Title: Assessment of filling of pregnancy status in the X-ray request forms of the female patients of child bearing age by the clinicians

Project Lay Summary

The use of any kind of diagnostic imaging procedure on a pregnant woman is extremely risky and harmful to the fetus. When a pregnant woman presents for such a procedure, extreme care is taken to ensure that the patient and the fetus are exposed to the minimum possible amount of radiation. However, there may be cases when a female patient presenting for an x-ray is unaware that she is pregnant, especially during the first one or two months of her pregnancy. Hence, it is extremely important to take measures to completely eliminate the possibility of pregnancy before proceeding for an x-ray.

There are several guidelines by important health committees all over the world that have made it mandatory for female patients of child bearing age presenting for an x-ray to have a negative β-HCG test before the procedure to rule out pregnancy. However, these guidelines are not adhered to strictly in many parts of the world increasing risk to a possibly pregnant woman. Also, a number of clinicians working in the Radiology departments of hospitals are unaware of the risks of performing an x-ray on a pregnant woman. Hence, this study will be undertaken to understand how pregnancy status is documented in x-ray request forms by clinicians in the Riyadh Security Forces Hospital Program.

This will be a cross-sectional sample survey to identify the clinicians' knowledge and practices regarding the completion of x-ray request forms for female patients of child bearing age. All clinicians working in the Radiology Department of the Riyadh Security Forces Hospital Program will be invited to participate in the survey. Questionnaires will be distributed to all participants and all answers will be collected in a paper-based format. This data will be extracted and saved electronically and analyzed using standard statistical methods. The results obtained will be used to assess the level of care taken by the clinicians in handling female patients of child bearing age and will pave the way for improvement in healthcare services.

Background of the study

There are strict regulations detailed by the International Atomic Energy Agency (IAEA) regarding the use of radiopharmaceuticals in pregnant women. It is strongly recommended that every female patients' menstrual history is recorded and considered before carrying out an x–ray procedure on the patient. According to these guidelines, women of childbearing age need to have minimum exposure to radiation and the pregnancy and lactation status of each patient should be explicitly noted. There are certain types of procedures that cannot be performed on pregnant women, such as thyroid uptake measurement, whole body imaging, administration of Lugol's solution, elective bone scintigraphy, and radioimmunoscintigraphy. Hence, it is highly risky for the fetus if a pregnant patient goes through these procedures (IAEA, 2006).

As per the form designed by Alberta Health Services located in different cities of the United States, it is mandatory for every female patient of child bearing age to go through a β-HCG test and provide the date of her Last Menstrual Period (LMP) on the x-ray request form before proceeding for the prescribed test (Alberta Health Services, 2014). The Galway clinic in Ireland requires all female patients of child bearing age to follow the 10-day rule, i.e. x-ray can only be performed on the patient during the first 10 days of her menstrual cycle. If this rule

cannot be followed in case of emergencies, a pregnancy test should first be performed and then the patient should proceed with the x-ray procedure (Galway Clinic).

A literature review of practices and policies regarding x-ray in Saudi Arabia resulted in very little information. Neither are there any clear guidelines for processing x-ray request of female patients of child bearing age nor is there any clear evidence regarding hospital policies in such scenarios. The only field related to pregnancy that can be found on x-ray request forms in Saudi Arabia is whether a female patient is pregnant or not (Saudi Arabia Visa Medical Form). In the absence of awareness of risks related to x-ray during pregnancy, a patient might often not speak up if there is any possibility of pregnancy, leading to dangerous consequences.

Studies conducted in Saudi Arabia focusing on x-rays conducted during pregnancy mostly belong to the dental field. A survey of dental interns conducted in 2014 in Saudi Arabia found that their knowledge regarding the handling of pregnant patients in dental clinics is insufficient and needs to be improved (Aljulayfi et al., 2014). Another study conducted in three hospitals in Riyadh, Saudi Arabia found that the knowledge of pregnant women visiting dental clinics was lacking and they were quite unaware of the risks associated with procedures like x-rays during pregnancy (Al-Swuailem et al., 2013).

There are also other studies that have explored and determined safe levels of radiation during pregnancy (Abdalla and Elshikh, 2015; Khan and Idrees, 2014); however, there is no evidence regarding the extent to which safety is practiced in x-ray departments of hospitals during the imaging of pregnant or possible pregnant patients. There is also no literature on the knowledge and expertise of clinicians who collect patient data before x-rays in Saudi Arabia hospitals. Hence, there is a clear need to identify the extent to which standard policies are followed regarding imaging of pregnant patients in hospitals in Saudi Arabia.

