BMJ Open

Biometric palm vein authentication of psychiatric patients for reducing in-hospital medication errors: A pre–post observational study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-055107
Article Type:	Original research
Date Submitted by the Author:	06-Jul-2021
Complete List of Authors:	Sawa, Minoru; Hokutokai Sawa Byoin, Psychiatry Inoue , Tomomi ; Hokutokai Sawa Byoin, Psychiatry Manabe, Shinichi ; Hokutokai Sawa Byoin, Psychiatry
Keywords:	PSYCHIATRY, Dementia < NEUROLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Biometric palm vein authentication of psychiatric patients for reducing in-hospital medication errors: A pre–post observational study

Author's information

Minoru Sawa MD, PhD (Corresponding Author)

Tomomi Inoue

Shinichi Manabe

Affiliation

Department of Psychiatry, Sawa Hospital, Hokutokai

1-9-1, Shiroyamacho, Toyonaka, Osaka, Japan

Tel: 81-6-6565-1211; Fax: 81-6-6865-1261

Email: msawa@hokuto-kai.com

Abstract

Objectives: Medication administration error is a critical safety concern, which may exacerbate for patients with dementia or severe psychiatric disorders. This study aimed to evaluate a biometric palm vein authentication system to prevent medication administration errors in psychiatric hospitals.

Design: This is a pre–post observational study.

Setting: We developed and introduced a new medication administration cart in two psychiatric hospitals in Japan, in which each patient-specific drug box had to be electronically opened only by palm vein authentication.

Participants: A total of 3444 and 3523 patients were present 18 months before and after introducing the cart, respectively. Of the 212 nurses recruited, 28 were excluded due to a lack of experience with the conventional medication administration system and incomplete questionnaires.

Primary and secondary outcome measures: Primary outcome was the efficacy of this system by comparing the incidence of medication administration errors before and after introducing the cart. Secondary outcome was a survey regarding nurses' attitudes toward this system.

Results: Six medication administration errors were observed before introducing the authentication system, whereas no incidents were reported after training on palm vein authentication. Among 184 nurses, 182 responded that anxiety regarding administration errors reduced using this system. Male nurses reported a greater increase in work burden than female nurses (OR=3.11, 95% CI=1.44–6.72). Nurses working in chronic care wards reported greater time pressure than nurses working in emergency wards (OR=3.33, 95% CI=1.16–9.57). Nurses working in dementia care wards reported a greater patient care burden than nurses working in emergency wards (OR=5.67, 95% CI=1.22–26.27).

Conclusions: This new system holds great potential for reducing the patient misidentification risk during medication and the anxiety experienced by nurses concerning administration errors. However, system usability and efficiency must be improved to reduce additional work burden, time pressure, and patient care burden.

Strengths and limitations of this study

- Biometric palm vein authentication system can reduce the risk of medication misidentification errors for psychiatric patients and patient with dementia.
- The new system also reduced the anxiety experienced by nurses concerning administration errors.
- The system needs to be improved to reduce the work burden, time pressure, and patient care burden of nurses.

INTRODUCTION

Medication administration error is a major patient safety concern due to the potential for severe adverse reactions to incorrect medications and disease relapse from missed doses.[1] Indeed, drug administration errors have a substantial economic impact and are major contributors to patient morbidity and mortality.[2, 3] Further, these errors can result in costly malpractice lawsuits. Medication is delivered primarily by nurses so administration errors are a particularly great source of anxiety among this group of healthcare workers.[4]

Manual double-checking is the standard practice for reducing medication administration errors,[5] but this method is still subject to human error, especially when workloads are increased or medication must be delivered quickly. Alternatively, barcode-assisted medication verification has been shown to significantly reduce medication administration errors in the emergency department.[6] Nonetheless, it is difficult to completely eliminate the possibility of medication administration error. These risks are enhanced when treating patients with dementia or severe psychiatric disorders.[7–9] In Japan, the duration of in-patient psychiatric hospital care is longer than general hospital care,[10] and many long-term patients will remove barcoded wristbands used for identification. Further, patients with dementia or severe psychiatric disorders may not give their correct name. Therefore, an alternative verification system is required to prevent or reduce medication administration errors among psychiatric hospital patients.

Several previous reports have evaluated the efficacy of nonconventional systems for preventing medication administration errors, including real-time error detection systems [11] and intravenous smart pumps.[12] Biometric authentication is also widely used in other fields, such as for smart phones, automated teller machines, and border control/immigration systems, but there are no studies on the use of biometric authentication systems for drug administration. Several biometric authentication methods are in common use, including fingerprint, face, retina, palm vein, and voice recognition. A major advantage of palm vein recognition is ease of application for elderly patients and others with dementia or severe mental illness. Further, the precision of these devices is improving.

The aim of this study was to evaluate the efficacy of a medication cart equipped with a palm vein authentication system for reducing drug administration errors in psychiatric hospitals.

METHODS

Developmental of a medication cart with palm vein authentication

We have jointly developed a new medication administration cart equipped with a vein authentication system in conjunction with Two-One Co. (Nagoya, Aichi, Japan). Each cart has 20 or 30 medication boxes for individual patients with a computer tablet and biometric vein detector for patient authentication. Each box is automatically unlocked and opened only when the vein authentication detector registers a match. For emergency situations such as a loss of electricity due to disaster, the box can be opened manually by nurses.

The new cart and authentication system is operated as follows. First, the nurse registers by inputting their own name, sex, photograph, and vein authentication information into the system using the tablet and detector. Next, the nurse assists each patient to register their own information and palm scan in the same manner and also assigns a personal medication box. The patient's medications are brought to the ward from the hospital pharmacy with barcoded information. When a nurse scans the medication barcode, only the applicable patient's medication box is opened to store the medication. To receive medication from the nurse, the patient must put their palm on the vein authentication detector to re-open the medication box.

We introduced this authentication system to nine wards of two psychiatric hospitals in phases starting at the end of August 2019. The test sites included four wards for emergency care, four for chronic care, and one for dementia care.

Comparison of medication administration error incidence before and following introduction of the new authentication system and evaluation of nurses' attitude toward the new system

We evaluated the efficacy of this system by comparing the incidence of medication administration errors over two 18-month periods before and after introduction. Before introduction, nurses used the conventional double-checking system. In addition, we conducted a questionnaire survey of nurses' attitudes toward the new system. The questionnaire contained sections for the nurse's (i) gender, (II) age, (iii) length of work experience (years), (iv) previous experience administering medication without vein authentication (Yes/No), (v) anxiety concerning medication administration error, (vi) work burden due to the new medication administration system, (vii) time pressure due to the new system, and (viii) patient care burden due to the new system. Items (v)–(viii) were measured using a 5-level Likert scale from "greatly reduced" to "greatly increased" compared to before introduction. Responses were also grouped according to whether the nurse reported "increased" or "reduced or no change". The questionnaire was distributed by a co-researcher to participant nurses. Among 225 psychiatric nurses working in the

nine wards, 212 (94.2%) provided informed consent for study participation. Candidates were exclude if they had no experience with conventional medication administration (to allow for a comparison with the conventional method as the pre-introduction condition) and incomplete answers on the questionnaire

Statistical analyses

The change in number of medication errors between pre- and post-introduction periods was evaluated using the Wilcoxon signed rank test. Categorical variables were compared by chi-square test and binominal logistic regression analysis was performed with questionnaire items (v)–(viii) as dependent variables and items (i)–(iv) as covariates. We also compared the average time spent on medication administration per patient after introduction of the vein authentication system (average of five administrations for each ward type) to investigate whether there was any difference in medication administration time per patient across various wards. All statistical analyses were conducted using SPSS version 23.

Patient and Public Involvement statement

Patients or the public WERE NOT involved in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

Comparison of medication administration error rate before and after introduction of the palm vein authentication system (Table 1)

Table 1. Comparison of medication error incidents before and after introduction of the biometric palm vein medication authentication system

	18-months before	18-months after
Total number of patients	3444	3523
Total number of errors	1209	1051
Type of medication administration error misidentification	6	0

Manually opened	0	2
Non-compliant medication	1	3

During the 18 months before introduction of the new medication cart equipped with a vein authentication system, 3444 patients were admitted to the two psychiatric hospitals, while 3523 patients were admitted to the same hospitals during the 18 months after introduction. While six medication administration errors due to patient misidentification occurred during the 18-month period before the introduction of the vein authentication system, only two occurred after introduction, both due to nurses inappropriately opening the medication box manually because they could not properly identify a dementia patient by palm vein scan. After learning the proper method for palm vein authentication, there were no more such incidents. During the 18 months before introduction of the system, there was one medication administration error caused by a medication change. During the 18 months after introduction of the system, there was also one incident of error due to medication resetting, as well as one incident of liquid medication administration as it was a non-compliant medication type, and one incident of unscheduled medication (Pro Re Nata, PRN) as there were no settings for prevention of incorrect drug form and PRN medication errors.

We then examined whether these errors after introduction of the vein authentication system occurred due to the additional time and work burdens associated with use compared to conventional authentication. During the 18 months before introduction, there were a total of 1209 medical errors reported (385 in chronic care wards, 411 in the ward for dementia patients, and 413 in the emergency psychiatric wards), while during the 18 months after introduction, there were a total of 1051 medical errors reported (228 in chronic care wards, 409 in the ward for dementia patients, and 414 in emergency psychiatric wards). The Wilcoxon signed rank test revealed no statistically significant differences in total error rates between pre- and post-introduction periods for a given ward. Hence, medication errors were reduced in the absence of any significant reduction in all-cause errors.

