American Journal of Infection Control 49 (2021) 963–965

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Brief Report

Assessing the clinical accuracy of a hand hygiene system: Learnings from a validation study

Marco Bo Hansen MD, PhD [a,*], Nina Wismath MD [b], Evelyn Fritz MD [b], Alexandra Heininger MD, PhD [b]

[a] Konduto ApS, Sani Nudge, Copenhagen, Denmark
[b] Department of Hospital Hygiene, University Hospital Mannheim, Germany

Key Words:
Compliance
Electronic monitoring
Reminder systems
Nudging
Healthcare-acquired
Infection prevention

There is a need to establish validation standards that allow for comparison of automated hand hygiene systems. To assess the accuracy of an innovative monitoring tool (Sani nudge), 2 test nurses performed clinical standard tasks while being observed by 2 infection preventionists. Data from the direct observations were compared with data obtained from the hand hygiene system (Sani nudge) using an independent-event approach. We identified 54 true-positive events (100% system accuracy) and 4 true-negative events (100% system accuracy). No false-positive or false-negative events were identified. We found this approach to be feasible and clinically useful to validate hand hygiene systems in the future.

BACKGROUND

Healthcare systems are facing an increasing pressure from accreditation bodies to measure and document hand hygiene compliance as part of quality assurance, but it is a manual and time consuming process.[1] Automation of the measurements can reduce some of the increased workload that infection prevention teams experience as a result of the coronavirus pandemic. A number of hand hygiene traceability systems have become commercially available, but in order to become widely adopted, the systems must be validated upon implementation. However, only a few studies have calculated the accuracy of such solutions and they only focused on room entries and exits.[2]

No studies have assessed the accuracy of hand hygiene traceability systems based on the principles of the World Health Organization's (WHO) guidelines on hand hygiene in real-life clinical settings.[3] One of the main barriers is that standardized validation methods are lacking. First, the method should allow for comparison with direct observations. Second, accuracy must be tested during clinical practice to avoid over- or underestimation. Third, a simple setup is required, taking into consideration that infection prevention departments have limited time and resources and that each ward often needs a completed validation upon implementation before they feel confident using the hand hygiene system. However, the method must still be clear and precise to allow for comparison between solutions or healthcare organizations. Finally, the approach should be able to calculate sensitivity and specificity as well as positive and negative predictive values. To our knowledge, no currently described method meets these criteria.

We aimed to assess the accuracy of an automated hand hygiene system using a clinically relevant validation method.

METHODS

We conducted a single-site validation study in an internal medical department at the University Hospital Mannheim, Germany. After obtaining internal approval of the hospital management and personnel board, the hand hygiene system (Sani nudge, Denmark, https://saninudge.com. Accessed October 12, 2020) was installed in accordance with the instructions: (1) on existing dispensers (hand event registrations), (2) near the headboard of the patient beds creating a patient zone, and (3) an anonymous sensor on the name badge of each healthcare worker.[4,5] The system measures healthcare workers' movements with high precision in real-time, their use of alcohol-based hand rub and adherence to the WHO's Moments 1, 4, and 5.

The clinical validation was accomplished by assessing clinically relevant predefined test scenarios (Table 1) and comparing the direct observations with the data obtained by the system (Fig 1). Both compliant and noncompliant scenarios were included. Compliance was defined as *use* of alcohol-based hand rub divided by *opportunities* when alcohol-based hand rub should have been used. The direct observations were performed by two infection preventionists (in this case two doctors) from the hospital, who used an app on their phone

* Address correspondence to Marco Bo Hansen MD, PhD, Konduto ApS, Sani Nudge, Mikkel Bryggers Gade 4, 1460 Copenhagen, Denmark.
E-mail address: marcobhansen@gmail.com (M.B. Hansen).
Conflicts of interest: None to report.

https://doi.org/10.1016/j.ajic.2021.01.006

Table 1
Overview of the clinical tasks performed by 2 test nurses while being observed by 2 infection preventionists

Clinical task in a single bedroom	Compliant scenario	Hand event before	Patient contact	Hand event after			
Measure pulse and blood pressure	Yes	Yes	Yes	Yes			
Measure pulse and blood pressure	Yes	Yes	Yes	Yes			
Measure pulse and blood pressure	No	Yes	Yes	No			
Measure pulse and blood pressure	No	Yes	Yes	No			
Measure pulse and blood pressure	No	Yes	Yes	No			
Measure pulse and blood pressure	No	Yes	Yes	No			
Give a message to the patient	Yes	No	No	No			
Give a message to the patient	Yes	No	No	No			
Measure respiratory rate and oxygen saturation	Yes	Yes	Yes	Yes			
Measure respiratory rate and oxygen saturation	Yes	Yes	Yes	Yes			
Measure respiratory rate and oxygen saturation	No	No	Yes	Yes			
Measure respiratory rate and oxygen saturation	No	No	Yes	Yes			
Give a message to the patient	Yes	No	No	No			
Give a message to the patient	Yes	No	No	No			
Clinical task in a twin bedroom	Compliant scenario	Hand event before	Patient 1 contact	Hand event after	Hand event before	Patient 2 contact	Hand event after
Examination of eyes, mouth and abdomen of two patients in a multiple bed room	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Examination of eyes, mouth and abdomen of two patients in a multiple bed room	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Examination of eyes, mouth and abdomen of two patients in a multiple bed room	No	Yes	Yes	No	No	Yes	Yes
Examination of eyes, mouth and abdomen of two patients in a multiple bed room	No	Yes	Yes	No	No	Yes	Yes

Each hand hygiene event (hand event and patient contact) was subsequently compared with data obtained by the Sani nudge system using an independent-event approach. Both compliant and noncompliant scenarios were included according to WHO's "My 5 moments of Hand Hygiene."

