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

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6 1 **Biometric palm vein authentication of psychiatric patients for reducing in-hospital**
7 2 **medication errors: A pre–post observational study**
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6 37 **Abstract**

7 38 **Objectives:** Medication administration error is a critical safety concern, which may
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9 39 exacerbate for patients with dementia or severe psychiatric disorders. This study aimed
10 40 to evaluate a biometric palm vein authentication system to prevent medication
11 41 administration errors in psychiatric hospitals.

12
13 42 **Design:** This is a pre–post observational study.

14 43 **Setting:** We developed and introduced a new medication administration cart in two
15 44 psychiatric hospitals in Japan, in which each patient-specific drug box had to be
16 45 electronically opened only by palm vein authentication.

17
18 46 **Participants:** A total of 3444 and 3523 patients were present 18 months before and after
19 47 introducing the cart, respectively. Of the 212 nurses recruited, 28 were excluded due to a
20 48 lack of experience with the conventional medication administration system and
21 49 incomplete questionnaires.

22 50 **Primary and secondary outcome measures:** Primary outcome was the efficacy of this
23 51 system by comparing the incidence of medication administration errors before and after
24 52 introducing the cart. Secondary outcome was a survey regarding nurses' attitudes toward
25 53 this system.

26 54 **Results:** Six medication administration errors were observed before introducing the
27 55 authentication system, whereas no incidents were reported after training on palm vein
28 56 authentication. Among 184 nurses, 182 responded that anxiety regarding administration
29 57 errors reduced using this system. Male nurses reported a greater increase in work burden
30 58 than female nurses (OR=3.11, 95% CI=1.44–6.72). Nurses working in chronic care wards
31 59 reported greater time pressure than nurses working in emergency wards (OR=3.33, 95%
32 60 CI=1.16–9.57). Nurses working in dementia care wards reported a greater patient care
33 61 burden than nurses working in emergency wards (OR=5.67, 95% CI=1.22–26.27).

34 62 **Conclusions:** This new system holds great potential for reducing the patient
35 63 misidentification risk during medication and the anxiety experienced by nurses
36 64 concerning administration errors. However, system usability and efficiency must be
37 65 improved to reduce additional work burden, time pressure, and patient care burden.

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6 73 **Strengths and limitations of this study**

- 7 74 ● Biometric palm vein authentication system can reduce the risk of medication
8 75 misidentification errors for psychiatric patients and patient with dementia.
9 76 ● The new system also reduced the anxiety experienced by nurses concerning
10 77 administration errors.
11 78 ● The system needs to be improved to reduce the work burden, time pressure, and
12 79 patient care burden of nurses.
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80 INTRODUCTION

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

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

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

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

114 METHODS

115 Developmental of a medication cart with palm vein authentication

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6 116 We have jointly developed a new medication administration cart equipped with a vein
7 117 authentication system in conjunction with Two-One Co. (Nagoya, Aichi, Japan). Each
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9 118 cart has 20 or 30 medication boxes for individual patients with a computer tablet and
10 119 biometric vein detector for patient authentication. Each box is automatically unlocked
11 120 and opened only when the vein authentication detector registers a match. For emergency
12 121 situations such as a loss of electricity due to disaster, the box can be opened manually by
13 122 nurses.

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16 123 The new cart and authentication system is operated as follows. First, the nurse registers
17 124 by inputting their own name, sex, photograph, and vein authentication information into
18 125 the system using the tablet and detector. Next, the nurse assists each patient to register
19 126 their own information and palm scan in the same manner and also assigns a personal
20 127 medication box. The patient's medications are brought to the ward from the hospital
21 128 pharmacy with barcoded information. When a nurse scans the medication barcode, only
22 129 the applicable patient's medication box is opened to store the medication. To receive
23 130 medication from the nurse, the patient must put their palm on the vein authentication
24 131 detector to re-open the medication box.

