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Original Research

Recommendation discrepancies between vaccine licensure and vaccination practices: knowledge, practice, and attitude of healthcare providers

Jakub N. Khzouz , Shereen M. Aleidi , Rima A. Hijazeen , Abla M Albsoul-Younes , Mohammad H. Alajmi , Sief-Addeen B Shehadeh

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Abstract

Objectives: This study aimed to identify discrepancies between Jordan Food and Drug Administration (JFDA) vaccine licensure indications and directorate of communicable diseases (DCD) on immunization practices recommendations and assess the knowledge, practices, and attitudes of healthcare providers regarding these discrepancies. **Study Design:** A cross-sectional study. **Methods:** Data was extracted from Jordan National Drug Formulary documents, and corresponding information was collected from the DCD at the ministry of health and the National Immunization Technical Advisory Group. Self-administered Survey was used to assess knowledge and practices of paediatricians and gynaecologists related to vaccine licensure indications and recommendations differences. Descriptive statistics were used for data analysis. **Results:** Twelve cases of discrepancies were identified and, mainly were related to age indications, administration schedules, and management differences. The survey included 116 gynaecologists and 100 paediatricians with an overall response rate of approximately 46% and 50%, respectively. A total of fifty-nine gynaecologists (50.9%) correctly responded that only the JFDA licensure indications in the package inserts were required before vaccines may be marketed and only 44 paediatricians (n=44, 44%) correctly responded that only the DCD at the ministry of health is the lead organization that makes recommendations for vaccine use in Jordan. Analysis shows that only 64.7% (n=75) of gynaecologists and one-third (n=27, 27%) of paediatricians were aware of the differences between JFDA licensure and the DCD at the ministry of health recommendations for any specific vaccine. Most gynaecologists (n=81, 69.8%) and almost half of the paediatricians (n=46, 46%) stated that they follow publications from specific guidelines as the primary source of information on immunization schedules and vaccine recommendations. **Conclusions:** The findings suggest a need for better communication and coordination between regulatory bodies and healthcare providers to ensure consistent and evidence-based immunization practices..

Keywords: discrepancies; vaccine licensure; immunization; vaccine; food and drug administration; questionnaire

Jakub N. KHZOUZ. M.D. Consultant Histopathology, King Hussein Cancer Center, Department of Pathology and laboratory Medicine, Amman 11941, Jordan. jkhzouz@khcc.jo

Shereen M. ALEIDI. Pharmacy, M.Sc. Clinical Pharmacy, PhD in Clinical Biochemistry, Associate Professor in Biochemistry, Department of Biopharmaceutics and Clinical Pharmacy, Amman 11942, Jordan. s.aleidi@ju.edu.jo

Rima A. HIJAZEEN*. B.Sc. Pharmacy, M.Sc. Clinical Pharmacy, PhD Clinical Pharmacy Practice, Assistant Professor in Clinical Pharmacy Practice, The University of Jordan Faculty of Pharmacy Department of Biopharmaceutics and Clinical Pharmacy, Amman 11942, Jordan. r.hijazeen@ju.edu.jo

Abla M Albsoul-YOUNES. B.Sc. Pharmacy, PhD Pharmacology and therapeutics.Professor of Pharmacology and therapeutics. The University of Jordan Faculty of Pharmacy Department of Biopharmaceutics and Clinical Pharmacy, Amman 11942, Jordan. ablabsou@ju.edu.jo

Mohammad H. ALAJMI. Undergraduate Pharmacy student, The University of Jordan, Faculty of Pharmacy, Amman 11942, Jordan. mohammadalmrhan@gmail.com

Sief-Addeen B SHEHADEH. Undergraduate Pharmacy student, The University of Jordan Faculty of Pharmacy, Amman 11942, Jordan. saifalkiswani2@gmail.com

INTRODUCTION

Immunization is the most significant public health intervention to influence global health in terms of cost-effectiveness, efficacy, and safety.[1,2] It is estimated that every year immunization prevents between two and three million deaths globally.[1,2] National immunization programs (NIP) have resulted in a steady decline in overall morbidity and mortality through the widespread use of effective and quality-assured vaccines and technology, along with immunization-safe practices.[3] Jordan has made remarkable progress in combating communicable diseases due to following several important policies and strategies, such as the institutionalization of the national vaccination program, which continues to evolve (The National Strategy for Health Sector in Jordan 2016-2020).[4-6] The Jordanian Food and Drug Administration (JFDA), the National Immunization Technical Advisory Group (NITAG) of Jordan, and the Directorate of Communicable Diseases (DCD) at the ministry of health are responsible for licensing, regulating, and controlling vaccine use in Jordan. The JFDA is a regulatory body that develops indications for the licensure of vaccines. The NITAG of Jordan provides evidence-based recommendations on immunization policy to the ministry of health to foster evidence-informed policies by the DCD at the ministry of health. The Drug directorate, Registration department/ Sera, and vaccines registration committee of the JFDA regulate

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vaccine use in Jordan based on data submitted by a vaccine manufacturer.

