

# **Epidemiology and impact of a staff training in controlling complications related to central venous catheter in 4 intensive care units in a French University Hospital: Protocol of a Prospective Quasi-Experimental/cross-over Study**

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# Epidemiology and impact of a staff training in controlling complications related to central venous catheter in 4 intensive care units in a French University Hospital: Protocol of a Prospective Quasi-Experimental/cross-over Study

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## Abstract

**Background:** Central venous catheters (CVCs) are essential tools in intensive care units (ICUs) but are associated with infectious, mechanical and thrombotic complications. Despite established clinical guidelines, variability in adherence persists, contributing to preventable morbidity and mortality. In 2022, an audit at Edouard Herriot Hospital (Hospices Civils de Lyon (HCL), Lyon, France) revealed a degree of variation in adherence to current protocols. Specifically, certain practices were not in accordance with evidence-based recommendations, particularly hand hygiene, flushing procedures, asepsis, among others.

**Objective:** This study aims to evaluate the impact of an educational program on adherence to national guidelines for CVC management, assess its effect on clinical outcomes, and identify factors associated with CVC-related complications.

**Methods:** A prospective quasi-experimental cross-over study is ongoing in four ICUs at a French university hospital. The design includes audits, educational sessions based on the recommendations of the French Society of Hospital Hygiene, and clinical data on patients with CVC.

**Results:** Compliance and complication rates will be assessed before and after the intervention. The primary outcome is the rate of CVC-related complications per catheter-days. Secondary outcomes include rehospitalizations, mortality, and adherence improvement.

**Conclusions:** This study will evaluate the efficacy of an educational program in enhancing adherence to national guidelines and improving clinical outcomes. Ultimately, this initiative will offer a reproducible model for other institutions seeking to enhance care quality and mitigate patient risks.

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**Epidemiology and impact of a staff training in controlling complications related to central venous catheter in 4 intensive care units in a French University Hospital: Protocol of a Prospective Quasi-Experimental/cross-over Study**

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**Running title: Management of central venous catheter**

**Abstract**

**Background:** Central venous catheters (CVCs) are essential tools in intensive care units (ICUs) but are associated with infectious, mechanical and thrombotic complications. Despite established clinical guidelines, variability in adherence persists, contributing to preventable morbidity and mortality. In 2022, an audit at Edouard Herriot Hospital (Hospices Civils de Lyon (HCL), Lyon, France) revealed a degree of variation in adherence to current protocols. Specifically, certain practices were not in accordance with evidence-based recommendations, particularly hand hygiene, flushing procedures, asepsis, among others. This study aims to evaluate the impact of an educational program on adherence to national guidelines for CVC management, assess its effect on clinical outcomes, and identify factors associated with CVC-related complications.

**Methods and analysis:** A prospective quasi-experimental cross-over study is ongoing in four ICUs at a French university hospital. The design includes audits, educational sessions based on the recommendations of the French Society of Hospital Hygiene, and clinical data on patients with CVC. Compliance and complication rates will be assessed before and after the intervention. The primary outcome is the rate of CVC-related complications per catheter-days. Secondary outcomes include rehospitalizations, mortality, and adherence improvement.

**Discussion**

This study will evaluate the efficacy of an educational program in enhancing adherence to national guidelines and improving clinical outcomes. Ultimately, this initiative will offer a reproducible model for other institutions seeking to enhance care quality and mitigate patient risks.

**Keywords:** audit, central venous catheter, CVC, complications, education, guidelines, practices, training

## Background

Central venous catheter (CVC) are frequently used in intensive care units (ICUs). Despite their significant benefits, their use is associated with both mechanical and infectious complications that can be acquired during their insertion, maintenance, and management. Central line-associated bloodstream infection (CLABSI) is considered as a major challenge for healthcare workers (HCW) in ICUs, leading to an increased length of hospital stay, healthcare cost, and mortality .

Over the past decade, hospitals have made significant progress in preventing CLABSI. A bundle of measures, including hand hygiene, maximum barrier precautions during catheter insertion, appropriate skin antisepsis (mainly alcoholic), catheter site selection, management of port line occlusions, daily assessment of the need for the device, etc. have successfully reduced CLABSI incidence and have been incorporated into clinical practice . However, despite these advancements, CLABSI remains a significant health concern. The incidence of CLABSI varies depending on the setting and population studied, but estimates suggest that it ranges between 0.5 and 5 per 1,000 catheter days . In a recent multinational multicenter prospective, the pooled CLABSI rate was 4.82 CLABSIs per 1,000 CVC days, which is significantly higher than previously reported . In recent years, the attack rates of CLABSI in our hospital remained steady between 1.2 and 2.8%.

