# Operation and Rectification of Monitoring Systems for Under-Reported Healthcare Adverse Event: Experience from a Tertiary Medical Center

**YaoHui Wang[1,2], HaiXiao Chen[2], LiNa He[2], QuanLong Liu[1], XinChun Li[1,*]**

[1]Key Construction Bases of Philosophy and Social Sciences in Jiangsu Universities, School of Management, China University of Mining & Technology, Xuzhou , China
[2]Taizhou Hospital of Zhejiang Province, Taizhou，China
*Corresponding author:ezwyh@163.com

**Keywords:** Adverse event, under-reported, monitoring

**Abstract:** This study is based on the related background of adverse event reporting system and existing issues in our hospital, proposing the ubiquitous phenomenon of healthcare adverse event being under-reported in various hospitals. Combined with the practical experience in TaizhouHospital since over 6 years ago, this study comprehensively describes the monitoring system of under-reported healthcare adverse events, including definition, monitoring and optimization of the system. Thereafter, it is thoroughly analyzed about the running process of the healthcare adverse event reporting system in Taizhou Hospital of Zhejiang Province. Afterwards, based on discussions and analyses of statistics, several constructive comments are proposed, which are about the monitoring system of under-reported healthcare adverse event.

## 1 Introduction

Medical security management forms the main component of hospital management, and also the core content of medical quality management[1]. As an important component of constructing patient security safeguard system, the adverse event reporting system plays a role in reducing harmful incidents to patients and sharing security information by detecting potential defects in systems and processes of medical services. And hence, the system has become an important way to control medical security risks in different hospitals from various countries[2]. During the course of designing our adverse event reporting system of our hospital, the principle of voluntary reporting and non-punitive reporting was generally followed. So far, a lot of literature has pointed out that voluntary reporting has an impact on the responsibilities of medical staff to report adverse events, which is unfavorable to inspire the enthusiasm of medical staff to find out and compensate potential risks[3].

Due to the existing of under-reported healthcare adverse events, it affects the authority of the adverse event reporting system[4]. For the sake of optimizing the function of the system in medical security management, it is of great significance about how to monitor and optimize the adverse event reporting system in hospitals. Taizhou Hospital of Zhejiang Province set to explore how to establish sentinel event reporting system from year 2005 on. In practical working, there have arisen some phenomena of bad compliance of medical staff and the high level of under-reported healthcare adverse events. On account of all of these, this survey is based on the database of common adverse event reporting system in Taizhou Hospital of Zhejiang Province and comprehensively describes the overall situations of adverse event reporting from Jan. 1st.2010. to Dec.31st.2015, and especially the monitoring system of under-reported healthcare adverse events from Jan. 1st.2013. to Dec.31st.2015. In addition, in order to establish the monitoring system of under-reported healthcare adverse events, analyses and discussions of related statistics are carried on to sort out practical experience of great benefit.

## 2. Materials and methods

### 2.1. Definition of under-reported healthcare adverse events

#### 2.1.1. The category of under-reported healthcare adverse events

In Taizhou Hospital of Zhejiang Province, adverse event reports are divided into three types.

Compulsive reporting: levelI(sentinel events),level II(events causing adverse outcomes),related departments and responsible persons must carry on the adverse event reporting system within stipulated time.

Voluntary reporting: level III(events not causing outcomes), level IV(events approximating mistakes and risks), related departments and responsible persons must initiatively carry on the adverse event reporting system[5].

Non-punitive reporting: if there happen adverse events, related persons and departments, obeying medical rules, initiatively taking effective measures and carrying on the reporting system, are able to apply for non-punitive reporting[6].

Based on classifications above, with discussions in hospital, it came into a conclusion that by comparison, voluntary reporting and non-punitive reporting are allowed to be under-reported, but compulsive reporting cannot be failed.

#### 2.1.2. Timeline of under-reported healthcare adverse events

Compulsive reporting must be proposed in 4 hours principally in hospitals. However, taking into consideration of time of incidents and sequences of persons involved addressing the medical problems, the criterion of compulsive proposing is adverse event reporting being proposed in 24 hours. If adverse events are not proposed in 24 hours, they are regarded as under-reported healthcare adverse events and compensate reporting of adverse events.