The JFDA licenses a vaccine based on the review of Registration Requirements for Pharmaceutical Finished Products according to CTD (Common Technical Dossier) Format submitted by a vaccine manufacturer. The CTD form consists of substantial evidence to prove vaccine efficacy, safety, potency, and manufacturing consistency. Following the evaluation of efficacy and safety data, the sera and vaccines registration committee provides recommendations to the JFDA. The JFDA requires package insert information to guide healthcare providers regarding indications, potential benefits, and risks from vaccine use. The JFDA licensure process can be described on the JFDA website.[7,8] The NITAG is considered an advisory group that provides expert external advice and guidance regarding the use of vaccines, in which recommendations for policy decisions are based on a structured and comprehensive approach. NITAG's purpose is to provide independent, evidence-informed advice to policymakers and program managers on issues related to immunization, vaccines, and technologies. It considers observational studies and broader population-based public health and epidemiologic considerations to develop vaccine recommendations, including studies published post-FDA licensure. However, NITAGs themselves were not engaged in final decision-making or policy implementation. The DCD at the ministry of health was involved in the stages of the policy-making process, such as reviewing advice provided by the NITAG and participating in policy design, endorsement, implementation, monitoring, and evaluation.[9-10] These differences in approach and data sources may result in divergence between JFDA package insert information and the DCD recommendations. The objectives of the present study were to categorize discrepancies between FDA licensure indications contained in vaccine package inserts and the DCD at the ministry of health vaccine recommendations as published for vaccines licensed from 2000 through 2020. A second objective was to assess the knowledge and practices of paediatricians and gynaecologists regarding the concordance or discrepancies between JFDA licensure instructions and the DCD at the ministry of health vaccine recommendations.

METHODS

Data Abstraction

The DCD at the ministry of health recommendations and the NITAG of Jordan recommendations on immunization policy to the Ministry of Health were extracted from the relevant publication[5,11-14] and FDA licensure information was extracted from Jordan National Drug Formulary documents.[15]

Study design and subjects

The study was a cross-sectional questionnaire-based conducted from June 2021 through February 2022. A purposive convenience sample was used to include all paediatricians and gynaecologists who are both accessible and willing to participate in the study. The criteria for selecting HCPs were intended to be as inclusive as possible. As such, all paediatricians and gynaecologists with specific experiences or roles in immunization and vaccines and registered members of their respective professional societies in Jordan were eligible to participate, provided that written consent was given.

Study instrument

A previously developed questionnaire was used to assess the knowledge and practices of paediatricians and gynaecologists.[16] Expert healthcare professionals (HCPs) in vaccine and immunization from representative medical societies evaluated the questionnaires for face validity. After minor amendments to wording for applicability to the Jordanian settings, the reviewed draft of the surveys was piloted on a small sample of five paediatricians and gynaecologists , each to receive feedback on the survey's appropriateness, clarity, and length. The piloted sample was not included in the final analysis. Using a publicly available email address and contact phone number, the researchers (MA and SS are male, trained undergraduate pharmacy students) contacted the administrators at each society and asked them to send research information and the researcher's contact information to members at each society. Administrators of each respective society distributed electronic mail invitations to members of the Jordanian Society of Obstetrics and Gynecology (JSOG), which has an approximate membership of 746, and the Jordan Paediatric Society (JPS), with an approximate membership of 650. Paediatricians and gynaecologists who replied by email expressing their initial willingness to participate in the study were considered eligible to participate. Paediatricians and gynaecologists were recruited by sending a standard invitation letter, research information, and a questionnaire to the potential research participant's workplace.

Written and verbally informed consent was obtained from all participants, who were assured of data confidentiality and their right to withdraw at any time and asked to complete the questionnaire individually. The researcher arranged with each HCP to collect the self-completed questionnaire. The questionnaire took an average of ten minutes to complete. The questionnaires' cover page included a brief description of the research, how and why they have been selected, by whom the research is being conducted, what it involves, how the data will be used, a statement that ensure the confidentiality of the study findings, and the researcher contact information. The first part of the questionnaire gathered non-identifiable demographic information, specifically gender and years of experience in the field. The second part contained items directed to assess general knowledge, attitudes, and practices regarding immunization delivery to children, adolescents, and pregnant women with free-text items. Permission to use the survey was sent to the author directly. No incentives were offered to the participants who participated voluntarily.

Statistical analysis

Responses were coded and entered into the SPSS [IBM Statistical Package for the Social Sciences Statistics for Windows, Version 24.0. Armonk, NY] for statistical analysis. Descriptive statistical tests were applied to the data to calculate frequencies,

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percentages, means, medians, and standard deviations (SDs).

RESULTS

Comparison of JFDA Licensure Indications and DCD Vaccine Recommendations

Twelve cases were identified where differences exist between DCD vaccine recommendations and JFDA licensure indications. Differences were based on three areas: (1) age indications; (2) administration schedules; and (3) management differences.

Age Indication Differences

The three vaccines that differed for age indications are Diphtheria and Tetanus vaccine (DT) for children, Diphtheria and Tetanus vaccine (Td) for adults, and the measles, mumps, and rubella vaccine (MMR) (Table 1). A specific example of a vaccine with differing age indications is the measles, mumps, and rubella vaccine (MMR). In 2000, The MMR became part of the NIP and is given to children at 12 months and a second dose at 18 months. The JFDA recommended the first dose of MMR at 12 months and the second dose at four years of age to provide immunization against measles, mumps, and rubella.

