

The use of app-based IRS (incident report system) respecting WHO (World Health Organization) concept: A pragmatic cluster randomized controlled trial and the initial outcome.

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1) Introduction

In recent years, the Incident Reporting System (IRS) has emerged as a vital component in medical facilities worldwide. The success of an IRS is, with purpose, associated with specific characteristics, including non-punitiveness, confidentiality, independence, expert analysis, timeliness, a systems-oriented approach, and responsiveness. In accordance with these principles, we developed an app-based IRS comprising a user-friendly application and an online database[Fig.1]. This system incorporates minimal information based on the WHO concept². Our hypothesis posits that the implementation of a robust IRS in medical facilities would contribute to fostering a patient safety culture.

2) Methods

A pragmatic cluster randomized controlled trial was planned in 13 medical facilities. The facilities ranged from outpatient clinics to a 390-bed general hospital, encompassing a variety of healthcare settings [Table1]. Staffs in the facilities responded to the Japanese version of patient safety culture survey (SOPS) two times before and after the use of the presented system. The targeted staff of the involved medical facilities utilized the web-based reporting system for 6 months duration after knowledge calibration with a tailor-made instruction video course respectively for the reporters and administrators Data of incident reports were automatically collected to formulate the database through web-based application. The SOPS data were assembled through a facility survey conducted at all involved medical facilities[fig.2]. The proportion of one or more incident reports was analyzed using a generalized linear mixed model with fixed effects for intervention and time and random effects for the interaction between medical facility and time.

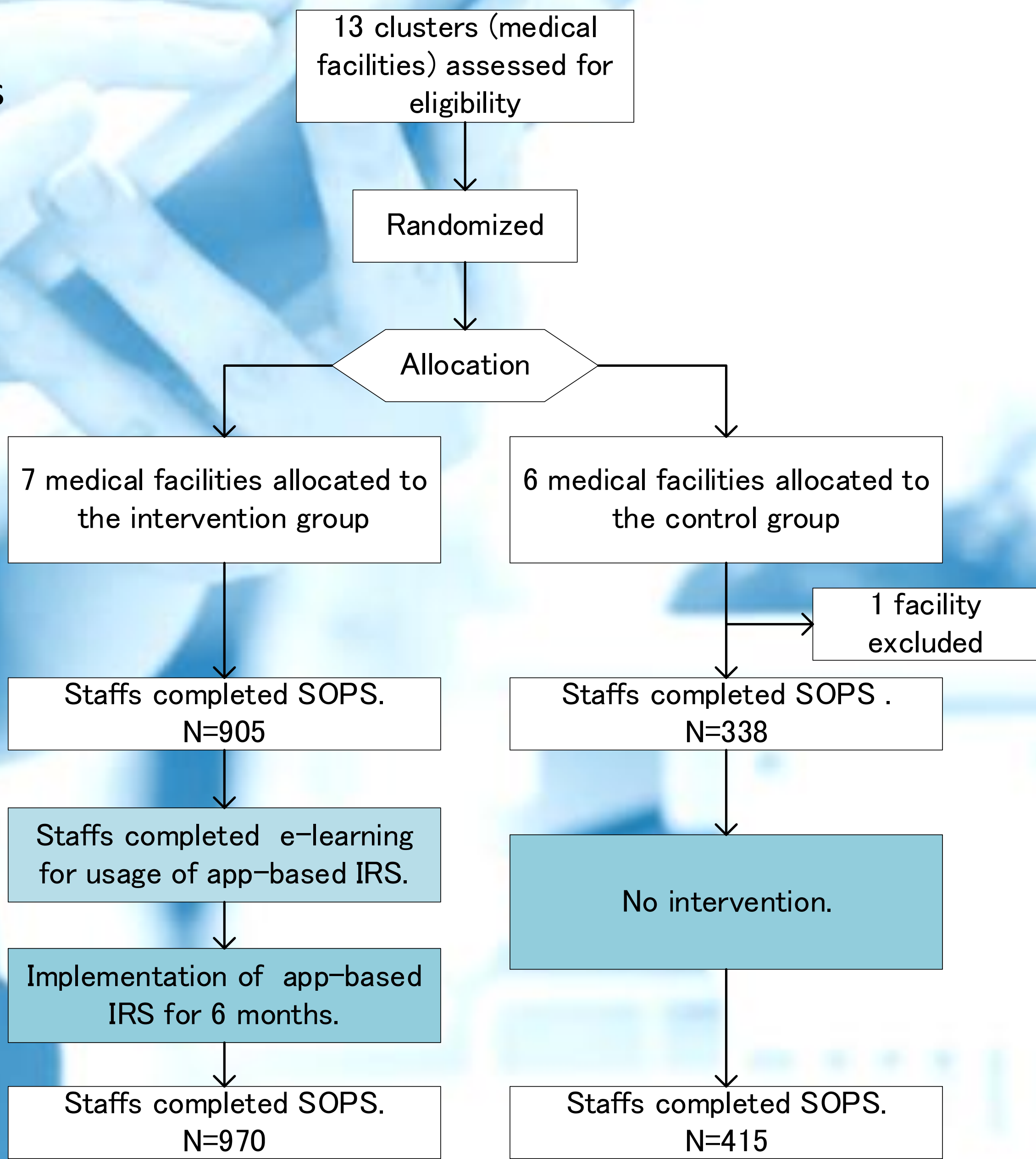
[Table1] Overview of participating facilities

