

Preventive Maintenance of Fetal Monitors Based on Risk Assessment and Risk Control

Lu He-qing¹, Wang Wen-gang¹, Li Bin^{2,*}, Qian Jian-guo³, Su Qi¹ and Yan Hao¹

¹ Shanghai First Maternity and Infant Hospital, Tongji University School of Medicine/Department of Medical Equipment, Shanghai, China

² Shanghai No.6 People's Hospital/Department of Medical Equipment, Shanghai, China

³ Huashan Hospital Affiliated to Fudan University/Department of Medical Equipment, Shanghai, China

*Corresponding author:

Author: Li Bin

Institute: Shanghai No.6 People's Hospital

Street: No.600, Yishan Road

City: Shanghai

Country: China

Email: luheqing0811@126.com; libin2001@hotmail.com

Phone Number: 13371985141

Abstract—Objectives Preventive maintenance of fetal monitors based on risk assessment and risk control was investigated. The objectives of the study were to investigate the application of fetal monitors in hospitals and develop corresponding strategies through quality-control inspection, and therefore to reduce clinical application risk. **Materials and Methods** We established a risk-level classification and assessment system, and developed and implemented a quality-control inspection and preventive maintenance program in our hospital (*Shanghai First Maternity and Infant Hospital, Tongji University School of Medicine, Shanghai, China*). We also assessed risk levels of monitors based on inspection results and fixed unqualified monitors. **Results** Among the total 142 fetal monitors in the hospital, 41 monitors were unqualified. In particular, 15 monitors had heart rate-error rates beyond 5%; 26 monitors had incorrect system times; 17 monitors had non-English system languages; eight monitors had to be switched off improperly; and six monitors did not have standard operating procedures that were easily accessible. Other inspected items had 100% qualification results. In addition, the qualification ratio of monitors that had been used less than three years was significantly higher than that of those used for more than three years. After preventive maintenance, all monitors were qualified with 100% qualifications for the various inspection criteria. **Conclusions** Our quality-control inspection program detected unsafe conditions in the application of fetal monitors in our hospital and we developed corresponding rectification and improvement strategies. Preventive maintenance strategies targeted monitors that had been in use for a long time or were beyond their warranty periods, in order to reduce potential safety issues in the future and improve the safety and serviceability rate in their application.

Keywords—Fetal monitors, Risk assessment, Risk level, Risk control, Preventive maintenance

I. INTRODUCTION

Fetal heart monitoring is a simple and painless prenatal examination^[1]. Fetal heart rate is one of the major indicators that reflect fetal physiological activities in real time. The condition of the fetus in the uterus can be accurately evaluated by observing the relationship between fetal movement when there are no contractions and the fetal heart rate changes. Fetal heart monitoring is one of the important tools in fetal prenatal diagnosis. It can effectively prevent fetal asphyxia and reduce the incidence of various complications and fetal mortality^[2,3]. As a major tool for monitoring fetal heart rate, fetal monitors are commonly used in rendering daily medical diagnoses in hospitals, with a large number of monitors widely distributed in many departments and in frequent use. Taking into consideration the role and function of fetal monitors that are used to diagnose fetal asphyxia and other fetal abnormalities^[4,5], a guarantee of their quality and safety, as well as effective control of their application risks and potential safety risks, are especially important. Both should be a concern of any modern medical instrument management staff.

The remainder of our paper presents the quality and safety control strategies and program of fetal monitors in our hospital (*Shanghai First Maternity and Infant Hospital, Tongji University School of Medicine, Shanghai, China*).

II. MATERIALS AND METHODS

A. Risk Assessment

A.1 Establishment of Risk-Level Classification

The risk-level classification of medical instruments

comprises the fundamental references for the development of a quality-control and inspection program. Risk assessment is a “personalized” process. Different risk-assessment agents could have different results on the same types of medical instruments. Therefore, to effectively develop a quality-control and inspection program, it was essential to establish an assessment system with risk-level classifications appropriate and applicable to the medical instrument management system in our hospital.