Administration Schedule Differences

Differences in administration schedules were noted for six vaccines, including inactivated poliomyelitis vaccine (IPV), oral poliomyelitis vaccine (OPV), influenza virus vaccine, tetanus vaccine (Toxoid), diphtheria and tetanus vaccine (Td) for adults (Booster vaccination) and rabies vaccine (Table 2). The FDA licenses the influenza virus vaccine as a single-dose vaccination regimen. In 2017, the DCD at the ministry of health updated recommendations to a 2-dose schedule (either 0.25 mL or 0.5 mL administered at least four weeks apart) for children six months through eight years who are not previously vaccinated or with unknown vaccination history. Furthermore, if previously vaccinated, one or two doses and a single dose (0.5 mL) of influenza vaccine for patients aged nine years and older. Two doses, influenza vaccine based partly on evidence from clinical studies and epidemiologic surveillance. These data were not submitted to the JFDA by the vaccine manufacturer. Tetanus vaccine (Toxoid) is a single-component vaccine for primary immunization in adults who have not received childhood immunization against tetanus and for reinforcing immunization. The discrepancies between the DCD at the ministry of health and JFD recommendations were apparent in the case of fully immunized individuals with tetanus-prone wounds and with boosters up-to-date (< 5 years have elapsed since the last dose). The DCD recommends a booster dose in addition to antibacterial prophylaxis and anti-tetanus immunoglobulin. The JFDA recommends antibacterial prophylaxis and anti-tetanus immunoglobulin without a booster dose. Because of hypersensitivity reactions, routine boosters at intervals of 10 and 20 years are recommended by the JFDA (a booster is also needed in the case of a tetanus-prone wound if it is >5 years since the last dose.). Unlike the DCD recommendations, the JFDA also recommends a booster to all adults aged 50 years who have not received one in the previous five years.

Management Differences

Differences in the immunization decision between FDA vaccine licensure and ACIP recommendations were noted for varicella (chickenpox), pneumococcal infection, and anti-D human Immunoglobulin indications (Table 3). For example, using Rh (D) Immunoglobulin in pregnant women represents a difference. The JFDA recommends the use of Rh (D) Immunoglobulin in females who are Rh (D)-negative and are at or below child-bearing age for prevention of Rh (D) sensitization. The JFDA considered universal prophylaxis with Rh (D) immunoglobulin for Rh(D)-negative women with no preformed anti-D antibodies at 28 and 34 weeks gestation as best practice. The DCD at the ministry of health recommends the use of Rh (D) Immunoglobulin at 28 weeks gestation for prevention of Rh (D) sensitization in females who are Rh (D)-negative.

Questionnaire Results

A total of 116 gynaecologists and 100 paediatricians returned a completed questionnaire with an overall response rate of approximately 46% and 50%, respectively. Descriptive analysis revealed that more than half of the gynaecologists (n=71, 61.2%) and paediatricians (n=46, 46%) reported medical practice experience of ≥ 20 years. Most paediatricians (n=77, 77%) said their practice offered immunization, whereas most gynaecologists (n=108, 93.1%) reported that their practice did not offer it.

Gynaecologists' knowledge, attitude, and practice

Gynecologist knowledge of the process by which vaccines are licensed and recommended for use was assessed.

Table 1. Summary of age indication differences between Jordan Food and Drug Administration approved labels and directorate of communicable diseases recommendations for vaccines

Vaccine	JFDA instructions	DCD recommendations
Diphtheria and Tetanus vaccine (DT) for children	It is used in children under the age of 10 years for reinforcing immunization against diphtheria and tetanus.	It is used in children under the age of 6 years for reinforcing immunization against diphtheria and tetanus.
Diphtheria and Tetanus vaccine (Td) for adults	It is used for reinforcing immunization in persons over the age of 10 years.	It is used for reinforcing immunization in persons over the age of 6 years and is now the recommended booster for school children
Measeles,Mumps And Rubella vaccine (MMR)	First dose of MMR at 12 months and second dose at 4 years of age	First dose of MMR at 12 months and second dose at 18 months of age.

JFDA: Jordan Food and Drug Administration
DCD: directorate of communicable diseases
NITAG: National Immunization Technical Advisory Group

Table 2. Summary of administration schedule differences between Jordan Food and Drug Administration approved labels and directorate of communicable diseases recommendations for vaccines

