

A Cross-Cultural Adaptation in Reporting Perinatal Safety Events

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Abstract. Incident reporting enables clinicians to examine historical patient safety events and to target different levels of analysis toward actionable knowledge. The cross-cultural adaptation of reporting instruments promotes the international communication on medical errors and patient safety culture. This study initializes a translation and adaptation of the Common Formats (in US) to Chinese and a localized reporting on perinatal incidents in a Chinese hospital. The results demonstrate the validity of the cross-cultural translation and diversity in a typical perinatal incident reported by Chinese clinicians. These findings suggest (1) a comprehensive data report format is critical in the incident reporting; (2) an imperative need of cross-cultural study on incident reporting; (3) future direction of incident reporting and patient safety culture.

Keywords: Perinatal safety · Data quality · Clinical information system · Cross-cultural study

1 Introduction

Following the Institute of Medicine's (IOM) report 'To Err Is Human', patient safety reports record and communicate information relevant to patient safety events and quality problems [1]. To date, patient safety reporting has gained increasing attention because it leads to learning from the causation of previous incidents and preventing potential harms [2, 3]. It has been documented that collecting, analyzing, and communicating patient safety information play important roles in reporting [4–6]. Challenges to these aspects of reporting are recognized as (1) the difficulty of collecting data in high quality [5]; (2) the lack of effective analytics of generating actionable knowledge [4]. Most importantly, data collection is one of the cornerstones of the reporting since it enables analytics at different levels [7]. A recent study indicated that a comprehensive definition and classification of reports can facilitate information integration and the disclosure of hidden and recurring harms that point to system vulnerabilities [8, 9].

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In 2009, the Agency for Healthcare Research and Quality (AHRQ) in the US developed standardized definitions and reporting formats for patient safety events, i.e. Common Formats. The Common Formats receive and aggregate patient safety related information ranging from general concerns to frequently occurred and clinically significant events [10]. In practice, the use of the Common Formats demonstrates the capacity of enhancing information classification, error identification, and harm scaling [11–13].

When it comes to the discussion of patient safety in China, there are concerns about patient safety reporting in a wide spectrum of patient safety events [14, 15], in which cultural competence and health information technology (i.e., data exchange and system interoperability) have been recognized recently [14, 16, 17]. This paper aims to perform a field trial of utilizing the Common Formats in a perinatal safety reporting system in a Chinese Hospital. The challenges of reporting perinatal incidents reside in the quality of reported data and substantial analytical bias [18–23]. The detailed tasks include (1) translating relevant Common Formats into Chinese; (2) employing cross-cultural adaptation; (3) utilizing translated forms to report patient safety events in the Chinese hospital; (4) performing quantitative and qualitative analysis from the perspective of health informatics.

2 Background

2.1 Incident Reporting

Incident reporting is recognized as one important factor to improve to the safety culture [24]. The goal of incident reporting in a hospital is to prevent recurrence of incidents by collecting useful clinical information from documented incidents. Therefore, a reporting system as such should include a comprehensive data entry design for categorizing incidents and more importantly, the clinical information underlying the description of the incident [25]. In many countries, the structure of such categorization varies between hospitals [5, 26, 27]. The inconsistency in language has become another barrier that affects the utility of reporting [2, 28]. These problems jointly hamper the incident reporting from improvement.

In the US, incident reporting has drawn ascending attention as a nationwide patient safety program [29, 30]. Although incident reporting has been broadly implemented in US hospitals, the ever-existing question is how the reporting can advance safety efforts effectively [31, 32]. To maximize the safety efforts through reporting, US hospitals may work with AHRQ funded patient safety organizations (PSO), which provide expertise in incident reporting, to aggregate patient safety events through the existing reporting systems. In addition, the Common Formats were developed to facilitate the aggregation of patient safety information.

2.2 Perinatal Safety

Improving perinatal safety is a complex undertaking that involves multidisciplinary team care and various components of such a care. An initiative of perinatal safety is to identify problems and generate actionable knowledge to reduce future harm [33]. The use of clinical

information requires effective data communication, error analysis, and clinical decision support where information technology plays an important role [34].

The Common Formats contribute to the data collection, organization, and communication in an early stage of perinatal incident reporting. In the Common Formats, a perinatal incident form is designed for event-specific information that is highly important in perinatal incidents. Information that is required, but not specific for perinatal incidents is collected through the generic formats.

2.3 Cross-Cultural Adaptation in Healthcare

The globalization of healthcare indicates a great need for cross-cultural research [35]. The clinicians and researchers need valid and reliable instruments in a diverse language and culture. Accordingly, various methodologies were established for translating, adapting, and validating healthcare instruments in the cross-cultural context. The current version of the Common Formats is designed for the US hospitals and healthcare institutes use but not for such healthcare settings abroad the US.

Table 1. Qualifications of the translators.