Nurses' attitudes toward the new vein authentication system (Table 2, Table 3)

Table 2. Demographic characteristics of the participant nurses and nurses' attitudes toward the new medication authentication system

211

Variable		Ward type Chronic	Dementia	Emergency
Gender	Male	25	6	34
	Female	51	12	56
Age group (years)	20–29	10	3	11
	30–39	15	6	26
	40–49	37	5	31
	50–59	12	3	20
	Over 60	2	1	2
Work experience (years)	Less than 3	7	1	5
	3–4	14	5	10
	5–9	14	4	22
	10–19	25	3	34
	20–29	11	5	13
	30–39	4	0	5
	Over 40	1	0	1
Anxiety	Reduced or no Change	75	17	90
	Increased	1	1	0
Work burden	Reduced or no Change	19	5	33
	Increased	56	13	56
Time pressure	Reduced or no Change	5	1	17
	Increased	71	17	73
Burden for patient care	Reduced or no Change	30	2	37
	Increased	46	16	53

Average administration time per patient (s)	Per patient	90.2 ± 7.1	179.6 ± 17.1	82.7 ± 4.2

Table 3. Results of logistic analyses

Dependent variable	Covariates	Odds Ratio	95% CI	p
Work burden	Gender (male/female)	3.11	1.44–6.72	<0.01*
	Work experience	0.85	0.63–1.14	0.27
	Ward type (chronic/emergency)	1.86	0.92–3.75	0.09
	Ward type (dementia/emergency)	1.55	0.49–4.94	0.46
	Age group (every 10 years)	0.89	0.60–1.30	0.54
Time pressure	Gender (male/female)	0.87	0.34–2.22	0.77
	Work experience	1.06	0.71–1.60	0.77
	Ward type (chronic/emergency)	3.33	1.16–9.57	0.03*
	Ward type (dementia/emergency)	4.02	0.50–32.44	0.19
	Age group (every 10 years)	0.99	0.58–1.68	0.97
Burden for patient care	Gender (male/female)	1.27	0.66–2.43	0.48
	Work experience	1.03	0.78–1.35	0.86
	Ward type (chronic/emergency)	1.09	0.58–2.04	0.79
	Ward type (dementia/emergency)	5.67	1.22–26.27	0.03*
	Age group (every 10 years)	0.90	0.63–1.30	0.59

* statistically significant

Of the 212 nurses recruited, 19 were excluded from the questionnaire component of the study due to a lack of experience with the conventional medication administration system (double-checking), and another 9 were excluded due to incomplete questionnaires. The demographic characteristics and responses of the remaining 184 nurses are presented in Table 2.

Among these 184 nurses, 182 (98.9%) reported reduced anxiety over medication administration error using the new system. However, a majority (125 or 68.7%) reported an increased work burden for medication administration, with male nurses reporting an increase more frequently than female nurses ($p = 0.002$). A substantial majority (161 or 87.5%) also reported increased pressure on their time and 115 (62.5%) reported increased patient care burden using the new system.

Correlation analyses revealed significant associations between age group and duration of work experience ($r = 0.51$), work burden and time pressure ($r = 0.39$), work burden and patient care burden ($r = 0.43$), and time pressure and patient care burden ($r = 0.39$). There were also significant differences in average time spent per patient on medication administration, with medication administration to dementia patients requiring significantly more time than administration to chronic care patients and psychiatric emergency ward patients (179.6 ± 17.1 s vs. 90.2 ± 7.1 and 82.7 ± 4.2 s, both $p < 0.01$). In contrast, there was no significant difference in medication administration time per patient between chronic care and psychiatric emergency patients ($p = 0.37$).

Based on these results, we then conducted binominal logistic regression analysis with work burden, time pressure, and patient care burden as dependent variables and age, gender, work experience duration, and ward type as covariates. Anxiety was not chosen as a dependent variable because few nurses reported increased anxiety compared to the number reporting reduced anxiety. Male nurses reported a greater increase in work burden than female nurses using the new system (OR = 3.11, 95% CI = 1.44–6.72), while nurses working in chronic care wards reported more time pressure than nurses working in emergency wards (OR = 3.33, 95% CI = 1.16–9.57). Finally, nurses working in the dementia care ward reported a greater patient care burden than emergency ward nurses using the new system (OR = 5.67, 95% CI = 1.22–26.27). Results of logistic binominal regression analyses are summarized in Table 3.

DISCUSSION

Many protocols have been devised to prevent medication administration errors due to

patient misidentification, from the use of simple order sheets[13] to placing more of the onus on patients for empowerment.[14] To our knowledge, there have been no studies investigating the use of palm vein authentication for the prevention of medication administration errors. Here we demonstrate that such a system can reduce the incidence of misidentification, although the system as currently conceived does increase nurse work burden.

This new system is advantageous in that it permits proper identification and contingent access to the patient's medication even in cases where the patient is unable to respond due to cognitive impairment. Alternatively, the system does depend on a power supply for battery recharging, which could be lost in the case of a natural disaster. In such cases, the nurse would have to open the medication box manually and rely on conventional verification methods such as double-checking. Another disadvantage to the current system is that the cart is relatively large due to the electronic instruments. Further, the palm vein scan can be time-consuming for uncooperative patients. Also, while the system did reduce misidentification errors, it is still necessary to improve nurses' attitudes toward its use.

According to the questionnaire, medication administration error is a substantial source of anxiety among nurses, and this anxiety was dramatically reduced by the palm vein authentication system. However, work burden, time pressure, and patient care burden were reported to increase, and these attitudes were mutually related. It is thus important to educate nurses on the efficacy of this system to reduce misidentification during medication administration, especially in psychiatric hospitals and wards with dementia patients who may have difficulty self-identifying or in recognizing medication errors. In a previous study,[15] both time pressure and workload were shown to increase the medication error rate. Although work burden, time pressure, and patient care burden were increased, it is significant that overall medical error incidence rates were not increased, suggesting that the system will not introduce additional errors in other aspects of care.

Surprisingly, this reported increase in work burden differed according to sex, with more male nurses reporting an increase, which may be due to the relatively greater proportion of male nurses in emergency wards. A difference in reported time pressure was also found between chronic and emergency wards, possibly due to the greater difficulty in accessing patients in crowded chronic wards. Drug-related problems are common among patients with dementia and cognitive impairment,[16] so this difference in reported time pressure may be attributable to the greater proportion of patients with cognitive impairment in chronic care facilities. Indeed, the average time required for medication administration was significantly higher in dementia wards. However, this difference in time pressure

between chronic and emergency wards was not reflected by differences in average time spent administering medication to individual patients, so there may be other factors contributing to the stress associated with medication administration independent of the authentication system, such general workplace environment, accessibility of social supports, relationships with colleagues and patients, and working hours.

There are limitations to the present study. First, the study was conducted at only two hospitals, limiting generalizability. We also cannot establish causal relationships due to the observational study design. The system as currently configured cannot prevent the administration of certain non-compliant medications. Future research should focus on confirming these findings and explore ways to reduce the workload associated with this vein authentication system.

CONCLUSION

Medication administration error is a common occurrence in hospitals. Biometric technology is continually improving and widely used for personal identification in our daily lives. Palm vein authentication proved superior to conventional methods for patient identification as evidenced by the decrease in medication errors after introduction. However, further improvements are needed to reduce nurse work burden, time pressure, and patient care burden.

ACKNOWLEDGEMENTS

We are grateful to Dr. Aya Kinjo, Associate Professor, Division of Environmental and Preventive Medicine, Department of Social Medicine, Faculty of Medicine, Tottori University, for advice on statistical analyses.

ETHICS STATEMENTS

The study protocol was approved by the hospital ethics board (approval number; 2021001). All nurses provided informed written consent and patients were informed of their right to opt-out. Otherwise, patient consent was assumed.

FUNDING

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

COMPETING INTERESTS

None declared

CONTRIBUTORS

Minoru Sawa (MS) conceptualized the study with input from all the co-authors. Tomomi Inoue (TI) and Shinichi Manage (SM) are the co-authors. MS performed the statistical analysis and wrote the first draft of the manuscript, and all the authors provided critical scholarly feedback. All the co-authors approved of the final version of the manuscript. The corresponding author attests that all the listed authors meet the authorship criteria and that no authors meeting the criteria have been excluded from the acknowledgment.

DATA AVAILABILITY STATEMENT

Data used in this study are available upon reasonable request the authors.

REFERENCES

1. McCullagh M, Slattery D. Medication related litigation in Ireland: A 6-year review. *Br J Clin Pharmacol* 2019;85:2155–62.

2. Walsh EK, Hansen CR, Sahm LJ, *et al.* Economic impact of medication error: a systematic review. *Pharmacoepidemiol Drug Saf* 2017;26:481–97.

3. Wittich CM, Burkle CM, Lanier WL. Medication errors: an overview for clinicians. *Mayo Clin Proc* 2014;89:1116–25.

4. Star K, Nordin K, Pöder U, *et al.* Challenges of safe medication practice in paediatric care—a nursing perspective. *Acta Paediatr* 2013;102:532–8.

5. Kellett P, Gottwald M. Double-checking high-risk medications in acute settings: a safer process. *Nurs Manag (Harrow)* 2015;21:16–22.

6. Bonkowski J, Carnes C, Melucci J, *et al.* Effect of barcode-assisted medication administration on emergency department medication errors. *Acad Emerg Med* 2013;20:801–6.