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27 132 We introduced this authentication system to nine wards of two psychiatric hospitals in
28 133 phases starting at the end of August 2019. The test sites included four wards for
29 134 emergency care, four for chronic care, and one for dementia care.
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31 136 **Comparison of medication administration error incidence before and following** 32 137 **introduction of the new authentication system and evaluation of nurses' attitude** 33 138 **toward the new system**

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36 139 We evaluated the efficacy of this system by comparing the incidence of medication
37 140 administration errors over two 18-month periods before and after introduction. Before
38 141 introduction, nurses used the conventional double-checking system. In addition, we
39 142 conducted a questionnaire survey of nurses' attitudes toward the new system. The
40 143 questionnaire contained sections for the nurse's (i) gender, (ii) age, (iii) length of work
41 144 experience (years), (iv) previous experience administering medication without vein
42 145 authentication (Yes/No), (v) anxiety concerning medication administration error, (vi)
43 146 work burden due to the new medication administration system, (vii) time pressure due to
44 147 the new system, and (viii) patient care burden due to the new system. Items (v)–(viii)
45 148 were measured using a 5-level Likert scale from "greatly reduced" to "greatly increased"
46 149 compared to before introduction. Responses were also grouped according to whether the
47 150 nurse reported "increased" or "reduced or no change". The questionnaire was distributed
48 151 by a co-researcher to participant nurses. Among 225 psychiatric nurses working in the
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6 152 nine wards, 212 (94.2%) provided informed consent for study participation. Candidates
7 153 were exclude if they had no experience with conventional medication administration (to
8 154 allow for a comparison with the conventional method as the pre-introduction condition)
9 155 and incomplete answers on the questionnaire
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13 157 **Statistical analyses**

14 158 The change in number of medication errors between pre- and post-introduction periods
15 159 was evaluated using the Wilcoxon signed rank test. Categorical variables were compared
16 159 by chi-square test and binominal logistic regression analysis was performed with
17 160 questionnaire items (v)–(viii) as dependent variables and items (i)–(iv) as covariates. We
18 161 also compared the average time spent on medication administration per patient after
19 162 introduction of the vein authentication system (average of five administrations for each
20 163 ward type) to investigate whether there was any difference in medication administration
21 164 time per patient across various wards. All statistical analyses were conducted using SPSS
22 165 version 23.
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29 168 **Patient and Public Involvement statement**

30 169 Patients or the public WERE NOT involved in the design, or conduct, or reporting, or
31 170 dissemination plans of our research.
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36 173 **RESULTS**

37 174 **Comparison of medication administration error rate before and after introduction** 38 175 **of the palm vein authentication system (Table 1)**

39 176
40 177 Table 1. Comparison of medication error incidents before and after introduction of the
41 178 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

179

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

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

206

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

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

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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
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213 Table 3. Results of logistic analyses

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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

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

221 Among these 184 nurses, 182 (98.9%) reported reduced anxiety over medication
222 administration error using the new system. However, a majority (125 or 68.7%) reported
223 an increased work burden for medication administration, with male nurses reporting an
224 increase more frequently than female nurses ($p = 0.002$). A substantial majority (161 or
225 87.5%) also reported increased pressure on their time and 115 (62.5%) reported increased
226 patient care burden using the new system.

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

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

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249 DISCUSSION

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

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6 251 patient misidentification, from the use of simple order sheets¹³ to placing more of the
7 252 onus on patients for empowerment.¹⁴ To our knowledge, there have been no studies
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9 253 investigating the use of palm vein authentication for the prevention of medication
10 254 administration errors. Here we demonstrate that such a system can reduce the incidence
11 255 of misidentification, although the system as currently conceived does increase nurse work
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13 256 burden.

