Study protocol: Evaluation of the National tool for observation of infection prevention measures in the healthcare (NOST) – a cluster randomized trial

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Introduction

Effective infection prevention and control (IPC) is essential to ensure high-quality healthcare services. Infections that occur during hospitalization and because of services provided may interfere with the outcome of needed medical treatments[1]. For example, postoperative infections may limit the health benefits of surgery.

In order to prevent healthcare-associated infections (HAIs), it is essential that all healthcare personnel are well trained in and follow standard IPC measures during patient care. Standard precautions include hand hygiene, use of personal protective equipment, and more. Although healthcare professionals may have a high level of knowledge about the correct performance and indications for hand hygiene, compliance can vary greatly between different service sites and professions[2].

The Norwegian Institute of Public Health (NIPH) is introducing a new electronic tool and national template for direct observation of compliance with recommended IPC measures in healthcare. The solution is called the National Tool for Observation of Infection Prevention Measures (NOST). Training and implementation started in hospitals in the autumn of 2022 and will continue in hospitals and nursing homes in 2023.

NOST is a quality improvement tool that includes a web-based solution for observing and recording the degree of compliance with recommendations for hand hygiene and other IPC measures. Through NOST, healthcare personnel will be able to identify the local level of compliance, which in turn can reveal areas for improvement. The effect of measures taken to improve compliance and quality of IPC, can be followed through the results of the recordings made in NOST. The objective of NOST is to increase the quality of infection prevention and control in healthcare services.

Protocol for evaluating NOST follows the plan established for the implementation of NOST in Norwegian hospitals, as described in the National Standard for Hand Hygiene Observation. NOST will be implemented in the first quarter of 2023. All hospitals must, according to the Action Plan for Better Infection Control, use the solution and report data according to the standard. Participating in the evaluation of NOST is voluntary for the hospitals, and they do not need to decide on participation until later in 2023. However, we ask the hospitals to prepare for future evaluation. Therefore, we ask that the hospitals contribute the following upon the implementation of NOST:

1. The hospitals send an overview of which wards can implement NOST
2. The hospitals implement NOST in wards that are randomly selected to be intervention wards
3. The hospitals do not implement NOST in wards that are randomly selected to be potential control wards in the later evaluation of NOST

Points 1 and 2 are in line with the planned implementation of NOST and must be carried out by all hospitals regardless of participation in the evaluation study, while Point 3 is necessary preparation for the later evaluation of NOST. Hospitals will later in 2023 receive an invitation to participate in the evaluation of NOST. This will include an invitation to conduct a measurement of hand hygiene compliance in control wards, and approval for the NIPH to use data on infection occurrence and length of stay as outcome measures in addition to hand hygiene compliance.

Objectives

The objective of evaluating NOST is to:

- measure if implementation of NOST leads to increased compliance with hand hygiene recommendations, and
- measure if implemented NOST affects the epidemiology of HAIs in healthcare institutions and the length of hospital stays.

Methods

Study design and setting

This protocol includes the evaluation of NOST in hospitals. The evaluation is designed as a cluster-randomized controlled trial with two arms where eligible wards in hospitals are randomly allocated into an intervention and a control arm. NOST is implemented in the intervention wards at the start of the evaluation period, and compliance with hand hygiene and other outcomes are measured in both the interventions and control wards one year later.

Intervention

The intervention in the study is to implement NOST, which includes:

- observation and recording of compliance with hand hygiene recommendations
- reporting the results back to the relevant wards
- identification of areas for improvement
- training or other actions taken to improve IPC in general or compliance with hand hygiene.

Thus, the intervention includes both observation of compliance and any additional improvement measures initiated as a result of the introduced NOST.

Observations of hand hygiene will be carried out in sessions of 20-30 minutes. During this period, all situations where hand hygiene is indicated (recommended) and whether hand hygiene is performed or not, are recorded. The number of hand hygiene indications during a session varies but will often be between 7 and 20.

When the intervention group has implemented and followed NOST for a year, we will measure compliance with hand hygiene recommendations, diagnosed HAIs and length of stay, in wards that have had NOST and in wards that have not introduced NOST.

The intervention arm will be followed over time with repeated measurements of both compliance with hand hygiene and other outcome measures, to see if the effect increases in line with implemented observations and quality improvement measures, or if the effect decreases during the study period.

Study populations

The evaluation of NOST in hospitals consists of two parts with different study populations. Part 1 is a quality improvement project and measures the effect in terms of increased compliance with hand hygiene recommendations. The study population in part 1 is employees with patient-related work.