Fig. 1. Data collection and comparison. (A) Data collected by the hand hygiene system during a clinical task where the test nurse measured pulse and blood pressure on a patient. Blue lines indicate hand events and the turquoise bar indicates the time in the patient zone (patient contact). (B) Example of data comparison between the direct observations and the hand hygiene system.

designed for the purpose (observation tool "Observe" from HARTMANN, Germany). This approach allowed to assess interobserver variability.

We used an independent-event approach: Each dispenser event and patient contact was treated as independent events to allow for the identification of inaccuracies during the test. Two test nurses performed the clinical tasks related to the predefined test scenarios. The test nurses were provided with a test sensor on their name badges with a known identification number to ensure that each event could be identified in the database retrospectively.

Statistical analyses were conducted with the statistical software IBM SPSS Statistics 20 (SPSS Inc., Chicago, IL).

RESULTS

The test took 2 hours to complete and required 2 test nurses, 2 test patients (mimicked by technicians), and 2 observers.

True-positive and false-positive events

Events both captured through direct observations and by the system: The test nurses performed 26 hand sanitizations according to the guidelines and had 18 patient contacts according to the 2 direct observers. Of these, 26 (100%) hand sanitizations and 18 (100%) patient contacts were accurately attributed by the system. The 2 infection preventionists observed 10 missed hand events, and the same 10 (100%) events were properly detected by the system (detection of the test nurses in the patient zone but with no hand event either before and/or after patient contact). There were no false-positive events, that is, events that are not observed but are captured by the system.

True-negative and false-negative events

The test nurses walked into the patient room 4 times to give a message to the patient without touching the patient or surroundings, and without sanitizing hands according to the WHO's 5 Moments. There were no false-negative events, that is, events that are observed but not captured by the system.

DISCUSSION

In this clinical validation study, we found that the accuracy of a hand hygiene system can be assessed by using a simple but clinically relevant independent-event approach. Limper et al. have previously suggested a similar approach, but their method only focuses on the technical aspects of a system validation[6]: An investigator follows a planned path, activating each device to ensure that all devices are activated correctly when being used. The setup does not take into account the behavior of the healthcare workers.

A strength of this clinical validation approach is that you can assess the hand hygiene of the healthcare workers while they perform clinical tasks. In addition, the method allows you to choose as many test scenarios, healthcare workers and observations as you want to include until you feel confident using the system. The challenge is to ensure a setup in which you can be certain that the observed events can be identified in the database subsequently. It will require unique identifiers that will vary from system to system and must therefore be modified accordingly. For this system, all devices and sensors on name badges had unique identifiers, allowing for the association of each event with a specific device and location.

Some limitations exist: First, we only assessed hand hygiene compliance using alcohol-based hand rub. However, hand hygiene with water and soap can also be assessed using this method. Second, this study only validated one type of hand hygiene system. Third, this was a small-scale validation study.

Future clinical validation studies with more healthcare workers and clinical tasks are feasible and needed. However, we believe that this study provides a template for future research on this area and contributes to developing industry standards and recommendations. This will hopefully make it easier for infection prevention teams to validate and implement hand hygiene traceability systems which is highly needed as part of the COVID-19 response.

CONCLUSION

The method described provides a standardized way of clinically validating hand hygiene traceability systems in an effective way using minimal resources. In this study, the accuracy rate was 100% between the events obtained with the direct observations and the Sani nudge system.

Acknowledgments

We thank the HCWs who took part in the study and HARTMANN for granting access to their eHealth application "Observe". There was no financial support for this study.

References

1. National Patient Safety Goals 2020: Monitoring of hand hygiene (goal 7). The Joint Commission. Available at: https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/2020/npsg_chapter_hap_jul2020.pdf. Accessed October 12, 2020.
2. Ward MA, Schweizer ML, Polgreen PM, Gupta K, Reisinger HS, Perencevich EN. Automated and electronically assisted hand hygiene monitoring systems: a systematic review. *Am J Infect Control*. 2014;42:472–478.
3. World Health Organization: my 5 moments for hand hygiene. WHO. Available at: http://www.who.int/infection-prevention/campaigns/clean-hands/5moments/en/. Accessed October 12, 2020.
4. Iversen A-M, Kavalaris CP, Hansen R, et al. Clinical experiences with a new system for automated hand hygiene monitoring: a prospective observational study. *Am J Infect Control*. 2020;48:527–533.
5. Iversen A-M, Stangerup M, From-Hansen M, et al. Light-guided nudging and data-driven performance feedback improve hand hygiene compliance among doctors and nurses. *Am J Infect Control*. 2021;49:733–739.
6. Limper HM, Garcia-Houchins S, Slawsky L, Hershow RC, Landon E. A validation protocol: assessing the accuracy of hand hygiene monitoring technology. *Infect Control Hosp Epidemiol*. 2016;37:1002–1004.