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15 257 This new system is advantageous in that it permits proper identification and contingent
16 258 access to the patient's medication even in cases where the patient is unable to respond
17
18 259 due to cognitive impairment. Alternatively, the system does depend on a power supply
19 260 for battery recharging, which could be lost in the case of a natural disaster. In such cases,
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21 261 the nurse would have to open the medication box manually and rely on conventional
22 262 verification methods such as double-checking. Another disadvantage to the current
23
24 263 system is that the cart is relatively large due to the electronic instruments. Further, the
25 264 palm vein scan can be time-consuming for uncooperative patients. Also, while the system
26
27 265 did reduce misidentification errors, it is still necessary to improve nurses' attitudes toward
28
29 266 its use.

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31 267 According to the questionnaire, medication administration error is a substantial source
32 268 of anxiety among nurses, and this anxiety was dramatically reduced by the palm vein
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34 269 authentication system. However, work burden, time pressure, and patient care burden
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36 270 were reported to increase, and these attitudes were mutually related. It is thus important
37 271 to educate nurses on the efficacy of this system to reduce misidentification during
38 272 medication administration, especially in psychiatric hospitals and wards with dementia
39 273 patients who may have difficulty self-identifying or in recognizing medication errors. In
40 274 a previous study,¹⁵ both time pressure and workload were shown to increase the
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42 275 medication error rate. Although work burden, time pressure, and patient care burden were
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44 276 increased, it is significant that overall medical error incidence rates were not increased,
45 277 suggesting that the system will not introduce additional errors in other aspects of care.

46 278 Surprisingly, this reported increase in work burden differed according to sex, with more
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48 279 male nurses reporting an increase, which may be due to the relatively greater proportion
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50 280 of male nurses in emergency wards. A difference in reported time pressure was also found
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52 281 between chronic and emergency wards, possibly due to the greater difficulty in accessing
53 282 patients in crowded chronic wards. Drug-related problems are common among patients
54 283 with dementia and cognitive impairment,¹⁶ so this difference in reported time pressure
55 284 may be attributable to the greater proportion of patients with cognitive impairment in
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57 285 chronic care facilities. Indeed, the average time required for medication administration
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59 286 was significantly higher in dementia wards. However, this difference in time pressure
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6 287 between chronic and emergency wards was not reflected by differences in average time
7 288 spent administering medication to individual patients, so there may be other factors
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9 289 contributing to the stress associated with medication administration independent of the
10 290 authentication system, such general workplace environment, accessibility of social
11 291 supports, relationships with colleagues and patients, and working hours.

12
13 292 There are limitations to the present study. First, the study was conducted at only two
14 293 hospitals, limiting generalizability. We also cannot establish causal relationships due to
15 294 the observational study design. The system as currently configured cannot prevent the
16 295 administration of certain non-compliant medications. Future research should focus on
17 296 confirming these findings and explore ways to reduce the workload associated with this
18 297 vein authentication system.

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23 299

25 300 **CONCLUSION**

26 301 Medication administration error is a common occurrence in hospitals. Biometric
27 302 technology is continually improving and widely used for personal identification in our
28 303 daily lives. Palm vein authentication proved superior to conventional methods for patient
29 304 identification as evidenced by the decrease in medication errors after introduction.
30 305 However, further improvements are needed to reduce nurse work burden, time pressure,
31 306 and patient care burden.

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9 326 Preventive Medicine, Department of Social Medicine, Faculty of Medicine, Tottori
10 327 University, for advice on statistical analyses.
11
12

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14 329 **ETHICS STATEMENTS**

15 330 The study protocol was approved by the hospital ethics board (approval number;
16 331 2021001). All nurses provided informed written consent and patients were informed of
17 332 their right to opt-out. Otherwise, patient consent was assumed.
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20 333

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23 336 commercial or not-for-profit sectors.
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27 338 **COMPETING INTERESTS**

28 339 None declared
29
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31 340

32 341 **CONTRIBUTORS**

33 342 Minoru Sawa (MS) conceptualized the study with input from all the co-authors.
34 343 Tomomi Inoue (TI) and Shinichi Manage (SM) are the co-authors. MS performed the
35 344 statistical analysis and wrote the first draft of the manuscript, and all the authors provided
36 345 critical scholarly feedback. All the co-authors approved of the final version of the
37 346 manuscript. The corresponding author attests that all the listed authors meet the
38 347 authorship criteria and that no authors meeting the criteria have been excluded from the
39 348 acknowledgment.
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46 350 **DATA AVAILABILITY STATEMENT**