In part 2, the occurrence of HAI and length of stay for hospitalized patients, and outbreaks of infectious disease among patients and staff are examined. When measuring HAI and length of stay, the study population is patients who are hospitalized in intervention or control units when the annual surveillance of HAI is conducted in the Norwegian Surveillance System for Antibiotic Use and Healthcare-Associated Infections (NOIS), together with all inpatients in the study period using data from the Norwegian Patient Registry (NPR). When measuring the number of outbreaks and the

number of secondary cases in outbreaks, the study population is both staff and inpatients in intervention or control wards during the outbreak periods.

Data collection and outcomes

Hospitals will send the results of 30 hand hygiene observations from each included intervention ward every four months in accordance with the plan for the implementation of NOST in hospitals. The first submitted results will constitute the baseline measurement.

When NOST has been performed for a year, new measurements will be taken in the intervention wards and corresponding baseline measurements in the control wards. This will also include a minimum of 30 hand hygiene observations from each ward. The measurements in both arms will be conducted by observers who have received training and gained experience with NOST measurements during the year NOST has been carried out in the intervention wards.

The measurements from intervention wards that have had NOST for one year will be compared with contemporaneous baseline measurements in the control wards. The difference in compliance with hand hygiene in the intervention arm compared to the control arm will constitute the effect of having implemented NOST and performed quality improvement measures for one year. Repeated measurements over time in the intervention wards will be used to investigate whether the effect has increased and remains throughout the study period, or if the effect diminishes before comparison is made after one year.

The primary outcome is the number of measured indications for hand hygiene and the number of hand hygiene performed on indicated events, the proportion of correct compliance, and variation in correct compliance in the form of intra-class correlation coefficient (ICC).

Comparison of HAIs in the two arms will be made using surveillance data that is routinely collected from all hospitals. This includes:

- infectious disease outbreaks reported to the Norwegian Institute of Public Health's web-based outbreak notification system (VESUV), including the microbiological cause of the outbreak and the number of people infected among patients and staff
- number of patients recorded with infections in cross-sectional studies conducted in the Norwegian Surveillance System for Antibiotic Use and Healthcare-Associated Infections (NOIS)
- number of patients receiving antibiotic treatment recorded in NOIS
- number of patients recorded with postoperative infections in the surveillance of infections in surgical sites (NOIS-POSI)

In addition, we will apply for data from the Norwegian Patient Registry (NPR) for patients admitted to intervention or control wards during the study period. We will use the number and proportion of patients diagnosed with infection defined as HAI (according to European definitions used in NOIS), and the number of days hospitalized per stay.

A summary of the type of data and outcome measures is shown in Table 1.

Table 1. Data and outcome measures used to evaluate the impact of NOST on compliance with hand hygiene recommendations and the occurrence of HAI and outbreaks in hospitals

	Numerator	Denominator	Outcome measure per arm

Hand hygiene observations	• Number of hand hygiene performed on indicated events	• Number of indicated events observed	• Proportion of correct compliance, in total and by occupation
Outbreaks of infectious diseases (VESUV)	• Number of outbreaks • Number of infected patients and staff	• Number of wards • Number of inpatients • Number of full-time positions	• Proportion of outbreaks per ward • Secondary attack rate (SAR) by inpatients and staff
Surveillance of HAI (NOIS)	• Number of infected patients • Number of patients treated with antibiotics	• Number of inpatients	• Proportion of infected inpatients by type of infections
Surveillance of postoperative site infections (NOIS-POSI)	• Number of patients with postoperative site infections	• Number of surgical patients	• Proportion of infected patients by type of surgery and type of infections
HAI-diagnoses (NPR)	• Number of patients with infections defined as HAI	• Number of bed-days	• Number of infected patients per 1000 patient days, by type of HAI
Length of stay (NPR)	• Number of bed-days per patient per stay	• Number of hospital stays	• Mean and median bed-days per stay

The number of outbreaks per arm will be collected from VESUV. At the start of the evaluation period, we will ask participating hospitals to submit the number of full-time positions per included ward. The number of inpatients per ward per day will be obtained from NPR. The number of positions and inpatients will be used as denominators when estimating the secondary attack rate in outbreaks. The number of patients registered in NOIS will be compared to the number of daily inpatients registered in NPR. If the number of inpatients per day changes over time, we will make a new collection of the number of full-time positions to capture significant changes in the organization and size of included wards.

NOIS and NOIS-POSI are surveillance systems where numerators and denominators are registered. From these systems, it is sufficient to receive the results for each ward in the form of the proportion of patients with different types of infections.

From NPR, we will apply for data for all hospitalized patients at both intervention and control wards from and including 1. January 2020 up to the time of application in 2024, giving numerators and denominators for the periods before, during and after the intervention.

When comparing intervention and control groups, we will estimate relative risk (RR) and absolute risk difference (ARF) with 95% confidence intervals (table 2). We will report two-sided p-values where applicable and use the significance criterion $p<0.05$.

We will use modified Poisson regression to compare hand hygiene compliance one year after NOST was introduced in the intervention wards[3]. We will adjust for the factor used in stratification (hospitals) as a fixed effect.