Clinical practice guidelines exist to assist the decision-making processes of health professionals and patients regarding appropriate healthcare interventions in specific clinical circumstances. However, these guidelines are not exempt from challenges. The number of guidelines has increased significantly, and their implementation remains a complex process that is not without difficulties. Concurrently, patients have become older and are hospitalized with more severe conditions.

In recent years, healthcare systems in developed countries have focused on reducing the variability of healthcare practices by implementing strategies to effectively enhance knowledge and capacities to address the challenges presented by clinical practice variability and provide optimal quality of care to patients .

Studies have demonstrated that written policies, formal trainings and experience contributed to an increase in knowledge, practice and positive attitudes regarding the prevention of CLABSI. Understanding evidence-based strategies for the management and administration of CVC is crucial to the prevention of associated complications . The results of audits and educational programs play an important role in bridging the gap between knowledge and practice in infection prevention, helping HCW adopt and apply evidence-based prevention measures .

In 2022, an audit conducted at Edouard Herriot Hospital (Hospices Civils de Lyon (HCL), Lyon, France) in collaboration with Becton Dickinson (BD) laboratory highlighted variations in

compliance with existing protocols. While over 70% of observations showed adherence to best practices-such as the use of gauze and alcoholic antiseptic for line handling, as well as proper flushing at the end of the procedure-some practices deviated from evidence-based recommendations, particularly hand hygiene, flushing techniques, and aseptic measures .

A multifaceted intervention combining audit, education, and reinforcement of current guidelines should enhance professional knowledge and reduce the incidence and risk of CVC-complications. The efficacy of utilizing of concept of *bundling* key steps from extensive practice guidelines into a set of point-of-care reminders to improve staff compliance have been demonstrated .

### **Objectives**

The objectives of this study are as follows:

1. To evaluate the impact of the educational program on adherence to the national recommendations of the French Society of Hospital Hygiene (SF2H)
2. To determine whether an educational program could enhance adherence to current guidelines of the SF2H and improve patient outcomes related to CVC: CLABSI, deep vein thrombosis (DVT), mechanical damage, readmission for CVC-associated complications, and related mortality
3. To assess factors associated with CVC-related complications: CLABSI, DVT, mechanical damage, readmission for CVC-associated complications, and related mortality