7. Maidment ID, Lelliott P, Paton C. Medication errors in mental healthcare: a systematic review. *Qual Saf Health Care* 2006;15:409–13.

8. Procyshyn RM, Barr AM, Brickell T, *et al.* Medication errors in psychiatry: a comprehensive review. *CNS Drugs* 2010;24:595–609.

9. Mann K, Rothschild JM, Keohane CA, *et al.* Adverse drug events and medication errors in psychiatry: methodological issues regarding identification and classification. *World J Biol Psychiatry* 2008;9:24–33.

10. Okayama T, Usuda K, Okazaki E, *et al.* Number of long-term inpatients in Japanese psychiatric care beds: trend analysis from the patient survey and the 630 survey. *BMC Psychiatry* 2020;20:522.

11. Ni Y, Lingren T, Hall ES, *et al.* Designing and evaluating an automated system for real-time medication administration error detection in a neonatal intensive care unit. *J Am Med Inform Assoc* 2018;25:555–63.

12. Giuliano KK. Intravenous smart pumps: usability issues, intravenous medication administration error, and patient safety. *Crit Care Nurs Clin North Am* 2018;30:215–24.

13. Opfer KB, Wirtz DM, Farley K. A chemotherapy standard order form: preventing errors. *Oncol Nurs Forum* 1999;26:123–8.

14. Stout L, Joseph S. Blood transfusion: patient identification and empowerment. *Br J Nurs* 2016;25:138–43.

15. Kunac DL, Tatley MV, Seddon ME. A new web-based medication error reporting programme (MERP) to supplement pharmacovigilance in New Zealand—findings from a pilot study in primary care. *N Z Med J* 2014;127:69–81.

16. Pfister B, Jonsson J, Gustafsson M. Drug-related problems and medication reviews among old people with dementia. *BMC Pharmacol Toxicol* 2017;18:52.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1-3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4-6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*4-6*
Bias	9	Describe any efforts to address potential sources of bias	4-6
Study size	10	Explain how the study size was arrived at	4-6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	6
		(*b*) Describe any methods used to examine subgroups and interactions	6
		(*c*) Explain how missing data were addressed	6
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	6
		(*e*) Describe any sensitivity analyses	N/A

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6-10
		(b) Give reasons for non-participation at each stage	6-10
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6-10
		(b) Indicate number of participants with missing data for each variable of interest	6-10
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	N/A
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	*6-10*
		Cross-sectional study—Report numbers of outcome events or summary measures	N/A
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-10
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6-10
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10-12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	10-12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Foot note

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Biometric palm vein authentication of psychiatric patients for reducing in-hospital medication errors: A pre–post observational study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-055107.R1
Article Type:	Original research
Date Submitted by the Author:	13-Dec-2021
Complete List of Authors:	Sawa, Minoru; Hokutokai Sawa Byoin, Psychiatry Inoue , Tomomi ; Hokutokai Sawa Byoin, Psychiatry Manabe, Shinichi ; Hokutokai Sawa Byoin, Psychiatry
Primary Subject Heading:	Medical management
Secondary Subject Heading:	Mental health
Keywords:	PSYCHIATRY, Dementia < NEUROLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Biometric palm vein authentication of psychiatric patients for reducing in-hospital medication errors: A pre–post observational study

Author's information

Minoru Sawa MD, PhD (Corresponding Author)

Tomomi Inoue

Shinichi Manabe

Affiliation

Department of Psychiatry, Sawa Hospital, Hokutokai

1-9-1, Shiroyamacho, Toyonaka, Osaka, Japan

Tel: 81-6-6565-1211; Fax: 81-6-6865-1261

Email: msawa@hokuto-kai.com

Abstract

Objectives: Medication administration error is a critical safety concern, which may exacerbate for patients with dementia or severe psychiatric disorders. This study aimed to evaluate a biometric palm vein authentication system to prevent medication administration errors in psychiatric hospitals.

Design: This is a pre–post observational study.

Setting: We developed and introduced a new medication administration cart in two psychiatric hospitals in Japan, in which each patient-specific drug box had to be electronically opened only by palm vein authentication.

Participants: A total of 3444 and 3523 patients were present 18 months before and after introducing the cart, respectively. Of the 212 nurses recruited, 28 were excluded due to a lack of experience with the conventional medication administration system and incomplete questionnaires.

Primary and secondary outcome measures: Primary outcome was the efficacy of this system by comparing the incidence of medication administration errors before and after introducing the cart. Secondary outcome was a survey regarding nurses' attitudes toward this system.

Results: After introduction of the new system, the number of medication errors due to misidentification of persons relative to the total number of admitted patients was significantly reduced ($p<0.0001$). Among 184 nurses, 182 responded that anxiety regarding administration errors reduced using this system. Male nurses reported a greater increase in work burden than female nurses (OR=3.11, 95% CI=1.44–6.72). Nurses working in chronic care wards reported greater time pressure than nurses working in emergency wards (OR=3.33, 95% CI=1.16–9.57). Nurses working in dementia care wards reported a greater patient care burden than nurses working in emergency wards (OR=5.67, 95% CI=1.22–26.27).

Conclusions: This new system holds great potential for reducing the patient misidentification risk during medication and the anxiety experienced by nurses concerning administration errors. However, system usability and efficiency must be improved to reduce additional work burden, time pressure, and patient care burden.

Strengths and limitations of this study

- Biometric palm vein authentication system can reduce the risk of medication misidentification errors for psychiatric patients and patient with dementia.
- The new system also reduced the anxiety experienced by nurses concerning administration errors.
- The system needs to be improved to reduce the work burden, time pressure, and patient care burden of nurses.

INTRODUCTION

Medication administration error is a major patient safety concern due to the potential for severe adverse reactions to incorrect medications and disease relapse from missed doses.[1] Indeed, drug administration errors have a substantial economic impact and are major contributors to patient morbidity and mortality.[2, 3] Further, these errors can result in costly malpractice lawsuits. Medication is delivered primarily by nurses so administration errors are a particularly great source of anxiety among this group of healthcare workers.[4]

Manual double-checking is the standard practice for reducing medication administration errors,[5] but this method is still subject to human error, especially when workloads are increased or medication must be delivered quickly. Alternatively, barcode-assisted medication verification has been shown to significantly reduce medication administration errors in the emergency department.[6] Nonetheless, it is difficult to completely eliminate the possibility of medication administration error. These risks are enhanced when treating patients with dementia or severe psychiatric disorders.[7–9] In Japan, the duration of in-patient psychiatric hospital care is longer than general hospital care,[10] and many long-term patients will remove barcoded wristbands used for identification. Further, patients with dementia or severe psychiatric disorders may not give their correct name. Therefore, an alternative verification system is required to prevent or reduce medication administration errors among psychiatric hospital patients.

Several previous reports have evaluated the efficacy of nonconventional systems for preventing medication administration errors, including real-time error detection systems [11] and intravenous smart pumps.[12] Biometric authentication is also widely used in other fields, such as for smart phones, automated teller machines, and border control/immigration systems, but there are no studies on the use of biometric authentication systems for drug administration. Several biometric authentication methods are in common use, including fingerprint, face, retina, palm vein, and voice recognition. A major advantage of palm vein recognition is ease of application for elderly patients and others with dementia or severe mental illness. Further, the precision of these devices is improving.

The aim of this study was to evaluate the efficacy of a medication cart equipped with a palm vein authentication system for reducing drug administration errors in psychiatric hospitals.

METHODS

Developmental of a medication cart with palm vein authentication

We have jointly developed a new medication administration cart equipped with a vein authentication system in conjunction with Two-One Co. (Nagoya, Aichi, Japan). Each cart has 20 or 30 medication boxes for individual patients with a computer tablet and biometric vein detector for patient authentication. Each box is automatically unlocked and opened only when the vein authentication detector registers a match. For emergency situations such as a loss of electricity due to disaster, the box can be opened manually by nurses.

The new cart and authentication system is operated as follows. First, the nurse registers by inputting their own name, sex, photograph, and vein authentication information into the system using the tablet and detector. Next, the nurse assists each patient to register their own information and palm scan in the same manner and also assigns a personal medication box. The patient's medications are brought to the ward from the hospital pharmacy with barcoded information. When a nurse scans the medication barcode, only the applicable patient's medication box is opened to store the medication. To receive medication from the nurse, the patient must put their palm on the vein authentication detector to re-open the medication box (Figure 1,2).

We introduced this authentication system to nine wards of two psychiatric hospitals in phases starting at the end of August 2019. The test sites included four wards for emergency care, four for chronic care, and one for dementia care.