We selected five risk-assessment factors by consulting *Medical Equipment Quality Assurance: Inspection Program Development and Procedures*^[6] and considering the practical situation in our hospital. The five factors are as follows: 1) clinical function (the function of medical instruments in patients’ treatments or in support of treatments), for which the rubric represents the intervention extent of medical instruments in the treatment of patients; 2) risks resulting from instrument malfunction, including all risks related to instrument malfunction, for which the rubric represents the disaster assessment resulting from instrument malfunction; 3) the possibility of avoiding risks, including the possibility of instrument malfunction calculated based on the historical data of repairs and maintenance; 4) the possibility of adverse incidents, including the possibility of reoccurrence of adverse incidents based on historical data; and 5) special requirements from specifications of manufacturers or local laws. These factors embody the most effective and direct references for the development of a medical instrument risk-level classification and management program^[7], and the risks inherent in the use of medical instruments are assessed based on them. The higher is the value, the higher is the risk.

A.2 Risk Assessment

The method of risk assessment for fetal monitors are shown in Table 1.

Table 1 Risk assessment of fetal monitors^[6]

Risk type	Weight	Score
<i>Clinical application risk</i>		
Do not touch patients	1	3
Directly touch patients	2	
Used for diagnosis or direct monitoring	3	
Directly used for patients' treatments	4	
Used for life support	5	
<i>Instrument malfunction risk</i>		
Malfunction will not cause risks	1	3
Malfunction will cause risks	2	
Malfunction will cause diagnostic errors, treatment failures, or monitoring failures	3	
Malfunction could cause patients' or users' serious injury or even death	4	

<i>Preventive maintenance risk</i>		
Preventive maintenance will not affect the reliability of instruments	1	
The effect of preventive maintenance is not significant (instrument malfunction cannot be predicted)	2	2
Preventive maintenance suggests possible instrument malfunctions	3	
Preventive maintenance can avoid instrument malfunctions	4	
Requires special inspections and manufacturers' recommended preventive maintenance	5	
<i>Incident history</i>		
No incident history	1	1
Significant incident history	2	
<i>Manufacturer/Management Department requirements</i>		
No	1	1
Yes	2	
<i>Total score</i>		10
<i>Period of preventive maintenance and inspection</i>		
0.5, 1, 2 or 4 times annually		1

A.3 Determination of Risk-Level Based on Assessment Results

As shown in Table 1, the full score of risk assessment is 10. According to our risk-assessment rubrics, the risk level of our fetal monitors is of medium rank. The fetal monitors are required to have an annual quality-control inspection and preventive maintenance.

B. Safety Risk and Quality Control Inspection

B.1 Program Establishment

In establishing the safety risk and quality-control inspection program, we primarily consulted various safety factors frequently occurred in daily hospital work. We also consulted technical parameters and maintenance items provided by manufacturers. Taking into consideration our current available quality-inspection instruments, we determined four categories comprising 13 items as the major inspection items in our program. The four categories are 1) device appearance state, 2) electrical safety, 3) performance measurement, and 4) preventive maintenance.

B.1.1 Device-Appearance-State Inspection

Device-appearance-state inspection included examination of the fetal monitor’s exterior housing and other components. The housing should be labeled with basic instrument information, including device name, manufacturer, model specification, serial number, and production date. The monitor should be clean and not appear to be in poor condition. The probe and other components should be undamaged. The ventilator

should be clean and the switch and set buttons should be sensitive. The printer rollers and paper-guide devices should be functional and the standard operating procedures (SOPs) for the unit should be directly available.

B.1.2 Electrical safety test

The electrical safety test, conducted using an electrical safety analyzer, included the following steps. The power cord of a fetal monitor was connected to the instrument socket of the analyzer. The ground terminal of the monitor was connected to the input socket of the analyzer. The analyzer was switched on, and the model based on the IEC 62353 standard was selected. The ground impedance and housing leakage current of the fetal monitor were tested. According to the technical specifications for general electrical safety and quality inspection of medical instruments, it is required that the ground impedance be $\leq 0.2 \Omega$ and the housing leakage current be $\leq 100 \mu\text{A}$.

