



# A multi-centre study of the effects of direct observation of hand hygiene practices on alcohol-based handrub consumption

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## ARTICLE INFO

### Article history:

Received 25 July 2022

Accepted 4 October 2022

Available online 20 October 2022

### Keywords:

Hand hygiene

Alcohol-based hand rub

Intervention study

Acute-care hospital

Non-acute-care facility

Compliance

Monitoring



## SUMMARY

**Introduction:** The World Health Organization recommends monitoring alcohol-based handrub (ABHR) consumption and direct observation of hand hygiene practices to ensure compliance. In Japan monitoring of ABHR consumption is widely performed. However, direct observation is not common, particularly in small facilities and non-acute-care facilities. Hence, the current study aimed to evaluate the longitudinal effects of direct observation of hand hygiene practices and monitoring of ABHR consumption with provision of feedback to healthcare personnel on ABHR consumption and hand hygiene compliance.

**Methods:** We conducted a 4-year prospective intervention study. Monitoring of ABHR consumption and direct observation of hand hygiene practices with monthly feedback to healthcare personnel was implemented in 17 facilities. These consisted of 11 acute-care facilities of varying sizes and six non-acute-care facilities. A generalized linear mixed model analysis was performed to assess factors associated with ABHR consumption.

**Results:** All facilities implemented ABHR consumption monitoring within one month of starting the study. However, the mean time required to implement direct observation of hand hygiene practices was 24.7 ( $\pm 19.1$ ) months. The ABHR consumption increased significantly ( $P < 0.0001$ ) in all medical facilities after implementing the direct observation. Multivariable regression analysis showed the hospital ward type, duration of ABHR consumption monitoring, and duration of direct observation of hand hygiene practices were independently associated with ABHR consumption.

**Conclusions:** Direct observation of hand hygiene practices with feedback should be implemented more widely in combination with ABHR consumption monitoring to help increase hand hygiene compliance.

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**Abbreviations:** ABHR, alcohol-based hand rub; WHO, World Health Organization.

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<https://doi.org/10.1016/j.infpip.2022.100256>

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## Introduction

Hand hygiene with the use of effective hand washing or alcohol-based hand rubs (ABHR) is one of the most effective and important practices that can prevent infection. Measures that can improve handwashing compliance among healthcare workers have been implemented in medical facilities worldwide. However, hand hygiene compliance rates are generally poor, thereby posing a major problem in medical safety and infection control [1–6].

The World Health Organization (WHO) Guideline on Hand Hygiene in Healthcare [7] released in 2009 emphasized ABHR use for many reasons, including relative speed and convenience vs. hand washing. The guideline recommended a multi-modal strategy, including routine evaluation of hand hygiene compliance, as a key means for improving and maintaining hand hygiene compliance rates among healthcare personnel. To evaluate compliance rates, two evaluation methods are recommended: (1) monitoring the volume of ABHR used (also known as consumption) and (2) direct observation of hand hygiene practices by healthcare personnel. The guideline further explained the importance of compiling these data and providing effective feedback to all healthcare personnel.

The WHO guideline refers to direct observation as the gold standard to monitor compliance with hand hygiene practice, specifically highlighting the ability to assess the five moments model [8]. The WHO Hand Hygiene Technical Reference Manual [9] goes into detail about the about practising, teaching and observing hand hygiene. It points out that “A direct observation method is chosen because it generates the most accurate data on health-care workers’ compliance with the recommendations on hand hygiene, although the results should not be considered a perfect representation of the actual situation.” [9]. Monitoring of the volume of ABHR used helps to get a more complete assessment, and more recent evidence suggesting automated monitoring tools can be effectively combined with direct observation [10]. Finally, the WHO Technical Reference Manual recommends a sample size for direct observations be calculated but points out there is no clear evidence on the ideal sample size, suggesting at least 200 observations per unit per observation period [9].