Comparison of medication administration error incidence before and following introduction of the new authentication system and evaluation of nurses' attitude toward the new system

We evaluated the efficacy of this system by comparing the incidence of medication administration errors over two 18-month periods before and after introduction. Before introduction, nurses used the conventional double-checking system. Medication errors are included in the total errors, such as incorrect patient care methods, wrong food delivery, immature medical techniques, unexpected deterioration of physical condition, and claim of medical services from patients and their families. All errors were reported through the ISO incident and accident reporting system by employees from all departments of the two hospitals, including nurses, doctors, pharmacists, occupational therapists, and medical clerks. In addition, we conducted a questionnaire survey of nurses' attitudes toward the new system. The questionnaire contained sections for the nurse's (i) gender, (II) age, (iii) length of work experience (years), (iv) previous experience administering medication without vein authentication (Yes/No), (v) anxiety concerning medication administration error, (vi) work burden due to the new medication administration system, (vii) time

pressure due to the new system, and (viii) patient care burden due to the new system. Items (v)–(viii) were measured using a 5-level Likert scale from "greatly reduced" to "greatly increased" compared to before introduction. Responses were also grouped according to whether the nurse reported "increased" or "reduced or no change". The questionnaire was distributed by a co-researcher to participant nurses. Among 225 psychiatric nurses working in the nine wards, 212 (94.2%) provided informed consent for study participation. Candidates were exclude if they had no experience with conventional medication administration (to allow for a comparison with the conventional method as the pre-introduction condition) and incomplete answers on the questionnaire

Statistical analyses

The change in number of medication errors between pre- and post-introduction periods was evaluated using the Wilcoxon signed rank test. Categorical variables were compared by chi-square test and binominal logistic regression analysis was performed with questionnaire items (v)–(viii) as dependent variables and items (i)–(iv) as covariates. We also compared the average time spent on medication administration per patient after introduction of the vein authentication system (average of five administrations for each ward type) to investigate whether there was any difference in medication administration time per patient across various wards. All statistical analyses were conducted using SPSS version 23.

Patient and Public Involvement statement

Patients or the public WERE NOT involved in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

Comparison of medication administration error rate before and after introduction of the palm vein authentication system (Table 1)

Table 1. Comparison of medication error incidents before and after introduction of the biometric palm vein medication authentication system

	18-months before	18-months after	p value*
total number of patients	3444	3523	

total number of incidents of errors	1209	1051	
type of medication administration errors			
misidentification	6	2	
non compliant medication	1	3	
total number of incidents of errors/total number of patients	1209/3444	1051/3523	<0.0001
misidentification errors /total number of incidents of errors	6/3444	2/3523	<0.0001

*statistically significant

During the 18 months before introduction of the new medication cart equipped with a vein authentication system, 3444 patients were admitted to the two psychiatric hospitals, while 3523 patients were admitted to the same hospitals during the 18 months after introduction. While six medication administration errors due to patient misidentification occurred during the 18-month period before the introduction of the vein authentication system, only two occurred after introduction, both due to nurses inappropriately opening the medication box manually because they could not properly identify a dementia patient by palm vein scan. After learning the proper method for palm vein authentication, there were no more such incidents. During the 18 months before introduction of the system, there was one medication administration error caused by a medication change. During the 18 months after introduction of the system, there was also one incident of error due to medication resetting, as well as one incident of liquid medication administration as it was a non-compliant medication type, and one incident of unscheduled medication (Pro Re Nata, PRN) as there were no settings for prevention of incorrect drug form and PRN medication errors. According to the results of McNemar test, the number of total errors relative to the total number of admitted patients was significantly reduced ($p<0.0001$), and the number of medication errors due to misidentification of persons relative to the total number of admitted patients was also significantly reduced ($p<0.0001$).

We then examined whether these errors after introduction of the vein authentication system occurred due to the additional time and work burdens associated with use compared to conventional authentication. During the 18 months before introduction, there were a total of 1209 medical errors reported (385 in chronic care wards, 411 in the ward

for dementia patients, and 413 in the emergency psychiatric wards), while during the 18 months after introduction, there were a total of 1051 medical errors reported (228 in chronic care wards, 409 in the ward for dementia patients, and 414 in emergency psychiatric wards). The Wilcoxon signed rank test revealed no statistically significant differences in total error rates between pre- and post-introduction periods for a given ward. Hence, medication errors were reduced in the absence of any significant reduction in all-cause errors.

Nurses' attitudes toward the new vein authentication system (Table 2, Table 3)

Table 2. Demographic characteristics of the participant nurses and nurses' attitudes toward the new medication authentication system

Variable		Ward type		
		Chronic	Dementia	Emergency
Gender	Male	25	6	34
	Female	51	12	56
Age group (years)	20–29	10	3	11
	30–39	15	6	26
	40–49	37	5	31
	50–59	12	3	20
	Over 60	2	1	2
Work experience (years)	Less than 3	7	1	5
	3–4	14	5	10
	5–9	14	4	22
	10–19	25	3	34
	20–29	11	5	13
	30–39	4	0	5
	Over 40	1	0	1

Anxiety	Reduced or no Change	75	17	90
	Increased	1	1	0
Work burden	Reduced or no Change	19	5	33
	Increased	56	13	56
Time pressure	Reduced or no Change	5	1	17
	Increased	71	17	73
Burden for patient care	Reduced or no Change	30	2	37
	Increased	46	16	53
Average administration time per patient (s)	Per patient	90.2 ± 7.1	179.6 ± 17.1	82.7 ± 4.2

Table 3. Results of logistic analyses

Dependent variable	Covariates	Odds Ratio	95% CI	p
Work burden	Gender (male/female)	3.11	1.44–6.72	<0.01*
	Work experience	0.85	0.63–1.14	0.27
	Ward type (chronic/emergency)	1.86	0.92–3.75	0.09
	Ward type (dementia/emergency)	1.55	0.49–4.94	0.46
	Age group (every 10 years)	0.89	0.60–1.30	0.54
Time pressure	Gender (male/female)	0.87	0.34–2.22	0.77
	Work experience	1.06	0.71–1.60	0.77
	Ward type (chronic/emergency)	3.33	1.16–9.57	0.03*

	Ward type (dementia/emergency)	4.02	0.50–32.44	0.19
	Age group (every 10 years)	0.99	0.58–1.68	0.97
Burden for patient care	Gender (male/female)	1.27	0.66–2.43	0.48
	Work experience	1.03	0.78–1.35	0.86
	Ward type (chronic/emergency)	1.09	0.58–2.04	0.79
	Ward type (dementia/emergency)	5.67	1.22–26.27	0.03*
	Age group (every 10 years)	0.90	0.63–1.30	0.59

* statistically significant

Of the 212 nurses recruited, 19 were excluded from the questionnaire component of the study due to a lack of experience with the conventional medication administration system (double-checking), and another 9 were excluded due to incomplete questionnaires. The demographic characteristics and responses of the remaining 184 nurses are presented in Table 2.

Among these 184 nurses, 182 (98.9%) reported reduced anxiety over medication administration error using the new system. However, a majority (125 or 68.7%) reported an increased work burden for medication administration, with male nurses reporting an increase more frequently than female nurses ($p = 0.002$). A substantial majority (161 or 87.5%) also reported increased pressure on their time and 115 (62.5%) reported increased patient care burden using the new system.

Correlation analyses revealed significant associations between age group and duration of work experience ($r = 0.51$), work burden and time pressure ($r = 0.39$), work burden and patient care burden ($r = 0.43$), and time pressure and patient care burden ($r = 0.39$). There were also significant differences in average time spent per patient on medication administration, with medication administration to dementia patients requiring significantly more time than administration to chronic care patients and psychiatric emergency ward patients (179.6 ± 17.1 s vs. 90.2 ± 7.1 and 82.7 ± 4.2 s, both $p < 0.01$). In contrast, there was no significant difference in medication administration time per patient between chronic care and psychiatric emergency patients ($p = 0.37$).

Based on these results, we then conducted binominal logistic regression analysis with work burden, time pressure, and patient care burden as dependent variables and age,

gender, work experience duration, and ward type as covariates. Anxiety was not chosen as a dependent variable because few nurses reported increased anxiety compared to the number reporting reduced anxiety. Male nurses reported a greater increase in work burden than female nurses using the new system (OR = 3.11, 95% CI = 1.44–6.72), while nurses working in chronic care wards reported more time pressure than nurses working in emergency wards (OR = 3.33, 95% CI = 1.16–9.57). Finally, nurses working in the dementia care ward reported a greater patient care burden than emergency ward nurses using the new system (OR = 5.67, 95% CI = 1.22–26.27). Results of logistic binominal regression analyses are summarized in Table 3.

DISCUSSION

Many protocols have been devised to prevent medication administration errors due to patient misidentification, from the use of simple order sheets[13] to placing more of the onus on patients for empowerment.[14] To our knowledge, there have been no studies investigating the use of palm vein authentication for the prevention of medication administration errors. Here we demonstrate that such a system can reduce the incidence of misidentification, although the system as currently conceived does increase nurse work burden.

This new system is advantageous in that it permits proper identification and contingent access to the patient's medication even in cases where the patient is unable to respond due to cognitive impairment. Alternatively, the system does depend on a power supply for battery recharging, which could be lost in the case of a natural disaster. In such cases, the nurse would have to open the medication box manually and rely on conventional verification methods such as double-checking. Another disadvantage to the current system is that the cart is relatively large due to the electronic instruments. Further, the palm vein scan can be time-consuming for uncooperative patients. Also, while the system did reduce misidentification errors, it is still necessary to improve nurses' attitudes toward its use.

According to the questionnaire, medication administration error is a substantial source of anxiety among nurses, and this anxiety was dramatically reduced by the palm vein authentication system. However, work burden, time pressure, and patient care burden were reported to increase, and these attitudes were mutually related. It is thus important to educate nurses on the efficacy of this system to reduce misidentification during medication administration, especially in psychiatric hospitals and wards with dementia patients who may have difficulty self-identifying or in recognizing medication errors. In

a previous study,[15] both time pressure and workload were shown to increase the medication error rate. Although work burden, time pressure, and patient care burden were increased, it is significant that overall medical error incidence rates were not increased, suggesting that the system will not introduce additional errors in other aspects of care.

