*4*). When considering the social restrictions imposed as a result of the efficiency of COVID19 transmission, virtual social networking might be the best replacement for traditional face-to-face psychological interventions.

Tabriz University of Medical Sciences has implemented activities to address this need. Psychological intervention teams have been set up by the university's Department of Psychiatry to coordinate and manage the operation. Based on the conduct of group therapy, small groups have been established using social networking applications, organized by two supervisors in each group. Information is provided only to answer the direct needs of participants and information overload is deliberately avoided. Participants are encouraged to describe their daily experiences followed by relevant and directed discussions, and the groups are effectively participant-led, with supervisor facilitation.

In addition, an online platform has been established to screen for those who need a more thorough psychiatric intervention and addresses excessive levels of stress, anxiety and depression. Coupled with this platform is telephone guidance to help deal with mental health problems that care givers might be experiencing as a result of the current COVID19 situation.

Despite these support interventions, mental health care for health professionals is still not a consideration in Iranian national guidelines on COVID-19. While adequate medical resources will bring some sense of support, it remains clear that communication and accurate updates about the coronavirus outbreak will decrease the sense of uncertainty, while adequate health care support will assure quality of care and decrease workload. Thus, revised and focused guidelines are fundamental in the current situation.

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Unlocking towns and cities: COVID-19 exit strategy

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Introduction

The novel Coronavirus SARS-2 represents a major global challenge since the first cases were diagnosed in China and reported to the World Health Organization (WHO) on 31 December 2019 (*1*). On 9 January 2020, WHO issued a statement warning of the 'risk' of human-to-human transmission, although China did not report such a method of transmission (*2*). WHO officially declared a Public Health Emergency on 30 January 2020 and the disease was named COVID-19 on 11 February 2020. On 11 March, it was characterized as a pandemic when the number of cases increased 13-fold. At this point, it had spread to over 60 countries across all continents except Antarctica, with an immediate and profound effect on societies and brought social and economic life to a virtual standstill. As of 30 April, 2020, 3 271 892 cases of COVID-19 were reported globally with 232 817 deaths (*3*). More than one-third of the world population was locked down (*4*), as part of the 'suppression' strategy first proposed by Imperial College London, United Kingdom (*5*). Such a strategy is aimed at reducing the spread of infection, protect health services and save lives. However, it has a major economic impact globally and has had a deep social and psychological impact on many people. Therefore, it is not feasible to maintain the current lockdown indefinitely. This commentary aims to define the public health principles and the measures that must be considered for a science-based political decision to unlock towns and cities.

Unlocking towns and cities

At any stage of the pandemic, political decisions must be built upon a mixture of scientific evidence of the outbreak control and political imperative to ensure economic continuity. The fear of a second wave must always be uppermost in the mind of decision-makers and the country should have a clear plan and preparation for such an eventuality. Indeed, the director of the Centers for Disease Control and Prevention, United States, warned that a second wave of COVID-19 is inevitable, and it is 'likely to be more devastating' (*6*). Any decision on unlocking towns and cities should consider a range of existing and emerging evidence so far.

We know that the world is facing a new virus and a new dynamic. Novel evidence is emerging day-by-day as we learn how to tackle the virus effectively (*7*). Still, many gaps in our knowledge do exist. These include the absence of a vaccine, despite major efforts both publicly and commercially, and no definitive treatment despite the use of antimalarial drugs, antibiotics, antiviral medication, anticoagulants, Interleukin (IL-6) inhibitors, blood transfusions and plasma treatment (*7,8*). Furthermore, little evidence of full immunity is available (*9*) and reinfection is reported (*10*). Some countries are assessing the level of immunity through antibodies' tests (*11*), yet emerging studies demonstrate that there is more than one genotype of COVID-19 virus (SARS-CoV-2) with different infectivity level, spread and immunity (*12*). In the absence of a vaccine or treatment, modelling suggests that it can take nine waves of infection to achieve herd immunity (*13*).

While science is progressing, the mill of misinformation or "fake news", is fed by some scientists reporting non-evidence-based experiences and opinions, and public "fear" is at its highest. This is aggravated by some politicians who are happy to trigger blame and even agitate populations for action against national and local lockdown rules, mainly to score political points (*14*). Others have criticised the strict public health measures and advocated for more liberal approaches to achieve herd immunity. However, such policies proved less effective than initially thought and restrictive public health measures were gradually introduced (*15*). The current coronavirus is not like seasonal influenza and the next wave, if any, will be during any season. Even though this has yet to be proven, we must remember that seasonality does not constrain new viruses in the same way that long-existing viruses are affected (*16*). Although 81% of the COVID-19 cases are either subclinical or mild, the lack of credible treatment to deal with moderate and severe cases (*17*) and the absence of a vaccine to achieve full herd immunity, may lead some countries to endure repeated waves of infection (*6*). Overall, we are aware that our social life and economy are suffering, jobs are lost, families are separated, and mental health is at risk (*18*). Any analysis or risk assessment for unlocking should

be framed within public health principles outlined as follows, and consider the above scientific evidence, or lack of it.

Public health principles for unlocking towns and cities

Governments cannot continue locking down towns and cities forever. A clear and explicit "exit strategy" to unlock and restore "normality" is needed for each country with emphasis on key public health principles and indicators unique to the population. Each government, based on these principles, must decide how long the lockdown and social distancing should continue, what should be eased, the stages of easing such a lockdown and measures taken to monitor the abatement of the virus. Most countries need to develop a collaborative stepwise approach and prepare for the transition to ease the shutdown, especially those with shared borders or land mass. Four important principles should be carefully analysed and calibrated. Relaxed measures should be a holistic approach incorporating all the four public health principles rather than the decline of infection. These principles are; infection status; community acceptance; public health capacity; and health system spare capacity.

The Infection Status

Key indicators should be considered. We suggest the use of the following if effective measurements are available, based on epidemic thresholds and techniques for analysis of infectious disease data (construction and use of epidemic curves, generation number, exception reporting, identification of significant clusters).

First, the rate of infection, expressed as an incidence rate. This is the number of new cases within a time period, as a proportion of the number of people at risk. A declining incidence rate is evidence that the virus transmission has slowed down, i.e., the infection curve is flattening and the basic reproduction number (Ro) is below 1. Second, the doubling rate of infection, referring to the number of days needed to double the number of infected people. Increase in doubling time indicates a slowdown in transmission (if underlying reporting remains unchanged). A doubling rate between two weeks and one month, or longer, could allow for easing restriction. Third, case contacts, ideally expecting the number of contacts generated per case to be one or less. Fourth, testing positivity rate as the proportion of all samples testing positive; this should be no more than 5%.

Different methods can be used to monitor the infection status. Smartphone applications could track, trace and follow-up contacts, mild symptomatic cases and positive cases with no symptoms (*19*). Data must be accurate, timely and thus there will be heavy reliance and trust in official communication streams regarding numbers.

Community acceptance

Unlocking, partially or completely, is a political decision based on clear and specific public health advice at the highest level in government. The measures that need to be taken may continue to affect communities' economy and lifestyle in the short and long term. Therefore, to ensure full public engagement, it is vital that governments are transparent and include community acceptance in the equation. This is a complex issue and the "new normal" means adjusting work, social, and economic activities, which may not be fully resumed until an effective treatment and / or a vaccine are available.

Some elements of social distancing should continue. These range from prohibiting gatherings (social, religious, conferences, large sport events, cinemas, gyms, theatres etc.); limiting movement of people between towns and cities depending on the subnational analysis of the rates of infection; to continuation of shielding people over the age of 70 years old, vulnerable children and those at high risk (e.g. immune-compromised) until further notice. Avoidance of customary greetings such as handshakes and kissing as well as concurrent vigorous hand washing advice will be the norm for some time to come. Travel on public transport and commercial aircraft will be redesigned to maintain social distancing through seat spacing and passengers number restrictions. Shopping and other social activities should follow strict rules on social distances and protect workers in the service industry. The gradual reopening of schools in phases, starting with pupils up to the age of 11 years old, may be feasible following Denmark's example (*20*).

Student learning and examinations, including those of medical schools, should seek to continue to comply with social distancing measures. Economically, the population must accept new or increases in taxation for a period to forfeit the dire economic situation created by COVID-19's lockdown. Furthermore, certain employees, public and private, may need to accept "reasonable" reductions in incomes and reduced benefits. These indicators must be assessed fully regarding public engagement and acceptance. At the same time, immediate measures must be introduced to prevent worsening poverty and to alleviate any suffering caused by COVID-19.

Public health capacity and measures

Public health capacity draws not only on resources but also on organizational structures, partnerships, leadership and governance in the country specific context. So far in this pandemic, strict public health measures are showing to be effective (*21*). This response has required recruitment at short notice to bridge gaps in the workforce. Therefore, it is vital that public health capacity is given the full support required in terms of workforce, laboratories, transport, medical equipment, personal protective equipment, settings and other logistics. National and local governments should provide sufficient legal power for public health agencies at national and local level to take further actions as deemed necessary. Data collection, analysis, modelling, projections and reporting should be given full priority in collaboration with academia and international organisations such as WHO and the United Nations Children's Fund (UNICEF).

Surveillance is a vital part of public health functions. Public health agencies nationally and locally should have in place highly effective surveillance systems in a variety of settings to assess current infections and predict any possible new wave(s) of infections, thereby triggering the correct measures for suppressing it (being ahead of the curve). Such surveillance should include a well-defined system of active case finding, testing, isolation of positive cases, tracking all immediate contacts, and ensuring quarantine accommodation is decent and under continuous surveillance. All ports of entry should also be subjected to such a system.

Public health agencies, at national and local level, should provide adequate, transparent and timely public information, which should be in all languages used by the communities. It has been reported, for example in Sweden, that the numbers of COVID-19 cases were much higher among immigrants, who represent about 25% of the total population (*15*). Last but not least, the emergency preparedness plan must be updated on a regular basis taking into account the speed of development in this pandemic. Such updated plans must be shared with all sections of government, which should ensure that indicators of public health capacity are at the appropriate level before considering relaxing lockdown measures.

Health system spare capacity

Protecting the health system to ensure that it will not be overwhelmed is one of the major public health challenges during this pandemic. Except for a few countries, most health systems around the world were not prepared for this pandemic (*21*). This was reflected in weak public health infrastructure, shortages in intensive care beds, shortage of equipment (oxygen supply, ventilators, personal protective equipment, transport, morgues, etc.), and shortages of staff. In reality, most health systems were operating at near 99% capacity before the pandemic. Therefore, in preparation for the partial or complete "unlock", the entire health system must be ready. Singapore, Taiwan and South Korea have learnt the lesson of SARS-1 and MERS in the last two decades and prepared their health systems for such eventualities (*21*). These countries invested in their health systems for the future to save lives and reduce the economic cost in the event of a pandemic repeat. Other countries should do the same.

Some of the vital measures that must be taken in preparation for another spike if lockdown is partially or completely removed include hospitals having spare capacity of at least 20%, especially in intensive care (*22*). Germany has less deaths due to COVID-19 compared with other European countries mainly due to the huge spare bed capacity including intensive care (*22*). However, not all hospitals should receive COVID-19 patients. If another wave appears after a partial or complete unlock, hospitals receiving COVID-19 patients should be redesigned with clear infection and prevention control procedures; e.g., red areas with restricted access, amber areas for recovered patients and green for normal hospital activities. Such measures protect staff, reduce cross infection and save lives. Staff should be trained to move to other duties (redeployment) to respond to another wave, e.g., higher needs in intensive care units.

Intensive care training should be mandatory for all medical and nursing students. Primary care should be structured to deliver more effective services to suspected cases and contacts, as well as continue to provide the vital health care services as the first point of contact within the health system while maintaining high level of continuity of care. Patients discharged from intensive care require follow-up and primary care should be well positioned to do so. Ambulance services should be enhanced, both in number and training, to provide a wide range of COVID-19 care from immediate intervention at home and support during transportation, to setting patients at home with oxygen therapy. Finally, volunteer services and community groups should be structured and organised to avoid any future confusion.

All these measures should be part and parcel of the country or local emergency preparedness plans, which must be robust, evidence-based and ensure community engagement. We must be vigilant through surveillance, monitoring and risk assessment and it must be clear to the public that, if the trend shows an increase in the number of new cases, a quick re-introduction of physical distancing measures to contain the virus will be required.

Conclusions

While some countries are reporting a decline in new COVID-19 cases, many others are yet to feel the full impact of the virus. Maintaining current aggressive social distancing measures until an effective treatment or vaccine are available, is not practical. Gradually relaxing restrictions when infection indicators (decreased transmission and spread of the virus) and other conditions are met, could help further easing of measures until the authorities are sure that no new cases are reported for a reasonable length of time. Governments must ensure that their unlocking plan can be implemented in practice, clearly communicated and enforced. The psychological, social and economic impacts of COVID-19 on individuals, communities and businesses are immediate, profound and with long-term consequences. Humanity is in a challenging scenario with this novel coronavirus and the only road we should take is to fight together and to fight smart.

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Recommendations from the 4th International Conference on Mass Gatherings Medicine, Saudi Arabia

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Keywords: mass gatherings; medicine; public health; communicable diseases, Saudi Arabia

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Background

Mass gatherings health is a recently formalized scientific discipline that deals with all aspects of health at mass gatherings (*1*). The latter are occasions that attract a sufficient number of people to strain the planning and response capabilities of the organizing hosts. Saudi Arabia, with its extensive and prolonged experience in hosting the Hajj mass gathering, was a leader in advancing the global mass gatherings health agenda and the establishment of the mass gatherings health discipline (*2*). Starting by hosting the 1st International Conference on Mass Gatherings Medicine, entitled "Global Forum on Mass Gathering Medicine", organized by the Saudi Ministry of Health and the Lancet Infectious Diseases journal (*3*). The conference took place in Jeddah in 2010 where the "Jeddah Declaration" was adopted at the end of the event. The declaration proposed steps for the formalization of the new discipline of mass gatherings health and called for the establishment of the Global Centre for Mass Gatherings Medicine (GCMGM) in Saudi Arabia, as well as the hosting of regular international conferences on mass gatherings medicine (*4*).

The 4th International Conference on Mass Gatherings Medicine

Since the 2010 conference, the Saudi Ministry of Health, led by the GCMGM, organized a further two conferences: the 2nd and 3rd International Conferences on Mass Gatherings Medicine, in 2013 and 2017 respectively. True to the legacy of the Jeddah Declaration, and to the commitment to sharing and advancing knowledge in the area of mass gatherings health as a World Health Organization (WHO) collaborating centre, the GCMGM organized the 4th International Conference on Mass Gatherings Medicine between 10-13 December, 2019 in Jeddah, Saudi Arabia. The slogan for the conference was, "Model of Healthcare for Mass Gatherings", which was in keeping with current discussions around mass gatherings globally, including the ongoing Saudi health transformation, including its mass gatherings. The conference comprised 4 plenary and 15 parallel sessions, 8 workshops, and a number of side meetings in addition to poster sessions and an exhibition by industry and stakeholders in mass gatherings health and management. The event attracted over 1000 attendees and involved over 100 expert speakers from 16 countries arriving from the Eastern Mediterranean Region, Europe, North America, Africa, Asia and Australia, and sharing a total of 96 presentations.

The event served as an international platform for knowledge acquisition, sharing and dissemination, developing consensus on key areas of healthcare at mass gatherings, as well as setting forth the way forward for the mass gatherings health discipline including areas of research and capacity building. As such, further galvanizing interest in the field of mass gatherings health both within Saudi Arabia and globally, and adding another milestone in the development of the mass gatherings health discipline and in advancing its agenda both nationally and internationally.

In addition, the event also witnessed the launching of the Middle East and North Africa (MENA) chapter of the World Association for Disaster and Emergency Medicine (WADEM) with the aim of providing evidence-based improvement, education, and advocacy of emergency and disaster health care and disaster risk reduction in the MENA region.

Recommendations

The 4th International Conference on Mass Gatherings Medicine concluded with the below recommendations

and calls for action within the six conceptual principles in MGs health highlighted in Figure 1.

Clinical practice

- Develop international guidelines for health care at mass gatherings, including suggested minimum, risk-relevant health care services that should be available at mass gatherings. These could serve as initial frameworks for standard of care at mass gatherings, customized by local authorities.
- Explore and apply modern technologies in mass gatherings health and management, including Artificial Intelligence (AI), crowd technologies, telemedicine and rapid point of care testing.

Research and knowledge management

- Encourage and support research in the field of mass gathering health and management and bridge the gap between academia and operations, in order to strengthen the evidence base for guidelines, standards and policies.
- Create channels for dissemination of research outcomes in the area of mass gatherings health, including the establishment of a mass gathering and public health scientific journal.
- Develop and standardize risk assessment tools for mass gathering to enable optimum planning and risk management at these events.
- Support mass gathering legacy reporting (ideally in a standard format/template) to enable experience sharing of challenges and best-known practices in the planning and management of mass gathering events.
- Encourage international knowledge and experience sharing in planning and managing mass gathering events, with a more prominent role for WHO and its mass gathering collaborating centres and networks.

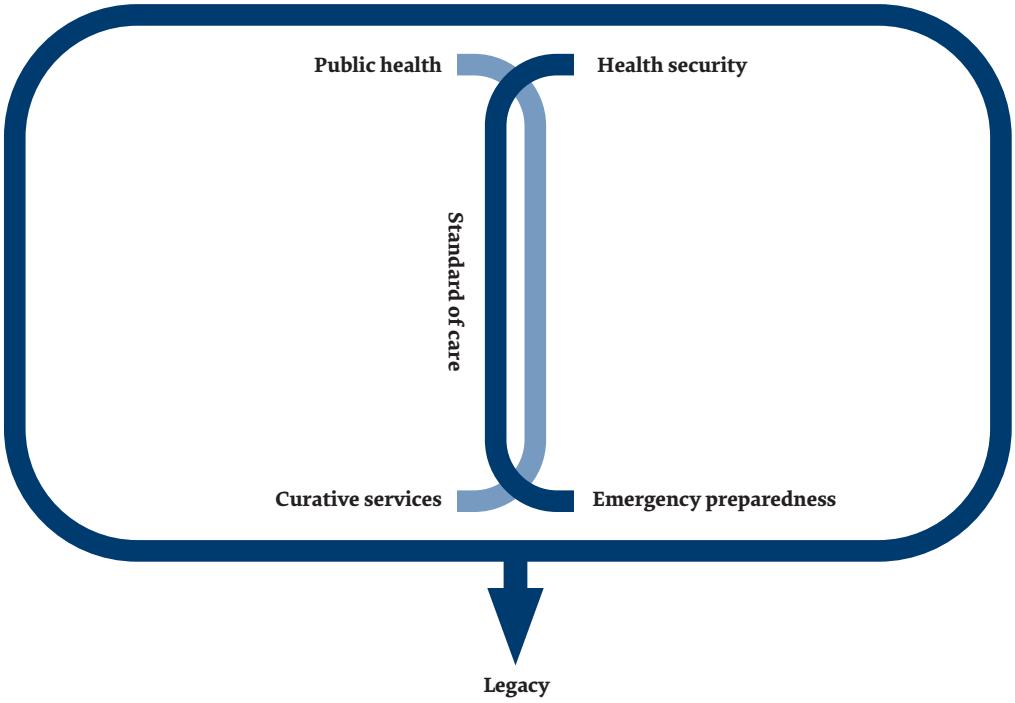
Education and capacity building

- Build capacity in the area of mass gatherings health and management, including academic tracks, curricula and training programs that involve multiple response agencies and stakeholders.
- Invest in capacity building and developing strategies for effective and timely risk communication at mass gatherings.

Health security and planning

- Address the need for effective engagement with and coordination between multi-sectoral stakeholders in mass gatherings including events organizers, governments, public health sector, service providers and community-based organizations, to support breaking down silos and improve safety at mass gatherings.
- Continue to strengthen global health security in the face of increasing number and types of mass gathering events, locally, nationally and internationally.
- Implement health early warning and response systems at mass gatherings and encourage intentional collaboration with travel-associated surveillance networks for early detection of potential international outbreaks.

Figure 1 Six conceptual principles of mass gatherings health



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Developing a questionnaire to assess Iranian nurses' knowledge of and attitude to Middle East respiratory syndrome

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Abstract

Background: With the emergence of Middle East respiratory syndrome (MERS), health care preparedness has received increasing attention, which requires valid tools to assess the knowledge and attitude of health workers, such as nurses, with regard to this disease.

Aims: This study aimed to develop and evaluate a knowledge and attitudes questionnaire on MERS coronavirus for Iranian nurses.

Methods: A questionnaire was developed based on international and national guidelines and a literature review. Ten nurses were recruited to assess face validity and 11 experts reviewed the instrument to determine the content validity ratio and index. Exploratory factor analysis was then done with a random sample of 155 nurses in Tabriz city, Islamic Republic of Iran.

Results: Following determination of face and content validity, 78 items (61 knowledge and 17 attitude) were retained in the final version of the questionnaire. The knowledge scale had an average content validity index of 0.80 and the attitude scale a value of 0.91. In the exploratory factor analysis, five dimensions with eigenvalues > 1 and loading level ≥ 0.4 were extracted for the knowledge scale (46 items) and two for the attitude scale (16 items). The Kuder–Richardson 21 coefficient and intraclass correlation coefficient for the knowledge scale were 0.94 and 0.91 respectively. In the attitude scale, the Cronbach alpha coefficient and intraclass correlation coefficients were 0.82 and 0.89 respectively.

Conclusions: The scale developed in this study is reliable and stable and a suitable instrument for evaluating the knowledge and attitude of nurses about MERS-CoV.

Keywords: Middle East respiratory syndrome, surveys and questionnaires, knowledge, attitude, health care providers, Islamic Republic of Iran

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Introduction

Middle East respiratory syndrome (MERS) is a respiratory disease caused by a coronavirus (MERS-CoV). The disease was first reported in Saudi Arabia in 2012. Coronaviruses are a large family of viruses that can cause various diseases from colds to severe acute respiratory syndrome (SARS) (*1*). Since it was first reported in 2012 to 27 April 2017, 1952 laboratory-confirmed cases of infection with MERS-CoV have been reported to the World Health Organization (WHO), including at least 693 related deaths (*2*). Cases of MERS have been reported in 27 countries in and around the Arabian peninsula, including the Islamic Republic of Iran, and more distant countries – Germany, United Kingdom, United States of America, Korea, Turkey, Egypt and Malaysia – as a result of travel to affected countries (*3*). In the Islamic Republic of Iran, a cluster of the disease was reported in five people in 2014 (*4*) and another case was reported in 2015 (*5*).

The disease is transmitted through direct or indirect contact with infected camel secretions and/or droplets of people with the virus. Symptoms of MERS resemble those of influenza-like illness with fever, cough and severe dyspnoea *(6)*. No vaccines and treatments are available for the disease. The highest prevalence of MERS is reported from health centres *(1,7)*. In Korea *(8)* and Jeddah, Saudi Arabia *(9)*, for example, the disease spread through contact with affected people in hospital. Disease transmission through common interpersonal contact between people is unknown in the community.

Since most reported cases of MERS are from the Middle East, and Iranians frequently travel to neighbouring Arab countries, including Saudi Arabia *(10)*, health care personnel in the Islamic Republic of Iran need to have an understanding of the disease and the infection control measures that should be used *(11)*. At the same time, health care providers may have concerns about occupational safety and disease transmission to friends and family while providing health services to patients with MERS. To manage coronavirus diseases, it is therefore essential to evaluate the knowledge and

attitudes of health care providers about the disease in order to determine the extent to which they are prepared for the necessary measures for this disease and to provide in-service training where required *(12)*.

Given that the disease has emerged quite recently, few studies have been conducted and a limited number of instruments developed to assess the knowledge and attitudes of health care providers about MERS-CoV. Despite the importance of a valid and reliable instrument to evaluate health care workers knowledge and attitudes about the virus and the disease, a review of the literature suggests inadequacies in the design and psychometry of existing tools *(10,13–17)*.

Researchers in Saudi Arabia used a questionnaire to examine the knowledge and attitudes of health care providers about MERS-CoV in 2015 *(13)*, but the results for content validity ratio and content validity index of the items was not reported, nor was the reliability of the questionnaire, even though these measures were done. In another similar study in Saudi Arabia *(10)*, the questionnaire used was evaluated for face and content validity but no results were presented for the content validity ratio and index. The Cronbach alpha for reliability of the questionnaire was given as 0.74, but it was not clear whether this value applied to the attitude or knowledge scale. In a study in the Republic of Korea on knowledge, preventive behaviour and risk perception of nursing students at the outbreak of MERS-CoV in the country, the authors reported the content validity index and Kuder–Richardson values, but they provided no data on the content validity ratio, face validity and construct validity *(14)*. A study in Turkey on the knowledge, attitude, and practices of Hajj and Umra pilgrims about MERS did not report the validity and reliability of the questionnaire used *(15)*. Similarly, these measures were not reported in a study on the knowledge of physicians about MERS-CoV in Pakistan *(16)* and another study on the knowledge, attitude and practices of health care providers in Saudi Arabia *(17)*.

Reliable and valid instruments to measure the knowledge and attitude of health care providers about coronaviruses are also lacking in the Islamic Republic of Iran. This study, therefore, aimed to develop and evaluate a knowledge and attitude scale for MERS-CoV.

Methods

Study design

A methodological study with cross-sectional data collection was conducted to develop a knowledge and attitude scale for nurses about MERS-CoV and make a psychometric evaluation.

Development of the scale

Guidelines on MERS were obtained from the websites of WHO, Centers for Disease Control and Prevention (CDC), USA and the Iranian Centre for Communicable Disease Management. The guidelines were analysed for quantitative content and the aspects of MERS that a nurse should be aware of. Scopus, PubMed, ProQuest and Google Scholar, and Iranmedex, Scientific Information Database (SID) and MagIran in the Islamic Republic of Iran were searched for articles and related tools. A combined search method was used in order to incorporate dimensions and attributes not identified previously. Keywords used were: knowledge, attitude, design, psychometry and Middle East respiratory syndrome. In the literature review, the questionnaire designed by Nour and colleagues in 2015 was used to extract knowledge and attitude items after obtaining permission from the developers of the questionnaire *(13)*.

The scale was divided in two sections. The first part contained the knowledge items with six dimensions and 46 items in a triple-choice response scale (true, false and don't know). The dimensions were: nature of the disease (eight items), transmission of the disease (five items), characteristics of people infected by the coronavirus (three items), prevention (three items), actions in dealing with suspected, probable and confirmed cases (24 items), and precautionary measures by health care providers (three items). The second part of the scale contained items on attitude including 11 items with a 5-point Likert scale (strongly agree, agree, uncertain, disagree and strongly disagree).

Face and content validity

The validity of the scale was assessed though face and content validity. Ten nurses working at Tabriz University of Medical Sciences were selected by convenience sampling and were interviewed to get their views on the appearance, simplicity, and understandability of the items. The nurses were also asked to judge the importance of the items for assessing knowledge and attitudes about MERS-CoV using a 5-point Likert scale: 1, unimportant; 2, slightly important; 3, important; 4, very important; and 5, extremely important. For each item, an impact score was calculated by the number nurses who scored the item 4 or 5 in the importance scale multiplied by the mean score of the item's importance. Items with impact scores of less than 1.5 were excluded from the questionnaire *(18)*.

A panel of 11 experts was then selected: four experts in infection control working in selected hospitals in Tabriz, four infectious disease specialists—one each from Imam Reza Hospital in Tabriz, the Centre for Infectious Diseases Control, the Treatment Department of East Azerbaijan Province and the Iranian Centre for Communicable Disease Control—and three researchers and lecturer in emerging diseases at the Faculty of Nursing and Midwifery of Tabriz University of Medical Sciences. After obtaining necessary permission from the Ethics Committee of Tabriz University of Medical Sciences, the experts were sent the revised scale after face validity and invited to undertake content validity assessment. All the 11 experts responded.

To examine the content validity ratio, the panellists were asked to rate the items on the scale as: necessary, useful but not necessary, or not necessary. Then, the content validity ratio for each item was calculated with

the formula: content validity ratio = $(N_e - N/2)/N/2$, where N is the number of panellists in the content validity evaluation and N_e is the number of panellists who rated the item as essential *(19)*. Items with a content validity ratio value less than 0.62 (the critical value in the Lawshe table for 11 panellists) were excluded *(19)*.

After excluding items in the content validity assessment, the content validity index of the scale was determined according to the Waltz and Bausell criteria *(20)*. The comments of the 11 experts on the relevance of each item to whatever had to be measured were assessed based on the following responses: not relevant, item needs some revision, relevant but needs minor revision, and very relevant *(20)*. Experts were also asked to comment on the face validity of items in order to correct them accordingly. The content validity index was calculated for each item and as an average for the whole scale (S-CVI/Ave). To calculate the content validity index of each item, the number of panellists who judged the item as very relevant and relevant but needs minor revision was divided by the total number of panellists.

Items with content validity indexes greater than 0.79 were retained in the scale, those with content validity indexes between 0.70 and 0.79 were revised, and those with content validity indexes less than 0.70 were excluded *(21)*. The content validity index values of all the items were averaged to obtain the S-CVI/Ave for the knowledge and attitude scales.

Construct validity

To determine the construct validity of the scale, 155 nurses were randomly selected from hospitals affiliated with Tabriz University of Medical Sciences (Table 1). The nurses self-completed the knowledge and attitude scales that had been revised after face and content validity between October 2016 and April 2017. Exploratory factor analysis was used, applying the Kaiser–Meyer–Olkin test for sampling adequacy, the Bartlett test of sphericity, principal component analysis, scree plot and varimax rotation with a cut-off point of 0.4 for factor loading to extract the dimensions of the scale or for the simplification of interrelated measures to discover patterns in a set of variables *(22)*.

Reliability assessment

Internal consistency and stability reliability were used to determine the reliability of the revised scale. In a pilot study with 25 randomly selected nurses working in a research environment, the internal consistency of the knowledge scale was determined using the Kuder–Richardson-21 formula and that of the attitude scale was ascertained by the Cronbach alpha method. In order to determine the stability of both scales, the same 25 nurses completed the scales two weeks later and the intraclass correlation coefficients were calculated for the scores.

Data analysis

Data were analysed using *SPSS*, version 21. The Pearson correlation coefficient was calculated and exploratory factor analysis done. $P < 0.05$ was considered statistically significant.

Table 1 Participants' characteristics

Characteristic	Mean (SD)
Age (years)	31.40 (6.57)
Years of nursing experience	7.28 (6.24)
Years in current position	4.11 (4.11)
	No. (%) (n = 155)
Sex	
Female	137 (88.4)
Male	18 (11.6)
Degree	
Diploma	2 (1.3)
Bachelor	145 (93.5)
Masters	8 (5.2)
Position	
Paramedic	3 (1.9)
Nurse	144 (92.9)
Head nurse	4 (2.6)
Supervisor	4 (2.6)

SD: standard deviation.

Ethical considerations

This study was approved by the ethics committee of Tabriz University of Medical Sciences (IR.TBZMED.REC.1395.1065). All stages of data collection were carried out with the agreement of the managers of the study hospitals and head nurses. Prior to data collection, the research objectives were explained to participating nurses and their written informed consent was obtained. They were assured of the confidentiality of their answers and that they had the right to withdraw from the study at any time.

Results

Face and content validity

Based on the qualitative judgment of the 10 nurses of the completeness of the dimensions of the knowledge scale, an additional dimension was added called "treatment of the disease". For this new dimension, five items were generated based on the Iranian, WHO and CDC guidelines. The content validity of these new items were then evaluated.

In addition, items were added to the following dimensions.

- Nature of the disease: (i) the coronavirus is contagious up to 24 hours after fever and other symptoms have gone.
- Transmission of the disease: (i) disease transmission from asymptomatic patients and/or those in the disease incubation period, (ii) communicability of MERS by injection of a needle infected with patient's secretions and (iii) communicability of MERS from

deceased patients.

- Actions in dealing with suspected, probable and confirmed cases: (i) cleaning all contaminated surfaces with a diluted (10%) bleach solution (ii. elimination of MERS-COV by70% alcohol.
- Precautionary measures by health care providers: (i) use of personal protective equipment by those responsible for the transfer of deceased patients.

After face and content validity, the knowledge scale had seven dimensions with 61 items. S-CVI/Ave was 0.80.

In the attitude scale, based on the comments of the 11 panellists, an item was excluded (coronavirus infection can be treated at home), 10 items were corrected, and seven items were added to the content validity: dimension 1, statements 1–5 and 10, dimensions 2, statement 5 (Table 2). This resulted in a 17-item attitude scale in one dimension. S-CVI/Ave was 0.91.

Construct validity

In the exploratory factor analysis for the items of the attitude questionnaire, the sampling adequacy was examined with the Kaiser–Meyer–Olkin test which gave a result of 0.758. The Bartlett test was used to determine whether the correlation matrix obtained was significantly different from zero and could be justified based on factor analysis ($P < 0.001$). In exploratory factor analysis using varimax rotation, two components with eigenvalues greater than 1.0 were extracted which explained 45.72% of the variance. The first component with 11 items accounted for 27.72% of the variance and was called "fear and threats of MERS-CoV". The second component accounted for 18.0% of the variance with five items and was called "beliefs about the prevention of MERS-CoV" (Table 2).

To assess the validity of the knowledge scale, the sampling adequacy was examined by the Kaiser–Meyer–Olkin test which gave a result of 0.864 and the Bartlett test was significant ($P < 0.001$). In the exploratory factor analysis using varimax rotation, five components with eigenvalues more than 1.0 were extracted which explained 41.23% of the variance. The first component with nine items accounted for 5.30% of the variance and was called "nature of the disease" The second component with seven items accounted for 4.63% of the variance and was called "transmission of the disease". The third component with 20 items accounted for 18.54% of the variance and was called "actions in dealing with suspected, probable and confirmed cases". The fourth component with five items accounted for 15.5% of the variance and was called "precautionary measures by health care providers". Finally, the fifth component with five items accounted for 5.15% of the variance and was called "treatment of the disease" (Table 3).

Table 2 Results of exploratory factor analysis using a rotated component matrix for attitude to Middle East respiratory syndrome coronavirus (MERS-CoV) infection

Dimensions of attitude scale	Factor load	
Dimension 1: Fear and threats of MERS-CoV (27.72% of variance)		
I am afraid of working in places where patients suspected of MERS-CoV infection are admitted/cared for	0.80	
I am afraid of caring for a patient with MERS-CoV infection	0.79	
Despite the use of personal protective equipment and observing infection transmission precautions, the risk of MERS-CoV infection is high among health care staff	0.61	
I think that the equipment and facilities required to protect health care workers from MERS-CoV have not been sufficiently provided in the care settings	0.60	
Higher pay should be received when caring for patients with MERS-CoV infection	0.56	
I am afraid that a family member of mine may be affected by MERS-CoV infection	0.55	
In case of MERS-CoV outbreak, schools and workplaces should be closed	0.51	
MERS-CoV is highly transmissible in hospital	0.49	
Health education has no effect on the prevention of MERS-CoV infection	0.48	
I think that training on MERS-CoV is effective in protecting me from the disease in case of likely exposure (Reverse-scored)	0.45	
Caring for patients with MERS-CoV infection may be a threat to health care personnel	0.40	
Dimension 2: Beliefs about prevention of MERS-CoV disease (18.0% of variance)		
Public health agencies can control Outbreak of MERS		0.75
MERS can have a negative effect on the economies of the countries involved		0.74
It is important to report suspected cases to health authorities		0.72
MERS is preventable		0.64
It is imperative to use a surgical mask when working with the patient with MERS		0.57
Total amount of explained variance: 45.72% of variance		

Table 3 Results of exploratory factor analysis using the rotational component matrix for knowledge of Middle East respiratory syndrome coronavirus (MERS-CoV) infection

Dimensions of knowledge scale	Factor load		
Dimension 1: Nature of the disease (5.3% of variance)			
The symptoms of MERS are fever with/without chilling, cough, and dyspnea	0.60		
Recommended diagnostic approach in human is sampling of upper and lower airways secretions and PCR (polymerase chain reaction) examination	0.57		
People infected with MERS-CoV typically travelled to countries near the Arabian Peninsula	0.54		
Some types of fruit-eating bats are the main sourse of the disease in wildlife	0.70		
The causative agent of MERS-CoV is coronavirus	0.46		
MERS-CoV can be eliminated with 70% alcohol	0.41		
MERS-CoV can be prevented with the injection of a vaccine (Reverse-scored)	0.47		
The incubation period of MERS is 2–14 days	0.59		
The coronavirus can survive for 48 h in the environment	0.42		
Dimension 2: Transmission of disease (4.63% of variance)			
MERS-CoV is transmitted through direct contact with respiratory tract secretions		0.51	
The disease can be transmitted through direct contact with contaminated camel's secretions, including urine, saliva, respiratory secretions, and blood		0.66	
The disease can be transmitted through the consumption of raw products and raw/half-baked meat of infected camels		0.65	
MERS-CoV is transmissible through haemodialysis (Reverse-scored)		0.47	
Camels are one of the sources of transmission of MERS-CoV to human		0.41	
MERS-CoV is probably transmissible from infected deceased patients		0.76	
The disease can be transmitted from asymptomatic patients or those who are in the latent period of the disease (Reverse-scored)		0.84	
Dimension 3: Actions in dealing with suspected, probable and confirmed cases (18.54% of variance)			
The use of personal protective equipment is necessary during aerosol production procedures, such as suction sputum sampling and intubation			0.81
The complete collection of data, including disease history, clinical presentation, complications and completion of the relevant form are required after confirmed diagnosis of MERS-CoV infection			0.79
Suspected cases of MERA-CoV infection after triage should be taken into care in a negative pressure respiratory isolation room			0.79
Training and observation of standard precautionary measures are required by care-giving personnel in suspected and probable cases of MERS-CoV infection			0.72
It is advisable to sample all respiratory secretions from all patients admitted to the hospital with a primary diagnosis of pneumonia and suspicion of MERS-CoV infection			0.67
Suspected and probable cases of MERS-CoV infection must be reported immediately to the infectious disease control centre			0.67
A complete list should be provided of all people who have been in contact with the confirmed patient with MERS-CoV infection			0.66
The use of N95 masks is necessary when sampling of induced sputum from patients suspected of MERS-CoV infection			0.64
Visitors to patients with suspected, probable and confirmed cases of MERS-CoV infection should be limited both in hospital and at home			0.64
The number of care-giving personnel for suspected, probable and confirmed cases of MERS-CoV infection, including physicians and nurses, should be limited and certain.			0.64
Exposed people with symptoms of fever, cough and diarrhoea should have sputum samples taken and PCR testing			0.63

Table 3 Results of exploratory factor analysis using the rotational component matrix for knowledge of Middle East respiratory syndrome coronavirus (MERS-CoV) infection (*concluded*)

Dimensions of knowledge scale	Factor load		
Admitted patients should be hospitalized in the respiratory isolation room, preferably with negative pressure	0.62		
All members of the family of a patient with MERS-CoV infection are considered to have a history of contact with the disease	0.49		
If no isolation room is available, patients with a diagnosis of MERS-CoV infection can be put in the same room with beds 1 m apart	0.40		
After confirming the diagnosis of MERS-CoV infection, patient's contacts in the past 14 days must be checked and controlled	0.42		
After diagnosis of MERS-CoV infection, it is necessary to find possible patients among those who have been in contact with the patient	0.51		
The N95 mask is required to be put on when entering the room of a patient with MERS-CoV infection and caring at a distance of 2 m from the patient	0.43		
A person with mild symptoms of MERS must remain at home until resolution of clinical symptoms and negative results of the PCR test	0.55		
Patients with MERS-CoV infection admitted to an isolation room should use a surgical mask when moving and leaving the room for diagnostic and therapeutic procedures	0.48		
All surfaces contaminated by the patients with MERS-CoV infection should be cleaned with diluted (10%) bleaching solution	0.57		
Dimension 4: Precautionary measures by health care providers (5.15% of variance)			
Droplet precautions should be followed by health care providers in dealing with suspected, probable and confirmed cases of MERS-CoV infection		0.40	
Contact precautions should be followed by health care providers in dealing with suspected, probable and confirmed cases of MERS-CoV infection		0.65	
People in the high-risk group with heart, lung and kidney disease can be selected as care providers at home and in hospital (Reverse-scored)		0.62	
Standard precautions should be followed by health care providers in dealing with suspected, probable and confirmed cases of MERS-CoV infection		0.60	
Airborne precautions should be followed by health care providers in dealing with suspected, probable and confirmed cases of MERS-CoV infection		0.56	
Dimension 5: Treatment of the disease (5.15% of variance)			
Oxygen therapy should be given to all cases of severe MERS with acute respiratory infection			0.52
Antibiotic therapy is required for the treatment of pneumonia until confirmation of suspected cases of MERS-CoV infection			0.76
Ventilation with an endotracheal tube must be carried out in patients with confirmed or suspected coronaviruses with clinical manifestations of acute respiratory distress syndrome			0.74
High doses of systemic corticosteroids should be avoided in patients with confirmed or suspected MERS-CoV infection and clinical manifestations of viral pneumonia			0.61
Treatment for patients with MERS-CoV infection is currently symptomatic			0.54
Total amount of variance explained: 4123% of variance			

The correlation matrix in Table 4 shows significant correlations between total knowledge scores and total attitude scores ($P < 0.001$), beliefs about the prevention of MERS-CoV ($P < 0.001$) and the fears and threats of MERS-CoV ($P = 0.019$).

Reliability

The total internal consistency of the knowledge scale, assessed using Kuder–Richardson-21, was 0.94; its five dimensions Kuder–Richardson-21 ranged from 0.72 to

Table 4 Correlation between knowledge and attitude scores, and their dimensions

Factors	2	3	4	5	6	7	8	9
Nature of the disease	0.725 ($P < 0.001$)	0.640 ($P < 0.001$)	0.758 ($P < 0.001$)	0.590 ($P < 0.001$)	0.426 ($P < 0.001$)	0.132 ($P = 0.101$)	0.879 ($P < 0.001$)	0.279 ($P < 0.001$)
Transmission of the disease	1	0.527 ($P < 0.001$)	0.607 ($P < 0.001$)	0.513 ($P < 0.001$)	0.329 ($P < 0.001$)	0.119 ($P = 0.140$)	0.757 ($P < 0.001$)	0.229 ($P = 0.004$)
Precautions		1	0.698 ($P < 0.001$)	0.506 ($P < 0.001$)	0.379 ($P < 0.001$)	0.121 ($P = 0.133$)	0.779 ($P < 0.001$)	0.251 ($P = 0.002$)
Actions in dealing with suspected, probable and confirmed cases			1	0.655 ($P < 0.001$)	0.417 ($P < 0.001$)	0.173 ($P = 0.031$)	0.951 ($P < 0.001$)	0.308 ($P < 0.001$)
Treatment of the disease				1	0.410 ($P < 0.001$)	0.247 ($P = 0.002$)	0.755 ($P < 0.001$)	0.365 ($P < 0.001$)
Attitude: beliefs about the prevention of MERS-CoV					1	0.292 ($P < 0.001$)	0.464 ($P < 0.001$)	0.641 ($P < 0.001$)
Attitude: fears and threats of MERS-CoV						1	0.188 ($P = 0.019$)	0.921 ($P < 0.001$)
Knowledge total scale							1	0.339 ($P < 0.001$)
Attitude total scale								1

0.93. The internal consistency of the attitude scale was evaluated using the Cronbach alpha which gave values of 0.81, 0.73 and 0.82 for the dimensions of fears and threats of MERS-CoV, beliefs about the prevention of MERS-CoV, and for the entire scale respectively. When the questionnaire was assessed again after a two-week interval in the same sample of nurses, the value of the intraclass correlation coefficient for the entire knowledge scale was 0.91 and ranged from 0.76–0.88 for its dimensions. Intraclass correlation coefficient values for the two dimensions of attitude were 0.85 for beliefs about the prevention of MERS-CoV and 0.89 for fears and threats of MERS-CoV, and 0.89 for the entire scale (Table 5).

Scoring of the instrument

Our final MERS-CoV instrument is composed of both knowledge and attitude scales. The knowledge scale includes five domains and 46 items in a triple-choice response scale (true, false and don't know) including: actions to deal with suspected, probable and confirmed cases (20 items), nature of the disease (9 items), precautionary measures by health care providers (5 items), treatment of the disease (5 items) and transmission of the disease (5 items). True answers scored 1 point and others scored 0. A high score on the knowledge scale represents a high level of knowledge about MERS disease. The principle for scoring these scales is the same in all cases: (i) Estimate the sum of the items that contribute to the subscale – this is the raw score and (ii) Use a linear transformation to standardize the raw score so that scores range from 0 to 100 – a higher score represents a higher level of knowledge. The linear transformation score is derived as follows: linear transformation score = (raw score – minimum total score)/(maximum total score – minimum total score) × 100. For example, in the subscale of actions to deal with suspected, probable and confirmed cases, the range of scores is 0 to 20 and the linear transformation score is equal to (raw score – 0)/(20 – 0) × 100.

The attitude scale includes two domains, one with 11 items (fears and threats of MERS-CoV) and one with five (beliefs about the prevention of MERS-CoV) which are rated on a 5-point Likert response scale. Therefore, scores in the two subscales range from 11 to 55, and 5 to 25 respectively. For example, in the first subscale of attitude, the linear transformation score is (raw score – 11)/(55 – 11) ×100.

Discussion

We aimed to design and psychometrically evaluate an instrument and to assess nurses' knowledge of and attitude to MERS-CoV. Acceptable S-CVI/Ave values of 0.80 and 0.91 were obtained for the knowledge and attitude scales respectively *(21,23)*.

In the exploratory factor analysis of the knowledge and attitude scales, the Kaiser–Meyer–Olkin sampling adequacy indexes (0.864 and 0.758 respectively) and Bartlett's test ($P < 0.001$) indicated that implementation of factor analysis was justifiable based on the correlation

Table 5 Intraclass correlation coefficient, Cronbach alpha values, Kuder–Richardson-21 reliability coefficient the knowledge and attitude scales and subscales

Scale	Number of items	Cronbach alpha	Intraclass correlation coefficient
Attitude scale on MERS-CoV			
Dimension 1: fears and threats of MERS-CoV	11	0.81	0.89
Dimension 2: beliefs about the prevention of MERS-CoV	5	0.73	0.85
Total	16	0.82	0.89
Knowledge scale on MERS	Number of items	Kuder–Richardson-21	Intraclass correlation coefficient
Dimension 1: nature of the disease	9	0.75	0.76
Dimension 2: transmission of the disease	7	0.82	0.87
Dimension 3: actions in dealing with suspected, probable and confirmed cases	20	0.93	0.85
Dimension 4: precautionary measures by health care providers	5	0.72	0.88
Dimension 5: treatment of the disease	5	0.81	0.79
Total	46	0.94	0.91

MERS: Middle East respiratory syndrome.

matrix obtained in the sample. A Kaiser–Meyer–Olkin level greater than 0.5 allows factor analysis *(24)*.

The internal consistency of the knowledge scale assessed by the Kuder–Richardson-21 formula equalled to 0.94 for the total knowledge scale and 0.72–0.93 for its dimensions. Cronbach alpha values of 0.73 and 0.81 were obtained for the dimensions of the attitude scale; values equal to or higher than 0.7 are acceptable and indicative of internal consistency of a scale *(25)*. The intraclass correlation coefficient for the entire knowledge scale was 0.91 and that for the attitudes scale was 0.89; values equal to or more than 0.4 are acceptable *(26)*, indicating that the questionnaires developed in our study was stable and reliable.

Following exploratory factor analysis, the knowledge scale items were categorized in five dimensions. The dimension that explained the greatest score variance in the knowledge scale (18.45%) was actions in dealing with suspected, probable and confirmed cases. This dimension addresses measures on infection control, isolation, disinfection of surfaces, and actions in dealing with suspected, probable and confirmed cases *(27)*. Nature of the disease explained 5.30% of the variance; this dimension focuses on the causative agent, disease reservoirs, diagnosis path, incubation period and the disease symptoms *(28,29)*. Precautionary actions by health care providers explained 5.15% of the score variance; this dimension emphasizes standard precautions, airborne and contact precautions, and high-risk groups *(30)*. Treatment of the disease explained 5.15% of the score variance; this dimension concentrates on disease treatment approaches *(30)*. Finally, disease transmission explained 4.63% of the variance; this dimension refers to the ways the disease is transmitted from animals to humans and/or from infected individuals to others *(8,31,32)*.

Attitude items were categorized into two dimensions (fears and threats of MERS-CoV) which explained 27.72% of the variance, and beliefs about prevention of MERS-CoV which explained 18.0% of the variance. The items of our scale on fears and threats of the disease are not consistent with those of the Korean study (*14*). This can be explained by the fact that the researchers developed the questionnaire based on one that assessed the public fear of severe acute respiratory syndrome.

The findings of our study are in line with a study in Saudi Arabia in 2014 with regard to knowledge questions (nature, etiology, symptoms, consequences, transmission, prevention and treatment). However, no measures were included in the Saudi Arabian questionnaire dealing with suspected, probable and confirmed cases, and precautions (*10*). All items in our questionnaire are also consistent with those used in a 2015 study in Saudi Arabia on the knowledge, attitude and practice of health care providers, although some of their questions had more than one answer (*13*). Moreover, three dimensions of our knowledge scale (nature, and treatment and prevention of the disease) agree with that of a Chinese study in 2015 that investigated MERS and knowledge, attitudes and practices of medical students related to MERS (*33*).

To the best of our knowledge, our study is one of the most rigorous studies to develop a reliable and valid instrument for assessing the knowledge and attitude of nurses in the front line of health care provision for people with MERS-CoV infection (*34*). We used face and content validity (quantitative and qualitative) methods, construct validity using exploratory factor analysis, and scale reliability using two methods of internal consistency and stability. Another significant feature of our study is using CDC and WHO guidelines on MERS as well as those of the Iranian Centre for Communicable Diseases. In addition, relevant scientific literature was reviewed to determine the content domains of MERS and generate items for the knowledge and attitude scales.