## Methods/Design

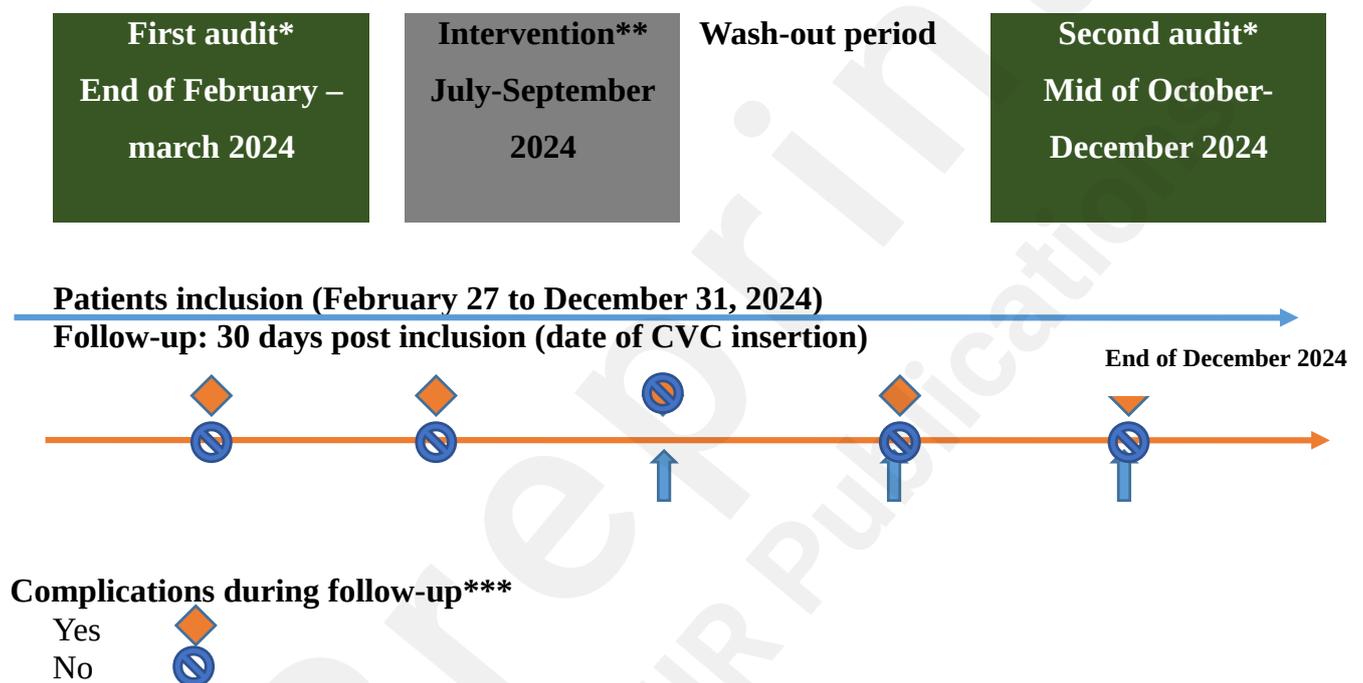
### Study site

The study is currently being conducted in the four ICUs wards of Edouard Herriot Hospital, a university hospital in Lyon, France.

### Study design

A prospective quasi-experimental/cross-over design combining audits, interventions, and clinical data. The diagram (Figure 1) below summarizes the main stages and provisional dates of this project:

Figure 1: study design



\*Audits will be done using BD Signature Solutions™. The second audit will be realized after a wash out period of 2-3 months after the last session of educational intervention; \*\* Intervention = educational program; \*\*\*complications: CLABSI, DVT, mechanical damage, readmission for complications associated to CVC and related death.

## Participant's recruitment

The recruitment of all consecutive patients aged 18 years or older, hospitalized for at least 48 hours in one of the four ICU units of the hospital, with a CVC including PICCs (Peripherally Inserted Central Catheter), and affiliated with the national health care insurance was conducted between February 27 and December 31, 2024. Patients who had hemodynamic instability, receiving palliative care, or unable to engage in the informed-consent process independently or through a surrogate representative were excluded. The inclusion and exclusion criteria are detailed in Table 1.

Table 1 Inclusion and exclusion criteria for selection of study participants

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>• At least 18 years of age</li> <li>• Hospitalized (<math>\geq 48</math> hours)</li> <li>• Having a CVC, including PICCs</li> <li>• Affiliated to national health care insurance</li> <li>• Informed consent by the patient</li> </ul>	<p>The presence of any of the following will preclude participation:</p> <ul style="list-style-type: none"> <li>• Age under 18 years</li> <li>• Patient without CVC</li> <li>• Patient not affiliated to national health care insurance</li> <li>• Any other significant medical or psychiatric history rendering the subject ineligible</li> <li>• Refute to participate</li> </ul>

## Study procedures

### Audits

A standardized auditing tool was developed based on the current practices and the recommendations of the SF2H . The questionnaire is made up of hundred questions, relating to hand hygiene, skin antisepsis; CVC insertion, maintenance, and removal; CVC documentation; professional education and length of clinical experience. These latter 2 characteristics were considered variables that influence adherence to recommendations. Signature Solutions™, a digital tool developed by BD, is utilized to capture the observations in real time . Two audits will be conducted in this study (pre-and post-education).

### The intervention (educational program)

The educational interventions comprise face-to face exchange sessions with the project team, departmental poster displays, and electronic communication. The objectives are to discuss device care protocols (insertion, drugs can be used, preparation, manipulation, verification of reflux and tract patency, removal of unnecessary catheters, and awareness of CVC associated risks) and infection control measures, specifically hand hygiene, disinfection (type of antiseptic and formulation), manipulation of vascular lines, flushing modalities (syringe,

volume and technique), personal protective equipment, and implementation of full-barrier precautions during insertion. The intervention is based on national recommendations of the SF2H.

### **Data collection**

Following verification of inclusion criteria, enrollment will be conducted upon the insertion of the first CVC and/or admission with an inserted CVC, including PICCs. For each participating patient, a standardized questionnaire is completed, which included the following characteristics: age, gender, co-morbidities as defined by International Classification of Diseases-10 codes, information on hospital stay, total number of catheters on admission and during stay in ICU, products administered by CVC, details on CVC (type, date and site of insertion, dressing,...). Data on antibiotics (molecule and duration) will be fully collected. Patients will be monitored daily until hospital discharge, death, or withdrawal from the study. Patients discharged with a CVC will be contacted every 15 days until CVC removal and/or the conclusion of the study to determine whether complications have occurred in the interim within 30 days of inclusion. No additional testing was requested for the purpose of this study.

The data collection is ongoing and will be completed during the first trimester of 2025.

### **Data Entry**

Location of and information on sampling wards and data will be recorded on paper specific clinical record folder (CRF) and electronic database. Epi info will be used to create digital survey and data entry. Different tables with data at admission, during hospital stay and follow-up will be created. For each table, a unique key will be used to allow the link with the main questionnaire.