Surprisingly, this reported increase in work burden differed according to sex, with more male nurses reporting an increase, which may be due to the relatively greater proportion of male nurses in emergency wards. A difference in reported time pressure was also found between chronic and emergency wards, possibly due to the greater difficulty in accessing patients in crowded chronic wards. Drug-related problems are common among patients with dementia and cognitive impairment,[16] so this difference in reported time pressure may be attributable to the greater proportion of patients with cognitive impairment in chronic care facilities. Indeed, the average time required for medication administration was significantly higher in dementia wards. However, this difference in time pressure between chronic and emergency wards was not reflected by differences in average time spent administering medication to individual patients, so there may be other factors contributing to the stress associated with medication administration independent of the authentication system, such general workplace environment, accessibility of social supports, relationships with colleagues and patients, and working hours.

There are limitations to the present study. First, the study was conducted at only two hospitals, limiting generalizability. We also cannot establish causal relationships due to the observational study design. In this study, before and after comparisons were made in only two hospitals, but future studies such as randomly assigning wards in a multi-center setting would be desirable. The system as currently configured cannot prevent the administration of certain non-compliant medications such as PRN medications. Another limitation was that medication administration time and nurses' awareness were not measured using conventional methods. Future research should focus on confirming these findings and explore ways to reduce the workload associated with this vein authentication system.

CONCLUSION

Medication administration error is a common occurrence in hospitals. Biometric technology is continually improving and widely used for personal identification in our daily lives. Palm vein authentication proved superior to conventional methods for patient identification as evidenced by the decrease in medication errors after introduction. However, further improvements are needed to reduce nurse work burden, time pressure,

and patient care burden.

ACKNOWLEDGEMENTS

We are grateful to Dr. Aya Kinjo, Associate Professor, Division of Environmental and Preventive Medicine, Department of Social Medicine, Faculty of Medicine, Tottori University, for advice on statistical analyses.

ETHICS STATEMENTS

The study protocol was approved by the hospital ethics board (approval number; 2021001). All nurses provided informed written consent and patients were informed of their right to opt-out. Otherwise, patient consent was assumed.

FUNDING

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

COMPETING INTERESTS

None declared

CONTRIBUTORS

Minoru Sawa (MS) conceptualized the study with input from all the co-authors. Tomomi Inoue (TI) and Shinichi Manage (SM) are the co-authors. MS performed the statistical analysis and wrote the first draft of the manuscript, and all the authors provided critical scholarly feedback. All the co-authors approved of the final version of the manuscript. The corresponding author attests that all the listed authors meet the authorship criteria and that no authors meeting the criteria have been excluded from the acknowledgment.

DATA AVAILABILITY STATEMENT

Data used in this study are available upon reasonable request the authors.

REFERENCES

1. McCullagh M, Slattery D. Medication related litigation in Ireland: A 6-year review. *Br J Clin Pharmacol* 2019;85:2155–62.

2. Walsh EK, Hansen CR, Sahm LJ, *et al.* Economic impact of medication error: a systematic review. *Pharmacoepidemiol Drug Saf* 2017;26:481–97.

3. Wittich CM, Burkle CM, Lanier WL. Medication errors: an overview for clinicians. *Mayo Clin Proc* 2014;89:1116–25.

4. Star K, Nordin K, Pöder U, *et al.* Challenges of safe medication practice in paediatric care—a nursing perspective. *Acta Paediatr* 2013;102:532–8.

5. Kellett P, Gottwald M. Double-checking high-risk medications in acute settings: a safer process. *Nurs Manag (Harrow)* 2015;21:16–22.

6. Bonkowski J, Carnes C, Melucci J, *et al.* Effect of barcode-assisted medication administration on emergency department medication errors. *Acad Emerg Med* 2013;20:801–6.

7. Maidment ID, Lelliott P, Paton C. Medication errors in mental healthcare: a systematic review. *Qual Saf Health Care* 2006;15:409–13.

8. Procyshyn RM, Barr AM, Brickell T, *et al.* Medication errors in psychiatry: a comprehensive review. *CNS Drugs* 2010;24:595–609.

9. Mann K, Rothschild JM, Keohane CA, *et al.* Adverse drug events and medication errors in psychiatry: methodological issues regarding identification and classification. *World J Biol Psychiatry* 2008;9:24–33.

10. Okayama T, Usuda K, Okazaki E, *et al.* Number of long-term inpatients in Japanese psychiatric care beds: trend analysis from the patient survey and the 630 survey. *BMC Psychiatry* 2020;20:522.

11. Ni Y, Lingren T, Hall ES, *et al.* Designing and evaluating an automated system for real-time medication administration error detection in a neonatal intensive care unit. *J Am Med Inform Assoc* 2018;25:555–63.

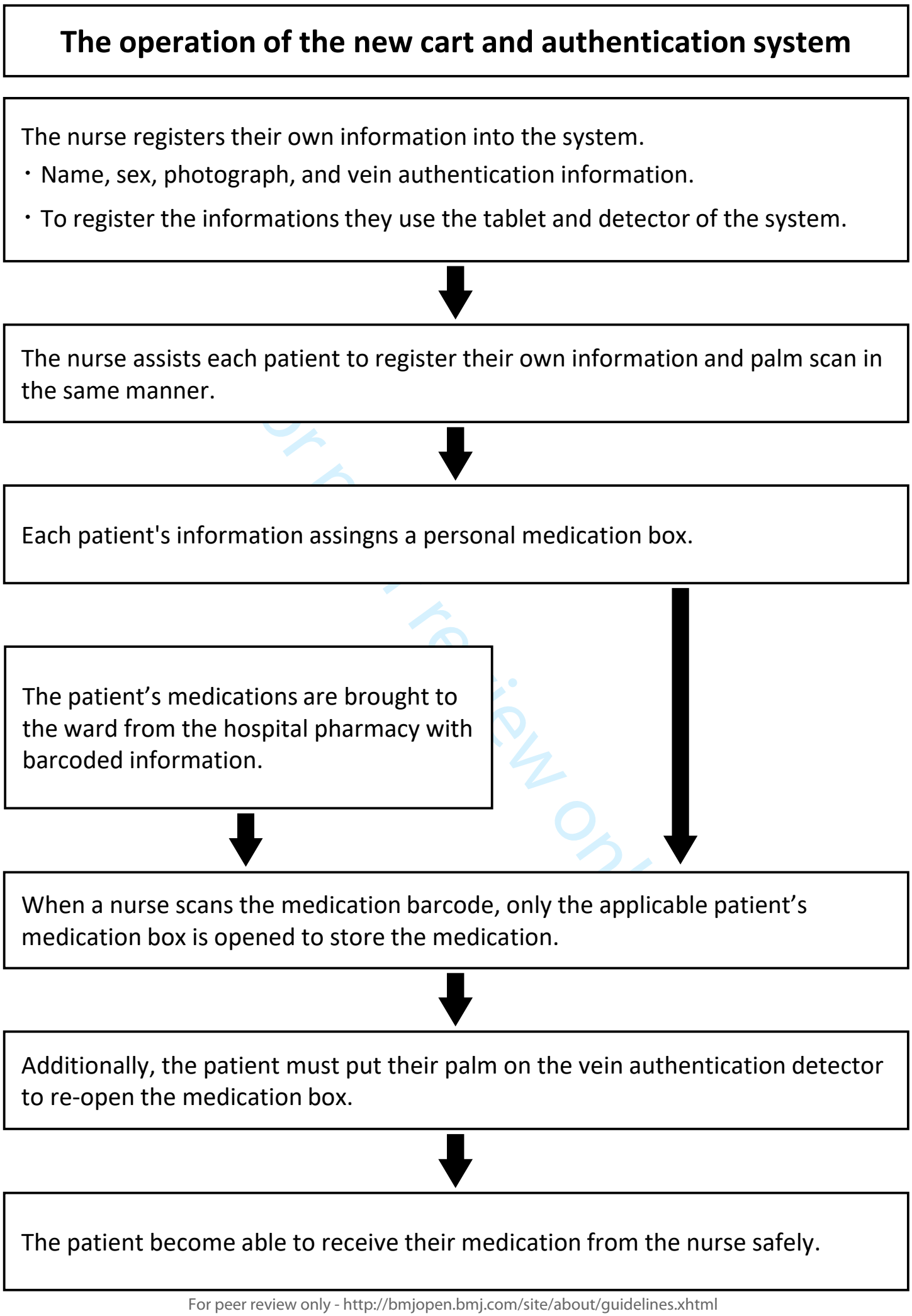
12. Giuliano KK. Intravenous smart pumps: usability issues, intravenous medication administration error, and patient safety. *Crit Care Nurs Clin North Am* 2018;30:215–24.

13. Opfer KB, Wirtz DM, Farley K. A chemotherapy standard order form: preventing errors. *Oncol Nurs Forum* 1999;26:123–8.

14. Stout L, Joseph S. Blood transfusion: patient identification and empowerment. *Br J Nurs* 2016;25:138–43.

15. Kunac DL, Tatley MV, Seddon ME. A new web-based medication error reporting programme (MERP) to supplement pharmacovigilance in New Zealand—findings from a pilot study in primary care. *N Z Med J* 2014;127:69–81.

16. Pfister B, Jonsson J, Gustafsson M. Drug-related problems and medication reviews among old people with dementia. *BMC Pharmacol Toxicol* 2017;18:52.


