Infection Diseases Section

<u>Original Article</u>

Contribution of Indirect Causes to Maternal Mortalities Based on a Methodological Approach to Clinical Epidemiology in Iran

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Abstract

Introduction: Level of mothers' literacy, pregnancy history of more than four times, residence in villages, lack of receiving intensive care during pregnancy, as well as inaccessibility to obstetric emergency services have been reported, in Iran and the world, as major factors for maternal mortality. Considering significance of identifying indirect causes of maternal mortalities, the present study was aimed to determine the contribution of indirect causes to maternal mortalities in Markazi province, Iran.

Methods: This retrospective, descriptive-analytical study analyzes root causes and sentinel events through describing a case of maternal mortality reported in Markazi province. The data were gathered through interviews and documents' investigation, and Bayesian analysis and calculation of conditional probability in Netica 5.08 software were used.

Results: Findings on a 36-year-old mother, in the 37th week of her third pregnancy and suffering from cardiomyopathy, indicated that lack of receiving prenatal care on time, insensitivity of health and medical personnel to pursuing the patient's timely referrings according to Ministry of Health and Medical Education guidelines, lack of coordination and monitoring on the part of team of specialists responsible for the pregnant mother's treatment in hospital, and indifference toward appropriate management of treatment were determined as indirect causes of the mother's death.

Conclusion: While cardiomyopathy was registered as direct cause of death, according to root cause analysis indirect causes had a 43% contribution to the mother's death. Thus, planning for determination of major causes and eliminating indirect causes are very important for reducing maternal mortalities.

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Introduction

Pregnancy is one of the natural phenomena that helps to preserve generations. It is an enjoyable expectation that may happen in every married life and sometimes be accompanied by fear, pain, or even death. Maternal mortality causes irreversible damages to the family and society [1]. For measuring and quantifying the maternal mortalities

caused by the complications of pregnancy and delivery, maternal mortality ratio (MMR) is used. MMR refers to the number of mothers that die during pregnancy and/or labor, or 42 days after the end of pregnancy for any reason except accidents per 100000 live births. This rate is an important development index showing development status in any country through determining the



number of maternal mortalities per 100000 live births. Several social, economic, and cultural factors affect the increase or decrease in this index [2-4]. It depends on the women's literacy and access roads, the availability of medical and health services and obstetric and labor emergencies, the cost of medical services and their productivity rate, household income, etc [2, 3].

Based on the latest reports of World Health Organization (WHO) in 2013, maternal mortalities were 278000 all over the world in 2010 [2]. Generally, this index has been reported as less than 10 cases in developed countries and more than 500 cases in developing countries. From 2000 to 2015, the decline in the maternal mortalities was considered as one of the important goals of the third millennium development. In Iran, this index was 274 in 1975, 150 in 1990, 94 in 1995, 38 in 2005, and according to the latest report, it has declined to 20.3 cases per 100000 live births in 2013. This rate is expected to register 15 cases per 100000 live births, according to the fifth National Development Plan Act. This rate is 24.95 per 100000 live births in Markazi province, Iran [3-6]. Different studies in the world and Iran have shown the factors affecting maternal mortality, including level of the mothers' literacy, pregnancy history of more than four times, residence in villages, lack of receiving intensive care during pregnancy, as well as inaccessibility to obstetric emergency services [7-11]. Another study indicated that unplanned pregnancy played a major role in maternal mortality, and the most prevalent causes of death were bleeding (25%) and amniotic fluid embolism [12-14]. Considering that the maternal mortality is an unpleasant but avoidable and preventable incidence and the contribution of indirect reasons leading to this incidence has not yet been assessed in Iran, we conducted the present study to introduce an applied methodology in clinical epidemiology and clinical governance as well as to determine indirect causes of maternal mortalities with a focus on the fifth National Development Plan Act.