Task	Translator	Title	Expertise	Tenure of research
Translation	A	Associate professor	Clinical care	16
	B	Lecturer	Specialized English in nursing	3
Back-translation	C	Professor	Perinatal nursing	23
	D	Lecturer	Perinatal nursing	6
Reconciliation	E	Professor	Perinatal nursing	23
	F	Chief physician	Obstetrics and gynecology	20
	G	Lecturer	Nursing in obstetrics and gynecology	6

3 Design and Implementation

3.1 Cross-Cultural Translation and Adaptation of the Common Formats

Seven independent health care professionals were involved in the cross-cultural translation and adaptation of the Common Formats. The task includes translation, back-translation, and reconciliation as listed as follows [36–38]. (1) Five perinatal related forms were translated to Chinese, which comprise of healthcare event reporting form (HERF), patient information form (PIF), summary of initial report (SIR), Perinatal Form, and Perinatal Event Description. Translators A and B performed the translation. Items in the original Common Formats that do not fit in Chinese settings were modified or removed. (2) To maximize the equivalence of meaning between the source and target text, translators C and D performed the back-translation that translates the Chinese

translation back to English. (3) In the reconciliation, translators E, F, and G compared the original text with the back-translated text for issues such as confusion, ambiguities, and errors. A reconciliation report with notes of these issues and the recommended edits and adjustments was sent to the panel of seven translators (A, B, C, D, E, F, and G) for discussion. A consolidated version of Chinese translation is formed once all issues are addressed. See Table 1 for qualifications of the seven translators.

Table 2. An example of de-identified incident description.

An adverse event of obstetrics
A female, 32 y/o, gave birth to her first fetus after cesarean section 5 years ago. She came to our hospital waiting for her second baby delivery on Sep, 18th, 2014.
She was diagnosed as Full-term pregnancy (38 + 4 weeks), second fetus, ROA. She had no vaginal bleeding, no abdominal pain, no premature rupture of fetal membranes. Because of her scarred uterus, she applied for her second caesarean. We performed uterine lower segmental cesarean to her on 19th, September 2014. The operation process was successful, the new baby's weight is 3800 g and the APGAR score is 9–10. But we found her new baby's right elbow eversion and felt bone friction sensation. We doubted neonate bone fracture, so an orthopedist came and suggested an X-ray examination. Later the X-ray confirmed the diagnosis of neonate right humeral fracture. Quickly the new baby was applied reduction and external fixation of fracture. Baby's other body indexes were good except the fracture. On the 11th day after neonate birth, the second X-ray showed favorable restoration and new poroma.
The mom-baby left our hospital on the same day.

3.2 Reporting and Data Collection

The Perinatal Form and Perinatal Event Description were utilized to report a perinatal incident de-identified from a Chinese hospital and written in Chinese (see Table 2). Twenty-one graduate students in the School of Nursing participated in the reporting. Table 3 shows the demographics of the participants.

The participants were instructed prior to the reporting, where the Perinatal Event Description Form was utilized for the definitions of concept/terminology. Each participant was asked to provide general information regarding education, degree, specialty, and clinical training prior to the reporting. The reporting was administered utilizing paper-based materials. We previewed the returned forms (response rate: 100 %) and found all responses were complete and adequate.

4 Results

The demographics of the participants are shown in Table 3. The Perinatal Form comprises of 20 items directly related to perinatal incidents. For a complete form, please direct to https://www.psoppc.org/web/patientsafety/version-1.2_documents, and access Perinatal Form. The discrepant responses were found in five items (25 %):

Table 3. Demographic characteristics of the participants.

Characteristics	n	%
School grade		
1 st year	11	52.3
2 nd year	6	28.5
3 rd year	4	19.0
Previous clinical training		
Urinary surgery	2	9.5
ICU	1	4.7
Pediatrics	1	4.7
Gynecology and obstetrics	2	9.5
Surgery	1	4.7
Endocrinology	1	4.7
No previous clinical training	13	61.9
Area of research		
Nursing management	4	19.0
Surgical nursing	1	4.7
Nosocomial infection management	1	4.7
Nursing ethics	1	4.7
Psychiatric nursing	4	19.0
Aged nursing	1	4.7
Nursing of gynecology and obstetrics	1	4.7
Nursing education	4	19.0
Nursing psychology	4	19.0

The percentage is rounded to tenths.

Figure 1 shows a part of items with diverse responses. In Item 5, four participants accounted that only the neonate was affected by the event, while the rest accounted both of mother and neonate. In Item 6, 16 participants identified the outcomes to the mother as ‘injury to body part or organ’, whereas the rest specified ‘psychological influence’. In Item 11, 19 participants chose ‘Birth trauma/injury as listed under ICD-9-CM 767 or ICD-10-CM P10-P15’, whereas one chose ‘Five-min Apgar < 7 and birth-weight > 2500 g’ and the other one chose both. In Item 16, 15 participants identified an induced labor, while five other participants identified an augmented labor, and one specified ‘unknown’. In Item 19, 14 participants identified there was no instrumentation used to assist vaginal delivery, whereas the rest identified ‘unknown’.