47 351 Data used in this study are available upon reasonable request the authors.
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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) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —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 <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4-6
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —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) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —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) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N/A
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	6-10
		<i>Cross-sectional study</i> —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	Footnote

*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

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

For peer review only

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 systems¹¹ 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

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6 We have jointly developed a new medication administration cart equipped with a vein
7 authentication system in conjunction with Two-One Co. (Nagoya, Aichi, Japan). Each
8 cart has 20 or 30 medication boxes for individual patients with a computer tablet and
9 biometric vein detector for patient authentication. Each box is automatically unlocked
10 and opened only when the vein authentication detector registers a match. For emergency
11 situations such as a loss of electricity due to disaster, the box can be opened manually by
12 nurses.
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16 The new cart and authentication system is operated as follows. First, the nurse registers
17 by inputting their own name, sex, photograph, and vein authentication information into
18 the system using the tablet and detector. Next, the nurse assists each patient to register
19 their own information and palm scan in the same manner and also assigns a personal
20 medication box. The patient's medications are brought to the ward from the hospital
21 pharmacy with barcoded information. When a nurse scans the medication barcode, only
22 the applicable patient's medication box is opened to store the medication. To receive
23 medication from the nurse, the patient must put their palm on the vein authentication
24 detector to re-open the medication box (Figure 1,2).
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30 We introduced this authentication system to nine wards of two psychiatric hospitals in
31 phases starting at the end of August 2019. The test sites included four wards for
32 emergency care, four for chronic care, and one for dementia care.
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36 **Comparison of medication administration error incidence before and following** 37 **introduction of the new authentication system and evaluation of nurses' attitude** 38 **toward the new system** 39

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

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

23 Many protocols have been devised to prevent medication administration errors due to
24 patient misidentification, from the use of simple order sheets¹³ to placing more of the
25 onus on patients for empowerment.¹⁴ To our knowledge, there have been no studies
26 investigating the use of palm vein authentication for the prevention of medication
27 administration errors. Here we demonstrate that such a system can reduce the incidence
28 of misidentification, although the system as currently conceived does increase nurse work
29 burden.
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34 This new system is advantageous in that it permits proper identification and contingent
35 access to the patient's medication even in cases where the patient is unable to respond
36 due to cognitive impairment. Alternatively, the system does depend on a power supply
37 for battery recharging, which could be lost in the case of a natural disaster. In such cases,
38 the nurse would have to open the medication box manually and rely on conventional
39 verification methods such as double-checking. Another disadvantage to the current
40 system is that the cart is relatively large due to the electronic instruments. Further, the
41 palm vein scan can be time-consuming for uncooperative patients. Also, while the system
42 did reduce misidentification errors, it is still necessary to improve nurses' attitudes toward
43 its use.
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49 According to the questionnaire, medication administration error is a substantial source
50 of anxiety among nurses, and this anxiety was dramatically reduced by the palm vein
51 authentication system. However, work burden, time pressure, and patient care burden
52 were reported to increase, and these attitudes were mutually related. It is thus important
53 to educate nurses on the efficacy of this system to reduce misidentification during
54 medication administration, especially in psychiatric hospitals and wards with dementia
55 patients who may have difficulty self-identifying or in recognizing medication errors. In
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6 a previous study,¹⁵ both time pressure and workload were shown to increase the
7 medication error rate. Although work burden, time pressure, and patient care burden were
8 increased, it is significant that overall medical error incidence rates were not increased,
9 suggesting that the system will not introduce additional errors in other aspects of care.