### 2.2. Monitoring of under-reported healthcare adverse events

#### 2.2.1. Adverse event reporting

It is distributed to lower levels in hospital about the adverse event reporting system, which defines responsible persons and temporal requirements. Notably, all the adverse event reporting is carried on by the adverse event reporting system, which was self-developed by our hospital. From Jan. 1st. 2013 to Dec.31st.2015, the number of voluntary reporting of adverse events from the departments of hospital is 6932.

#### 2.2.2. Verification of under-reported healthcare adverse events

Statistical sorting of Top 10 events happened in hospital was carried on with the HIS system and medical recoding system. Afterwards, statistics of the adverse event reporting system are verified, including statistics whether or not have been proposed and actual proposing time, and then under-reported healthcare adverse events are compared. Supervision projects are well monitored in proper time by information technologies, including related departments, persons, time, and types of reporting failures. From Jan.1$^{st}$.2013 to Dec.31$^{st}$ .2015, by verification, the number of under-reported healthcare adverse events reached 123.

#### 2.2.3. Addressing of under-reported healthcare adverse events

In every quarter of a year, noticing about responsible persons will be carried on in order to call for related responsible persons to analyze the existing issues and the reasons of healthcare adverse events being under-reported in time, for the sake of reforming and optimization. When noticing, related departments and persons will be found out, and hence it will stimulate responsible to reform

and optimize. As consequences of under-reported healthcare adverse events noticing, related responsible persons will not get punished economically, and they will be initiative to improve, most notably, the awareness of reporting in time will get enhanced if confronted with reports needed to propose.

### 2.3. Reforming and optimization of under-reported healthcare adverse events

Based on the previous running system of adverse event reporting and combined with PDCA reforming processes of adverse events, the role of adverse events sharing is well displayed. With regard to under-reported healthcare adverse events, the reasons of them ought to be thoroughly analyzed and related responsible persons ought to be recognized. What's more, under-reported healthcare adverse events are prior to be considered in PDCA reforming and reorganization objects.

From Jan.1st.2013 on, in Taizhou Hospital of Zhejiang Province, under-reported compulsive reporting events have been under public noticing every quarter of a year, the continuous process of which contains verification, addressing, and reforming. In the past over 3 years, considerable effects are achieved.

## 3. Analysis and discussion

### 3.1. The total number of adverse events reporting

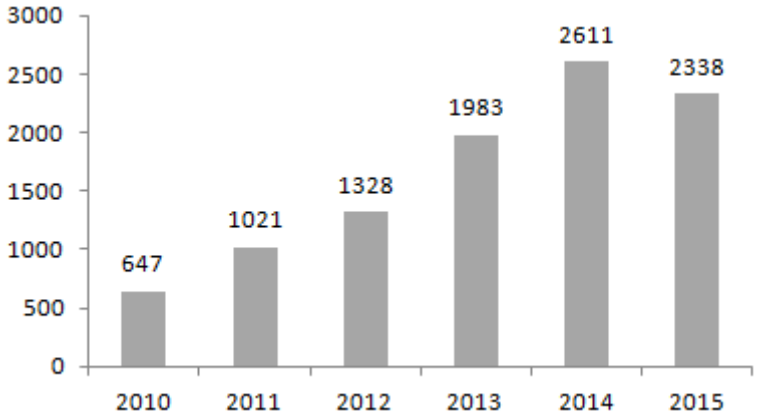


Figure 1 The number of adverse event reporting during the year of 2010 to 2015

From year 2010 to year 2012, the cardinal numbers are relatively low and the increases are relatively high; from year 2013 to year 2015, the cardinal numbers of reported healthcare adverse events are increasing evidently, the growth of which tends to slow (Figure 1). It indicates that there is objective existence of under-reported healthcare adverse events, and the number of under-reported healthcare adverse events is considerably high. On the other hand, it indicates that the atmosphere and customs of adverse event reporting, especially the awareness of responsibilities of medical staff are improved effectively, by monitoring under-reported healthcare adverse events.