5 Discussion and Future Work

Utilizing the Common Formats in a cross-cultural study shows that some items may not be completely adapted to the reporting forms in the local Chinese hospital, even though the rigorous translation and verification process were in place. For example, in the Common Formats, a perinatal period extends from the 20th week of gestation through

5. Who was affected by the event? CHECK ALL THAT APPLY:

- a. Mother
- b. Fetus(es)
- c. Neonate(s)

6. Which adverse outcome(s) did the mother sustain? CHECK ALL THAT APPLY:

- a. Hemorrhage requiring transfusion
- b. Eclampsia
- c. Magnesium toxicity
- d. Infection
- e. Injury to body part or organ
- f. Death
- g. Other: PLEASE SPECIFY _____

7. Which of the following maternal infections? CHECK ONE:

- a. Chorioamnionitis
- b. Endometritis
- c. Other: PLEASE SPECIFY _____

8. Which body part(s) or organ(s)? CHECK ALL THAT APPLY:

- a. Uterine rupture
- b. Third- or fourth-degree perineal laceration
- c. Ureter
- d. Bladder
- e. Bowel
- f. Other: PLEASE SPECIFY _____

11. Which adverse outcome(s) did the neonate sustain? CHECK ALL THAT APPLY:

- a. Birth trauma/injury as listed under ICD-9-CM 767 or ICD-10-CM P10-P15
- b. Five-minute Apgar < 7 and birthweight > 2500 grams
- c. Anoxic or hypoxic encephalopathy
- d. Seizure(s)
- e. Infection (e.g., group B strep)
- f. Unexpected death
- g. Other: PLEASE SPECIFY _____

12. Which birth trauma/injury? CHECK ONE:

- a. Subdural or cerebral hemorrhage
- b. Injury to brachial plexus, including Erb's or Klumpke's paralysis
- c. Other: PLEASE SPECIFY _____

16. Was labor induced or augmented? CHECK ONE:

- a. Yes
- b. No
- c. Unknown

17. Which one? CHECK ONE:

- a. Induced
- b. Augmented

19. Regardless of the final mode of delivery, was instrumentation used to assist vaginal (or attempted vaginal) delivery? CHECK ONE:

- a. Yes
- b. No
- c. Unknown

20. What instrumentation was used? CHECK ONE:

- a. Vacuum
- b. Forceps
- c. Vacuum followed by forceps

Fig. 1. Items selected from the perinatal form of the common formats.

four weeks (28 days) postpartum, whereas Chinese healthcare systems use the 28th week of gestation through seven days postpartum. WHO defines a perinatal period of the 22th week of gestation through seven-day postpartum.

The diversity shown in the reports may partially depend on the understanding of the sample case and the interoperability of the report form. (1) The various understandings may be due to specialties and clinical experiences. For instance, in item six, ‘Which adverse outcomes did the mother sustain?’, five out of 21 participants suggested that the mother was psychologically affected by the adverse event. Three of them are specialized in nursing psychology, one is in nursing ethics, and the other one is nursing in psychiatry. As indicated in the results, reporters who received training in nursing psychology or psychiatry tend to conclude psychological influences from the report. Regulations may be developed in reporting formats to reduce such ambiguities. The responses from the other participants reflect their clinical speciality and previous training to a certain extent.

It remains unclear if the Common Formats allow reporters to include reasonable assumptions based on their clinical expertise. (2) The results from item 5 indicate a subject judgment is involved in the reporting. There were four participants out of 21 did not check that ‘mother was affected by the event’. Two participants amongst the four argued there was no mention of the mother in the description, whereas the other two believed that compared to the fetal fracture mother was barely affected by the event. (3) The diverse responses to item 11 and 19 indicate a discrepant understanding of the incident due to the incompleteness of information from the report and the oversimplified items in the perinatal form.

Based on our findings, we suggest improving the perinatal safety in two aspects. First, structured data entry is recommended in the collection of the data. A number of the discrepant responses are due to the loss and ambiguity of the information. Structured data entry may reduce such vulnerability. This suggestion is in line with the advantages of the Common Formats as they provide a framework for structured data entry for patient safety events. Second, further studies should expand to the translation of all the other Common Formats, which would help a quick adaptation in using a reporting standard of patient safety events. Our findings in perinatal reporting have disclosed a pressing need of cross-cultural adaptation of perinatal incident reporting in Chinese hospitals. When it comes to the discussion of patient safety in China, there are concerns of incident reporting in a wide spectrum of medical adverse events [14, 15].

Acknowledgement. This project is in part supported by a grant on patient safety from the University of Texas System and a grant from AHRQ grant 1R01HS022895.

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