B.1.3 Performance measurement and analysis

The performance measurement included the following steps. A fetal monitor was switched on. The patient's heart simulator was set in mechanical heart-rate mode. The simulation output heart rates were selected to be 120, 140, 160, and 180 beats/min, and were used as control values. The mechanical fetal heartbeat output probe of the heart simulator was placed on the head of the fetal heartbeat probe of the fetal monitor. The displayed fetal heart rates were read and compared to the control values. The heart-rate error was calculated by the formula $(\text{displayed heart rate}) - (\text{simulation heart rate}) / (\text{simulation heart set rate})$. An ideal error is no more than 5%.

Two marks were made on the recording paper of the monitor, with the second mark made 120 s after the first. The paper speed of the printer was 3 cm/min. The distance between the two marks should be between 58 and 62 mm.

Fetal monitors were divided into two groups based on their use history, namely in use for less than three years or in use for three or more years. We compared the difference in the inspection qualification ratios between the two groups.

Data were analyzed using STATA 14 software, and the Pearson χ^2 test was used. The significance level was $\alpha = 0.05$.

B.1.4 Preventative maintenance

The preventative maintenance included the following steps. A fetal monitor was switched on, and the accuracy of the system time displayed was checked.

Any deviations were corrected. The default language was checked, and if not English it was corrected.

B.2 Quality-Control-Inspection Tools

B.2.1 Electrical safety

We used a Vpad-353 electronic safety analyzer (Datrend Systems, Inc., Richmond, BC, Canada). This analyzer complies with general medical electrical measurement standards, including those for voltage, current, and resistance measurements, such as the IEC 62353, 3551, AAMI/ANSI Es-1, and IEC 60601 standards.

B.2.2 Fetal-Heart-Rate simulation

We used a Datrend AMPS-1 patient's heart simulator, which provides various patient heart-rate simulation outputs, such as multiple outputs of complete 12-lead electrocardiogram simulation, arrhythmia simulations in multiple choices, and mechanical fetal-heart-rate output.

B.3 Quality-Control Inspection

Our hospital uses the fetal monitors whose model series is *Sonicaid Team standard* (Huntleigh, UK). There were, in total, 142 fetal monitors in use. According to the established quality-control-inspection requirements, all fetal monitors were inspected and data were recorded.

III. RESULTS AND DISCUSSION

A. Data Overview

Among the total 142 fetal monitors, 72 monitors were unqualified. In particular, 15 monitors had fetal-heart-rate errors beyond 5%. Six monitors had accessible SOPs, 26 had system-time deviations, and 17 had a non-English default language. In addition, eight monitors could not be properly switched off and had to be turned off by unplugging their power cords. Table 2 lists the qualification results of all inspection items.

Unqualified monitors were repaired and retested until they all were qualified.

B. Analysis and Rectification Measures

We analyzed unqualified items that were found in executing the quality-control-inspection program.

B.1 Fetal-heart-rate errors beyond 5%

Table 2 Ratio of qualification in quality-control inspection

Inspection category	Inspection item	Ratio of qualification
Appearance state	Monitors are clean and do not appear to be in poor condition	100%
	Labels and manufacturer's serial numbers are accurate and clearly visible	100%
	Host, monitor, probe, and other components are not damaged	100%
	Switch and set buttons are sensitive	100%
	SOPs are readily available	95.77%
	Ventilators are clean	100%
Electrical safety	Printer rolls and paper-guide device are functional	100%
	Ground impedance ($<0.2 \Omega$)	100%
	Housing leakage current ($\leq 100 \mu A$)	100%
Performance measurement	Accuracy error of fetal heart rate $\pm 5\%$	89.43%
	Recording speed (3 cm/min) $\pm 4\%$	100%
Preventive maintenance	Accuracy of system time	81.69%
	System language environment and relevant settings	88.02%