Purpose of the study

The consequences of imaging a pregnant woman, especially in her first trimester, can be severe. Several guidelines and reports have stressed the importance of correctly identifying the pregnancy status of a female patient presenting for x-ray (Department of Health, 2006). Due to insufficient information of the practices followed in Saudi Arabia hospitals regarding imaging of pregnant women, it is empirical to identify how strictly guidelines are imposed and how well they are followed. The main purpose of this study is to identify how precisely the pregnancy status of female patients of child bearing age is recorded by clinicians in the Radiology Department of the Security Forces Hospital Program in Riyadh, Saudi Arabia.

The implications of the results of this study are quite significant in terms of female reproductive and fetal health. Use of incorrect documentation procedures of pregnancy status of patients is an issue that needs to be looked into immediately. As the first trimester of pregnancy is the most critical and requires the maximum amount of care, it is important that the possibility of pregnancy be completely ruled out before proceeding with an x-ray.

Research design and methods

This study will be a qualitative cross-sectional survey conducted in the Riyadh Security Forces Hospital Program in Saudi Arabia. A list of clinicians working in the Radiology Department of the Security Forces Hospital Program will be drawn up and each of them will be personally invited to participate in the survey. An information sheet will be provided to all

participants which will include information about confidentiality measures, protection of the participants' identity, how the data will be used in future research and endeavors, who will have access to the data and how long the data will be stored. All participants willing to take part in the project will be made to sign an informed consent sheet before proceeding with the survey. Thus, this will be a sample survey where a non-probability sampling method will be used. All participants' responses, including the complete or incomplete participation, of each of the clinicians will be tabulated. Once the clinicians confirm their participation, a questionnaire will be distributed to them.

The questionnaire will comprise questions relating to the clinicians' education and training background, their experience with pregnant or possible pregnant patients, sufficiency of documentation of pregnancy status in x-ray request forms, patient awareness of the dangers of imaging during pregnancy, and their opinion on the levels of adherence to hospital guidelines and recommendations by clinicians. The questionnaire will be distributed as a hard copy and all questions will be objective rather than subjective. Most questions will be closed where 4 or more options will be provided to the participant and some of the questions will be open to enable the participant to provide their personal opinions or comments. Other types of questions that will be used include multiple choice questions, checklist questions, ranking questions and rating questions. The layout of the questionnaire will be as follows: it will begin with an introduction which will give the participants general instructions and pointers on completing the questions, this will be followed by opening questions which will introduce the topic of the survey to the participants, followed by sensitive questions that will inform the survey objectives and hypotheses, and will end with closing questions for demographic and classification purposes. Transitional statements will be used between sections to improve flow of the questions.

The data will be collected by the method of self-enumeration, where each participant will complete the questionnaire independently without the assistance of an interviewer. The questionnaire will be well-structured, easy-to-follow and will have clear instructions for the participant. It will be short, simple, and stand-alone, which means it will carry all the necessary information to help the participants complete the questionnaire. A helpline number will be provided on the questionnaire in case a participant requires help in understanding the instructions. More response categories will be provided for each question in order to give the participants wider choice in providing a response. Most questions will use technical terminology as it is intended for people working in the Radiology Department. It also needs to be kept in mind that most participants may not be comfortable with English and so, it might need to be translated in languages they are more likely to understand.

Once completed, the paper questionnaires will be collected personally from each participant. Incomplete questionnaires or questionnaires where complete personal and background information is not provided will be eliminated. In some cases, if there is evidence of large-scale misinterpretation of the instructions or questions, a follow-up may be required to ensure successful completion of the questionnaire by the participants.

The data will be coded by assigning a numerical value to each response. This process will be re-checked independently to ensure that no errors have been introduced in the collection and processing of data. As the data obtained will be qualitative, it will be categorized thematically, where each theme will correspond to a single type of response from the participants. Based on

the type of questions, proportions and total counts will also be used to document the results. Once codes and categories are generated, the data will be electronically captured in a computer.

As the types of questions in the questionnaire will vary, so will the data and hence, different forms of data analyses will be adopted. In case of categorical data, relative frequency statistics will be used where the total number of similar responses to a question will be calculated and expressed as a percentage. Contingency tables will also be used to make the data more meaningful and the categories included will be newly appointed clinicians and experienced clinicians in order to identify differences in the knowledge level between these two categories. Ordinal data will be generated for questions where participants need to indicate their level of agreement or disagreement with a given statement. Again, a contingency table or a relative frequency table will be used to analyze this data. The data will also be represented in the form of bar charts which will make analysis easier. Interval data will be obtained for questions where participants will respond with numbers on a given scale, for example 1 – 10. This data will be treated as ordinal data and contingency tables and bar charts will be used for analysis.