The WHO recommendations have been adopted in guidelines used in many countries and are now recognized as the global standard [11–13]. Several studies have shown that the WHO evaluation methods are effective [14–18]. However, they have been conducted in one or few facilities, thereby limiting the generalizability of the results. In addition, studies were generally conducted in large-scale, acute-care healthcare facilities. Evaluation by direct observation requires significantly more work than ABHR consumption monitoring and it is difficult to validate the evaluation results recorded by each observer (i.e., inter-rater reliability). Thereby making its implementation especially challenging in settings with limited resources, such as middle-to-small-sized hospitals and non-acute-care healthcare facilities [18]. We are unaware of any study to assess whether the combination of direct observation of hand hygiene practices and monitoring ABHR consumption can improve hand hygiene performance in middle-to-small-sized hospitals and non-acute-care healthcare facilities.

The current study aimed to evaluate the longitudinal combined effect that direct observation of hand hygiene practices and monitoring of ABHR consumption accompanied with monthly feedback has on hand hygiene frequency. This research assesses the efficacy of these methods in healthcare facilities of different types and sizes, in a relatively large multicentre study.

## Materials and methods

### Study design

We conducted a prospective multicentre before-and-after study. Direct observation of hand hygiene practices was conducted typically once per week at random times chosen by the observer, to achieve at least 50 times per month. Feedback was provided to healthcare personnel monthly during the observation period. The difference in ABHR consumption before vs. after the intervention was assessed as the primary outcome measure.

### Setting and intervention

This study was initiated with healthcare facilities in Japan that applied during the registration period from January 2012 to January 2016. Information about the study objectives and design were posted at academic conferences and in infection control trade journals in Japan to recruit participants. A primary enrollment criteria for each healthcare facility was that they had not implemented ABHR consumption monitoring nor direct observation of hand hygiene practices at the time of registration, with consent to implement both as instructed by the investigators. We provided training to infection control personnel regarding the direct observation of hand hygiene practices, monitoring of ABHR consumption, procedures involved in data analysis, and modes of feedback to the person in charge of infection management at each facility. None of the infection control personnel had previous experience in this approach to manage and measure hand hygiene. Using the direct observation method, infection control personnel visited the ward and observed whether the healthcare worker performed hand hygiene practices according to the 5-moment criteria [8] recommended by the WHO [7,9].

The direct observations were recorded, and results were tabulated monthly. The aggregated results of the direct observations and ABHR consumption monitoring, using a data analysis and results reporting tool for tablet computers, were fed back to a wide variety of healthcare personnel every month. This aimed to raise awareness of hand hygiene with the main target for feedback being personnel who work around patients in the wards (this includes physicians, nurses, pharmacists, physical therapists, occupational therapists, speech therapist, laboratory technicians, and clinical engineers). At each facility when poor hand hygiene technique was observed the observer provided verbal guidance and training to the staff members immediately (i.e., real-time feedback). The recommendation was to observe more than 50 moments for hand hygiene monthly per ward, and the compliance rate was reported by the 5-moment criteria [8]. To validate direct observation and to reduce the burden on auditors, we created support tools including educational materials for the

healthcare staff, a monitoring/data analysis tool for tablets computers, and models for feedback materials. These were provided to the auditors of each facility. Moreover, we also provided training about the tools to use to collect results and posting them to a centralized website for the purpose of storage and for the investigators to use in analysis [19–21]. Infection control personnel at each facility attended research group conferences held every 6 months. During this conference, the status of evaluation activities, ABHR consumption, and hand hygiene compliance at each facility were assessed and advice was provided.

### Data collection

The characteristics of each healthcare facility included the facility type (large-scale acute-care with  $\geq 300$  beds, middle-to-small-scale acute-care with  $< 300$  beds, and non-acute-care), number of beds, type of hospital ward (intensive care unit/neonatal intensive care unit or general ward), presence of infection control personnel, and number of staff responsible for infection control activities. During the study period, ABHR consumption was measured by both 1) checking ABHR bottles on site weekly to determine the amount consumed and 2) checking the number of ABHR bottles released to the ward from the drug department supply inventory. ABHR consumption was calculated monthly per 1000 patient-days. To increase the hand hygiene compliance rates at each facility during the observation period, we encouraged and documented the local interventions per the WHO guideline [7], such as posting of reminders and posters about hand hygiene, expanding the number of ABHR locations, increasing opportunities for staff education regarding hand hygiene, and releasing hand hygiene information to patients. In addition, to understand facility specific infection control practices more broadly, we also collected data about other surveillance activities, such as monitoring medical device associated infections and surgical site infections, and antimicrobial stewardship activities.