Table 3 Comparison of accuracy of fetal heart rate recorded by monitors in use for different lengths of time

Group	Qualified (number)	Unqualified (number)	Total
In use for less than three years	45	1	46
In used for more than three years	82	14	96
Total	127	15	142

Table 3 lists the qualification ratios of the two groups of instruments (in use for less than three years and in use for three years or more) in terms of fetal heart rate. Comparison of the results of the two groups revealed a significant difference ($P>0.05$). The qualification ratio of monitors used for less than three years was significantly higher than that of monitors used for more than three years. The major reason for this difference was the three-year warranty. Within the warranty period, manufacturers provided professional regular maintenance. After the warranty period, monitors would mostly undergo maintenance only when they were not functioning in order to reduce operational costs. Therefore, we recommended that the maintenance skills of Instrument Department engineers be improved by training in maintenance procedures. In addition, we recommended the purchase of products with longer warranty periods or the purchase of extended warranties.

We conducted a statistical analysis of fetal heart monitors with larger errors that included historical years of use, use intensity, and technical maintenance history. The results indicated that most of these monitors had been in use for more than three years and had been intensively used. They were distributed in clinical departments, such as outpatient fetal monitoring and delivery rooms. Although there were no impairments in their appearance, the ultrasound transmission chips in their fetal heartbeat probes (there were seven chips in each probe) in these monitors were partially non-functional and ineffective.

To guarantee medical safety, such a situation should be immediately dealt with once discovered

through daily use or by quality-control inspection by replacing ineffective chips. In the meantime, the maintenance interval for such intensively used fetal monitors in these clinical departments should be adjusted from annually to biannually.

B.2 Incorrect system time and change of default language

One reason for the unsafe status of these two items was the insertion of under-powered 3.6-V batteries into the monitor mainboards, which was discovered after consulting the user manual and/or the manufacturer's support engineers. These monitors resumed normal functions after replacement with proper batteries. Another reason was unexpected and improper operation of the monitor by staff; specifically, some fetal monitors had not been properly switched off; instead, they were powered off by unplugging their power cords. According to the fetal-monitor-operation procedures provided by the manufacturer, improper switching off causes system-time and language setting errors.

With the above issues in mind, the hospital Instrument Department double-checked the batteries in fetal monitors that had been in use for several years. Batteries with low voltage were replaced. The monitor operations training manual was updated accordingly and clinical staff trained in proper procedures.

B.3 Loss of SOP documentation and illegal switching off of monitors

Investigation of the status of these two safety items revealed that clinical departments did not conduct appropriate daily management of medical instruments, and that operations staff did not appropriately operate the instruments.

We reported our quality-control-inspection results to the hospital administration, and then organized training sessions in cooperation with the Nursing Department to promote medical instrument maintenance and to reinforce the responsibilities of both instrument management and operations staff. The training sessions involved instrument management staff from each department and were conducted in various ways, including on-site live demos and PowerPoint presentations.

IV. CONCLUSIONS

Implementation of our recommended quality-control-inspection program resulted in the discovery that most of the fetal monitors in our hospital were qualified, but some had disqualification issues. These disqualification issues were caused by the monitors themselves as well as inappropriate operation by the staff. Therefore, we established an effective assessment system using a medical instrument risk-level classification. We also noted that it was important to establish reasonable quality-control-inspection specifications, to enhance the quality control and preventative maintenance of medical instruments, particularly those that have been in use for extended periods and/or beyond their warranty coverage periods. Such measures will effectively reduce the occurrence of malfunctions, ensure the effectiveness of medical instruments, and reduce the occurrence of incorrect diagnoses and

medical disputes caused by defects in medical instrument quality and by unsafe equipment.

ACKNOWLEDGMENTS

This study was supported by the project (No. 201640316) funded by the Scientific Research Foundation of Shanghai Municipal Commission of Health and Family Planning in China. The authors sincerely thank the staffs from medical equipment department of Shanghai No.6 People's Hospital and Huashan Hospital Affiliated to Fudan University participating in this survey.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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