The data entry is expected during May 2025.

### **Outcomes**

#### **Primary clinical outcomes**

The primary outcome is the number of complications per patient and per month. Complications will be documented on specific form to harmonize data collection. The overall complication rate is the number of associated complications per catheter-days that occurred during its use.

Complications are defined as following:

- CLABSI is defined as a laboratory confirmed bloodstream infection in a patient where the CVC was in place for at least 48 hours with no other apparent source except the catheter.
- CVC-associated DVT is defined by clinical (swelling, pain, redness,...) and radiologic findings.
- Mechanical complications are defined as obstruction, occlusion, breakage, migration or dislodgment (accidental withdrawal) of the catheter.
- Mechanical damage will be considered in the presence of catheter rupture requiring repair or replacement with a new catheter.

**Secondary clinical outcomes**

The number of consultations and rehospitalisations postdischarge within the follow-up period will be used to determine the clinical impact beyond the initial hospitalization. The CVC-related hospital readmission is defined as admission due to a catheter related complication.

**Primary educational outcome**

The overall improvement in compliance with the National recommendations of the SF2H following the intervention will be evaluated. Global and stratified scores will be compared pre- and post- the intervention. The score will be defined at the ICU rather than on an individual basis.

**Main statistical analyses**

The statistical analysis will consist of an exploration of the descriptive data of the sample, and bivariate analysis with parametric and non-parametric tests, depending on the nature of the distributions (correlation, ANOVA, chi-square). Results will be reported as frequencies (n) and proportions (%) for categorical data and mean (SD) for continuous data. The distribution of continuous variables will be checked.

Epidemiological, clinical and microbiological will be described and interpreted independently. Participants will be categorized into different groups, according to status with respect to end-points (complications or not). Same analyzes will be done to compare the compliance with national recommendations before and after the educational program.

Appropriate statistical tests (Chi-square, Fisher's exact test, t-test, Mann Whitney U test, ...) will be used for comparison between the pre- and post-intervention periods with a significance level of  $< 0.05$ . Poisson regression will be done to calculate rate ratio (RR) and 95% confidence interval (CI) for complications incidence rates. Therefore, a multivariate regression models (Logistic, Cox or Poisson) will be used to compare groups and to identify factors significantly associated with complications.

Data will be analyzed using the program SPSS IBM Statistics version 21.

The complete results are expected in the third quarter of 2025.

**Data curation**

The collected data will be stored in the hospital's information systems and will be accessible exclusively to the hospital investigators (data will not be shared with BD). Data retention will adhere to the archival period required by the national regulations.

**Discussion/Conclusion**

Managing complications related to CVC remains a significant challenge despite advancements in clinical practices and training. This study will evaluate the efficacy of an educational program in enhancing adherence to national guidelines and improving clinical outcomes. Through the integration of audits, targeted educational interventions, and reminders of best practices, variability in care can be minimized, potentially leading to improved patient outcomes. Ultimately, this initiative will offer a reproducible model for other institutions seeking to enhance care quality and mitigate patient risks.

## **Ethics and dissemination**

### ***Ethical permission***

The study participants' personal information will be gathered and handled exclusively on the legal basis established by the regulations, in line with Lyon University hospitals' public service missions. Participants are provided with an information letter outlining the study's objectives and follow-up procedures.

The research protocol has been submitted to the Institutional Ethical Board who approved it with the reference number 2024 06 27 20. Additionally, the Comité National de l'Informatique et des Libertés of HCL has granted approval for the study under reference number 23-115.

### ***Dissemination***

The findings will be disseminated through an original article and scientific presentations at National and international conferences.

### **Consent for publication**

Not Applicable.

### **Availability of data and materials**

### **Funding**

This work was supported by BD. The funder had no role in the study design, clinical data collection, management and analysis, and decision to publish or preparation of the manuscript.

### **Competing interest**

None to declare. All authors approved the final version of the manuscript and assure that it is not being considered for publication elsewhere.

### **Authors' contributions**

All authors meet standard criteria for authorship. Specifically, Dr Nagham Khanafer contributed to the conception of this project, drafting of manuscript and final approval; she is involved in data acquisition and will complete final analysis and interpretation, as well as drafting of final results; Pr Anne-Claire Lukaszewicz and Pr Laurent Argaud participated in patients inclusion, revision and final approval of the manuscript; Dr Elisabetta Sola-Kuczewski participated in elaboration of questionnaire, she is actively involved in patients inclusion and data collection; Pr Philippe Vanhems participated in conception, revision and final approval of the manuscript.

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