### Sample size calculation

To determine the required number of participating facilities, we referenced results from six previous studies of hand hygiene compliance [1–6], setting the clinically significant change in volume of ABHR consumed at 5 L/1000 patient-days. Based on the results of an unpublished 2016 survey of a variety of 30 healthcare facilities (including acute and non-acute), we concluded the population standard deviation for the volume of ABHR consumed was 6.07 L/1000 patient-days, and that the within-facility correlation coefficient was 0.5. A *P* value of 0.05 was considered statistically significant, and a statistical power of 0.9 based on the *t*-test was used to compare the volume of ABHR consumed before and after the intervention [22]. Using these parameters, the minimum number of facilities was determined to be 18.

### Statistical analysis

Statistics for ABHR consumption were calculated before and after the implementation of direct observation of hand hygiene practices, and the change in ABHR consumption was calculated. The paired *t*-test was used to assess the statistical significance of changes. A generalized linear mixed model analysis

was performed to assess factors associated with ABHR consumption, which was a dependent variable. Hospital ward type, number of staff responsible for infection control activities, duration of monitoring of ABHR consumption (months), duration of direct observation of hand hygiene practices (months), and the presence of additional interventions for improving hand hygiene compliance (e.g., expanding the number of ABHR locations, increasing opportunities for staff education about hand hygiene, and providing information to patients) were used as fixed effects in the regression model. In addition, to control other factors affecting ABHR consumption, facility-specific equipment, environment, and infection control measures were considered as random effects in the regression model. A *P* value of  $< 0.05$  was considered statistically significant. Data were analysed with SAS version 9.4 (SAS Institute, Cary, North Carolina).

### Ethical considerations

This study was conducted in accordance with the Declaration of Helsinki, and it was approved by the ethics board of Juntendo University (approval number: 18–014). An institutional manager each healthcare facility agreed to participation in the study. An individual informed consent was not required because the study was a health care audit with no added risk to the employees or patients.

### Results

In total, 21 healthcare facilities were initially enrolled in this study. These comprised 6 large-scale acute-care facilities with  $> 300$  beds, 8 middle-to-small-scale acute-care facilities with  $< 300$  beds, and 7 non-acute-care facilities (see Table 1). ABHR consumption monitoring was implemented in all facilities prior to the direct observation intervention, and this was continued throughout the data collection period. Four facilities were excluded because one had implemented direct observation prior to the start of data collection and 3 facilities never properly implemented direct observation. ABHR consumption was evaluated before vs. after the implementation of direct observation. The 17 participants included in the analysis were 5 large- and 6 middle-to-small-scale acute-care facilities and 6 non-acute-care facilities.

The total observation time was 1,225 months (625 months before direct observation, 600 months after direct observation), and the average observation time per facility was 36.0 months ( $\pm 27.5$ ). The mean length of time by hospital type was 51.3 months ( $\pm 30.0$ ) for large acute care facilities, 32.5 months ( $\pm 25.7$ ) for small and medium acute care facilities, and 26.8 months ( $\pm 25.7$ ) for non-acute care facilities.

The mean time before implementing direct observation was 24.7 ( $\pm 19.1$ ) months. According to hospital type, the mean time to collect direct observation data was 31.8 ( $\pm 15.0$ ) months for large-scale acute-care facilities, 24.5 ( $\pm 18.9$ ) months for middle-to-small-scale acute-care facilities, and 17.8 ( $\pm 24.2$ ) months for non-acute-care facilities. There was no significant difference between the different facilities in terms of the implementation time of the hand hygiene direct observation intervention.

Figure 1 depicts the volume of ABHR consumed over time, which was stratified according to hospital type. There was a