Considering the use of extensive literature review and expert opinion for designing this scale and the evidence of the validity and reliability of our MERS-CoV knowledge and attitude scale, we recommend its use to assess the knowledge and attitudes of nurses and hospital managers before and after training courses on the disease and in other research.

A limitation of this study was that it was only conducted among nurses and in two hospitals affiliated to Tabriz University of Medical Sciences. Nonetheless, the reliability of the scale can be examined for other health care service providers (e.g. physicians, paramedics, and medical, paramedical and nursing students), and in different locations in the Islamic Republic of Iran or even other parts of the world.

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Mise au point d'un questionnaire pour évaluer les connaissances et les attitudes des personnels infirmiers iraniens vis-à-vis du Syndrome respiratoire du Moyen-Orient

Résumé

Contexte : Avec l'émergence du Syndrome respiratoire du Moyen-Orient (MERS), une attention croissante a été accordée à la préparation en matière de soins de santé, nécessitant des outils valables pour évaluer les connaissances et les attitudes vis-à-vis de cette maladie chez les agents de santé, tels que les personnels infirmiers.

Objectifs : La présente étude visait à mettre au point et à évaluer un questionnaire sur les connaissances et attitudes vis-à-vis du coronavirus du Syndrome respiratoire du Moyen-Orient (MERS-CoV) à l'attention des personnels infirmiers iraniens.

Méthodes : Un questionnaire a été préparé sur la base des directives internationales et nationales et d'une revue de la littérature. Dix membres du personnel infirmier ont été recrutés pour évaluer la validité apparente et 11 experts ont examiné l'instrument pour déterminer le ratio et l'indice de validité du contenu. Une analyse factorielle exploratoire a ensuite été réalisée sur un échantillon aléatoire de 155 personnels infirmiers dans la ville de Tabriz, en République islamique d'Iran.

Résultats : Après avoir déterminé la validité apparente et du contenu, 78 items (61 pour les connaissances et 17 pour les attitudes) ont été retenus dans la version finale du questionnaire. L'échelle des connaissances avait un indice de validité du contenu moyen de 0,80 et l'échelle d'attitudes une valeur de 0,91. À l'analyse factorielle exploratoire, cinq dimensions ayant des valeurs propres supérieures à 1 et un coefficient de saturation supérieur ou égal à 0,4 ont été extraites pour l'échelle des connaissances (46 items) et deux pour l'échelle d'attitudes (16 items). Le coefficient de Kuder-Richardson formule 21 et le coefficient de corrélation intra-classe pour l'échelle des connaissances étaient respectivement de 0,94 et 0,91. Dans l'échelle d'attitudes, le coefficient alpha de Cronbach et le coefficient de corrélation intra-classe étaient respectivement de 0,82 et 0,89.

Conclusions : L'échelle mise au point dans cette étude est fiable et stable. Elle constitue également un instrument approprié pour évaluer les connaissances et les attitudes des personnels infirmiers au sujet du MERS-CoV.

إعداد استبيان لتقييم معلومات واتجاهات الممرضين الإيرانيين تجاه متلازمة الشرق الأوسط التنفسية

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الخلاصة:

الخلفية: حظيت استعدادات الرعاية الصحية باهتمام متزايد مع ظهور متلازمة الشرق الأوسط التنفسية، مما يتطلب أدوات صالحة لتقييم معلومات واتجاهات العاملين الصحيين مثل الممرضين تجاه هذا المرض.

الأهداف: هدفت هذه الدراسة إلى إعداد استبيان لتقييم المعلومات والاتجاهات بشأن فيروس كورونا المسبب لمتلازمة الشرق الأوسط التنفسية لدى الممرضين الإيرانيين.

طرق البحث: أُعد استبيان يستند إلى المبادئ التوجيهية الدولية والوطنية وإلى مراجعة المؤلفات. وجرى تعيين عشرة من طاقم التمريض لتقييم موثوقية الاستبيان (المدى الذي يقيس به الاستبيان المفهوم الذي يهدف إليه)، واستعرض 11 خبيرًا الاستبيان لتحديد نسبة موثوقية محتواه ومؤشره. ثم أجري "تحليل العوامل الاستكشافية" على عينة عشوائية مكونة من 155 من طاقم التمريض في مدينة تبريز، بجمهورية إيران الإسلامية.

النتائج: بعد تحديد موثوقية الوجه والمحتوى للاستبيان، استُبْقِيَ على 78 بندًا في الصيغة النهائية للاستبيان (61 للمعلومات و17 للاتجاهات). وكان متوسط مؤشر صحة المحتوى لمقياس المعلومات 0.80، وقيمة مقياس المواقف 0.91. وفي تحليل العوامل الاستكشافية، استخرج خمسة أبعاد كانت القيم الخاصة لها أكبر من 1 ومستوى التحميل أكبر من أو يساوي 0.4 لمقياس المعلومات (46 بندًا)، واستخرج اثنان لمقياس المواقف (16 بندًا).

وكان معامل "كودر ريتشاردسون" 21، ومعامل الترابط داخل الفئة لمقياس المعلومات 0.94 و0.91 على التوالي. وفي مقياس الاتجاهات، كان معامل "كرونباخ ألفا"، ومعامل الترابط داخل الفئة 0.82 و0.89 على التوالي.

الاستنتاجات: المقياس الذي أعدته هذه الدراسة موثوق به وثابت، ويعد أداة مناسبة لتقييم المعلومات والاتجاهات لدى طاقم التمريض بشأن فيروس كورونا المسبب لمتلازمة الشرق الأوسط التنفسية.

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Association between the nationality of nurses and safety culture in maternity units of Oman

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Abstract

Background: Patient safety culture/climate in maternity units has been linked to better safety outcomes. Nurses have a crucial role in patient safety and represent the majority of staff in maternity units. In many countries, nurses are recruited from abroad, bringing their own perceptions of patient safety culture. Nonetheless, little is known about the relationship between perceptions of patient safety culture and nurses' nationality. Understanding this relationship will assist stakeholders in designing a responsive programme to improve patient safety culture.

Aims: To investigate the association between nurses' nationality and their perceptions about patient safety culture in maternity units in Ministry of Health hospitals in Oman.

Methods: In 2017, the Safety Attitude Questionnaire (SAQ) was distributed to all staff (892 distributed, 735 returned) in 10 maternity units.

Results: About three-quarters (74%, 541/735) of the returned SAQs were completed by nurses, of whom 34% were non-Omani, 21.8% were Omani and 44.7% did not report their nationality (missing). Overall, the mean safety score for non-Omani nurses was significantly higher than for the Omani nurses: 3.9 (SD 1.3) vs 3.6 (SD 1.2) ($P < 0.001$). The mean safety score for stress recognition was significantly lower for non-Omani nurses: 2.8 (SD 1.5) vs 3.2 (SD 1.3) ($P < 0.001$).

Conclusion: Non-Omani nurses have a more positive perception of patient safety culture than Omani nurses except in respect of stress recognition. Decision-makers, directors, and clinicians should consider these differences when designing interventions to improve patient safety culture.

Keywords: patient safety culture, nurses, maternity units, nationality, Oman

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Introduction

Improving staff perceptions about safety culture (or climate) has been associated with improved patient safety and better health outcomes (*1*). Since nurses form the majority of the workforce in maternity care and have a crucial influence on patient safety, understanding the factors that affect their perceptions will support patient safety improvement projects (*2*). Variables such as education level, work hours and years of experience have been found to impact nurses' perceptions (*2–5*). Moreover, in countries which rely heavily on nurses from abroad, with varying cultural and linguistic backgrounds, the perceptions of patient safety may differ between local and international nurses (*6*).

Despite the increasing number of studies examining safety culture, studies exploring the association between safety culture and nationality/ethnicity are not common (*6*). Our search of the literature (Tables 1,2) found 7 studies only (*6–12*); 2 were conducted in Saudi Arabia, 2 in the United States of America (USA) and the rest in Norway, Belgium and Switzerland. Four studies focused on variation among nurses and the remaining studies included other categories of staff. No study focused on a particular unit/department within a hospital. The tools used to examine safety culture in these studies included the Hospital Survey on Patient Safety Culture, the Safety Climate Survey, and the Safety Organizing Scale, but not the Safety Attitudes Questionnaire (SAQ).

A study which examined nurses' perceptions of safety culture in Saudi Arabia found that the non-Arabic speaking nurses had a greater positive response compared with the Arabic speaking nurses (*7*). Ari et al. studied the factors affecting the perception of nurses on safety culture, however, there was no discussion on the association between ethnicity and safety culture (*4*). In Oman, where the present study was conducted, 2 studies assessed safety culture at the hospital level using the Hospital Survey on Patient Safety Culture, but neither examined the association between respondents' nationality and safety culture (*6,13*).

This is the first study to investigate the association between the nationality of nurses and their perceptions of safety culture in maternity care units in Ministry of Health hospitals in Oman. The results of this study will inform policy-makers, hospital administrators, researchers and nurse managers on designing and

Table 1 **List of databases, search terms and number of studies screened/included in the systematic search**

Item	Details
Databases used	CINAH, Medline, PsycInfo, Embase, ASSIA
Month and year of conducting search	March 2018
Language	English
Year of publication	No limit was used
Search terms combinations	(Safety culture or safety climate) combined with (ethnic* or rac* or nationality or language)
Total articles found	302
Screened after removing duplicates	206
Considered for full text review	14
Included in the review	7

planning a more responsive patient safety improvement programme.

Methods

Design

The current study is a descriptive cross-sectional study.

Sample and settings

Oman is a developing country located in the South-Eastern corner of the Arabian Peninsula. The nursing staff is predominantly female and 42% of nurses working in the Omani Ministry of Health institutions are recruited from countries such as India and the Philippines (*14*). This study was conducted in all maternity units in Ministry of Health hospitals in Oman. The complete survey targeted a number of staff categories: bedside nurses, midwives, physicians, students and residents who had worked for a minimum of 4 weeks before conducting the study.

The Safety Attitudes Questionnaire

The English short form of the SAQ (https://med.uth.edu/chqs/files/2018/05/SAQ-Short-Form-2006.pdf) was used to examine the safety culture in this study. The SAQ was developed by the University of Texas and has 36 questions covering 6 domains: teamwork climate (items 1–6), safety culture (items 7–13), job satisfaction (items 15–19), stress recognition (items 20–23), perception of management (items 24–28), and working conditions (*29–32*). Items 14 and 33–36 are not part of the scales above. All 36 questions use a 5-point Likert scale as follows: strongly disagree = 1; slightly disagree = 2; neutral = 3; slightly agree = 4 and strongly agree = 5 (*15*). In the original quess tionnaire, items 24–28 asked staff about their perception of management in the department as well as in the hospital at large, but for this study, results were only kept for the department level. This tool was chosen because it has been tested in different countries, including the USA, the United Kingdom and Norway, and its validity and reliability has been proven (*15–17*). Cronbach's alpha for the original scale was 0.93 (*18*), and in our study it was 0.91. Additionally, the relatively short completion time (15–20 minutes) made the SAQ more acceptable (*17*).

Survey distribution and collection

The survey was piloted in January 2017 in one hospital to identify any potential challenges (e.g. low response rate, distribution problems) before conducting it in the remaining hospitals during April–May 2017. The data from the pilot site were included in the final analysis as no change was made to the survey or sample. Heads of the quality departments were met in April 2017 and given the study guideline to standardize the survey distribution and collection in all hospitals. The surveys were copied and coded according to the published guidelines (*19*).

The surveys were handed out to participants by a quality department staff member during or after their

Table 2 **List of references considered for full text review but excluded from the final review**

Study	Reason for exclusion
Gabrani et al. http://dx.doi.org/10.1111/jnu.12236	Measured safety culture but ethnicity/nationality not discussed
Groves et al. https://doi.org/10.1111/j.1365-2648.2011.05619.x	Discussed the theory of safety culture. Not an original study.
Hamdan et al. https://doi.org/10.1093/intqhc/mzt007	Association between safety and ethnicity/nationality/language not discussed
Kagawa-Singer et al. http://dx.doi.org/10.1016/j.soncn.2009.11.008	A review not a primary study; association not discussed in the reviewed studies
Alayed et al. https://doi.org/10.1108/IJHCQA-04-2013-0042	Did not discuss association, just outlined that cultural heterogeneity needs further analysis
Smith et al. https://doi.org/10.1177/1043659611404423	Safety culture and its association with ethnicity/nationality not discussed; did discuss the ability of validated tool to detect transcultural variation
Zhu et al. http://dx.doi.org/10.1007/s10488-016-0740-7	Measured safety culture but ethnicity/nationality not discussed

morning meeting. The nurse-in-charge collected surveys from the nurses and the quality departments sent all surveys to a central department in the Ministry of Health. Data were then entered by a coordinator working for the principal investigator, who double checked the data for accuracy.

Ethical considerations

The study was approved by the Research and Ethical Review and Approval committee, Ministry of Health, Oman (MoH/DGPS/CSR/PROPOSAL_APPROVED/2/2017). Participants were given a cover page with the questionnaire explaining that participation was voluntary, confidentiality would be maintained, and information able to identify the person was not requested.

Statistical analysis

The survey Likert scales were used to measure the mean score for all except 2 of the 36 safety items; these were items 11 and 36, which were appropriately reverse coded as per the guidelines (*19*). The overall mean scores were calculated by summing the score from all respondents and dividing by the number of responses. Similarly, the mean score for each safety domain was calculated by adding the scores of items for each domain and dividing by the number of responses. To calculate the percentage of positive responses, these responses were regrouped into negative (strongly disagree, slightly disagree), positive (strongly agree, slightly agree) and neutral response (*15*). This study targeted different staff categories, but this paper focuses on nurses as they represent the majority of the workforce and have a major impact on safety culture.

Data were presented as mean and standard deviation (SD) and proportions. Radar plots were used for data visualization, given their usefulness in presenting health care data (*20*). The *t*-test was used to determine the statistically significant difference in mean scores between non-Omani and Omani nurses. We used chi-squared to test for association between variables. Statistical significance was set at $P < 0.05$. When nurses' nationality and other variables were not reported (missing), data were considered as a separate category in our analysis. All data cleaning and analysis were conducted using *Stata* statistical software.

Results

Survey responses and respondent's characteristics

Out of the 892 targeted population, a total of 735 (82%) questionnaires were returned from the 10 hospitals, of which 541 (74%) were from nurses.

The response rate among non-Omani nurses was higher than that of Omani nurses (33.5% vs 21.8%) (Table 3). In all categories of years of experience, the proportion of Omani nurses was higher than the non-Omani nurses except in the < 5 years category (33.2% of non-Omani nurses, 23.7% of Omani nurses.

Safety scale for safety domains, years of experience and the 36 items

The non-Omani nurses had a statistically significantly higher overall mean score (3.9) compared with the Omani nurses (3.6) (Table 4). Among both Omani and non-Omani nurses, job satisfaction (4.2) had the highest mean score while stress recognition (3.1) had the lowest score. Non-Omani nurses scored higher for job satisfaction than Omani nurses (4.5 vs 4.0), however, non-Omani nurses had a lower mean score for stress recognition than Omani nurses (2.8 vs 3.2). In 5 out of the 6 safety domains, the non-Omani nurses had significantly higher mean scores compared with the Omani nurses. These differences were all statistically significant ($P < 0.001$) (Table 4).

Non-Omani nurses had significantly higher mean scores across all the categories of experience compared with Omani nurses (Table 4) and a significantly higher mean score across all the 36 safety items except items 20–23, which are part of the stress recognition domain ($P < 0.001$) (Figure 1).

Just 58.5% of nurses rated safety culture as positive but this was higher among non-Omanis (66.9%) compared with Omanis (56.0%) (Table 5). The proportion of positive responses for all safety domains was < 75%. The domain that attracted the highest positive response was job satisfaction (72.8%) followed by safety culture (62.1%), while stress recognition had the lowest value (42.8%). The positive proportion in all safety domains was higher

Table 3 Distribution of nurses in Omani maternity hospitals according to nationality and years of experience

Years of experience	Omani nurses	Non-Omani nurses	Missing	All	$\chi 2$	*P*-value
	No. (%)	No. (%)	No. (%)	No. (%)		
< 5	28 (23.7)	60 (33.2)	73 (30.2)	161 (29.8)	20.8	0.002
5–10	44 (37.3)	60 (33.2)	92 (38.0)	196 (36.2)		
11–20	35 (29.7)	51 (28.2)	55 (22.7)	141 (26.1)		
≥ 21	5 (4.2)	7 (3.9)	12 (5.0)	24 (4.4)		
Missing	6 (5.1)	3 (1.7)	10 (4.1)	19 (3.5)		
Total	**118 (21.8)**	**181 (33.5)**	**242 (44.7)**	**541 (100)**		

Table 4 Mean scores covering all items in each safety domain and years of experience categories

Category	Nationality of nurses							
	Omani		Non-Omani		Missing		All	
	Score							
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)
Overall	**4094**	**3.6 (1.2)**	**6411**	**3.9 (1.3)**	**8365**	**3.6 (1.2)**	**18870**	**3.7 (1.3)**
Domain								
Job satisfaction	571	4.0 (1.1)	898	4.5 (0.9)	1166	4.0 (1.1)	2635	4.2 (1.1)
Perception of management	550	3.5 (1.1)	877	3.8 (1.3)	1152	3.5 (1.2)	2579	3.6 (1.2)
Safety culture	810	3.6 (1.1)	1251	4.1 (1.1)	1629	3.6 (1.2)	3690	3.8 (1.2)
Stress recognition	451	3.2 (1.3)	712	2.8 (1.5)	926	3.3 (1.4)	2089	3.1 (1.4)
Teamwork climate	691	3.7 (1.2)	1076	4.0 (1.2)	1400	3.6 (1.2)	3167	3.8 (1.2)
Work condition	461	3.3 (1.2)	714	3.8 (1.3)	927	3.4 (1.3)	2102	3.5 (1.3)
Missing	560	3.6 (1.2)	883	3.8 (1.2)	1165	3.6 (1.2)	2608	3.7 (1.2)
Years experience								
< 5	955	3.6 (1.1)	2128	3.8 (1.2)	2457	3.6 (1.2)	5540	3.7 (1.2)
5–10	1534	3.6 (1.1)	2120	3.9 (1.3)	3231	3.5 (1.3)	6885	3.6 (1.3)
11–20	1229	3.7 (1.2)	1819	3.9 (1.3)	1928	3.7 (1.3)	4976	3.8 (1.3)
≥ 21	176	3.4 (1.2)	237	3.8 (1.4)	424	3.7 (1.4)	837	3.6 (1.4)
Missing	200	3.3 (0.9)	107	4.1 (1.0)	325	3.4 (1.0)	632	3.5 (1.0)

SD = standard deviation.

Figure 1 Radar plot showing the mean scores for each item on the Safety Attitudes Questionnaire among maternity nurses in Oman according to nationality ($P < 0.001$ for all categories)

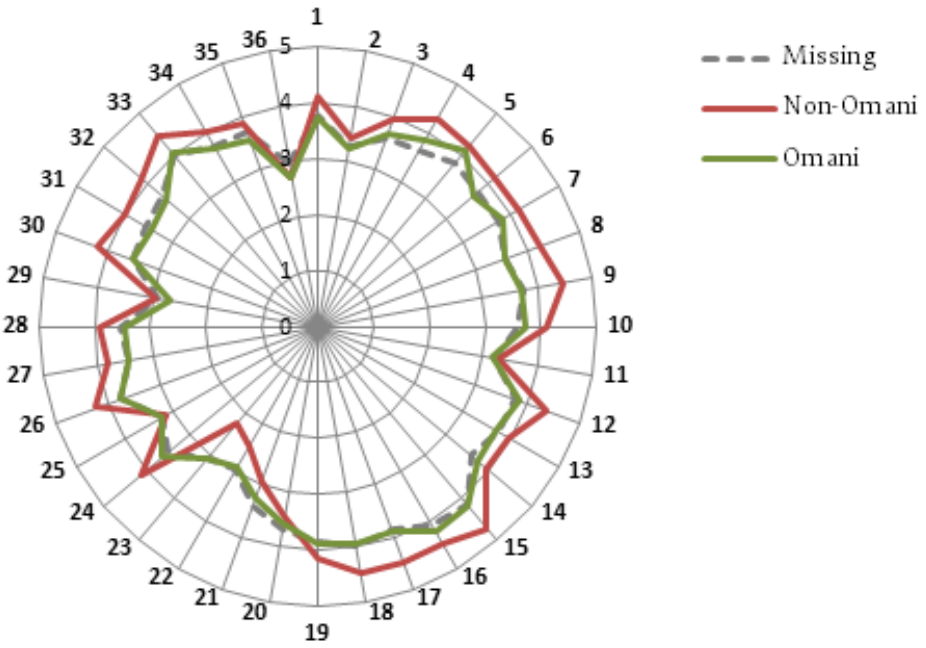

Table 5 **Distribution of responses for all items in each safety domain according to nationality**

Domain	Nationality of nurses			
	Omani	Non-Omani	Missing	All
	No. (%)	No. (%)	No. (%)	No. (%)
All domains	3658	5611	7502	16771
Positive	2047 (56.0)	3755 (66.9)	4016 (53.5)	9818 (58.5)
Negative	598 (16.3)	895 (16.0)	1403 (18.7)	2896 (17.3)
Neutral/missing/not applicable	1013 (27.7)	961 (17.1)	2083 (27.8)	4057 (24.2)
Job satisfaction	590	905	1210	2705
Positive	419 (71.0)	747 (82.5)	803 (66.4)	1969 (72.8)
Negative	48 (8.1)	28 (3.1)	137 (11.3)	213 (7.9)
Neutral/missing/not applicable	123 (20.8)	130 (14.4)	270 (22.3)	523 (19.3)
Perception of management	590	905	1210	2705
Positive	291 (49.3)	573 (63.3)	582 (48.1)	1446 (53.5)
Negative	79 (13.4)	131 (14.5)	212 (17.5)	422 (15.6)
Neutral/missing/not applicable	220 (37.3)	201 (22.2)	416 (34.4)	837 (30.9)
Safety culture	826	1267	1694	3787
Positive	489 (59.2)	931 (73.5)	931 (55.0)	2351 (62.1)
Negative	130 (15.7)	138 (10.9)	297 (17.5)	565 (14.9)
Neutral/missing/not applicable	207 (25.1)	198 (15.6)	466 (27.5)	871 (23.0)
Stress recognition	472	724	968	2164
Positive	207 (43.9)	275 (38.0)	444 (45.9)	926 (42.8)
Negative	122 (25.9)	319 (44.1)	281 (29.0)	722 (33.4)
Neutral/missing/not applicable	143 (30.3)	130 (18.0)	243 (25.1)	516 (23.8)
Teamwork climate	708	1086	1452	3246
Positive	427 (60.3)	764 (70.4)	802 (55.2)	1993 (61.4)
Negative	113 (16.0)	148 (13.6)	269 (18.5)	530 (16.3)
Neutral/missing/not applicable	168 (23.7)	174 (16.0)	381 (26.2)	723 (22.3)
Work conditions	472	724	968	2164
Positive	214 (45.3)	465 (64.2)	454 (46.9)	1133 (52.4)
Negative	106 (22.5)	131 (18.1)	207 (21.4)	444 (20.5)
Neutral/missing/not applicable	152 (32.2)	128 (17.7)	307 (31.7)	587 (27.1)

among non-Omani nurses except for stress recognition where 43.9% of Omani nurses agreed that safety culture was positive compared with 38.0% of non-Omani nurses.

Discussion

We found that the overall mean score of patient safety among nurses was not positive (i.e. below 4.0). However, the non-Omani nurses had a positive perception in 3 domains: job satisfaction, safety culture, and teamwork climate while the Omani nurses had a positive score in the job satisfaction domain.

Our findings suggest that there is an association between the nationality of nurses and perceptions of safety culture. Other studies support our findings even though different surveys were used to measure safety culture. For example, a study in Saudi Arabia using the Safety Climate Survey examined the perception of safety culture among nurses from diverse backgrounds (*6*). There was a significant variation between nurses of different backgrounds, although it was not reported which category had a more positive perception. Another study in Saudi Arabia concluded that the scores of the patient safety culture domains were significantly higher for non-Arabic-speaking nurses for than Arabic-speaking nurses, but without reporting country of origin (*7*). Similarly, a 2017 study in the USA used the Hospital Survey on Patient Safety Culture to examine the safety culture perceptions among American and immigrant nurses (*21*). They found that immigrant nurses had a more positive perception. An ethnographic study examining how Korean nurses adapted to USA hospitals found that Korean nurses brought their own culture (beliefs, values, perceptions) with them (*22*). Although the study was not specific to safety culture, but culture in general, it emphasizes that immigrant nurses do have different perceptions, especially during the first 5 years after immigration.

Our study was a national study focusing on a specific,

but important, aspect of service, maternity care. It has a good response rate indicating the feasibility for continuous monitoring of safety culture in both maternity and non-maternity units. It informs stakeholders and researchers on the areas of patient safety that need further attention for each group of nurses (i.e. Omani and non-Omanis). It also emphasises the need to consider the nationality of staff when considering initiatives to improve safety and safety culture.

The main limitation of this study was the high proportion of respondents (45%) who did not report their nationality. However, other studies had similar issues, such as Almutairi et al. (*6*) who had 53% of participants who did not report their nationality. In our study, the perception of safety culture among those who did not report their nationality was very similar to the Omani nurses, which may be an indication that the majority of the unreported nurses were Omani. However, this could not be confirmed in our study. Another limitation, as is the case with other similar studies, was that the reasons for the variations between nationalities could not be explained by cross sectional studies. The greater opportunity for training and exposure might represent a potential explanation for the lower score among the non-Omani nurses with regard to stress recognition. However, further studies will be needed to examine the reasons for these variations.

Conclusion

The nationality of nurses has an influence on their perception of safety culture. Stress recognition is one safety domain that needs attention from various stakeholders, with special attention on the non-Omani nurses. Decision-makers, executive directors, and clinicians need to consider these differences in perception when designing any interventions to improve safety culture (e.g. training programme, awareness events and orientation plans). Future studies are needed to explain the reasons for the variation of perception between Omani and non-Omani staff with measures to ensure lower rates of missing data.

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Lien entre la nationalité des personnels infirmiers et la culture de sécurité dans les services de maternité d'Oman

Résumé

Contexte : Un lien a été établi entre la culture/le climat de sécurité des patients dans les services de maternité et de meilleurs résultats sur le plan de la sécurité. Les infirmiers(ères) jouent un rôle crucial dans la sécurité des patients et représentent la majorité du personnel des services de maternité. Dans de nombreux pays, les personnels infirmiers sont recrutés à l'étranger et apportent leurs propres perceptions de la culture de la sécurité des patients. Néanmoins, le lien entre les perceptions de la culture de la sécurité des patients et la nationalité des personnels infirmiers est mal connu. Comprendre ce lien aidera les parties prenantes à concevoir un programme pertinent pour améliorer la culture de sécurité des patients.

Objectifs : La présente étude visait à examiner le lien entre la nationalité des personnels infirmiers et leurs perceptions de la culture de la sécurité des patients dans les services de maternité des hôpitaux du ministère de la Santé à Oman.

Méthodes : En 2017, le « *Safety attitudes Questionnaire* » (SAQ) a été distribué à l'ensemble du personnel de dix services de maternité (892 questionnaires distribués, 735 questionnaires retournés).

Résultats : Près des trois quarts (74 %, 541/735) des questionnaires SAQ retournés ont été remplis par des infirmiers(ères), parmi lesquel(le)s 34 % n'étaient pas omanais(es), 21,8 % étaient omanais(es) et 44,7 % n'avaient pas indiqué leur nationalité (manquante). Globalement, le score de sécurité moyen pour les personnels infirmiers non omanais était beaucoup plus élevé que pour ceux qui étaient omanais : 3,9 (E.T. 1,3) contre 3,6 (E.T. 1,2) (p < 0,001). Le score de sécurité moyen concernant la reconnaissance du stress était beaucoup moins élevé pour les personnels infirmiers non omanais : 2,8 (E.T. 1,5) contre 3,2 (E.T. 1,3) (p < 0,001).

Conclusion : Les personnels infirmiers non omanais ont une perception plus positive de la culture de la sécurité des patients que les ceux qui sont de nationalité omanaise, excepté pour la reconnaissance du stress. Les décideurs, les directeurs et les cliniciens devraient prendre en compte ces différences pour concevoir des interventions visant à améliorer la culture de la sécurité des patients.

الارتباط بين جنسية طواقم التمريض وبين ثقافة السلامة في وحدات الأمومة في عُمان

وليد الندابي، محمد فيصل، محمد أمين محمد

الخلاصة

الخلفية: ارتبطت ثقافة/ بيئة سلامة المرضى في وحدات الأمومة دائما بتحقيق مخرجات أفضل فيما يتعلق بالسلامة. وتلعب طواقم التمريض دورا حاسما في تحقيق سلامة المرضى حيث تمثل غالبية الموظفين العاملين في وحدات الأمومة. وفي كثير من البُلدان، تُعيَّن طواقم التمريض من خارج البلاد، ويكون لديها تصوراتها الخاصة حول ثقافة سلامة المرضى. وبالرغم من ذلك، فليس ثمة الكثير من المعلومات حول العلاقة بين التصورات المتعلقة بثقافة سلامة المرضى وجنسية طواقم التمريض. وسوف يساعد فهم تلك العلاقة الأطراف المعنية على تصميم برنامج استجابة يهدف إلى تحسين ثقافة سلامة المرضى.

الأهداف: هدفت هذه الدراسة إلى استقصاء الارتباط بين جنسية طواقم التمريض وتصوراتهم بشأن ثقافة سلامة المرضى في وحدات الأمومة في المستشفيات التابعة لوزارة الصحة في عُمان.

طرق البحث: في عام 2017، وُزِّع "استبيان اتجاهات السلامة" على جميع العاملين (وُزِّع 892، وأُعيد 735) في 10 وحدات أمومة.

النتائج: استكملت طواقم التمريض ثلاثة أرباع (74%، 541 من 735) استبيانات اتجاهات السلامة التي أُعيدت بعد استكمالها، وكان من هؤلاء 34% غير عُمانيين، و21.8% عُمانيين، و44.7% لم يُبلغوا بجنسيتهم (معلومات ناقصة). وإجمالا، فقد كان متوسط درجة السلامة لدى طواقم التمريض غير العُمانية أعلى بكثير من طواقم التمريض العُمانية: 3.9 (انحراف معياري 1.3) في مقابل 3.6 (انحراف معياري 1.2) (p <0.001)، كما كان متوسط درجة السلامة بالنسبة للتعرف على التوتر أقل بكثير لطواقم التمريض العُمانية: 2.8 (انحراف معياري 1.5) في مقابل 3.2 (انحراف معياري 1.3) (p <0.001).

الاستنتاج: تحظى طواقم التمريض غير العُمانية بتصور أكثر إيجابية بشأن ثقافة سلامة المرضى من طواقم التمريض العُمانية، فيما عدا ما يتعلق بالتعرف على التوتر. ويتعين على صُناع القرار، والمديرين، والأطباء السريريين أخذ تلك الاختلافات في الحسبان عند تصميم التدخلات الرامية إلى تحسين ثقافة سلامة المرضى.

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Development of a medical error scale for nurses in Turkey

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Abstract

Background: Medical errors can have an adverse effect on patients, health care providers and health care organizations. Determining the likelihood of such errors is important to implement appropriate and effective solutions to minimize errors.

Aims: The aim of this study was to develop a valid and reliable scale to evaluate the likelihood of medical errors by Turkish nurses.

Methods: The draft scale (with 94 items) was developed based on primary references and the opinions of nursing experts. Content validity was assessed using 15 nursing experts. Construct validity of the scale was assessed with exploratory and confirmatory factor analyses using 298 nurses at a university hospital in Trabzon, Turkey. To assess test–retest reliability of the scale, another group of 50 nurses were included.

Results: The content validity index of the scale was 0.82, Cronbach alpha was 0.89, and item–total correlation values ranged from 0.31 to 0.54. Kaiser-Meyer-Olkin was 0.81, Bartlett test was 5909.75, $P < 0.0001$, and the anti-image correlations ranged between 0.63 and 0.90. In the four rotations done with varimax rotation, 42 items were excluded because their factor loadings were less than 0.45. The final scale had 43 items and six subscales: falls, blood and blood products transfusion, medication practices, care practices, communication, and other controlled practices. The six-subscale structure was confirmed by confirmatory factor analysis, and the fit between the scale and its subscales was good.

Conclusion: The scale is a valid and reliable tool to collect consistent data on medical errors in the patient-related practices of nurses.

Keywords: medical errors, nursing, patient safety, instrument validation, Turkey

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Introduction

One of the main responsibilities of nurses is to identify unexpected situations and adverse effects in patient care. They also play a key role in the early identification and prevention of risks and in the diagnosis and disclosure of errors in patient care *(1)*. However, it is reported that nurses also make medical errors because of the insufficient number of nurses in medical institutions and the resulting fatigue and burnout *(2–6)*, long working hours *(4)*, heavy workload and high number of night shifts a month *(2,5,6)*, ineffective communication between health care staff *(3,7,8)*, working with critically ill patients, substantial job stress, unfavourable working conditions, and shift work *(3,9,10)*. Nursing staff can also make medical errors because of a lack of knowledge or professional experience, carelessness or negligence *(11)*. Another study reported that reasons for medical errors included lack of training and communication, indifference to the job, lack of motivation and hectic working schedule *(12)*. The most common medical errors made by nurses are errors in medications, infections, falls, communication errors and use of incorrect or inappropriate materials (e.g non-sterile material) *(2,13)*.

Medical errors should be identified and reported as early as possible before they can cause serious harm to people. In addition, the causes should be identified, solutions offered and lessons learnt from such experiences *(14)*.

Valid and reliable measurement tools have been developed and used to help identify the areas in which nurses are more likely to make errors, and the precautions that should be taken to reduce the risk of these errors occurring. A review of the literature in Turkey indicated that several such tools already exist, one of which assesses malpractice in nursing *(2)*. Although the malpractice study discussed some aspects of medical errors, it neglected care practices, which is an important role of nurses. Another published scale in Turkey assesses the attitudes of nurses to medical errors *(15)* rather than the nursing practices that can lead to medical errors. In a study in the Islamic Republic of Iran, a data collection instrument was used to identify the types and causes of medical error, but the instrument had unsatisfactory validity tests *(16)*. Another survey developed in the United States of America examined the causes of medication errors *(17)*. In addition, national and adapted international scales about the patient safety have been developed in Turkey *(18,19)*.

In these scales, however, medical errors were discussed either as a single dimension or as a subscale of other dimensions.

The aim of our study was to develop a valid and reliable scale on medical errors in nursing, so that the areas in which errors are more likely to occur can be identified, precautions can be taken against the causes of these errors and the likelihood of these errors occurring can be minimized.

Methods

Population and sample

The population consisted of 560 nurses working at a university hospital in Trabzon, Turkey, from which a sample of 298 nurses was drawn to assess the construct validity of the scale through explanatory and confirmatory factor analysis. The sample included nurses who were not on leave at the time of the study and agreed to participate. In the factor analysis, a sample size of 300 is considered good *(20)* so our sample was very close to good. In addition, Cronbach alpha and item total correlations were tested. To assess test–retest reliability of the scale, a different sample of 50 nurses from the same university hospital were included. A minimum of 50 nurses is suggested for test–retest analysis *(21)*.

Instruments

The data were collected using an information form and a draft version of the Medical Errors Scale for Nurses. The form contained 13 questions on sociodemographic characteristics: age, marital status, educational status, position, years of working, and years of working at the hospital. The draft scale was developed by the researchers based on several primary references *(1–5,9–11,17,19)* and the opinions of experts in nursing, nursing management and nursing ethics about medical errors and patient safety.

The draft scale was developed in Turkish and initially consisted of 94 items; the components focused on nursing care practices, medication practices, blood and blood product transfusion, prevention of falls, infection control and communication. A five-point Likert scale was used to rate items as: always (5), often (4), sometimes (3), rarely (2) and never (1). Scores close to 5 on the scale indicated that the nurses were behaving in an appropriate manner with respect to medical errors, while the scores close to 1 indicated that the nurses might not be.

Data collection

Data on the validity and reliability of the draft scale were collected from 17 to 30 June, 2014. The test–retest data were collected from 15–31 July, 2014. The process of the scale development was in four stages: (i) face validity was assessed with 3 nurses; (ii) face and content validity were then evaluated with 15 specialist nurses; (iii) then construct validity was assessed with exploratory and confirmatory factor analyses with the 298 nurses; and (iv) test–retest reliability of the 43-item scale was assessed with a different group of 50 nurses working at the same university hospital. It was administered on two occasions with a two-week interval in between, and the nurses were asked to complete the scale using a pseudonym.

Data analysis

For analyses of the scale, the normality of the distribution was evaluated using Kolmogorov–Smirnov tests (one sample) which showed normal distribution.

The validity of the scale was evaluated by exploratory and confirmatory factor analyses. The exploratory factor analysis was performed with Kaiser–Meyer–Olkin and Bartlett tests, anti-image correlation, principal components analysis, and varimax rotation. Confirmatory factor analysis was tested with the chi-squared test, root mean square error of approximation, comparative fit index and incremental fit index. To evaluate the suitability and compliance of each item to the scale, *t*-tests and regression analyses were used.

The Cronbach alpha, item total correlations and test–retests were calculated to assess the reliability of the scale.

Ethical considerations

Written permission was obtained from the management of the university hospital on 25 July, 2013 to carry out the study with volunteer nurses whose informed consent had already been obtained. Ethical approval was granted by the Ethics Committee of the Medical Faculty of Karadeniz Technical University on 2 December, 2013.

Results

Sociodemographic characteristics of the nurses

Of the 298 nurses who volunteered, 65% were married, 89% had a clinical nursing position and 70.5% had a bachelor's degree in nursing. The mean age and standard deviation (SD) of the nurses was 32.11 (SD 7.6) years, with a mean of 10.24 (SD 7.2) years of work. The mean number of years working at the university hospital was 9.10 (SD 7.4) years.

Face validity and content validity

For face validity, the scale was given to three nurses, who were asked to assess the comprehensibility and length of the items. In addition, when the group of nursing experts evaluated content validity, face validity was also assessed – whether the items were expressed accurately and clearly. Nine items were revised to improve the comprehension.

Content validity was tested using Lawshe's technique *(22)*. The draft scale was given to 15 experts in nursing who were asked to rate each item as: essential, useful but not essential or not necessary. Based on their opinions, nine items with a content validity ratio less than 0.49 were excluded from the draft scale. This left a scale with 85 items with a mean content validity index of 0.82.

Construct validity

Construct validity was tested with exploratory factor analysis and confirmatory factor analysis. For exploratory factor analysis, principal components analysis and varimax rotation were used. The 85-item draft scale had a Kaiser–Meyer–Olkin value of 0.81. The Bartlett test gave a chi-squared value of 5909.75, $P < 0.0001$, and the anti-image correlation coefficients ranged between 0.63 and 0.90. Four rotations were performed with a rotated component matrix, and 42 items were excluded because their loadings were less than 0.45. The final version of the scale showed no overlap and contained 43 items in six subscales: factor 1 – falls (F1), factor 2 – blood and blood products transfusion (F2), factor 3 – medication practices (F3), factor 4 – care practices (F4), factor 5 – communication (F5), and factor 6 – other controlled practices (F6) (Table 1).

A scree plot graph also showed that the slope plateaued after the sixth point, supporting the finding that the scale consisted of six factors *(20)*. These factors accounted for 51.58% of the total variance (Table 1).

Confirmatory factor analysis was done to confirm the factor structure of the 43-item scale *(20,23)*. The resulting fit indexes were as follows: chi-squared = 2143.65, degrees of freedom = 2.52, root mean square error of approximation = 0.072, comparative fit index = 0.91, and incremental fit index = 0.90. In addition, the independent *t*-test was performed for the upper and lower 27% of the sample. The results of the *t*-test were as follows: $t = -24.703$ for the overall scale, $t = -17.887$ for F1, $t = -6.428$ for F2, $t = -6.829$ for F3, $t = -12.069$ for F4, $t = -8.246$ for F5, and $t = -11.582$ for F6, all with *P*-values < 0.0001.

Reliability analysis

The internal consistency of the draft scale was tested using Cronbach alpha, Spearman–Brown coefficient and Guttman coefficient. For the overall scale, the Cronbach alpha was 0.89, Spearman–Brown coefficient was 0.71 and the Guttman coefficient was 0.70. Item–total correlation values, which are used to test reliability, validity and internal consistency and also as an item analysis or item-discrimination analysis, ranged between 0.31 and 0.54 for all subscales ($P < 0.0001$). The test–retest correlation values for the overall scale were $r = 0.562$ and $P < 0.0001$, whereas $t = 0.197$ and $P = 0.845$, indicating that the scale does not change over time and is reliable.

Scoring of the scale

The final version of the scale consisted of 43 items in six subscales: 12 items in F1, six items in F2, six items in F3, eight items in F4, five items in F 5 and six items in F6 (Table 1). A score close to 215 (maximum score 43 × 5) indicated the nurse was disciplined or cautious about medical errors, whereas a score close to 43 (minimum score 43 × 1) indicated that he/she was not careful about medical errors or was at risk of making medical errors. Mean scores of the total scale and subscales were divided by the number of items to facilitate comparisons, which yielded a value between 1 and 5 for the overall scale and the subscales.

Discussion

The development of valid and reliable measurement tools in many areas is crucial to achieve consistent and accurate data. For this reason, we aimed to develop a valid and reliable instrument to evaluate the likelihood of medical errors by nurses or to determine whether nurses acted carefully to avoid medical errors in their patient-related practices.

The face validity and content validity of the scale were first studied. Face validity is the extent to which a scale appears to assess the notion being studied *(24)*. It also involves an analysis of the scale's legibility, comprehensibility of the terminology, and length of the statement *(23)*. We asked three nurses in our immediate circle to assess the comprehensibility and length of the items.

For the content validity of the scale, a group of experts was asked to assess both the content validity and face validity of the scale. As a result, nine items were excluded from the 94-item draft scale, and the 85-item scale had a content validity index of 0.82. This finding suggests an acceptable content validity, because a content validity index of 0.80 and higher is considered acceptable *(24)*.

The scale was also evaluated using exploratory and confirmatory factor analyses. The objective of factor

Table 1 Distribution of the items in the Medical Errors Scale for Nurses by mean values and factor loadings

Factor	Variance (%)	Items	Min.	Max.	Mean (SD)	Factor loadings
F1 – falls	11.71	49–51, 55, 59–66	2.17	5.0	4.40 (0.52)	0.67–0.51
F2 – blood and blood product transfusion	9.19	42–47	3.0	5.0	4.83 (0.35)	0.85–0.59
F3 – medication practices	8.66	21–26	2.33	5.0	4.79 (0.37)	0.80–0.60
F4 – care practices	8.46	1–5, 7, 11, 12	1.75	5.0	4.57 (0.44)	0.78–0.49
F5 – communication	6.87	76, 78–81	2.60	5.0	4.76 (0.40)	0.74–0.53
F6 – other controlled practices	6.67	15–17, 29, 30, 39	1.67	5.0	4.62 (0.28)	0.79–0.47
Total	51.58		2.99	5.0	4.49 (2.83)	0.85–0.47

SD: standard deviation.

analysis is to determine the dimensions that account for specific constructs *(25)*. A prerequisite for factor analysis is a certain amount of correlation between the variables *(26)*. The Bartlett test is used to determine whether variables are sufficiently related to each other. If the *P*-value of this test is less than the level of significance ($P < 0.05$), the correlation between the variables is sufficient for factor analysis *(26)*. The factor analysis of the 85-item scale showed that the Kaiser–Meyer–Olkin value, a measure used to determine whether the overall group of questions was adequate for factor analysis, was above the acceptable limit, and Bartlett test was highly significant. A Kaiser–Meyer–Olkin value higher than 0.50 suggests that factor analysis of the data can be done *(23,25,27)*. On the other hand, anti-image correlation is a coefficient that tests whether each item/question is suitable for factor analysis, and this coefficient should not be less than 0.50. If the value of any of the items is less than 0.50, it should be removed *(23,26,27)*. The anti-image correlation coefficient of the draft scale was more than 0.62. These results indicated that factor analysis could be done. In the varimax rotations, 42 items were excluded from the scale because their factor loadings were too low (less than 0.45). Ideally, factor loadings should be between 0.45 and 0.50 or higher *(25)*.

Thus the final version of the scale consisted of 43 items in six subscales: falls, blood and blood product transfusions, medication practices, care practices, communication and other controlled practices. The six-factor structure was confirmed by the explained variance and by the fact that the scree plot line plateaued after the sixth point *(20)* – the six subscales accounted for more than 0.50 of the total variance, which was acceptable in practice *(27)*.

The exploratory factor analysis was followed by confirmatory factor analysis to confirm the constructs that emerged. Confirmatory factor analysis tests whether a previously defined or restricted construct can be confirmed as a model or not *(20)*. Alternatively, it tests the accuracy of a correlation that was previously determined by the researcher *(27)*. All items with significant *t*-test values were confirmed by the confirmatory factor analysis to be significant. The fit indices were used to test the validity of the model. One of the most common ways to assess fitness is the chi-squared goodness-of-fit *(20)*. Our scale had a fit index of 2.5, suggesting that the items fit the subscales well. In studies with large samples, a chi-squared index less than 3 represents an excellent fit *(20)*. The root mean square error of approximation of the path scheme was 0.72, suggesting that the scale had a good fit. A root mean square error of approximation less than 0.5 represents excellent fit, whereas one less than 0.8 indicates good fit *(20,26)*. The comparative fit index and incremental fit index are two other fit indices. They are known to produce very reliable and impartial predictions when the assumption of a normal distribution is not violated. A comparative fit index and incremental fit index more than 0.95 indicates excellent fit, and one more than 0.90 represents a good or acceptable fit *(28)*. In this study, the comparative fit index (0.91) and incremental fit index (0.90) suggest good or acceptable fit. All the observed variables in the model indicating the factor structure of the scale and the coefficients of the correlations between the factors were sufficient. Given the fit indices calculated with the confirmatory factor analyses, the construct of the scale was consistent with the data.

The factor analyses were followed by internal consistency and item-discrimination analyses. The difference in the mean scores between the upper and lower 27% of the sample showed that the items had significant discriminating power and could appropriately distinguish between the upper and lower groups. In other words, the items were highly valid, could appropriately distinguish between nurses' erroneous medical practices, and measured the same behaviour.

The next step was to measure the internal consistency of the 43-item scale to test its validity and determine its homogeneity. Using a single measurement instrument in one session, internal consistency analyses attempt to determine whether items can consistently measure a certain construct *(23)*. In the present study, the Cronbach alpha, Spearman–Brown coefficient, and Guttman coefficient were all 0.70 or higher for the overall scale. The higher these values, the more consistent the items are and the better they can measure the same property *(23)*. An internal consistency coefficient of 0.70 and higher is considered sufficient for the reliability of the test scores *(23,25)*.

Item–total correlation refers to the correlation between the score of an individual item and the overall score of the test *(23)*. In this study, the item–total correlation coefficients of the 43-item scale were more than 0.31. Certain limit values are accepted to represent standards for interpreting item–total correlation analysis. It is reported that items should have an item–total correlation coefficient of 0.30 and higher, as these items can discriminate well between individual items *(23)*. As the coefficients were high in this study, the items belonged to the same construct and the overall scale was reliable.

According to the results of the *t*-test, which determines whether a property measured by a test changes over time and how consistently the test measures a construct or how similar the answers it obtains are independent of time *(21)*, the scale gave consistent and reliable results when administered at different times. It was therefore reliable in terms of the coefficient of continuity.

Conclusion

The results of the reliability and validity analyses suggest that the scale is valid and reliable. This scale can thus accurately and consistently measure whether nurses are careful to avoid medical errors, which areas they are more likely to have problems in, and which areas they need to make improvements in. This study can also be used as a guide or reference for future studies on scale development. Our scale is intended for use with nurses

on an individual level and enables the detection of wider and multidimensional medical errors and error areas in nursing than previously developed scales. Our scale was developed based on the opinions of nurses working in a university hospital. For this reason, it would be useful to evaluate the scale with samples of nurses working in private and public hospitals.

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Mise au point d'une échelle d'erreur médicale pour le personnel infirmier en Turquie

Résumé

Contexte : Les erreurs médicales peuvent avoir un impact indésirable sur les patients, les prestataires de soins de santé et les organisations oeuvrant dans ce domaine. Il est important de déterminer la probabilité de ce type d'erreur afin de fournir des solutions appropriées et efficaces pour limiter les erreurs.

Objectifs : La présente étude avait pour objectif de mettre au point une échelle valide et fiable pour évaluer la probabilité d'erreurs médicales commises par le personnel infirmier en Turquie.

Méthodes : Un projet d'échelle (comptant 94 items) a été mis au point à partir des références primaires et de l'opinion d'experts en soins infirmiers. La validité du contenu a été évaluée par 15 experts en soins infirmiers. La validité du construit de l'échelle a été évaluée à l'aide d'analyses factorielles exploratoires et confirmatoires, menées auprès de 298 membres du personnel infirmier d'un hôpital universitaire de Trabzon (Turquie). Pour évaluer la fiabilité de test-retest de l'échelle, un autre groupe de 50 infirmiers a été inclus.

Résultats : L'indice de validité du contenu de l'échelle était de 0,82, l'alpha de Cronbach était de 0,89 et les valeurs de corrélation item-total variaient entre 0,31 et 0,54. La mesure Kaiser-Meyer-Olkin était de 0,81, le test de Bartlett donnait une valeur de 5 909,75, $p < 0,0001$, et les corrélations anti-image se situaient entre 0,63 et 0,90. Dans les quatre rotations effectuées selon la méthode varimax, 42 items ont été exclus, car leur saturation factorielle était inférieure à 0,45. L'échelle finale comptait 43 items et six sous-échelles : chutes, transfusion de sang et de produits sanguins, pratiques médicamenteuses, pratiques de soins, communication et autres pratiques contrôlées. La structure à six sous-échelles a été confirmée par l'analyse factorielle confirmatoire, et l'adéquation entre l'échelle et ses sous-échelles était satisfaisante.