Vaccine	JFDA instructions	DCD recommendations
Inactivated Poliomyelitis vaccine (IPV)	Consist of two doses (0.5 ml) administered at age 2 and 3 months	Inactivated Polio vaccine (IPV) (Salk). Consist of three doses (0.5 ml) administered at age of 2,3, and 4 months
Oral Poliomyelitis vaccine (OPV)	Consist of four doses (2 drops) administered at age 3,4,18 months, and 6 years	Consist of five doses (2 drops) administered at age 3,4,9,18 (booster dose) months, and 6 years
Influenza Virus vaccine	Annual immunization with single dose (half adult dose) is recommended in children 6 months or 3 years depends on the product. And a single dose (0.5 mL) influenza vaccine for adult patients.	In children 6 months through 8 years who are not previously vaccinated or with unknown vaccination history. Administer two doses, either 0.25 mL or 0.5 mL Administer at least 4 weeks apart. And one or two doses either 0.25 mL or 0.5 mL if previously vaccinated. and a single dose (0.5 mL) influenza vaccine for patients aged 9 years and older.
Diphtheria and Tetanus vaccine (Td) for adults (Booster vaccination)	Booster vaccination with diphtheria and tetanus at 50 years of age is recommended (after a primary course of 3 doses, and at least 2 booster doses of diphtheria–tetanus Vaccine)	Booster vaccination with diphtheria and tetanus should be given every 10 years
Tetanus vaccine (Toxoid) at the time of injuries	In the case of fully immunized individuals with tetanus-prone wounds and with boosters up-to-date (< 5 years have elapsed since the last dose). The JFDA recommends the need for antibacterial prophylaxis and anti-tetanus immunoglobulin, without a booster dose. Give a booster to all adults at 50 years who have not received one in the previous 5 years (consider using dTp) Give a booster 10 and 20 years after the primary course if this was given to an adult (a booster is also needed in the case of a tetanus-prone wound if it is >5 years since the last dose.)	In the case of fully immunized individuals with tetanus-prone wounds and with boosters up-to-date (< 5 years have elapsed since the last dose). The DCD recommends the need for a booster dose in addition to antibacterial prophylaxis, and anti-tetanus immunoglobulin. Not recommended Give a booster if > 5 since the last dose.
Rabies vaccine	Post-exposure if non-immune: 5 doses at 0, 3, 7, 14, 30 (and a sixth dose is considered immunosuppressed at 90 days); plus rabies immunoglobulin (if within 7 days of exposure).	Post-exposure prophylaxis if non-immune: 6 doses at 0, 3, 7, 14, 30, and 90 days of exposure plus rabies immunoglobulin (within 8 days of first dose). Plus a booster dose of the tetanus vaccine if he has been vaccinated previously and a period of one year has not passed * Post-exposure prophylaxis should be continued for the duration of the 10-day observation period or the waiting period for laboratory results. Vaccination can be stopped if it is proven that the animal is not infected with rabies.

JFDA: Jordan Food and Drug Administration
DCD: directorate of communicable diseases
NITAG: National Immunization Technical Advisory Group

Table 3. Summary of management difference between Jordan Food and Drug Administration approved labels and directorate of communicable diseases recommendations for vaccines

Disease	JFDA recommended treatment	DCD recommended treatment
Varicella, Chickenpox	**Varicella vaccine** Routine 2-dose vaccination. First dose at age 12 through 15 months. Second dose at age 4 through 6 years	**Varicella vaccine** Similar recommendations for varicella vaccine, however, not included in the National Immunization Program. The treatment in most of the cases is only by giving anti-pyretic, anti-histamine, and the anti-viral; acyclovir Varicella Zoster Human Immunoglobulin (VZIG) must be given to neonates whose mother develops chickenpox 7 or fewer days before delivery to 30 days after delivery, and to non-immune pregnant women (test for varicella zoster antibodies)

Pneumococcal infection	**7-valent pneumococcal conjugate vaccine (7vPCV)** ➢ All babies and children older than 2 months of age ➢ Any child <5 years with a specific chronic illness that predisposes them to invasive pneumococcal disease, eg cystic fibrosis ➢ Catch-up immunization for children 3–23 months. ➢ Offer all babies of <28 weeks gestation, or with chronic lung disease, 7-valent pneumococcal vaccine at 2, 4, 6 and 12 months and a Pneumococcal polysaccharide vaccine (PPSV23) booster at 4–5 years of age. **23-valent pneumococcal polysaccharide vaccine (23vPPV)** Sickle-cell disease >2 years of age Splenectomy (>14 days before if possible), functional or anatomical asplenia in people >5 years CSF leak in people >5 years Tobacco smokers Immunocompromised patients >5 years at increased risk of pneumococcal infection, eg acute nephrosis, organ transplant, HIV (before development of AIDS), myeloma, lymphoma People >5 years with chronic illness that increases risk of complications from pneumococcal infection, eg diabetes,alcohol dependence, heart, renal or pulmonary disease Most people need only one dose of PPSV23 and for certain high-risk groups a second dose of PPSV23, and another type of pneumococcal vaccine called PCV13, are recommended. Booster at 4–5 years in children who have had a primary course of conjugated vaccine and who are predisposed to high incidence or severity of pneumococcal disease, eg cystic fibrosis, cochlear implant	**7-valent pneumococcal conjugate vaccine (7vPCV)** Is the only potential Pneumococcal vaccine recommended by the DCD at ministry of health Offer all babies 3 doses of 7-valent pneumococcal vaccine at 3, 5, and 12 months. A booster dose at 4–5 years of age generally unnecessary Not included in the National Immunization Program **23-valent pneumococcal polysaccharide vaccine (23vPPV)** Similar recommendations, however, not included in the the National Immunization Program and not available in Jordan
Prevent a rhesus-negative mother from forming antibodies to fetal rhesus-positive cells	**Rh (D) Immunoglobulin** Prevention of Rh(D) sensitisation in females who are Rh(D)-negative and are at or below child-bearing age. Universal prophylaxis with Rh(D) immunoglobulin for Rh(D)-negative women with no preformed anti-D antibodies at 28 and 34 weeks gestation is generally regarded as best practice. It should be administered following any potentially sensitizing episode immediately or within 72 hours of the episode however, if not given within 72 hours, a dose given within 9–10 days may provide protection. Patients treated with routine antenatal prophylaxis still require Rh(D) immunoglobulin following delivery	**Rh (D) Immunoglobulin** Prevention of Rh(D) sensitisation in females who are Rh(D)-negative and should be administered at 28 weeks gestation and following any potentially sensitizing episode (for example abortion, miscarriage, still-birth) immediately or within 72 hours of the episode Patients treated with routine antenatal prophylaxis still require Rh(D) immunoglobulin following delivery

