Shiraz E-Medical Journal
Volume 24 · Issue 3 · e135224

OPEN PEER REVIEW

Promoting the Safety of Pregnant Women: Information Management System Strategy for the COVID-19 Vaccination

Farkhondeh Asadi, Roya Shakiba, Reza Rabiei, Hassan Emami

SUBMITTED	REVISED	ACCEPTED	DOI
25 Jan 2023	4 Mar 2023	12 Mar 2023	10.5812/semj-135224

About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

More about open peer review: brieflands.com/knowledgebase/opr

Contents

1 **Original submission** Associate Editor 2
2 **Revision 1** 3
Authors' reply to reviewers 4
Reviewer and editor comments 11

1 Original submission

1 comment · 14 Feb 2023

Associate Editor

MAJOR REVISION 14 Feb 2023

Dear Authors
Please revise your manuscript precisely according to the comments on the attached PDF.

2

Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Manuscript ID: 135224

Response to Reviewers

Dear Reviewer,

Thank you for giving us the opportunity to submit a revised draft of the manuscript " Promoting the safety of pregnant women: Information management system strategy for the COVID-19 vaccination " for publication in the journal of Shiraz E-Medical. We appreciate the time and effort that you and the reviewers dedicated to providing feedback on our manuscript and are grateful for the insightful comments on and valuable improvements to our paper.

We have incorporated most of the suggestions made by reviewers. Those changes are highlighted within the manuscript. Please see below, in italic, for point by point response to the reviewers comments and concerns. All page numbers refer to the revised manuscript file with tracked changes.

Reviewers Comments to the Authors:

Comment 1

Main key findings of this study and their related figures should be mentioned in the result part.

Response:

This comment has been applied on page 1 and the results part as follows.

The findings were categorized into two main groups, included the structural components (responsible organization and data bases, surveillance center, participating organizations, data sources) and informational process (data set, data collection, quality control, data exchanges, data processing, reporting) that reached 100% consensus of experts.

Comment 2:

Conclusion should be about the key message of your study.

Response:

This comment has been applied on page 1 and the conclusion part as follows.

For developing IMS for the COVID-19 vaccination of pregnant women, it is necessary to specify the responsible organization and the participating centers, to create surveillance center and databases, and also to define the information management system process.

Comment 3:

full word should be mentioned for the 1st time. (C-section)

Response:

This comment has been applied on page 2, paragraph 2, line 5 as Cesarean section.

Comment 4:

Mention the key findings as text in the result part.

Response:

This comment has been applied on page 3, line 5 to 12, result part as follows.

The findings of this study are presented in three sections as follows:

First part: Findings from the comparative study of the IMS for the vaccination of pregnant women in selected countries

In this part of the study, the IMS for the COVID-19 vaccination of pregnant women was examined from two points of view: Structural components (includes system goals,

surveillance systems, monitoring method, responsible organization, data sources, participating centers) and Informational process (includes data set, data collection, data quality control, data exchange, data processing, reporting) in selected countries, which are shown in lists 1 and 2.

Second part: List 3 shows the proposed model of the IMS for pregnant women's COVID-19 vaccination in Iran that Structural components (including responsible organization and data bases, surveillance center, participating organizations, data sources) and Informational process (including data set, data collection, data quality control, data exchange, data processing, reporting).

Third part: Table 1 shows the findings from the validation of the proposed model of the IMS for pregnant women's COVID-19 vaccination in Iran and figure 1 shows the schematic form of the model for the IMS for pregnant women's COVID-19 vaccination in Iran.

Comment 5:

In the 1st paragraph of discussion, it is better to be paid to the your findings and proposed model.

Response:

This comment has been applied on page 4, paragraph 1, discussion part as follows.

A management and surveillance system should be used to assess and monitor the safety of COVID-19 vaccination during pregnancy. Considering that there is no information management system for the COVID-19 vaccination of pregnant women in Iran, therefore, in this study, the national model of the information management system for COVID-19 vaccination of pregnant women as a strategy to improve the safety of pregnant women by studying the surveillance systems of COVID-19 vaccination of pregnant women in the leading countries and the special needs of the country were prepared and presented.

