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BMJ Open Development and evaluation of an algorithm for peripheral venous catheter placement (ALCOV): protocol for a quasi-experimental study

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ABSTRACT

Introduction Multiple punctures during peripheral venous catheter (PVC) placement increase the risk of complications. Scoring for adult difficult intravenous access (A-DIVA Scale) exists but has never been assessed in the framework of a care algorithm (scoring associated with a new decision-making tree for puncture conditions, the A-DIVA Tree). We seek to implement a catheter placement algorithm to decrease the mean number of punctures per patient. The algorithm will be adjusted based on obstacles and levers revealed by the analysis of clinical data. The benefits of the algorithm will be assessed using a step-by-step implementation of the approach.

Methods and analysis 794 PVC placements will be recorded in two inclusion centres (50%/50%). In phase I, 297 PVC placements will be collected, and 16 individual semistructured interviews will be conducted to evaluate the centres' practices. In phase II, 200 PVC placements will be recorded to assess the impact of the A-DIVA Scale alone. The interphase will allow preliminary results based development of the A-DIVA Tree. In phase III, 297 PVC placements will be recorded to assess the impact of the algorithm on the mean number of punctures per patient.

Ethics and dissemination The study and related consent forms were approved by an institutional review board (Comité de Protection des Personnes Sud-Méditerranée I) on 25 April 2023 under reference number 2023-A00223-42. The results will be disseminated in the form of original articles, presentations and guidelines.

Trial registration number NCT05935228.

INTRODUCTION

Two billion peripheral venous catheters (PVCs) are used per year worldwide.¹ Nearly 80% of hospitalised patients have at least one PVC placed in the hospital setting, making catheterisation the most frequently performed invasive procedure.² Nearly a quarter of all people requiring vascular access have difficult intravenous access (DIVA).²⁻³ Multiple complications, such as obesity, intravenous drug addiction, vascular pathologies and cancers, are a source of difficulty and

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A mixed (quantitative and qualitative), multicentre, prospective study to develop and assess a peripheral venous catheter (PVC) placement algorithm.
- ⇒ A step-by-step process with control and experimental groups to analyse the practices, constraints and expectations of practitioners regarding PVC placement.
- ⇒ A 30-month study involving a large number of healthcare professionals.
- ⇒ An analysis based on semistructured individual interviews, data collection on care procedures, sociodemographic data and multiprofessional workgroups.
- ⇒ A multiphase study in which each phase must be blinded to subsequent ones to avoid spontaneous modifications in healthcare professionals' practice.

failure in vascular access placement and may result in the need for alternative puncture methods.³⁻⁷ The consequences on an individual and collective scale can be significant, with delays in care or prolonged hospital stays. For example, patients require a PVC showed systemic infections (rate: 0.5/1000⁸), infiltrations and venous thrombosis (23% and 12%⁹).¹ Additionally, multiple iterative punctures increase the risk for complications, such as haemorrhages and haematomas, local or systemic infections, skin or nerve damage, pain and psychological trauma and gas embolism.^{1-3 8-16} Complications associated with DIVA affect practitioners' workflow, particularly that of nursing staff responsible for providing this care. The feeling of incompetence inherent in failures and complications is also a source of discouragement for practitioners.¹⁷ Finally, in the current context of hospital tension, these daily difficulties can contribute to the increased pressures that



healthcare institutions encounter in terms of staffing turnover and economic level.¹⁸

Because of the frequency of DIVA and its related complications, substantial interest in this topic has arisen in the scientific community over the last decade, and the number of publications related to the subject has significantly increased.¹⁹ Van Loon *et al* developed and tested a scale called the A-DIVA Scale, for adults, to assess the risk of DIVAs in patients in 2016 (modified in 2019).^{15 16} The scale comprises five items (visibility of the vein, palpability of the vein, diameter of the vein, a history of DIVAs and the practitioner's expectation of difficult intravenous cannulation) and allows patients to be classified according to the risk of failed puncture (online supplemental table 1). The number of failures has been found to increase with the A-DIVA Score, suggesting the effectiveness of this scale in anticipating practitioner difficulties.^{16 20–22}

