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4 Abstract (155 words)

- 5 BACKGROUND: Bar-code technology, used for verification of patients and their
- 6 medication, could prevent medication errors in clinical practice.
- 7 OBJECTIVE: Retrospective analysis of electronically stored medical error reports was
- 8 conducted in a university hospital.
- 9 METHODS: The number of reported medication errors of injected drugs, including
- wrong drug administration and to the wrong patient, was compared before and after
- implementation of the bar-code verification system for inpatient care.
- 12 RESULTS: A total of 2867 error reports associated with injection drugs were extracted.
- Wrong patient errors decreased significantly after implementation of the bar-code
- verification system (17.4 /year vs. 4.5 /year, p<0.05), although wrong drug errors did
- not decrease sufficiently (24.2 /year vs. 20.3 /year). The source of medication errors due
- to wrong drugs was drug preparation in hospital wards.
- 17 CONCLUSION: Bar-code medication administration is effective for prevention of
- wrong patient errors. However, ordinary bar-code verification systems are limited in

1 their ability to prevent incorrect drug preparation in hospital wards.

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3 **Key words:**

4 Bar-code technology; Error report; Injection drug; Medical safety; Wrong patient

1. Introduction

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2 Administration of injected medications to inpatients is one of the primary tasks of nurses and doctors, and is potentially associated with medical errors involving wrong 3 drugs, wrong patients and wrong doses. According to a previous report, the rate of 4 administration and wrong patients was 5 wrong drug around 15% all 6 medication/infusion events.[1]. Healthcare information technology (IT) can play an 7 important role in the prevention of medical errors caused by human factors [2]. The 8 bar-code is a classic technological tool for identifying and managing products in 9 logistics and retailing. Recently, the bar-code has become a useful tool for patient 10 management, especially in terms of medical safety, through the use of bar-code 11 medication administration (BCMA) at hospitals. For example, bar-coded wristbands can 12 substitute for Identifier (ID) cards in an inpatient setting. To enhance medical safety, the 13 bar-code verification system was applied to electronic medication-administration 14 systems, in an attempt to reduce medical errors, including dispensing errors and 15 administration errors [3]. However, limitations of BCMA were pointed out [4] and other 16 new technology, such as radio-frequency identification, has been introducing in some 17 specific area[5]. Therefore, preparing an environment for appropriate use of bar-code 18 verification system is important for effective BCMA implementation [6].

1 Medication administration errors have five domains (right patient, right drug, right 2 time, right dose, and right route), and appropriate application of the bar-code verification system to each domain is still under consideration [7]. The number of 3 4 medication errors in clinical practice is one indicator of whether a new method or 5 technology effectively contributes to medical safety. In the 2003 fiscal year, an incident reporting system was initiated in the hospital. Bar-coded wristbands and a drug-patient 6 7 bar-code matching system were introduced in the 2008 fiscal-year. The aim of this study 8 was to evaluate the rate of medical errors associated with medication administration 9 before and after implementation of the bar-code verification system, and to find efficacy 10 and limitation of BCMA in clinical practice settings.

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2. Methods

- 13 2.1. Design and Data source
- Retrospective analysis of electronically stored incident reports at the Hokkaido
 University Hospital was performed. Incident is defined as any deviation from usual
 medical care that causes an injury to the patient or poses a risk of harm at Hokkaido
 University Hospital. Incidents are voluntarily reported by every hospital staffs through
 intranet via easy-access ordering terminal. When reporting, staffs must choose a

- 1 pre-registered type of error (drug, fall, tube trouble, unpreventable complication, etc.). If 2 they choose drug error, then they must choose a pre-registered type of drug error (wrong 3 drug or patient, wrong speed, wrong route, etc.). Each report is verified by staffs in the 4 division of hospital safety management and amended if necessary, therefore consistency 5 of incident reports are assured. Staffs in the division of medical information planning manage the database of incident reports. Incident reports included type of error, error 6 7 level, date, and interpretation of the cause of the error. This study included reports 8 submitted from April 2003 to March 2012, each fiscal-year being defined from April to 9 March of a particular year (e.g., the 2003 fiscal year was from April 2003 to March 10 2004). The bar-code verification system between patients and injection drugs for 11 inpatient care was implemented in April 2008. This study was approved by the 12 Institutional Review Board of Hokkaido University Hospital.
- 13 2.2. Injection drugs operation and Bar-Code verification system
- Inpatients at the hospital wear a bar-coded wristband during the hospital stay. Personal digital assistant (PDA) devices with bar-code readers are used for verification between bar-coded wristbands and order-printed labels with bar-codes on the drugs to be injected.