Methods

In this retrospective study a case of maternal mortality has been described and analyzed. The type of description method adopted was case report and the analytical method was root cause analysis (RCA), an important method applied in clinical epidemiology. This method is one of the components of safety and quality promotion process that is very important for *strategic management of clinical governance in hospitals and health treatment centers*. In health and medicine arena, this process is aimed to understand, identify, and determine basic causal factors leading to a sentinel event and to find solutions for eliminating these causes [14-16]. RCA is conducted through a step by step approach in order to deal with the identification of root causes and solution of sentinel events. The process of RCA is done through answering the ten questions below:

- 1- What was the exact sentinel event? Or what happened?
- 2- Which sequence of causes or events did lead to this sentinel event? Or why and how did it occur?
- 3- Was it avoidable?
- 4- Is there any mistake leading to this sentinel event?
- 5- What were (direct or indirect) root cause(s) of the sentinel event and any error?
- 6- Does an error or root cause involve a defect or inefficiency in the system?
- 7- Is it necessary to redesign the system?
- 8- Are the measures taken by staff in encountering the sentinel event helpful?
- 9- Is it necessary to start an action concerning the staff?

10- What can be learned from the sentinel event? A team consisting of four experts on clinical area and investigation was formed and, through some meetings, oral autopsy and gathering and registration of the information and facts regarding potential causes of horrible event which had been elicited from all people directly or indirectly related to the event were undertaken. Brainstorming ideas, the team identified the network of direct or indirect causal factors that were potentially avoidable and intervenable. Then, indirect causes were organized and fishbone diagram or flowchart was drawn, the relationship among the causes and the relevant probabilities were determined, and root analysis and assessment of prediction correctness were conducted. The root analysis was based on Bayesian analysis. In root analysis, the structure of network could be drawn and studied in three (serial, diverging, and converging) ways within a

flowchart. In this study, the converging method or complex graph was used. The complex mode includes serial and diverging methods and assumes that there are two or more underlying causes leading to an event (for example a maternal mortality). Using the conditional independence assumptions, the RCA in the present study calculated the probability of the occurrence of the direct causes and prediction of the mother's death. For drawing flowchart and doing necessary calculations and RCA, Netica 5.08 software was used [14-17].

Results

In examining the health file of the deceased woman's family in the health treatment center, the hospital file, and the file discussed in the university committee, we found that the mother was 36 years old, had two live children, and died when she was 37 weeks pregnant. She prevented from pregnancy by injecting Cyclofem from 2005 to the end of 2010, and from that time onwards she did not refer to the health center. Her last pregnancy was about 6 years ago which ended in abortion and her recent pregnancy was unplanned. She was seriously addicted (to heroin and crack) for about 7-8 years. At the end of 2011, she was accidentally seen twice by an employee in charge of family planning in the health center in the city. The employee questioned her about her family planning status, and she replied she had recently got pregnant. The employee reminded her of referring to the health center for pregnancy test, but she didn not. On 31/03/2011 at 3:00 pm the patient complaining of epigastritis, nausea, and vomiting referred to the maternity of the hospital. She was visited by the the midwife of that shift. Her blood pressure and gestational age were recorded as 110.80 mm/Hg and 16 weeks. The woman's condition was reported to the gynecologist on call, and according to the order she was given some medications, taken to the emergency, and discharged from there. With inattention to the instructions of Ministry of Health and Medical Education (on how to deal with an addicted pregnant woman at first sight, mentioned on the page 50 of the booklet of integrated care of out-hospital mothers' health and on the page 124 of the booklet of integrated care of in-hospital mothers' health, and on how to deal with anemic pregnant women on the page 40 of the booklet of integrated

care of out-hospital mothers' health) the gynecologist did not visit the patient and the release feedback was not sent to the health center by the health communicator responsible for the mother and infant; moreover, the mother received no pregnancy care and was forgotten.

Again on 22/06/2011 at 4:10 am, the mother complaining of runny nose during the past half an hour referred to the maternity of a hospital in Markazi province. The signs of life at arrival were as follows: blood pressure: 100/70; pulse: 100; respiratory: 28; and temperature: 37.

After vaginal examination, the data below were gathered: dilatation: one finger; efface mane: 10%; Station: float; fetal heart rate: regular.