Compliance will be analyzed and reported for each occupational group and total for all healthcare personnel. Outbreaks will be analyzed and reported as the number of outbreaks and secondary attack rate per arm, in total and distributed by patients and staff. The incidence of infection in patients will be analyzed and reported in total and by types of infection.

A more detailed description of the analyzes of the main and secondary outcomes will be published in a separate analysis plan.

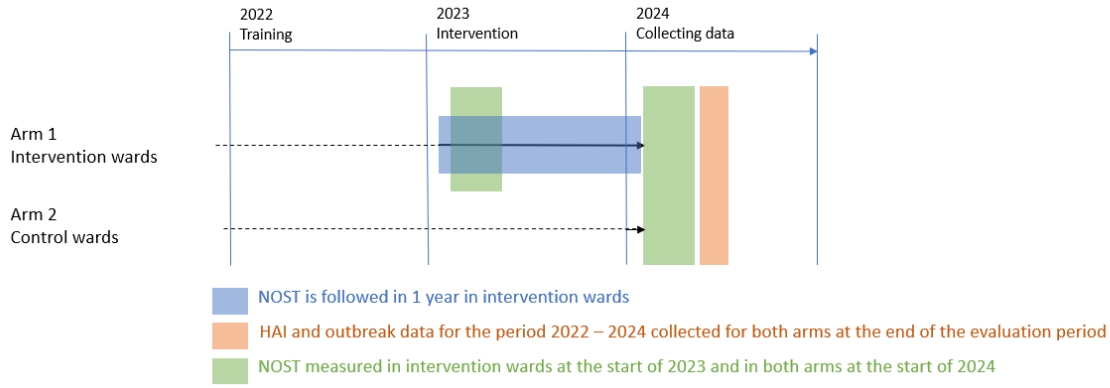

Figure 1. Overview and schedule for the intervention and measurements in the evaluation

Table 2. Dummy table with results for compliance with hand hygiene recommendations

	Intervention arm	**Control arm**	**ICC**	**Adjusted RR (95% CI)**	**ARF (95% KI)**	**p-value**
Primary outcome						
Compliance hand hygiene	540/900[1] (0.60)	369/900[1] (0.41)	0.020	1.683 (1.654 – 1.713)	0.279 (0.270-0.288)	<0.05

[1]Number of hand hygiene performed by indicated events

Sample size

Sample size calculation (number of wards needed in each arm) is based on the following:

- Type I error rate: 0.05
- Power: 0.80
- Primary outcome is dichotomous with expected baseline proportion: 0.40
- Outcome is measured as simple difference at the end of the intervention period
- Intraclass correlation coefficient (ICC) of primary outcome: 0.10
- Expected number of measured events per cluster (hospital ward): 30
- Degrees of freedom used when adjusting for cluster-level covariates in the analysis: 2
- A priori stratification in the design and analyses
- Hypothesized intervention effect (increased proportion of compliance): 0.20

The estimation of necessary number of wards in both arms is conducted in parallel cluster-randomized trials calculator published by the National Institutes of Health (https://researchmethodsresources.nih.gov/grt-calculator).

Table 3 shows the function of the number of clusters (wards) per arm, and the number of events measured in each ward. The first row shows the number of clusters, while the first column shows the number of events measured per ward. The inner cells show the magnitude of the difference (increase in proportion) that we can identify as significant with a power of 80%. We assume that we

can detect a difference of at least 20%, and the calculations show that we have enough power for this if we have 26 wards in each arm, if there are 30 hand hygiene sessions measured in each ward.

Table 3. Detectable difference in the arms, distributed by number of participating wards per arm and number of events measured per ward

Absolute Detectable Difference
Clusters (wards) per arm

		24	**25**	**26**	**27**	**28**
Events measured per ward	**15**	0,2266	0,2219	0,2175	0,2134	0,2094
	23	0,2113	0,2069	0,2028	0,199	0,1953
	30	0,2042	0,2	**0,1961**	0,1923	0,1888
	38	0,1992	0,1951	0,1912	0,1876	0,1841
	45	0,1962	0,1922	0,1884	0,1848	0,1814

Group allocation

The National standard for observation of Hand Hygiene (NOST) is planned to be implemented in all hospitals in Norway and it is expected that the hospitals will participate in the evaluation of the initiative. Therefore, we expect the participation to be equivalent to the participation in the annual surveillance of HAIs (NOIS), which covers around 60 hospitals. Further we expect up to 10 wards from each hospital will participate in the evaluation. This will result in several hundred wards being included in the evaluation of NOST.

According to the national standard, hospitals are required to report the results of observed hand hygiene from three to five wards per hospital every four month, depending on the hospital size. We plan to randomize wards stratified by hospital level to ensure an equal number of intervention and control wards at each hospital.