**Table I**  
Characteristics of the participating facilities

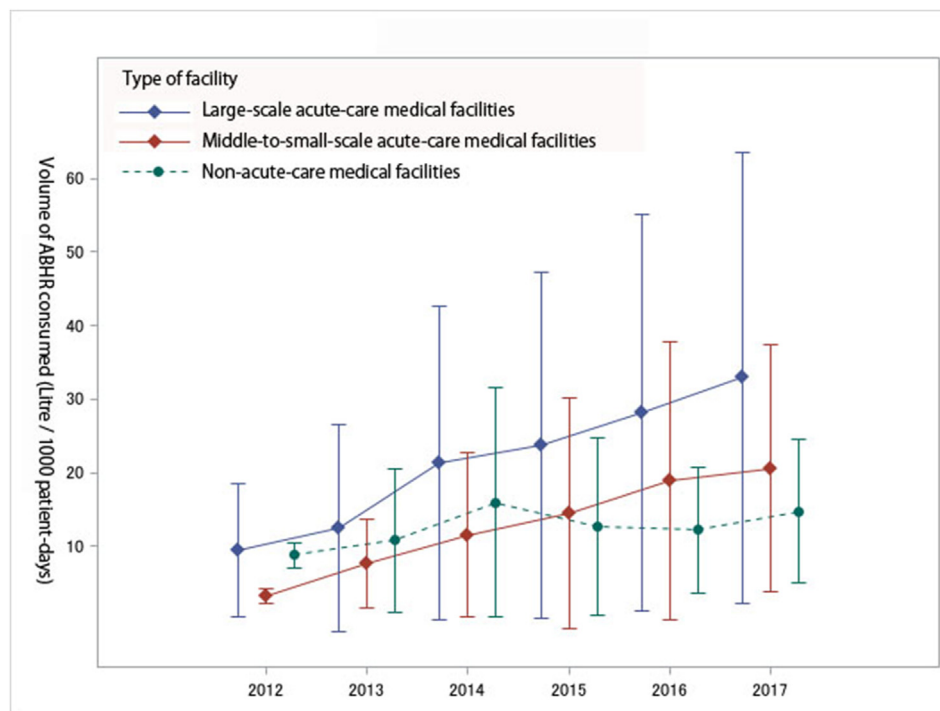
	All facilities	Large- acute-care (≥300 beds)	Middle-to- small- acute-care (<300 beds)	Non-acute-care
Number of facilities (%)	21 (100)	6 (28.6)	9 (42.9)	6 (28.57)
Mean number of beds (range)	293 (88–634)	501 (310–634)	209 (135–299)	212 (88–400)
Presence of infection control personnel (%)	21 (100)	6 (100)	9 (100)	7 (100)
Mean number of full-time staffs (range)	0.8 (0–2)	1 (1)	0.9 (0–2)	0.5 (0–1)
Mean number of interlocking staffs (range)	8.2 (3–27)	12.3 (5–27)	4.9 (3–8)	5.2 (4–17)
Interventions to increase hand hygiene compliance rates during the observation period (%):				
Expanding locations for ABHR	19 (90.5)	6 (100)	8 (88.9)	5 (83.3)
Increasing opportunities for staff education about hand hygiene	20 (95.2)	6 (100)	8 (88.9)	6 (100)
Posting of reminders and posters about hand hygiene	20 (95.2)	5 (83.3)	9 (100)	6 (100)
Releasing of information to patients	13 (61.9)	3 (50)	5 (55.6)	5 (83.3)
Surveillance in place excluding hand hygiene (%):				
central line-associated bloodstream infection	12 (57.4)	4 (66.7)	6 (66.7)	2 (33.3)
catheter-associated urinary tract infection	13 (61.9)	4 (66.7)	5 (55.6)	4 (66.7)
ventilator-associated pneumonia/event	7 (33.3)	3 (50)	2 (22.2)	2 (33.3)
surgical site infection	14 (66.7)	5 (83.3)	8 (88.9)	1 (16.7)
multidrug-resistant organisms	18 (85.7)	5 (83.3)	9 (100)	4 (66.7)
Antimicrobial stewardship (%)	17 (80.1)	6 (100)	8 (88.9)	3 (50)

significant increase in ABHR in large and middle-to-small-scale acute-care facilities ( $P < 0.0001$ ). However, there was not a significant increase for ABHR consumption in non-acute-care facilities ( $P = 0.14$ ).