The woman was asleep, and according to her statements, the last time she had used drugs was the day before. According to the sonography, gestational age was 37 weeks on 02/04/2013. The gynecologist on call was informed of her condition, and she visited her at 5:00 am and made a request for the AIDS, hepatitis type C, and blood cell count tests. The results were normal. Another request was made for the pelvis X-ray in order to diagnose the presentation and reserve two units of blood. On 1390/04/01 at 9 am the pelvis X-ray was made, and with the diagnosis of abnormal presentation, she was taken to the operating room at 11:15 am. During the Cesarean operation, the condition of the patient was stable and an infant girl with the Apgar score of 9/10 was born. Fully conscious, the patient was taken to the women's operation room with natural bleeding. The doctor ordered kephalin 2 gr injection once every 8 hours. At 13:30 the blood pressure of the patient was 170/100. The gynecologist on call was informed of the conditions by telephone, and she gave the order of intravenous injection of hidralizine 5 mg, and if the blood pressure did not decrease after 10 minutes, another intravenous injection of hidralizine 5 mg, and if the blood pressure rose to higher than 160/110, other measures would have been taken after informing the gynecologist on call. Urinalysis was also ordered. Hydralizine was injected twice and the blood pressure lowered to 150/80. At 3:00 pm, and the patient developed hypotension of 100/60, tachycardia (140), tachypnea (46), hydrosis, dyspnea, and rhonchus. The gynecologist visited her and ordered one injection of morphine 5 mg and Lasix

40 mg. The cardiologist also ordered keeping the patient at half-sitting position, breathing through oxygen mask, making an electrocardiograph and pulse oximetry. Again, blood cell count test was done; the results were normal. The cardiologist was informed of the condition of the patient by telephone, and made an order to take her to the cardiac care unit at 4:30 pm with the diagnosis of pulmonary edema and signs of life as follows:

temperature: 37; respiratory: 24; pulse: 90; and blood pressure:135/80.

The cardiologist visited the patient at 5:00 pm and gave an order to take the tests below:

blood cell count; coagulation; and the level of sodium, potassium, fasting blood sugar, calcium, creatinine, urea, acid; and base in blood.

The results were normal. The patient developed dyspnea and the level of oxygen in the blood circulation was 80-90%. Heart rhythm was sinusoidal and not arrhythmic. In 22/06/2011 at 10:12 pm, the patient had intensive respiratory distress, tachypnea, tachycardia (130-140), hydrosis, and blood pressure of 230/110 mm/Hg. The gynecologist on call was informed of the conditions, and ordered to put her on trinitroglycerin (TNG) drip in 5-10 mg/min, and inject morphine 6 mg twice (3 mg in every injection) and then 1 mg every an hour. She was still breathing through the oxygen mask (6 liters per minute). Hemoglobin was checked again and it was 11/4; she had dieresis too. The patient did not bleed and the oxygen in the blood lowered to 50%, but rose gradually. In the morning of 23/06/2011, the patient was under heart monitoring, the heart rhythm was sinusoidal, and the patient was conscious. She was put on the morphine, TNG, and Lasix drips. At 8:30 am, she was visited by the cardiologist, and according to the order, administered with ceftriaxone 2g/BD, Metoral pill 50mg/BD, and amlodipine pill 5 mg/BD, anesthetized, and heparin 5000 units BD was injected to her.

The patient again was visited by the gynecologist, and according to the order, liquid regimen began and bleeding was controlled. At 9:20 am, the anesthesiologist visited her and gave an order to do the required tests. The oxygen circulation was 75% in the blood, and pH = 7.47. Clonidine pill 0.2 mg/BD, methadone ampul 5 mg/QID/IM, and midazolam drip 1 mg/h were prescribed for her. According to the results of the arterial blood gases

test, the amount of the morphine drip increased from 1 mg/h to 2 mg/h through controlling the blood pressure. Because of tachypnea and bad conditions of the patient, the anesthesiologist gave an order to do intravenous injection of fentanyl 2cc and methadone 5 mg. Oxygen circulation in blood was 84% and blood pressure was 120/70 mm/Hg. In the afternoon shift of 24/4/2011 the patient developed an oxygen drop by 50% and tachycardia (160). Her condition was reported to the cardiologist and according to the order Lasix drip decreased from 10 mg/h to 5 mg/h, TNG drip of at most 10 mg/h continued, and Lasix 40 mg was injected once. The anesthesiologist's advice was sought and one intravenous injection of fentanyl 2cc and one injection of methadone 5 mg were ordered.