Conclusion : L'échelle est un outil valide et fiable permettant de collecter des données cohérentes sur les erreurs médicales en matière de pratiques des personnels infirmiers auprès des patients.

وضع مقياس للخطأ الطبي لطواقم التمريض في تركيا

حوى أوزترك، ايلك نور قهرمان

الخلاصة

الخلفية: قد يترتب على الأخطاء الطبية أثر ضار بالمرضى، ومقدمي الرعاية الصحية، وبالمنظمات العاملة في مجال الرعاية الصحية. ومن المهم تحديد إمكانية حدوث تلك الأخطاء حتى يتسنى تنفيذ الحلول الملائمة والفعالة من أجل الحد من تلك الأخطاء.

الأهداف: هدفت هذه الدراسة إلى إعداد مقياس فعّال وموثوق لتقييم احتمالية حدوث الأخطاء الطبية من جانب طواقم التمريض في تركيا.

طرق البحث: أُعدَّ مشروع المقياس (الذي تضمن 94 بندا) استنادا إلى المرجعيات والآراء الأولية الصادرة عن خبراء التمريض. وجرى تقييم صلاحية المضمون من خلال الاستعانة بخمسة عشر خبيرا في مجال التمريض. كما تم تقييم صلاحية تركيب المقياس باستخدام تحليلات العوامل الاستطلاعية والتوكيدية وتطبيقها على 298 ممرضا وممرضة في إحدى المستشفيات الجامعية في ترابزون، بتركيا. ومن أجل تقييم موثوقية الاختبار وإعادة الاختبار، أُضيفت مجموعة أخرى قوامها 50 ممرضا وممرضة.

النتائج: حقق مؤشر صلاحية مضمون المقياس 0.82، بينما كانت قيمة ألفا كرونباخ 0.89، وتراوحت قيم الارتباط الكامل بين البنود بين 0.31 و 0.54. وحقق اختبار قيصر–ميير–أولكين 0.81، بينما حقق اختبار بارتليت 5909.75، (p <0.0001)، وتراوحت قيم ارتباط الصورة العكسية بين 0.63 و 0.90. وفي التدويرات الأربعة التي تمت باستخدام تدوير فاريماكس، تم استثناء 42 بندا لأنها أظهرت قيمة لتحميل العوامل أقل من 0.45. تضمن المقياس النهائي 43 بندا وستة مقاييس فرعية: مرات السقوط، نقل الدم ومنتجات الدم، ممارسات الأدوية، ممارسات الرعاية، التواصل، وغير ذلك من ممارسات مضبوطة. وتم توكيد تركيب المقاييس الستة الفرعية باستخدام التحليل العاملي التوكيدي، وكان التوافق بين المقياس ومقاييسه الفرعية جيدا.

الاستنتاج: يعدُّ المقياس أداة صالحة وموثوقة لجمع البيانات المتسقة حول الأخطاء الطبية التي تحدث في ممارسات طواقم التمريض.

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Priority setting for research in the field of medical ethics in the Islamic Republic of Iran: a Delphi study

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Abstract

Background: Priority-setting is one way to develop research in a particular field.

Aims: We aimed to identify and prioritize the most important medical ethics issues for research in the Islamic Republic of Iran.

Methods: A 3-round Delphi survey was conducted using a questionnaire covering 77 medical ethics topics in 10 categories and subcategories (extracted from literature review); this was emailed to 40 experts in medical ethics. The participants rated categories and subcategories for importance on a 5-point Likert scale and ranked the topics based on their research priorities. The highest Likert score showed the most important issue and the lowest priority score indicated the first priority.

Results: After consensus, the panel identified 6 categories as the highest priority and most important areas: professionalism [priority score = 2.66, standard deviation (SD) 2.63, importance score = 4.45, SD 0.72], education (priority score= 3.12, SD 1.89, importance score = 4.25, SD 0.84), end of life (priority score = 3.79, SD 1.91, importance score = 4.47, SD 0.66), beginning of life (priority = 4.62, SD 1.68, importance score= 4.26, SD 0.61), public health (priority score = 5.20, SD 2.39, importance score = 4.29, SD 0.75), and ethics in research (priority score = 5.33, SD 1.97, importance score = 4.34, SD 0.64).

Conclusion: The rankings for priority and importance was not the same. Our results highlight a lack of applicable knowledge in the areas of professionalism and end of life. This study could be used as a foundation for developing further investigations by ensuring the most appropriate use of limited resources.

Keywords: priority setting, research, medical ethics, Islamic Republic of Iran

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Introduction

Modern health care systems are confronting new ethical challenges along with global medical developments, which highlights the need for more investigations.

Apart from universal moral standards, any society's culture, religion and behaviour patterns have major impacts on ethical norms (*1*) and bring different necessities. Medical ethics has a long history in the Islamic Republic of Iran, going back to the Zoroastrianism era, in association with the worthy influences of the Muslim scientists (*2,3*). However, modern developments in medical ethics started in 2002 via the medical ethics strategic plan of the Academy of Medical Sciences (*4,5*): insisting on high quality research, 2 of the 6 strategies for research development in medical ethics are "foundation of needs assessment studies and prioritizing research in medical ethics" and "supporting high-priority research projects" (*6*). Those goals reflect the importance of research in medical ethics; limited resources mean that prioritizing research activities is extremely important.

After operationalizing the strategic plan in 2002, scientific production increased as exemplified by the number of articles published during 1990–2014 by Tehran University of Medical Sciences (315), Shahid Beheshti University of Medical Sciences (126) and Shiraz University of Medical Sciences (58) (*7*).

From another standpoint, in order to support professional development and the advancement of research, designing a research road map for medical ethics activities is required. Road mapping is a consensual process which identifies the best way to proceed (*8*). It provides step-by-step direction to achieve the specific research objectives, explaining the ideal situation, and helping medical ethicists to identify the gap between recent developments and requirements (*9,10*). Prioritizing research areas is the primary step for road mapping (*10*); it identifies a clear strategy for future investigations by addressing specific research questions and changing priorities (*11*).

Moreover, the limited financial and human resources are more pressing in developing countries and have major impact in research planning (*11*). Thus, interventions should arise from valid prioritization of problem.

In the Islamic Republic of Iran, limited studies have been conducted to identify the most important and prioritized medical ethics topics (*12*); none were

conclusive. Further, those studies did not concentrate on the views of ethicists on ethical issues in a particular heath care context did they seek the opinion of clinical bioethicists. In order to determine the research road map, we aimed at identifying the most prioritized and important issues in medical ethics to be further investigated.

Methods

Study design

A 3-round Delphi study was conducted to identify and prioritize the most important medical ethics issues for research. The study was performed in the Medical Ethics and History of Medicine Research Center of Tehran University of Medical Sciences from October 2015 until April 2016. We used the Delphi method to achieve experts' consensus on specific issues and make the prioritization process possible (*13*), to increase forecast accuracy and to achieve accurate estimation by experts' opinions in a particular field (*14*). Experts having sufficient clinical and ethical expertise were selected from various parts of the health system as a nominal group who consented verbally and communicated via email. To maximize reliability, the same participants were chosen for all 3 rounds. Two of the authors working independently checked the responses and clarified the themes. Credibility was assured by providing explicit descriptions of the issues and the decision-making process.

Round 1: Identifying medical ethics research topics

In the first round, we reviewed the most relevant literature and resources, including books, encyclopaedias and articles; then the most relevant research topics were extracted. The Delphi questionnaire was designed by 2 of the authors; it consisted of 77 topics divided into 10 categories and subcategories.

The questionnaire, along with a letter explaining the aim of the study, was emailed to 40 experts in medical ethics. The experts were asked to give their opinion about our categorization and add other topics if they thought we had missed any. Email reminders were sent to non-responders after 4 weeks.

Then, the categories were revised based on the received feedback. They were collated through a process of discussion to achieve agreement by 2 researchers.

Round 2: Determination of priority and importance

The data obtained from the first round were incorporated into a new questionnaire to determine the importance and priority of the 10 categories and the subcategories. The participants were asked to rate categories and subcategories on a 5-point Likert scale (1 = least important; 5 = most important) according to their perceptions of the level of importance. They were also asked to identify the research priority of the topics (1 = highest priority and 5 = lowest priority).

Round 3: Reaching consensus

In the third round, the questionnaire was emailed to participants who responded to the first 2 rounds. The participants received the descriptive statistics (means) for categories and subcategories. To reach consensus, the participants were allowed to reflect on the scores and to rate the importance and priority of each category and subcategory again.

Data were analysed using *SPSS*, version 23. Descriptive statistics [mean and standard deviation (SD)] were used to evaluate consensus agreement for level of importance and priority. To ensure external validity, a minimum response rate of 50% was considered.

Ethical considerations:

This study was part of a PhD dissertation in medical ethics. The research ethics committee of Tehran University of Medical Sciences approved the project. Participation was voluntary. The participants' identity remained anonymous to other members. Informed consent was assumed by the return of the questionnaire.

Results

Round 1

Demographic characteristics of the panel members are presented in Table 1. Thirty four participants of the 40 who were originally selected (85% response rate) returned the questionnaire; the number of relevant research topics was raised to 95. Any duplication was eliminated and the questionnaire was finalized. All 10 categories and their subcategories are itemized in Figure 1.

Table 1 Demographic characteristics of the panel members

Variable	Round 1	Round 2	Round 3
No. (%) participants	34 (85.0)	31 (77.5)	25 (62.5)
Sex (No. female/male)	17/17	15/16	13/12
Level of higher education (No.)			
Doctoral degree	26	25	21
Master's degree	1	1	–
Specialty degree	5	4	3
Doctoral & specialty degree	2	1	1

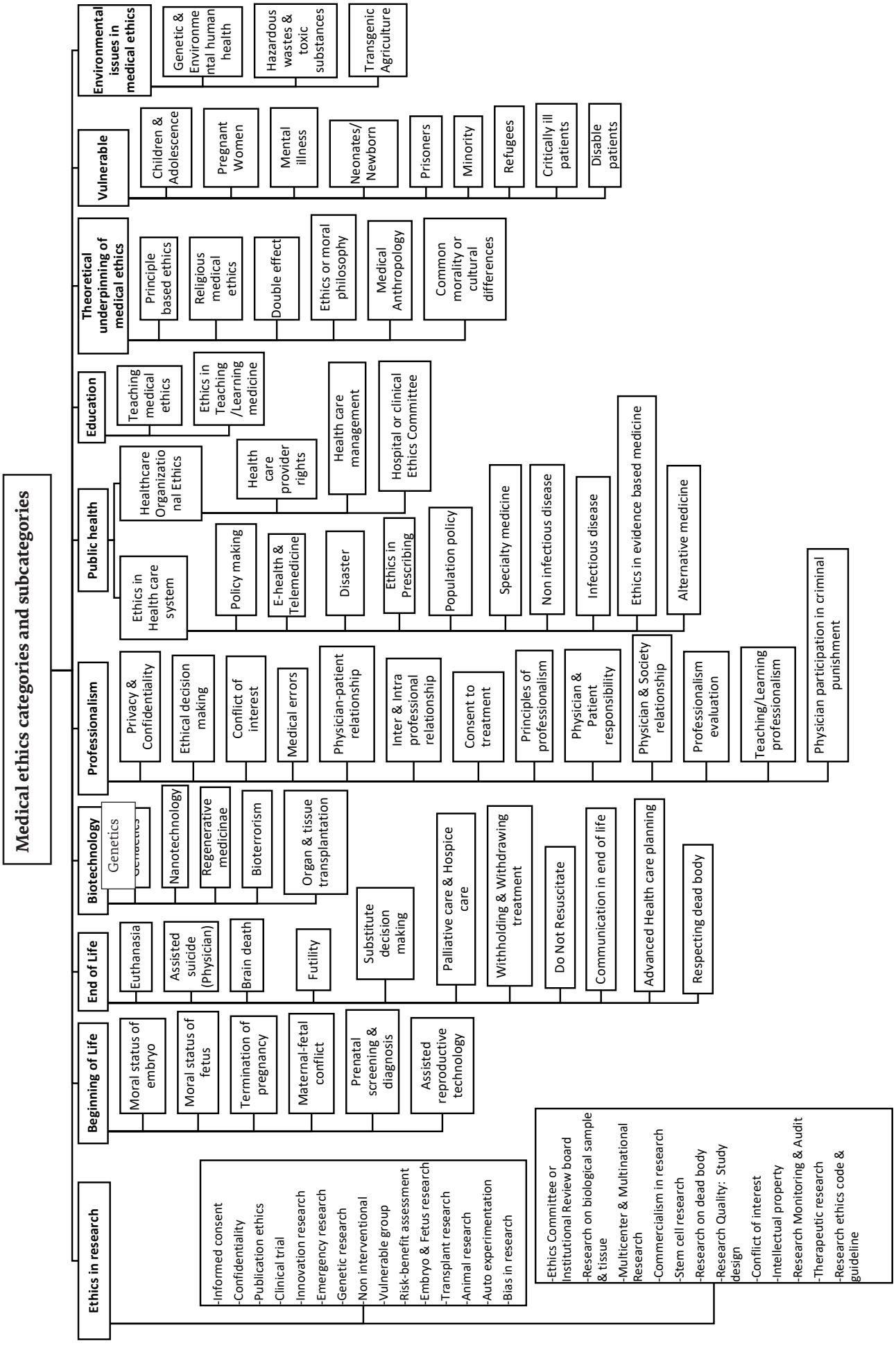

Figure 1 Categories and subcategories of medical ethics research topics

Round 2

Thirty-one (77.5%) panel members returned the questionnaire.

In this round, professionalism (mean priority score = 3.75, SD 2.60, mean importance score ± = 4.63, SD 0.61), education (mean priority score = 3.93, SD 2.49, mean importance score = 4.53, SD 0.63), end of life (mean priority score = 4.27, SD 2.08, mean importance score = 4.55, SD 0.57), the beginning of life (mean priority score = 4.37, SD.36, mean importance score = 4.44, SD 0.63), ethics in research (mean priority score = 4.68, SD 2.23, mean importance score = 4.33, SD 0.60), theoretical underpinning of medical ethics (mean priority score = 5.20, SD 3.10, mean importance score = 4.14, SD 0.70), and public health (mean priority score = 5.51, SD 2.51, mean importance score = 4.44, SD 0.63) gained the highest priority scores.

The categories ranked as the least priority included vulnerable groups, biotechnology, and environmental issues in medical ethics.

The top 10 priority subcategories in all groups were physician–patient relationship, ethics in teaching/learning medicine, withholding/withdrawing treatment, termination of pregnancy, informed consent in research, religious medical ethics, and policy-making.

Round 3

Twenty-five (62.5%) panel members completed the third round. The panel identified 6 categories as the highest priority areas: professionalism, education, end of life, beginning of life, public health, and ethics in research (Table 2).

Informed consent in research (mean importance score = 4.80, SD 0.40), policy-making (mean importance score = 4.69, SD 0.47), and the physician–patient relationship (mean importance score = 4.68, SD 0.55) were the most important subcategories (Table 2).

Discussion

In this Delphi study consensus opinion ranked professionalism as the highest priority. Although research priorities indicate genuine ethical concerns, there are a few surprises in our findings. The 6 topics ranked as highest priority also gained the highest importance scores, however their order was not the same. This Delphi consensus rated the most important category as end of life. It is interesting that the panel experts prioritized the topics by considering the importance of this issue. For instance, the end of life issue was the most important one in medical ethics while panel experts preferred more research on professionalism, and so on.

Bagheri surveyed Iranian medical ethics priorities in 2011 and reported patient rights, the physician–patient relationship, informed consent and the financial relationship between physician and patient among the top 10 priorities (*12*). Since these topics are categorized under the theme of professionalism, it seems that our study is in line with the Bagheri study, although the methods used were different.

In another study, Bagheri introduced the top 10 bioethical challenges in Islamic countries in which Muslim bioethicists ranked "the relationship between law, ethics, and fatwa", "human rights" and "Islamic principles of bioethics" as 1st, 2nd and 8th respectively (*15*), whereas we considered these topics as subcategories of "theoretical underpinning of medical ethics", which was rated as the 7th priority in our study. This difference in ranking shows that Iranian ethicists are emphasizing more on practical issues than theoretical ones.

The priorities and importance identified by panel members will affect patients in different ways and to varying degrees because identifying and resolving ethical problems can improve the quality of health care delivery (*16*). The effect size of each issue on the intended field is also important in priority setting. Professionalism and its most important subcategory, the physician–

Table 2 Importance and priority of ethical issues (Round 3) and high priority subgroups

Issue	Round 3 score[a]				High priority subgroup
	Priority		Importance		
	Mean	SD	Mean	SD	
Professionalism	2.66	2.63	4.45	0.72	Physician–patient relationship
Education	3.12	1.89	4.25	0.84	Ethics in teaching/learning medicine
End of life	3.79	1.91	4.47	0.66	Withholding & withdrawing treatment
Beginning of life	4.62	1.68	4.26	0.61	Termination of pregnancy
Public health	5.20	2.39	4.29	0.75	Policy-making
Ethics in research	5.33	1.97	4.34	0.64	Informed consent
Vulnerable	6.25	2.30	4.04	0.69	Children & adolescence
Theoretical underpinning of medical ethics	6.50	3.02	4.04	0.70	Religious medical ethics
Biotechnology	8.66	0.96	3.41	0.92	Genetics
Environmental issues in medical ethics	9.29	0.99	3.27	0.98	Genetics & environmental human health

SD = standard deviation.

[a]*For priority, the lower the score, the greater the priority; for importance, the higher the score, the greater the importance.*

patient relationship, have a major impact on patient care. The most interesting result of this study is ranking professionalism and the physician–patient relationship as the highest priority: this also receives much attention in the media and at the level of government. For instance the "Professionalism enhancement package" for making evolution in education of medical sciences, establishment of "Professionalism offices" in medical universities, inclusion of professionalism in the medical ethics course for undergraduates, and holding seminars and congresses on professionalism (all of which necessitates research and education through the issue) demonstrate the great emphasis on professionalism. Furthermore, to solve the challenges of professionalism, we should approach these via the physician–patient relationship as the main problem and the most prevalent reason for medical complaints in our country (*17*). Today, professionalism has a central role in patient care, is considered as a competency and has shifted from a conceptual domain to one of the 6 main medical education competencies (*18*,*19*). Ziring et al. advocate long-term studies for the identification and remediation of professionalism in medical students (*20*).

Our approach to medical education as the 2nd priority has 2 dimensions: ethics in medical education and teaching medical ethics. Amini et al. highlighted professionalism and ethics as the 4th research priority in medical education in the Eastern Mediterranean Region (*21*). Rhodes and Cohen believe that both concepts of medical ethics should be considered in designing medical education (*22*). Nabeiei et al. reported medical ethics and professionalism as the first priority in medical education in the Iranian context, and for professors' education, medical ethics was the highest priority subcategory (*23*).

Students first encounter medical ethics concepts when confronting role models' (medical teacher) behaviour (informal education) and its role in medical education is undeniable. Ethics education enables both medical students and professionals to understand ethical principles and to recognize ethical considerations in practice. Therefore, we should empower medical education, specifically professionalism and ethics education, in parallel with other needs of medical students at different levels. Madani et al. recommended virtue-centred education and education on controlling moral emotions to facilitate ethical internalization and teaching ethical practices (*24*). It is of note that current medical students will have a significant role in training the next generation of physicians, thus teaching ethical principles to medical students and considering ethical observations in teaching has long-term benefits in health care delivery systems and public health.

The 3rd priority was end of life, although the Islamic bioethicists did not give priority to end of life (*15*). Accordingly, death indicators and length of time that efforts should be continued to sustain life should be defined (*25*). Religious beliefs, social situation, cultural considerations and professional attitudes impact on medical practice and professionals' ethical sensitivity (*26*,*27*), especially since Iranian Islamic law has a pivotal role on end of life decision-making and its ethical considerations.

As specified in Islamic teachings, human life does not belong to the person and should be preserved as much as possible. Mobasher et al. showed that in Islamic society (in the Shiite perspective), decision-making for the end of life is an important issue, and patient autonomy cannot be considered as the basis for it (*25*).

The category "beginning of life" was rated as the 4th priority. For ethical decision-making at the beginning of life and termination of pregnancy, the definition of human life and the time when human life begins should be determined to define the moral status of the human embryo and its rights as a human being (*28*). In the Islamic view, ensoulment as a religious concept shapes our moral judgment about beginning of life issues. Although termination of pregnancy is forbidden after ensoulment in all schools of Islamic jurisprudence, it is allowed before ensoulment under certain circumstances (*28*). Based on the views of the Shiite authorities (fatwas), the Therapeutic Abortion Act was approved in May 2005 by the Iranian parliament. It seems that we will require ethical studies focusing on all aspects of this issue and on identifying the indications for termination.

Contrasting with our study, assisted reproductive technology (ART) did not get priority in the Bagheri study (*15*). Further, ART, especially third party reproduction techniques, raises several ethical considerations (*29*) that need to be answered. The concept of kinship is different in different religious and cultural contexts, and its definition has legal, ethical and religious consequences which affects motherhood, marriage and inheritance for couples who use ART (*29*). Among the Muslim Middle Eastern countries, only in the Islamic Republic of Iran and Lebanon is the use of third party assisted reproductive techniques permitted (*30*).

Earlier, the primary focus of medical ethics was on patients' rights and the physician–patient relationship; currently the international policies give more emphasis to public health (*31*), and the emergence of new ethical challenges makes this area more attractive and more prominent (*32*). In public health, the whole community is regarded as a patient, and health care services should be provided based on public interest (*33*). Equity in access to resources was ranked as the 2nd highest ethical challenge of the public health care system in a study from Saudi Arabia (*34*). This point may explain why our participants rated public health as the 5th highest priority for more studies.

Medicine requires scientific investigation for the development of knowledge and technologies. After the events of World War II and the Nazi experiments, the world was sensitive to ethics in biomedical research: efforts were made to comply with and implement codes of research ethics, and to obligate researchers to respect the codes.

In the late 1990s, the number of biomedical research studies increased in the Islamic Republic of Iran; this growth raised ethical concerns in the field of research. Therefore, the national codes of research ethics were compiled and national and organizational research ethics committees established (35). The paternalism paradigm shifted after the establishment of the regulatory system (35); new issues were raised necessitating more investigations.

Theoretically, the basic principles of bioethics have been discussed for years by Iranian scholars and still there is open debate. Although biotechnological development and environmental issues are extremely important and the related challenges are rapidly changing, we need to focus more on basic practical issues. Additionally, the results of any such study may change dramatically within a few years.

The main limitation of our study is its (non) generalizability outside the country because our participants were probably influenced by the dominant atmosphere of the health system. However we predict that professionalism will be ranked as one of the most prioritized issues.

In addition, as our participants were clinical and ethical experts, the results may not be representative of the health system as a whole. One of the strengths of our study was the lack of face to face encounters and interrelationships during consensus. So there is the hope that we reached genuine consensus.

Focusing on the top priorities helps us to highlight the research road map of medical ethics in showing new directions to knowledge and refocusing new investigations.

Conclusion

Emphasizing the priorities for further investigations in medical ethics highlights the lack of proper knowledge in those areas. The results of this study may indicate poor dissemination of information due to improper publication of studies, lack of attentiveness to research information, poor methodology, and lack of proper perception of the published information because of aberrant interpretation of research data. Although we do not claim the resulting list of research priorities to be perfect, it is assumed that it could provide useful information for initiating more investigations. In order to make this study more meaningful and applicable, we have to use this study as a basis for identifying an action plan and designing a road map for future research; doing this will create a foundation for developing more investigations by ensuring the most appropriate use of limited resources. This will persuade the profession to construct research collaborations in priority domains.

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Competing interests: None declared.

Détermination des priorités pour la recherche dans le domaine de l'éthique médicale en République islamique d'Iran : étude selon la méthode de Delphes

Résumé

Contexte : La détermination des priorités constitue l'une des façons pour développer la recherche dans un domaine particulier.

Objectifs : La présente étude visait à identifier et à hiérarchiser les questions d'éthique médicale les plus importantes pour la recherche en République islamique d'Iran.

Méthodes : Une étude à trois séries d'interrogations selon la méthode de Delphes a été menée en utilisant un questionnaire couvrant 77 thèmes liés à l'éthique médicale dans dix catégories et sous-catégories (extraites d'une revue de la littérature). Ce questionnaire a ensuite été envoyé par courrier électronique à 40 experts de l'éthique médicale. Les participants ont évalué l'importance des catégories et sous-catégories selon une échelle de Likert à cinq points et ont classé les thèmes en fonction de leurs priorités de recherche. Le score le plus élevé sur l'échelle de Likert indiquait la question la plus importante, et le score de priorité le moins élevé indiquait la première priorité.

Résultats : Après consensus, le panel a identifié six catégories comme prioritaires et les domaines les plus importants : le professionnalisme [score de priorité = 2,66, écart type (E.T.) 2,63, score d'importance = 4,45, E.T. 0,72], l'éducation (score de priorité = 3,12, E.T. 1,89, score d'importance = 4,25, E.T. 0,84), la fin de vie (score de priorité = 3,79, E.T. 1,91, score d'importance = 4,47, E.T. 0,66), le début de vie (score de priorité = 4,62, E.T. 1,68, score d'importance = 4,26, E.T 0,61), la santé publique (score de priorité = 5,20, E.T. 2,39, score d'importance = 4,29, E.T. 0,75) et l'éthique de la recherche (score de priorité = 5,33, E.T. 1,97, score d'importance = 4,34, E.T. 0,64).

Conclusion : Les classements par ordre de priorité et d'importance étaient différents. Nos résultats mettent en lumière un manque de connaissances applicables dans les domaines du professionnalisme et de la fin de vie. Cette étude pourrait servir de base pour mettre au point des recherches plus poussées en garantissant l'utilisation la plus appropriée de ressources limitées.

ترتيب أولويات البحوث في مجال الأخلاقيات الطبية في جمهورية إيران الإسلامية: دراسة باستخدام أسلوب دلفي

مهشاد نوروزي، باقر لاريجاني، سحرناز نجات، كيارش آرامش، بونه سالاري

الخلاصة

الخلفية: يعد ترتيب الأولويات أحد أساليب تطوير البحوث في مجال ما.

الأهداف: هدفت الدراسة إلى تحديد أهم المسائل المتعلقة بالأخلاقيات الطبية وترتيب أولوياتها لأغراض بحثية في جمهورية إيران الإسلامية.

طرق البحث: أُجري مسح باتباع أسلوب دلفي على ثلاث مراحل باستخدم استبيان شمل 77 موضوعا تتصل بالأخلاقيات الطبية ضمن 10 فئات وفئات فرعية (اسْتُمدَّت من استعراض الأدبيات في هذا الموضوع)؛ وأُرسل المسح إلى 40 خبيرا من خبراء الأخلاقيات الطبية. ورتب المشاركون الفئات والفئات الفرعية من حيث الأهمية باستخدام مقياس ليكرت ذي الخمس نقاط وصنفوا الموضوعات استنادا إلى الأولويات البحثية. وأظهرت الدرجة الأعلى على مقياس ليكرت الموضوع الأكثر أهمية، بينما أظهرت درجة الأولوية الأدنى الأولوية الأولى.

النتائج: بعد التوصل إلى توافق في الآراء، حدد فريق الخبراء 6 فئات تمثل الأولوية الأولى والموضوعات الأكثر أهمية، وهي: الاحتراف المهني [درجة الأولوية = 2.66، بانحراف معياري 2.63، درجة الأهمية = 4.45، بانحراف معياري 0.72]، والتعليم (درجة الأولوية = 3.12، بانحراف معياري 1.89، درجة الأهمية = 4.25، بانحراف معياري 0.84)، ونهاية الحياة (درجة الأولوية = 3.79، بانحراف معياري 1.91، درجة الأهمية = 4.47، بانحراف معياري 0.66)، وبداية الحياة (درجة الأولوية = 4.62، بانحراف معياري 1.68، درجة الأهمية = 4.26، بانحراف معياري 0.61)، والصحة العامة (درجة الأولوية = 5.20، بانحراف معياري 2.39، درجة الأهمية = 4.29، بانحراف معياري 0.75)، وأخلاقيات البحوث (درجة الأولوية = 5.33، بانحراف معياري 1.97، درجة الأهمية = 4.34، بانحراف معياري 0.64).

الاستنتاج: لم يكن هناك تطابق في تصنيفات الأولوية والأهمية. وتبرز النتائج التي توصل لها الباحثون غياب المعرفة التطبيقية في مجالات الاحتراف المهني ونهاية العمر. ويمكن الاستفادة من هذه الدراسة كأساس يمكن البناء عليه لإجراء مزيد من الاستقصاءات عبر ضمان الاستخدام الأكثر ملاءمة للموارد المحدودة.

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Knowledge of, attitudes to and participation in clinical trials in Jordan: a population-based survey

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Abstract

Background: Clinical trials are important to improve public health care. However, recruiting participants for trials can be difficult.

Aims: This study assessed public knowledge of and willingness to participate in clinical trials in Jordan and examine the sociodemographic characteristics associated with knowledge and willingness and the reasons behind unwillingness to participate.

Methods: The questions were part of a representative, population-based survey in 2011 that included 3196 Jordanian individuals. In a home-based interview, participants were asked about: sociodemographic characteristics, and knowledge of and participation in clinical trials

Results: Only 21.8% of respondents knew what a clinical trial was and (1.2%) had participated in a trial. About 25% of respondents indicated their willingness to enrol in a trial. Significantly more men (24.1%) than women (19.3%) knew what clinical trials were ($P < 0.001$), whereas more women (4.3%) than men (2.9%) said they would be very likely to agree to participate in trials. People aged 40–49 years had better knowledge of and greater willingness to participate in trials than other age groups. Income was positively associated with knowledge of trials but negatively associated with willingness to participate. Higher education was positively correlated with knowledge of and willingness to take part in trials. The main reasons for not participating in trials were concern about the risk to own health (61.1%) and not being convinced about the outcome and benefits of clinical trials (29.7%).

Conclusion: The low level of knowledge of and willingness to participate in clinical trials indicates that strategies are needed to educate the public about the nature and importance of clinical trials.

Keywords: clinical trials, attitudes, public health, Jordan

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Introduction

Clinical trials are important for the continuing growth of medical knowledge and health care. Economically, they also create many jobs in the health care, pharmaceutical and research fields and contribute to increased profits for companies involved and national institutions (*1–3*). However, recruiting participants for clinical trials is not easy. This is an important problem given that participation of varied groups is necessary to understand how successful an intervention is and the factors that affect this success (*4,5*).

International efforts have long been underway to determine public perception of clinical trials and the factors that influence participation. In Australia, a qualitative study interviewing breast cancer patients showed poor knowledge of the importance and process of clinical trials (*6*). In Japan, trust in doctors was shown to have a considerable role in participation, and the concepts of placebo, randomization and double-blind trials were perceived adversely (*7*). Results of a study in Denmark showed a more positive attitude to clinical trials, however, the study concluded that fear of the unknown and unease with randomization were the most common reasons for not participating (*8*). Regionally, in Saudi Arabia, most participants in a study were aware of clinical trials but had several misconceptions about them and an uncooperative attitude (*9*). On the other hand, a study in Oman reported low levels of knowledge of clinical trials (*10*). All the aforementioned studies highlighted the importance of education on and increased awareness of clinical trials among the general public. Studies in the United States of America (USA) have shown that women, people aged more than 65 years, people of low socioeconomic status, African Americans and other non-white ethnicities are underrepresented populations in cancer studies (*11–13*). In Jordan, no studies on the public's knowledge and perception of clinical trials have been conducted.

In order to develop a strong platform of clinical trials in Jordan, it is important to understand the factors that determine public participation in clinical trials, including people's knowledge of clinical trials, likelihood

to participate and reasons for not participating, and the effects of sociodemographic factors on these factors. Understanding these factors will allow stakeholders to determine the best approach for the health care system to encourage more clinical trials and to encourage people's participation. As Jordan has a similar cultural background as other Middle Eastern countries, findings from our study could also guide initiatives on clinical trials in nearby countries.

Methods

Study design

The questions on clinical trials were part of a wider quantitative cross-sectional survey entitled "Knowledge, attitudes, practices towards cancer prevention and care in Jordan" (*14*). This survey was conducted at the national level and consisted of 10 sections, one of which was on new fields of cancer research in Jordan. In this section, public knowledge of and attitudes to clinical trials were assessed. More details about the survey can be found elsewhere (*15–17*).

Participants and procedures

The survey was conducted nationwide in the three regions of Jordan (North, Central and South) covering the 12 governorates. The survey sample was selected using the 2004 Population and Housing Census as the sampling frame in order to ensure that the final sample reflected the socioeconomic and geographic composition of Jordan. Participants were approached by college-educated, trained, female interviewers in their homes. Face-to-face interviews were held with 3196 individuals aged 18 years and more from January to March, 2011. Selected houses were re-visited twice before excluding them; about 5% of houses were excluded.

Data collection

Data were collected using a questionnaire in Arabic, with an available English translation, when needed. International references/tools, such as the Health Information National Trends Survey *(18)*, were used to guide the development of the questionnaire. The questionnaire was adapted to the local context and was reviewed by the advisory committee of the knowledge, attitudes, practices survey (*15–17*), the research team from Center of Consultation at the University of Jordan and experts from the Jordanian Department of Statistics, in order to ensure content validity and clarity.

Participants were asked about the following: (i) sociodemographic characteristics – sex, age, education level, marital status and income; (ii) their knowledge of clinical trials (yes/no); (iii) their previous participation in clinical trials after explaining what they were (yes/no); (iv) the likelihood that they would be willing to participate in clinical trials (measured on a 4-point Likert scale – very likely, likely, unlikely, very unlikely); (v) perceived health status (excellent, very good, good, satisfactory and bad); and (vi) reasons for not wanting to participate in clinical trials for those not willing (open-ended question).

Statistical analysis

Data were analysed using SPSS, version 17.0. Descriptive statistics were used to report sample characteristics. Categorical variables are presented as frequencies with corresponding percentages. Chi-squared analyses were used to examine the strength of the association between the independent variables (age, sex, educational level, marital status and income) and the main outcome variables of interest (knowledge of and participation in clinical trials and likelihood of agreeing to participate in one). In addition, the association between self-perceived health status and willingness to participate in clinical trials was assessed. The Pearson correlation coefficient (r) was used to assess the relationship between sociodemographic characteristics and attitudinal statements.

Ethical considerations

Ethical approval for the study was obtained from a special committee at the Center of Consultation at the University of Jordan.

Before the interview, participants were briefed about the purpose and outcomes of the study, and their right to voluntarily participate, withdraw or refuse to participate. Verbal informed consent was obtained (agreement of the participants to be interviewed in their houses was considered as consent).

Results

Sociodemographic characteristics of participants

A total of 3196 respondents were included in the analysis for this report. Just over half (51.5%) of the participants were men and 78.4% were under 50 years (Table 1).

Knowledge of and participation in clinical trials

When asked whether they had ever heard or read about clinical trials, only 21.8% of respondents had some knowledge of the term (Table 1), with significantly more men having knowledge of clinical trials than women (24.1% versus 19.3% respectively, $P < 0.001$). In addition, significantly more respondents aged 40–49 years knew about clinical trials than those in other age groups ($P < 0.001$). Higher educational level ($r = 0.178$, $P < 0.001$) and income ($r = 0.137$, $P < 0.001$) were also positively associated with increasing knowledge of clinical trials.

After informing survey participants of the definition of a clinical trial, they were asked if they had ever participated in a trial. As expected, most respondents (98.8%) indicated that they had never participated in a clinical trial with only 1.2% of them confirming their participation. No association was found between participation in clinical trials and age, education, sex and income (Table 2).

Table 1 Knowledge of clinical trials by sociodemographic characteristics

Have you ever heard or read about clinical trials?	No	Yes	Total	Statistical tests
	No. (%)	No. (%)	No. (%)	
Total	**2500 (78.2)**	**696 (21.8)**	**3196 (100.0)**	
Sex				$\chi^2 = 10.804$, $P < 0.001$
Males	1250 (75.9)	397 (24.1)	1647 (51.5)	
Females	1250 (80.7)	299 (19.3)	1549 (48.5)	
Age (years)				$\chi^2 = 17.919$, ($r = -0.007$, $P = 0.706$)
18–29	758 (78.6)	206 (21.4)	964 (30.2)	
30–39	730 (79.8)	185 (20.2)	915 (28.6)	
40–49	457 (72.8)	170 (27.1)	627 (19.6)	
50–59	208 (76.8)	63 (23.2)	271 (8.5)	
60+	347 (82.8)	72 (17.2)	419 (13.1)	
Education level				$\chi^2 = 1.025$, $P < 0.001$ ($r = 0.178$, $P < 0.001$)
Elementary or lower	559 (91.0)	55 (9.0)	614 (19.2)	
Preparatory to high school	1285 (78.4)	353 (21.6)	1638 (51.3)	
Diploma and above	655 (69.4)	289 (30.6)	944 (29.5)	
Monthly income[a] (Jordanian dinars[b])				$\chi^2 = 65.933$, $P = 0.379$ ($r = 0.137$, $P < 0.001$)
< 300	1264 (84.5)	231 (15.5)	1495 (47.1)	
300–599	902 (73.5)	325 (26.5)	1227 (38.7)	
600+	320 (70.8)	132 (29.2)	452 (14.2)	

[a]*Since 22 respondents did not wish to declare their income, the total responses of the income category were 3174.*

[b]US$ 1 = *0.07 Jordanian dinars.*

Table 2 Participation in clinical trials by sociodemographic characteristics

Have you ever participated in a clinical trial?	No	Yes	Total	Statistical tests
	No. (%)	No. (%)	No. (%)	
Total	**3157 (98.8)**	**39 (1.2)**	**3196 (100.0)**	
Sex				$\chi^2 = 0.875$, $P = 0.421$
Male	1624 (98.6)	23 (1.4)	1647 (51.5)	
Female	1533 (99.0)	16 (1.0)	1549 (48.5)	
Age (years)				$\chi^2 = 3.988$, $P = 0.408$ ($r = -0.030$, $P = 0.091$)
18–29	947 (98.2)	17 (1.8)	964 (30.2)	
30–39	904 (98.7)	12 (1.3)	915 (28.6)	
40–49	622 (99.2)	5 (0.8)	627 (19.6)	
50–59	269 (99.3)	2 (0.7)	271 (8.5)	
60+	414 (99.0)	4 (1.0)	418 (13.1)	
Education level				$\chi^2 = 2.518$, $P = 0.284$ ($r = 0.025$, $P = 0.164$)
Elementary or lower	608 (99.0)	6 (1.0)	614 (19.2)	
Preparatory to high school	1621 (99.0)	17 (1.0)	1638 (51.3)	
Diploma and above	928 (98.3)	16 (1.7)	944 (29.5)	
Monthly income[a] (Jordanian dinars[b])				$\chi^2 = 1.272$, $P = 0.529$ ($r = 0.015$, $P = 0.387$)
< 300	1478 (98.9)	17 (1.1)	1495 (47.1)	
300–599	1213 (98.9)	14 (1.1)	1227 (38.7)	
600+	444 (98.2)	8 (1.8)	452 (14.2)	

[a]*Since 22 respondents did not wish to declare their income, the total responses of the income category were 3174.*

[b]US$ 1 = *0.07 Jordanian dinars.*

Willingness to participate in clinical trials

The willingness of respondents to participate in clinical trials was investigated. Those who indicated that it was "very likely" or "likely" that they would be willing to participate constituted 3.6|% and 21.1% of respondents respectively (Table 3). Most respondents were unwilling to participate in clinical trials: 35.0% and 40.3% of survey participants respectively indicated that it would be unlikely or very unlikely that they would agree to participate. Significantly more women than men said they would be very likely to agree to participate in clinical trials (4.3% versus 2.9% respectively, $P = 0.025$). At the same time significantly more women than men said they would be very unlikely to agree to participate in clinical trials (42.0% and 38.7% respectively, $P = 0.025$). Willingness to participate in clinical trials was also significantly associated with age ($P < 0.001$) but without a clear trend ($r = 0.031$, $P = 0.081$). Respondents between the ages of 40 and 49 years were very likely (4.0%) or likely (26.5%) to be willing to participate in clinical trials. Decreasing income was significantly correlated with a higher likelihood of willingness to participate in clinical trials ($r = 0.071$, $P < 0.001$). On the other hand, no significant correlation was found between educational level and willingness to participate in clinical trials. Perceived health status was significantly associated with willingness to participate in clinical trials; those who perceived their health status as bad or satisfactory were less likely to be willing to participate in clinical trials ($P < 0.001$).

Reasons for not participating in clinical trials

The 2406 respondents who said they would be unlikely or very unlikely to agree to participate in clinical trials were given the chance to explain their reason(s) why (Table 4). The most common reason for not wanting to participate in a clinical trial was its perceived high risk to their health (61.1% of participants). This was followed by not being convinced about the outcome and benefits of clinical trials (29.7%).

Discussion

Based on feedback from both patients and clinical research associates, the reasons influencing participation in clinical trials have been classified into physician-relat-

Table 3 Likelihood of respondents agreeing to participate in clinical trials

How likely is it that you would be willing to participate in a clinical trial?	Very likely	Likely	Unlikely	Very unlikely	Total	Statistical tests
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	
Total	**115 (3.6)**	**675 (21.1)**	**1118 (35.0)**	**1288 (40.3)**	**3196 (100.0)**	–
Sex						$\chi^2 = 9.317$, $P = 0.025$
Male	48 (2.9)	367 (22.3)	594 (36.1)	638 (38.7)	1647 (51.5)	
Female	66 (4.3)	309 (19.9)	524 (33.8)	650 (42.0)	1549 (48.5)	
Age group (years)						$\chi^2 = 32.224$, $P < 0.001$ ($r = 0.031$, $P = 0.081$)
18–29	31 (3.2)	218 (22.6)	330 (34.2)	385 (39.9)	964 (30.2)	
30–39	41 (4.5)	176 (19.2)	328 (35.8)	370 (40.4)	915 (28.6)	
40–49	25 (4.0)	166 (26.5)	199 (31.7)	237 (37.8)	627 (19.6)	
50–59	6 (2.2)	47 (17.3)	92 (33.9)	126 (46.5)	271 (8.5)	
60+	11 (2.6)	68 (16.3)	169 (40.4)	170 (40.7)	418 (13.1)	
Education level						$\chi^2 = 5.767$, $P = 0.450$ ($r = -0.013$, $P = 0.446$)
Elementary or lower	21 (3.4)	117 (19.1)	225 (36.6)	251 (40.9)	614 (19.2)	
Preparatory to high school	66 (4.0)	349 (21.3)	555 (33.9)	667 (40.7)	1637 (51.2)	
Diploma and above	27 (2.9)	210 (22.2)	337 (35.7)	370 (39.2)	944 (29.5)	
Monthly income[a] (Jordanian dinars[b])						$\chi^2 = 32.906a$, $P < 0.001$ ($r = 0.071$, $P < 0.001$)
< 300	54 (3.6)	339 (22.7)	537 (35.9)	566 (37.8)	1496 (47.2)	
300–599	46 (3.7)	253 (20.6)	452 (36.8)	476 (38.8)	1227 (38.7)	
600+	12 (2.6)	81 (17.9)	124 (27.4)	236 (52.1)	453 (14.3)	
Perceived health status						$\chi^2 = 7.604$, $P < 0.001$ ($r = 0.009$, $P = 0.597$)
Excellent	49 (4.8)	191 (18.9)	309 (30.6)	462 (45.7)	1011 (31.6)	
Very good	45 (3.8)	277 (23.3)	456 (38.3)	412 (34.6)	1191 (37.3)	
Good	17 (2.1)	178 (22.1)	282 (34.9)	330 (40.9)	807 (25.2)	
Satisfactory	4 (2.7)	23 (15.3)	55 (36.7)	68 (45.3)	150 (4.7)	
Bad	0 (0.0)	6 (15.8)	16 (42.1)	16 (42.1)	38 (1.2)	

[a] *Since 22 respondents did not wish to declare their income, the total responses of the income category were 3174.*

[b] US$ 1 = *0.07 Jordanian dinars.*

Table 4 **Participants' reasons for not participating in clinical trials**

Reason	No. (%)
Risk to my health	1688 (61.1)
Not convinced about the outcome and benefits of clinical trials	819 (29.7)
Old age and poor health status	85 (3.1)
Have not thought about this	71 (2.6)
No time	46 (1.7)
Religious and cultural barriers	27 (1.0)
Lack of knowledge	14 (0.5)
Dislike of hospitals and physicians	12 (0.4)
Total responses	2762 (100.0)

ed, patient-related and system-related (*19*). Our study focused on public understanding of and attitude to clinical trials. Our results clearly show a lack of understanding of what clinical trials are, with a significant difference according to sex, age, education and income. Only 21.8% of our sample had any knowledge of clinical trials, which is comparable to that reported in Oman, where 31.3% of survey respondent knew what the term meant (10). Jordanian men appeared to be more knowledgeable of clinical trials than women. In addition, more respondents aged 40–49 years knew of clinical trials. It is probable that the lower awareness in younger age groups is because of a lack of life experiences, whereas poorer education could be the reason why older people were the least knowledgeable. Moreover, there was a significant association between both increasing educational level and increasing income, and increasing knowledge of clinical trials. This is similar to the results found in a study in the USA, which concluded that low education levels and low income were predictors of lack of awareness of clinical trials, and were associated with lower participation in trials (20).

A study in 2004 reported that enrolment of cancer patients in clinical trials in the USA was low overall and ranged from 0.5% to 3% depending on ethnicity and age group (*12*). These percentages are similar to the actual participation of individuals in Jordan in clinical trials, which was indicated by only 1.2% of respondents. Whereas the American study found a strong inverse correlation between age and enrolment (*12*), we did not find any correlation between willingness to participate in clinical trials and age, education, sex and income. The rate of participation in clinical trials is expected to be higher among those in need, such as cancer patients. In fact, one study showed that only 3% of cancer survivors had participated in cancer clinical trials but a large proportion of cancer survivors (65%) would have participated in trials had they known about them (*21*). A study in Saudi Arabia also showed that 61% of the cancer patients and their family members were aware of clinical trials and 58% were willing to take part in them (*22*).

We found that significantly more men than women were willing to participate in clinical trials which is similar to the various studies in the USA (*11,12*). However, women in Jordan were more decisive in their responses with a slightly higher percentage answering very likely or very unlikely than men. People more than 50 years were the least likely to be willing to participate in clinical trials, which is similar to other reports (*23,24*). Income level was an important factor in our study; respondents in higher income levels were significantly less likely to be willing to participate in clinical trials. Interestingly, this is in contrast to other studies in which lower rates of participation were reported in people with lower incomes (*13,25*). In Jordan, this difference may be due to perceived better access to health care and certain benefits (e.g. monetary compensation) among the lower income groups if they participate in clinical trials. In addition, although old age and poor health status were associated with unwillingness to enrol in a clinical trial, only 3.1% of our participants gave this as a reason for not participating in a clinical trial.

When asked about the reasons for not participating, the most common reason given by the participants was concern of an adverse effect on health, which accounted for 61.1% of responses. This was followed by not being convinced about the outcome and benefits of clinical trials (29.7%). These responses are in line with other studies. For example, concern of health risks was the main reason for lack of participation in clinical trials among African Americans (*26*). In a Danish study, fear of adverse effects from treatments in clinical trials was the most common reason for not participating (*27*). Participant-related factors that affect participation in clinical trials include, but are not limited to, demographic characteristics, lack of interest, time and transportation, physical limitations, and fear of emotional effect (*28*). Research-related factors may also influence the decision to participate in a clinical trial, such as random assignment and the effect on the participants' daily routine. Finally, lack of trust in physicians was reported in a pilot study across the Middle East, with many participants believing that doctors conduct studies without consent and that withdrawal from a study would lead to a poorer level of health care services provided (*29*).

The fact that the top three reasons why respondents in our study were not willing to participate in clinical trials are related to a lack of understanding of clinical trials and their importance highlights the need to raise

awareness and educate the public in Jordan. One way to do this is to incorporate the concept of clinical trials in the Jordanian educational curricula. This will ensure that future generations are fully aware of the importance of clinical trials and what they entail. More importantly, the role of the media and mass communication must be recognized and directed to the issue. Television programmes are reported to be the most important way to convey medical-related information in Jordan (*30*). Furthermore, physicians play an important role in the recruitment of individuals in clinical trials. Participation of cancer survivors in clinical trials was found to be directly related to physician involvement (*21*). Thus, it is important to examine the factors that influence physician involvement and the health care system. The Saudi Arabian study on public perception of clinical trials, for example, noted that physician–patient interaction is a key factor in determining willingness to participate; 74% of Saudi Arabians interviewed reported that they would have to consult a physician involved in their care before agreeing to participate in a clinical trial (*9*). Therefore, it is important to increase physician involvement in the recruitment process of clinical trials as well as holding information sessions about clinical trials and the ethics of them. The need for such approaches in the Middle East is highlighted by another study in Saudi Arabia where clinicians had limited knowledge of clinical trials, several misconceptions about them and little time to conduct them (*31*).

Jordan and other countries in the Middle East and North Africa are underrepresented in the percentage of clinical trials conducted globally (*32*), so there is room for improvement. The presence of qualified health care professionals, well-equipped health care centres and institutions, and well-established regulatory laws make Jordan an ideal place to conduct clinical trials (*33*). Jordan was the first Arab country in the Middle East and North Africa that enacted clinical trial regulations in 2001. The Clinical Studies Division of the Drug Directorate at the Jordan Food and Drug Administration was founded in 2004 and currently oversees all clinical trials conducted in Jordan (*34*).