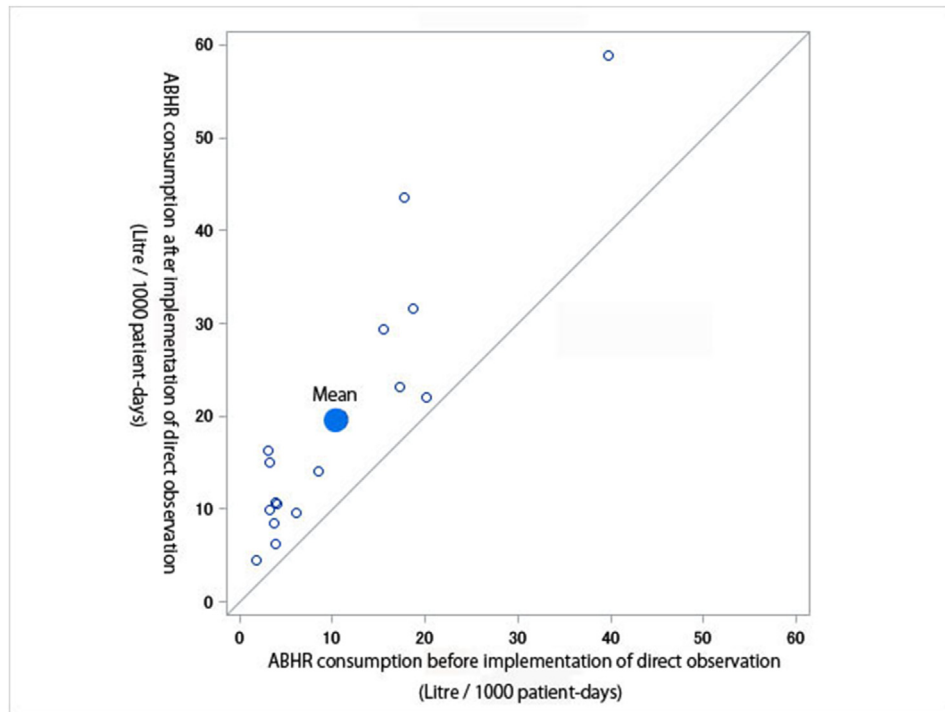
Figure 2 shows the ABHR consumption before and after the implementation of direct observation. The ABHR consumption increased in all participating facilities that implemented direct observation during the study period.

Table II depicts ABHR consumption before and after the implementation of direct observation, which was stratified according to hospital type. Results showed that the ABHR consumption in all facilities increased significantly after the implementation of direct observation.

Table III presents the results of the generalized linear mixed model analysis. Hospital ward type and time to monitoring of ABHR consumption and direct observation of hand hygiene



**Figure 1.** Annual changes in the volume of alcohol-based handrub (ABHR) consumption averaged by healthcare facility type.



**Figure 2.** The change in Alcohol-based handrub (ABHR) consumption before to after implementing direct observation for each individual healthcare facility.

**Table II**

Comparison of ABHR consumption before and after implementing direct observation (liter/1000 patient-days)

	Before the direct observation of ABHR consumption, mean ( $\pm$ SD)	After the direct observation of ABHR consumption, Mean ( $\pm$ SD)	Mean difference (95% confidence interval)	P value*
Large-scale acute-care medical facilities	17.3 ( $\pm$ 19.6)	30.0 ( $\pm$ 28.3)	-12.3 (-19.9, -4.7)	0.01
Middle-to-small-scale acute-care medical facilities	12.9 ( $\pm$ 10)	19.2 ( $\pm$ 19.3)	-9.5 (-16.5, -2.5)	0.02
Non-acute-care medical facilities	8.6 ( $\pm$ 3.9)	9.7 ( $\pm$ 5.2)	-5.6 (-9.5, -1.7)	0.02
All facilities	14.0 ( $\pm$ 14.4)	21.9 ( $\pm$ 23.2)	-9.2 (-12.4, -5.9)	<0.0001

\* Paired t-test

**Table III**

Results of the generalized linear mixed model analysis with ABHR consumption as a dependent variable

Factors	Estimated regression coefficients	Standard error	t-value	P Value
Intercept	-15.7464	15.0892	-1.04	0.3131
Hospital ward type (ICU/NICU)	32.0721	0.6644	48.27	<0.0001
Time from the implementation of ABHR consumption monitoring (month)	0.2094	0.0226	9.26	<0.0001
Time from the implementation of direct observation (month)	0.2119	0.03843	5.51	<0.0001
Posting of reminders and posters about hand hygiene	11.693	9.4511	1.24	0.235
Expanding locations for ABHR	9.3761	6.7823	1.38	0.1867
Increasing opportunities for staff education about hand hygiene	0.4725	9.4686	0.05	0.9609
Releasing of information to patients	-3.6459	4.5546	-0.8	0.4359
Number of full-time healthcare personnel	-0.1318	4.1142	-0.03	0.9749

The following variables were input into the regression model as categorical variables: type of ward, posting of reminders and posters about hand hygiene, expanding locations for ABHR, increasing opportunities for staff education about hand hygiene, releasing of information to patients. The following variables were input into the regression model as continuous variables: time from the implementation of ABHR consumption monitoring and direct observation and number of full-time healthcare personnel.

practices were found to be significantly associated with ABHR consumption.