 Three different ways of injection drug preparation and administration pathway at pharmacy and hospital ward were performed at our hospital (Fig. 1). Total parenteral

nutrition drugs and anti-cancer drugs are premixed and packaged together in a common container in the hospital pharmacy, for transport to the hospital wards, if the orders are received one or more days before drug administration. These packages have a bar-coded label with drug and patient information (left flow in Fig. 1). Injection drugs other than total parenteral nutrition and anti-cancer drugs are transported to hospital wards without mixing, bar-coded labels being simultaneously transported, although unattached to the drugs. In the hospital wards, nurses mix the drugs and attach the bar-coded labels to the drugs, if the orders have been created one or more days before administration (center flow in Fig. 1). In the hospital pharmacy, pharmacists use a bar-code reader for verifying between an order-printed label and bar-codes on drug labels attached by pharmaceutical companies. Injection drugs ordered on the administration day are prepared from hospital ward storage and mixed in hospital wards by the ward staff. Bar-coded labels with drugs and patient information are printed in the ward and stuck to the drug bottles or put beside the drugs when vials or ampoules are too small. Verifying between a bar-coded label printed at the hospital and bar-codes on drug labels attached by pharmaceutical companies was not performed in hospital wards because of performance of PDA and workloads of nurses (right flow in Fig. 1). In these latter two ways, preparation and mixing of injection drugs are performed under a double check

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- 1 process (two staff verification).
- 2 2.3. Analysis
- 3 The effect of implementation of the BCMA was evaluated by comparing the rate of
- 4 annual error reports in each category of injection drugs before (2003 FY 2007 FY) and
- 5 after (2008 FY- 2011 FY) implementation of the BCMA. Efficacy of the BCMA for
- 6 minimizing wrong patient errors was evaluated by the number of error reports per year
- 7 using the Mann-Whitney U test. Statistical significance was defined as a two-tailed p
- 8 value of <0.05 for all analyses. All statistical analysis was conducted by STATA version
- 9 12.0 (STATA Corporation, College Station, TX, USA).

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3. Results

- A total of 2867 (Before BCMA: 1550, After BCMA: 1317) error reports associated
- with injection drugs were extracted from the incident reporting system. Time trends of
- 14 the number of total incident reports, reports of injection drugs error, and inpatients
- showed an increased trend of total errors per patient, but injection drug errors were
- unchanged (Fig. 2). The percentage of errors of wrong patient and wrong drug to all
- error reports associated with drug injection were 13% (208/1550) before the BCMA
- 18 (2003FY-2007FY) and 8% (99/1317) after the BCMA (2008FY-2011FY), respectively.

1 The changes in numbers of errors associated with injection drugs before and after 2 implementation of the BCMA are shown in Table 1. The mean of wrong patient/drug errors per year (41.6/year) was reduced by 40% after the implementation of the BCMA 3 4 (24.8/year). Time trends of errors with wrong patient and wrong drug were shown in Fig. 5 3-A/B. Wrong patient errors decreased significantly after implementation of the BCMA (17.4 /year vs. 4.5 /year, p<0.05), although wrong drug errors did not decrease (24.2 6 7 /year vs. 20.3 /year, p=0.33) significantly. The demographics of wrong drug errors are 8 shown in Table 2. Wrong drug errors were mainly caused by drug preparation in 9 hospital wards. Typical case of wrong drug preparation was due to similar drug name, such as Veen D®/Veen F® or Amigrand®/Aminofluid®, during hospital ward 10 11 preparation (Fig. 1). A typical case of bedside error occurs in the following situation: a 12 nurse takes two or more injection drugs for a couple of patients to a multi patient room 13 and performs bar-code verification at bedside all in one piece. When injection, a wrong 14 drug is picked up and administered.