The operation of the new cart and authentication system
The nurse registers their own information into the system.
・Name, sex, photograph, and vein authentication information.
・To register the informations they use the tablet and detector of the system.
The nurse assists each patient to register their own information and palm scan in the same manner.
Each patient's information assingns a personal medication box.
The patient’s medications are brought to the ward from the hospital pharmacy with barcoded information.
When a nurse scans the medication barcode, only the applicable patient’s medication box is opened to store the medication.
Additionally, the patient must put their palm on the vein authentication detector to re-open the medication box.
The patient become able to receive their medication from the nurse safely.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1-3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4-6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*4-6*
Bias	9	Describe any efforts to address potential sources of bias	4-6
Study size	10	Explain how the study size was arrived at	4-6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	6
		(*b*) Describe any methods used to examine subgroups and interactions	6
		(*c*) Explain how missing data were addressed	6
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	6
		(*e*) Describe any sensitivity analyses	N/A

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6-10
		(b) Give reasons for non-participation at each stage	6-10
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6-10
		(b) Indicate number of participants with missing data for each variable of interest	6-10
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	N/A
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	*6-10*
		Cross-sectional study—Report numbers of outcome events or summary measures	N/A
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-10
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6-10
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10-12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	10-12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Foot note

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Biometric palm vein authentication of psychiatric patients for reducing in-hospital medication errors: A pre–post observational study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-055107.R2
Article Type:	Original research
Date Submitted by the Author:	12-Apr-2022
Complete List of Authors:	Sawa, Minoru; Hokutokai Sawa Byoin, Psychiatry Inoue , Tomomi ; Hokutokai Sawa Byoin, Psychiatry Manabe, Shinichi ; Hokutokai Sawa Byoin, Psychiatry
Primary Subject Heading:	Medical management
Secondary Subject Heading:	Mental health
Keywords:	PSYCHIATRY, Dementia < NEUROLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Biometric palm vein authentication of psychiatric patients for reducing in-hospital medication errors: A pre–post observational study

Author's information

Minoru Sawa MD, PhD (Corresponding Author)

Tomomi Inoue

Shinichi Manabe

Affiliation

Department of Psychiatry, Sawa Hospital, Hokutokai

1-9-1, Shiroyamacho, Toyonaka, Osaka, Japan

Tel: 81-6-6565-1211; Fax: 81-6-6865-1261

Email: msawa@hokuto-kai.com

Abstract

Objectives: This study aimed to evaluate a biometric palm vein authentication system to prevent medication administration errors in psychiatric hospitals.

Design: This is a pre–post observational study.

Setting: Conventionally, the medication was distributed after a double-check. We developed and introduced a new medication administration cart in two psychiatric hospitals in Japan, in which each patient-specific drug box had to be electronically opened only by palm vein authentication.

Participants: A total of 3444 and 3523 patients were present 18 months before and after introducing the cart, respectively. Of the 212 nurses recruited, 28 were excluded due to a lack of experience with the conventional medication administration system and incomplete questionnaires.

Primary and secondary outcome measures: Primary outcome was the efficacy of this system by comparing the incidence of medication administration errors before and after introducing the cart. Secondary outcome was a survey regarding nurses' attitudes toward this system.

Results: After introduction of the new system, the number of medication errors due to misidentification of persons relative to the total number of admitted patients was significantly reduced from 6/3444 to 2/3523 ($p<0.0001$). Among 184 nurses, 182 responded that anxiety regarding administration errors reduced or unchanged using this system. Male nurses reported a greater increase in work burden than female nurses (OR=3.11, 95% CI=1.44–6.72). Nurses working in chronic care wards reported greater time pressure than nurses working in emergency wards (OR=3.33, 95% CI=1.16–9.57). Nurses working in dementia care wards reported a greater patient care burden than nurses working in emergency wards (OR=5.67, 95% CI=1.22–26.27).

Conclusions: This new system might have potential for reducing the patient misidentification risk during medication without increasing the anxiety experienced by nurses concerning administration errors. However, system usability and efficiency must be improved to reduce additional work burden, time pressure, and patient care burden.

Strengths and limitations of this study

- Biometric palm vein authentication system can reduce the risk of medication misidentification errors for psychiatric patients and patient with dementia.

- The new system also did not increase the anxiety experienced by nurses concerning administration errors.
- The system needs to be improved to reduce the work burden, time pressure, and patient care burden of nurses.

INTRODUCTION

Medication administration error is a major patient safety concern due to the potential for severe adverse reactions to incorrect medications and disease relapse from missed doses.[1] Indeed, drug administration errors have a substantial economic impact and are major contributors to patient morbidity and mortality.[2, 3] Further, these errors can result in costly malpractice lawsuits. Medication is delivered primarily by nurses so administration errors are a particularly great source of anxiety among this group of healthcare workers.[4]

Manual double-checking is the standard practice for reducing medication administration errors,[5] but this method is still subject to human error, especially when workloads are increased or medication must be delivered quickly. Alternatively, barcode-assisted medication verification has been shown to significantly reduce medication administration errors in the emergency department.[6] Nonetheless, it is difficult to completely eliminate the possibility of medication administration error. These risks are enhanced when treating patients with dementia or severe psychiatric disorders.[7–9] In Japan, the duration of in-patient psychiatric hospital care is longer than general hospital care,[10] and many long-term patients will remove barcoded wristbands used for identification. Further, patients with dementia or severe psychiatric disorders may not give their correct name. Therefore, an alternative verification system is required to prevent or reduce medication administration errors among psychiatric hospital patients.

Several previous reports have evaluated the efficacy of nonconventional systems for preventing medication administration errors, including real-time error detection systems [11] and intravenous smart pumps.[12] Biometric authentication is also widely used in other fields, such as for smart phones, automated teller machines, and border control/immigration systems, but there are no studies on the use of biometric authentication systems for drug administration. Several biometric authentication methods are in common use, including fingerprint, face, retina, palm vein, and voice recognition. A major advantage of palm vein recognition is ease of application for elderly patients and others with dementia or severe mental illness. Further, the precision of these devices is improving.

The aim of this study was to evaluate the efficacy of a medication cart equipped with a palm vein authentication system for reducing drug administration errors in psychiatric hospitals.

METHODS

Developmental of a medication cart with palm vein authentication

We have jointly developed a new medication administration cart equipped with a vein authentication system in conjunction with Two-One Co. (Nagoya, Aichi, Japan). Each cart has 20 or 30 medication boxes for individual patients with a computer tablet and biometric vein detector for patient authentication. Each box is automatically unlocked and opened only when the vein authentication detector registers a match. For emergency situations such as a loss of electricity due to disaster, the box can be opened manually by nurses.

The new cart and authentication system is operated as follows. First, the nurse registers by inputting their own name, sex, photograph, and vein authentication information into the system using the tablet and detector. Next, the nurse assists each patient to register their own information and palm scan in the same manner and also assigns a personal medication box. The patient's medications are brought to the ward from the hospital pharmacy with barcoded information. When a nurse scans the medication barcode, only the applicable patient's medication box is opened to store the medication. To receive medication from the nurse, the patient must put their palm on the vein authentication detector to re-open the medication box (Figure 1,2).

We introduced this authentication system to nine wards of two psychiatric hospitals in phases starting at the end of August 2019. The test sites included four wards for emergency care, four for chronic care, and one for dementia care.

Comparison of medication administration error incidence before and following introduction of the new authentication system and evaluation of nurses' attitude toward the new system

We evaluated the efficacy of this system by comparing the incidence of medication administration errors over two 18-month periods before and after introduction. Before introduction, nurses used the conventional double-checking system that the medication was distributed after a double-check by two nurses, who verbally confirmed the patient's name and a picture of his/her face taken with the patient's consent. Medication errors are included in the total errors, such as incorrect patient care methods, wrong food delivery, immature medical techniques, unexpected deterioration of physical condition, and claim of medical services from patients and their families. All errors were reported through the ISO incident and accident reporting system by employees from all departments of the two hospitals, including nurses, doctors, pharmacists, occupational therapists, and medical clerks. In addition, we conducted a questionnaire survey of nurses' attitudes toward the new system. The questionnaire contained sections for the nurse's (i) gender, (II) age, (iii) length of work experience (years), (iv) previous experience administering medication

without vein authentication (Yes/No), (v) anxiety concerning medication administration error, (vi) work burden due to the new medication administration system, (vii) time pressure due to the new system, and (viii) patient care burden due to the new system. Items (v)–(viii) were measured using a 5-level Likert scale from "greatly reduced" to "greatly increased" compared to before introduction. Responses were also grouped according to whether the nurse reported "increased" or "reduced or no change". The questionnaire was distributed by a co-researcher to participant nurses. Among 225 psychiatric nurses working in the nine wards, 212 (94.2%) provided informed consent for study participation. Candidates were exclude if they had no experience with conventional medication administration (to allow for a comparison with the conventional method as the pre-introduction condition) and incomplete answers on the questionnaire

Statistical analyses

The change in number of medication errors between pre- and post-introduction periods was evaluated using the Wilcoxon signed rank test. Categorical variables were compared by chi-square test and binominal logistic regression analysis was performed with questionnaire items (v)–(viii) as dependent variables and items (i)–(iv) as covariates. We also compared the average time spent on medication administration per patient after introduction of the vein authentication system (average of five administrations for each ward type) to investigate whether there was any difference in medication administration time per patient across various wards. All statistical analyses were conducted using SPSS version 23.