A strength of our study is the involvement of a representative sample of the Jordanian population. In addition, our results could reflect views of Middle Eastern people in general because of the cultural and religious similarities. However, being a self-report interview study, individuals may be reluctant to explicitly state their views objectively and might rather provide biased, socially acceptable responses. Furthermore, this survey was part of a long questionnaire with possibly insufficient time for respondents to think about this new concept. Nevertheless, our results highlight the need to establish awareness campaigns to promote public involvement in clinical trials.

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Essais cliniques en Jordanie : connaissance, attitudes connexes et participation mesurées par une enquête en population

Résumé

Contexte : Les essais cliniques sont importants pour améliorer les soins de santé publique. Cependant, le recrutement des participants pour ces essais peut s'avérer difficile.

Objectifs : La présente étude visait à évaluer la connaissance publique des essais cliniques et la volonté d'y participer en Jordanie, et à examiner les caractéristiques sociodémographiques associées, ainsi que les raisons expliquant leur réponse négative.

Méthodes : Les questions ont été posées dans le cadre d'une enquête en population représentative menée en 2011 auprès de 3 196 Jordaniens. Lors d'un entretien conduit à domicile, des questions ont été posées aux participants sur leurs caractéristiques sociodémographiques, leur connaissance des essais cliniques et leur participation à ces derniers.

Résultats : Seuls 21,8 % des personnes interrogées savaient ce qu'est un essai clinique, et 1,2 % d'entre elles avait déjà participé à ce type d'essai. Près de 25 % des personnes interrogées ont signifié leur volonté de participer à un essai clinique. Les hommes étaient significativement plus nombreux (24,1 %) que les femmes (19,3 %) à savoir ce qu'est un essai clinique ($p < 0,001$). À l'inverse, davantage de femmes (4,3 %) que d'hommes (2,9 %) ont indiqué être très susceptibles d'accepter de participer à des essais cliniques. Les personnes âgées de 40 à 49 ans avaient une meilleure connaissance des essais cliniques et une plus grande volonté d'y participer que les autres groupes d'âge. Les revenus étaient associés de façon positive à la connaissance des essais cliniques, mais de façon négative à la volonté d'y participer. Un niveau d'éducation élevé avait une corrélation positive avec la connaissance des essais cliniques et la volonté d'y participer. Les principaux motifs de non-participation aux essais étaient l'inquiétude concernant le risque pour la santé personnelle (61,6 %) et le fait de ne pas être convaincu des résultats et du bénéfice des essais cliniques (29,7 %).

Conclusion : Le faible degré de connaissance et de volonté de participer à des essais cliniques indique que des stratégies de sensibilisation du grand public à la nature et à l'importance des essais cliniques sont nécessaires.

المعلومات والاتجاهات الخاصة بالتجارب السريرية، والمواقف تجاهها، والمشاركة فيها في الأردن: مسح سكاني

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الخلاصة

الخلفية: تكتسي التجارب السريرية أهمية من أجل تحسين الرعية الصحية العامة. وبالرغم من ذلك، فإن اختيار المشاركين لإجراء تلك التجارب قد تغلب عليه بعض الصعوبة.

الأهداف: هدفت هذه الدراسة إلى تقييم المعلومات العامة بالتجارب السريرية والرغبة في المشاركة فيها في الأردن، كما درست السمات الاجتماعية والسكانية المرتبطة بتلك المعلومات والرغبة، والأسباب وراء الإحجام عن المشاركة فيها.

طرق البحث: شكلت الأسئلة جزءا من مسح سكاني تمثيلي أُجري في عام 2011 وشمل 3196 شخصا أردنيا. ومن خلال إجراء مقابلات منزلية، سأل الباحثون المشاركين حول: السمات الاجتماعية السكانية، والمعرفة بالتجارب السريرية والمشاركة فيها.

النتائج: كان لدى 21% وحسب من المستجيبين إلمام بالتجارب السريرية كما شارك (1.2%) منهم في إحدى التجارب. كما أبدى 25% من المستجيبين استعدادهم للانضمام إلى إحدى التجارب. وبصورة ملحوظة، تبيّن أن عدد الرجال الملمين بالتجارب السريرية (24.1%) كان أكبر من النساء (19.3%) (p <0.001)، بينما كان عدد النساء اللواتي رجحن موافقتهن على المشاركة في التجارب السريرية (4.3%) أكبر من عدد الرجال (2.9%). وكان الأشخاص الذين تراوحت أعمارهم بين 40 و 49 سنة أكثر إلماما بالتجارب السريرية وأكثر استعدادا للمشاركة فيها من أية فئة عمرية أخرى. وارتبط الدخل بصورة إيجابية بالمعلومات الخاصة بالتجارب السريرية والاستعداد للمشاركة فيها. كما ارتبط مستوى التعليم العالي بصورة إيجابية بالإلمام بالتجارب والاستعداد للمشاركة فيها. وتمثلت الأسباب الرئيسية وراء الإحجام عن المشاركة في التجارب في القلق من تعرض الصحة للخطر (61.1%) وعدم الاقتناع بحصيلة التجارب السريرية ومنافعها (25%)

الاستنتاج: يشير تدني مستوى المعلومات الخاصة بالتجارب السريرية وعدم الرغبة في المشاركة فيها إلى الحاجة إلى استراتيجيات رامية إلى تثقيف الجماهير بشأن طبيعة تلك التجارب وأهميتها.

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Equity in utilization of health care services in Turkey: an index based analysis

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Abstract

Background: Equity in the use of health care services is an issue which has increasingly been on the health policy agenda over recent years in both middle- and low-income countries.

Aims: The purpose of this study was to investigate the degree and progress of equity in health care utilization in Turkey during 2008–2012.

Methods: Wed use data from health surveys (2008, 2010, 2012) conducted by the Turkish Statistical Institute. The concentration index (CI) and the horizontal equity index (HI) were calculated as a measure of equity, and a Blinder–Oaxaca decomposition analysis was applied.

Results: The general practitioner (GP), specialist and inpatient visits display a pro-poor orientation. Averages of the CI and HI indices for 2008–2012 were 0.74 and −0.17 for GP visits, 0.75 and −0.13 for specialist visits, 0.83 and −0.31 for inpatient visits.

Conclusion: Our findings indicate that health care utilization in Turkey appears to have become equitable over the years; however, the sustainability of equity is an issue of concern.

Keywords: Horizontal equity, utilization of health care services, concentration index, horizontal equity index, Oaxaca decomposition

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Introduction

Equity in the use of health care services is an issue, which has increasingly been on the health policy agenda in recent years in both middle- and low-income countries. (1). Equity and equality are different terms, which should be described with caution. Equity, with its moral and ethical features, differs from equality, which indicates a simple mathematical condition, meaning 2 things being equivalent. Therefore, inequality in health care utilization is related to unequal utilization, which is due to characteristics such as age, sex and socioeconomic status (2). In this regard, equity can be defined as everyone in equal need of treatment using similar treatment regardless of any economic or other conditions (3). In other words, differences relating to the utilization of health care services between the advantaged and disadvantaged segments of a population should be eliminated in order to provide equity (4).

Equity is evaluated through 2 main aspects. "Vertical equity" requires payments should be related to ability to pay (5), whereas "horizontal equity" relates to the opportunity of utilizing equal treatments for equal needs regardless of socioeconomic status (3). In other words, equity can be said to exist in cases where need is the primary cause of the utilization of health care services (6,7). Therefore, equity is evident when, for example, enabling factors such as income and health insurance do not play a significant role in determining the beneficiaries of health care services (8). In this respect, a number of existing studies for Turkey have investigated vertical equity (9–11). In consequence, our study focuses on the concept of horizontal equity in the Turkish health care system. Specifically, the aim of this paper is to examine equity in the use of health care services in Turkey by using the 2008, 2010 and 2012 health surveys implemented by the Turkish Statistical Institute (TurkStat).

As a first step, we calculated and graphed the concentration index (CI) as described by O'Donnell et al. (1). The need-standardized horizontal inequity (HI) index proposed by Wagstaff and Van Doorslaer (3) was also calculated. The HI index has been increasingly used in equity studies over recent decades, especially for the developed countries (5,12–14). However, it is clear that low- and middle-income countries are at more risk of suffering from inequity in the utilization of health care services compared with high-income countries. Therefore, some studies turn their attention to experiences of incurring inequity in the health care system in low- and middle-income countries (15–18). The Oaxaca–Blinder type decomposition is used to further investigate the differences between income groups following the methodology suggested by O'Donnell et al. (1)

In the case of Turkey, most studies have focused on analysing the determinants for utilization of different types of health care (19,20). To our best knowledge, there is only one study focusing on inequity in the utilization of health care services for 2008 (21). The researchers

found evidence on pro-rich inequity in specialist and dental care and pro-poor distribution for emergency care, inpatient care and general practitioner (GP) visits. Although this study is important in terms of offering a starting point for the evaluation of inequity of utilization of health care services in Turkey, it has the limitation of not providing the improvement of equity (or inequity) over time. However, it is important to examine the progress of equity in Turkey, which is a particular policy area given the ongoing health reforms since 2003 through the Health Transformation Programme (HTP). The HTP has been focusing on 3 main policy areas: the financing, organization and delivery of health care services (22). In the General Health Insurance System, health care financing depends largely on premiums which are directly or indirectly collected from people utilizing health care services. Furthermore, the purchaser and provider functions of the Ministry of Health hospitals were separate. After 2003, Turkey extended the scope of financial protection against high levels of health care expenditures by expanding the health insurance coverage to improve equity in the utilization of health care services. The years 2010 and 2012 are especially important in the restructuring of the Turkish health care system as a person list-based family medicine model was completely implemented in 2010 and the public hospitals were unified under a single umbrella in 2012. Other than these 2 important health policies, many reforms relating to, for example, co-payments, hospital structure and extra payments for private hospitals have been implemented since 2003, which may have considerable effects on the utilization of health care services in Turkey. Our study extends the existing research by calculating both the CI and HI using the 2008, 2010 and 2012 health surveys and, thus, offers a set of policy implications for a long policy period in Turkey.

Methods

TurkStat, as a nationally representative survey, administers the Turkish Health Survey biennially. The most recent available survey is for 2012 for equity analysis. Even though the 2014 and 2016 surveys are available, they lack crucial questions to evaluate equity in health utilization.

TurkStat used strata and 2-phase cluster sampling methods as sampling methodologies for the surveys. For external stratification, rural–urban difference was used (settlements with a population 20 000 and under are regarded as rural; settlements with a population of 20001+ are regarded as urban). The first stage-sampling unit is the blocks selected from clusters, containing an average of 100 households, and the second stage-sampling unit is the households selected systematically from each cluster.

In 2008, among urban areas 5580 households were selected within 372 clusters containing 15 households in each block. In 4294 of these households, questionnaires were completed. In rural areas, 2330 households were selected from 233 clusters containing 10 households in each cluster. In 1846 of these households questionnaires were completed.

In 2010, among urban settlements, 5696 households were selected from 356 clusters containing 15 households in each cluster. In 4682 of these households, questionnaires were completed. In rural settlements, 2190 households were selected from 219 clusters containing 10 households in each cluster. Questionnaires were completed in 1869 of these households.

In 2012, among urban settlements, 10 656 households were selected from 888 blocks containing 12 households in each cluster. In 8928 of these households, questionnaires were completed. In rural settlements; 3744 households were selected from 468 blocks containing 8 households in each cluster. In 3232 of these households, questionnaires were completed.

Weighting procedures were carried out by TurkStat to obtain parameters from the dataset resulting from sampling. The sampling frame of the surveys was the National Address Database, which constitutes a base for an "address based registry system", which was completed in 2007 and updated in February 2012. Settlements with population less than 132 were not included in the frame because it was considered that an adequate number of sample households might not be reached. All residential areas located within the coverage of Turkey were included in the sample selection and all members who had received health services in the previous year were covered. Survey questions are available for the 0–6 and 7–14 years age groups, however, our study includes only those aged 15+ years. In total, 20 624 individual interviews were completed for 2008, 20 200 for 2010 and 37 979 for 2012. The surveys were administered to different individuals each year and hence are not in panel data format.

As a first step of analysing equity, this study employs the concentration index (CI), employed for its computational simplicity and the concentration curves (CC) are drawn for easy visualization and for comparison purposes. However, it should be noted that the CC and CI are used to capture socioeconomic inequalities rather than inequities (1). Therefore, only HI index results are interpreted.

CI is calculated following O'Donnell et al. (1):

$$CI = \frac{2}{N\mu} \sum_{i}^{n} = 1 h_i r_i - 1 - \frac{1}{N} \quad [1]$$

Where, h_i denotes the health variable, in this case health service utilization, and μ represents its mean; r_i represents rank of the individual with I = 1 for poorest and I = N for the richest, where N is the total number of living standards groups. Alternatively, the CI can be defined using the concentration curve. The CI is calculated as twice the area between the concentration curve and the line of equality. The index takes the value of zero if there is no inequality between income groups. The CI takes values between –1 and 1. When the concentration curve lies above the line of equality, the CI takes a negative value and this indicates pro-rich inequalities in the health variable of interest (1).

The HI index proposed by Wagstaff and Van Doorslaer (3) is calculated in 3 basic steps. As a first step, the utilization variable (y_i) is used as a dependent variable and regressed against "need" and "non-need" variables.

$$y_i = a + \sum_k y_k X_k + \sum_p \delta_p Z_p + \in_i \quad [2]$$

Where, y_i is the use of health care services by the i_{th} individual. In this study the choice for dependent variables are: GP visits, specialist visits and inpatient visits. Since these dependent variables are all in binary form, probit regression is employed rather than linear regression. In equation [2], X_k is a vector of need determining variables and Z_p is a vector of non-need variables. α, δ_k, δ_p, γ_k and γ_p are parameters and ε is the error term. The need variables include the following factors; sex, age, self-assessed health status, physical illnesses and chronic illnesses or any kind of discomfort reported by the individual which will cause the individual to utilize health services. Non-need variables, on the other hand, include factors other than need variables but which still have an impact on utilization; marital status, education, employment, residence and health insurance.

Equation [2] is used to generate the i_{th} individual's "predicted" demand on the basis of need. The predicted demand, $\widehat{y_i^x}$, generated using equation [2] is shown in equation [3]. The need and non-need variables are represented as $\check{X}_k$ and $\check{Z}_p$ in equation [3] in order to differentiate from equation [2].

The second stage is to standardize the predicted yi values according to need variables (X). Non-need variables (Z) are also used as control variables.

$$\widehat{y^x}_i = \hat{a} + \hat{\beta}\ \mathrm{In}\ (\widetilde{inc}_i) + \sum_k \hat{y}_k \check{X}_k + \sum_p \hat{\delta}_p \check{Z}_p \quad [3]$$

Then, standardized demand for a particular health service is calculated as follows:

$$\hat{y}^s_i = y_i - \hat{y}^x_i + \bar{y} \quad [4]$$

Where $\hat{y}^s_i$ represents the standardized predicted demand, represents the actual demand, represents the predicted demand and represents the mean value. Finally, the HI index is calculated as the third stage:

$$HI = 2\int_0^1 [L_p(p) - L_m(p)]dp \quad [5]$$

Where, $L_p(p)$ is the $L_m(p)$ concentration curve for the predicted demand and is the concentration curve for the actual demand, shown in Figures 1–3 for visualization of the data. Twice the integral of the area between the 2 curves yields the standardized HI index. The HI index ranges from –2 to 2. A positive HI index value is interpreted as the existence of inequities favouring rich over poor (pro-rich) and a negative value is interpreted as the existence of pro-poor inequities (3).

Finally, this study employs a Blinder–Oaxaca type decomposition of the HI index. The Oaxaca decomposition is utilized in order to assess and analyse the main components of inequities. The decomposition explains the differences among the means of the selected outcome variables between 2 groups (1). The outcome variables in this study are GP visits, inpatient visits and specialist visits and the decomposition reveals the differences in the means of the calculated HI index among poor and non-poor groups.

Results

The data indicate that utilization of health care services increased considerably from 2008 to 2012 for both GP and specialist visits (Table 1). However, the inpatient visits were steady throughout the years under consideration. The increased use of health care for GP and specialist visits brings out the important question of equity. The representation of males and females was almost equal across all survey years. In 2008 almost 70% of those surveyed lived in an urban area and in 2012 this had increased to around 73%. The proportion of individuals with health insurance was over 85% for 2008 and had increased to 89.78% in 2012; this can be regarded as a reflection of the General Health Insurance scheme implemented in Turkey since 2008. Almost 38% of the individuals stated that they had a health problem that lasted more than 6 months and this did not improve substantially over the period of the study, indicating that there are individuals in "need" of medical treatment.

The proportion of individuals who felt the need to use health services but were unable to do so severely diminished over the years for all types of health care (Table 2). Furthermore, in 2008 almost 40% of the individuals in the lowest income group had felt a need to use specialist services in the previous year but could not. This decreased to just over 15% in 2012. There is also a declining trend for individuals in the poor income group. However, for the middle income, rich and very rich groups, the ratio increased over time. For inpatient care, the proportion of individuals who felt the need to use health services but were not able to decreased for the 2 lowest and for the highest income groups. It can be argued that there was an improvement in equity over time since opportunities changed in favour of those in the lower income groups.

Calculating CI and HI, this study employed utilization of health care services as the health variable. The outcome variables were GP, specialist and inpatient visits, all of which are binary. Figures 1 to 3 show the concentration curves for classical and standardized demands for GP, specialist and inpatient visits. The results indicate that health service utilization is pro-poor oriented and that it improved over the years. (Detailed estimation results are available on request.)

Figure 4 presents the results of the Oaxaca decomposition (23). Our results indicate that the importance of non-need factors is increasing over time (detailed estimation results are available on request).

Figure 1 Concentration curves for classical and standardized demands for general practitioner (GP) visits, Turkey, 2008–2012 (HI = horizontal equity index)

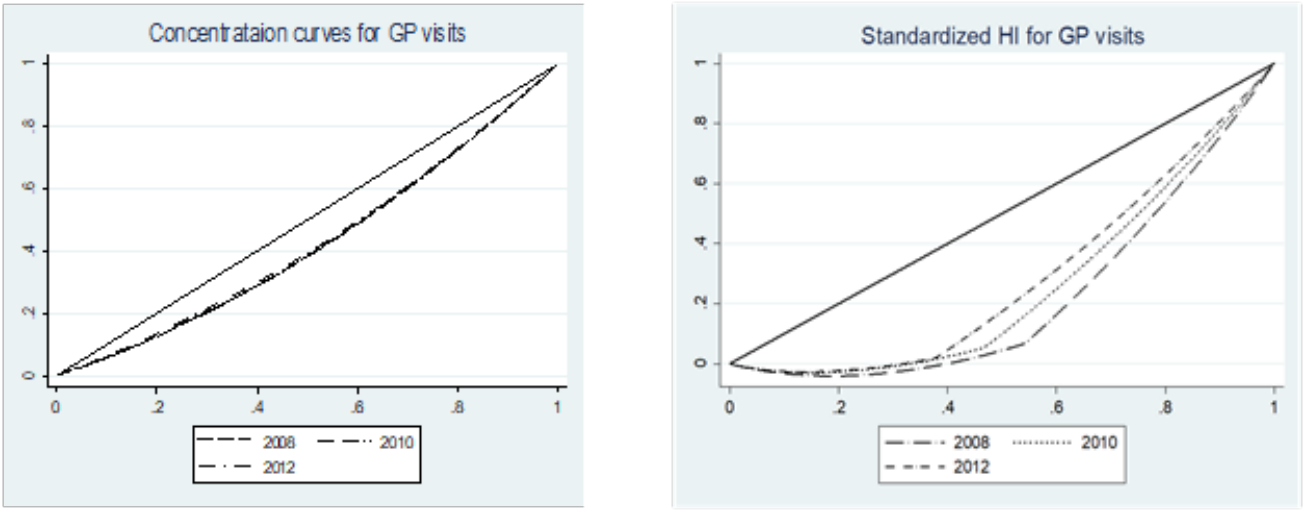


Figure 2 Concentration curves for classical and standardized demands for specialist visits, Turkey, 2008–2012 (HI = horizontal equity index)

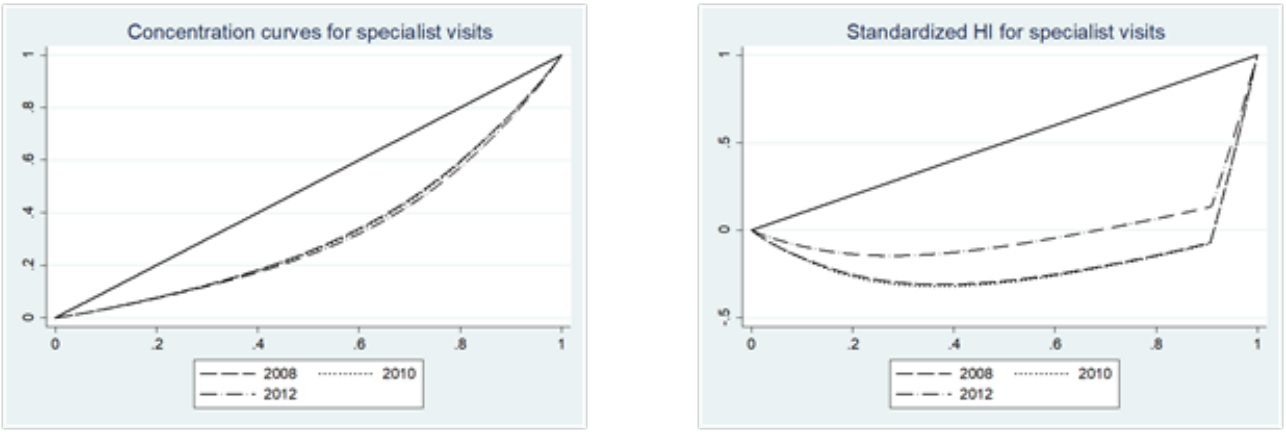


Figure 3 Concentration curves for classical and standardized demands for inpatient visits, Turkey, 2008–2012 (HI = horizontal equity index)

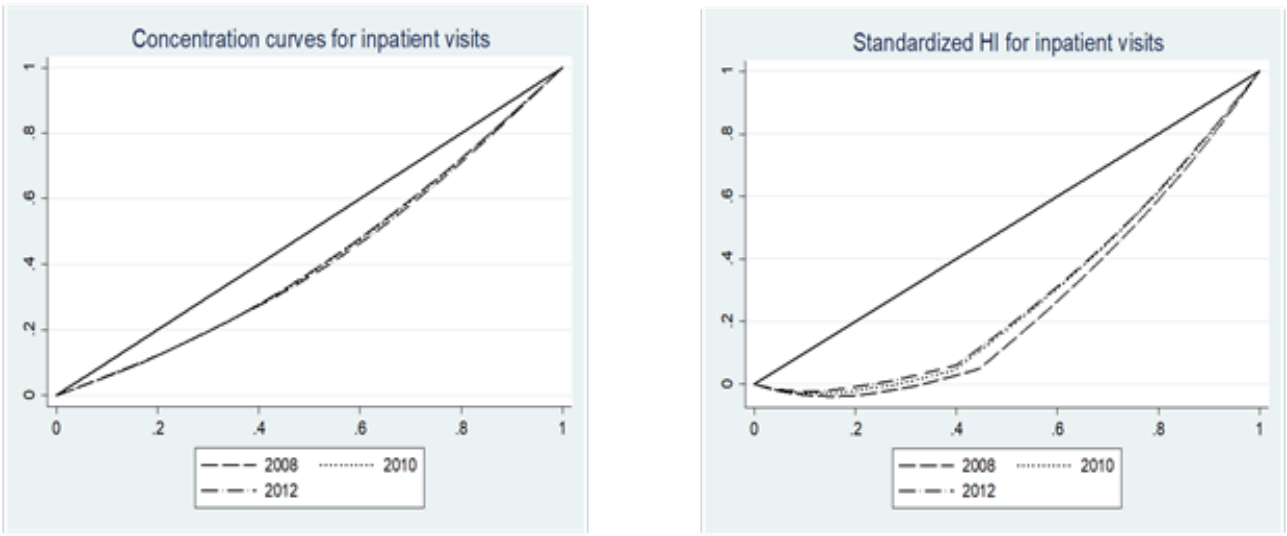


Table 1 Distribution of demographic and health care characteristics, Turkish health surveys 2008–2012

Characteristic	Year		
	2008 (%) (*n* = 14 655)	2010 (%) (*n* = 14 447)	2012 (%) (*n* = 28 055)
Female	54.54	56.48	53.93
Age group (years)			
15–24	19.64	18.46	18.25
25–34	22.59	20.09	19.98
35–44	19.71	19.51	19.80
45–54	16.57	17.34	17.54
55–64	10.98	12.15	12.33
65–74	6.46	7.72	7.54
75+	4.05	4.73	4.56
Urban residence	68.87	71.13	73.63
Insured	86.05	85.54	89.78
Education status			
Illiterate	12.60	11.41	10.37
Literate[a]	7.06	7.64	5.96
Primary school	39.52	37.47	35.31
Secondary school	15.33	17.41	18.75
High school	16.77	15.78	17.60
University	8.09	9.60	11.16
Graduate	0.64	0.69	0.85
Marital status			
Single	22.27	21.89	22.82
Married	70.13	69.43	68.51
Divorced-widowed	7.60	8.68	8.67
Employment status: employed	26.54	36.29	37.23
Income group[b]			
Very poor (≤ $271)	27.47	17.60	8.85
Poor ($272–$390)	21.26	21.58	12.33
Middle income ($391–$546)	20.91	20.73	24.51
Rich ($547–$800)	16.94	19.73	22.21
Very rich (≥ $801)	12.53	19.49	30.92
Non-respondent	0.89	0.87	1.18
Health problems for more than 6 months	37.59	37.52	36.11
Used GP services in previous 12 months	45.89	53.30	62.22
Used outpatient health care in previous 12 months	55.49	60.41	60.01
Use of inpatient health care in previous 12 months	9.31	9.29	9.07

[a] *Individuals who are literate but have no formal education certificate or diploma.*

[b] *Turkish liras converted to US$ at the July 2018 rate of 4.65.*

GP=general practitioner

According to Oaxaca type decomposition, positive values are associated with pro-rich orientation, whereas negative values are associated with pro-poor orientation. Age/sex represent all age and sex combinations. Health is designed as a measure of health status and includes self-assessed health, physical functioning limitations and chronic conditions. In line with the calculations of the concentration index, age/sex factors and health status are treaded as need factors and residence, insurance, education, marital status, employment and income are treated as non-need factors. When the contribution of need factors is investigated, a clear pattern of pro-poor orientation emerges. For non-need factors, it is possible to argue an overall pro-rich orientation.

Table 2 Distribution of individuals who felt the need to use health care in the previous year but could not obtain service (according to income quintile), Turkey 2008–2012

Type of care needed/ income quintilea	2008 (%)	2010 (%)	2012 (%)
Specialist	16.11	14.50	9.30
Very poor (≤ $271)	40.77	29.82	15.12
Poor ($272–$390)	20.65	22.86	14.18
Middle income ($391–$546)	17.75	18.88	23.95
Rich ($547–$800)	12.74	15.01	20.28
Very rich (≥ $801)	7.15	12.64	25.19
Inpatient	3.68	2.99	1.93
Very poor (≤ $271)	43.98	37.97	18.08
Poor ($272–$390)	20.07	25.20	15.06
Middle income ($391–$546)	16.51	16.08	23.15
Rich ($547–$800)	12.15	10.28	21.23
Very rich (≥ $801)	6.20	9.61	1.36

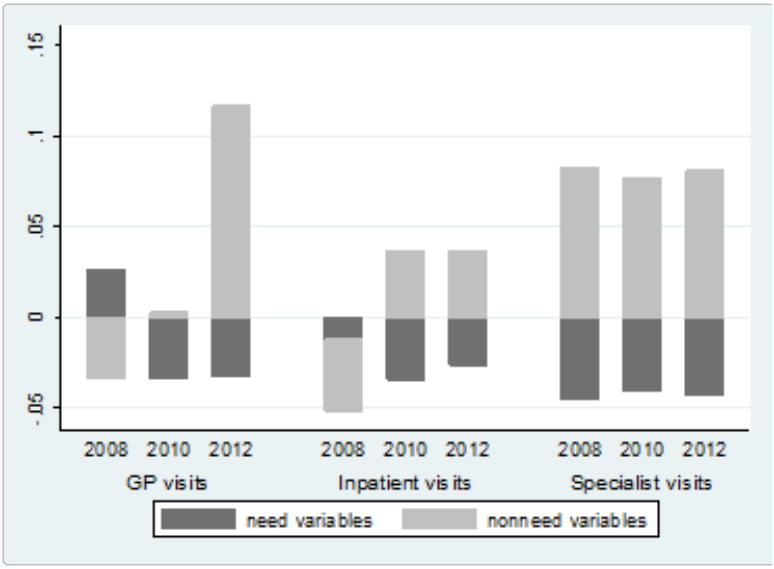
[a]*Turkish liras converted to US$ at the July 2018 rate of 4.65.*

Discussion

Turkey has been experiencing important changes to its health system resulting from health reforms that started at 2003. The Health Transformation Programme, which has been implemented in Turkey since 2003, is based on the joint report prepared by a commission of specialists from Turkey and the World Bank (*24*). It aims to intervene in the 3 basic fields of the health system: organization, finance and health service supply. With this programme, Turkey agreed to execute 2 important changes to the health system. First, to integrate 3 main security institutions under one umbrella institution. Second, to introduce GP services countrywide. The programme specifically aims to increase equity in access and utilization of health services. Therefore, via assessing the level and progress of equity in the utilization of health services in Turkey, our study fills in an important gap in the existing literature. Furthermore, this study is important to show the effects of the specific policy changes which have occurred over time and also to determine accurate policy implications for the Turkish health system.

Prior to 2003, Turkey had 3 main government-based security institutions financing health services. Private security companies were also active. However, a significant part of the population was not covered by any type of social security. For example, in 2003, only 25% of the poorest population were insured. One of the main aims of HTP was to increase access to health care and, thus, increase the percentage of population who are insured. After 13 years in the programme, the percentage of insured in this group has increased to 95% (*25*). In line with the increase in social security coverage, utilization

Figure 4 Decomposition of the concentration index (Oaxaca decomposition) , Turkey, 2008–2012



of health services has also increased, for example, the average number of physician consultations per year has increased 141% over the 2003–2012 period (*26*).

The integration of 3 main security institutions under one umbrella institution was implemented in 2008. In October 2008, the finance system was unified and the General Health Insurance (GHI) system was suggested. The implementation of the GHI started in 2012. The second important step of the HTP, a person list-based family medicine model, has been implemented since 2010. And GP services have been free of charge since the beginning of the programme. However, GP services for Turkey are far from their counterpart services in other European countries. The main problem is an inadequate work force, high numbers of patients per GP and the lack of multidisciplinary implementation (*27,28*). In contrast to GP services, specialist care and inpatient care are subject to payment. The amount of out-of-pocket payments necessary for these services was at its lowest level at 2010 (*29*).

At the end of 2011, the government introduced a performance based supplementary payment system for physicians. This ensures that a supplementary payment has been made to the physicians according to their "contribution" to services. The contribution can be in the form of patients examined, operations, workups or any type of services that can be listed as a source of income to the hospital (*29*). Finally, extra payments that private hospitals can receive are bounded with law in Turkey. The amount of extra payments that private hospitals can charge has increased from 30% to 90% from 2008 to 2012. Since this study covers both public and private health facilities, such a dramatic increase is an important factor in considering the effects of the reforms on the utilization of health care services.

For the years under consideration in this study, health care utilization in Turkey appears to have become equitable. To be specific, GP and specialist visits display a pro-poor orientation and inpatient visits display the highest pro-poor orientation among all types of health care. When considering the change over time, it can be argued that for GP visits and inpatient visits the inequities are improving while for specialist visits they stay the same over time. Due to the person list-based family medicine model, which is an important component of the HTP, free of charge and countrywide GP coverage increases the number of GP visits for individuals in the most disadvantaged segments of the population. Therefore, improving pro-poor inequities in GP visits can be attributed to the implementation of the GP care system in HTP.

There is a stable pro-poor orientation for all years for specialist visits. Evan though after 2010 necessary out-of-pocket payments for both public and private health facilities increased, the indices still favour the poor. The highest levels of pro-poor inequity are also observed in inpatient visits. Furthermore, there is an increasing trend in pro-poor inequities in inpatient visits. This can mainly be attributed to the fact that individuals belonging to the high-income group choose private facilities for inpatient visits. With the rapid increases in necessary out-of-pocket payments for private health services, it is expected to observe inequities favouring the poor.

Overall, government policies aimed at increasing access have led to a fairer health care utilization pattern over time in Turkey as indices for all types of health care suggest pro-poor orientation.

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Competing interests: None declared.

Équité dans l'utilisation des services de soins de santé en Turquie : analyse basée sur des indices

Résumé

Contexte : Ces dernières années, l'équité dans l'utilisation des services de soins de santé est une question de plus en plus présente dans les programmes concernant les politiques de santé, à la fois dans les pays à revenu faible et intermédiaire.

Objectifs : La présente étude visait à examiner le degré d'équité et sa progression dans le recours aux services de soins de santé en Turquie pour la période comprise entre 2008 et 2012.

Méthodes : Nous avons utilisé les données d'enquêtes de santé (2008, 2010, 2012) menées par l'Institut statistique de Turquie. L'indice de concentration (IC) et l'indice d'équité horizontale (EH) ont été calculés pour mesurer l'équité, et l'analyse de décomposition de Blinder - Oaxaca a été appliquée.

Résultats : Les chiffres relatifs aux visites rendues à un médecin généraliste, un spécialiste et aux patients hospitalisés démontrent une orientation centrée sur les pauvres. Les indices IC et EH moyens pour la période de l'étude étaient de 0,74 et –0,17 pour les visites chez le médecin généraliste, de 0,75 et –0,13 pour les visites chez un spécialiste, et de 0,83 et –0,31 pour les visites rendues aux patients hospitalisés.

Conclusion : Nos résultats indiquent que le recours aux soins de santé en Turquie semble être devenue équitable au fil des ans. Toutefois, la pérennité de l'équité demeure un sujet de préoccupation.

الإنصاف في الاستفادة من خدمات الرعاية الصحية في تركيا: تحليل قائم على المؤشرات

سيلسين أوزتورك، ديليك بصر

الخلاصة

الخلفية: أصبح الإنصاف في الاستفادة من خدمات الرعاية الصحية من الموضوعات التي أخذت تظهر بصورة متزايدة ضمن برامج السياسات الصحية في السنوات الأخيرة في كل من البُلدان المنخفضة والمتوسطة الدخل.

الأهداف: هدفت هذه الدراسة إلى تحري مستوى الإنصاف في الاستفادة من خدمات الرعاية الصحية في تركيا والتقدم المحرز في هذا الصدد خلال الفترة من 2008 و 2012.

طرق البحث: استخدم الباحثان بيانات مستمدة من المسوحات الصحية (2008، 2010، 2012) التي أجراها معهد الإحصاء التركي. واحتسب الباحثان كل من مؤشر التركيز ومؤشر الإنصاف الأفقي لقياس الإنصاف، كما اسْتُخدم تحليل بلايندر–أوكساكا التفكيكي.

النتائج: أظهرت زيارات الممارسين العموم، والأخصائيين، والمرضى الداخليين ميلا نحو مناصرة الفقراء. وكانت متوسطات مؤشر التركيز ومؤشر الإنصاف الأفقي للفترة من 2008 و 2012 0.74 و 0.17– لزيارات الممارسين العموم، و 0.75 و 0.13– لزيارات الأخصائيين، و 0.83 و 0.31– لزيارات المرضى الداخليين.

الاستنتاج: تشير النتائج إلى أن الحصول على خدمات الرعاية الصحية في تركيا أصبح يتسم بالإنصاف بمرور السنين؛ لكن تظل استدامة الإنصاف مسألة باعثة على القلق.

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Community pharmacists' perceptions, awareness and practices regarding counterfeit medicines: a cross-sectional survey in Alexandria, Egypt

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Abstract

Background: Counterfeit medicines are a threat to public health and the national economy in Egypt. The many community pharmacists in the country could help prevent counterfeit medicines reaching the patient. Information on community pharmacists' perceptions of counterfeit medicines is lacking.

Aims: This study assessed the awareness, practices and perceptions of community pharmacists in Alexandria, Egypt with regard to counterfeit medicines. The aim was to identify gaps and inadequacies in pharmacy practice that might allow infiltration of counterfeit medicines in the legitimate medicine supply chain.

Methods: A cross-sectional study was conducted of 175 community pharmacists in Alexandria in 2014–2015. A semi-structured interview questionnaire was used to assess their perceptions, awareness and practices. The chi-squared test was used to assess the relationships between selected pharmacists' characteristics and their awareness, purchasing practice and training related to counterfeit medicines.

Results: Most pharmacists thought medicine counterfeiting was widespread in Egypt and that they could contribute to combatting the problem. However, most also lacked a clear perception of counterfeit medicines, an awareness of their danger to patients or the legislation to reduce them. Their procurement practices and detection of counterfeit medicines and handling of incidents of counterfeit medicines were inadequate. Pharmacists who thought counterfeit medicines were widespread or a health threat were significantly more likely to purchase medicines from certified sources ($P < 0.05$).

Conclusion: Pharmacists should be developed as a frontline resource to combat counterfeit medicines. To enhance their role, the pharmacy curriculum needs to be updated and continuing professional development activities mandated.

Keywords: pharmacist, counterfeit drugs, perception, Egypt

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Introduction

As initially defined by the World Health Organization (WHO), a counterfeit medicine is "one which is deliberately and fraudulently mislabelled with respect to identity and/or source" *(1)*. More recently, new definitions have been introduced where medical products that deliberately or fraudulently misrepresent their identity, composition or source are termed falsified products *(2)*. Despite efforts by international and national agencies to combat counterfeiting and falsification of medicines, this problem is still a serious threat to global health *(3–5)*. Counterfeit medicines are widespread and varied, and encompass all types of therapeutic classes, ranging from life-saving to lifestyle products *(6,7)*. Estimates indicate that up to 15% of drugs are counterfeit and, in parts of Africa and Asia, this figure exceeds 50% *(5,8)*.

In Egypt, powerful factors both on the supply and demand side drive counterfeiting of medicines and are threat to the health care system and patient safety. The supply of counterfeit medicines is driven by the large market size, huge profits, and the availability of sophisticated counterfeiting technology. At the same time, drug shortages and the demand for inexpensive medicines by an ever-increasing population encourage the spread of counterfeit medicines, making Egypt a target for illegal local manufacturing, and smuggling and trafficking of counterfeit medicines *(9,10)*. The situation is made worse by a lack of awareness of the problem of counterfeit medicines and limited resources to combat it. Moreover, the Egyptian pharmacy practice law, number 127 dates back to 1955 and lacks provision for dealing with the spread of counterfeit medicines. This complex situation undermines efforts to reduce counterfeit medicines, leaving the patient the victim of ineffective or harmful medicines *(9)*.

In such an environment, pharmacists could be enlisted to help safeguard patient safety if supported by the necessary professional development and partnership. The views and attitudes of pharmacists about counterfeit medicines have been surveyed in several developing countries and they suggest improvements could be made *(11–14)*. Indeed, the involvement of pharmacists could

be influential in Egypt because of their large number *(15,16)*, which is higher than average in the Middle East and is one of the highest in the world *(17)*. Furthermore, community pharmacies are often the first point of access to affordable health care and clinical services for patients in Egypt *(18)*. However, studies to assess the practices in community pharmacy in Egypt in relation to the spread of counterfeit medicines and efforts to limit the spread are lacking.

In this study, we explored the perceptions, awareness, and practices of community pharmacists in Alexandria, Egypt with regard to counterfeit medicines. We aimed to identify specific gaps and inadequacies in the educational, regulatory and professional components of pharmacy practice that facilitate infiltration of counterfeit medicines into the legitimate medicine supply chain and affect pharmacists' involvement in efforts to control the spread of counterfeit medicines.

Methods

Study design and sample

This was a cross-sectional study of 175 randomly selected private community pharmacies in Alexandria, Egypt in 2014–2015. *Epi Info*, version 6 was used to calculate the sample size based on an expected awareness of counterfeit medicines of 50% of pharmacists, 95% confidence level, 5% level of significance, a permissible error of 5% around the expected prevalence, and a type one error of 0.05. The sample was selected using a two-stage cluster technique that involved random selection of two of the seven health administrative zones in Alexandria, Eastern and Borg Al-Arab zones. Then the number of listed private community pharmacies in each zone was selected proportionately to population size. Pharmacies received an invitation letter delivered by hand explaining the purpose of the study and importance of its outcomes. Working in a private community pharmacy (one pharmacist from each pharmacy) and at least one year of experience were the inclusion criteria.

Data collection tool

Data were collected using a semi-structured interview questionnaire. After arranging an appointment with the community pharmacies, face-to-face interviews were conducted at the pharmacies by an investigator (the first author) trained in the interview process. The questionnaire was developed in English, then translated to Arabic and back-translated to English. The final version was checked against the original version and validated by five pharmacists representing different stakeholders (community pharmacists, syndicate of pharmacists, academia, the pharmaceutical industry and the Ministry of Health and Population). Questions were divided into sections including demographic information and pharmacists' perceptions, awareness and practices with regard to counterfeit medicines. A pilot study was conducted among 25 randomly selected community pharmacists included in the main study and the reliability of the questionnaire assessed using the Cronbach alpha test. The questionnaire was slightly modified following the pilot study. Differently worded questions were used to reduce social desirability bias in responses that suggested undesirable behaviour. The Cronbach alpha was 0.73 indicating reliability of the questionnaire.

Statistical analysis

Data were analysed using SPSS, version 16.0. For knowledge- and practice-related questions, responses were scored poor, fair and good, while for attitude-related questions, responses were scored negative, neutral and positive. Frequencies, percentages, means and standard deviations (SDs) were used to describe numerical variables. The chi-squared test was used to test the statistical significance of relationships between selected personal and professional characteristics of the pharmacists and their awareness, purchasing practice and training related to counterfeit medicines. $P \leq 0.05$ was considered statistically significant.

Ethical issues

The study protocol was approved by the Research Ethics Committee of the Faculty of Pharmacy, Alexandria University (AU-PREC-8113). Informed written consent was obtained from the participating pharmacists. Participants were assured of the confidentiality of personal data, voluntary participation, and the absence of conflicts of interest.

Results

A total of 270 pharmacies were invited to participate in the survey; of these, 95 declined to participate (response rate 65%). The average interview lasted 40 minutes. Demographic characteristics of the pharmacists are given in Table 1. The mean age of the pharmacists was 36.3 (SD 13.9) years, 60.6% were male, and 61.1% were pharmacist managers.

Perception of counterfeit medicines

In a series of questions with multiple responses allowed, of the 175 pharmacists, 66.8% perceived counterfeit medicines as inactive, 61.7% as harmful and 28.6% as less effective/less expensive medicines. Only 98 of the 175 respondents (56.0 %) were familiar with the different counterfeiting methods. As shown in Table 2, most pharmacists (87 of 98) thought counterfeit medicines were products not containing an active pharmaceutical ingredient and 37 considered they were medicines with altered expiry date or label information. Based on their practice, the respondents indicated that the drug classes most likely to be counterfeited were erectile dysfunction medicines (74.9% of the 175 pharmacists), weight control medicines (43.4%), dietary supplements (39.4%) and narcotic products (29.1%) and, to a lesser extent, antibiotics, anticoagulants, cardiovascular medicines and antihistamines .

Table 1 **Characteristics of the study participants (*n* = 175)**

Characteristic	Value
Sex [No. (%)]	
Male	106 (60.6)
Female	69 (39.4)
Age (years)	
Mean	36.26 (13.92)
Range	21–73
Years of experience (range)	1–53
Educational level [No. (%)]	
Bachelor's degree	160 (91.4)
Postgraduate degree	15 (8.6)
Position [No. (%)]	
Second pharmacist	68 (38.9)
Pharmacist manager	107 (61.1)
Previous training in counterfeit medicines [No. (%)]	
Yes	8 (4.6)
No	167 (95.4)

SD: standard deviation.

As regards medicine counterfeiting in Egypt, 96% of the 175 respondents believed that the problem existed with 50% of them considering it widespread. Inadequate legislation and regulatory control by the Egyptian Drug Authority and large profits for counterfeiters were considered the main driving factors of the spread of counterfeit medicines (Figure 1). Most of the 175 respondents perceived counterfeit medicines as harmful to the national drug industry (82.9%) and public health (71.4%) while the rest (38.3%) did not perceive a threat.

Awareness of methods to detect counterfeit medicines

Most of the 175 respondents (70.3%) said that they could visually distinguish a counterfeit medicine much or some of the time. Package characteristics and appearance of the medicine were the main elements of product authenticity noted by these pharmacists. Of these 123 pharmacists, 14.6% mentioned seals and package quality, 53.6% shape, 17.1% colour, 24.4% embossing, and 69.9% product-specific authentication marks as the elements of product authenticity they recognized. Most of the pharmacists who said they could distinguish counterfeit medicines (84.6%) had developed their awareness and ability to detect counterfeit medicines through personal experience. About a third (35.0%) also relied on information provided by pharmaceutical inspectors, other pharmacists (4.9%), the Syndicate of Pharmacists (3.2%), medical representatives (2.4%) and their undergraduate education (2.4%). Only 53.1% of the 175 respondents were aware of common anti-counterfeit medicine authentication techniques; digital watermarks were the most well-known. Most of the respondents were not aware of legislation to control medicine distribution (85.1%) or reduce counterfeit medicines (88.0%). However, they identified inadequate legislation and regulatory control by the Egyptian Drug Authority as the main factor driving the spread of counterfeit medicines, and expressed the need for specific legislation on drugs with heavier penalties for counterfeiting.

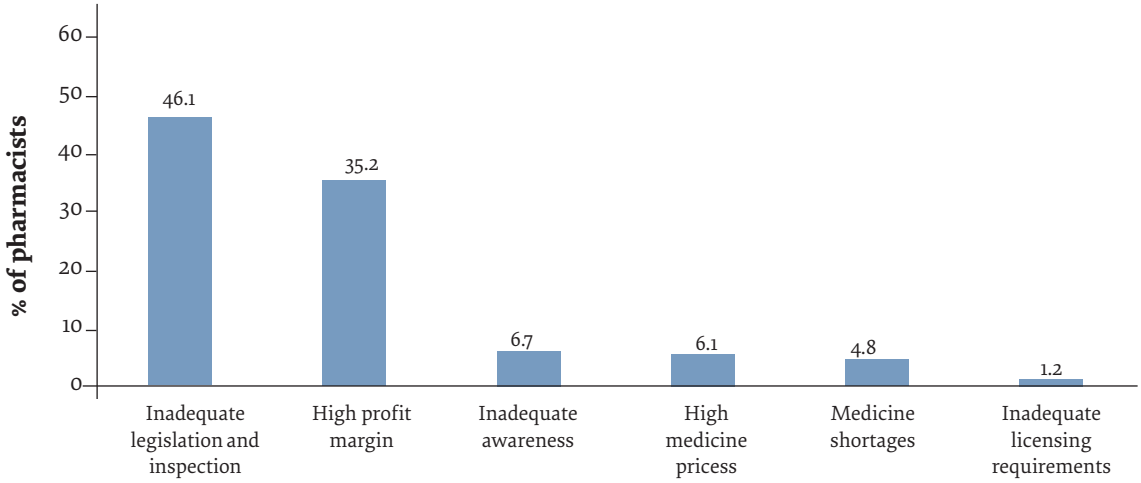
Practices related to counterfeit medicines

A large percentage of the 175 pharmacists (70.9%) verified the credibility of the supply source for medicines purchased; 20.0% did not seek verification and 9.1% did not know about it. However, most of the pharmacists (84.6%)

Table 2 **Pharmacists' perception of the categories of counterfeit medicines**

Category, medicines with:	No. (*n* = 98)
No active pharmaceutical ingredient	87
Reduced amount of active pharmaceutical ingredient	28
Low quality/price ingredients	8
Toxic materials and/or high levels of impurities and contaminants	21
Altered expiry date	21
Illegally modified label information	16

Figure 1 Pharmacists' perception of the factors driving medicine counterfeiting in Egypt (*n* = 165). More than one response was allowed

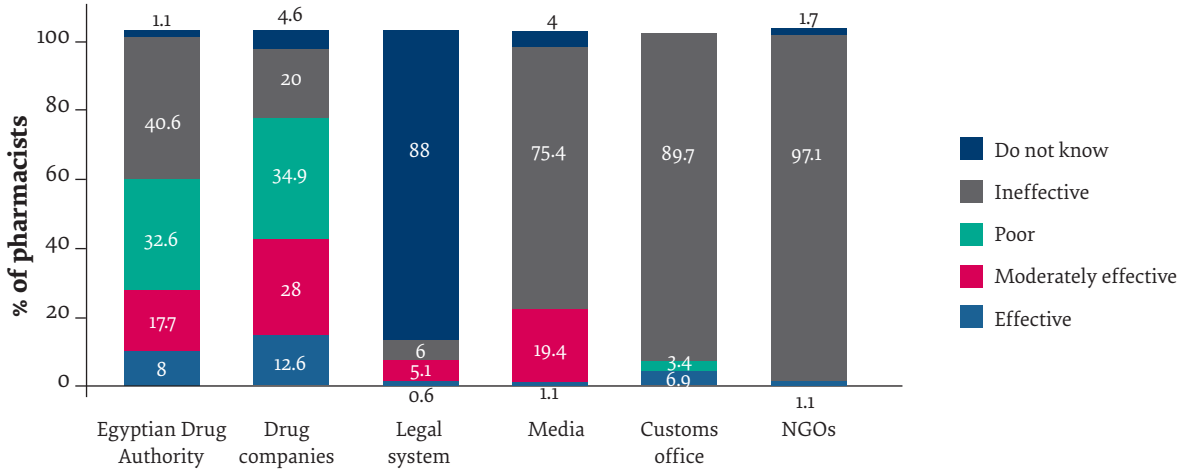


did not regularly check the batch number of received medicines against that in purchasing invoices. Almost half of the respondents (83; 47.4%) admitted stocking counterfeit medicines unintentionally. Of these 83, 50.6% reported detecting counterfeit medicines during purchase, 20.5% after stocking, 1.2% during dispensing and 21.7% after dispensing (multiple answers were allowed). Detection was based on a personal check (51.8%), customer complaints (22.9%), alerts from the Egyptian Drug Authority (16.9 %) and other pharmacists (12%) or other sources (4.8%). When encountering an incident of counterfeit medicines, 77.7% of all respondents said they returned the suspect medicine to the supplier; only 23.4% reported the incident to the Egyptian Drug Authority. Furthermore, 75.4% of all respondents said they had accepted products with modified/unusual package characteristics.