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

25
26 There are limitations to the present study. First, the study was conducted at only two
27 hospitals, limiting generalizability. We also cannot establish causal relationships due to
28 the observational study design. In this study, before and after comparisons were made in
29 only two hospitals, but future studies such as randomly assigning wards in a multi-center
30 setting would be desirable. The system as currently configured cannot prevent the
31 administration of certain non-compliant medications such as PRN medications. Another
32 limitation was that medication administration time and nurses' awareness were not
33 measured using conventional methods. Future research should focus on confirming these
34 findings and explore ways to reduce the workload associated with this vein authentication
35 system.

36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 **CONCLUSION**

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

7 **ACKNOWLEDGEMENTS**

8 We are grateful to Dr. Aya Kinjo, Associate Professor, Division of Environmental and
9 Preventive Medicine, Department of Social Medicine, Faculty of Medicine, Tottori
10 University, for advice on statistical analyses.
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14 **ETHICS STATEMENTS**

15 The study protocol was approved by the hospital ethics board (approval number;
16 2021001). All nurses provided informed written consent and patients were informed of
17 their right to opt-out. Otherwise, patient consent was assumed.
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22 **FUNDING**

23 This research received no specific grant from any funding agency in the public,
24 commercial or not-for-profit sectors.
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26
27

28 **COMPETING INTERESTS**

29 None declared
30
31

32 **CONTRIBUTORS**

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

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

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.



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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) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —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 <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4-6
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —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) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —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) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N/A
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	6-10
		<i>Cross-sectional study</i> —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	Footnote

*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.

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

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

For peer review only

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 systems¹¹ 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

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6 We have jointly developed a new medication administration cart equipped with a vein
7 authentication system in conjunction with Two-One Co. (Nagoya, Aichi, Japan). Each
8 cart has 20 or 30 medication boxes for individual patients with a computer tablet and
9 biometric vein detector for patient authentication. Each box is automatically unlocked
10 and opened only when the vein authentication detector registers a match. For emergency
11 situations such as a loss of electricity due to disaster, the box can be opened manually by
12 nurses.
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16 The new cart and authentication system is operated as follows. First, the nurse registers
17 by inputting their own name, sex, photograph, and vein authentication information into
18 the system using the tablet and detector. Next, the nurse assists each patient to register
19 their own information and palm scan in the same manner and also assigns a personal
20 medication box. The patient's medications are brought to the ward from the hospital
21 pharmacy with barcoded information. When a nurse scans the medication barcode, only
22 the applicable patient's medication box is opened to store the medication. To receive
23 medication from the nurse, the patient must put their palm on the vein authentication
24 detector to re-open the medication box (Figure 1,2).
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30 We introduced this authentication system to nine wards of two psychiatric hospitals in
31 phases starting at the end of August 2019. The test sites included four wards for
32 emergency care, four for chronic care, and one for dementia care.
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36 **Comparison of medication administration error incidence before and following** 37 **introduction of the new authentication system and evaluation of nurses' attitude** 38 **toward the new system** 39

40 We evaluated the efficacy of this system by comparing the incidence of medication
41 administration errors over two 18-month periods before and after introduction. Before
42 introduction, nurses used the conventional double-checking system that the medication
43 was distributed after a double-check by two nurses, who verbally confirmed the patient's
44 name and a picture of his/her face taken with the patient's consent. Medication errors are
45 included in the total errors, such as incorrect patient care methods, wrong food delivery,
46 immature medical techniques, unexpected deterioration of physical condition, and claim
47 of medical services from patients and their families. All errors were reported through the
48 ISO incident and accident reporting system by employees from all departments of the two
49 hospitals, including nurses, doctors, pharmacists, occupational therapists, and medical
50 clerks. In addition, we conducted a questionnaire survey of nurses' attitudes toward the
51 new system. The questionnaire contained sections for the nurse's (i) gender, (ii) age, (iii)
52 length of work experience (years), (iv) previous experience administering medication
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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 excluded 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*
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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 ($p = 0.37$).