Care will be taken to use the right types of graphs and the axes coordinates and scale of the graphs will be chosen carefully to present the most accurate and meaningful results. The data will be analyzed and presented in a number of formats for easy interpretation. Frequency distributions will be presented in the form of bar charts or pie charts. The survey results will be analyzed using the Statistical Package for the Social Sciences (SPSS) and logistic regression analysis will be used. A p-value <0.05 will be considered statistically significant. Odds ratio will be calculated for different categories of responses and they will be further analyzed to form definitive conclusions.

Location of study and access arrangements

The study will be carried out in the Radiology Department of the Security Forces Hospital Program in Riyadh, Saudi Arabia. Approval and written consent to carry out this project will be obtained from the ethical committee, management of the hospital, and head of the Radiology Department. The location of the survey will be two conference rooms within the hospital premises. Prior permission will be obtained from the hospital management before using these rooms and it will be ensured that the rooms are not required for any other purpose during the entire period of the survey.

The list of all technicians working in the Radiology Department will be obtained from the hospital and an information sheet and a signed consent form will be obtained from each of them before starting the project. All participants will be asked to select convenient dates and timings for the study from a pre-prepared list. Based on their individual preferences, slots will be allotted to the participants and they will be asked to take part in the survey during those slots. The researcher will be present at the premises to help the participants with any doubts or questions.

Resource Implications

All costs for the survey will be borne by the researcher. No money will be spent on equipment as the methodology of the project is a survey questionnaire. There will also be no travel expenses as all participants are present at their site of employment where the survey will be carried out. The estimated cost of refreshments that will be provided to the participants during the survey is £20. The estimated cost of paper, printing and photocopying of the questionnaires

and other stationery such as pens, pencils and erasers is £15. Possible payments for ethical committee clearance and/or hospital permissions have not been included. Data processing and analysis will be done independently by the researcher.

Ethical considerations

Ethical clearance for carrying out the project will be obtained from the ethical committee of the university and the Riyadh Security Forces Hospital Program. Permissions will also be obtained from the hospital management and the Radiology Department for carrying out the survey and using the conference rooms. Care will be taken to inform all authorities about the need and scope of this project and precautions that will be taken to protect the privacy rights of the participants.

An information sheet will be provided to all participants at least one week before the study that will explain in detail the aims and objectives of the study and how the results will be used in future healthcare decisions. It will also include in detail confidentiality and privacy protection measures that will be undertaken by the researcher. In case, a participant is unable to understand the contents of the information sheet, it will be read out to the participant to ensure that there is no misunderstanding regarding the requirements of the study. Based on the mother tongue of the majority of participants, instructions will be translated in more than one language so that they do not have difficulty in understanding them. The researcher will be available during this period to answer questions and clear doubts of the participants. After giving the participants one week to go through the information sheet and decide if they want to be a part of the survey, a consent form will be provided to each participant. All participants interested in taking part in the survey will sign the consent form and return it to the researcher. However, any participant is free to withdraw from the survey at any time without providing any particular reason. In this case, an assurance will be taken from the participant that the subject of the survey and other related information is not revealed to any third party without the consent of the researcher.

All personal information of participants, including their responses, will be maintained strictly confidential. No person except the researcher will have access to these. All information will be kept in a locked cabinet, the keys of which will only be in the possession of the researcher. All completed questionnaires and data files will be password protected and all hard copies will be stored in a locked cabinet until the end of the project, after which they will be destroyed. Each participant will be assigned a number and all responses will be stored with the respective number in the computer to protect their privacy. All risk assessments will be performed in accordance with the university guidelines and hospital policies.

Possible concerns of participants include the risk of disclosure of their personal information. All participants will be assured that they are not bound to provide any information that they are not comfortable in providing and may contact the researcher at any time with such issues. Participants also have the liberty to request the withdrawal of any information from the study after the process of data collection has taken place, in which case the participant will no longer be a part of the study. On the same note, all participants will also need to ensure that they do not divulge any sensitive information related to the study.

Project timetable

Activity	Start Date	Completion Date

Review of literature	Month, Year	Month, Year
Development of proposal	Month, Year	Month, Year
Obtaining consent and clearance from the ethical committee	Month, Year	Month, Year
Obtaining consent from the authorities of the Riyadh Security Forces Hospital Program	Month, Year	Month, Year
Surveying the sample population to be included in the research	Month, Year	Month, Year
Preparing questionnaires	Month, Year	Month, Year
Contacting participants and obtaining informed consent	Month, Year	Month, Year
Distribution of questionnaires to the participants and data collection	Month, Year	Month, Year
Sorting, coding and categorizing of data	Month, Year	Month, Year
Analysis of data	Month, Year	Month, Year
Representation of data in visual format eg. tables and charts	Month, Year	Month, Year
Final report of the data and completion of dissertation	Month, Year	Month, Year
Final submission of the thesis	Month, Year	Month, Year

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