Each hospital will submit a list of wards eligible to introduce NOST. The list must at least include the number of departments needed to participate in the evaluation, i.e., 10 departments at large and up to 10 at smaller hospitals, so that each hospital gets the right number of wards implementing NOST and a corresponding number of control wards that do not introduce NOST. When NIPH has received the list from the individual hospital, each ward will be assigned a random number and then sorted by ascending random number. The (up to or including 10) wards with the lowest randomly drawn numbers are allocated to an equal number of intervention and control wards per hospital.

Allocation of wards will be performed as follows:

1. The hospital sends a list of eligible wards to the NIPH employee in charge of the introduction of NOST (NOST coordinator), who creates a code for each ward and sends the code to researcher A. At the same time, the code and full hospital and ward name are sent to researcher B
2. Researcher A generates a random number for each ward code where each ward is allocated in ascending random order to the intervention and control arms respectively. The ward codes with the result of allocation are then sent back to the NOST coordinator and researcher B
3. The NOST coordinator sends the result of allocation to the hospital and to researcher B

4. Researcher B controls that the ward's names and codes have not been changed from coding until the result is sent back to the hospital

When all participating hospitals have received feedback on which wards are allocated to each arm, the full names of the hospitals and wards are entered into the randomized list so that it is clear which arm each ward is allocated to and collected data for each ward and future results of measurements can be added for the hospitals participating in the evaluation.

When baseline measurements are submitted from the intervention wards, we will verify that the wards performing NOST measurements are in accordance with the group allocation. Hospitals that do not comply with the allocation will be excluded from the evaluation study, i.e., wards at the hospital may continue NOST but will not be included in the evaluation.

Ethics

Performing hand hygiene during patient-related work is considered necessary to provide proper healthcare and professional practice, and can therefore be seen as mandatory, based on requirements in the Specialist Health Services Act, the Health and Care Services Act and the Health Personnel Act. The National Action Plan for Improved Infection Control (2019-2023) sets guidelines for the healthcare sector to improve infection control, including compliance with hand hygiene recommendations. The plan states that hospitals must (and nursing homes should) establish a program for monitoring how hand hygiene recommendations among healthcare personnel are followed. Monitoring should be carried out according to a national standard solution. The introduction of the NOST is the reply to meet this requirement.

Performing hand hygiene and monitoring compliance can be considered a requirement based on laws and the action plan. However, on the NIPH's website about NOST, it is emphasized the importance of caution when observing and handling data. The following is stated on the website about NOST:

For some, it may be unfamiliar and perhaps uncomfortable to be observed while performing their work. It is important that observers are aware of this, and that they are conscious of their ethical responsibilities. During observation, the observer should show consideration for patients and staff. Observations made by individuals should be treated as confidential data and not shared. This is a topic that will be covered in the training provided to observers and coordinators.

According to the Action Plan for better infection control, NIPH must compile national data on compliance with hand hygiene in healthcare institutions. However, the evaluation of NOST sets out to compare compliance with hand hygiene, as well as other outcome measures, at both intervention and control wards. The evaluation thus includes more data than what the hospitals register through NOST. Participating in the evaluation of NOST is not mandatory. During 2023, the management at each hospital will be sent an invitation to participate in the evaluation of NOST. Necessary approvals and a data protection impact assessment will accompany the invitation. Each hospital's management has the freedom to choose whether wards will participate in the evaluation and follow the group allocation (introduce NOST in intervention wards and not in control wards). It will be clearly communicated from NIPH that hospitals can freely choose not to participate in the evaluation and that they can introduce NOST on certain or all departments, before or after allocation is performed and thus not participate in the planned evaluation.

Introducing NOST and evaluating the effect of compliance with infection control measures is a quality improvement measure. NIPH considers that using recorded compliance in this evaluation project is not covered by the requirements of the Health Research Act. However, adding outcome measures that include health information, such as infection rates, are covered by the requirements of the Health Research Act and require prior approval from the regional ethical committee (REK). We will apply for REK's approval to use surveillance data on infection rates and outbreaks, together with patient data from the National Patient Register, as secondary outcomes in the evaluation project.

In this project, we will not register or collect direct identifiable personal data. In the hand hygiene observations, only the events and occupation are recorded, but not personal data on the people observed. Furthermore, we will only ask for statistics from VESUV and NOIS/NOIS-POSI. This data will include the number of people infected in outbreaks per ward distributed by employees and inpatients, as well as the number of inpatients with relevant types of infection in the surveillance of HAI. These data are regularly published at the hospital level. We will apply for data from NPR that includes information on each patient admitted to the relevant wards in the period from 1 January 2022 to mid-2024. However, we will ask for data without directly personally identifiable information (data without name and social security number).

Together with the data protection officer at NIPH, we will perform a data protection impact assessment (DPIA) related to the collection and handling of data in the project.

References

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