In the night shift of 25/06/2011, she had sinusoidal heart rhythm, tachycardia, severe dyspnea, and agitation, and was breathing through oxygen mask 10 lit/min. Half-sitting, she was according to the instructions on morphine, Lasix, midazolam, and TNG drips. Methadone was injected once every 6 hours. At 2:50 am, the patient developed bradycardia and then asystole, and was given cardiac massage and two atropine injections. The emergency doctor visited her immediately and the anesthesiologist was present at 3 am. The patient was intubated and injected with adrenaline once every 5 minutes. Blood pressure could not be measured. They began dopamine drip for her. Yet, the blood pressure could not yet be measured. Two sodium bicarbonate ampoules were injected. At 3:45 am, the patient developed heart failure. 200 j Shock was given to her once, but finally, after a rescue operation of one hour 25 minutes the patient unfortunately died. Her death certificate was signed and cardiomyopathy was declared as the cause of the death. On 17/07/2011, the university committee meeting on this incidence was held in the office of the chancellor of the university, the relevant staff attended the meeting, and the death was discussed by cardiologists, gynecologists, surgeons, medical examiners, internists, and other members of the committee. These experts did not reach an agreement on cardiomyopathy as the determined direct cause of the patient's death; therefore, the file was sent to Forensic Medicine.

Considering the status of the indirect causes of the death and conducting the root analysis, Diagram represents the conditional probability of the indirect causes of the death. According to the diagram of indirect causes of death and the comments of the relevant experts, unplanned pregnancy, drug addiction, the level of literacy, lack of social support, lack of care during pregnancy, failure to monitor timeliness of the patient's referrings on the part of healthcare staff, failure to pursue ministerial and provincial circulars as well as instructions, lack of teamwork and coordination among different specialists, lack of medical staff's awareness of treatment management for the drugaddicted pregnant woman, and failure to give feedback to the involved levels were determined as the indirect causes of this woman's death. The contribution of these causes to the death was assessed 43%

Discussion

Considering that the present study is the first study conducted quantitatively based on RCA and as far as we searched no similar study has been done to date, we have to compare our findings with those of studies conducted outside Iran, as well as consider and discuss the comments of the university committee's members on maternal mortalities. The aim of holding the committee meeting on the maternal mortality is to investigate the causes of death, and to plan for and take decisions on the intervention for preventing similar deaths. According to the investigations, there are three important issues subject to discuss. On taking care during pregnancy, although drug-addicted patients are considered to be at high risk and when referring to the healthcare system need active follow-up, nothing has been done for this woman, and even when she went there for the first time and was hospitalized, the health communicator of mother and infant did nothing for her. Furthermore, managing and dealing with the addiction of the deceased woman were not appropriate. It is obvious that poorly informed medical team provided ineffective treatment and inappropriate consultation before any action and ignored national instructions concerning management of drug-addicted pregnant women. Despite many efforts made by relevant specialists, diagnosis and treatment of cardiac and pulmonary problems

were not effective in some cases. In a similar study to determine the root causes of delay in diagnosis and treatment of disease, difficulties in coordination and team decisions, incomplete collaboration among patients and medical staff, and poor information of medical staff were reported as the causes [18]. The gynecologists believed that the deceased woman did not receive emergency care during pregnancy. In her first referring to the hospital, because of trauma history and presence of nausea and vomiting surgical consultation was required, but no consultation was done. Only symptomatic treatment was provided, and sonography and tests were ordered on an outpatient basis. According to the results of the hemoglobin 9/9 test, the measures taken were unsatisfactory and at least the iron pill should have been prescribed. Having referred to the hospital for the second time, the patient was not effectively examined for preeclampsia although she was sleepy and drug-addicted. Despite increase in creatinine, sonography of kidney and urinary tracts was not performed.