Figure 2 shows the respondents' views on the effectiveness of stakeholders' contributions to the national effort to combat counterfeit medicines. Most of the pharmacists considered the contributions of the Egyptian Drug Authority, the media, customs office, and nongovernmental organizations generally ineffective. Most did not know what role law enforcement agencies played and if they were effective. As regards pharmacists' potential contribution to combating counterfeit medicines, 78.3% believed they could make a substantial contribution while 21.7% thought that combating counterfeit medicines was not part of their job. In addition, respondents considered that their current knowledge and skills were inadequate (quality of information they have) (56.6%) or limited (amount of information they have) (26.3%) for effective contribution to reducing counterfeit medicines and they highlighted a need for educational and continuing professional development activities.

Neither the pharmacists' age nor length of practice

Figure 2 Pharmacists' views on the effectiveness of the contribution of stakeholders to the national efforts to combat medicine counterfeiting in Egypt (*n* = 175)



significantly affected their awareness of counterfeit medicines (Table 3). However, awareness of female pharmacists was significantly lower than that of their male counterparts (P = 0.020). Pharmacists who thought the problem of counterfeit medicines was widespread (P = 0.035) or was a health threat (P = 0.023) and those who had unintentionally purchased counterfeit medicines (P = 0.013) were significantly more likely to purchase medicines from sources certified by the Egyptian Drug Authority. The small number of pharmacists who attended a training course on counterfeit medicines reported a slightly greater ability to differentiate between authentic and counterfeit medicines and to report suspicious offers to the Egyptian Drug Authority; however this association was not statically significant. Furthermore, training significantly increased the pharmacists' eagerness to verify the drug supply source and purchase medicines from sources certified by the Egyptian Drug Authority.

Discussion

Pharmacists' perceptions of counterfeit medicines revealed deficiencies in professional knowledge and awareness of some aspects of medicine counterfeiting. Perceptions were not based on a clear definition of counterfeit medicines and an inability to distinguish counterfeit medicines from substandard products was reported. An unclear perception of counterfeit medicines has also been reported by pharmacists elsewhere *(19)*. In fact, lack of a worldwide consensus on a definition of counterfeit medicines and variation in the term from one country to another *(1,20,21)* may contribute to an imprecise understanding among health professionals. Pharmacists' awareness of methods of medicine counterfeiting was limited, which is worrying. Nonetheless, their perception that erectile dysfunction products were the most likely to be counterfeited is in line with the high demand for such products in Egypt *(22)* and worldwide. In addition, most of the pharmacists considered that inadequate legislation and large profits were the main reasons for the spread of counterfeit medicines, which is consistent with global views *(1,23–25)*. That most pharmacists recognized that counterfeit medicines existed in Egypt and half considered it a widespread problem could be a first step towards their effective involvement in combatting this problem.

Responses in the second section of the questionnaire revealed that pharmacists relied mainly on their personal experience to develop awareness and skills to detect counterfeit medicines in the pharmacy. As expected, pharmacists' ways to detect counterfeit medicines were limited to common packaging/labelling authentication features, which implies they lack sufficient skills and funds to improve their capability to detect counterfeit medicines in the pharmacy. Similar responses have been reported by pharmacists in both developing and developed countries *(26,27)*. Furthermore, inadequate awareness of the pharmacists of current legislation in Egypt on anti-counterfeiting of medicines and medicine distribution is disturbing as this lack of knowledge may greatly affect their attitudes and practices. However, respondents stressed the urgent need for specific drug legislation with heavier anti-counterfeiting penalties. In fact, the current law in Egypt does not address the underlying public health threat of counterfeit medicines and has lenient penalties such as small fines (the equivalent of US$ 1100 to 2780) and a two-year prison sentence. The adoption of a specific law on counterfeit medicines with heavy penalties was the recommendation of a study in Hong Kong that reviewed regulations and court cases related to counterfeit drugs and conducted in-depth interviews with stakeholders *(23)*.

The purchasing procedures for medicines of the pharmacists were worrying. Even though the Egyptian Drug Authority certifies drug sources, about a fifth of the respondents used uncertified sources, justifying their practice because of a greater profit margin, uninterrupted medicine supply and physician or patient satisfaction. A similar practice was reported by more than

Table 3 Association between personal or professional characteristics of the pharmacists and their awareness, purchasing practice and training related to counterfeit medicines

Variable	P-value[a]
Awareness	
Age	0.406
Gender	0.020
Years of experience	0.275
Purchasing medicine from certified sources	
Perception of the spread of counterfeit medicines in Egypt	0.035
Perception of the health threat of counterfeit medicines	0.023
Unintentional purchase of counterfeit medicines	0.013
Training on counterfeit medicines	
Ability to differentiate between authentic and counterfeit medicines	0.696
Reporting unsolicited suspicious medicine offers to the Egyptian Drug Authority	0.070
Verification of credibility of medicine supply source	0.001

[a]*Chi-squared. P < 0.05 indicates statistical significance.*

50% of pharmacists in a study in the Islamic Republic of Iran *(28)*. This practice, together with insufficient skills to detect counterfeit medicines, greatly increases the risk of bringing unsafe medicines into the pharmacy. Thus, pharmacists need to be educated in the dangers of counterfeit medicines and that they need to refer to, among other resources, guidance and drug purchasing guidelines of the Egyptian Drug Authority *(29)*, WHO checklist *(30)* and other guidance publications *(31–33)*. At the same time, ensuring secure business practices, and establishing an accreditation system of wholesale distributors and an inventory management system to avoid drug shortages should minimize the perceived need to use uncertified sources *(34)*.

Another alarming practice was the unintended stocking of counterfeit medicines by almost half of the respondents. A similar trend has been reported in other developing countries *(26,28)*. In contrast, a survey of pharmacists in California, United States of America, indicated a much lower incidence stocking counterfeit medicines *(27)*, which highlights the relationship between strong regulatory control and the extent of infiltration of counterfeit medicines into the legitimate supply system and good medicine purchasing practices.

Detection of the presence of counterfeit medicines after stocking and dispensing and the fact that pharmacists often lack the skills to identify counterfeit medicines and rely mostly on customer complaints implies that counterfeit medicines are reaching the patient. This presents a real threat particularly for life-saving drugs as well as drugs that produce a therapeutic response which cannot be easily perceived by the patient. Examples of the latter group of drugs include drugs used in prophylactic or preventive therapies or drugs with a delayed therapeutic effect such antidepressant drugs.

If pharmacists suspected a counterfeit medicine, about three quarters returned it to the supplier to avoid loss of the capital invested in the purchase. A similar trend was reported by 80% of pharmacists in a survey in Nigeria *(26)*. Furthermore, the majority of respondents said that they had accepted products with modified/unusual packaging because they believed such modifications had been introduced by the manufacturer without notification. Such poor practices may prevent seizure of the suspect product and the issuance of a drug alert or recall notice and encourage further redistribution, which necessitates enhancement of partnership among stakeholders. Pharmacists must be urged to use relevant guidelines *(35)* for handling and reporting incidents of counterfeit medicines. In addition, pharmacists should educate patients about counterfeit medicines and identify and reach out to patients who might have received a product suspected to be counterfeit after being dispensed.

Although stakeholder partnership was generally considered ineffective by our pharmacists, it was encouraging that most of them believed that they could make a substantial contribution to the national effort to combat counterfeit medicines if they were partnered with and received relevant professional development. A small percentage of respondents thought that combating counterfeit medicines was not part of their job mainly because they would be unable to effectively detect counterfeit medicines. This was consistent with views expressed by 18% of pharmacists surveyed in the Islamic Republic of Iran *(28)*.

Increasing pharmacists' awareness of different aspects of counterfeit medicines and their involvement in continuing professional development activities would greatly enhance their contribution to combating efforts.

Our study has several strengths. The sample included pharmacists from two large health administrative zones in Alexandria. Pharmacists were addressed in their native language, Arabic. Furthermore, an interview-supported questionnaire allowed ambiguous or interesting responses to be transcribed and provided flexibility to explore relevant issues. The study limitations related to pharmacists' concerns of their rights, confidentiality of responses, the time spent to complete the interview and the nature of the study topic. Replication of the study in different parts of Egypt is recommended to test generalizability of our findings.

Conclusion

The perceptions, awareness, and practices of community pharmacists in Alexandria towards counterfeit medicines revealed deficiencies that make the current pharmacy system, legislation, and stakeholder partnership not well able to safeguard patient safety. In the current pharmacy practice environment, pharmacists need to be professionally developed as a frontline resource to actively combat counterfeit medicines. This is a responsibility most of our respondents were willing to assume. To enhance pharmacists' role in tackling counterfeit medicines, the pharmacy curriculum needs to be updated and continuing profession development activities mandated. At the same time, a national strategy to tackle counterfeit medicines is needed backed by strong legislation on drug distribution and counterfeiting. A recently instituted Egyptian Medicines Administration responsible for establishing national standards responsible for establishing national standards for drug importation, manufacture, registration, distribution, tracking, inspection and recall will greatly contribute to preventing counterfeit medicines. Promotion of partnerships between stakeholders and collaboration with international organizations are also essential. More research should be undertaken to explore gaps in different components of the current pharmacy practice system and to document progress.

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Perceptions, connaissances et pratiques des pharmaciens d'officine à l'égard des médicaments contrefaits : étude transversale à Alexandrie (Égypte)

Résumé

Contexte : La contrefaçon de médicament constitue une menace pour la santé publique et l'économie nationale en Égypte. Les nombreux pharmaciens d'officine du pays pourraient contribuer à empêcher les médicaments contrefaits de parvenir jusqu'aux patients. Les informations relatives aux perceptions des pharmaciens d'officine quant à la contrefaçon de médicament font défaut.

Objectifs : La présente étude visait à évaluer les perceptions, les connaissances et les pratiques des pharmaciens d'officine d'Alexandrie (Égypte) à l'égard des médicaments contrefaits. L'objectif était d'identifier les lacunes et les insuffisances dans la pratique pharmaceutique susceptibles de permettre l'infiltration de médicaments contrefaits dans la chaîne d'approvisionnement des médicaments licites.

Méthodes : Une étude transversale a été menée auprès de 175 pharmaciens d'officine à Alexandrie durant la période comprise entre 2014 et 2015. Un questionnaire d'entretien semi-structuré a été utilisé pour évaluer leurs perceptions, connaissances et pratiques. Le test khi carré a été utilisé pour évaluer les liens entre les caractéristiques de certains pharmaciens et leurs connaissances, leurs pratiques d'achat et leur formation en association avec les médicaments contrefaits.

Résultats : La plupart des pharmaciens pensaient que la contrefaçon de médicament était répandue en Égypte et qu'ils pouvaient contribuer à lutter contre ce problème. Cependant, ils n'avaient pas non plus pour la plupart de perception claire de la contrefaçon de médicament, de connaissance du danger qu'elle représente pour les patients, ni de la législation en vigueur pour la limiter. Par ailleurs, leurs pratiques d'approvisionnement en médicaments, leur détection des médicaments contrefaits et leur gestion des incidents relatifs à la contrefaçon de médicament étaient inadaptées. Les pharmaciens qui pensaient que les médicaments contrefaits étaient répandus ou représentaient une menace pour la santé étaient beaucoup plus susceptibles d'acheter les médicaments auprès de sources certifiées ($p < 0,05$).

Conclusion : Les pharmaciens devaient être placés en première ligne de lutte contre la contrefaçon de médicament. Pour renforcer leur rôle, le programme d'études de pharmacie doit être mis à jour, et des activités de formation professionnelle continue doivent être rendues obligatoires.

مفاهيم الصيادلة المجتمعيين ودرجة وعيهم وممارساتهم فيما يتعلق بالأدوية المزيفة: مسح مقطعي في الإسكندرية، مصر

أميرة بشير، سالي جلال ، علياء رمضان، أشرف وهدان، لبيبة الخردجي

الخلاصة

الخلفية: تشكل الأدوية المزيفة خطرا يحدق بالصحة العامة والاقتصاد القومي في مصر. ويمكن للكثير من الصيادلة المجتمعيين المساعدة في الوقاية من وصول الأدوية المزيفة إلى المرضى. وتغيب المعلومات حول اتجاهات الصيادلة المجتمعيين بشأن الأدوية المزيفة.

الأهداف: قيّمت هذه الدراسة درجة وعي الصيادلة المجتمعيين، وممارساتهم، واتجاهاتهم بشأن الأدوية المزيفة في الإسكندرية، بمصر. وتمثل الهدف في تحديد الفجوات وأوجه النقص في الممارسات الصيدلانية التي قد تؤدي إلى تسلل الأدوية المزيفة إلى سلسلة إمداد الأدوية المشروعة.

طرق البحث: أُجريت دراسة مقطعية شملت 175 صيدليا مجتمعيا في الإسكندرية عامي 2014 و 2015. واستُخدم استبيان شبه منظم قائم على المقابلات من أجل تقييم تصورات أولئك الصيادلة، ودرجة وعيهم وممارساتهم. واستُخدم اختبار "مربع كاي" لتقييم العلاقات بين بعض خصائص الصيادلة المختارة ودرجة وعيهم، وممارساتهم الشرائية، وتدريبهم فيما يتعلق بالأدوية المزيفة.

النتائج: كان لدى معظم الصيادلة اعتقاد بأن تزييف الأدوية واسع الانتشار في مصر، وأنهم بإمكانهم المساهمة في مكافحة تلك المشكلة. وبالرغم من

ذلك، فقد افتقد أغلبهم التصور الواضح بشأن الأدوية المزيفة، والوعي بخطورتها على المرضى، أو التشريعات التي تحد منها. وغلب القصور على ممارساتهم الشرائية واكتشافهم للأدوية المزيفة وكيفية التعامل مع مواقف انطوت عليها. وبالنسبة للصيادلة الذين يعتقدون أن الأدوية المزيفة منتشرة على نطاق واسع وأنها تمثل خطرا على الصحة، فقد ازدادت احتمالية شرائهم الأدوية من مصادر معتمدة (p <0.05)،

الاستنتاج: ينبغي تنمية قدرات الصيادلة ليكونوا في صدارة جهود مكافحة الأدوية المزيفة. ولتعزيز الدور الذي يضطلعون به، ينبغي تحديث المناهج الدراسية بكليات الصيدلة وتكليفهم بأنشطة للتطوير المهني المستمر.

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Predictors of the burden on family carers of patients on haemodialysis in Jordan

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Abstract

Background: Family caregivers of patients on haemodialysis can experience life changes and depression.

Aims: This study assessed the self-perceived burden on their family caregivers of haemodialysis patients in Jordan, and the caregivers' perceived burden of caregiving and depression. The predictors of caregiver outcomes were determined.

Methods: This cross-sectional study included 190 patients on haemodialysis and their caregivers in Jordan. Patients' self-perceived burden on their caregivers was assessed using the self-perceived burden scale. For caregivers, burden was assessed using the Oberst caregiving burden scale and Bakas caregiving outcomes scale – difficulty subscale. Caregivers' depression was assessed using the patient health questionnaire-9. Mean scores and standard deviations (SD) were calculated. Multiple regression analysis was done to determine the predictors of caregiver outcomes.

Results: Patients thought that they were a moderate to severe burden on their caregivers (mean score 36.31, SD 3.48). Caregivers perceived themselves as moderately burdened, and thought that their lives had changed for the worse because of caregiving (mean score 2.82, SD = 0.98). Caregivers were moderately depressed (mean score 1.80, SD 0.42). Multiple regression analysis showed that the perceived difficulty of caregiving tasks and patients' self-perceived burden predicted the caregiver outcomes. The difficulty of caregiver tasks explained 38% of the overall variance in the caregiver outcomes. Patient's self-perceived burden on their caregivers explained 16.4% of the variance.

Conclusion: Factors that affect the burden on caregivers of dialysis patients should be identified and interventions considered to support caregivers and reduce this burden.

Keywords: renal dialysis, caregiver, burden, depression, Jordan

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Introduction

In Jordan, the number of people with end-stage renal disease who receive dialysis in 2016 increased to 5130 *(1)*. Most of these people (5048, 98%) received haemodialysis and 2% received peritoneal dialysis *(1)*. However, the number of sessions a week varied between patients: 2% received treatment four times a week, 71% received treatment three times a week, 26% twice a week and 1% once a week, with the average duration of the treatment session being about four hours *(1)*. Therefore, family members, including spouses and children, or friends, usually provide care for people on dialysis, which can be a challenge *(2)*. Factors that can affect the burden on caregivers include patient characteristics and caregiver-related factors *(3)*.

Data on family caregivers for people with chronic kidney disease are not yet available in Jordan *(1)*. However, the prevalence of haemodialysis is increasing and family members often have to take over the responsibility of care for the person receiving dialysis. According to Jordanian culture and traditions, family members have a commitment to caring for the sick *(4)*.

Previous studies indicate that family caregivers can suffer from depression as a result of caregiving. A study in Turkey found that the burden on caregivers has a direct effect on the quality of the caregiving delivered *(5)*. The study further reported that emotional and psychological distress were common in caregiver spouses in relation to their cultural and traditional values. Other studies in Turkey reported that caregivers perceived that the burden of caring for people on haemodialysis was high *(6,7)*. A more recent study also found that most patients with kidney disease and their family caregivers were depressed *(8)*. Depression in people on dialysis was associated with their socioeconomic and marital status, while the socioeconomic status of caregivers was associated with caregivers' depression *(8)*.

Another study reported that the burden of caregiving was associated with the perceived difficulty of the tasks the caregiver was required to do and this burden strongly predicted caregiver depression *(9)*. However, a study in Saudi Arabia found that caring for people receiving haemodialysis was a subjective burden that contributed to depression, social isolation, financial constraints and declining physical health *(10)*. Furthermore, the demands associated with the provision of care for people on dialysis may result in caregivers making ineffective decisions that could adversely affect the way the caregiver manages the personal health needs of the person on dialysis *(5)*.

The family caregiver burden in primary care clinics is linked to psychological, socioeconomic, and physical consequences *(11,12)*. However, the quality of life of family caregivers of patients on haemodialysis tends to be neglected, although they are distressed emotionally, financially and psychologically *(13)*. The burden on caregivers of dialysis patients has been acknowledged in recent investigations in the Middle East *(4,10)*.

The burden on family caregivers of haemodialysis patients in Jordan is likely to be substantial because of the challenges that caregivers and patients face. However, the extent of the burden is not known. The aim of this study therefore was to investigate: (i) self-perceived burden of patients' receiving haemodialysis on their caregiver, (ii) the burden the caregivers themselves felt, (iii) depression in the caregivers and (iv) the predictors of caregiving burden and depression in caregivers.

Methods

Design, sampling, participants and procedures

This was a cross-sectional survey of people on haemodialysis and their family caregivers. A non-probability purposive sampling technique was used to select participants for this study. I approached the directors of four outpatient haemodialysis units in two large cities in Jordan before starting the study and explained its purpose. After receiving permission from the unit director, two volunteer nurses approached patients on dialysis who had family caregivers to enquire if they would be willing to participate in the study. The research staff approached 204 patients who had unpaid family caregivers. Out of the 204 patients, 199 (97.5%) agreed to participate paired with their caregivers. Of the 199 patients, five patients did not meet the inclusion criteria. Out of the194 eligible patients and their respective caregivers, four (2%) patients and their caregivers withdrew before the beginning of the data collection. Patients' inclusion criteria: were 21 years of age and older, were able to read and write, had been on haemodialysis for one year or more and had an unpaid family caregiver. The caregivers were required to meet the following inclusion criteria: were unpaid, were able to read and write, were 21 years or older, lived with or near the patient on dialysis and had been providing care for at least one year.

Data collection

This study was conducted from January 2017 to August 2017. The author met the participants at the outpatient haemodialysis units in two cities in Jordan. After explaining the purpose of the study, participants (patients and caregivers) gave written consent to participate. Patients' characteristics were recorded (age, sex, duration of dialysis) and they completed the self-perceived burden scale *(14)*. The family caregivers' characteristics were recorded (age, sex, education, employment, relation to patient, duration of caregiving and means of transport) and they completed the Oberst caregiving burden scales *(15)*, Bakas caregiving outcomes scales *(16)* and patient health questionnaire-9 *(17)*. Participants were provided with the researcher's phone number if they had any questions about the forms. A box was placed at each dialysis unit for the caregivers to drop off the completed forms.

Patients' self-perceived burden

Patients' self-perceived burden was assessed using the self-perceived burden scale *(14)*, which is a reliable and valid 10-item scale developed for people on haemodialysis to evaluate their feelings about being a burden on their caregivers. Each item was scored on a 5-point response scale, where 1 = none of the time, 2 = a little of the time, 3 = some of the time, 4 = most of the time and 5 = all of the time. A higher total score indicates a higher level of patients' self-perceived burden.

The scores ranged from 0 to 50. The level of subjective burden scoring was categorized as follows: < 19 = no to little burden, 20–29 = mild to moderate burden, 30–39 = moderate to severe burden and > 40 = very severe burden, as previously suggested *(2,18)*. The Cronbach alpha of the 10 items was 0.85 *(14)*; for this study, it was 0.77.

Caregivers' burden

Caregivers' burden was measured by the Oberst caregiving burden scale – difficulty subscale *(15)* and the Bakas caregiving outcomes scale *(16)*. The Oberst scale is a 15-item scale that was developed to assess caregivers' perception of the difficulty of the tasks associated with caregiving. All the items are judged based on the difficulty of each item (responses to the difficulty subscale were: 1 = not difficult, 2 = slightly difficult, 3 = moderately difficult, 4 = very difficult and 5 = extremely difficult). A higher score indicates the greater perceived difficulty associated with caregiving tasks. The Cronbach alpha for the 15 items is 0.94 for difficulties *(15)*; for this study, it was 0.80.

The Bakas scale is a 15-item questionnaire that measures life changes in family caregivers. The items address changes in social function, subjective well-being and physical health as a result of caring for a family member. The items were scored on a 7-point scale with the responses ranging from: 1 = change for the worse to 7 = change for the better, and 4 = no change. A score of more than 4 indicates that the caregiver perceives his/her life has changed for the better; a score less than 4 indicates that life has changed for the worse *(16)*. The Cronbach alpha for the revised 15-item scale is 0.90 *(16)*; for this study, it was 0.88.

Caregiver's depressive symptoms

Depressive symptoms were measured using the patient health questionnaire – 9 *(17)*. This questionnaire is a 9-item scale that measures depressive symptoms in the past two weeks. The items are scored on a 4-point scale (0 = not at all (on no days), 1 = several days, 2 = more than half of the days and 3 = nearly every day). The total score ranges from 0 to 27 and a higher score indicates that the caregiver is more depressed. The severity index of depression score is categorized as follows: mild (5–9), mod-

erate (*10–14*), moderate to severe (*15–19*) and severe (*20*). The Cronbach alpha for PHQ-9 is 0.88 *(17)*; it was 0.80 for this study.

All the questionnaires were translated from English into Arabic in accordance with proposed guidelines for adaptation of health-related quality of life measures *(19)*. A pilot study was conducted on 12 patients and caregivers using the translated questionnaires to evaluate the feasibility of the scales. Participants indicated that there were unclear items in four questionnaires. The scales were reviewed by experts to ensure the appropriateness of the content and the items were rephrased in Arabic. A second pilot study was conducted on 10 different patients and caregivers. There was a marked improvement in the caregivers' understanding of the items as reflected by a decline in requests for clarifications of the meaning of statements and by the data analysis of the scale. The time to complete all the questionnaires, which was also estimated during the pilot studies, ranged between 20 and 30 minutes.

Data analyses

Descriptive statistics (mean and standard deviation (SD) and percentage) were calculated to describe the sociodemographic characteristics of patients and caregivers. Mean (SD) scores on questionnaires were calculated. Multiple regression analyses were also done to predict caregiving outcomes (perceived life changes) as a function of caregivers' burden using patients' self-perceived burden, difficulty of caregiving tasks and depressive symptom scores. The difficulty of caregiving tasks, self-perceived burden and depressive symptoms were used as dependent and independent variables since they are strong predictors of caregiving outcomes. Multiple regression analysis was done to assess the associations between perceived life changes, task difficulty, patients' self-perceived burden and caregiver depression.

A *P*-value less than 0.05 was considered statistically significant. Data were analysed using *SPSS*, version 21.0.

Ethical considerations

The study was approved by the internal review boards of the participating hospitals, and all participating patients and caregivers gave their informed consent. Participants were informed that they could withdraw from the study at any time for any reason and their names were kept confidential.

Results

The study included 190 people on dialysis and their caregivers. Their sociodemographic characteristics are shown in Table 1. The mean ages of the patients and caregivers were 63.62 (SD 8.79) years and 42.44 (SD 11.18) years respectively. Almost two thirds (65%) of the patients were male as were just over half (54%) of the caregivers.

The mean (SD) scores of the patients and caregivers on the questionnaires are given in Table 2. The mean score of patients on the patient self-perceived burden questionnaire was 36.31 (SD 3.48), indicating that the patients felt they were a moderate burden on their caregivers. Fourteen (7.4%) patients were mildly burdened, 135 (71%) were moderately burdened, 38 (20.0%) were moderately to severely burdened and 3 (1.6%) were very severely burdened.

The mean score on caregivers' perception of the difficulty of caregiving tasks was 3.01 (SD 0.31), indicating that caregivers felt moderately burdened by their caregiving. The mean score on the change to their life perceived by the caregivers was 2.82 (SD 0.98), which means that, overall, caregivers perceived their lives had changed for the worse. The mean score of caregivers on the depressive symptom scale was 1.80 (SD 0.42) and 71% of caregivers were moderately depressed.

Multiple regression analyses

Table 3 shows the predictors of the caregiver's perceived life changes. Caregivers' perception of the difficulty of their tasks was a statistically significant predictor of caregiver life changes ($R = 0.62$, $P < 0.001$). In addition, R^2 was 0.38, indicating that caregiver's perception of the difficulty of the caregiving tasks was the most significant predictor, explaining 38.0% of the variance of the life changes perceived by caregivers as a result of caregiving.

Patients' self-perceived burden was also significantly associated with life changes for the caregiver ($R = 0.40$, $P = 0.002$). Furthermore, R^2 was 0.164, indicating that the patients' self-perceived burden explained 16.4% of the variance of the life changes perceived by caregivers as a result of caregiving. However, depression in caregivers was not significantly associated with caregivers' life changes.

Table 4 shows four factors of caregivers' perceived task difficulty that predicted the caregiving outcome. Medical or nursing treatments ($P < 0.001$) and providing transportation ($P = 0.04$) were significant predictors of negative caregiver outcomes; an increase in the medical or nursing treatments and providing transportation decreased caregiving outcomes indicated a life change for the worse. However, assistance with personal care ($P < 0.001$) and structuring/planning activities ($P = 0.02$) were associated with positive caregiver outcomes: an increase in the assistance with personal care and structuring/planning activities increased the caregiving outcomes, indicating a life change for the better.

Table 5 presents three factors of patients' self-perceived burden on their caregiver that predicted the caregiving outcomes. The patient's worry that the caregiver was overextending him/herself in providing care was a predictor of negative caregiver outcomes ($P = 0.02$); the greater the patients' worry about caregivers' overextending themselves in helping, the greater the decrease in caregiving outcomes, indicating a life change for the worse. However, patient's belief that they made things hard for their caregiver and that they were a burden of their caregiver were a predictor of positive caregiving outcomes ($P = 0.01$), indicting a life change for the better for the caregiver.

Table 1 Demographic characteristics of the patients (*n* = 190) and caregivers (*n* = 190)

Patient characteristics	Value
Patient age (years), mean (SD)	63.62 (8.79)
Patient sex, no. (%)	
Male	124 (65)
Female	66 (35)
Years on haemodialysis, mean (SD)	4.99 (2.98)
Caregiver characteristics	
Caregiver age (years), mean (SD)	42.44 (11.18)
Caregiver sex, no. (%)	
Male	103 (54)
Female	87 (46)
Duration of caregiving (years), mean (SD)	4.30 (2.65)
Travelling time for one round trip (hours), mean (SD)	68.18 (17.58)
Means of transport, no. (%)	
Private car	67 (35)
Taxi	22 (12)
Public transport	59 (31)
Carpool	42 (22)
Caregiver's education, no. (%)	
High school and below	66 (35)
Community college	48 (25)
University/graduate school	76 (40)
Caregiver's employment, no. (%)	
Yes	73 (38)
No	117 (62)
Caregiver's relation to patient, no. (%)	
Spouse	62 (33)
Son	72 (38)
Daughter	52 (29)

SD: standard deviation.

Table 2 Descriptive statistics of the patient and caregiver burden

Variable	Mean scores (SD)
Patient's self-perceived burden	36.31 (3.48)
Caregiving burden	
Caregiver's perceived tasks difficulties	3.01 (0.31)
Perceived life changes in family caregivers	2.82 (0.98)
Depressive symptoms	1.80 (0.42)
	No. (%)
Severity of patients' perceived burden (n = 190)	
Mild	14 (7.4)
Moderate	135 (71.0)
Moderate to severe	38 (20.0)
Very severe	3 (1.6)

SD: standard deviation.

Table 3 Multiple regression analysis of the associations between life changes in family caregivers, perceived task difficulty, perceived burden and caregiver depression

Variable	Unstandardized B	Unstandardized SE	Standardized B	R	R^2	Adjusted R^2	*P*-value
Caregiver's perceived task difficulty [a]	−0.160	0.046	0.151	0.621	0.380	0.29	< 0.001
Patient's self-perceived burden on caregiver [b]	−0.072	0.038	−0.100	0.405	0.164	0.108	0.002
Caregiver depression [c]	−0.038	0.067	−0.044	0.125	0.016	0.002	0.453

B: beta coefficient, SE: standard error,

[a]*Dependent variables: caregiving outcomes and patient's self-perceived burden.*

[b]*Dependent variables: caregiving outcomes and caregiver's perceived task difficulty.*

[c]*Dependent variables: caregiving outcomes, caregiver's perceived task difficulty and patient's self-perceived burden.*

Table 4 Association between factors of caregiver's perception of the difficulty of tasks and caregiving outcomes: regression analysis

Perceived task difficulty	Unstandardized coefficients		Standardized coefficient	*t*	*P*-value
	B	SE	B		
Constant	3.55	0.35		10.17	< 0.001
Medical or nursing treatments	−0.11	0.04	−0.25	−2.92	< 0.001
Assistance with personal care	0.11	0.03	0.33	3.71	< 0.001
Providing transportation	−0.06	0.03	−0.18	−2.13	0.04
Structuring/planning activities	0.07	0.03	0.19	2.33	0.02

B: beta coefficient, SE: standard error.

P < 0.05 was considered statistically significant.

Discussion

This study investigated patients' self-perceived burden on their caregiver, caregivers' burden, caregiver depression and the predictors of caregiving outcomes (e.g. social function, subjective well-being and health as a result of providing care for a family member). The results of this study are in line with previous studies that found that patients perceived their burden on caregivers to be moderate to severe, caregivers perceived their burden of caregiving to be moderate and caregivers were mildly depressed *(2,3)*.

The multiple regression analysis showed that the tasks perceived to be difficult by the caregiver – providing medical or nursing treatment and transportation – were significant independent predictors of worse caregiving outcomes. These results indicate the importance of assessing both patients' and caregivers' understanding and knowledge of patients receiving haemodialysis, and assessing patients' and caregivers' need for transportation to the dialysis units and physician appointments. The other tasks perceived to be difficult – assistance with personal care and structuring/planning activities – were significant predictors of positive caregiver outcomes over time (life change for the better). This positive finding in the caregiver outcomes indicates a decrease in the caregiver burden which will enable the caregiver to continue providing care for their family member. The caregiving task-related factors explained 38.0% of the overall variance in the caregiving outcomes, while patient's self-perceived burden explained 16.4% of the variance in the caregiving outcomes.

Notably, the greater the patient's belief that his/her caregiver was overextending him/herself in providing care, the more the caregiving outcomes were negative. However, the patient's belief that he/she made things hard for the caregiver and that he/she was a burden on the caregiver predicted more positive caregiving outcomes. These findings reflect the influence of the patients' self-perceived burden on the caregiving outcomes. Assessing patients' sense of perceived burden and improving the caregiving outcomes by identifying patients' and caregivers' roles and relationship is beneficial in the assessment process for future intervention. However, in a qualitative study on end of life patients, the patients' self-perceived burden main themes were: "concern for others", the physical, social and emotional burden patients feel they impose on caregivers, and "implications for self", reflecting patients' thoughts and feelings about being a burden to others resulting in patients' burden and distress *(20)*. The results of the present study highlight that patients' self-perceived burden and caregivers' burden are interrelated and of concern since the burden is as a result of chronic illness and its treatment.

Although caregivers in the current study were moderately depressed, depression symptoms in caregivers were not a significant predictor of patients'

Table 5 Association between factors of patient's self-perceived burden on their caregiver and caregiving outcomes: regression analysis

Patient's self-perceived burden	Unstandardized coefficients		Standardized coefficients	t	P-value
	B	SE	B		
Constant	2.40	0.36		6.65	< 0.001
Worry that my caregiver is overextending him/herself in helping me	−0.06	0.03	−0.20	−2.30	0.02
Think that I make things hard for my caregiver	0.08	0.03	0.21	2.79	0.01
Feel that I am a burden on my caregiver	0.11	0.04	0.21	2.74	0.01

B: beta coefficient, SE: standard error.

P < 0.05 was considered statistically significant.

self-perceived burden or caregivers' perceived burden. This finding contradicts the hypothesis that higher rates of depression symptoms would be a predictor of caregiver burden *(8,9)*. The present study had a cross-sectional design and therefore conclusions cannot be drawn on causation. However, the results confirm that caregivers were depressed and needed management to minimize depression.

This study has some limitations. As a cross-sectional study, cause and effect cannot be determined. The selection of patients and caregivers did not include haemodialysis units in the northern or southern parts of the country and did not include patients who had paid caregivers, which might cause a bias that could influence the caregiving outcomes. The results cannot therefore be generalized to all caregivers of patients receiving haemodialysis in Jordan, and future research should include a wider and more representative sample. The use of a non-probability sampling technique is also a limiting factor for the generalizability of the findings beyond the study sample.

Patients and any family member providing care should be included in patient assessment and decisions about treatment. The assessment should include caregivers' social function, subjective well-being and physical health. Such practice may help haemodialysis units to establish and implement interventions that reduce caregiver and patient burden.

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Facteurs prédictifs de la charge pour les aidants familiaux de patients sous hémodialyse en Jordanie

Résumé

Contexte : Les aidants familiaux de patients sous hémodialyse peuvent être confrontés à des changements de vie et à la dépression.

Objectifs : La présente étude visait à évaluer la charge pour les aidants familiaux telle que perçue par les patients sous hémodialyse en Jordanie, ainsi que la charge perçue par les aidants eux-mêmes par rapport aux soins et à la dépression. Elle a permis de déterminer les facteurs prédictifs de l'impact pour les aidants.

Méthodes : Cette étude transversale comprenait 190 patients sous hémodialyse et leurs aidants en Jordanie. La charge pour les aidants familiaux telle que perçue par les patients a été évaluée à l'aide de l'échelle d'auto-perception de la charge. Concernant les aidants, l'évaluation a été réalisée à l'aide de l'échelle d'Oberst, qui évalue la charge pour les aidants, et de l'échelle de Bakas, qui mesure l'impact pour les aidants, à travers la sous-échelle des difficultés. La dépression chez les aidants a été évaluée à l'aide du questionnaire de santé des patients à 9 items. Les scores moyens et les écarts-types (ET) ont été calculés. L'analyse de régression multiple a été réalisée afin de déterminer les facteurs prédictifs de l'impact pour les aidants.

Résultats : Les patients estimaient représenter une charge modérée à sévère pour leurs aidants (score moyen : 36,31 ; ET : 3,48). Les aidants percevaient quant à eux la charge comme modérée et estimaient que leur vie avait empiré du fait de leur rôle d'aidant (score moyen : 2,82, ET : 0,98). Les aidants étaient modérément déprimés (score moyen : 1,80 ; ET : 0,42). L'analyse de régression multiple a montré que la difficulté perçue relativement aux tâches liées à la prise en charge et la charge perçue par les patients eux-mêmes étaient des facteurs prédictifs de l'impact pour les aidants. La difficulté des tâches liées à la prise en charge expliquait 38 % de la variance globale dans la mesure de l'impact pour les aidants. La charge pour les aidants telle que perçue par leurs patients expliquait 16,4 % de la variance.

Conclusion : Les facteurs influant sur la charge pour les aidants de patients sous dialyse devraient être identifiés, et des mesures devraient être envisagées afin de fournir un appui aux aidants et de réduire cette charge.

العوامل الـمُنبئة بالعبء الذي يتحمله أفراد الأسرة الذين يقدمون الرعاية لمرضى غسيل الكلى في الأردن

إيمان خميس النزلي

الخلاصة

الخلفية: قد يتسبب تقديم أفراد الأسرة الرعاية لمريض غسيل الكلى في تغيير حياتهم وإصابتهم بالاكتئاب.

الأهداف: هدفت هذه الدراسة إلى تقييم العبء المدرك ذاتيا لدى أفراد الأسرة من مقدمي الرعاية لمرضى غسيل الكلى في الأردن، وكذلك العبء المُدرك الواقع على عاتق مقدمي الرعاية جرّاء تقديم الرعاية والإصابة بالاكتئاب. كما حددت الدراسة العوامل الـمُنبئة بالمخرجات الخاصة بمقدم الرعاية.

طرق البحث: تضمنت هذه الدراسة المقطعية 190 مريضا يقومون بغسيل الكلى بالإضافة إلى مقدمي الرعاية لهم في الأردن. وقيمت الدراسة العبء الذي يدرك المرضى بأنفسهم وقوعه على عاتق مقدمي الرعاية، وذلك باستخدام مقياس العبء المدرك ذاتيا. وبالنسبة لمقدمي الرعاية، فقد قيمت الدراسة العبء باستخدام مقياس "أوبيرست" للعبء الناجم عن تقديم الرعاية ومقياس "باكاس" لمخرجات تقديم الرعاية – والمقياس الفرعي للصعوبة. وقُيِّمت إصابة مقدمي الرعاية بالاكتئاب باستخدام استبيان صحة المرضى9-. واحْتُسب كل من متوسط الدرجات والانحراف المعياري. وأُجري تحليل انحدار متعدد المتغيرات لتحديد العوامل المُنبئة بمخرجات مقدمي الرعاية.

النتائج: اعتقد المرضى بأنهم يمثلون لمن يقدمون الرعاية لهم عبئا يتراوح بين المتوسط والشديد (متوسط الدرجة 36.31، بانحراف معياري 3.48). بينما رأى مقدمو الرعاية أن العبء الملقى عليهم متوسط في شدته، كما اعتقدوا أن حياتهم تغيرت للأسوأ بسبب تقديم الرعاية (متوسط الدرجة 2.82، بانحراف معياري = 0.98). وتعرض مقدمو الرعاية لاكتئاب من النوع المتوسط الشدة (متوسط الدرجة 1.80، بانحراف معياري = 0.42). وأظهر تحليل الانحدار المتعدد المتغيرات أن الصعوبة الملحوظة على مهام تقديم الرعاية والعبء المدرك ذاتيا من جانب المرضى يُنبئان بمخرجات مقدمي الرعاية. وفسّرت صعوبة مهام تقديم الرعاية 38% من الفرق الإجمالي في مخرجات مقدمي الرعاية. وفسر إدراك المرضى ذاتيا للعبء الواقع على من يقدمون لهم الرعاية 16.4% من ذلك الفرق.

الاستنتاج: ينبغي تحديد العوامل المؤثرة على العبء الذي ينوء به مقدمو الرعاية لمرضى غسيل الكلى، والنظر في تصميم تدخلات لدعم مقدمي الرعاية من أجل الحد من ذلك العبء.

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Preferences of Lebanese adults for the gender of their surgeons: a cross-sectional study

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Abstract

Background: More females are specializing in surgery in Lebanon, but it is not known if a gender bias exists among Lebanese people in their preference of their surgeons.

Aims: This study investigated the preference of Lebanese men and women for the gender of surgeons and explored reasons for their preferences.

Methods: A convenience sample of 1000 Lebanese adults were asked about their preferences for the gender of surgeons of different specialties (paediatrics, cardiology, neurology, orthopaedics, ophthalmology, ear nose and throat, plastic surgery and obstetrics/gynaecology). The association between the participants' sociodemographic characteristics and gender preference for surgeons was examined in bivariate and multivariable regression analyses. Odds ratios (OR) and 95% confidence intervals (CI) were calculated.

Results: Half of the respondents had no gender preference for their surgeons whatever their speciality. Male surgeons were preferred over females for cardiac (44.2% versus 3.7% respectively), neurological (43.4% versus 4.1%) and orthopaedic procedures (41.9% versus 3.5%) whereas male and female obstetricians/gynaecologists were equally preferred (23.6% and 25.0% respectively). Being male (OR = 0.74, 95% CI: 0.57–0.97) or single (OR = 0.65, 95% CI: 0.44–0.96) decreased the likelihood of choosing a male heart surgeon whereas employment increased that likelihood (OR = 1.37, 95% CI: 1.03–1.83). Perceived competence, reputation and trustworthiness of male surgeons influenced participants' choices whereas the choice of an obstetrician/gynaecologist was related to privacy and comfort.

Conclusions: The preference for female surgeons in Lebanon varies by the type of surgical specialty. Qualitative studies exploring the social determinants of patients' preferences are needed.

Keywords: surgeons, gender, patient preferences, Lebanon.

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Introduction

Surgical professions in Lebanon are male dominated, with women constituting less than 0.5% of surgeons *(1)*. Recently however, we have observed an increasing trend of women wanting to specialize in non-surgical specialties. For example, at our institution, women make up 30–40% of the current ophthalmology, otolaryngology or obstetrics/gynaecology departments, as compared to 30 years ago when all physicians in these departments where men. This trend seems to parallel the trend observed in the United States of America *(2)*.

Research on patients' preferences about their physician's gender is lacking, especially in the Middle East. Studies from other countries show that patients have gender preferences that are mostly in favour of male physicians. This is because male doctors are perceived to be more confident and industrious, more knowledgeable, and to have greater technical competence *(3–5)*.

In this study, we examined whether a gender bias exists in choosing surgeons among Lebanese adults, and the reasons for the gender preference, if present. Our findings will shed light on the cultural barriers that may deter people from choosing a female surgeon in this country at a time when more women are becoming interested in surgical professions.

Methods

Study design

This was a cross-sectional survey that was conducted in Greater Beirut, Lebanon between December 2015 and February 2016.

Participants and setting

The study included a convenience sample of 1000 Lebanese adults older than 18 years who were recruited from six main public areas in Greater Beirut, such as big shopping centres and theatres. Adults visiting those public areas on weekend days during the study period were directly approached to participate in the study. Participants had to be competent in reading and writing in Arabic. Exclusion criteria were any physical challenge that could interfere with the ability of the participant to read or write, such as vision impairment.

Data collection

Data were collected using an anonymous self-administered questionnaire in Arabic. The questionnaire gathered information on sociodemographic variables such as sex, residence (Beirut Mount Lebanon, other), age, marital status (single, other), education (intermediate and lower, high school, university), monthly income and employment status (employed, not employed). Participants were asked to indicate what sex they preferred their surgeon to be for different specialties, whether for themselves or for another family member. The chosen specialists were: paediatrician (we assumed a neutral gender preference), cardiothoracic surgeon, neurosurgeon (high surgical risk); orthopaedic surgeon (physical strength of surgeon); ophthalmologist, otolaryngologist (lower surgical risk); plastic surgeon (cosmetic outcome); obstetrician-gynaecologist (highly sensitive condition). In addition, participants were asked to indicate the gender of their current surgeon, general practitioner or paediatrician (when applicable) and were prompted to provide comments on the reasons for their preferences. This was done to investigate whether the choice of the gender of their current surgeon, general practitioner or paediatrician corresponded with their answers on gender preference of surgeons in the different specialties given in the survey. The questionnaire was locally prepared for the purpose of the study (Supplement 1, available online) and its validity and reliability were not assessed.

Statistical analysis

Data were summarized as means for continuous variables and as frequencies and percentages for categorical variables. The reasons given for the preferred gender of physicians were grouped under main themes, such as competence, trustworthiness, experience, reputation and strength. As the themes were qualitative in nature, they were given codes that converted them to categorical data and they were analysed accordingly. Bivariate analysis was done to investigate the association between the participants' preferred gender of physician and their sociodemographic characteristics. A multivariable logistic regression analysis was done, adjusted for independents covariables, with the preferred gender of the surgeon being the dependent variable; no gender preference was the reference category. Sociodemographic variables with a *P*-value less than 0.2 in the bivariate analysis were included in the multivariable analysis. *SPSS*, version 23 was used for data entry, management and analysis. A *P*-value less than 0.05 was considered statistically significant.

Ethical considerations

The study was approved by the Institutional Review Board of the American University of Beirut. People who agreed to participate provided verbal consent.

Results

Our sample consisted of slightly more men than women (53.1%). Most of the participants were young (mean age 30.3 (standard deviation 13.3) years), had a university degree (67.8%) and lived in the capital city of Beirut (67.5%). Table 1 gives the sociodemographic characteristics of the sample.

Of 996 participants who reported how often they consulted a physician, 792 (79.5%) consulted one at least once a year, of whom 577 (72.9%) reported having male doctors as their general practitioner. Of the 349 participants who had a current surgeon, 320 (91.7%) had male surgeons. In comparison, of 375 participants who reported having a current paediatrician, 369 reported the gender, of whom 252 (68.3%) had a male paediatrician while 117 (31.7%) had a female paediatrician. Analysis of the participants' preferences of their surgeon's gender in the different surgical specialties showed that about half of them had no gender preference. The lack of a preference varied by the surgical specialty, from 439 (51.3%) for the gender of obstetrician/gynaecologist to 641 (65.6%) for the gender of the family ear nose and throat surgeon (Table 2). However, male surgeons were preferred over females for most specialties, especially in cardiology (44.2% versus 3.7% respectively), neurology (43.4% versus 4.1%) and orthopaedics (41.9% versus 3.5%). Only for obstetrics/gynaecology were female surgeons slightly more preferred than males (25.0% of the participants would

Table 1 Participants' sociodemographic characteristics.

Characteristic	No. (%)
Sex (n = 994)	
Male	528 (53.1)
Female	466 (46.9)
Age (years) (n = 985)	
18–30	644 (65.5)
31–49	246 (24.9)
50–85	95 (9.6)
Single marital status (n = 998)	
Yes	657 (65.8)
No	341 (34.2)
Residence (n = 953)	
Beirut	643 (67.5)
Mount Lebanon	185 (19.4)
Other	125 (13.1)
Highest education level (n = 989)	
Intermediate and lower	68 (6.9)
High school	250 (25.3)
University	671 (67.8)
Employed (n = 996)	
Yes	541 (54.3)
No	455 (45.7)
Monthly income (US$) (n = 747)	
< 500	151 (20.2)
500–999	265 (35.5)
1000–4999	268 (35.9)
≥ 5000	63 (8.4)

Table 2 **Preferred sex of surgeon by surgical specialty**

Surgical specialty	Preferred sex of surgeon		
	Male	Female	No preference
	No. (%)	No. (%)	No. (%)
Personal heart surgeon (*n* = 988)	437 (44.2)	37 (3.7)	514 (52.0)
Personal neurosurgeon (*n* = 951)	428 (43.4)	4 (0.4)	519 (52.6)
Personal orthopaedic surgeon (*n* = 984)	412 (41.9)	34 (3.5)	538 (53.7)
Personal ophthalmologic surgeon (*n* = 988)	332 (33.6)	61 (6.2)	595 (60.2)
Personal ear nose and throat surgeon (*n* = 986)	320 (32.5)	62 (6.3)	604 (61.3)
Personal plastic surgeon (*n* = 979)	316 (32.3)	115 (11.7)	548 (56.0)
Personal obstetric/gynaecological surgeon (*n* = 855)	202 (23.6)[a]	214 (25.0)	439 (51.3)
Family heart surgeon (*n* = 981)	410 (41.8)	23 (2.3)	548 (55.9)
Family neurosurgeon (*n* = 980)	396 (40.4)	32 (3.3)	552 (56.3)
Family orthopaedic surgeon (*n* = 982)	380 (38.7)	23 (2.3)	579 (59.0))
Family ophthalmologic surgeon (*n* = 978)	303 (31.0)	44 (4.5)	631 (64.5)
Family ear nose and throat surgeon (*n* = 977)	294 (30.1)	42 (4.3)	641 (65.6)
Family plastic surgeon (*n* = 975)	295 (30.3)	86 (8.8)	594 (60.9)
Family obstetric/gynaecological surgeon (*n* = 972)	196 (20.2)	223 (22.9)	553 (56.9)

[a]*It is not unusual in Lebanon for husband to choose the family's obstetrician. Some male participants may have answered on behalf of their wives.*

prefer a female obstetrician/gynaecologist versus 23.6% who would prefer a male). There was a higher preference for female plastic surgeons (11.7%) in comparison to other surgical fields except for obstetrics/gynaecology. Similar gender preferences were observed when choosing a surgeon for family members (Table 2).