ID	Number of beds	allocation
1	0	control
2	0	control
3	0	intervention
4	0	control
5	9	intervention
6	17	intervention
7	48	intervention
8	113	control
9	120	intervention
10	129	control
11	162	intervention
12	180	control
13	390	intervention

[Fig 1] App-based IRS



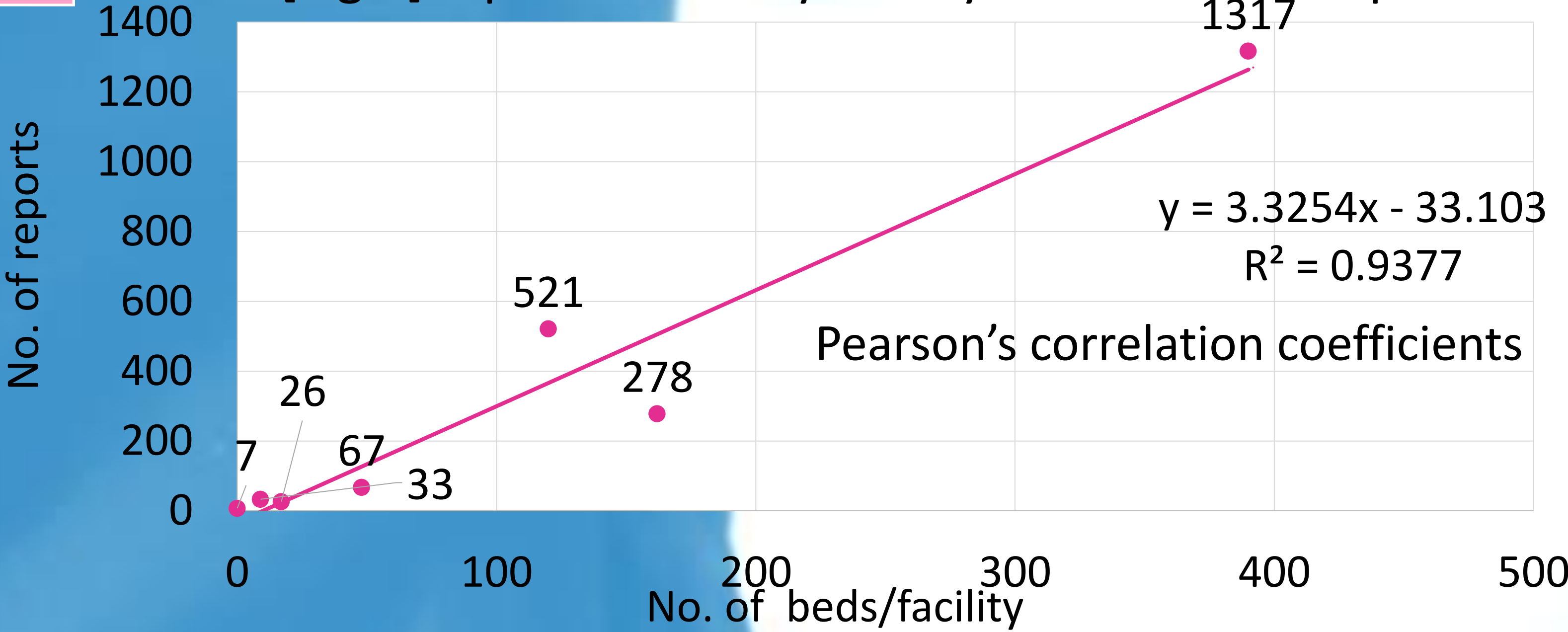
[fig.2] study design



3) Results

In the intervention group, 7 facilities were implemented app-based IRS for 6 months. Those were respectively characterized as 3 primary-care clinics, 3 short-stay hospitals and an acute general hospital. The total number of reported incidents were 2,249; (ranged from 7 to 1,317 in number per facility)[Fig.3]. In the SOPS, we asked how many incident reports were submitted within one year and analyzed this data statistically[Table2]. The odds ratio for one additional report in the intervention group compared to the control group is 1.60(p=0.398). Tests were conducted for each item of the SOPS, but no significant differences were also observed. In the second SOPS, the proportion of respondents who reported at least once remained unchanged among nursing staffs, however, was high at 61.6% in non-nursing staffs in the intervention group [Fig.4].