Patient and Public Involvement statement

Patients or the public WERE NOT involved in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

Comparison of medication administration error rate before and after introduction of the palm vein authentication system (Table 1)

Table 1. Comparison of medication error incidents before and after introduction of the biometric palm vein medication authentication system

	18-months before	18-months after	p value*

total number of patients	3444	3523	
total number of incidents of errors	1209	1051	
type of medication administration errors			
misidentification	6	2	
non compliant medication	1	3	
total number of incidents of errors/total number of patients	1209/3444	1051/3523	<0.0001
misidentification errors /total number of incidents of errors	6/3444	2/3523	<0.0001

*statistically significant

During the 18 months before introduction of the new medication cart equipped with a vein authentication system, 3444 patients were admitted to the two psychiatric hospitals, while 3523 patients were admitted to the same hospitals during the 18 months after introduction. While six medication administration errors due to patient misidentification occurred during the 18-month period before the introduction of the vein authentication system, only two occurred after introduction, both due to nurses inappropriately opening the medication box manually because they could not properly identify a dementia patient by palm vein scan. After learning the proper method for palm vein authentication, there were no more such incidents. During the 18 months before introduction of the system, there was one medication administration error caused by a medication change. During the 18 months after introduction of the system, there was also one incident of error due to medication resetting, as well as one incident of liquid medication administration as it was a non-compliant medication type, and one incident of unscheduled medication (Pro Re Nata, PRN) as there were no settings for prevention of incorrect drug form and PRN medication errors. According to the results of McNemar test, the number of total errors relative to the total number of admitted patients was significantly reduced ($p<0.0001$), and the number of medication errors due to misidentification of persons relative to the total number of admitted patients was also significantly reduced ($p<0.0001$).

We then examined whether these errors after introduction of the vein authentication system occurred due to the additional time and work burdens associated with use

compared to conventional authentication. During the 18 months before introduction, there were a total of 1209 medical errors reported (385 in chronic care wards, 411 in the ward for dementia patients, and 413 in the emergency psychiatric wards), while during the 18 months after introduction, there were a total of 1051 medical errors reported (228 in chronic care wards, 409 in the ward for dementia patients, and 414 in emergency psychiatric wards). The Wilcoxon signed rank test revealed no statistically significant differences in total error rates between pre- and post-introduction periods for a given ward. Hence, medication errors were reduced in the absence of any significant reduction in all-cause errors.

Nurses' attitudes toward the new vein authentication system (Table 2, Table 3)

Table 2. Demographic characteristics of the participant nurses and nurses' attitudes toward the new medication authentication system

Variable		Ward type		
		Chronic	Dementia	Emergency
Gender	Male	25	6	34
	Female	51	12	56
Age group (years)	20–29	10	3	11
	30–39	15	6	26
	40–49	37	5	31
	50–59	12	3	20
	Over 60	2	1	2
Work experience (years)	Less than 3	7	1	5
	3–4	14	5	10
	5–9	14	4	22
	10–19	25	3	34
	20–29	11	5	13
	30–39	4	0	5
	Over 40	1	0	1

Anxiety	Reduced or no Change	75	17	90
	Increased	1	1	0
Work burden	Reduced or no Change	19	5	33
	Increased	56	13	56
Time pressure	Reduced or no Change	5	1	17
	Increased	71	17	73
Burden for patient care	Reduced or no Change	30	2	37
	Increased	46	16	53
Average administration time per patient (s)	Per patient	90.2 ± 7.1	179.6 ± 17.1	82.7 ± 4.2

Table 3. Results of logistic analyses

Dependent variable	Covariates	Odds Ratio	95% CI	p
Work burden	Gender (male/female)	3.11	1.44–6.72	<0.01*
	Work experience	0.85	0.63–1.14	0.27
	Ward type (chronic/emergency)	1.86	0.92–3.75	0.09
	Ward type (dementia/emergency)	1.55	0.49–4.94	0.46
	Age group (every 10 years)	0.89	0.60–1.30	0.54
Time pressure	Gender (male/female)	0.87	0.34–2.22	0.77
	Work experience	1.06	0.71–1.60	0.77

	Ward type (chronic/emergency)	3.33	1.16–9.57	0.03*
	Ward type (dementia/emergency)	4.02	0.50–32.44	0.19
	Age group (every 10 years)	0.99	0.58–1.68	0.97
Burden for patient care	Gender (male/female)	1.27	0.66–2.43	0.48
	Work experience	1.03	0.78–1.35	0.86
	Ward type (chronic/emergency)	1.09	0.58–2.04	0.79
	Ward type (dementia/emergency)	5.67	1.22–26.27	0.03*
	Age group (every 10 years)	0.90	0.63–1.30	0.59

* statistically significant

Of the 212 nurses recruited, 19 were excluded from the questionnaire component of the study due to a lack of experience with the conventional medication administration system (double-checking), and another 9 were excluded due to incomplete questionnaires. The demographic characteristics and responses of the remaining 184 nurses are presented in Table 2.

Among these 184 nurses, 182 (98.9%) reported reduced or unchanged anxiety over medication administration error using the new system. However, a majority (125 or 68.7%) reported an increased work burden for medication administration, with male nurses reporting an increase more frequently than female nurses ($p = 0.002$). A substantial majority (161 or 87.5%) also reported increased pressure on their time and 115 (62.5%) reported increased patient care burden using the new system.

Correlation analyses revealed significant associations between age group and duration of work experience ($r = 0.51$), work burden and time pressure ($r = 0.39$), work burden and patient care burden ($r = 0.43$), and time pressure and patient care burden ($r = 0.39$). There were also significant differences in average time spent per patient on medication administration, with medication administration to dementia patients requiring significantly more time than administration to chronic care patients and psychiatric emergency ward patients (179.6 ± 17.1 s vs. 90.2 ± 7.1 and 82.7 ± 4.2 s, both $p < 0.01$). In contrast, there was no significant difference in medication administration time per patient between chronic care and psychiatric emergency patients ($p = 0.37$).

Based on these results, we then conducted binominal logistic regression analysis with work burden, time pressure, and patient care burden as dependent variables and age, gender, work experience duration, and ward type as covariates. Anxiety was not chosen as a dependent variable because few nurses reported increased anxiety compared to the number reporting reduced or unchanged anxiety. Male nurses reported a greater increase in work burden than female nurses using the new system (OR = 3.11, 95% CI = 1.44–6.72), while nurses working in chronic care wards reported more time pressure than nurses working in emergency wards (OR = 3.33, 95% CI = 1.16–9.57). Finally, nurses working in the dementia care ward reported a greater patient care burden than emergency ward nurses using the new system (OR = 5.67, 95% CI = 1.22–26.27). Results of logistic binominal regression analyses are summarized in Table 3.

DISCUSSION

Many protocols have been devised to prevent medication administration errors due to patient misidentification, from the use of simple order sheets[13] to placing more of the onus on patients for empowerment.[14] To our knowledge, there have been no studies investigating the use of palm vein authentication for the prevention of medication administration errors. Here we demonstrate that such a system can reduce the incidence of misidentification, although the system as currently conceived does increase nurse work burden.

This new system is advantageous in that it permits proper identification and contingent access to the patient's medication even in cases where the patient is unable to respond due to cognitive impairment. Alternatively, the system does depend on a power supply for battery recharging, which could be lost in the case of a natural disaster. In such cases, the nurse would have to open the medication box manually and rely on conventional verification methods such as double-checking. Another disadvantage to the current system is that the cart is relatively large due to the electronic instruments. Further, the palm vein scan can be time-consuming for uncooperative patients. Also, while the system did reduce misidentification errors, it is still necessary to improve nurses' attitudes toward its use.

According to the questionnaire, medication administration error is a substantial source of anxiety among nurses, and this anxiety was reduced or unchanged by the palm vein authentication system. However, work burden, time pressure, and patient care burden were reported to increase, and these attitudes were mutually related. It is thus important to educate nurses on the efficacy of this system to reduce misidentification during

medication administration, especially in psychiatric hospitals and wards with dementia patients who may have difficulty self-identifying or in recognizing medication errors. In a previous study,[15] both time pressure and workload were shown to increase the medication error rate. Although work burden, time pressure, and patient care burden were increased, it is significant that overall medical error incidence rates were not increased, suggesting that the system will not introduce additional errors in other aspects of care.

Surprisingly, this reported increase in work burden differed according to sex, with more male nurses reporting an increase, which may be due to the relatively greater proportion of male nurses in emergency wards. A difference in reported time pressure was also found between chronic and emergency wards, possibly due to the greater difficulty in accessing patients in crowded chronic wards. Drug-related problems are common among patients with dementia and cognitive impairment,[16] so this difference in reported time pressure may be attributable to the greater proportion of patients with cognitive impairment in chronic care facilities. Indeed, the average time required for medication administration was significantly higher in dementia wards. However, this difference in time pressure between chronic and emergency wards was not reflected by differences in average time spent administering medication to individual patients, so there may be other factors contributing to the stress associated with medication administration independent of the authentication system, such general workplace environment, accessibility of social supports, relationships with colleagues and patients, and working hours.

There are limitations to the present study. First, the study was conducted at only two hospitals, limiting generalizability. We also cannot establish causal relationships due to the observational study design. In this study, before and after comparisons were made in only two hospitals, but future studies such as randomly assigning wards in a multi-center setting would be desirable. The system as currently configured cannot prevent the administration of certain non-compliant medications such as PRN medications. Another limitation was that medication administration time and nurses' awareness were not measured using conventional methods. Future research should focus on confirming these findings and explore ways to reduce the workload associated with this vein authentication system.