JFDA: Jordan Food and Drug Administration
DCD: directorate of communicable diseases
NITAG: National Immunization Technical Advisory Group

Few respondents (n=4, 3.4%) were unfamiliar with the immunization licensure process. Forty-four (37.9%) answered that JFDA licensure and NIP recommendations were required for vaccine use. Few respondents (n=7,(6%) answered that neither JFDA licensure nor NIP recommendations were needed. While only two respondents (1.7%) stated that only NIP must be in place before vaccines can be administered, fifty-nine respondents (50.9%) correctly responded that only the JFDA licensure indications in the package inserts were required before they may be marketed. Gynaecologists' knowledge of differences between JFDA licensure and NIP recommendations for any specific vaccine was evaluated. Analysis shows that only 64.7% (n=75) of gynaecologists were aware of the differences, and 35.4% (n=41) were unaware that differences exist. A chi-square test of independence showed no significant association between years of practice and awareness of differences between JFDA licensure and NIP recommendations, $X2$ (8, N = 116) = 11.38, p = .181. Of the 75 respondents who expressed awareness of differences, 48 (41.4%) deferred their primary source, a publication from specific guidelines, and only 27 (23.3%) deferred JFDA vaccine licensure recommendations.

Gynaecologists ' attitudes and practices were investigated. Most respondents (n=81, 69.8%) stated that they follow

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publications from specific guidelines as the primary source of information on immunization schedules and vaccine recommendations. However, a fifth (n=25, 21.6%) of respondents considered JFDA vaccine package insert, a few respondents (n=7, 6%) reported Jordanian NIP schedules, and only three respondents (2.6%) reported using other references for immunization scheduling and vaccine recommendations. A chi-square test of independence showed that there was no significant association between years of practice and source of information on immunization schedules and vaccine recommendations, $X2$ (12, N = 116) = 13·24, p = .35· Figure 1 summarizes gynaecologists' methods of keeping up to date on immunization recommendations. Further analysis of the data shows that almost half of the gynaecologists (n=21, 52.5%) chose publications from NIP and review of vaccine package inserts to remain updated on immunization recommendations.

Gynaecologists recommend that pregnant women routinely receive Tdap, influenza, and tetanus toxoid vaccines (n=83,71.6%; n=69, 59.5%; and n=76, 65.5%, respectively). However, concerns do exist. Analysis shows that approximately more than half of respondents who expressed initial willingness to recommend vaccines were hesitant to offer Tdap, influenza, and tetanus toxoid vaccines (67.7%, 51.5%, and 58.7%, respectively) to pregnant women in their practice.

As illustrated in figure 2, gynaecologists ' responses were consistent across all concerns regarding the recommendation for receiving Tdap, influenza, and tetanus toxoid vaccines. Respondents expressed similar attitudes toward receiving Tdap, seasonal influenza, and tetanus toxoid vaccines during pregnancy. As such, they did not think that they were clinically necessary for pregnant women and generally did not have any concern about administering these vaccines during pregnancy. Compared to other concerns, safety concerns for the infant seemed to be the primary concern about following the recommendation to administer Tdap, influenza, and tetanus toxoid vaccines during pregnancy. However, cost burden was the least rated concern in administering Tdap, seasonal influenza, and tetanus toxoid vaccines during pregnancy.

Despite these concerns, seasonal influenza vaccine and tetanus toxoid vaccines are routinely recommended to pregnant women.

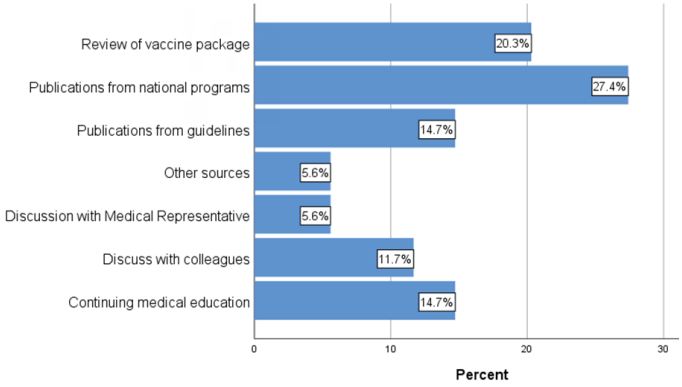

Figure 1. Gynaecologists' methods of keeping up to date on immunization recommendations

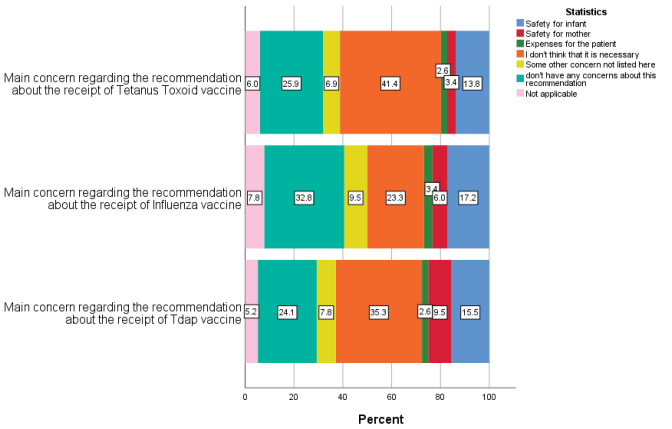

Figure 2. Gynaecologists ' concerns from recommeding Tdap, influenza, and tetanus toxoid vaccines