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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 sheets¹³ 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

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6 medication administration, especially in psychiatric hospitals and wards with dementia
7 patients who may have difficulty self-identifying or in recognizing medication errors. In
8 a previous study,¹⁵ both time pressure and workload were shown to increase the
9 medication error rate. Although work burden, time pressure, and patient care burden were
10 increased, it is significant that overall medical error incidence rates were not increased,
11 suggesting that the system will not introduce additional errors in other aspects of care.
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14 Surprisingly, this reported increase in work burden differed according to sex, with more
15 male nurses reporting an increase, which may be due to the relatively greater proportion
16 of male nurses in emergency wards. A difference in reported time pressure was also found
17 between chronic and emergency wards, possibly due to the greater difficulty in accessing
18 patients in crowded chronic wards. Drug-related problems are common among patients
19 with dementia and cognitive impairment,¹⁶ so this difference in reported time pressure
20 may be attributable to the greater proportion of patients with cognitive impairment in
21 chronic care facilities. Indeed, the average time required for medication administration
22 was significantly higher in dementia wards. However, this difference in time pressure
23 between chronic and emergency wards was not reflected by differences in average time
24 spent administering medication to individual patients, so there may be other factors
25 contributing to the stress associated with medication administration independent of the
26 authentication system, such general workplace environment, accessibility of social
27 supports, relationships with colleagues and patients, and working hours.
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29
30 There are limitations to the present study. First, the study was conducted at only two
31 hospitals, limiting generalizability. We also cannot establish causal relationships due to
32 the observational study design. In this study, before and after comparisons were made in
33 only two hospitals, but future studies such as randomly assigning wards in a multi-center
34 setting would be desirable. The system as currently configured cannot prevent the
35 administration of certain non-compliant medications such as PRN medications. Another
36 limitation was that medication administration time and nurses' awareness were not
37 measured using conventional methods. Future research should focus on confirming these
38 findings and explore ways to reduce the workload associated with this vein authentication
39 system.
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51 52 53 **CONCLUSION**

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55 Medication administration error is a common occurrence in hospitals. Biometric
56 technology is continually improving and widely used for personal identification in our
57 daily lives. Palm vein authentication proved superior to conventional methods for patient
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6 identification as evidenced by the decrease in medication errors after introduction.
7 However, further improvements are needed to reduce nurse work burden, time pressure,
8 and patient care burden.
9

10 11 **ACKNOWLEDGEMENTS**

12
13 We are grateful to Dr. Aya Kinjo, Associate Professor, Division of Environmental and
14 Preventive Medicine, Department of Social Medicine, Faculty of Medicine, Tottori
15 University, for advice on statistical analyses.
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18 19 **ETHICS STATEMENTS**

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21 The study protocol was approved by the hospital ethics board (approval number;
22 2021001). All nurses provided informed written consent and patients were informed of
23 their right to opt-out. Otherwise, patient consent was assumed.
24
25

26 27 **FUNDING**

28
29 This research received no specific grant from any funding agency in the public,
30 commercial or not-for-profit sectors.
31

32 33 **COMPETING INTERESTS**

34
35 None declared
36

37 38 **CONTRIBUTORS**

39
40 Minoru Sawa (MS) conceptualized the study with input from all the co-authors.
41 Tomomi Inoue (TI) and Shinichi Manage (SM) are the co-authors. MS performed the
42 statistical analysis and wrote the first draft of the manuscript, and all the authors provided
43 critical scholarly feedback. All the co-authors approved of the final version of the
44 manuscript. The corresponding author attests that all the listed authors meet the
45 authorship criteria and that no authors meeting the criteria have been excluded from the
46 acknowledgment.
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49 50 **DATA AVAILABILITY STATEMENT**

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52 Data used in this study are available upon reasonable request the authors.
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55 56 **FIGURE CAPTION**

57
58 Figure 1. The operation of the new cart and authentication system.

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60 Figure 2. The photograph of the new cart.

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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 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.

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.



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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) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —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 <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4-6
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —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) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —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) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N/A
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	6-10
		<i>Cross-sectional study</i> —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	Footnote

*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.