CONCLUSION

Medication administration error is a common occurrence in hospitals. Biometric technology is continually improving and widely used for personal identification in our daily lives. Palm vein authentication proved superior to conventional methods for patient

identification as evidenced by the decrease in medication errors after introduction. However, further improvements are needed to reduce nurse work burden, time pressure, and patient care burden.

ACKNOWLEDGEMENTS

We are grateful to Dr. Aya Kinjo, Associate Professor, Division of Environmental and Preventive Medicine, Department of Social Medicine, Faculty of Medicine, Tottori University, for advice on statistical analyses.

ETHICS STATEMENTS

The study protocol was approved by the hospital ethics board (approval number; 2021001). All nurses provided informed written consent and patients were informed of their right to opt-out. Otherwise, patient consent was assumed.

FUNDING

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

COMPETING INTERESTS

None declared

CONTRIBUTORS

Minoru Sawa (MS) conceptualized the study with input from all the co-authors. Tomomi Inoue (TI) and Shinichi Manage (SM) are the co-authors. MS performed the statistical analysis and wrote the first draft of the manuscript, and all the authors provided critical scholarly feedback. All the co-authors approved of the final version of the manuscript. The corresponding author attests that all the listed authors meet the authorship criteria and that no authors meeting the criteria have been excluded from the acknowledgment.

DATA AVAILABILITY STATEMENT

Data used in this study are available upon reasonable request the authors.

FIGURE CAPTION

Figure 1. The operation of the new cart and authentication system.

Figure 2. The photograph of the new cart.

REFERENCES

1. McCullagh M, Slattery D. Medication related litigation in Ireland: A 6-year review. *Br J Clin Pharmacol* 2019;85:2155–62.

2. Walsh EK, Hansen CR, Sahm LJ, *et al.* Economic impact of medication error: a systematic review. *Pharmacoepidemiol Drug Saf* 2017;26:481–97.

3. Wittich CM, Burkle CM, Lanier WL. Medication errors: an overview for clinicians. *Mayo Clin Proc* 2014;89:1116–25.

4. Star K, Nordin K, Pöder U, *et al.* Challenges of safe medication practice in paediatric care—a nursing perspective. *Acta Paediatr* 2013;102:532–8.

5. Kellett P, Gottwald M. Double-checking high-risk medications in acute settings: a safer process. *Nurs Manag (Harrow)* 2015;21:16–22.

6. Bonkowski J, Carnes C, Melucci J, *et al.* Effect of barcode-assisted medication administration on emergency department medication errors. *Acad Emerg Med* 2013;20:801–6.

7. Maidment ID, Lelliott P, Paton C. Medication errors in mental healthcare: a systematic review. *Qual Saf Health Care* 2006;15:409–13.

8. Procyshyn RM, Barr AM, Brickell T, *et al.* Medication errors in psychiatry: a comprehensive review. *CNS Drugs* 2010;24:595–609.

9. Mann K, Rothschild JM, Keohane CA, *et al.* Adverse drug events and medication errors in psychiatry: methodological issues regarding identification and classification. *World J Biol Psychiatry* 2008;9:24–33.

10. Okayama T, Usuda K, Okazaki E, *et al.* Number of long-term inpatients in Japanese psychiatric care beds: trend analysis from the patient survey and the 630 survey. *BMC Psychiatry* 2020;20:522.

11. Ni Y, Lingren T, Hall ES, *et al.* Designing and evaluating an automated system for real-time medication administration error detection in a neonatal intensive care unit. *J Am Med Inform Assoc* 2018;25:555–63.

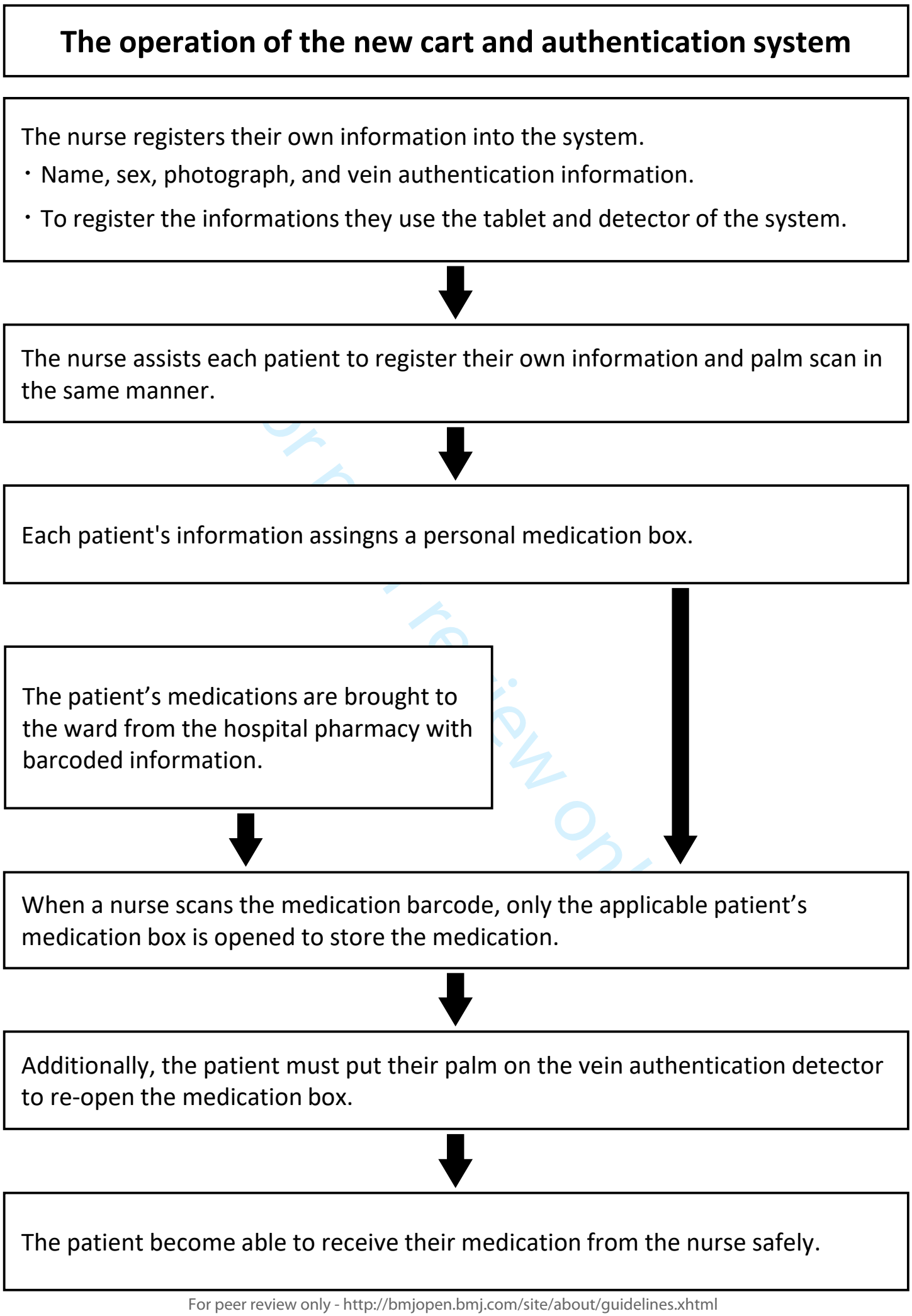
12. Giuliano KK. Intravenous smart pumps: usability issues, intravenous medication administration error, and patient safety. *Crit Care Nurs Clin North Am* 2018;30:215–24.

13. Opfer KB, Wirtz DM, Farley K. A chemotherapy standard order form: preventing errors. *Oncol Nurs Forum* 1999;26:123–8.

14. Stout L, Joseph S. Blood transfusion: patient identification and empowerment. *Br J Nurs* 2016;25:138–43.

15. Kunac DL, Tatley MV, Seddon ME. A new web-based medication error reporting programme (MERP) to supplement pharmacovigilance in New Zealand—findings from a pilot study in primary care. *N Z Med J* 2014;127:69–81.

16. Pfister B, Jonsson J, Gustafsson M. Drug-related problems and medication reviews among old people with dementia. *BMC Pharmacol Toxicol* 2017;18:52.


The operation of the new cart and authentication system
The nurse registers their own information into the system.
・Name, sex, photograph, and vein authentication information.
・To register the informations they use the tablet and detector of the system.
The nurse assists each patient to register their own information and palm scan in the same manner.
Each patient's information assingns a personal medication box.
The patient’s medications are brought to the ward from the hospital pharmacy with barcoded information.
When a nurse scans the medication barcode, only the applicable patient’s medication box is opened to store the medication.
Additionally, the patient must put their palm on the vein authentication detector to re-open the medication box.
The patient become able to receive their medication from the nurse safely.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1-3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4-6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*4-6*
Bias	9	Describe any efforts to address potential sources of bias	4-6
Study size	10	Explain how the study size was arrived at	4-6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	6
		(*b*) Describe any methods used to examine subgroups and interactions	6
		(*c*) Explain how missing data were addressed	6
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	6
		(*e*) Describe any sensitivity analyses	N/A

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6-10
		(b) Give reasons for non-participation at each stage	6-10
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6-10
		(b) Indicate number of participants with missing data for each variable of interest	6-10
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	N/A
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	*6-10*
		Cross-sectional study—Report numbers of outcome events or summary measures	N/A
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-10
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6-10
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10-12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	10-12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Foot note

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.