Pediatricians' knowledge, attitude, and practice

Pediatricians' knowledge of the lead organization responsible for providing vaccine recommendations for use was assessed. Only 44 respondents (n=44, 44%) correctly responded that only the NIP at the ministry of health is the lead organization that makes recommendations for vaccine use in Jordan. A similar number of respondents (n=45, 45%) responded that both JFDA licensure and NIP recommendations were required for vaccine recommendations. Only ten respondents (n=10, 10%) did not know which organization is responsible for vaccine recommendations. A total of 57(57%) respondents were unfamiliar with the immunization licensure process: Thirty (30%) respondents answered that data submitted to the JFDA by a pharmaceutical company, by NIP at the ministry of health, and data gathered independently by the JFDA were all considered in licensing a vaccine. Four (4%) respondents correctly answered that only data submitted to the JFDA by a pharmaceutical company was the only consideration in the JFDA licensure process. Six (6%) answered that data submitted to the JFDA by NIP at the ministry of health. Only three (3%) answered that data gathered independently by the JFDA were considered in licensing a vaccine. Pediatricians' knowledge of differences between JFDA licensure and NIP recommendations for any specific vaccine was evaluated. Analysis shows that only one-third (n=27, 27%) of paediatricians were aware of the differences, 41% (n=41) were not aware, and 32% (n=32) did not know that differences do exist. A chi-square test of independence showed no significant association between years of practice and awareness of differences between JFDA licensure and NIP recommendations, v $X2$ (8, N = 100) = 4.77, p = .782.

Further analysis for knowledge of differences between JFDA licensure and NIP recommendations for a specific vaccine was evaluated. Analysis showed that only 40% of respondents were aware of differences in the pneumococcal vaccine, 28% in the hepatitis A vaccine, 37% in the varicella vaccine, 29% in the influenza vaccine, 34% in the meningococcal vaccine, and only 4% were aware of differences in Typhoid vaccine. Of the 27 respondents who expressed awareness of differences,

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65 (65%) deferred their primary source, a publication from a specific guideline or JFDA vaccine package insert and licensure recommendations. In this regard, pediatrician attitudes and practices about the primary source of information on immunization schedules and vaccine recommendations were investigated. Almost half of the respondents (n=46, 46%) stated that they follow publications from the specific guideline. Almost similar numbers consider the JFDA vaccine package insert (n=41, 41%). However, few respondents (n=4, 4%) reported Jordanian NIP schedules, and only nine (9%) reported using other references for immunization scheduling and vaccine recommendations. A chi-square test of independence showed that there was no significant association between years of practice and source of information on immunization schedules and vaccine recommendations, $X2$ (16, N = 116) = 16, p = .45. Figure 3 summarizes pediatricians' methods of keeping up to date on immunization recommendations. Data shows that almost one-third of paediatricians (n=67, 27.5%) chose publications from NIP and review of vaccine package inserts to remain updated on immunization recommendations.

As illustrated in figure 4, Paediatricians tended not to recommend that children/adolescents receive any of the vaccines not listed within the JNI program (n=89,89). However, thirty-one (31%) did not have direct concerns regarding the recommendation about receiving any of the vaccines not listed within the JNI program. Compared to other concerns, cost burden (n=51, 51%) was the most rated concern to administering vaccines not listed within the JNI program.

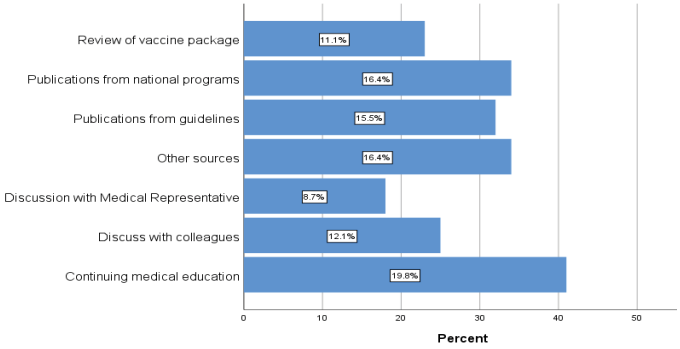

Figure 3. Paediatricians' methods of keeping up to date on immunization recommendations

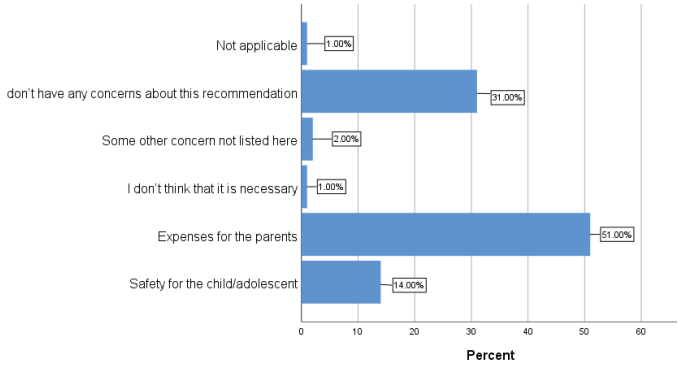

Figure 4. Paediatricians ' concerns from recommending vaccines not listed in the national immunization program