In bivariate analysis, preferred gender of the surgeon, whether for the participant or for a family member was significantly associated with the participant's sex, age, employment status, marital status, gender of current general practitioner and current surgeon in all the surgical specialties. Table 3 shows the bivariate analysis of the gender preference for a heart surgeon as an example. Similarly, multivariable regression analysis showed that the participant's sex, employment status and marital status were significant predictors of preferring a male surgeon, whether for the participant or for the family in all surgical specialties. For example, male participants were less likely to choose a male heart surgeon (OR = 0.74, 95% CI: 0.57–0.97) as were single participants (OR = 0.65, 95% CI: 0.44–0.96), whereas employed participants were more likely to choose a male heart surgeon (OR = 1.37, 95% CI: 1.03–1.83) (Table 4). In contrast, none of the covariates predicted the preference for a female heart surgeon (Table 4). Bivariate and multivariable regression analyses for the preferred gender of surgeons in the remaining specialties are shown in supplementary tables (Supplement 2, available online).

Analysis of the reasons for the participants preference for male surgeons (*n* = 223) were the following: 55 (24.7%) gave competence, experience and reputation of the surgeon as their reason, 48 (21.5%) said strength and courage and 28 (12.6%) said trustworthiness. In contrast, of the 238 participants who reported no gender preference for their surgeon, 216 (90.8%) cited competence as the main reason for choosing a surgeon and not gender. With regard to the preferred gender of an obstetrician/gynaecologist, 45/47 participants (95.7%) who provided a response to the question said they would base their choice on privacy issues and feeling comfortable.

Discussion

In this study, about half of the respondents had no gender preference when choosing a surgeon irrespective of the surgical specialty. This finding is important as it may imply that the Lebanese are accepting of female surgeons. Their choice of surgeon is mostly determined by the surgeon's competence and surgical skill, rather than his/her gender. Having no preference for the surgeon's gender is consistent with other studies in which patients had no gender preferences for their oral and maxillofacial surgeons *(6)*, plastic surgeons *(7)*, orthopaedic surgeons *(8)* or emergency physicians *(9)*.

When choosing an obstetrician, our participants had similar preference for female and male physicians. This finding differs from reports from other countries in the region in which female obstetricians were almost exclusively preferred *(10–12)*. This may be explained by the more conservative culture in other countries with Muslim majorities, where observant Muslim women refrain from exposing certain body parts in front of males who are unrelated to them by blood or marriage. Hence, the preference for female obstetricians in these countries is not surprising given the nature of the specialty where women tend to feel more comfortable if checked or operated on by a female physician. A recent survey of 405 female patients in Saudi Arabia about their preference of their surgeon's gender reported that 42% preferred male surgeons but would opt for any other surgeon in cases of emergency if a male surgeon was not available. However,

Table 3 Bivariate analysis of the association between sociodemographic variables and preferred sex of personal heart surgeon (*n* = 1000)

Variable	Preferred sex of heart surgeon			*P*-value
	Male (n = 437)	Female (*n* = 37)	No preference (*n* = 514)	
	No. (%)	No. (%)	No. (%)	
Sex				
Male (*n* = 523)	211 (40.3)	21 (4.0)	291 (55.6)	0.034
Female (*n* = 459)	223 (48.6)	15 (3.3)	221 (48.1)	
Age (years) (n = 973)				
18–30	247 (38.8)	29 (4.6)	360 (56.6)	
31–50	135 (55.6)	6 (2.5)	102 (42.0)	< 0.001
51–85	47 (50.0)	1 (1.1)	46 (48.9)	
Highest education (n = 977)				
Intermediate	31 (46.3)	4 (6.0)	32 (47.8)	
High school	99 (40.1)	10 (4.0)	138 (55.9)	0.474
University	303 (45.7)	23 (3.5)	337 (50.8)	
Employed (n = 984)				
Yes	261 (49.1)	24 (4.5)	247 (46.4)	0.001
No	174 (38.5)	13 (2.9)	265 (58.6)	
Monthly income (US$) (n = 736)				
< 1000	186 (45.8)	12 (3.0)	208 (51.2)	0.611
≥ 1000	140 (42.4)	12 (3.6)	178 (53.9)	
Single marital status (n = 987)				
Yes	249 (38.4)	27 (4.2)	373 (57.5)	< 0.001
No	187 (55.3)	10 (3.0)	141 (41.7)	
Sex of current general practitioner (n = 778)				
Male	323 (49.8)	14 (2.2)	311 (48.0)	< 0.001
Female	43 (33.1)	12 (9.2)	75 (57.7)	
Sex of current paediatrician (n = 367)				
Male	121 (48.4)	6 (2.4)	123 (49.2)	0.112
Female	56 (47.9)	8 (6.8)	53 (45.3)	
Sex of current surgeon (n = 342)				< 0.001
Male	174 (54.7)	11 (3.5)	133 (41.8)	
Female	11 (45.8)	6 (25.0)	7 (29.2)	

in obstetrics and gynaecology clinics, 46% preferred female obstetricians *(13)*.

Our finding that the surgeon's competence and skill, physical strength and trustworthiness were the most cited reasons for choosing surgeons is consistent with the findings of a recent systematic review *(14)*, where competence of the surgeon, surgeon's reputation and interpersonal skills were the most common reasons reported for choosing a surgeon.

Our study has some limitations. Our sample was a convenience sample of people visiting big shopping malls or theatres and hence it is not representative of the Lebanese population at large. Most of the participants were young people with a university degree living in Beirut. Hence, their preferences may not represent those of older people, those with less education, or those living in other provinces of the country. On the other hand, the study's main strength is its large sample size, and the fact that it examines a largely unaddressed issue in both Lebanon and the region.

Conclusion

This study provides insight into the current trend of the Lebanese preferences of the gender of their surgeons at a time when a growing number of women are pursuing careers in surgery. The reasons behind this trend could not be explored in depth in this study given its design. Qualitative studies are needed to understand the social factors that affect patients' preferences when choosing their surgeons.

Physicians' interact with their patients based on the nature of their illnesses. Patients, however, interact with

Table 4 Multivariable logistic regression analysis of factors associated with preferred sex of personal heart surgeon

Covariates	OR (95% CI)	*P*-value
Preference for male heart surgeon		
Male sex	0.74 (0.57–0.97)	0.03
Employed	1.37 (1.03–1.83)	0.03
Single marital status	0.65 (0.44–0.96)	0.03
Age category (years)		
18–30	Ref.	
31–50	1.29 (0.86–1.93)	0.20
51–85	1.01 (0.59–1.74)	0.90
Preference for female heart surgeon		
Male sex	1.02 (0.51–2.05)	0.90
Employed	2.09 (0.99–4.43)	0.05
Single marital status	0.62 (0.24–1.66)	0.30
Age category (years)		
18–30	Ref.	
31–50	0.41 (0.14–1.23)	0.10
51–85	0.17 (0.02–1.47)	0.10

OR: odds ratio; CI: confidence interval.
Dependent variable reference category was no gender preference.

physicians based on how they perceive their expertise, competence, reputation and other gender stereotyped traits. Hence, it is important to investigate how patients perceive female surgeons, as this could determine patient's choices of female surgeons. Addressing patient concerns about female surgeons' abilities and competence can determine their success and recognition as capable surgeons, thus maximizing patient trust and optimizing the patient–surgeon relationship.

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Authors' Contributions

Authors NAH, PB, MF, SH, AM and SLS contributed equally to conception and design of the study, literature review, protocol writing, data collection, data analysis and drafting of the manuscript. MN contributed to study design, protocol writing, data analysis, drafting and reviewing of the manuscript. All authors read and approved the final manuscript.

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Préférences des adultes libanais concernant l'appartenance sexuelle de leur chirurgien : étude transversale

Résumé

Contexte : Au Liban, les femmes sont plus nombreuses à se spécialiser en chirurgie, mais on ne sait pas si un biais sexospécifique existe parmi la population libanaise en matière de préférence pour le choix d'un chirurgien.

Objectifs : La présente étude avait pour objectif d'examiner la préférence des hommes et des femmes libanais quant à l'appartenance sexuelle des chirurgiens, ainsi que les raisons de leur préférence.

Méthodes : Un échantillon de commodité de 1000 adultes libanais a été interrogé sur ses préférences quant à l'appartenance sexuelle des chirurgiens dans différentes spécialités (pédiatrie, cardiologie, neurologie, orthopédie, ophtalmologie, otorhinolaryngologie, chirurgie esthétique et gynécologie/obstétrique). L'association entre les caractéristiques sociodémographiques des participants et leur préférence quant à l'appartenance sexuelle des chirurgiens a été examinée à l'aide des analyses de régression bivariées et multivariées. Les odds ratios (OR) et les intervalles de confiance (IC) à 95 % ont été calculés.

Résultats : La moitié des personnes interrogées n'avaient pas de préférence quant à l'appartenance sexuelle de leur chirurgien, quelle que soit sa spécialité. La préférence allait à un chirurgien plutôt qu'à une chirurgienne pour les procédures cardiaques (44,2 % contre 3,7 % respectivement), neurologiques (43,4 % contre 4,1 %) et orthopédiques (41,9 % contre 3,5 %). En revanche, pour les procédures d'obstétrique et de gynécologie, la préférence pour un chirurgien ou une chirurgienne était équivalente (23,6 % et 25,0 % respectivement). Le fait d'appartenir au sexe masculin (OR = 0,74, IC à 95 % : 0,57-0,97) ou d'être célibataire (OR = 0,65, IC à 95 % : 0,44-0,96) réduisait la probabilité de choisir un chirurgien cardiaque de sexe masculin, tandis que l'emploi augmentait cette même probabilité (OR = 1,37, IC à 95 % : 1,03-1,83 %). La compétence, la réputation et la fiabilité perçues des chirurgiens de sexe masculin influençaient le choix des participants. Pour un obstétricien/gynécologue, le choix était lié aux notions d'intimité et de confort.

Conclusions : La préférence pour les chirurgiennes au Liban varie selon le type de spécialité chirurgicale. Des études qualitatives s'intéressant aux déterminants sociaux des préférences des patients sont nécessaires.

تفضيلات اللبنانيين البالغين لجنس الجراحين المعالجين لهم: دراسة مقطعية

نورعبد الحليم، بول بعينه، مادلين فنيانوس، سليم جبران، أحمد مشيك، سيما شرارة، منى نابلسي

الخلاصة

الخلفية: يتزايد عدد الإناث اللواتي يتخصصن في الجراحة في لبنان، ولكن من غير المعلوم إذا كان هناك انحياز جندري في أوساط اللبنانيين إزاء اختياراتهم لجنس الجراحين المعالجين لهم.

الأهداف: هدفت هذه الدراسة إلى استقصاء تفضيلات اللبنانيين رجالا ونساء لجنس الجراحين المعالجين لهم واستكشاف الأسباب الكامنة وراء تلك التفضيلات.

طرق البحث: طُرح سؤال على عينة عشوائية قوامها 1000 لبناني من البالغين حول تفضيلاتهم بشأن جنس الجراحين المعالجين لهم من مختلف التخصصات (الأطفال، القلب، الأعصاب، تقويم العظام، العيون، الأنف والأذن والحنجرة، التجميل، والنساء والتوليد). وخضعت العلاقة بين الخصائص الاجتماعية السكانية للمشاركين وتفضيلاتهم لجنس الجراحين للدراسة باستخدام تحليلي انحدار أحدهما ثنائي المتغيرات والآخر متعدد المتغيرات. كما احتُسبَت نسب الاحتمال وفترات الثقة (95%).

النتائج: لم يكن لدى نصف المستجيبين تفضيل محدد لجنس الجراحين مهما كان تخصصهم. وفُضِّل الجراحون الذكور عن الإناث بالنسبة لجراحات القلب (44.2% في مقابل 3.7% على التوالي)، والأعصاب (43.4% في مقابل 4.1%) وجراحات تقويم العظام (41.9% في مقابل 3.5%). بينما تساوى أطباء النساء والتوليد ذكورا وإناثا من حيث التفضيل (23.6% و 25.0% على التوالي). وقلّل كون الجراح ذكرا (OR=0.74; 95% CI=0.57.-0.97) أو أعزبا (OR=0.65; 95% CI=0.44.-0.96) من احتمال اختيار جراح قلب من الذكور، بينما زاد التوظيف تلك الاحتمالية (OR=1.37; 95% CI=1.03-1.83) وأثرت الكفاءة الواضحة، والسمعة، والموثوقية في الجراحين الذكور على اختيارات المشاركين لهم، بينما اقترن اختيار طبيب النساء والتوليد بالشعور بالخصوصية والراحة.

الاستنتاجات: يتفاوت تفضيل الجراحين من الإناث في لبنان وفقا لنوع التخصص الجراحي المطلوب. وتمس الحاجة إلى إجراء دراسات نوعية لاستقصاء المحددات الاجتماعية لتفضيلات المرضى واختياراتهم.

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Seroprevalence of hepatitis E virus in pregnant women in northern Lebanon

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Abstract

Background: Hepatitis E virus is the main cause of acute hepatitis globally. Infection is especially serious in pregnant women in whom the death rate can reach 25%. The prevalence of hepatitis E virus in pregnant women in Lebanon is not known.

Aims: This study aimed to investigate the seroprevalence of hepatitis E virus infection in a sample of pregnant women in northern Lebanon.

Methods: A total of 450 pregnant women from Tripoli, North Lebanon were enrolled in the study. Sera were tested for the presence of anti-hepatitis E virus IgG antibodies using an ELISA technique. Information was collected on the sociodemographic characteristics of the women and their risk factors for hepatitis E virus infection (drinking-water source, blood transfusion and contact with animals).

Results: Only one woman was positive for hepatitis E virus giving a prevalence of 0.22%. She had good living conditions, socioeconomic status and educational level and reported no exposure to any risk factors associated with hepatitis E virus infection. Most of the women (87.3%) had a medium or high income level, 47.1% had a university education and 64.9% drank bottled water. Only a small proportion were exposed to risk factors for hepatitis E virus infection: 14.7% had direct contact with animals and 3.8% had had a blood transfusion.

Conclusion: The prevalence of hepatitis E virus infection in the sample was low (0.22%). However, further epidemiological studies among other population groups are required to determine the national prevalence of hepatitis E virus in Lebanon.

Keywords: hepatitis E virus, prevalence, pregnancy, Lebanon

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Introduction

Five forms of human viral hepatitis are known. Among them, hepatitis E virus is the most common cause of acute viral hepatitis and jaundice worldwide *(1)*. Globally, it is estimated that about 20 million hepatitis E infections occur every year, with more than three million symptomatic cases and about 44 000 hepatitis E-related deaths *(2)*.

Hepatitis E virus belongs to the genus *Hepevirus* within the family Hepeviridae. A single hepatitis E virus serotype and four major genotypes (HEV1, HEV2, HEV3 and HEV4) have been described *(3,4)*. Although these four genotypes are able to infect humans, they show different epidemiological patterns depending on their geographical distribution *(1)*. In developing countries, HEV1 and HEV2, which are associated with faecal–oral transmission and waterborne spread, cause numerous sporadic cases and outbreaks. HEV3 and HEV4 are common in several animal reservoirs; they are transmitted to humans through zoonotic foodborne routes and cause sporadic cases of increasing importance *(1,5–7)*.

Unsafe water supplies, poor hygiene, overcrowded living conditions, young adult age and close contact with animals, especially pigs, are risk factors for hepatitis E infection. Hepatitis E infection is generally an acute, self-limiting disease; however, in some cases, it can cause acute liver failure or chronic liver disease *(8,9)*. In pregnant women, hepatitis E infection can cause serious illness characterized by frequent occurrence of fulminant hepatitis *(10,11)* with a high mortality rate, which is 10-fold higher than the mortality rate in men or non-pregnant women *(12)*.

Hepatitis E infection can be detected using serological assays of anti-hepatitis E virus immunoglobulin M (IgM) and IgG in patient sera, mostly by enzyme-linked immunosorbent assays (ELISA) *(11,13)*. IgM antibodies decrease in the weeks following infection and subsequently are rarely detectable and even absent in most studies of hepatitis E virus seroprevalence. In contrast, detectable levels of anti-hepatitis E virus IgG may persist for years after infection *(11,13)*. These antibodies are therefore widely used to evaluate the prevalence of the virus in various populations including asymptomatic pregnant women *(11)*.

In Lebanon, the prevalence of anti-hepatitis E virus IgG antibodies has been investigated in only one study of blood donors and the results showed 4% positivity *(14)*.

However, the prevalence in pregnant Lebanese women has never been studied. Therefore, the aim of our study was to investigate the prevalence of hepatitis E virus infection in pregnant women in Tripoli, the main city of the North Lebanon governorate.

Methods

Study design and participants

This was a cross-sectional study conducted during a 5-month period (April to August 2015) in Tripoli in northern Lebanon.

The sample size was determined using the single population proportion formula: $N = z^2p(1-p)/w^2$, where z = standard normal distribution value at 95% confidence level which is equal to 1.96, p = the expected prevalence of hepatitis E virus in pregnant women and w = the margin of error, taken as 4%. As the prevalence of hepatitis E virus in pregnant women in Lebanon was not known, we used the highest prevalence (12.7%) reported from Turkey, a neighbouring country (*15*). Based on these parameters, the calculated minimum sample size was 267. Tripoli was divided into four geographical regions. From each region, one health facility of 19 attended by pregnant women was randomly selected. A trained nurse of the antenatal unit of the facility explained the purpose of the study to the potential participant, obtained her consent, filled the questionnaire with the participant and then collected the blood sample. In total, 450 women were enrolled in this study, representing all the pregnant women attending the selected health facilities during the study period. Non-Lebanese pregnant women were excluded from the study.

Data collection

The women were surveyed using a questionnaire which included the known risk factors for hepatitis E virus infection (drinking water source, blood transfusion, sociodemographic and contact with animals), pregnancy stage, sociodemographic characteristics (age, education level and income level). The minimum wage (675 000 Lebanese pounds; US$ 450) was used to classify the income level. Families with a monthly income below the minimum wage were classified as low income. Families with a monthly income ranging from the minimum wage to twice the minimum wage were classified as middle income. Families with a monthly income more than twice the minimum wage were considered high income

Serological tests

Three millilitres (3 mL) of venous blood were collected into a clot activator tube by venepuncture. Sera were separated immediately and kept frozen at –20 °C until tested. The presence of anti-hepatitis E virus IgG antibodies was examined using an ELISA kit (Euroimmun, Lübeck, Germany) following the manufacturer's instructions. According to the manufacturer, tests performed with this assay have a specificity and sensitivity of 100%.

Data analysis

Data were analysed using GraphPad Prism 6 software. Quantitative data are presented as mean and standard deviation (SD); categorical data are presented as frequencies.

Ethical considerations

Ethical approval for the study was obtained from ethics committee of the Azm Center for Research in Biotechnology and Its Applications, Lebanese University. Informed consent was obtained from each participant included in the study. Written consent was obtained from each literate participant. In the case of illiterate participants, the nurse explained the purpose of the study to the woman and a literate witness (another health care worker or a person accompanying the woman). If the illiterate women agreed to participate by giving her verbal consent, the literate witness signed on her behalf.

Results

A total of 450 pregnant women participated in the study. The age range of the participants was 15–43 years, with a mean age of 28.33 (SD 5.82) years. None of the participants had clinical symptoms associated with hepatitis E virus infection at the time of sample collection. Anti-hepatitis E virus IgG antibodies were found in only one participant (0.2%). She had good living conditions, socioeconomic status and educational level and reported no exposure to any of the risk factors associated with hepatitis E virus infection. Most of the women in the study had a medium (46.4%) or high (40.9%) income level, about half (47.1%) had a university education and two thirds (64.9%) drank bottled water (Table 1). Only a small proportion were exposed to the risk factors associated with hepatitis E virus infection: 14.7% had direct contact with animals and 3.8% had had a blood transfusion.

Discussion

To the best of our knowledge, our study is the first to determine the seroprevalence of anti-hepatitis E virus IgG antibodies in pregnant women in Lebanon. Our results revealed a very low prevalence of hepatitis E virus (0.22%). This prevalence was the lowest reported in other Mediterranean countries for the same group (Table 2). These data may reflect limited circulation potential of this virus in Lebanese pregnant women.

The status of hepatitis E virus infection has been reported in several countries of the Eastern Mediterranean Region including Egypt, Islamic Republic of Iran, Iraq, Saudi Arabia, Tunisia and United Arab Emirates (*26*). In these countries, numerous studies have been performed in different populations including blood donors, pregnant women, hepatitis patients and haemodialysis patients. In contrast, the prevalence of hepatitis E virus and its associated disease in Lebanon is largely unknown and epidemiological data are limited to a single study of seroprevalence performed on 100 blood donors in 1998 which showed a low prevalence (4% of positivity) (*14*).

Table 1 Demographic characteristics of the sample of pregnant women in Tripoli, Lebanon and risk factors for hepatitis E virus infection

Variable	No. (*n* = 450)	%
Age group (years)		
≤ 25	158	35.1
26–34	212	47.1
≥ 35	80	17.8
Pregnancy trimester		
First	111	24.7
Second	145	32.2
Third	194	43.1
Educational level		
Illiterate	9	2
Primary school	41	9.1
Middle school	107	23.8
Secondary school	81	18
University	212	47.1
Income level		
Low	57	12.7
Medium	209	46.4
High	184	40.9
Contact with animals		
Yes	66	14.7
No	384	85.3
Blood transfusion		
Yes	17	3.8
No	433	96.2
Drinking water source		
Bottled water	292	64.9
Tap water	111	24.7
Spring and well water	47	10.4

Several studies have obtained similar results to ours showing a low prevalence of hepatitis E virus infection in pregnant women: 0.4% in El Paso, United States of America (*27*), 1% in Rio de Janeiro, Brazil (*28*), 1.6% in Ciudad Juarez, Mexico (*27*) and 1.6% in Caracas, Venezuela (*29*). Importantly, even in endemic countries with suspected outbreaks of hepatitis E virus infection such as the Islamic Republic of Iran, a relatively low prevalence of hepatitis E virus (3.6%) was reported in pregnant women (*30*). In Lebanon, no hepatitis E virus outbreaks have occurred and the country is not considered endemic for the disease. Our data differ from those of other studies that examined pregnant women which showed a high prevalence of hepatitis E virus: 58.6% in Dakahlya Governorate, Egypt (*21*) and 28.8% in Rajasthan, India (*31*). Such discrepancies in hepatitis E virus prevalence in pregnant women in different countries are not surprising because even in the same country, considerable epidemiological differences exist. For example, a study in France in pregnant women showed a higher seroprevalence of hepatitis E virus in the south (29.3%) than in the north of the country (3.6%) (*22*). Changes of hepatitis E virus prevalence in different regions and countries may be explained, in part, by sociodemographic and sanitation differences.

Our study in pregnant women showed an even lower prevalence of hepatitis E virus (0.22%) than in Lebanese blood donors (4%) (*14*). In addition to differences in geographical area and population group examined, this difference may, to some extent, be due to sanitation and hygiene improvements in the country between 1998 and 2015. Progressive improvements of sanitation conditions, provision and wide use of filtered and bottled water, and organization of effective food safety campaigns may effectively reduce the faecal–oral transmission and waterborne spread of hepatitis E virus, which are the main modes of transmission of this virus in developing regions. Such improvements are therefore important to

Table 2 Seroprevalence of anti-hepatitis E virus antibodies in pregnant women in Mediterranean countries

Country	Sample size	% positive	Kit manufacturer	Year (reference)
Turkey	245	12.6 (IgG); 0 (IgM)	Virotech GmbH, Germany	2004 (15)
	386	7 (IgG)	Globe Diagnostics, Italy	2006 (16)
Spain	424	0.94 (IgG)	Abbott Diagnostics, United States of America	2004 (17)
	1517	5.45 (IgG); 0 (IgM)	Biokit, Spain	2010 (18)
	1040	3.6 (IgG); 0.67 (IgM)	DiaPro Diagnostic Bioprobes, Italy	2010 (19)
Egypt	2428	84.3 (NS)	In-house enzyme immunoassay	2006 (20)
	116	58.6 (IgG)	Genelabs Diagnostics, Singapore	2011 (21)
France	315	7.74 (IgG); 0 (IgM)	Wantai, China	2014 (22)
	263[a]	5.6 (IgG and IgM)	Abbott Laboratories, United States of America	1993 (23)
Tunisia	404	12.1 (IgG); 0 (IgM)	Globe Diagnostics SRL, Italy	2011 (24)
Greece	98[b]	2 (NS)	Abbott Laboratories, United States of America	1996 (25)

NS: not specified.

[a] *Pregnant women born outside France.*

[b] *Pregnant Albanian refugees.*

public health measures for decreasing hepatitis E virus infections and related mortality and morbidity.

Good hygiene and sanitation conditions are important factors in maintaining the low prevalence rate of hepatitis E and must continue to improve. However, the Syrian conflict has displaced millions of Syrians from Syria to neighbouring countries, including Lebanon which hosts about 1.5 million Syrian refugees. Because of their unfavourable living conditions, displaced populations and refugees are at higher risk of hepatitis E virus infection and large outbreaks of this virus in such populations have been documented, for example in Darfur, Sudan (*32*). Maintaining the low prevalence hepatitis E virus in Lebanon in these new circumstances requires more vigilance and careful epidemiological monitoring of the refugee population at risk.

It is important to note that the different serological tests available for hepatitis E virus detection show considerable discrepancies in their results (*33–37*). Indeed, significantly different IgG seroprevalence values have been reported in the same populations from the same geographical areas using different serological assays (3.6% and 16.2% in United Kingdom blood donors and 10.9% and 31.3% in French kidney and liver transplant recipients) (*35,37*). We used only one commercially available assay to test sera. It is possible therefore that our results may not reflect the actual prevalence of anti-hepatitis E virus IgG antibodies in our sample of pregnant woman. In addition, we did not check anti-hepatitis E virus IgM antibodies or the serum levels of liver enzymes such as alanine aminotransferase and aspartate aminotransferase which are important markers of an acute recent hepatitis E virus infection (*11,13*). We may therefore have missed possible subclinical asymptomatic cases of ongoing acute hepatitis E virus infection.

Since our study included only pregnant women from four health facilities in Tripoli in the north of Lebanon, our results may not reflect the actual prevalence of hepatitis E virus in the North governorate or at the national level. Moreover, in Lebanon, pregnant women are not all covered by the health system; therefore, we may have missed poorer women who are usually at higher risk of hepatitis E virus infection but who never or rarely seek antenatal care. Future studies that sample a wider range of the population would be more helpful.

Our results suggest that hepatitis E virus does not need to be included in routine prenatal screening programmes. However, further studies among both pregnant women and other populations in different areas of the country are needed to clarify the prevalence and epidemiological trends of hepatitis E virus infection in Lebanon.

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Séroprévalence du virus de l'hépatite E chez les femmes enceintes au nord du Liban

Résumé

Contexte : Le virus de l'hépatite E constitue la principale cause d'hépatite aiguë dans le monde. L'infection est particulièrement grave pour les femmes enceintes, chez qui le taux de mortalité peut atteindre 25 %. La prévalence du virus de l'hépatite E chez les femmes enceintes au Liban n'est pas connue.

Objectifs : La présente étude visait à étudier la séroprévalence de l'infection par le virus de l'hépatite E dans un échantillon de femmes enceintes au nord du Liban.

Méthodes : Au total, 450 femmes enceintes de Tripoli, dans le nord du Liban, ont été incluses dans l'étude. Des prélèvements sériques ont été effectués à la recherche d'anticorps de la classe des IgG dirigés contre le virus de l'hépatite E en recourant à la méthode ELISA. Des informations ont été recueillies sur les caractéristiques sociodémographiques de ces femmes et leurs facteurs de risque d'infection par le virus de l'hépatite E (source d'eau de boisson, transfusion sanguine et contact avec les animaux).

Résultats : Une seule femme a été testée positive au virus de l'hépatite E, pour une prévalence de 0,22 %. Ses conditions de vie, son statut socio-économique et son niveau d'études étaient bons, et elle n'avait indiqué aucune exposition à aucun facteur de risque associé à l'infection par le virus de l'hépatite E. La plupart des femmes (87,3 %) avaient un niveau de revenu moyen à élevé, 47,1 % d'entre elles avaient reçues une formation universitaire et 64,9 % buvaient de l'eau en bouteille. Seule une faible proportion d'entre elles étaient exposées à des facteurs de risque d'infection par le virus de l'hépatite E : 14,7 % d'entre elles avaient un contact direct avec des animaux et 3,8 % avaient reçu une transfusion sanguine.

Conclusion : La prévalence de l'infection par le virus de l'hépatite E dans l'échantillon était faible (0,22 %). Cependant, d'autres études épidémiologiques au sein d'autres groupes de population sont nécessaires pour déterminer la prévalence du virus de l'hépatite E à l'échelle nationale au Liban.

الانتشار المصليّ لفيروس التهاب الكبد E بين الحوامل في شمال لبنان

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الخلاصة

الخلفية: فيروس التهاب الكبد E هو السبب الرئيسي لالتهاب الكبد الحاد على مستوى العالم. وتكون العدوى به خطيرة خصوصاً بالنسبة للحوامل اللاتي قد يصل معدل الوفيات بينهن إلى 25%. وليس معروفاً سبب انتشار التهاب الكبد E بين الحوامل في لبنان.

الأهداف: هدفت هذه الدراسة إلى استقصاء أسباب الانتشار المصلي للعدوى بفيروس التهاب الكبد E في عينة من الحوامل في شمال لبنان.

طرق البحث: بلغ مجموع الحوامل اللاتي شملتهن هذه الدراسة 450 سيدةً من طرابلس، شمال لبنان. وقد فُحصت الأمصال للتحقق من وجود الأجسام المضادة من مجموعة الجلوبيولين المناعي IgG لفيروس التهاب الكبد E باستخدام مقايسة المُمْتز المناعي المرتبط بالإنزيم. وجُمعت معلومات حول الخصائص الاجتماعية السكانية للنساء، وعوامل الخطر المرتبطة بتعرضهن للإصابة بعدوى فيروس التهاب الكبد E (مصدر مياه الشرب، ونقل الدم، ومخالطة الحيوانات).

النتائج: تبين إصابة امرأة واحدة فقط بفيروس التهاب الكبد E، مما يمثل الانتشار بنسبة 0.22% فقط. وتتمتع هذه السيدة بظروف معيشية جيدة، ووضع اجتماعي واقتصادي جيد، ومستوى تعليمي جيد، وأفادت بعدم تعرضها لأي من عوامل الخطر المرتبطة بالعدوى بفيروس التهاب الكبد E. وكان مستوى الدخل لمعظم النساء اللاتي شملتهن الدراسة (87.3%) متوسطاً أو مرتفعاً؛ و47.1% منهن حاصلات على شهادة جامعية؛ و64.9% منهن يشربن الماء المعبّأ في قوارير. وتعرضت نسبة ضئيلة منهن فقط لعوامل خطر الإصابة بعدوى فيروس التهاب الكبد E: منهن 14.7% خالطن الحيوانات بشكلٍ مباشر؛ و3.8% خضعن لعملية نقل دم.

الاستنتاج: كان معدل انتشار العدوى بفيروس التهاب الكبد E منخفضا في العينة (0.22%). ولكن يلزم إجراء مزيدٍ من الدراسات الوبائية على مستوى الفئات السكانية الأخرى لتحديد انتشار فيروس التهاب الكبد E على المستوى الوطني في لبنان.

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Prevalence of allergenic arthropods in domestic dwellings of referrals to an asthma and allergy clinic in the Islamic Republic of Iran

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Abstract

Background: Allergenic arthropods are crucial agents in inducing medically important respiratory diseases like asthma and the inflammation of the respiratory tract worldwide.

Aims: This study was conducted to determine the prevalence of all arthropods in the dwellings of people referred to the asthma and allergy clinic in Shiraz.

Methods: This was was a cross-sectional descriptive study. Participants were 100 allergic patients who had tested positive (roach- and mite-sensitive). Mites were collected from their houses using a vacuum cleaner; other arthropods were caught with sticky traps. Direct observation and flotation methods were used and the samples were stored in 70% ethanol. Morphological characteristics were identified using valid taxonomic keys.

Results: Overall, 624 specimens were identified belonging to 14 orders (4 orders of mites: Astigmata, Cryptostigmata, Prostigmata and Mesostigmata; and 10 other arthropod orders: Diptera, Coleoptera, Hymenoptera, Thysanura, Thysanoptera, Entomobryomorpha, Blattodea, Siphonaptera, Pscoptera and Isopoda). The 2 most numerous species collected were *Musca domestica* and *Dermanyssus gallinae*.

Conclusion: A small number of dwellings were infested with cockroaches; none were infested with the common house dust mites. The allergies induced in these patients could likely be attributed to other arthropods that are not considered main allergens in asthma and allergy clinics in the Islamic Republic of Iran. Health surveillance and prevention of infestation for these arthropods could have an immense impact on the control of the allergenic arthropod community, prevention of respiratory diseases, and personal health in Shiraz.

Keywords: allergen, arthropod, asthma, allergy, indoor, urban

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Introduction

Background

Over a million species of arthropods are reported in nature as having a significant role in the ecosystem; only a small fraction of these species are linked to human health. Arthropod vectors of infectious disease agents have special importance in the developing countries. They are also associated with certain allergic conditions and may induce or intensify some allergic reactions among humans (*1,2*).

In sensitive people, asthma symptoms may be triggered by inhaling allergens. The triggers differ from person to person, most likely due to a combination of environmental and genetic factors. Common asthma-causing allergens include: arthropods (dust mites, cockroaches, etc.), animal hair or dander, dust, respired chemicals, mould, pollen and tobacco smoke (*1*).

House dust mites are widespread, tiny (45–200 μm) arthropods belonging to the family Pyroglyphidae, order: Astigmata, class: Arachnida (*3*). These feed on skin relics, hair dandruff and other organic debris. They live and reproduce among clothes, bedding, carpets, furniture, household utilities and floors in human dwellings. The inhalation of faecal drops and protein moieties from the bodies of mites could cause allergic reactions like asthma, permanent allergic rhinitis and atopic dermatitis (eczema) among sensitive individuals (*4,5*).

Objectives

Many other arthropods are also considered or identified as being allergenic such as cockroaches, house flies, mosquitoes, storage pests, biting insects, canine and feline fleas, butterfly larvae, bedbugs, horseflies, silverfish and non-biting midges (Chironomidae). These could cause various types of allergy in some people (*6*). Any plan to control and prevent the spread of these arthropods must be based on their proper identification and classification. This study was thus conducted to gain some insight on species diversity of these allergenic arthropods, their abundance and extent of distribution in Shiraz.

Methods

Study area

This was a cross-sectional descriptive study conducted in Shiraz (29°40' N, 52°33' E), the capital city of Fars province, Islamic Republic of Iran. It is located at about 1500 m above sea level. It has a subtropical, hot, semi-arid climate with a mean annual temperature of 18 °C, relative humidity of 41% and precipitation 337.8 mm. Its hilly landscape is corrugated with the Zagros mountain range, which run northwest–southeast across the country.

Patients

In this investigation of all patients who were referred to the asthma and allergy clinic at Shiraz during the year of study, samplings were randomly carried out on the houses of 100 consenting patients who had positive skin tests to the *Dermatophagoides farinae* allergen, *D. pteronyssinus* allergen of house dust mites (*D. farinae, D. pteronyssinus*) and cockroach allergen. Samplings included patients' domiciles, in the particular loci which saw the highest frequency of inhabitants' activities. Participants were from both sexes with no age range limitation. After explaining the sampling procedure by an expert, informed consent forms were signed by all research participants or their parents (for children). In order to compensate for the possible drop-out of volunteers, sampling was continued until the sample size was completed.

Allergic skin reaction tests

Skin tests were done by the wheal and flare reactions on patients' forearms. Overall, 79 different items (comprising such categories as pollen, tree, grasses, weeds, mould, animals and food) were included in these tests, the reaction from each of which was observed directly on skin and the size of each reaction was measured and subsequently recorded. A drop of 50% glycerin + 50% COCAS fluid (containing NaCl 0.5%, $NaHCO_3$ 0.0275%, sterile water for injection, preservative 0.4% phenol) was used as negative control. A drop of standardized D. pteronyssinus, 5 mL in 10 000 arbitrary units/mL was used as the positive control. The negative control had a wheal and flare reaction of 1–3 units, while the positive control reaction measured > 3 units. They were compared 20 minutes after the initial administration of the drops and their sizes measured and recorded accordingly.

Sample size

The sample size was calculated according to the following formula:

$$n = \frac{\left(z_{1-\alpha} + z_{1-\beta}\right)^2 p_0 q_0}{(p_1 - p_0)^2}$$

Sample size calculation for estimating a proportion p1					
Power	z-score	Precision	Variance	p1	p1 × (1–p1)
0.8	1.96	0.11	0.16	0.2	0.8
Sample size	100.7286				

Study design

At each house, samples were collected from different points using sticky traps or a vacuum cleaner to collect indoor arthropods. In the latter case, the content from each round of sampling (each 1m² in 1 minute) was emptied into a plastic freezer bag, labelled (collection place, relative humidity, ambient temperature, etc.) and frozen for later examination and identification in the laboratory. Sticky traps were fixed in different places and collected 24 hours later. The next day at the laboratory, equal weights of 200 mg portions from house dust samples were transferred into medium sized Petri dishes (minimum 5 times) and directly observed under a binocular microscope. Mites, being sensitive to light more slowly, were picked up and separated using the fine damp tip of entomological needle. They were then mounted onto microscope slides for further examination. Using diagnostic morphological features and valid taxonomic keys, they were identified to species level (3).

Statistical analysis

The collated data were uploaded onto the PC and analysed descriptively (frequencies and other descriptive statistics). We used *SPSS*, version 19, and *Excel* to tabulate results and draw histograms.

Results

A total of 624 specimens of arthropods were collected from the houses of 100 patients referred to the asthma and allergy clinic; these houses were located in various parts of Shiraz. From these, 46 mites and 578 other arthropods were identified. Table 1 shows the abundance order distribution of arthropods gathered from houses of patients referred to the asthma and allergy clinic. The species diversity in the insect orders and families was greater than in the class Arachnida. The specimens were classified into 14 orders based on their major morphological features. In the largest insect order, Coleoptera, 3 families, including 4 genera and 5 species, were identified (Table 1). In the medically important order Diptera, 4 families, including 4 species, were identified. Active search for arthropods using the vacuum cleaner method yielded a higher number of arthropod species (25 vs 16) than by the passive sticky trap collection method. The 2 most numerous species collected from patients' houses were *Musca domestica* and *Dermanyssus gallinae*. A total of 226 dipteran flies (129 *M. domestica*, 81 *Telmatoscopus proximus*, 11 *Chrysomya albiceps*, and 5 *Sarcodexia lambens)* were trapped from 7%, 20%, 3% and 2% of human residences, respectively (Table 1).

The moth fly, *T. proximus*, whose infestation by house was the highest among all Diptera (20%) (Figure 1), has a pair of dichoptic eyes, clear venation on tapered wings, and 16-segmented digitiform antennae, each segment of which is proximally barrel-shaped and equipped with multiple rings of unbranched sensory filaments or ascoid setae. This species is common in houses of Shiraz but is not considered an important allergenic arthropod by physicians or members of the health system. However,

Table 1 Abundance (%) order distribution of arthropods collected from houses of patients referred to the asthma and allergy clinic in Shiraz

Class	Family	Genus	Species	Common name	No. trapped	Abundance (%)	How collected
Insecta							
Collembola	Entomobryidae	Entomobrya	multifasciata	Spring tail	45	90	VC
			nicoletti	Spring tail	5	10	VC
Coleoptera	Tenebrionidae	Tribolium	castaneum	Red flour beetle	28	36.36	VC/ST
			confusum	Confused flour beetle	10	13	VC/ST
		Dichillus	Unidentified	Darkling beetle	8	10.38	VC
	Cucujiidae	Oryzaephilus	surinamensis	Saw-toothed grain beetle	4	5.19	VC/ST
	Dermestidae	Anthrenus	museorum	Museum/skin beetle	5/22	35.07	VC/ST
Hymenoptera	Formicidae	Myrmica	sabuleti	Sand ant	97	92.38	VC/ST
	Vespidae	Vespula	macalifrons	Eastern yellow jacket	2	1.91	ST
		Polistes	gallicus	Paper wasp	6	5.71	ST
Diptera	Muscidae	Musca	domestica	House fly	129	57.07	ST
	Calliphoridae	Chrysomya	albiceps	Blow fly	11	4.87	ST
	Sarcophagidae	Sarcodexia	lambens	Flesh fly	5	2.22	ST
	Psychodidae	Telmatoscopus	proximus	Moth fly	81	35.84	ST
Blattodea	Blattidae	Periplaneta	americana	American cockroach	12	43.55	ST
	Blatellidae	Blatella	germanica	German cockroach	20	56.45	ST
Thysanura	Lepismatidae	Lepisma	saccharina	Silver fish	15	100	VC
Thysanoptera	Thripidae	Frankliniella	tritici	Flower thrips	16	100	VC
Siphonaptera	Pulicidae	Pulex	irritans	Human flea	1	100	ST
Psocoptera	Liposcelididae	Liposcelis	paetus	Book louse	10	100	VC/ST
Malacostraca							
Isopoda	Cylisticidae	Cylisticus	convexus	Wood louse	16	100	VC/ST
Arachnida: Acarid mites							
Astigmata	Glycyphagidae	Glycyphagus	prunorum	Cheese mite	1	25	VC
	Suidasiidae	Suidasia	nesbitti	Scaly grain mite	3	75	VC
Cryptostigmata	Oppiidae	Aeroppia	SU	Oribatid mite	5	100	VC
Prostigmata	Bdellidae	Cyta	latirostris	Predator mite	1	100	VC
Mesostigmata	Laelaptidae	Haemolaelaps	glasgowi	Common rodent mite	3	8.33	VC
		Echinolaelaps	echidninus	Spiny rat mite	4	11.11	VC
		Laelaps	nuttalli	Domestic rat mite	3	8.33	VC
	Dermanyssidae	Dermanyssus	gallinae	Red fowl mite	13	36.15	VC
			americanus	American bird mite	6	16.66	VC
	Macronyssidae	Ornithonyssus	bursa	Tropical bird mite	3	8.33	VC
			sylviarum	Northern fowl mite	2	5.55	VC
	Ascidae	Blattisocius	tarsalis	Egg eating mite	1	2.77	VC
	Parasitidae	Holoparasitus	Unidentified	Gamasid mite	1	2.77	VC

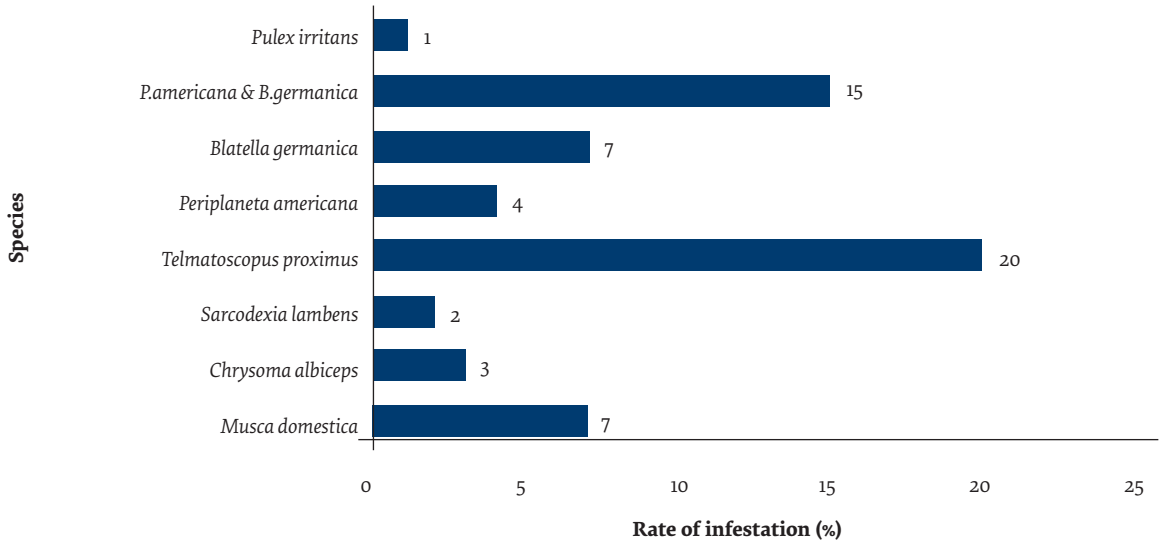
VC = vacuum cleaner; ST = sticky trap.

their hair and other part of their body could be allergenic to human.

The most numerous (n = 97) insect species found in patients' dwellings was the sand ant, *Myrmica sabuleti*, which was found in 24% of all infested houses (Figure 2). The second and third most frequent insect groups were the moth flies (mostly in suburban areas) and cockroaches (mostly in urban areas), being caught in 20% and 15% of all infested houses, respectively (Figure 1). All of the other insect species collected from patients' houses had infestation levels ≤ 10%.

The infestation frequencies of mites were more homogeneously restricted than insects, ranging from 1% to 5%, with the 2 species of red poultry mites (13

Figure 1 Distribution of infestations of dipterans, fleas and cockroaches in allergic patients' dwellings (*n* = 100) in Shiraz, 2016



Dermanyssus gallinae and 6 *D. americanus*) being found in 5% of infested houses (Figure 3). The red poultry mite, *D. gallinae*, also had the highest rate (36.15%) of abundance among the mesostigmatid mites (Figure 4).

Discussion and conclusion

Our findings showed that all (100%) patients' dwellings were infested with at least one allergenic arthropod group. Generally, simultaneous multiple infestation of the dwellings of allergic human is the rule. Within the Arachnida, the cosmopolitan mesostigmatid red poultry mite, *D. gallinae*, represents a domestic and occupational allergenic species reported mostly from indoors in birds' nests. The allergenic character of this mite has been confirmed through clinical evidence as well as from purification and sequencing of amino acids in allergens. In 1970, Bernecker reported that 2% of individuals who were positive to the allergic dermal test from *D. pteronyssinus* were also positive to *D. gallinae*. The concept of immunological cross-reactivity from skin prick tests between these 2 different arthropod species should not be ignored. Allergic signs are thus indicated which could be induced by the bites of the red poultry mite. From this species, a tropomyosin allergen belonging to the group 10 allergens (*D. gallinae* allergen) has been isolated, cloned and sequenced (7). Cases of human infestation with this species were

Figure 2 Distribution of infestations of non-dipteran insects found in allergic patients' dwellings (*n* = 100) in Shiraz, 2016

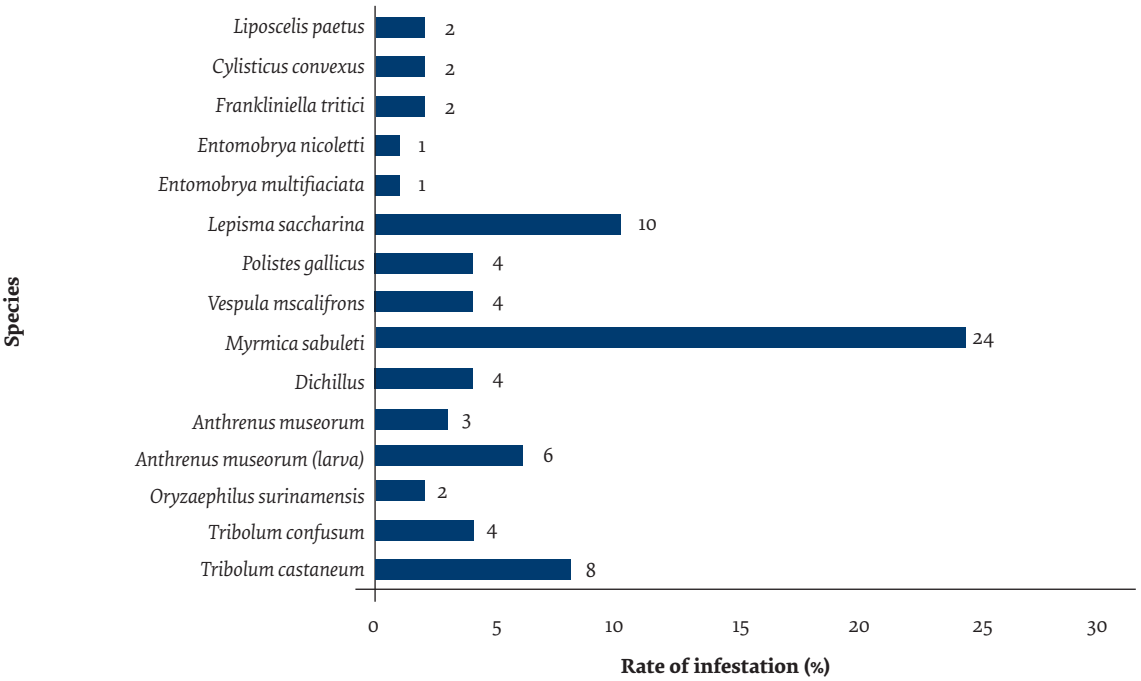
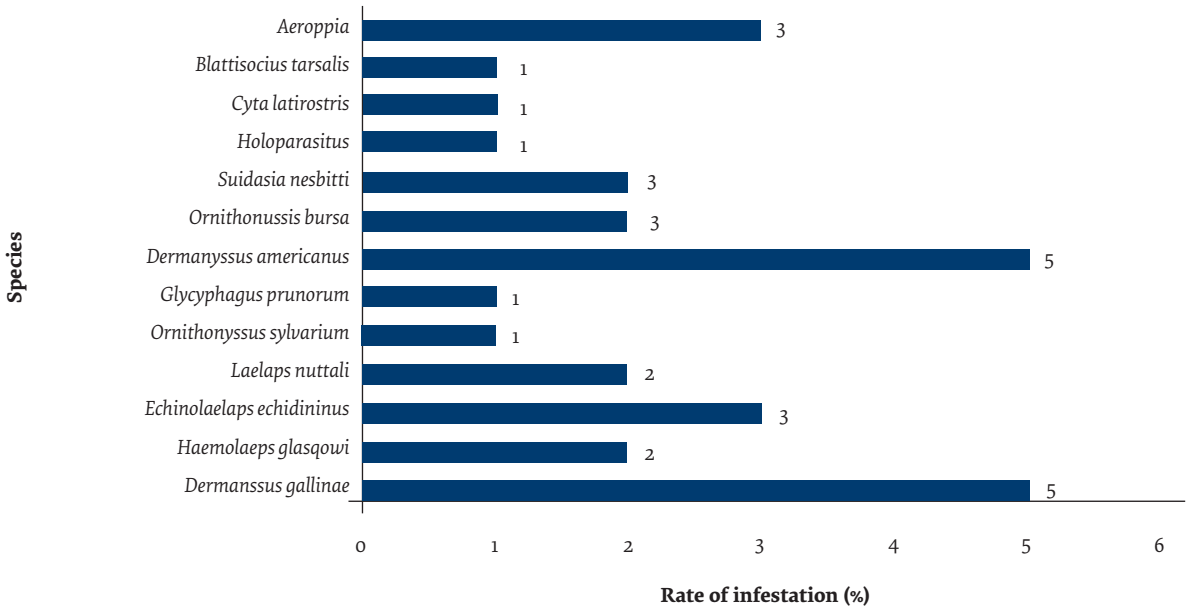


Figure 3 Distribution of all mites found in allergic patients' dwellings (*n* = 100) in Shiraz, 2016

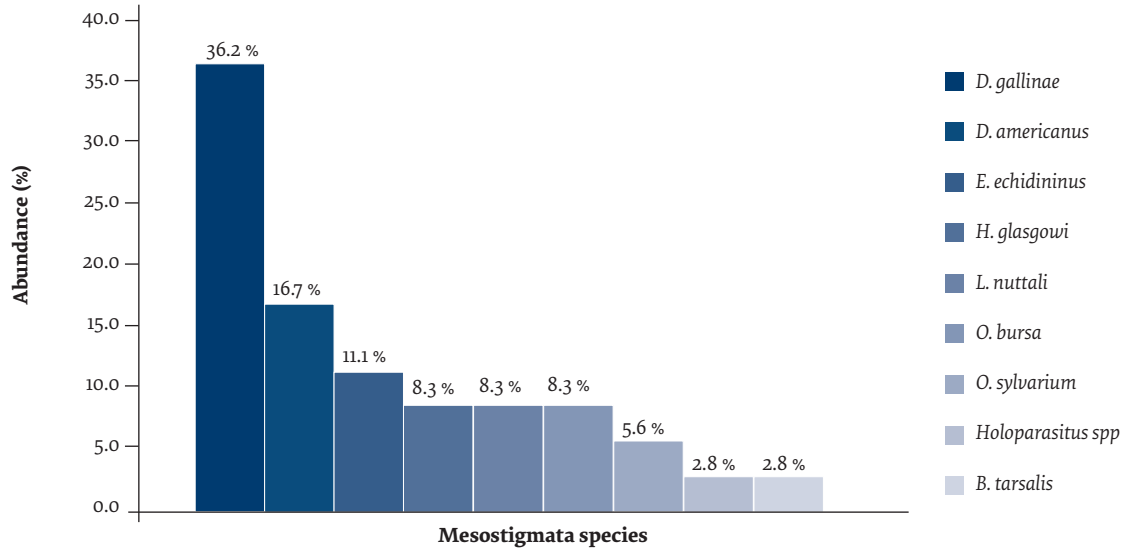


first reported in the Islamic Republic of Iran in 2014 (*8*). Some encephalitis viruses have been reported from this species, which is an indication of their medical importance. This species can also feed on humans, other mammals and birds and cause dermatitis and skin lesions. Cases of human infestation with *D. gallinae* are reported from Britain, Denmark, Egypt, France, Holland, Japan, Monte Negro, Morocco, Norway, Serbia and Turkey (*9*).