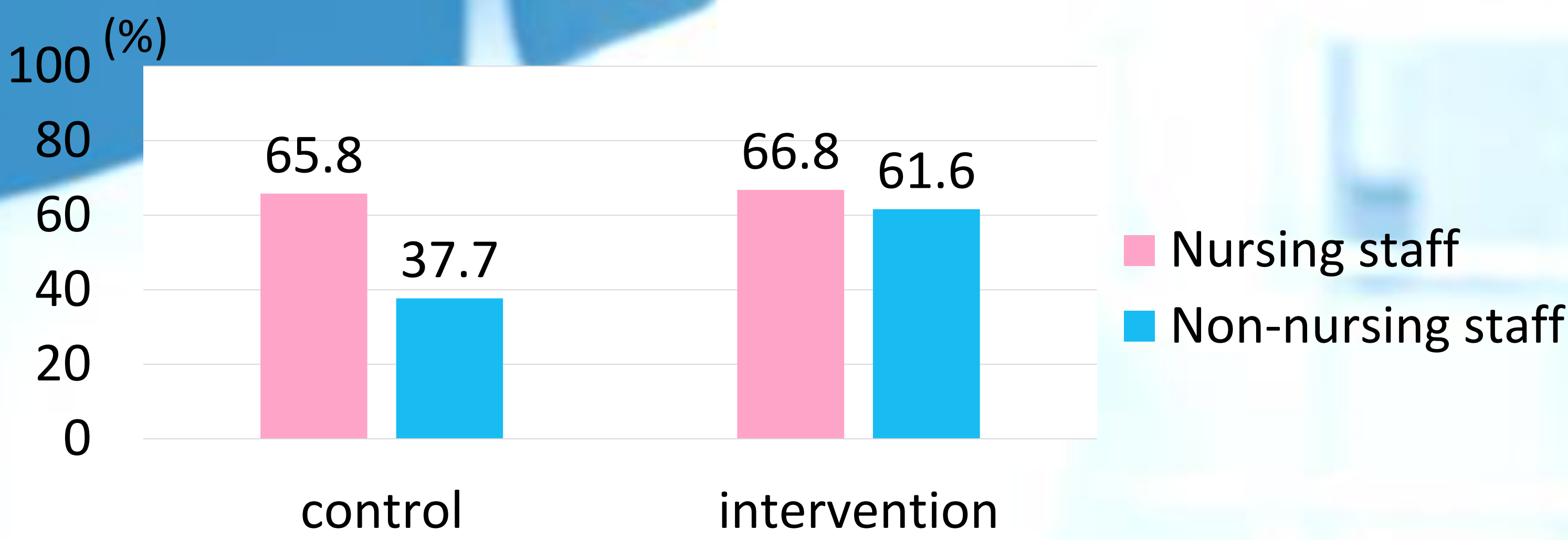
[Fig.3]Reports count by facility over a 6-month period



[Table2] Proportion of one or more incident reports in SOPS

Group	time 1		time 2			OR	95%CI	P-value
	(%)	n(≥1/total)	(%)	n(≥1/total)				
Intervention	76.20	690/950	63.5	577/908	Group	1.60	0.51 - 5.05	0.398
Control	66.00	223/338	47.8	194/406	Time	0.42	0.15 - 1.23	0.108

[Fig.4] The proportion of reporters by profession in the second SOPS.



4) Discussion

A non-punitive and confidential IRS operated using an app-based system was accepted by the service frontline staffs in every medical facility involved in this study. However, the study duration was too short to verify the effectiveness of the presented system. Additionally, due to the influence of the survey period, a tendency was observed for the results of the second survey after the intervention to be lower than those of the first survey. This suggests that reconsideration of the survey methods to mitigate the impact of staff turnover and other factors may be necessary. The app-based IRS is a tool with great utility. An extensive and longer- term interventions are mandatory to obtain a continuing and steady improvement of the organizational patient safety culture.

5) References

1. Patient safety incident reporting and learning systems: technical report and guidance.
<https://www.who.int/publications-detail-redirect/9789240010338>.
2. Minimal Information Model User Guide.
<https://www.who.int/publications-detail-redirect/WHO-HIS-SDS-2016.22>.