Medical examiners and poisoning experts believe that determination of the cause of death and drug poisoning and the way they were managed are two important issues which were not precisely and appropriately addressed by the treatment team. When hospitalized, the patient did not present the signs of poisoning and discontinuation of drug use, and became symptomatic after the cesarean. Tachycardia and hypertension could not be only the result of discontinuation of drug use. The oxvgen circulation level of less than 60% is an indication of intubation which was not performed on time. Moreover, the cardiologist, considering that the cause of death was unknown, was not authorized to sign the death certificate and should have reported the incidence to Forensic Medicine. In treatment of the patient, there are some crucial points from the cardiologists' point of view. The deceased woman had pulmonary problem which was deteriorated into respiratory failure. However, the cause of acute respiratory distress syndrome (ARDS) is unknown—whether it was cardiac, pulmonary, or drug addiction-associated. The patient should have been intubated because using oxygen mask at first was not acceptable. In the phase of ARDS, there were some defects in diagnosis and treatment, and the patient received

symptomatic treatment only. Repeatedly, the discontinuation of drug use which is less relevant for these cases was offered as diagnosis. The discontinuation of drug use does not result in hypoxia and hypotension to the extent in this case. Because of the embolism of the patient, giving Metoral contraindications was definite. The prescribed heparin dose was not sufficient as well. On issues concerning anesthesiology, the way the patient was dealt with, irrespective of the problems prior to labor, is the major problem. When the patient had respiratory distress, treatment should have been based on discontinuation of drug use rather than respiratory failure. After receiving oxygen for 5 minutes through an oxygen mask and being administered with morphine the patient, with low oxygen level, should have been first intubated and put on ventilator, and then other measures should have been taken. Injection of morphine and administration of midazolam make the breathing hard, and the patient gets sleepy. Thus, the mistakes made by the treatment staff are apparent. Hence, analyzing the root causes like those conducted in the studies outside Iran, we can detect the medical errors and relevant factors (related to environment, personnel, intersectoral cooperation, culture, and education) [19, 20].

According to the results of the tests done, respiratory failure was exacerbating and the patient at first needed intubation. Irrespective of the reason for respiratory failure, if the patient had been intubated, the course of treatment could have been extended; therefore, there might have been more time to take subsequent diagnostic and treatment measures. The sign of the death was apparently respiratory failure, while cardiologist signed the death certificate stating the cardiomyopathy was the cause of death and the patient did not receive any treatment for cardiomyopathy. The patient was not put on complete bed rest and tried to get off the bed. Also, the patient was not made nil per os and received oral drugs. In fact, there was no congruence among visits and medical orders given by the involved specialists. In view of the patient's symptoms, ARDS diagnosis could have been more relevant than pulmonary edema. However, the treatment was mainly respiratory edemabased. For the conscious patient, it is hard to make a decision on intubation, so the patient should

have been anesthesized and then intubated. When a patient gets into a non conscious phase, intubation is useless. In these cases venturi mask which could be fixated on the face and the patient could be ventilated through might be conducive. Unfortunately, there is often a delay in decision makings in these cases. Considering the aforementioned, fishbone diagram, converging diagram, and calculation of conditional probability, we identified 43% of the causes of the mother's death as indirect (Diagram). The use of RCA as an important method for quantifying the contribution of direct and indirect causes to the sentinel events in health system and clinical governance in hospitals seems necessary [18-20]. Lack of cooperation among personnel and the bereaved is one of the limitations of the present study. This study suggests that the RCA be considered as an important subject in the clinical governance in hospitals and health treatment facilities and epidemiologists be used in this area.

Conclusion

RCA indicated that the determination of cardiomyopathy as the main cause of death in the death certificate was wrong. The contribution of the indirect causes to this maternal mortality case was 43%. Thus, planning for determination and diagnosis of the major causes of death and eliminating indirect causes of death are important for decreasing maternal mortalities.

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Conflict of interest

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