Isolation of the common rat house mite, *Haemolaelaps glasgowi*, from human dwellings could be attributed to the population eruption of urban rats infiltrating human dwellings in recent years. No routine antigenic tests are currently done for rat mites in this part of the world. Two other bird mites, *Ornithonyssus sylviarum* and *O. bursa*, which are often found among feathers, once on a human host could induce itching and painful dermatitis due to long allergic reactions. Some encephalitis viruses have been isolated from these 2 mites (*10*).

Description of *H. glasgowi* was first reported as the most widespread rodent ectoparasite in the Islamic Republic of Iran almost 2 decades ago (*11*). Both this species and *O. sylviarum* were subsequently identified from rodents in the city of Khoramabad in the west of the country (*12*). The latter species, the northern fowl mite,

Figure 4 Frequency of different species of mesostigmatid mites found in allergic patients' dwellings, Shiraz, 2016



was recently described in sparrows in the west (*13*). The presence of these species was likely due to the breeding of either birds or rodents in human settlements in Shiraz.

The identification and medical importance of 3 other species of mesostigmatid mites, *Dermanyssus americanus*, *Laelaps nuttalli*, and *Echinolaelaps echidninus*, has been established in the Islamic Republic of Iran. All these species were reported as ectoparasites in a rodent control programme in the southern port city of Bandar-Abbas (*14*). The first of these, the American red poultry mite, often lives on birds. It can cause eczematous dermatitis in some individuals (*15*).

Only 2 species were found from the astigmatid mites, *Suidasia nesbitti* and *Glycyphagus prunorum*. Both of these have medical importance and could induce cross-reactivity with other allergenic mites. In addition, ingestion of foods infested with *S. nesbitti* could induce anaphylaxis in susceptible individuals (*16*). This species is known to be one of the group 2 allergen inducers. The cheese mite, *G. prunorum*, induces intense itching and pruritus by penetration into the fissures of the epidermal layers of foot, hand and face. It is most often found on workers in cereal, flour and vegetable storage facilities (*17*). This genus is considered to be a storage products and dust mite. Its allergens have been identified using the skin radioallergosorbent test (RAST), purification and amino acid sequencing. Cross-reactivity between this, storage, and house dust mites has previously been verified (*18*).

From the hexapods, beetles, including *Tribolium confusum*, were found, which are associated with rhinitis, conjunctivitis, wheal and signs of asthma in some individuals (*19*). The beetle genus Dichillus was first reported from Turkey in 2012 (*20*). No medical importance has so far been recorded for this genus.

From the order Hymenoptera, the sand ant, *Myrmica sabuleti*, was the most abundant species among the non-dipteran hexapods. In addition to fire ants, Solenopsis, other genera of ants like Formica and Myrmica could induce serious allergic reactions in people (*21*). The species *Vespula maculifrons*, the eastern yellow jacket, is of medical importance but has not been reported from the Islamic Republic of Iran so far.

The order Diptera includes house flies, *Musca domestica* being the most frequently captured insect in allergic patients' dwellings. Their medical significance is evidently recorded. This and a number of other flies are also implicated in forensic medicine. The flesh fly, *Sarcodexia lambens*, may be involved in myiasis (*22*). Allergic reactions and asthma, particularly among children, may result from dried faeces, somatic setae, secretions and saliva from these species of flies in the vicinity of victims (*19*).

Steam bugs, including German and American roaches, *Blatella germanica* and *Periplaneta americana*, are 2 of the primary sources of allergens indoors inducing asthma and allergic reactions in susceptible individuals (*23*). The allergenic role and clinical importance of roaches on Iranian children with asthma has previously been investigated (*24*).

At present, studies on the allergic skin reaction test, which is routinely implemented in relation to allergenic arthropods at asthma and allergy clinics, is restricted to house dust mites (*D. farinae* and *D. pteronyssinus*) and cockroaches. Data from our investigation show that although all individuals whose houses were explored for the presence of arthropods were positive for the allergic skin reaction test, our findings indicate that only 15% of dwellings were infested with roaches and none of them were infested with the common house dust mites. Considering the fact that most arthropods can cross-react with other allergenic species, the allergies induced in these people could likely be attributed to other less important arthropods. It is thus suggested that, in line with routine tests, certain standard tests be carried out with regard to other allergenic arthropods so that the main disease-causing agent can be identified and suitable control measures can be included in an integrated control programme for training patients.

Finally, since a number of parasitic and vector-borne diseases are endemic to our region, the collection of data on the numerous prevalent arthropods is beneficial to the planning and evaluation of control measures to reduce disease. In conclusion, it is suggested that in all of the patients' dwellings, infestation with a minimal number of allergenic arthropod species are evidently observed. Health surveillance and prevention of infestation with these arthropods could have an immense impact on the control of the allergenic arthropod community, the prevention of respiratory diseases, and personal health care.

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Competing interests: None declared.

Prévalence des arthropodes responsables de manifestations allergiques dans les habitations de patients orientés vers un centre spécialisé pour la prise en charge de l'asthme et des allergies en République islamique d'Iran

Résumé

Contexte : Les arthropodes responsables de manifestations allergiques sont des vecteurs fondamentaux de maladies respiratoires sévères comme l'asthme et l'inflammation des voies respiratoires partout dans le monde.

Objectifs : La présente étude a été menée pour déterminer la prévalence de tous les arthropodes dans les habitations de patients orientés vers le centre spécialisé pour la prise en charge de l'asthme et des allergies à Chiraz.

Méthodes : Une étude transversale descriptive a été menée. Les participants étaient 100 patients allergiques ayant eu des tests positifs (sensibilité aux cafards et aux acariens). Des acariens ont été prélevés dans leurs habitations à l'aide d'un aspirateur. Les autres arthropodes ont été attrapés au moyen de pièges adhésifs. Les méthodes de l'observation directe et de la flottation ont été employées, et les échantillons ont été placés dans de l'éthanol à 70 %. Les caractéristiques morphologiques ont été identifiées en utilisant des clés taxonomiques valides.

Résultats : En tout, 624 échantillons ont été identifiés. Ils appartenaient à 14 ordres (4 ordres d'acariens : Astigmata, Cryptostigmata, Prostigmata et Mesostigmata ; et 10 autres ordres d'arthropodes : Diptera, Coleoptera, Hymenoptera, Thysanura, Thysanoptera, Entomobryomorpha, Blattodea, Siphonaptera, Pscoptera et Isopoda). Les deux espèces les plus représentées parmi les échantillons étaient *Musca domestica* et *Dermanyssus gallinae*.

Conclusions : Un petit nombre d'habitations étaient infestées par les cafards. Aucune n'était infestée par les acariens de poussière de maison. Les allergies induites chez ces patients pourraient probablement être attribuées à d'autres arthropodes non considérés comme des allergènes majeurs dans les centres spécialisés pour la prise en charge de l'asthme et des allergies en République islamique d'Iran. La surveillance de santé et la prévention des infestations par ces arthropodes pourraient avoir un énorme impact sur le contrôle de la communauté d'arthropodes responsables de manifestations allergiques, la prévention des maladies respiratoires et la santé personnelle à Chiraz.

معدل انتشار المفصليات الـمُسببة للحساسية في مساكن المحالين إلى عيادات الربو والحساسية في جمهورية إيران الإسلامية

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الخلاصة

الخلفية: تُعدُّ المفصليّات المسببة للحساسية عوامل أساسية تؤدي إلى استثارة أمراض تنفسية ذات أهمية طبية في العالم كله، كالربو والتهاب الجهاز التنفسي.

الأهداف: هدفت هذه الدراسة إلى تحديد معدل انتشار المفصليات في مساكن الأشخاص المحالين إلى عيادات الربو والحساسية في شيراز.

طرق البحث: كانت هذه الدراسة وصفية ومقطعية. وكان المشاركون فيها 100 من المرضى المصابين بالحساسية ممن جاءت نتيجة اختبارهم إيجابية (حساسية من الصرصور والسوس). وجُمع السوس من منازل هؤلاء الأشخاص باستخدام مكنسة كهربائية؛ بينما التقطت مفصليات أخرى بواسطة مصائد لاصقة. واستخدمت الملاحظة المباشرة وطرق التعويم وخُزنت العينات في مادة الإيثانول بتركيز 70%. وحُدّدت الخصائص الظاهرية باستخدام مفاتيح تصنيفية صحيحة.

النتائج: بصورة عامة، حُدّدت 624 عينة تنتمي إلى 14 رُتبة (4 رُتب للسوس، وهي: الحمكيات، والقراضيات الخنفسية، وأماميات الفوهة، ومتوسطات الفوهة؛ و10 رُتب أخرى من المفصليات، وهي: ثنائيات الأجنحة، ومغمّدات الأجنحة، وغشائيات الأجنحة، وهدبيّات الذيل، وهدبيّات الأجنحة، والقافزات الذنبية سداسية الأرجل، والصرصوريات، والبرغوثيات، والقاضمات، والمتساويات الأرجل). وكانت أكثر الأنواع تعددا الذبابة المنزلية وواخز الجلد الدجاجي.

الاستنتاج: عدد قليل من المساكن كان موبوءا بالصراصير؛ ولم يكن أي منها موبوءا بسوس أتربة المنازل المعروف. ويمكن أن تُعزى الحساسية لدى أولئك المرضى إلى أنواع أخرى من المفصليات التي لا تعد مادة مثيرة لحساسية الربو في عيادات علاج الحساسية في جمهورية إيران الإسلامية. ويمكن أن يكون للترصُّد الصحي والوقاية من الإصابة بتلك المفصليات أثر بالغ على مكافحة مجموعة المفصليات المثيرة للحساسية، والوقاية من الأمراض التنفسية، والصحة الشخصية في شيراز.

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Heavy metal concentration in classroom dust samples and its relationship with childhood asthma: a study from Islamic Republic of Iran

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Abstract

Background: Classrooms are an important environment for young children as this is where they spend a large part of their time.

Aims: This study was designed to quantify the levels of heavy metals in classroom dusts in Shiraz, a city southwestern Iran. The potential association between heavy metal levels and childhood asthma was also investigated.

Methods: We selected 32 schools for collecting classroom dust samples during September–November 2016. The concentration of 10 heavy metals was measured in these dust samples by optical emission spectrometry. The diagnosis of childhood asthma was made using both the medical chart of each student and examination by an allergist. The data were analysed using *SPSS*, version 21.0.

Results: The concentration of heavy metals in classroom dust samples ranged from 7559 to 53 723.0 mg/kg (mean: 16 945.5 mg/kg) for Fe, 169.0 to 952.0 mg/kg (mean 288.9 mg/kg) for Mn, and 9.0 to 971.0 mg/kg (mean 258.8 mg/kg) for Pb. We found no correlation between heavy metals in classroom dust and childhood asthma.

Conclusion: In comparison with studies reported elsewhere, the maximum levels of lead in our study were greater. A potential explanation for the lack of correlation with childhood asthma is the large mass of the particles, preventing them from reaching the lower airways. Nevertheless, special attention should be paid to reducing high levels of heavy metals in classroom dust in this area.

Keywords: asthma, dust, heavy metals, environment, schoolchildren

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Introduction

Heavy metals (HMs) are metals with specific densities greater than 5 g/cm^3 which are found naturally on the earth in very small amounts. Many of these HMs, such as copper, chromium, iron, manganese and zinc, are essential to health. However, if they accumulate in the body in concentrations exceeding a certain threshold, they can cause serious damage to various organs. Soil is the major source for HMs released to the environment; they can enter the human body via direct ingestion of soil via contaminated hands, inhalation of dust and eating polluted plants grown close to roads with heavy traffic or contaminating industries (*1–5*).

Epidemiological and experimental studies have provided evidence for the adverse effects of HMs on respiratory diseases and allergic sensitization (*6,7*). Among these, the metals most commonly associated with allergic diseases of humans are arsenic, cadmium, lead, nickel, chromium and manganese (*8,9*). Human exposure to HMs has been studied mainly by monitoring the concentrations in body fluids such as blood or urine, or by studying their concentrations in ambient air. Chronic exposure to arsenic by drinking groundwater contaminated with low levels of arsenic can be harmful for the respiratory system (*10*), and a high blood level of arsenic is a risk factor for nasal polyposis (*11*). A recent study reported that the concentration of cadmium in the blood was significantly associated with asthma, but not with high total IgE levels (*12*). A high blood lead level in children with asthma has been identified as a risk factor for increasing asthma severity, eosinophilia and elevated immunoglobulin E levels (*13*). A Chinese study reported that the prevalence of asthma and cough was associated with high blood levels of chromium and manganese (*14*). Recent studies have also reported on environmental exposure to several HMs and their adverse effects on the respiratory system. A higher level of ambient nickel was associated with increased respiratory symptoms and wheezing in young children. The rate of emergency

department visits and hospitalization for paediatric asthma has increased in areas with higher levels of ambient zinc (*15,16*).

Dust, the main source of HMs, is the preferred non-invasive matrix for metal monitoring. However, information is limited concerning the association between HMs in dust or soil and health care utilization for respiratory diseases, especially among children.

Childhood asthma is increasing and environmental changes due to exposure to more pollutants in outdoor and indoor air are suspected as possible causes. The prevalence of asthma among Iranian children varied from 1.26% to 11.60% by all the studies in an Iranian meta-analysis (*17*). In 2015, a study showed increasing trends in air pollutants and patient admissions due to asthma in Shiraz (*18*). Young children spend much of their time at school, and are therefore exposed to classroom dusts. Dust contaminated with HMs potentially affects the students' health and induces respiratory diseases by inflammation, sensitization and even scar formation in the lung tissues (*19,20*). Few studies have been conducted on the association between asthma and the level of heavy metals in the classroom.

The aim of this study was to measure the levels of 10 HMs, including arsenic (As), cadmium (Cd), chromium (Cr),cobalt (Co),copper (Cu), iron (Fe), manganese (Mn), nickel (Ni), lead (Pb) and zinc (Zn) in classroom dust of 4 districts of Shiraz. The potential association between HM levels and childhood asthma was also investigated.

Methods

Study area

Shiraz, the capital of Fars province, has a total area 240 km^2 and a population of around 1.5 million. It is located in the Zagros mountain range in southwestern Islamic Republic of Iran at an elevation of 1486 m above sea level. The city has a moderate climate and an average annual rainfall of about 300 mm. Industrial activities in the city include an oil refinery, a cement factory and a thermal power plant. Shiraz is also one of the major centres for electronic industries: about 50% of the country's electronic investment is concentrated here.

Winds are the principal transport mechanism of dust particles; this city has been affected by dust storms coming from Iraq in warm seasons in recent years. Moreover, gaseous wastes from primitive forms of heating and automobile exhaust along with factory chemicals are the main cause of air pollution in the area studied. In addition to high population growth, the rate of urbanization has also increased: it is now a highly urbanized area.

Sample collection

Sampling was carried out in the main area of the city, which was divided into 4 educational districts based on geographical area. Moshir crossing is the central point of the division: the 1st district is the north-western, 2nd north-eastern, 3rd south-western and 4th south-eastern sectors of the city. We randomly selected 2 primary schools and 6 high schools in each of the subdomains. From each school, 4 dust samples were collected from 2 classrooms and they were mixed to form a single sample for examination. Thus, 8 dust samples were collected from the primary schools (children aged 6–11 years) and 24 from the high schools (children aged 12–17 years) during September–November 2016. The principals of schools were asked not to clean the classrooms for 1 week prior to dust collection. Dust samples were collected from window sills, bookshelves, and corners in the classrooms using a clean plastic brush, tray and containers. The study protocol was approved by the ethics committee of Shiraz University of Medical Sciences (approval number: 12988).

Sample preparation and analysis

The samples were immediately put in polythene bags, labelled and transported to the laboratory. Large pieces of grit and dirt were removed from the dried dust samples and then they were passed through a 2 mm stainless steel sieve. The fraction < 2 mm was ground using an agate mortar and pestle, and passed through a 63 micron sieve. In order to determine the concentration of metals (As, Cd, Cr, Co, Cu, Fe, Mn, Ni, Pb and Zn), we carried out complete dissolution of dust samples (approximately 1 g of each), using a mixture of HF, HNO_3, $HClO_4$ and H_2O_2 in a Teflon beaker in a sand bath at atmospheric pressure. The concentrations of the 10 heavy metals were determined by an accredited commercial laboratory (Zar Azma Laboratory, Tehran) using inductively coupled plasma mass spectrometry (ICP-MS) methods (Agilent 7700x, Agilent Technologies, Santa Clara, California). Detection limit for the analysed metals was: As 0.1 mg/kg, Cd 0.1 mg/kg, Co 1 mg/kg, Cr 1 mg/kg, Cu 1 mg/kg, Fe 100 mg/kg, Mn 5 mg/kg, Ni 1 mg/kg, Pb 1 mg/kg and Zn 1 mg/kg.

Subjects and environmental questionnaire

We used 2-stage cluster sampling; in the first stage, all schools in each of the 4 subdomains were considered a cluster and 8 schools were randomly selected. In the second stage all classes in the selected schools were considered a cluster and 2 classrooms were randomly selected. We considered all students in these selected classes as our sample.

All students at the time of entering the school have a health record which is completed free by a different general practitioner every year. Collection of data from the medical records of students was authorized by the Department of Education in Shiraz and the principal of each school.The same allergist examined the student health records, completed the International Study of Asthma and Allergies in Childhood (ISAAC) questionnaire by interview and carried out a physical examination of all students in 2 random classes of each school for diagnosis of childhood asthma (*21*).

A school environment questionnaire was created for this study by the authors; it was completed by the principal of the school to obtain information about the education level (primary school or high school), the

surface area of school, age of school building, number of students in each class, number of students in school, air conditioning (heating and cooling elements), mechanical ventilation and the number of trees in the school yard. Information about HMs in street dust related to this area (Shiraz) was taken from a 2015 study for comparison with our data (*22*).

Statistical analysis

The Mann–Whitney U-test and analysis of variance (ANOVA) were used to compare the level of heavy metals in the sample schools and other areas. Pearson correlation was done for assessing the association between heavy metals in classroom dusts with the area of the school, age of the school building, number of students in each class, number of students in school and the number of trees. We used independent sample t-test for comparing the means. Analyses were performed using SPSS, version 22, and statistical significance was set at $P < 0.05$.

Results

A total of 32 schools were selected for classroom dust sampling, 8 (25%) primary schools and 24 (75%) high schools. Out of 11 001 students in the selected schools, 856 (7.78%) had asthma. Descriptive data of the schools are shown in Table 1.

The mean, minimum and maximum concentrations of 10 HMs across the sampling sites are shown in Table 2. Descriptive statistics showed, in decreasing order of concentration, Fe> Mn > Pb > Zn >Cr >Cu >Ni > Co > As > Cd in the classroom dusts; the concentration of Fe, which had the highest level (mean 16 945.5 mg/kg), was more than 5 times greater than the concentration of Mn (2nd highest level; mean 288.9 mg/kg).

The results of the Mann–Whitney U-test showed there was no difference between the level of heavy metals in dusts of classrooms in primary schools and high schools ($P = 0.1$).

Sampling was done in 4 districts; the results of the Kruskal–Wallis test showed that levels of Zn ($P = 0.007$) and As ($P = 0.005$) were significantly higher in the 3rd district. We found no correlation between the surface area of the school, age of the school building and the number of trees in the school with the concentration of HMs in classroom dusts.

Comparison of the mean content of 10 heavy metals in this study with urban street dust of previous study (*21*) in this area is shown in Table 2. The levels of chromium and lead in classroom dusts were significantly higher than in street dust in Shiraz. All selected schools had air conditioning, including heating and cooling devices; mechanical ventilation was not found in any school.

There was no correlation between single HMs in the classroom dusts and childhood asthma (Table 3). The sum of 10 heavy metal variables was assessed as a single variable. Pearson correlation showed that there was a negative relationship between the sum of HM levels and number of students diagnosed as having asthma, but this was not statistically significant ($r = -0.18$, $P = 0.30$).

Discussion

This study presents the concentration of HMs in classroom dust in selected primary and high schools in Shiraz. The mean values of the metals were Fe > Mn > Pb > Zn > Cr > Cu > Ni > Co > As > Cd in our classroom dusts. Sources of HMs in schools could be natural outdoor sources, including industrialization, vehicle emissions and street soil, or via indoor activities carried out within the building by the students.

Consistent with our findings, a study in Malaysia showed a high Fe concentration in indoor floor dust in 3 nursery schools and another Malaysian study found elevated levels of Fe in dust samples from 10 preschools (*23,24*). Iron is abundant in the Earth's crust and motor vehicle emissions are also a main source of ambient Fe (*25,26*). It may be transmitted to schools via airflow stream and wind. Small amounts of iron are required for maintaining good health, but large amounts lead to cellular damage, mutation and other diseases (*27*).

In a study on the dusts of 51 French classrooms at 17 nurseries and primary schools, the highest metal loadings were for Mn and Cu, however, Fe was not measured (*28*). Manganese is the 12th most abundant HM on earth and is often found in combination with Fe; it was the second most common HM in our study. Automobile traffic density is strongly correlated with increased atmospheric Mn concentrations. It is an essential metal for health, however, excessive exposure can cause neurodegenerative disorders in humans (*29*).

Comparison of HM concentrations between our classroom dust samples with the findings of a study from classrooms in Ghana showed that the levels of Fe, Co and Pb were several-fold greater in the our study (Fe 16 945.5 mg/kg vs 4.8, Co 6.3 mg/kg vs 0.5, Pb 258.8 mg/kg vs 31.2)

Table 1 Descriptive data of 32 selected schools in Shiraz, 2016

Characteristic	Minimum	Maximum	Mean	SD
Area of school (m^2)	1900	20000	5443.7	4502.9
Age of school building (years)	2	54	22.8	15.1
No. of classrooms in the school	5	50	14.62	7.1
No. of trees in the school	5	150	26.8	34.5
No. of students in each school	64	700	343.7	153.1
No. (%) of asthma cases in each school	8 (3.3)	84 (15.0)	26.7 (9.1)	3.5

Table 2 Comparison of heavy metal concentrations in classroom dust samples in Shiraz (2016) and urban street dust reported in a 2015 study (22)

Metal	Mean (mg/kg)	SD	Minimum (mg/kg)	Maximum (mg/kg)	*P*-value
As					
Classroom dust	2.8	1.7	0.2	8.8	< 0.001
Street dust	6.6	0.8	5.3	8.6	
Cd					
Classroom dust	1.0	2.3	0.2	13.5	0.3042
Street dust	0.5	0.2	0.3	0.9	
Co					
Classroom dust	6.4	2.96	3.10	16.1	–
Cr					
Classroom dust	172.8	122.1	50.0	514	0.0007
Street dust	67.2	12.9	31.6	105.9	
Cu					
Classroom dust	40.0	22.4	14.0	118.0	
Street dust	136.3	51	49.8	232.5	< 0.001
Fe					
Classroom dust	16 945.5	8 691.1	7 559.0	53 723.0	0.0973
Street dust	20 254.6	2 636.3	16 300.0	24 900.0	
Mn					
Classroom dust	288.9	156.1	169.0	952.0	0.0002
Street dust	438.5	73.2	245.0	652.0	
Ni					
Classroom dust	50.1	22.5	25.0	117.0	< 0.001
Street dust	77.5	14.7	39.4	117.9	
Pb					
Classroom dust	258.8	268.2	9.0	971.0	0.0220
Street dust	115.7	56.3	36.8	234.3	
Zn					
Classroom dust	258.8	210.6	26.0	829.0	0.0142
Street dust	403.5	180.5	160.9	778.3	

SD = standard deviation.

(*30*). The mean concentration of Co was 12.5 times greater in our study than in the Ghana study; nevertheless, a dose of ≤ 23 mg/kg of Co is considered safe for all age groups (*31*). Cobalt compounds have been used for centuries to impart a rich blue colour, and more recently cobalt has been mostly used in batteries for mobile devices.

Lead concentration ranged from 9 to 971 mg/kg according to our results; perhaps this wide range was because some schools are near and some far from the main streets. In indoor dust in areas with heavy traffic, Pb concentration has been reported to be in the range of 5.80–639.10 mg/kg (*5*): the range of Pb in our classroom dust was much greater than that. There has been heavier traffic in recent years. According to the Shiraz Traffic Organization report, the number of vehicles increased from 250 000 in 2007 to 700 000 in 2014 (*32*). An effective way of maintaining a clean classroom is certainly by installing mechanical ventilation systems to reduce the level of indoor HMs, but costs and energy expenditure are often high.

The concentration of HMs in indoor dust varies depending on the location. We did not find any relationship between the concentrations of HMs in the dust of classrooms with school demographics; only the level of metals was shown to be significantly higher in the 3rd district. Rahmat Highway is a main road in the 3rd district, running from Motahari Boulevard east to Modarres Boulevard, where it becomes Sardaran Boulevard. The schools in this district are located in the old centre of Shiraz, an area subject to heavy traffic and automobile emissions, which highlights the need to pay attention to HM contamination in children's schools.

The concentrations of HMs in Shiraz classroom dust were compared with data reported for street dusts in the same area. The level of Cr and Pb in classroom dusts was significantly higher than that in street dust; it may

Table 3 Correlation between heavy metal levels in classroom dusts and proportion of students who have asthma, Shiraz 2016

Metal	Students with asthma (%)	
	Pearson correlation	*P*-value
As	−0.049	0.788
Cd	−0.226	0.214
Co	−0.069	0.62
Cr	−0.005	0.979
Cu	−0.170	0.352
Fe	−0.102	0.578
Mn	−0.270	0.136
Ni	−0.122	0.505
Pb	−0.002	0.992
Zn	−0.078	0.673

be an indication of an increase in the release of Cr and Pb into the school environment. Chromiu is extensively used in paper production industries, and Cr in the school dust might be attributed to the use of paper and books in classrooms. Lead, as an indoor pollutant, could be generated from such sources as building materials, cleaning and hygiene products, computers and printers (*33*). The range and mean concentration of As, Cu, Mn, Ni and Zn were greater in the street dust than the classrooms dust; without doubt, street dust is much more easily polluted by outdoor particles in this area.

Indoor pollutants inside such buildings as home, the work environment, and school have been well recognized as influencing human health due to the chronic nature of the exposure. Despite this, our findings showed that none of HMs in classroom dusts correlated with the symptoms of childhood asthma. A study from Glasgow, Scotland, reported a strong association between soil Ni levels ≥ 1038 mg/kg and respiratory cases (*34*). The maximum level of Ni was 117 mg/kg in our study; therefore, the low quantity of Ni particles in dusts may be the reason for low level of asthma in our children. There are insufficient data in previous research for comparison of classrooms dust HM content with respiratory diseases and asthma.

A number of studies have shown the effect of airborne HM concentration on respiratory health. A study in Japan evaluated the association between changes in airborne HM levels including Fe, Mn, Cd and Cr with increasing cough (*20*). In a study from New York, increased probability of wheezing was associated significantly with increased level of ambient Ni and V (vanadium) (*15*). A recent study has shown that exposure to ambient Mn, Ni and Cr might be associated with adverse respiratory symptoms in Italian adolescents (*35*).

Particle penetration fractions into the deepest part of the respiratory system depend on the size, shape and quantity of elements. It appears that settled HM particles in dust are larger and heavier than airborne HMs and might not reach deeply into the airways. It may also related to the small diameter of the lower airways in children, making entrance of HM particles difficult in this age group.

In conclusion, the concentrations of Pb were higher in classroom dusts of Shiraz than the values now being reported in the more developed countries and in street dust. Improved ventilation and regular cleaning procedures in schools as well as control of air pollution can decrease the levels of HM loading in classroom dusts. Although we did not find any relationship between the concentrations of HMs in classroom dusts and asthma, large sample size and longitudinal studies are suggested to evaluate developing asthma in older age.

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Concentration en métaux lourds dans des échantillons de poussière prélevés dans des salles de classe et lien avec l'asthme infantile : étude en République islamique d'Iran

Résumé

Contexte : Les salles de classe constituent un environnement important pour les jeunes enfants, étant donné qu'ils passent une grande partie de leur temps dans ce lieu.

Objectifs : La présente étude a été réalisée pour quantifier les niveaux de métaux lourds présents dans les poussières de salle de classe à Shiraz, ville du sud-ouest de la République islamique d'Iran. Le lien potentiel entre les concentrations de métaux lourds et l'asthme infantile a également été examiné.

Méthodes : Nous avons sélectionné 32 écoles pour y prélever des échantillons de poussière dans les classes entre septembre et novembre 2016. La concentration en dix métaux lourds dans ces échantillons a été mesurée par spectrométrie d'émission optique. Le diagnostic d'asthme infantile a été posé à la fois sur la base du dossier médical de chaque élève et d'un examen réalisé par un allergologue. Les données ont été analysées à l'aide du logiciel SPSS, version 21.0.

Résultats : La concentration en métaux lourds dans les échantillons de poussière des salles de classe variait de 7 559 à 53 723,0 mg/kg (moyenne : 16 945,5 mg/kg) pour Fe, de 169,0 à 952,0 mg/kg (moyenne : 288,9 mg/kg) pour Mn et de 9,0 à 971,0 mg/kg (moyenne : 258,8 mg/kg) pour Pb. Nous n'avons établi aucune corrélation entre les métaux lourds présents dans la poussière des salles de classe et l'asthme infantile.

Conclusion : Comparativement aux études menées ailleurs, les niveaux maximaux de plomb étaient supérieurs dans notre étude. L'absence de corrélation avec l'asthme infantile pourrait s'expliquer par la masse élevée des particules, qui pourrait les empêcher d'atteindre les voies respiratoires basses. Néanmoins, une attention particulière doit être portée à la réduction des hauts niveaux de métaux lourds présents dans les salles de classe de cette région.

تركز المعادن الثقيلة في العينات الترابية في الفصول الدراسية وعلاقتها بربوْ الطفولة: دراسة من جمهورية إيران الإسلامية

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الخلاصة

الخلفية: تشكل الفصول الدراسية بيئة مهمة للأطفال الصغار حيث يمضون جزءا كبيرا من أوقاتهم فيها.

الأهداف: صُمّمت هذه الدراسة من أجل تحديد مستويات المعادن الثقيلة بصورة كمية في الأتربة المأخوذة من الفصول الدراسية في مدينة شيراز التي تقع جنوب غربي جمهورية إيران الإسلامية. كما درس الباحثون العلاقة المحتملة بين مستويات المعادن الثقيلة والإصابة بالربو في مرحلة الطفولة.

طرق البحث: اختار الباحثون 32 مدرسة لجمع عينات من أتربة الفصول الدراسية خلال الفترة من سبتمبر/ أيلول وحتى ديسمبر/ كانون الأول 2016. وقيس تركيز 10 معادن ثقيلة في تلك العينات الترابية بواسطة المقياس البصري للطيف المنبعث. وتم التوصل إلى تشخيص الإصابة بربو الطفولة من خلال مراجعة الملف الطبي لكل طالب على حدة وفحصه على يد اختصاصي تحسُّس. واسْتُخدمت برمجية SPSS، الإصدارة 21.0، لتحليل البيانات.

النتائج: تراوح تركيز المعادن الثقيلة في عينات أتربة الفصول الدراسية بين 7559 وحتى 53723.0 ميلليجرام/ كيلوجرام (المتوسط: 16945.5 ميلليجرام/ كيلوجرام) للحديد، و 169.0 إلى 952.0 ميلليجرام/ كيلوجرام (متوسط: 288.9 ميلليجرام/ كيلوجرام) للمنجنيز، و 9.0 إلى 971.0 ميلليجرام/ كيلوجرام (متوسط 258.8 ميلليجرام/ كيلوجرام) للرصاص. لم يجد الباحثون علاقة ارتباطية بين المعادن الثقيلة في أتربة الفصول الدراسية وبين الإصابة بربو الطفولة.

الاستنتاج: بالمقارنة مع الدراسات التي أُجريت في أماكن أخرى، كانت المستويات القُصوى للرصاص في هذه الدراسة أعلى بكثير. ويمكن أن يُعزى عدم وجود ارتباط بربو الطفولة إلى الكتلة الكبيرة للجسيمات، ما يعوق وصولها إلى مجاري الهواء السفلية. وبالرغم من ذلك، ينبغي إيلاء تركيز خاص إلى الحد من المستويات المرتفعة للمعادن الثقيلة في أتربة الفصول الدراسية في تلك المنطقة.

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Validity, reliability and use of a Kuwait child nutrition knowledge assessment questionnaire

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Abstract

Background: Little is known about the nutritional knowledge of children in Kuwait and school-based nutrition interventions are scarce. No validated tool to assess the nutrition knowledge of schoolchildren in Kuwait is available.

Aims: This study determined the validity and reliability of a nutrition knowledge questionnaire in Kuwaiti primary-school children, and measured children's nutrition knowledge before and after a nutrition awareness intervention.

Methods: The questionnaire included five questions to measure nutritional knowledge. The face and content validity were assessed by nutrition and paediatric experts. To assess questionnaire reliability and nutrition knowledge, 642 schoolchildren (8–12 years) were assigned to an intervention, control or reliability group. Each group completed the questionnaire twice, one or two weeks apart. Students in the intervention group attended a nutrition knowledge presentation before completing the questionnaire the second time. Independent and paired samples *t*-tests were used to assess score differences between and within the intervention and control groups for changes in nutrition knowledge. Pearson correlation coefficients were used to measure score consistency in the reliability group.

Results: Overall, the questionnaire had good content validity and moderate to strong reliability ($r = 0.44$, $P < 0.001$). Students in the intervention group had significantly higher mean nutritional knowledge scores after the intervention (from 3.65 (SD 1.03) to 4.20 (SD 1.02); $P = 0.17$). Control group scores were mostly unchanged.

Conclusions: The Kuwait child nutrition knowledge questionnaire is a valid and reliable tool to assess nutritional knowledge in schoolchildren in Kuwait. Nutrition knowledge of Kuwaiti schoolchildren should be improved using age-appropriate interventions in school.

Keywords: nutrition, knowledge, schoolchildren, questionnaire, Kuwait

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Introduction

The prevalence of childhood obesity in Kuwait is as high as 19.9% in children between 5 and 13 years of age *(1)* and has exceeded 30% in adolescents *(2,3)*. Previous studies have found an association between nutritional knowledge and dietary intake, indicating that improving nutritional knowledge at an early age may help promote healthy eating patterns in children *(4,5)*. Little is known about the current levels of nutritional knowledge in young people living in Kuwait. Recent studies reported low overall nutritional knowledge in high-school and college students in Kuwait *(6,7)*. Successful school interventions have been reported in other regions, with some showing improvements in children's diets with an increase in nutritional knowledge *(8,9)*. According to the literature, one reason for failing to report consistent results is because nutritional knowledge before the design of intervention programmes has not been assessed, probably because few valid and reliable nutrition knowledge assessment tools are available *(10–12)*. Researchers aiming to deliver successful school-based interventions to improve nutritional knowledge should therefore identify gaps in nutritional knowledge before designed and implementing such programmes. A nutrition knowledge questionnaire was previously validated for use with adults living in Kuwait *(13)*. A few nutrition knowledge assessment tools for use with schoolchildren have been developed and validated in other regions *(11,14,15)*; however, none has been validated for use in children living in Kuwait or neighbouring countries. Therefore, the primary aim of our study was to develop a valid and reliable nutrition knowledge assessment tool for use in primary-school children in Kuwait. In addition, because delivering a nutrition presentation intervention is part of the validation process, our secondary aim was to evaluate children's nutritional knowledge scores before and after the presentation.

Methods

Questionnaire development

The Kuwait children nutrition knowledge questionnaire is an original self-administered questionnaire developed by two senior dietitians (see supplementary material,

available online). It consists of a short demographics section, followed by five multiple choice questions intended to measure nutritional knowledge in children aged 8–12 years living in Kuwait. The questions were developed to assess knowledge of applied nutrition such as energy in food, understanding of nutrition labelling and assessment of portion size. Thus, one question asked about the portion equivalency of a whole fruit, two questions asked about serving size and caloric content as provided on food labels to assess skills in understanding food labels, one question assessed knowledge of healthy lifestyle recommendations, and one question assessed the ability to identify foods high in fat. The questionnaire was made available in both English and Arabic, and was administered in the main teaching language used at the schools. To assess each item's clarity and any ambiguity, face validity was assessed by a paediatric dietitian who verified the suitability of the questions by testing them on parents and their children in a clinical setting. Furthermore, the final version of the questionnaire was reviewed by an expert panel of dietitians and a consultant paediatrician to determine its content validity index *(16)*. For the purposes of data analysis, score percentages were calculated by adding the total number of correct answers and dividing the result by the total number of questions (five), multiplied by 100.

Participants

Private and public schools in different governorates across Kuwait were invited to participate through email, telephone calls and onsite visits to schools. A convenience sample of schools (n = 11) was selected based on the administration's willingness to participate; all were private schools. All schoolchildren aged 8–12 years across each of the 11 schools were invited to participate. Invitation letters and parental consent forms were sent home to parents and/or guardians, and those who provided signed parental consent were included in the study. Consent was also obtained from all participating children before completing the questionnaire.

A total of 750 schoolchildren whose parents provided consent for participation were included in the study. Schoolchildren were recruited with no preference for ethnicity or gender, and both Kuwaiti and non-Kuwaiti students were included in the study. Recruitment was started and completed within the academic year of 2016–2017.

Sample size

A minimum of 500 participants was required to provide an 80% chance of detecting a difference between each group at $P < 0.05$ and 95% confidence interval. Sample size was further confirmed by assessing similar previous work *(12,14,15)* where sample sizes ranged between 201 and 576 children (aged 13–15 years).

Data collection

Participating schools were assigned to one of three study groups (intervention (3 schools), control (4 schools) or reliability (4 schools)) based on the schools' preference and scheduling convenience. Schools able to allocate time for the nutrition presentation were assigned to the intervention group, whereas those that were unable to do so were randomized into the control or reliability groups using simple randomization. Intervention school students completed the questionnaire at baseline (T_0) (before the nutrition knowledge intervention) and again one week after attending a nutrition presentation (T_1). Control school students also completed the questionnaire at baseline (T_0) and again after one week later (T_1), but did not attend a nutrition presentation. Students in the reliability group completed the questionnaire at baseline (T_0) and again two weeks later, without receiving a nutrition presentation. Administration of the questionnaire took place on school premises in the presence of both the teachers and the research team. The questionnaire took about 15–20 minutes for the children to complete.

Nutrition intervention

An interactive 60-minute nutrition presentation was delivered by a senior dietitian to students in the intervention group after they had completed the questionnaire at baseline (T_0). The presentation covered a number of basic nutrition topics appropriate for this age group, including: portion size and food label interpretation, relationship between healthy eating and good health, and physical activity recommendations based on the guidelines of the Centers for Disease Control and Prevention, United States of America *(17)*. Prior to the delivery of the intervention, schools were asked whether nutrition curricula were in place. No schools included in the study delivered standardized curricula for nutrition education.

Validity and reliability of the questionnaire

Validity of the questionnaire was measured by comparing the nutritional knowledge scores of the group that received the nutrition intervention and the group that did not (control group). This was done by comparing the score differences between the intervention and control groups at T_1, after the intervention group had attended a nutrition presentation that aimed to increase their nutritional knowledge. The reliability group was used to assess the test–retest reliability of the questionnaire, where scores of the same student were compared at T_0 and T_1, with a two-week interval between completing the questionnaire the first and second time. According to the literature, a two-week interval is short enough for children not to have gained additional nutritional knowledge and long enough to have forgotten the answers in the first attempt *(18)*.

Statistical analysis

Demographic differences between the intervention and control groups were assessed at baseline using the independent samples t-test for continuous variables and the chi-squared test for categorical variables. Construct validity was assessed using independent samples t-tests to an-

alyse differences in scores between the intervention and control groups at both T_0 and T_1. Within-group knowledge scores were also assessed using paired samples *t*-tests to evaluate test score differences for each group at T_0 and T_1. The maximum possible score that could be achieved was 5.0 and mean scores and standard deviations (SD) were calculated for the intervention and control groups at T_0 and T_1 to compare overall score differences. Analysis of variance (ANOVA) was done to test for between-group differences (intervention and control) in scores by grade. Pearson correlation coefficients were used to evaluate reliability by assessing knowledge score consistency at both the first (T_0) and second (T_1) administration of the questionnaire. Only children in the reliability group (n = 221) were included in the reliability analysis. All data were analysed using *Stata* software, version 14.0. $P < 0.05$ was considered statistically significant.

Ethical approval

Ethical approval for the study was obtained from the Ethical Review Committee of the Office of Research Affairs at the Dasman Diabetes Institute, Kuwait.

Results

Demographic characteristics

A total of 642 children (mean age 10.22 (SD 1.09) years) were included in the final analysis. In all, 108 (14.4%) were excluded as they did not complete the second questionnaire at T_1 because they were absent from school on the day it was given out. Of the 642 children included in the study, 294 (45.8%) attended the nutrition intervention, 127 (19.8%) did not (control group) and 221 (34.4%) were in the reliability group. The sample included about the same number of boys and girls. Intervention and control groups had comparable demographic characteristics with respect to age and sex, but not school grade, nationality and residence (governorate) (Table 1). Since score differences were tested across grades, school grade was not controlled for in the analysis.

Reliability and validity

The Kuwait children nutrition knowledge questionnaire showed good content validity when assessed for efficacy by peer reviewers at the Dasman Diabetes Institute. For the content validity index review of the five items, expert ratings were highest (≥ 80%) for clarity, level of complexity, significance in the specified content area and applicability to the target population. All five items of the questionnaire were therefore retained for the purposes of this study. Results from the test–retest reliability assessment showed that the overall questionnaire had moderate, significant reproducibility in schoolchildren between the ages of 8 and 12 years living in Kuwait (n = 221; r = 0.44, $P < 0.001$), with mean scores remaining almost unchanged when the students completed it the first and second times (3.78 (SD 0.95) to 3.86 (SD 0.91), respectively).

Table 1 Demographic characteristics of the children in the intervention and control groups

Variable	Intervention groups (n = 294)	Control groups (n = 127)	*P*-value [a]
Age (years), mean (SD)	10.12 (1.06)	10.20 (1.2)	0.54
Sex, no. (%)			
Female	142 (48.3)	66 (52.0)	0.49
Male	152 (51.7)	61 (48.0)	
Nationality, no. (%)			
Kuwaiti	198 (67.4)	62 (48.8)	< 0.001
Non-Kuwaiti	96 (32.6)	65 (51.2)	
School grade, no. (%)			
3	–	3 (2.3)	
4	98 (33.3)	44 (34.65)	< 0.001
5	105 (35.7)	28 (22.0)	
6	62 (21.1)	35 (27.6)	
7	29 (9.9)	17 (13.4)	
Governorate, no. (%)			
Capital	100 (34.0)	18 (14.2)	
Hawalli	159 (54.1)	33 (26.0)	< 0.001
Al-Farwaniya	14 (4.8)	–	
Al-Ahmadi	4 (1.4)	63 (49.6)	
Al-Jahra	5 (1.7)	9 (7.1)	
Mubarak-Al Kabeer	12 (4.1)	4 (3.2)	

SD: standard deviation.

[a] *Independent samples t-test for continuous variables; chi-squared test for categorical variables. Significance set at P < 0.05.*

Nutrition knowledge

Mean overall scores of the Kuwait children nutrition knowledge questionnaire were 3.73 (SD 1.00) at baseline and 4.03 (SD 1.00) at follow-up (n = 642). A comparison of the intervention and control groups showed an increase in mean scores at retest in the children who received the intervention, which reflected an 11.0% improvement of percentage correct score (Table 2). Scores for control school students remained relatively unchanged, with only a slight improvement seen at T_1 (Table 2). An assessment of score differences by grade in the intervention and control groups showed a similar trend, where students in the intervention group scored consistently higher than those in the control group at T_1 across all grades (Table 2). Students in grade 6 showed the greatest improvement in scores (16.8% improvement of percentage correct score), although grade 7 students in the intervention group had the highest score at T_1 (4.48, SD 0.63).

Discussion

Students who received the nutrition intervention scored significantly higher than the controls the second time both groups completed the Kuwait children nutrition knowledge questionnaire. The 11.0% score increase we found is higher than scores reported in similar studies *(14,19)* but lower than those of others *(20,21)*. However, it is important to note that while we delivered a presentation-focused, interactive intervention, it was just one 60-minute session. Other interventions were longer, ranging from 90 minutes to 3 years *(12,14,19–21)*, and the longer length of these interventions may explain the higher score differences some studies found. Despite its short length, the Kuwait children nutrition knowledge questionnaire includes items that cover some of the most relevant nutritional topics for this age group. The short length of the questionnaire did not appear to affect the validity of the results, as shown by the item-specific increase in correct scoring in the intervention group of schoolchildren. Children who received the nutrition intervention scored more correct answers at T_1 on each item than those who did not have the intervention, and average percentage correct scores increased on the second administration (73.0% to 84.0%). Control scores were approximately similar at retest (76.0% to 78.6%). These results are in line with reported values of an American study, which found that students who received the intervention scored higher at retest, while control scores also remained high but relatively unchanged *(14)*. Researchers in South Africa also found that nutrition knowledge in the intervention group significantly improved after completing the an intervention programme (HealthKick) and, as with our study, no significant differences were observed in controls *(22)*. The results obtained with our questionnaire are therefore similar to those observed in questionnaires that are longer and more varied in content.

Further assessment by grade showed that: intervention school students in grade 7 had the highest scores at retest; score increases differed significantly

Table 2 Mean scores at T0 (before the nutrition intervention) and at T1 (after the intervention) in intervention and control schools by school grade (n = 421)

School grade	Intervention schools (n = 3)					Control schools (n = 4)				P-value T0[a]	P-value T1[b]
	No. of students	Mean score (SD) T0	% correct	Mean score (SD) T1	% correct	No. of students	Mean score (SD) T0	% correct	Mean score (SD) T1	% correct		
3	0	–	–	–	–	3	4.67 (0.58)	93.4	4.33 (0.58)	86.6	< 0.05	0.25
4	98	3.65 (1.01)	73.0	4.13 (1.01)*	82.6	44	3.34 (0.86)	66.8	3.57 (1.11)	71.4	0.19	< 0.05
5	105	3.71 (1.00)	74.2	4.12 (1.17)*	82.4	28	3.89 (1.13)	77.8	4.04 (0.79)	80.8	0.68	0.34
6	62	3.47 (1.13)	69.4	4.31 (0.90)*	86.2	35	4.09 (0.89)	81.8	4.23 (0.69)	84.6	< 0.05	< 0.05
7	29	3.83 (1.00)	76.6	4.48 (0.63)*	89.6	17	4.12 (0.93)	82.4	4.00 (1.12)	80.0	0.25	< 0.05
Total	294	3.65 (1.03)	73.0	4.20 (1.02)	84.0	127	3.80 (0.99)	76.0	3.93 (0.96)	78.6	0.17	< 0.05

Within-group analyses for differences in mean scores between T_0 and T_1 were done using paired samples t-tests. Significant difference were found for the interventions group ($P < 0.05$) but not the control group.