The compliance rate of hand hygiene was excluded from the evaluation because validation of the direct observation was not performed.

## Discussion

This study examined the effects of direct observation of hand hygiene practices on ABHR consumption in medical facilities of different sizes and type (from large acute-care facilities to small-scale non-acute-care facilities). Results showed that the ABHR consumption increased in all facilities that implemented direct observation, but this was not statistically significant in non-acute-care facilities. Previous studies have shown that the WHO evaluation methods are effective [15–17]. However, they have been conducted in relatively few facilities, thereby limiting the generalizability of the results. This is the first multicentre study that we know of that evaluated the effects of direct observation in many healthcare facilities of varying sizes and types. Results showed that, regardless of facility size or type, the implementation and maintenance of direct observation was associated with a higher ABHR consumption.

Furthermore, the general linear mixed model analysis showed significant associations between ABHR consumption and hospital ward type and time to monitoring of ABHR consumption and direct observation of hand hygiene practices. The effects of monitoring of ABHR consumption and direct observation of hand hygiene practices on ABHR consumption over time were quantitatively evaluated. The assessment of ABHR consumption is relatively easy to perform and is widely used to monitor hand hygiene practices. However, implementing the direct observation of hand hygiene practices is substantially more labour-intensive. Moreover, it is not widely used, particularly in settings with limited resources, such as small and non-acute-care hospitals [18]. Our study showed that the effects of direct observation of hand hygiene practices are not based on the type of medical facility. It is unclear the specific effects of duration (i.e., how long to continue direct observation and ABHR consumption monitoring), however as [Figure 1](#) points out years are needed. We hope that this finding will lead to a wider adoption of the direct observation of hand hygiene practices. However, the rate of compliance with hand hygiene could not be assessed because the evaluator was unable to validate it. Nonetheless, it was useful in identifying situations where compliance was low (data not shown).

The current study had one major limitation. That is, the effects of four local interventions (expanding the number of ABHR locations, increasing the opportunities for staff education about hand hygiene, posting of hand hygiene reminders, and providing information to patients) on ABHR consumption were not included in the analysis. We attempted to collect data on the duration and content of these interventions. However, they were limited, and they varied; and it was challenging to accurately measure the frequency of interventions. Several facilities had their own specific interventions, and these did not change significantly before and after implementing the direct observation of hand hygiene practices. By analysing the effects of these interventions on ABHR consumption via a multivariate regression analysis, we could control, at least in

part, the effects of local interventions other than the direct observation of hand hygiene practices.

## Conclusions

The ABHR consumption data increased in all medical facilities after implementing the direct observation of hand hygiene practices. This was statistically significant in acute care facilities, regardless of size, but it was not a statistically significant increase for non-acute facilities. The hospital ward type, duration of ABHR consumption monitoring, and duration of direct observation of hand hygiene practices were independently associated with ABHR consumption. Direct observation of hand hygiene practices should be considered as an intervention more widely to help increase hand hygiene compliance. Future studies should be conducted in non-acute facilities and to better assess the effect of local interventions and ward type in combination with direct observation.

## CRedit author statement

**Retsu Fujita:** Validation, Formal analysis, Investigation, Data curation, Writing – Original draft, Visualization. **James W. Arbogast:** Validation, Writing – Review & editing, Visualization. **Rika Yoshida:** Methodology, Validation, Investigation, Writing – Review & editing, Project administration. **Satoshi Hori:** Conceptualization, Methodology, Validation, Investigation, Resources, Data curation, Writing – Review & editing, Supervision, Project administration.

## Conflicts of interest statement

None.

## Funding

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

## Acknowledgements

We want to thank the staff of the participating facilities for their cooperation.

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