DISCUSSION

The results of the present study showed that the discrepancies between JFDA licensure indications of and NITAG of Jordan and the DCD at the ministry of health recommendations for vaccines were noted to occur for 12 immunization indications for children, adolescents, and adults in Jordan for vaccines licensed for civilians from 2000 through 2020. These discrepancies in recommendations were in the context of vaccine shortage, lack of data on the safety and efficacy of immunization of pregnant women and children, and cost burden. However, understanding the rationale for the 12 identified discrepancies was not well known. To the best of our knowledge, this is the first study to report the knowledge, attitudes, and practice of Jordanian paediatricians and gynaecologists regarding vaccinations, however, related studies were performed in other countries.[7-21] diatricians and gynaecologists are key HCPs in the delivery of national immunization programs. The differing goals and processes by which JFDA licensure indications of and NITAG of Jordan and the DCD at the ministry of health recommendations for vaccines may challenge HCPs, who must select a source from which to draw their immunization recommendations. The ministry of health vaccine manual is the organization's primary source for immunization and infectious disease guidelines;[12-15] it formally has put together JFDA vaccine recommendations for children and adolescents with those of NITAG of Jordan and the DCD at the ministry of health since1979 when the first harmonized childhood immunization schedule was published. Improved harmonization of JFDA licensure and NITAG of Jordan and the DCD at the ministry of health recommendations would reduce the inherent challenges associated with complicated immunization schedules and optimize vaccine delivery. This can be achieved by suggesting that the NITAG of Jordan and the DCD at the ministry of health endorse a recommendation that differs from JFDA licensure, including a routine statement to clarify differences from JFDA licensure and reasons for differences and providing the rationale for the variance to optimize vaccine delivery.

This study provides novel insights into vaccination knowledge, attitudes, and practice among a sample of key HCPs in the delivery of national immunization programs. Although research participants may not represent the entire membership of their respective professional societies, they illustrate their general awareness of discrepant JFDA licensure and NITAG of Jordan and the DCD at the ministry of health recommendations, suggesting that the degree of HCP knowledge, attitudes, and beliefs would undoubtedly influence the promotion and administration of vaccines. In light of the present findings, the increasing involvement of paediatricians and gynaecologists in immunization provision in Jordan has led to recommendations that well-trained, sufficient and competent human resources, with adequate knowledge and skills, are the most important element for ensuring the success of increasingly complex immunization programmes. It is important to have written clinical guidelines to strengthen, instruct and support professionals at the time of vaccination, and that effective use of information technology would be beneficial.[22]

However, several limitations should be addressed. Firstly, this is a cross-sectional study and one could not establish causal relationships between HCPs' knowledge or attitude and their promotion and administration of vaccines. In addition, only HCPs working in the private sector were invited to participate, and their general awareness of discrepant JFDA licensure indications of and NITAG of Jordan and the DCD at the ministry of health recommendations of vaccine recommendations might differ to a certain extent with HCPs working in the public sector and the academic field. Therefore, the generalizability of the present findings could not be ascertained. Furthermore, this is a descriptive analysis and there could be potential confounders affecting clinical practice. Lastly, this cross-sectional study was conducted in 2021–2022, and it is anticipated that the perceptual variables pertinent to the vaccine will change with time as more promotional materials and media communications emerge. This review fills a gap in the literature, and thus, despite the limitations of our methodology, we believe that the benefits of illuminating this relevant topic overcome the limitations.

CONCLUSIONS

This study provides a novel and timely summary of discrepancies in vaccine recommendations. It contributes new evidence-based knowledge that can be utilized to inform clinical practice, education, and research regarding how paediatricians and gynaecologists perceive their role and contribution to the uptake of vaccines in national immunization programs. Findings suggest that some aspects of knowledge, attitudes, and practice of vaccination need to be improved. Consistent medical staff advice and educational programs seems to be the best tool to achieve favorable vaccination attitudes and practices. A time series of cross-sectional surveys to reflect the trends of changing knowledge, attitude and perceived barriers of offering immunization, could be the objective of a future research.

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COMPETING INTERESTS

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

AUTHOR CONTRIBUTIONS

Jakub N. Khzouz: Conceptualisation, project administration, investigation, methodology, analysis and interpretation of data, writing- original draft preparation. Shereen M. Aleidi: Conceptualisation, acquisition of data, analysis and interpretation of data, writing- original draft preparation, writing- reviewing and editing. Rima Hijazeen: Writing- original draft preparation, writing- reviewing and editing, supervision. Abla M. Albsoul-Younes: Methodology, validation, data curation, writing- original draft preparation, supervision. Mohammad H. Alajmi**:** Project administration, validation, acquisition of data, data curation, supervision. Sief-Addeen B Shehadeh: Project administration, validation, acquisition of data, data curation, supervision

Data availability

Raw data are not publicly available. Interested persons may contact the corresponding author for more information.

ETHICAL APPROVAL

The study was approved by the University of Jordan's Research Ethics Committee of the School of Pharmacy and the Higher Research Ethics Committee of the School of High Education at the University of Jordan. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

CONSENT TO PARTICIPATE

Informed consent was obtained from all individual participants included in the study.