All the aforementioned studies mention the risks inherent in the placement and use of PVCs and the need to assess people likely to experience DIVAs along with presenting alternative solutions.^{23–25} However, these actions occur after failures in an unanticipated and non-consensual manner. The techniques and tools developed thus far only offer a partial solution to the problem of multiple punctures that they are intended to prevent. Before any evaluation or performance of this invasive procedure, it is imperative to develop an organisation for managing peripheral vascular accesses based on the individuality of each patient and the reality of the care sites, particularly for patients with DIVAs. This need could be met by developing a gradual and specific response to the issue of multiple punctures. Therefore, this project aimed to create and evaluate a specific algorithm consisting of a risk assessment (the A-DIVA Scale) and a co-construction decision-making tree (the A-DIVA Tree). The latter will consider the realities and possibilities of practitioners to respond to the need for risk prevention by anticipating the actions to be taken and avoiding bad decisions and disorganisation (an example of the A-DIVA Tree is provided in online supplemental figure 1). This decision-making tree would permit systematically (and without loss of time) the choice of the correct operator (with sufficient seniority and technical background) and a good technique linked to the individual patient assessment. With it, the risk of associated care complications (such as infections, haematomas, pain, psycho traumas, etc) would decrease, as would care time, human and economic costs.

This original algorithm would offer a complete system, improving patient safety by reducing the number of punctures required for PVC placement and their exposure to the associated risks.

OBJECTIVES, OUTCOMES AND HYPOTHESIS

Primary objective

The primary objective is to assess the effect of implementing a PVC placement algorithm versus standard care on the mean number of punctures per patient.

Primary outcome

Number of punctures performed per patient after implementation of the algorithm.

Primary hypothesis

Implementing and systematically using a management algorithm for patients requiring peripheral venous access will reduce the number of punctures needed per patient to achieve PVC placement.

Secondary objectives

1. To co-construct a catheter placement algorithm based on the venous access difficulty score.
2. To assess the acceptability and feasibility of using the A-DIVA Score in isolation and the score in conjunction with the catheter placement algorithm.
3. To describe how patients feel in terms of pain during care and overall comfort before and after the implementation of a catheter placement algorithm.
4. To evaluate the effect of implementing the venous access difficulty score on the average number of venipunctures per patient.
5. To assess operators' professional practices in terms of insertion technique.
6. To assess operators' professional practices in terms of number of operators required for catheter insertion.
7. To assess operators' professional practices in terms of frequency of second-line referral to another practitioner.
8. To assess operators' professional practices in terms of success or failure.
9. To evaluate the strategies implemented in the event of difficulties encountered when inserting PVC.

Secondary outcomes

1. Number of participants who approve the co-constructed algorithm.
2. To meet this objective, caregivers' appreciation, use and feelings regarding the vascular access difficulties score and algorithm will be measured using a 23-item questionnaire scored on a 4-point Likert scale ('strongly disagree', 'disagree', 'agree', 'strongly agree'). This questionnaire will also measure the effect of the vascular access difficulties score and the algorithm on practices.
3. Patient pain score measured immediately after vascular puncture (phase of potential acute pain during catheter insertion) using a self-assessment tool (numerical scale ranging from 0: no pain; 10: maximum pain).
4. Number of venipunctures performed per patient after implementation of the venous access difficulty score.
5. Insertion technique used for catheter placement.
6. Number of operators required for catheter insertion.
7. Frequency of second-line referral to another practitioner.
8. Number of successful/failed punctures.
9. Strategies implemented in the event of difficulties will be measured using a multimodality question (several

answers possible): call another practitioner, use an alternative insertion technique, choose another type of venous line and give up.

METHODS AND ANALYSIS

Clinical investigation design

This is a mixed (quantitative and qualitative), multicentre, non-randomised, quasi-experimental, before-and-after, open, cross-sectional study with control and experimental groups comprising three principal phases. The project's expected duration is 30 months, starting in September 2023 and ending in March 2026 (projected).