[a]*Between-group analyses using ANOVA to test differences in mean scores across grades at T_0 (significance set at $P < 0.05$).*

[b]*Between-group analyses using ANOVA to test differences in mean scores across grades at T_1 (significance set at $P < 0.05$).*

across middle-to-older grades between intervention and control students; and students in higher grades appeared to have benefitted more from the intervention. Findings from another study also show that students in higher grades had markedly higher scores on a questionnaire before and after an intervention to increase nutrition knowledge, although in this case all students were exposed to the intervention *(12)*. Thus, while the nutrition intervention effectively increased all scores in the Kuwait children nutrition knowledge questionnaire at T_1, it was especially advantageous to older children. Students in higher grades are typically more adept at understanding material but are also more heavily burdened with other school work; without an intervention, older students may disregard the importance of the questionnaire or refrain from refreshing their nutritional knowledge. This was seen in our study where control students in grade 7 scored higher than the intervention group at baseline but significantly lower at retest. In addition, within-group differences showed significant score increases for the intervention group in grades 4 to 7. These results are more favourable than those described in a similar study where only children in grade 2 appeared to score higher at retest *(12)*.

The moderate to strong test–retest reliability of the overall questionnaire is comparable to that reported in similarly short questionnaires *(12,14)*. However, a longer questionnaire used by a study in Texas had stronger reliability correlations *(23)*. Interestingly, questions from the nutrition knowledge category of the questionnaire used in the Texas study showed the weakest reproducibility (r = 0.40), especially for serving size and label literacy items *(23)*. This was seen in our study, where the lowest correlations were reported in questions associated with reading nutrition labels.

Our study has several strengths. First, the Kuwait children nutrition knowledge questionnaire is the first valid and reliable nutritional knowledge assessment tool for children in Kuwait, without age or gender bias. Second, the short length and time needed to complete the questionnaire and receive the intervention made recruitment relatively easy, and the simplicity of the questions compared to other questionnaires allowed for easier comprehension. Finally, the short yet effective intervention was less time-consuming for students and was not a burden on busy school schedules. Some limitations to our study should be noted: given that all participants were recruited from private schools, the results may not be generalizable to children attending public schools in Kuwait. Moreover, randomization of intervention and control students was not done because the intervention schools were recruited based on their agreement to allocate time for the nutrition presentation. This may increase the possibility of selection bias and reduce the ability to generalize results to other populations.

Conclusion

Increasing nutritional awareness in schools is both beneficial and necessary for the health of schoolchildren. The Kuwait children nutrition knowledge questionnaire is the first valid and reliable tool for the assessment of nutritional knowledge in schoolchildren aged 8 to 12 years living in Kuwait. Results from the study, while promising, require further validation in the public-school setting. This questionnaire has the potential to identify gaps in nutritional knowledge and nutrition curricula in primary schools in Kuwait and neighbouring countries. When accompanied by a nutrition intervention, the questionnaire can be used to help develop more effective and well-designed school-based nutrition intervention programmes aiming to improve nutrition knowledge and prevent obesity-related diseases in later life. Future studies should consider testing the Kuwait children nutrition knowledge questionnaire in the general school-aged population of Kuwait by implementing the questionnaire in both public and private schools.

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Competing interests: None declared.

Validité, fiabilité et utilité d'un questionnaire d'évaluation des connaissances des enfants en matière de nutrition au Koweït

Résumé

Contexte : Peu d'informations sont disponibles sur les connaissances des enfants koweïtiens en matière de nutrition, et les interventions d'éducation nutritionnelle dans les écoles sont rares. Aucun outil validé permettant d'évaluer les connaissances des écoliers koweïtiens à cet égard n'est disponible.

Objectifs : La présente étude visait à déterminer la validité et la fiabilité d'un questionnaire d'évaluation des connaissances en matière de nutrition auprès d'écoliers du cycle primaire au Koweït, et à mesurer les connaissances des enfants à cet égard avant et après une intervention de connaissance nutritionnelle.

Méthodes : Le questionnaire comportait cinq questions visant à évaluer le niveau de connaissance nutritionnelle. La validité apparente et de contenu du questionnaire a été évaluée par des experts en pédiatrie et en nutrition. Afin de mesurer la fiabilité du questionnaire et le niveau de connaissance en matière de nutrition, 642 écoliers (âgés de 8 à 12 ans) ont été répartis en trois groupes : un groupe d'intervention, un groupe témoin et un groupe servant à garantir la fiabilité. Chaque groupe a répondu deux fois au questionnaire, à une ou deux semaines d'intervalle. Les écoliers du groupe

d'intervention ont assisté à une présentation sur la nutrition avant de répondre une deuxième fois au questionnaire. Des tests *t* d'échantillons appariés et indépendants ont été utilisés pour évaluer les différences de scores entre le groupe d'intervention et le groupe témoin et au sein de ces deux groupes dans le but d'interpréter l'évolution des connaissances nutritionnelles. Les coefficients de corrélation de Pearson ont été utilisés pour mesurer la cohérence des scores dans le groupe de fiabilité.

Résultats : Globalement, le questionnaire présentait une bonne validité de contenu et une fiabilité moyenne à élevée ($r = 0{,}44$, $p < 0{,}001$). Les écoliers du groupe d'intervention avaient des scores de connaissance nutritionnelle beaucoup plus élevés suite à l'intervention (passant de 3,65 (E.T. 1,03) à 4,20 (E.T. 1,02) ; $p = 0{,}17$). Les scores du groupe témoin étaient en grande partie restés inchangés.

Conclusions : Le questionnaire d'évaluation des connaissances des enfants koweïtiens en matière de nutrition constitue un outil valide et fiable pour mesurer le niveau de connaissance nutritionnelle des écoliers au Koweït. Des interventions adaptées à l'âge devraient être organisées dans les écoles afin d'améliorer le niveau de connaissance des écoliers koweïtiens en matière de nutrition.

صحة وموثوقية واستخدام استبيان تقييم المعرفة الغذائية للأطفال في الكويت

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الخلاصة

الخلفية: لا يتوافر قدر كبير من المعلومات حول مستوى المعرفة التغذوية لدى الأطفال في الكويت والتدخلات التغذوية المدرسية اللازم القيام بها. كما لا تتوافر أداة مُجازة لتقييم المعلومات التغذوية لدى أطفال المدارس في الكويت.

الأهداف: هدفت هذه الدراسة إلى تحديد موثوقية وعيارية استبيان المعلومات التغذوية لدى أطفال المدراس الابتدائية في الكويت، وقاست المعرفة التغذوية لدى الأطفال قبل القيام بتدخل لرفع الوعي التغذوي وبعد القيام به.

طرق البحث: اشتمل الاستبيان على خمسة أسئلة لقياس المعلومات التغذوية. وقام خبراء في التغذية والأطفال بتقييم الصحة الظاهرية للاستبيان وصحة محتواه. ولتقييم عيارية الاستبيان والمعرفة التغذوية، وُزِّع 642 طفلا من أطفال المدارس (تتراوح أعمارهم بين 8 سنوات و 12 سنة) على مجموعة التدخل، أو المجموعة الضابطة، أو مجموعة العيارية. واستكملت كل مجموعة الاستبيان مرتين، يفصل بين كل منهما أسبوع أو أسبوعان. وحضر الطلبة في مجموعة التدخل محاضرة حول التوعية التغذوية قبل استكمال الاستبيان للمرة الثانية. واستُخدمت اختبارات لعينات مستقلة وعينات مزدوجة لتقييم الفروق في الدرجات بين مجموعة التدخل والمجموعة الضابطة وداخل كل منهما لبيان التغيرات التي طرأت على المعرفة التغذوية. واستُخدمت معاملات ترابط "بيرسون" لقياس اتساق الدرجات في مجموعة العيارية.

النتائج: بصورة عامة، تضمن الاستبيان موثوقية جيدة من حيث المحتوى وعيارية تتراوح بين متوسطة إلى قوية ($r = 0.44$; $p < 0.001$)،.حقق الطلبة في مجموعة التدخل درجات أعلى بكثير في المعرفة التغذوية بعد إجراء التدخل من 3.65 (بانحراف معياري 1.03) إلى 4.20 (بانحراف معياري 1.02)؛ ($p < 0.05$)، وكانت درجات المجموعة الضابطة في معظمها ثابتة لم تتغير.

الاستنتاجات: يعد استبيان المعرفة التغذوية لدى الأطفال في الكويت وسيلة موثوقة وعيارية لقياس المعلومات التغذوية لدى أطفال المدارس في الكويت. ينبغي تحسين المعرفة التغذوية لدى أطفال المدارس في الكويت باستخدام التدخلات الملائمة للسنّ في المدرسة.

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Seroprevalence of Herpes simplex virus types 1 and 2 in Indian and Filipino migrant populations in Qatar: a cross-sectional survey

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Abstract

Background: The epidemiology of herpes simplex virus infections is of growing interest but information on its seroprevalence in many countries is scarce.

Aims: This study aimed to measure the seroprevalence of herpes simplex virus type 1 and type 2 in Filipino and Indian men living in Qatar.

Methods: Blood serum specimens were collected from male blood donors aged ≥ 18 years in Qatar from 2013 to 2016. HerpeSelect® 1/2 and Euroline-WB assays were used to measure antibodies to herpes simplex virus types 1 and 2 in 120 Filipino and 325 Indian men.

Results: The seroprevalence of herpes simplex virus-1 was 84.9% (95% confidence interval (CI): 78.4–90.0%) in Filipino men and 48.3% (95% CI: 43.6–53.0%) in Indian men. The seroprevalence of herpes simplex virus-2 was 8.3% (95% CI: 4.6–13.7%) in Filipinos and 3.7% (95% CI: 2.2–5.9%) in Indians. The seroprevalence of herpes simplex virus types 1 and 2 increased with age, but this trend was only statistically significant in Indian men (P = 0.013 and P = 0.011 respectively).

Conclusions: The seroprevalence rates of herpes simplex virus-2 in Filipino and Indian men living in Qatar were similar to those found in the Philippines and India. However, the seroprevalence of herpes simplex virus-1 in Indians, while similar to that found in India, was substantially lower than that of other countries in Asia and developing countries worldwide, which needs further investigation.

Keywords: herpes virus 1, herpes virus 2, herpes simplex, seroprevalence, seroepidemiological studies, Philippines, India, Qatar

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Introduction

Herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2) are widespread lifelong infections (*1–4*), and are associated with mild to severe health consequences. Symptoms of HSV-1 infection include oral and facial lesions and the infection can affect the central nervous system, leading to oral, ocular, cutaneous and neural clinical manifestations such as herpes labialis (cold sores), herpetic whitlow, gingivostomatitis, neonatal herpes, blindness, meningitis and encephalitis (*5,6*). HSV-2 infection is one of the leading causes, if not the leading cause, of genital herpes and genital ulcer disease worldwide (*3,4,7,8*).

HSV-1 is generally acquired through the oral route during childhood with mild to serious morbidity, but evidence from the United States of America (USA) and Western Europe indicates a growing sexual acquisition through oral sex (*5,9,10*). HSV-2 is nearly always acquired sexually and is strongly associated with HIV infection (*11–13*), with its prevalence patterns providing key inferences about the structure of sexual networks (*14*). Evidence suggests also an association between HSV-1 and HSV-2 infections (*15,16*).

The epidemiology of HSV infections is of growing interest – the World Health Organization is leading the development of a business case for HSV vaccines to tackle this infection and disease burden (17). This effort, however, is challenged by the limited information on the current antibody prevalence (that is, seroprevalence) as well as inadequate knowledge of the epidemiology of both HSV infections in many countries (*17*).

We recently provided measures of HSV-1 seroprevalence (*18*) and HSV-2 seroprevalence (*19*) in 10 national Middle Eastern and North African populations currently living in Qatar, including Qatari citizens. One of the findings was an unexpectedly low seroprevalence of HSV-1 in Pakistanis, suggesting that HSV-1 seroprevalence in populations from the Indian subcontinent could be lower than global levels; the reasons for this low seroprevalence are still not known. Existing data on HSV-1 seroprevalence in Indian populations seem to support this conjecture (*20–22*).

Against this background, and with the availability of blood donor serum specimens from the Indian migrant population in Qatar, where Indian expatriates constitute nearly 25% of Qatar's current resident population (*23*), we aimed to measure the seroprevalence of HSV-1 and

HSV-2 in an Indian population and compare them to other migrant populations in Qatar and Indians in India. In addition, as data on HSV-1 seroprevalence in Filipino populations are lacking (*21*) and Filipino people are the third largest group of migrants in Qatar (*23*), we aimed to measure HSV-1 seroprevalence in a Filipino migrant population using the blood donor serum specimens available. Stressing the importance of migrant health, the limitations in global HSV-2 seroprevalence data (*3,4*) and the availability of serum specimens, we further aimed to measure HSV-2 seroprevalence in these two populations. Lastly, we aimed to generate inferences about the similarities and differences in the seroprevalence of HSV-1 and HSV-2 in different countries and populations in order to deepen our understanding of the global epidemiology of these two infections.

Methods

Study samples

The study samples consisted of Filipino and Indian male blood donors who donated blood between June 2013 and June 2016 at Hamad Medical Corporation, the largest provider of health care in Qatar. The blood specimens were collected – originally for other studies (*24–27*) – from 120 Filipino and 620 Indian male adults aged ≥ 18 years.

We stratified the Filipino sample into three age groups: ≤ 34, 35–44 and ≥ 45 years. However, we categorized the larger Indian sample into seven 5-year age groups: ≤ 24, 25–29, 30–34, 35–39, 40–44, 45–49 and ≥ 50 years. We chose these age groups to optimize the assessment of the age-specific seroprevalence of HSV-1 and HSV-2, given the number of specimens available for each nationality.

For the Filipino sample, we tested all 120 specimens. For the Indian sample, we used a sample size of 50 specimens per age group for the analysis. This number was calculated based on a significance level of 5% and an HSV-1 seroprevalence for each age group of 88% with a 10% precision level, and an HSV-2 seroprevalence for each age group of 2% with a 4% precision level. We based the two seroprevalence figures used for the sample size calculations on previous studies conducted in different national populations living in Qatar (*18,19*), as well as global data (*3,4,12,21*). However, as there are limited to no data on HSV types 1 and 2 in Filipino and Indian populations, we set a higher precision level. We finally used 325 specimens for HSV serology testing for the Indian sample. For each of the age groups of 25–29, 30–34, 35–39, 40–44, and 45–49 years, we randomly selected 50 specimens from the available specimens using a random number generator. For the remaining age groups (≤ 24 and ≥ 50 years), we tested all available specimens (n = 40 and n = 35, respectively).

Specimen testing

Laboratory analysis methods have been described previously (*18,19,28,29*). Briefly, for HSV-1 serology testing, we used the HerpeSelect® 1 enzyme linked immunosorbent assay (ELISA) kit (Cat. No. EL0910G-5, Focus Diagnostics, USA). In light of known limitations of false positives for HSV-2 antibody in ELISA tests, we used a two-test algorithm to identify specimens positive for HSV-2 based on previous work (*19*). We first used the HerpeSelect® 2 ELISA kit (Cat. No. EL0910G-5, Focus Diagnostics, USA) to screen the sera. We then used the Euroline-WB assay (Cat. No. DY 2531-2401-1 G, Euroimmun Laboratory, Germany) to test all the positive and equivocal sera to confirm positivity. We followed manufacturers' instructions for interpretation of each assay.

Statistical analysis

We estimated the overall and age-specific seroprevalence of HSV-1 and HSV-2 and 95% confidence intervals (CI). We examined trends in seroprevalence by age using the Cochran–Armitage test. We set the significance level at 5% and used SPSS, version 24 for all analyses.

Ethical considerations

The ethic boards of Hamad Medical Corporation, Qatar University and Weill Cornell Medicine-Qatar approved the use of the anonymized specimens.

Results

Filipino sample

The median age of the Filipino sample was 37 years. Of the 120 serum specimens tested for antibodies to HSV-1 and HSV-2, 101 sera tested positive for HSV-1, 18 sera tested negative and one was equivocal, giving an HSV-1 seroprevalence of 84.9% (95% CI: 78.4–90.0%). HSV-1 seroprevalence increased with age, from 84.6% (95% CI: 74.0–92.1%) in those aged ≤ 34 years to 88.9% (95% CI: 73.7–96.9%) in those aged ≥ 45 years, but this trend was not statistically significant (*P*-value for trend = 0.693; Figure 1A).

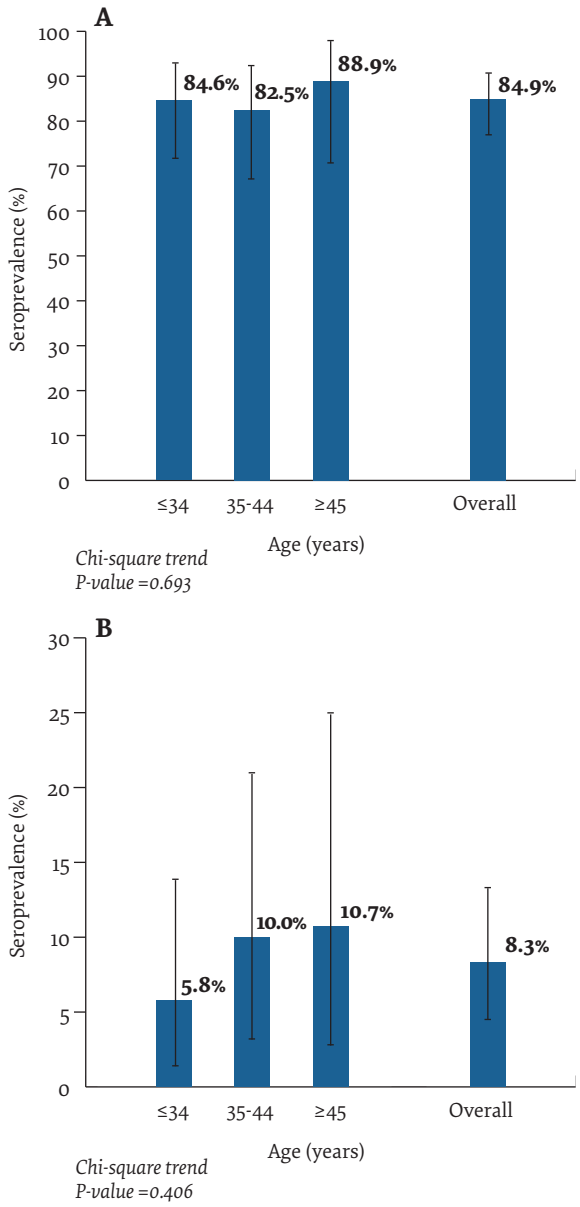
HSV-2 testing using HerpeSelect® 2 ELISA identified 10 sera as positive, 109 as negative and one as equivocal. Confirmatory testing was done on 11 specimens, and 10 were confirmed as positive and one as negative, giving an HSV-2 seroprevalence of 8.3% (95% CI: 4.6–13.7%). HSV-2 seroprevalence increased with age, from 5.8% (95% CI: 1.6–14.2%) in those aged ≤ 34 years to 10.7% (95% CI: 3.0 25.4%) in those aged ≥ 45 years, but this trend was not statistically significant (*P*-value for trend = 0.406; Figure 1B).

Indian sample

The median age of the Indian sample was also 37 years. Of the 325 serum specimens tested for HSV-1 and HSV-2 antibodies, 156 sera were positive for HSV-1, 167 were negative and two were equivocal, giving an HSV-1 seroprevalence of 48.3% (95% CI: 43.6–53.0%). HSV-1 seroprevalence increased with age, from 40.0% (95% CI: 26.9–54.2%) in those aged ≤ 24 years to 62.9% (95% CI: 47.6–76.4%) in those aged ≥ 50 years, a statistically significant trend (*P*-value for trend = 0.013; Figure 2A).

HSV-2 testing using HerpeSelect® 2 ELISA identified 20 sera as positive and 305 as negative. Confirmatory

Figure 1 Overall and age-specific seroprevalence of A) herpes simplex virus type 1 and B) herpes simplex virus type 2 in male Filipino blood donors living in Qatar



testing was done on 20 specimens, and 12 were confirmed as positive, seven as negative and one as equivocal, giving an HSV-2 seroprevalence of 3.7% (95% CI: 2.2–5.9%). HSV-2 seroprevalence increased with age, from 0.0% (95% CI: 0.0–7.2%) in those aged ≤ 24 years to 8.6% (95% CI: 2.4–20.7%) in those aged ≥ 50 years, a statistically significant trend (*P*-value for trend = 0.011; Figure 2B).

Discussion

Against a background of limited global data and using quality assays, we estimated the overall and age-specific seroprevalence of HSV-1 and HSV-2 in Filipino and Indian male migrant populations in Qatar. Of the Filipino sample, 85% were HSV-1 seropositive and < 10% were HSV-2 seropositive. Of the Indian sample, only 48% were HSV-1 seropositive and < 10% were HSV-2 seropositive. The seroprevalence of HSV-1 and HSV-2 in both samples showed increasing trend with age which reflects the higher cumulative exposure risk with age, as expected based on global data (*3*). However, this trend was not statistically significant for Filipino men.

To the best of our knowledge, this is the first time that HSV-1 seroprevalence has been reported in the literature for a Filipino population. HSV-1 seroprevalence in Filipinos was similar to that in other resident populations in Qatar (*18*) and to Asian populations in general (*21*). Of note, HSV-1 seroprevalence in Indians was much lower than that in other resident populations in Qatar (48% versus > 80%) (*18*), and in developing countries globally (> 80%) (*3,21,30–32*). However, it was similar to that reported in other studies on Indians, which was about 50% (*20–22*), which represents the home country rather than current residence, which can be explained because they had only recently migrated to Qatar.

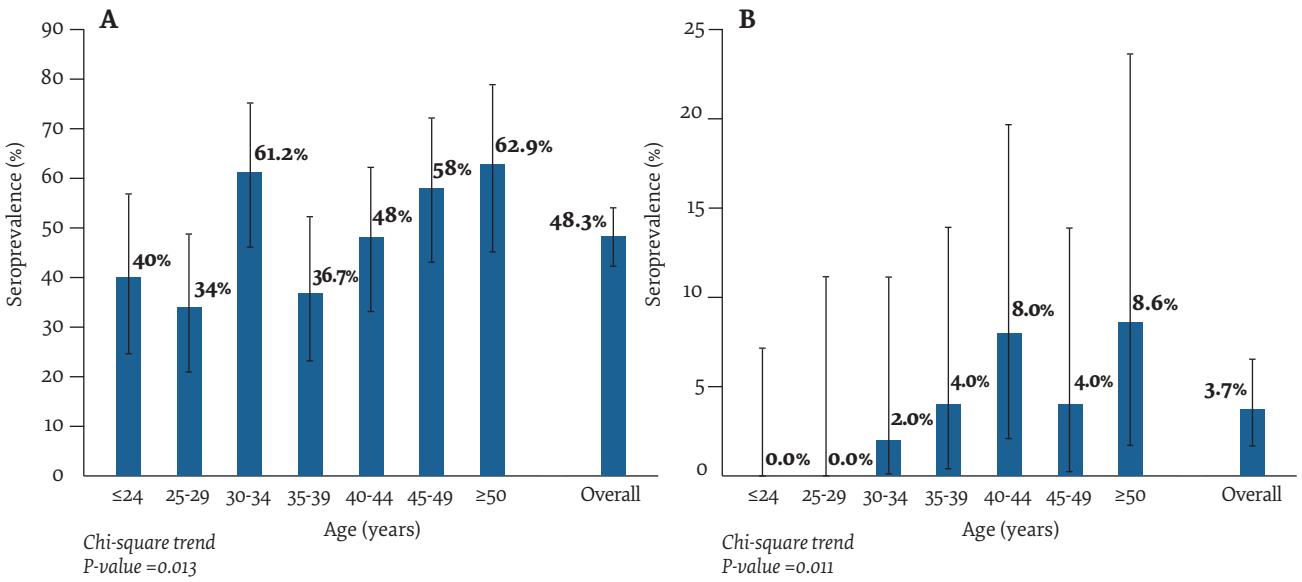
Our findings highlight an apparent unexplained anomaly in global HSV-1 seroprevalence data: low seroprevalence in the Indian subcontinent compared with what is expected for developing countries (*3,18,21,30–32*). These findings also suggest that about 50% of Indians may start their sexual activity lacking protective antibodies against HSV-1, and are thus potentially at risk of genital acquisition of HSV-1, which could lead to genital herpes.

HSV-2 seroprevalence in both our Filipino and Indian samples was consistent with that found in the Philippines (*33*) and in India (*34–37*), and comparable to that found in other resident populations in Qatar (*19*) as well as in Asia in general (*3,4*). This finding probably suggests lower levels of sexual risk behaviour (*14,38,39*), reflecting more conservative attitudes towards sexuality in these areas.

Our study has some limitations. The sample consisted of male blood donors and is not necessarily representative of women nor of the Filipino or Indian population at large, in each country. Blood donors are a healthy population with possibly lower levels of HSV infections. Only a few sociodemographic attributes were gathered, limiting the potential to assess associations with infection status. Although we used high-quality and validated commercial assays, existing data suggest potential population variation in assay sensitivity and specificity (*40*), which may affect the estimated seroprevalence.

In conclusion, this study fills a gap in the global map of HSV seroprevalence data. About 85% and < 10% of the Filipino migrant population in Qatar were HSV-1 and HSV-2 seropositive, respectively, while only about 50% and < 10% of the Indian migrant population were HSV-1 and HSV-2 seropositive, respectively. While HSV-1 levels in Filipinos followed global patterns, those in Indians affirm and demonstrate an anomaly of unexplained low HSV-1 seroprevalence in Indian subcontinent populations.

Figure 2 Overall and age-specific seroprevalence of A) herpes simplex virus type 1 and B) herpes simplex virus type 2 in male Indian blood donors living in Qatar



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Competing interests: None declared.

Séroprévalence du virus de l'herpès de types 1 et 2 parmi les populations migrantes indiennes et philippines au Qatar : enquête transversale

Résumé

Contexte : L'épidémiologie des infections par le virus de l'herpès suscite un intérêt croissant, mais les informations relatives à sa séroprévalence dans de nombreux pays sont rares.

Objectifs : La présente étude visait à mesurer la séroprévalence du virus de l'herpès de types 1 et 2 parmi les hommes philippins et indiens vivant au Qatar.

Méthodes : Des échantillons de sérum sanguin ont été prélevés sur des donneurs de sang masculins âgés d'au moins dix-huit ans au Qatar entre 2013 et 2016. Les tests HerpeSelect® 1/2 et Euroline-WB ont été utilisés pour mesurer les anticorps dirigés contre le virus de l'herpès de types 1 et 2 chez 120 hommes philippins et 325 hommes indiens.

Résultats : La séroprévalence du virus de l'herpès de type 1 était de 84,9 % (intervalle de confiance (IC) à 95 % : 78,4 - 90,0 %) chez les hommes philippins et de 48,3 % (IC à 95 % : 43,6 - 53,0 %) chez les hommes indiens. La séroprévalence du virus de l'herpès de type 2 était de 8,3 % (IC à 95 % : 4,6 - 13,7 %) chez les hommes philippins et de 3,7 % (IC à 95 % : 2,2 - 5,9 %) chez les hommes indiens. La séroprévalence du virus de l'herpès de types 1 et 2 augmentait avec l'âge, mais cette tendance n'était statistiquement importante que chez les homme indiens (p = 0,013 et p = 0,011 respectivement).

Conclusions : Les taux de séroprévalence du virus de l'herpès de type 2 parmi les hommes philippins et indiens vivant au Qatar étaient similaires à ceux constatés aux Philippines et en Inde. Toutefois, le taux de séroprévalence du virus de l'herpès de type 1 chez les Indiens, bien que comparable à celui relevé en Inde, était beaucoup moins élevé que celui des autres pays d'Asie et des pays en développement, ce qui mérite d'être étudié plus attentivement.

الانتشار المصلي لفيروس الهربس البسيط (النمط 1 والنمط 2) في أوساط المجموعات السكانية الهندية والفلبينية المهاجرة في قطر: مسح مقطعي

غياث نصر الله، سهى درغام، منال حرفوش، ليث أبو رداد

الخلاصة

الخلفية: يتزايد الاهتمام بدراسة السمات الوبائية لحالات العدوى بفيروس الهربس البسيط، غير أن المعلومات حول انتشاره مصليا في العديد من البُلدان شحيحة للغاية.

الأهداف: هدفت هذه الدراسة إلى قياس الانتشار المصلي لفيروس الهربس البسيط (النمط 1 والنمط 2) بين الرجال الذين يعيشون في قطر وينتمون إلى الجنسيتين الهندية والفلبينية.

طرق البحث: أُخذت عينات من مصل الدم من متبرعين بالدم من الذكور يبلغون من العمر 18 عاما أو أكثر في قطر في الفترة من 2013 وحتى 2016. واستُخدمت مقايستيْ HerpeSelect 1/2 ® و Euroline-WB لقياس الأجسام المضادة لفيروس الهربس البسيط (النمط 1 والنمط 2) لدى 120 رجلا فلبينيا و 325 رجلا هنديا.

النتائج: كانت نسبة الانتشار المصلي لفيروس الهربس البسيط (النمط 1) (90% - 78.4 = 95% CI; 84.9%) في صفوف الرجال من الجنسية الفلبينية و (53.0% - 43.6 = 95% CI; 48.3%) في صفوف الرجال من الجنسية الهندية. كانت نسبة الانتشار المصلي لفيروس الهربس البسيط النمط 2 (13.7% - 4.6 = 95% CI; 8.3%) في صفوف الرجال من الجنسية الفلبينية و (5.9% - 2.2 = 95% CI; 3.7%) في صفوف الرجال من الجنسية الهندية. وارتفع معدل الانتشار المصلي لفيروس الهربس البسيط (النمط 1 والنمط 2) مع تقدم العمر، غير أن هذا الاتجاه لم يُظهر أهمية إحصائية يُعتدُّ بها إلا بين الرجال من الجنسية الهندية (P=0.011; P=0.013) على التوالي.

الاستنتاجات: كانت معدلات الانتشار المصلي لفيروس الهربس البسيط النمط 2 في صفوف الرجال من الجنسيتين الفلبينية والهندية الذين يعيشون في قطر مماثلة لنفس المعدلات الموجودة في الفلبين والهند. ولكن بالنسبة لمعدل الانتشار المصلي لفيروس الهربس البسيط النمط 1 في صفوف الرجال من الجنسية الهندية، وبالرغم من مماثلته للمعدل الموجود في الهند، فقد كان أقل بصورة ملحوظة من بُلدان أخرى في قارة آسيا وفي بُلدان نامية أخرى حول العالم، وهو الأمر الذي يتطلب مزيدا من الدراسة.

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Performance of Eastern Mediterranean Region laboratories in the World Health Organization external quality assessment programme for arbovirus diagnostics

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Abstract

Background: Arboviruses such as dengue virus, yellow fever virus, Zika virus and chikungunya virus are major threats to human health globally, including countries in the Eastern Mediterranean Region (EMR).

Aims: This study aimed to assess laboratory proficiency in EMR countries for detection of dengue virus, yellow fever virus, Zika virus and chikungunya virus.

Methods: A global external quality assessment programme for arbovirus diagnostics was developed and run in 2016 and 2018. National-level public health laboratories were instructed to apply the polymerase chain reaction detection method on specimen panels containing dengue virus, yellow fever virus, Zika virus and chikungunya virus.

Results: Over both rounds of the programme, 100% of participating EMR laboratories correctly detected yellow fever virus and chikungunya virus, ≥ 84.6% detected dengue fever virus and ≥ 76.9% detected Zika virus.

Conclusion: While participating EMR countries demonstrated good proficiency in detecting arboviruses, only half of them were enrolled in the global external quality assessment programme, providing an incomplete picture of regional capacity. Effort should be put into increasing participation in subsequent rounds.

Keywords: arbovirus, diagnostics, quality, laboratory, assessment

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Introduction

Arboviruses spread by *Aedes* mosquitoes, particularly flaviviruses like dengue virus (DENV), yellow fever virus (YFV) and Zika virus (ZIKV), and alphaviruses like chikungunya virus (CHIKV), are major threats to human health worldwide. Several countries in the World Health Organization (WHO) Eastern Mediterranean Region (EMR) have been affected. Since 2005, chikungunya outbreaks have been reported in Djibouti, Pakistan, Sudan, and Yemen (*1*); dengue outbreaks have occurred in Djibouti, Egypt, Pakistan, Saudi Arabia, Somalia, Sudan and Yemen (*2*); the first-ever incidence of autochthonous transmission occured in Oman in 2019 (*3*); and Sudan has experienced multiple yellow fever outbreaks (*4*). Zika virus disease has seemingly not made its way to the Region, although the *Aedes* vectors are present in the countries mentioned and suitable habitats may be found in several of the Region's other countries (*5*).

Laboratory detection and characterization of arboviruses is key to diagnosis, clinical and environmental intervention, and epidemiological study. An external quality assessment programme (EQAP) is a means for laboratories to independently demonstrate adequate testing proficiency and detect deficiencies. WHO recently developed a global EQAP for arbovirus diagnostics to determine proficiency in countries in order to adequately detect the priority alpha- and flaviviruses, CHIKV, DENV, YFV and ZIKV. The first round of this global EQAP took place in 2016 as a continuation and global expansion of an EQAP initially developed in the WHO Western Pacific Region (*6*). Here we summarize the performance of laboratories in the EMR in the first (2016) and second (2018) rounds of the WHO global EQAP for arbovirus diagnostics.

Methods

The WHO EQAP for arbovirus diagnostics was implemented by the Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP), Australia. It assessed laboratory proficiency to detect DENV, CHIK, ZIKV and YFV (supplementary) by polymerase chain reaction (PCR). The core arbovirus panel consisted of 12 specimens of inactivated, lyophilized DENV, CHIKV, ZIKV, Japanese encephalitis virus (JEV) and either West Nile virus (WNV) or YFV (2016) or tick-borne encephalitis virus (TBEV, 2018). Two of the specimens were double spiked to simulate co-infection. Specimens were tested for homogeneity and stability and verified at referee laboratories. The supplementary 5-specimen YFV strain

panel was similarly prepared. The 2018 round of the EQAP additionally offered a serological specimen panel for anti-DENV antibody detection, but this is not examined here. Panels were distributed to participating national-level public health laboratories between October and December.

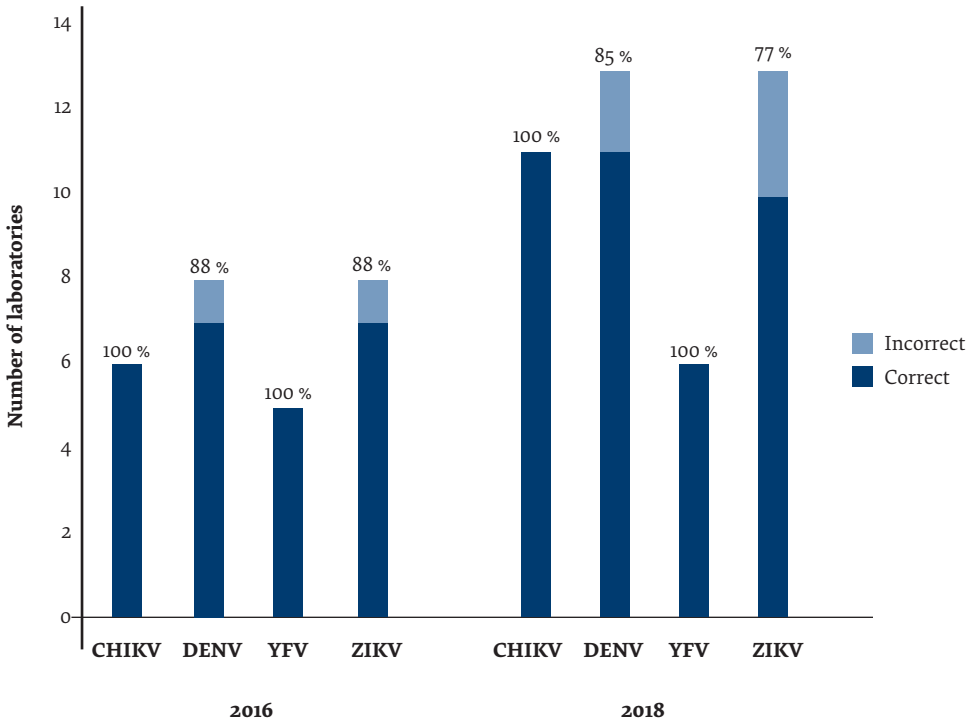
All participants were requested to report the absence or presence of DENV, CHIKV and ZIKV (and YFV, if relevant) in each specimen by PCR. Optionally, they could report the absence or presence of other alpha- and flaviviruses, perform DENV serotyping, or identify ZIKV lineage. Participants were assigned code numbers for confidentiality, which is maintained in any subsequent reporting by WHO and RCPAQAP. Participants received individual performance reports in March of the following year. Global reports were shared shortly thereafter.

Results

In 2016, 96 laboratories participated in the programme globally including 9 laboratories from 7 countries[1] in the EMR. Of the EMR laboratories, 100% (6/6) correctly identified CHIKV each time it was present, 100% (5/5) correctly identified YFV, and 87.5% (7/8) correctly identified DENV and ZIKV (Figure 1). Four testing errors were observed in this round of the EQA, evenly distributed among specimens, but primarily (3/4) committed by a single laboratory. PCR diagnostics for DENV, CHIK, ZIKV and YFV were available in 5 laboratories. JEV and WNV mostly went undetected as several laboratories did not test for them and instead only reported the absence or presence of the other viruses. One laboratory chose to perform an optional test, DENV serotyping, and did so with 100% accuracy.

In the second (2018) round of the EQAP, 107 laboratories participated globally. Thirteen, including 5 repeat participants, represented 11 EMR countries[2]. Of the EMR laboratories, 100% (6/6) correctly identified YFV, 100% (11/11) identified CHIKV, 84.6% (11/13) identified DENV and 76.9% (10/13) identified ZIKV (Figure 1). Of the 5 repeat participants, 100% (5/5) accurately detected CHIKV in each round, ≥ 75% (3/4 in 2016, 4/5 in 2018) accurately detected DENV and ≥ 60% (4/5 in 2016, 3/5 in 2018) accurately detected ZIKV. Note that one of the laboratories did not test for DENV in 2016. A smaller subset of 3 repeat participants tested for YFV in each round and did so correctly. Most errors (4/6) in the 2018 round were observed in a single DENV-ZIKV double-spiked specimen: 3 false negatives made by 2 laboratories and a clerical error by a third. However, the false negatives appeared to be coincidental as referee laboratories did not flag the specimen as problematic (defective specimens are withdrawn from scoring in EQAPs). The laboratory with the most errors in 2016 made none in 2018. PCR diagnostics for DENV, CHIK, ZIKV and YFV were available in 6 laboratories. Similar to 2016,

Figure 1 Proficiency of laboratories in the WHO EMR participating in the global EQAP for arbovirus diagnostics, 2016 and 2018



CHIKV=chikungunya virus; DENV=dengue virus; EMR=Eastern Mediterranean Region; EQAP= external quality assessment programme; YVF=yellow fever virus; ZIKV=Zika virus

[1] 2016: Egypt, Islamic Republic of Iran, Morocco, Oman, Saudi Arabia, Sudan and Tunisia.
[2] 2018: Bahrain, Egypt, Islamic Republic of Iran, Jordan, Kuwait, Lebanon, Morocco, Oman, Pakistan, Tunisia and United Arab Emirates.

laboratories reported solely on the absence or presence of DENV, CHIK, ZIKV and YFV, leaving the additional viruses (JEV and TBEV) undetected. DENV serotyping was again the only optional test chosen in 2018, this time by 5/13 laboratories that all performed the assay correctly.

Discussion

Although WHO invited roughly the same number of EMR countries in both years, almost double the number participated in 2018 compared to 2016. Participation is increased through WHO's direct interactions with, and encouragement of, targeted laboratories or through general advocacy efforts such as laboratory network meetings, trainings or publications (7). Participation nevertheless is voluntary and, particularly in the EMR, may at times be impacted by crises, limited resources, imposed sanctions and challenges with customs authorities. Four of the laboratories from 2016 could not join the second round. Participation of three of these, all from one country, was declined by the government in 2018 until a new national laboratory started to function. The fourth laboratory signed up but sanctions ultimately prevented RCPAQAP from working with couriers to deliver the EQAP panel to them.

EMR laboratories demonstrated good proficiency in arbovirus detection. In both EQAP rounds, ≥ 84.6% of laboratories accurately tested for DENV, CHIKV and YFV while ≥ 76.9% accurately tested for ZIKV. A minority of laboratories both years neglected to provide information supporting their results, such as assays used, target sequences or number of PCR cycles ran. Such incomplete recording hinders the EQAP organizer's ability to identify problematic areas and relay this information back in order to allow the relevant laboratories to take corrective actions.

While the EMR laboratories participating in the 2016 and 2018 rounds of the EQAP demonstrated good proficiency, they represent only half of the countries in the Region, providing an incomplete picture of national capacities for arbovirus diagnostics. In addition, few countries with arbovirus outbreaks have consistently, or ever, participated. For some this is due to conflict, other priorities or difficulty in sourcing the necessary reagents. WHO helps countries in the region obtain arbovirus diagnostic reagents and protocols as needed, as well as facilitates regional and in-country trainings to build laboratory capacity for arbovirus detection for preparedness or during emergency response. WHO will continue to assist where it can as well as encourage the enrolment of more countries in the programme to ensure that quality testing for arboviruses is available in the Region.

Conclusion

Arboviral infections continue to have an impact on countries in the EMR region, making it essential that national-level public health laboratories be able to adequately detect these pathogens. The EQAP for arbovirus diagnostics is an important measure of the ability of these laboratories to accomplish this and they have demonstrated good performance in the two rounds of the programme conducted thus far. Weak points revealed through the programme offer laboratories (and WHO, as needed) the opportunity to implement corrective actions to improve the quality of testing available. As EMR country representation in the programme still leaves room for improvement, particularly from countries with arbovirus disease outbreaks, WHO will endeavour to advocate for greater participation in upcoming rounds.

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Comepeting interests: None declared.

Performance des laboratoires de la Région de la Méditerranée orientale dans le cadre du programme d'évaluation externe de la qualité de l'Organisation mondiale de la Santé en matière de diagnostic des arbovirus

Résumé

Contexte : Les arbovirus tels que le virus de la dengue, le virus de la fièvre jaune, le virus Zika et le virus chikungunya constituent des menaces majeures pour la santé humaine dans le monde, y compris dans les pays de la Région de la Méditerranée orientale.

Objectifs : La présente étude visait à évaluer l'aptitude des laboratoires dans les pays de la Région pour la détection des virus susmentionnés.

Méthodes : Un programme mondial d'évaluation externe de la qualité pour le diagnostic des arbovirus a été mis au point et adopté en 2016 et 2018. Les laboratoires de santé publique nationaux ont reçu l'instruction d'appliquer la méthode de détection par amplification génique sur des panels d'échantillons de laboratoires contenant le virus de la dengue, le virus de la fièvre jaune, le virus Zika et le virus chikungunya.

Résultats : Au cours des deux cycles du programme, 100 % des laboratoires participants de la Région de la Méditerranéenne orientale ont correctement détecté le virus de la fièvre jaune et le virus du chikungunya, un pourcentage supérieur ou égal à 84,6 % ont détecté le virus de la dengue et un pourcentage supérieur ou égal à 76,9 % de ces laboratoires ont détecté le virus Zika.

Conclusions : Alors que les pays participants de la Région de la Méditerranée orientale ont démontré une bonne maîtrise de la détection des arbovirus, seulement la moitié d'entre eux étaient inscrits au programme mondial d'évaluation externe de la qualité, fournissant une image incomplète de la capacité régionale. Des efforts devraient être déployés pour accroître la participation aux cycles suivants.

أداء مختبرات إقليم شرق المتوسط في برنامج تقييم الجودة الخارجي لمنظمة الصحة العالمية لتشخيص الفيروسات المنقولة بالمفصليات

رينال سكويرز، كريستوفر أوكسنفورد، سيباستيان كوجنات، فرانك كونينجس

الخلاصة

الخلفية: تشكل الفيروسات المنقولة بالمفصليات مثل فيروس حمى الضنك، وفيروس الحمى الصفراء، وفيروس زيكا، وفيروس الشيكونجونيا، تهديدات رئيسية لصحة الإنسان على الصعيد العالمي بما في ذلك بلدان إقليم شرق المتوسط.

الأهداف: هدفت هذه الدراسة إلى تقييم الكفاءة المختبرية في بلدان إقليم شرق المتوسط للكشف عن فيروس حمى الضنك وفيروس الحمى الصفراء وفيروس زيكا وفيروس الشيكونجونيا.

طرق البحث: أُعد ونُفذ برنامج عالمي لتقييم الجودة الخارجية لتشخيص الفيروسات المنقولة بالمفصليات في عامي 2016 و 2018. وصدرت تعليمات إلى مختبرات الصحة العامة على الصعيد الوطني بتطبيق طريقة التفاعل السلسي للبوليميراز (PCR) على مجموعة عينات تحتوي على فيروس حمى الضنك، وفيروس الحمى الصفراء، وفيروس زيكا، وفيروس الشيكونجونيا.

النتائج: خلال جولتي البرنامج العالمي اكتشفت المختبرات المشاركة في التقييم فيروس الحمى الصفراء وفيروس الشيكونجونيا اكتشافًا صحيحًا بنسبة 100%، واكتشفت فيروس حمى الضنك بنسبة أكبر من أو يساوي 84.6%، واكتشفت فيروس زيكا بنسبة 76.9%.

الاستنتاج: برغم أن بلدان إقليم شرق المتوسط المشاركة أظهرت إتقانًا جيدًا في الكشف عن الفيروسات المنقولة بالمفصليات، فقد سُجِّل نصفها فقط في برنامج تقييم الجودة الخارجية العالمي، وهذا يعرض صورة غير مكتملة لقدرات الإقليم. وينبغي بذل الجهود لزيادة المشاركة في الجولات التالية.

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Second Eastern Mediterranean/Arab States regional summit of national ethics and bioethics committees

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Introduction

At the 11th Global Summit of National Ethics/Bioethics Committees, held in Berlin, Germany, 16–18 March 2016 (1), it was proposed to hold regional summits between global summits to discuss bioethical issues relevant to particular regions. The first Eastern Mediterranean/Arab States regional summit was held by the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the World Health Organization (WHO) in Muscat, Oman, 5–6 April 2017, in collaboration with the Omani National Bioethics Committee and Sultan Qaboos University (2). Two years later, the second summit, jointly organized by the UNESCO Regional Bureau for Sciences in the Arab States and WHO Regional Office for the Eastern Mediterranean, was held at the WHO Regional Office in Cairo, Egypt, on 15–16 December 2019 (3). The summit was followed by a workshop on training of trainers for ethics in implementation research, held at the WHO Regional Office, Cairo, 17 December 2019 (4).

Participants of the regional summit included representatives of national ethics and bioethics committees, ministries of health and higher education, academic and research institutions, and the League of Arab States, as well as international experts and staff from WHO and UNESCO. The overall aims of the second regional summit were to explore a regional approach to ethics policy processes and share experiences in promoting ethics, prior to the 13th global summit (which was planned to be held in Portugal during 2020).

The specific objectives of the summit were to:

- follow up on outcomes of the first regional bioethics summit;
- discuss outcomes of the last global bioethics summit held in 2018 and plan for the upcoming summit in 2020;
- outline and discuss methods of regional collaboration, with a special focus on fostering national ethics/bioethics committees;
- develop strategies to strengthen linkages between bioethics committees and policy-makers (ministries of health, education, science and technology); and
- share experiences and deliberate on current ethical issues, such as migration ethics and artificial intelligence.

Summary of discussions

During the meeting, linkages were established between bioethics committees and policy-makers, who were provided with evidence-based advice. The high quality of exchange between organizations was fruitful, as illustrated by WHO/UNESCO collaborative activities on one hand, as well as League of Arab States/UNESCO cooperation on the "Charter of Ethics of Science and Technology in the Arab Region" (5), on the other. It was stressed that at the political level, proposals are usually welcomed, adopted and supported during the meetings of ministers of health, showing real political will (for the Charter). In addition, it was also noted that WHO can help to assist national ethics/bioethics committee teams in their accreditation processes.

Recommendations

To WHO

- Enhancing multisectoral involvement in the work of national ethics/bioethics committees, including the media and civil society.
- Fostering bioethics principles within health sciences' curricula and beyond.
- Building the capacities of health care providers in medical and research ethics.

To Member States

- Promoting the use of new tools, such as virtual training, rather than face-to-face training.
- Strengthening training-of-trainers (TOT) courses in bioethics.
- Extending networking to national ethics/bioethics committees beyond the Region.
- Developing a roadmap on improving national capacity in bioethics and an action plan for implementation.
- Developing bylaws and regulations addressing the main ethical issues.

1 This report is based on the Summary Report on the Second Eastern Mediterranean/Arab States regional summit of national ethics and bioethics committees, 15–16 December 2019, Cairo, Egypt (http://applications.emro.who.int/docs/EMRPC047E.pdf?ua=1).

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