### 3.2. The number of under-reported healthcare adverse events

Absolute values and proportions of under-reported healthcare adverse events, from Jan.1st.2013 to Dec.31st.2015,inTaizhou Hospital of Zhejiang Province, are as the chart below:

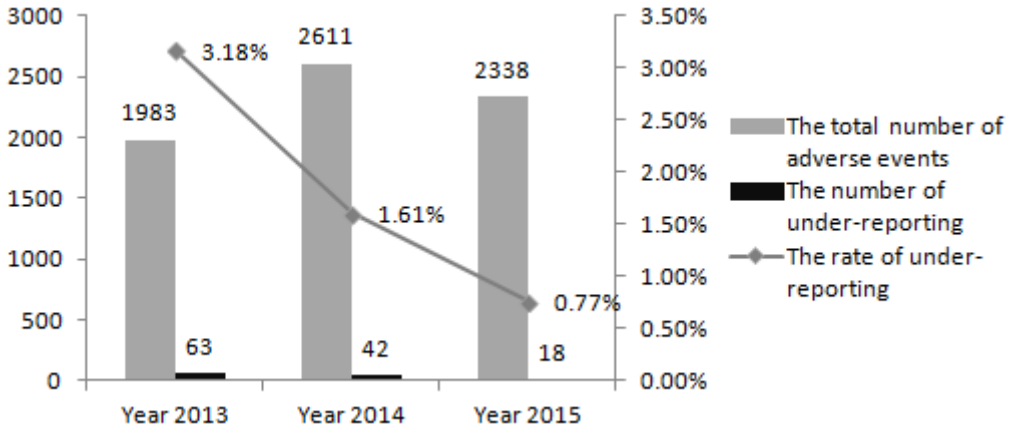


Figure 2 The rate of under-reporting adverse events

According to the activity of monitoring in the past 3 years, the number of adverse event reporting has decreased continuously year by year, from 63 cases in 2013, 42 cases in 2014, to 18 cases in 2015. Most notably, the proportion of under-reported healthcare adverse events in adverse event reporting decreases about 50% every year.

Statistics indicate that the number of under-reported healthcare adverse events has come down year by year, with the total reported adverse events increasing, which may benefit from the running monitoring system of under-reported healthcare adverse events, the follow-up supporting management measures, ever-enhanced responsible awareness of medical staff, post-monitoring noticing, and reforming methods.

### 3.3. Classifications and distributions of under-reported healthcare adverse events

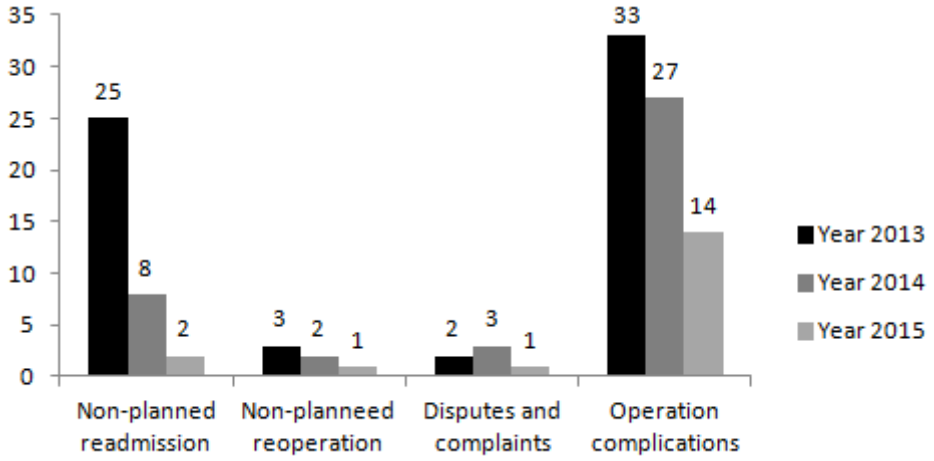


Figure 3 The number of main under-reporting adverse events

According to classifications and distributions in recent 3 years, under-reported healthcare adverse events mainly include non-planned readmissions, non-planned operations and operation complications, the remainder of which are in good order. Under-reported healthcare adverse events indicating operation complications have become one of the main contents, and other adverse events are continually reformed, that is, consecutively optimized. Meanwhile, according to the statistical trends in the three years, it can be known that the number of under-reported non-planned events decreases considerably. In addition, although operation complications account for many of the events generally, they are under effective control. In 2015, under-reported operation complications account for more than 70%. In recent 3 years, under-reported operation complications account for over 50 %.

### 3.4 The initiatives under-reported healthcare adverse events

The main barrier of adverse event reporting lies in the fearing of being punished. Although the management hierarchy in the hospital hammers that adverse event reporting will not lead to direct punishment. However, this kind of fearing is not excess because staff don't necessarily worry about being punished economically or being punished directly. In deep interviewing with staff engaged in under-reported healthcare adverse events, the further reasons why they failed to report include the fact of being punished directly or indirectly. Compared with healthcare adverse events being under-reported, proposing reports will lead to slighter punishment, which may bring about more or less troubles to medical staff. If they realize the fact that they would take greater consequences if they are found failing to report adverse events, they will tend to propose adverse events, which only involves extra work on reforming and improving[7].