Phase I, the observational phase (4 months), will provide information on the actual practices (including the mean number of punctures for successful placement) and organisation. The main objective of this phase is to provide an in-depth and detailed description of existing practices for PVC placement in the centres using quantitative and qualitative data. Phase I relies on the principles of a feasibility study since the aim is to investigate the context to adapt the implementation of the intervention in development to the key context dimensions of healthcare and the health system, as recently recommended by the medical research council.²⁶ This phase will consist of a systematic collection of PVC placement practices to obtain quantitative data (point-of-care questionnaires) and individual semistructured clarifying interviews (until 16 interviews, 8 per centre) with professionals. The aim of the clarifying interview method is to encourage the verbal description of how a task is effectively realised. Verbalising is rarely descriptive, mostly refers to generalities, and almost never refers to how an action is realised. The principles of the clarifying interview method consist of focusing the participant on a single real situation (time and space situated) and directly encouraging the verbal elaboration of procedural action.²⁷ To apply a maximum variation sampling strategy, we identified the healthcare professionals to include in the semistructured interviews as the main dimension of variation. Thus, we included nurses, specialised nurses (anaesthetic nurses) and physicians attached to the department will be the nurses, specialised nurses (anaesthetic nurses) and physicians attached to the department.²⁸ The semistructured individual interview guide for professionals is shown in online supplemental figure 2.

Phase II, an interventional phase (4 months), aims to evaluate the impact of implementing the A-DIVA Scale alone (classification score for venous access difficulties) on practitioners' approaches to peripheral venous access placement. It consists of a systematic collection of peripheral venous access placement practices to obtain quantitative data (including the mean number of punctures for successful placement) and an ad hoc open-ended questionnaire on what is known, believed and achieved with the A-DIVA Scale.^{29 30} The main objective of this phase is to recognise the potential appearance of changes in practices through implementing a systematic assessment of

vascular access difficulties alone and optimising its implementation in the future.

The interphase (between phases II and III: 8 months) will allow us to analyse the data collected in phases I and II to develop the A-DIVA Tree. The scientific team (principal investigator and the Centre d'Investigation Clinique-Epidémiologie Clinique) will analyse the data. Then, two workgroups (one group with varied profiles of three to six practitioners per centre and the corresponding principal investigator) will co-construct the algorithm. Data will be submitted to the working group to inform the construction of the algorithm. In particular, discussions should enable us to define the organisation of PVC insertion in terms of care stratification, material and service resources. As operator's skills and seniority have a tangible impact on the success in placing PVC, this phase will also highlight the operator's characteristics needed to achieve the objective of reducing the average number of punctures per patient. The deliberations of the two working groups will be compared and reconciled and resubmitted to the two groups until complete validation.

Phase III, which is interventional (4 months), will allow the implementation and assessment of the effectiveness of the complete algorithm (A-DIVA Scale and A-DIVA Tree). It will consist of a systematic collection of PVC practices to obtain quantitative data (including mean number of punctures for successful placement), an ad hoc open-ended questionnaire and a satisfaction questionnaire (23 questions, Likert scales) addressed to professionals distributed at the end of phase III (see online supplemental table 2). The main objective of this phase is to evaluate the impact of the algorithm on the efficiency of PVC placement. The criterion for objectively determining the impact of the algorithm is the increase or decrease in the mean number of punctures required for the successful placement of the PVC.

The postprocessing phase (10 months) will allow the analysis of all the data (from phase I to phase III) to identify preliminary indicators of the process from the perspective of the deployment of the algorithm in the framework of a national implementation trial, the production of reports and scientific articles and the drafting of the final report of the algorithm for peripheral venous catheter placement (ALCOV) project.

The detailed study schedule is shown in [figure 1](#).

Investigators and practitioners

Two principal investigators will co-ordinate and lead the study (one per centre). They will not directly participate in the quantitative data collection.

All the local practitioners (nurses and physicians) will contribute to the data collection when performing a puncture for peripheral venous access (participant enrolment and point-of-care questionnaire completion).

Recruitment of patients

All eligible patients will be recruited after receiving information about the study and giving oral and written