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4. Discussion

This study confirmed the effect of the bar-code verification system in reduction of the rate of errors associated with injection drug administration, and found injection drugs

- 1 prepared in hospital wards to be an unresolved source of errors, at least within the
- 2 BCMA system.
- 3 Medication administration errors are fundamental problems of medical safety [8]. As 4 evaluated using a hospital information system, bar-code technology is becoming a primary tool for the prevention of medical errors. Medication administration errors can 5 be reduced by implementation of the BCMA [9]. The bar-code verification system has 6 7 been shown to increase the safety of blood transfusion in terms of wrong patient 8 administration errors [10]. However, since infusion drug administration is potentially 9 associated with several types of errors, including wrong site, wrong procedure, wrong 10 drug, and wrong patient [11], BCMA can reduce the administration errors but cannot 11 eliminate them [3]. Moreover, errors due to wrong time of drug administration are a 12 limitation of conventional bar-code technology [12]. However, modified application of 13 bar-code technology can reduce the wrong time errors of drug administration in a 14 certain circumstance [13]. This suggests that bar-code technology should be adapted for 15 each hospital or department with regard to workflows and workloads [14]. As also 16 shown in previous studies [7, 15], our study confirmed the fact that bar-code technology 17 reduces injection drug administration errors, although drug preparation in hospital 18 wards remains unresolved source of errors, especially preparation using hospital ward

1 storage (Fig. 1). This risk in hospital ward was classified in dispensing errors and 2 similar names, packaging or labeling of drugs cause of it [16]. In addition to verification 3 between bar-coded wristbands and order-printed labels, using bar-codes on drug labels 4 attached by pharmaceutical companies may reduce the drug preparation errors in 5 hospital wards. 6 Medication errors occur at several stages from prescription to administration, therefore 7 strategy using IT to prevent medication errors is not only BCMA but computerized 8 physician order entry, automated transcription, automated dispensing machines, or 9 intravenous medication safety systems [17]. There have been many reports about IT to 10 prevent medication errors, however, optimization of administration technologies for 11 drug delivery system is still under discussion and requiring more theoretically driven 12 researches [18]. On the other hand, IT systems can adversely affect clinical care by 13 generating more work or new work for clinicians and nurses, causing workflow 14 problems, or even generating new kinds of errors [19, 20]. Further, no matter how 15 excellent a system is, a certain type of error due to inappropriate use of PDA is 16 unpreventable without optimized application of the system in clinical practice. As future 17 perspectives of technologies for medical safety, integration of technologies and standard

procedures of clinical practice is important for application of technologies.

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5. Limitations

A limitation of this study is that the data were taken retrospectively from stored 3 4 incident reports. The presence of unreported errors in the incident reporting system has 5 been pointed out as an important and unavoidable problem of the study [1, 21, 22]. On 6 the other hand, comprehensive log archiving of bar-code verification system can be a 7 complementary data source for error reports. This problem should be considered in future studies using error reports. Lack of qualitative evaluation regarding the 8 9 preparation of injection drugs in hospital wards is another limitation of this study. Some 10 studies using ethnographic methods described negative side effects and non-compliance 11 of nurses for BCMA [23, 24]. These points of view are important to find the best 12 practice for the preparation of injection drugs in hospital wards.

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6. Conclusion

In conclusion, the bar-code verification system is effective for prevention of the wrong patient error during injection drug administration. However, drug preparation in hospital wards is an unresolved source of administration errors of injected drugs.

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1 Tables

2 Table 1. Mean error reports before and after implementation of the bar-code verification

3 system

| | Before bar-code (/year) (2003 FY-2007 FY) | After bar–code (/year) (2008 FY–2011 FY) | Ratio (After/Before) |
|------------------------|---|--|-------------------------|
| Wrong dose | 50.0 | 89.8 | 180% |
| Wrong speed | 76.0 | 53.5 | 70% |
| Skipped administration | 46.4 | 48.8 | 105% |
| Wrong patient or drug | 41.6 | 24.8 | 60% |
| Wrong preparation | 39.6 | 32.5 | 82% |
| Wrong time | 11.6 | 15.0 | 129% |
| Wrong route | 10.0 | 13.3 | 133% |
| Other | 34.8 | 51.8 | 149% |

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1 Table 2. Demographics of wrong drug errors

| Error type | Implementation of bar-code verification system | |
|--|--|-------|
| | Before | After |
| Wrong drug preparation in hospital wards | 79 | 54 |
| Wrong drug injection at bedside* | 11 | 10 |
| Time lag error [†] | 7 | 3 |
| Unclassified | 24 | 14 |

^{2 *}Such as mistake target patient injection drugs with another patient injection drugs due

³ to inappropriate use of PDA or inappropriate drug handling

^{4 &}lt;sup>†</sup> Caused by time lag between drug change order and order change transmission

1 Figure captions

- 2 Fig. 1
- 3 Three different ways of injection drug preparation and administration pathway at
- 4 pharmacy and hospital ward were performed at Hokkaido University Hospital.
- 5 Dispensing and preparation errors at hospital ward were only caused at hospital ward
- 6 preparation pathway. Administration errors caused by inappropriate PDA use were
- 7 caused in every pathway.