Comment 6:

The main week points of the discussion part:

1- In the discussion you focused mainly on the definition of surveillance system and its components and their importance. In the discussion you should interpret the findings of your study and compare its strengths and weak points with other reports.

2. You did not any statements about cost-effectiveness of implementation of such proposed model.

3. No any recommendation which may complete your findings was mentioned.

4. Conclusion is not related directly to your findings.

Response:

This comment1 has been applied on page 4 and 5, discussion part as follows.

A management and surveillance system should be used to assess and monitor the safety of COVID-19 vaccination during pregnancy. Considering that there is no information management system for the COVID-19 vaccination of pregnant women in Iran, therefore, in this study, the national model of the information management system for COVID-19 vaccination of pregnant women as a strategy to improve the safety of pregnant women by studying the surveillance systems of COVID-19 vaccination of pregnant women in the leading countries and the special needs of the country were prepared and presented.

The findings revealed that the IMS for the COVID-19 vaccination of pregnant women should be studied from different dimensions.

The proposed model of the IMS for the COVID-19 vaccination of pregnant women in Iran was analyzed from two structural and informational dimension. Accordingly, from a structural point of view, the first point in planning an IMS is to determine the ownership of the system. In all the countries studied, the Ministry of Health takes ownership. In the proposed model of the IMS for the COVID-19 vaccination of pregnant women in Iran, the principal organization supervising the system is the disease control and prevention center in the Ministry of Health.

From a structural point of view, various surveillance systems and data sources have been formed in the studied countries according to the type of activity of organizations and participating centers in order to manage and monitor the safety of the Covid-19 vaccination in pregnant women. In the proposed model of the present study the creation of a surveillance center in the Disease Control and Prevention center of the Ministry of Health, and the creation of a database in each of the data centers are presented. In addition to, comprehensive data sources for IMS vaccination of pregnant women in Iran are provided.

The dimension of the information process in this research includes data sets, data collection, quality control, data exchange, processing and reporting, which are fully and clearly specified, as well as precise sub-criteria for the main components, are comprehensively and clearly determined.

The data set is a standard tool for data collection that ensures accurate and correct health data achievement. The basis of any vaccine safety management and surveillance system is the routine monitoring of adverse events after vaccination. When a serious adverse event is identified in a mother or newborn/infant after immunization, the information on when the vaccine was exposed during pregnancy, as well as the presence of other causes, should be collected. In addition, details of birth outcomes should be collected for further evaluation of information. The data set in the model of the IMS for the COVID-19 vaccination of pregnant women designed in the current study includes patient demographic information and clinical data, information about the COVID-19 vaccine, Information about attitudes towards COVID-19 vaccination, side effects after vaccination, complications during pregnancy, and the outcomes of the newborn/infant. Also, Data collection is based on a manual and electronic questionnaire form.

Effective and efficient management of data and monitoring and control of information at different levels, by management and surveillance systems, leads to the production of data with high quality and accurate, as well as the timely exchange of data and information with related organizations. To ensure the quality of information in the proposed model, a variety of information quality control methods (includes review of duplicate cases, review of

incorrect and missing, irrelevant and inappropriate information, review of medical records) have been provided.

Data exchange in the studied countries is in the form of linking surveillance systems with each other and sending the required information. In the proposed model for Iran, data exchange in the form of sending a summary of information online, from information systems in urban centers to information systems in provincial and national centers.

Data analysis and interpretation is usually performed by comparing in reported data with other data is conducted, to detect the presence or absence of abnormalities; which may require further investigation or other actions. These monitoring data, considering that the data is continuously collected, monitored and managed over time, can identify changes compared to the background data and analyze them. In the proposed model, data processing includes calculating the frequency of COVID-19 vaccination in pregnant women, calculating adverse pregnancy outcomes after vaccination (including pregnancy complications and delivery outcomes), and comparing the ratio of adverse maternal and neonatal complications in exposed groups and non-exposed groups.