### 3.5. The reforming of under-reported healthcare adverse events and its effects

With regard to under-reported healthcare adverse events, the system of compulsive reforming is carried on in our hospital. In other words, all of the under-reported healthcare adverse events ought to be reformed with PDCA according to quality improvement measures of the hospital. For instance, if there happen events of falling out of bed in the emergency department, giving rise to reoperations, the department ought to propose the events in 24 hours, otherwise, noticing about them will be carried on. More critically, after noticing, the quality improvement department in the hospital will appoint this department to hold a plenary meeting for the purpose of discussing the reasons of healthcare adverse events being under-reported and figuring out management improvement measures of patients' falling out of bed. Furthermore, related departments will be tracked and monitored by the quality improvement department to ensure that the reforming measures are put into practice. Additionally, the experience achieved will be shared among the departments in the hospital, and hence, other departments in the hospital will cope with similar issues when confronted with them. It is no doubt that the awareness of responsibilities of healthcare adverse events proposers is required in the reforming of under-reported healthcare adverse events[8]. According to the statistics in recent three years in the hospital, it is indicated that the number of under-reported healthcare adverse events comes down, of which the relative rate decreases more evidently.

## 4. Conclusions

With monitoring and improving the system of under-reported healthcare adverse events, culture, atmosphere and customs are gradually formed between medical staff, and greatly increase enthusiasm of adverse event reporting between medical staff. The experience of Taizhou Hospital of Zhejiang Province indicates that compulsive reporting is the core and fundamental of all adverse event reporting, which will also stimulate voluntary reporting. On the contrary, adverse event reporting system will merely play a titular role if under-reported healthcare adverse events are ubiquitous. Moreover, effects of the adverse event reporting system cannot be assessed without monitoring under-reported healthcare adverse events in compulsive reporting. Additionally, the closed-loop system of proposing, systemic verification, public noticing and reforming of adverse event reporting is established, which plays a commendable role in monitoring under-reported healthcare adverse events and increases initiatives and atmosphere of voluntary reporting. On the whole, this monitoring system pushes forward an immense influence on the excepted consequences.

## Acknowledgments

This work was supported by the Think Tank of Energy Mining Economy (2018 "Double First-Class" Initiative Project for Cultural Evolution and Creation of CUMT) (Grant no. 2018WHCC01) and the Fundamental Research Funds for the Central Universities (Grant no. 2019CXNL07).

## References

[1] Buja A, Saieva AM, Vinelli A, et al. Adverse event reporting and patient safety at a University Hospital: Mapping, correlating and associating events for a data-based patient risk management.Int J Risk Saf Med. 2016 ,28(3):163-70.

[2] Hatoun J, Suen W, Liu C, Shea S, et al. Elucidating Reasons for Resident Underutilization of Electronic Adverse Event Reporting.Am J Med Qual. 2016 ,31(4):308-14.

[3] Kim J, Kim S, Jung Y, et al.Status and problems of adverse event reporting systems in korean hospitals.Healthc Inform Res. 2010 ,16(3):166-76.

[4] Farley DO, Haviland A, Champagne S, et al. Adverse-event-reporting practices by US hospitals: results of a national survey.QualSaf Health Care.2008 ,17(6):416-23.

[5] Wu JH, Shen WS, Lin LM, et al. Testing the technology acceptance model for evaluating healthcare professionals' intention to use anadverse event reporting system.Int J Qual Health Care. 2008, 20(2):123-9.

[6] Coldiron B, Fisher AH, Adelman E, et al. Adverse event reporting: lessons learned from 4 years of Florida office data.Dermatol Surg. 2005 ,31(9 Pt 1):1079-92; discussion 1093.

[7] Flink E, Chevalier CL, Ruperto A, et al. Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems.In: Henriksen K, Battles JB, Marks ES, Lewin DI, editors. Advances in Patient Safety: From Research to Implementation (Volume 3: Implementation Issues). Rockville (MD): Agency for Healthcare Research and Quality (US); 2005 Feb.

[8] Demiris G, Patrick TB, Austin Boren S. Assessing patient safety awareness and needs in rural hospitals in one US state. Inform Prim Care. 2004;12(3):157-62.