9 Fig. 2.

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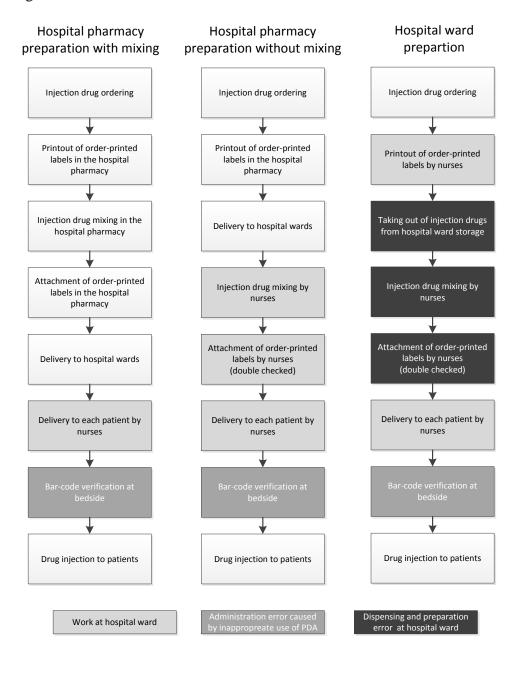
- 10 Cumulative time trend of the total number of inpatients and number of error reports. The
- number of total error reports increased gradually compared to the number of inpatients.
- 13 Fig. 3.

- 14 Fig. 3-A.
- 15 Time trend of wrong patient error showed a significant reduction (17.4/year vs. 4.5/year,
- p<0.05) in the incidence of such errors after bar-code implementation.
- 17 Fig. 3-B.
- 18 There was no significant reduction (24.2 /year vs. 20.3 /year, p=0.33) in the time trend of

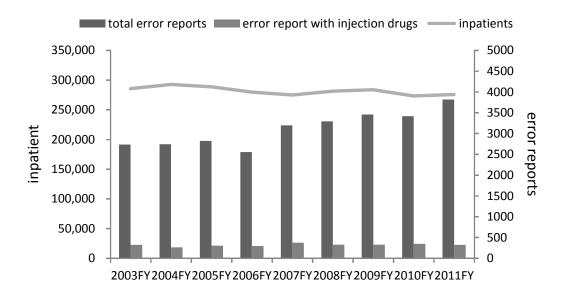
1 wrong drug error after bar-code implementation.

1 Figures

Fig. 1.

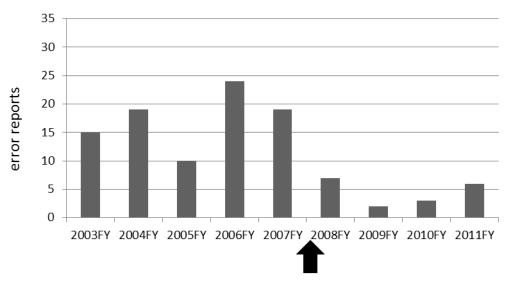


1 Fig. 2.



- 2 Fig. 3.
- 3 Fig. 3-A.

wrong patient administration



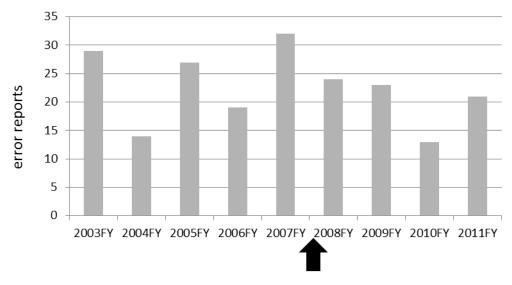
Implementation of bar-code

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2 Fig. 3-B.

wrong drug administration



Implementation of bar-code