Reporting of information through different methods provides the possibility of comparing data at different levels for informed decision-making and appropriate actions by doctors and health stakeholders. A variety of reporting methods and report users are proposed in this study.

An IMS affects population health by identifying and collecting data and providing information that physicians and health stakeholders can use to improve the quality of their decisions as well as the effectiveness of their actions. An effective information management system that collects accurate, consistent, and relevant data in a timely manner can improve planning and better monitoring of health programs and service delivery, and in turn helping increase the effectiveness of appropriate interventions. On the other hand, the most appropriate data sources and data sets help to provide the required information and the cost-effectiveness. Therefore, implementation of the information management system, will reduce the time spent on manual work, increase the accuracy and availability of health care data in electronic format, and as a result, it will be the cost effectiveness and improve the effectiveness of the service.

Therefore, the proposed model in this study is a comprehensive and optimal tool for managing the data of the vaccination of COVID-19 in pregnant women, that the results of this model can be the basis for implementing the information management system of COVID-19 vaccination in pregnant women in the country.

Comment 7:

Unit

Response:

This comment has been applied on page 4, paragraph 3, line 6, discussion part as (Center instead of unit).

Comment 8:

Conclusion should be about the key message of your study.

Response:

This comment has been applied on page 5, conclusion part as follows.

By implementing the information management system for the vaccination of pregnant women, it is possible to provide all kinds of reports and statistics related to the health of pregnant women. Also, the possibility of various decisions by officials regarding the allocation of resources, monitoring the status of vaccination and increased coordination among health service providers will be achieved. In addition, creating a rich source of data and information as an effective tool will be available to research centers and researchers to conduct clinical and epidemiological studies.

Comment 9:

Where does the Information Technology Department of the Ministry of Health, as an ?independent unit, fit into this, and why has it not been mentioned

Response:

This comment has been applied on page 8, list 3, Participating organizations part.

Participating organizations in the system: Chronic Disease Prevention Center, Epidemiological Research Center, Food and Drug Administration, Statistics Center, Maternal, Fetus, and Newborn Research Center, Information Technology Unit of the Ministry of Health, Infectious Diseases Center, Birth Defects Center, Chronic Respiratory Disease Research Center, Scientific Committee on COVID-19

Comment 10:

full word SIB?

Response:

This comment has been applied on page 8, list 3 as integrated health system (SIB).

Comment 11:

Risk perception, Attitude and Practice of pregnant women about COVID-19 vaccination uptake is essential and was neglected in the proposed model.

Response:

This comment has been applied on page 8, list 3, data sets part as follows.

Data sets: Patient demographic information, Patient clinical data, Information about the COVID-19 vaccine, Information about attitudes towards COVID-19 vaccination, Side effects after vaccination, Complications during pregnancy, Newborn/infant outcomes

Comment 12:

please, mention in detail opinions regarding each item of list 3

Response:

This comment has been applied on page 9, Table 1 as follows.

Experts' opinions		**The Delphi technique**		**Description**
Suggested components		**Agree percentage**	**Disagree percentage**	
Structural components	***Goals***	100	-	-
	The monitoring system ownership	100	-	-
	Data sources	*87*	*13*	The Integrated Health System (SIB) should be used as one of the data sources to record the information
	Participating centers	100	-	-
	Databases	100	-	-
	Surveillance centers	80	20	The monitoring center of the IMS for the vaccination of pregnant women against COVID-19 should be established in the disease control and prevention center of the Ministry of Health.
Informational processes	***Data set***	100	-	-
	Data collection	100	-	-
	Quality control	100	-	-
	Data processing	100	-	-
	Data exchange	100	-	-
	Reporting	*87*	*13*	The Ministry of Health should be considered as one of the users of the reports. In the development of the software based on the proposed model, a dynamic report generator should be added to the collection.

Comment 13:

86+13=99

Response:

This comment has been applied on page 9, Table 1 as follows.
Agree percentage: 87, Disagree percentage: 13

[*Translated from Persian by the Brieflands editorial office*]

2 Revision 1

0 comments

No public comments in this round.