ACCESS TO DATA

All authors had full access to all of the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

TRANSPARENCY DECLARATION

The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

DECLARATION OF INTERESTS

- The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.
- The authors declare the following financial interests/ personal relationships which may be considered as potential competing interests.

References

1. (CDC) C for DC and P. Ten great public health achievements—United States, 1900-1999. MMWR Morb Mortal Wkly Rep n.d.;48:241-3.
2. World Health Organization Eastern Mediterranean Regional Office. Eastern Mediterranean Vaccine Action Plan. 2016-2020 2019.
3. Haider EA, Willocks LJ, Anderson N. Identifying inequalities in childhood immunisation uptake and timeliness in southeast Scotland, 2008-2018: A retrospective cohort study. Vaccine. 2019;37:5614-24. https://doi.org/10.1016/J.VACCINE.2019.07.080
4. The Hashemite Kingdom of Jordan High Health Council The National Strategy for Health Sector in Jordan 2016- 2020 2020.
5. Hayajneh WA, Daniels VJ, James CK, Kanlbir MN, Pilsbury M, Marks M, et al. Correction to: Public health impact and cost effectiveness of routine childhood vaccination for hepatitis a in Jordan: A dynamic model approach (BMC Infectious Diseases (2018) 18:1 (119). BMC Infect Dis. 2019;19:1-12. https://doi.org/10.1186/s12879-019-4533-y
6. U.S Depertment of health and human services. The jordan report. Accelerated development of vaccines 2007 2007:3.
7. https://www.ammanchamber.org.jo/Uplaoded/PRNews/757(2).pdf Accessed July 2023
8. Haqaish WS Al, Obeidat H, Patel P, Walker S. The Jordan Food and Drug Administration: Comparison of its Registration Process with Australia, Canada, Saudi Arabia and Singapore. Pharmaceut Med. 2017;31:21-30. https://doi.org/10.1007/s40290-016-0172-4
9. Panero MS, Khuri-Bulos N, Biscayart C, Bonvehí P, Hayajneh W, Madhi SA. The role of National Immunization Technical Advisory Groups (NITAG) in strengthening health system governance: Lessons from three middle-income countries—Argentina, Jordan, and South Africa (2017-2018). Vaccine 2020;38:7118-28. https://doi.org/10.1016/j.vaccine.2020.08.069
10. Buffardi AL, Njambi-Szlapka S. The role of National Immunisation Technical Advisory Groups in evidence-informed decision-making Enablers, constraints and future support options 2019.
11. Abdullat M, Hayajneh W, Issa AB, Alshurman A, Marar B, Al-Hajajrah A, et al. Use of health care resources for varicella in the paediatric population, Jordan. East Mediterr Heal J. 2021;27:159-66. https://doi.org/10.26719/2021.27.2.159
12. Mohammad Alabdallat, Mohammad Sroor, Sameer Faouri, Kamel Abusel, Ali Muhaidat, Wail Hayajneh NS. Ministry of Health vaccine manual. Amman: 2017.
13. The Directorate of Communicable Diseases (DCD) at the ministry of health. Surveillance Guidelines. Amman: 2015.
14. Sroor R. No Title. Amman: 2017.
15. http://jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/JNDF-Book/JNDF%20V2%202011.pdf . Accessed July 2023
16. Bell CE, Shane AL, Pickering LK. Discrepancies Between US Food and Drug Administration Vaccine Licensure Indications and Advisory Committee on Immunization Practices Recommendations: Provider Knowledge and Attitudes. Clin Ther. 2018;40:1308-1319.e16. https://doi.org/10.1016/j.clinthera.2018.07.004
17. Leask J, Quinn HE, Macartney K, Trent M, Massey P, Carr C, et al. Immunisation attitudes, knowledge and practices of health professionals in regional NSW. Aust N Z J Public Health. 2008;32:224-9. https://doi.org/10.1111/j.1753-6405.2008.00220.x
18. Herzog R, Álvarez-Pasquin MJ, Díaz C, Del Barrio JL, Estrada JM, Gil Á. Are healthcare workers intentions to vaccinate related to their knowledge, beliefs and attitudes? A systematic review. BMC Public Health 2013;13:154.https://doi.org/10.1186/1471-2458-13-154
19. Nichol KL, Zimmerman R. Generalist and subspecialist physicians' knowledge, attitudes, and practices regarding influenza and pneumococcal vaccinations for elderly and other high-risk patients. Arch Intern Med 2001;161:2702-8. https://doi.org/10.1001/archinte.161.22.2702
20. Tomboloni C, Tersigni C, De Martino M, Dini D, González-López JR, Festini F, et al. Knowledge, attitude and disinformation regarding vaccination and immunization practices among healthcare workers of a third-level paediatric hospital. Ital J Pediatr. 2019;45(1):104. https://doi.org/10.1186/s13052-019-0684-0
21. Pelullo CP, Della Polla G, Napolitano F, Di Giuseppe G, Angelillo IF. Healthcare workers' knowledge, attitudes, and practices about vaccinations: A cross-sectional study in Italy. Vaccines. 2020;8(2):148. https://doi.org/10.3390/vaccines8020148
22. Nicoll A, Elliman D, Begg NT. Immunisation: causes of failure and strategies and tactics for success. BMJ Br Med J. 1989;299:808. https://doi.org/10.1136/BMJ.299.6703.808