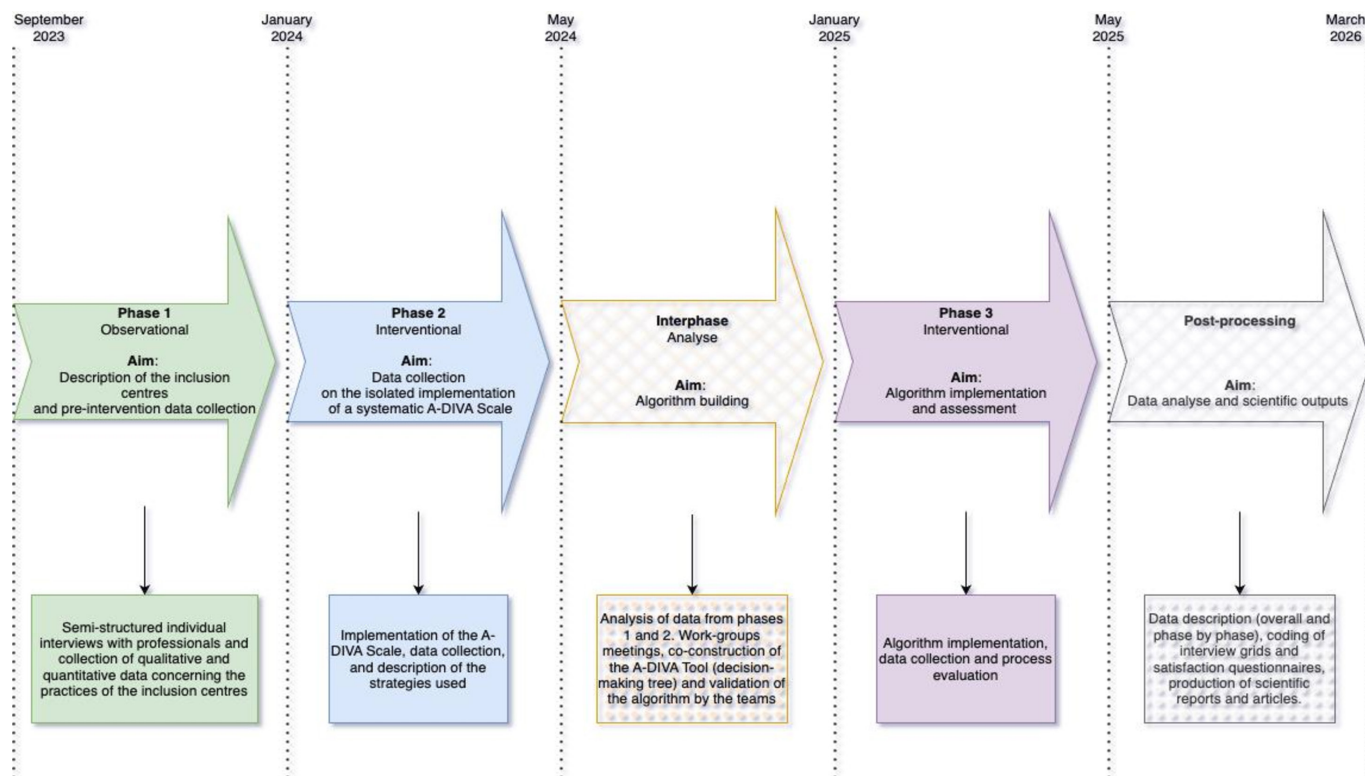


Figure 1 Description of estimated timeline. A-DIVA, adult difficult intravenous access.

consent (online supplemental figure 3). The inclusion and exclusion criteria are presented in [table 1](#).

Recruitment will take place at the University Hospital of Nancy (CHRU de Nancy) and Pont-à-Mousson Hospital. Given the nature of the study (based on the collection of the care procedure: placement of PVCs), some patients may be enrolled several times during the data collection period. They will be given a new anonymisation number for each procedure, and each inclusion will be considered as a single event.

Inclusion criteria	Exclusion criteria
Adult patient	Minor patients
Patients initially requiring at least one peripheral venous catheter (PVC)	Patients under curators or guardianship
Patients having given their consent for the study	Patients who are non-communicative or unable to give consent
	Patients not requiring a PVC, polytrauma patients and patients in shock (septic, haemorrhagic, cardiogenic, spinal, specific to certain centres and equipped upstream)
	Patients who already have catheters on arrival

We will include 794 patients over 12 months, made possible by the high potential for inclusion at the selected sites. For example, the operating theatre of CHRU de Nancy performs care activities requiring the placement of 100–150 PVCs per week (5000–7800 placements per year). At the Pont-à-Mousson emergency department, in 2018, 881 PVCs were placed within 3 months (over 3500 placements per year).

Nature of the collected data

The practitioners who perform the care will fill in the point-of-care questionnaire, allowing the collection of quantitative data related to the placement of PVCs. This dataset will provide an understanding of the functioning and issues of this care (phase I control group) and the impact of the introduction of tools (phase II, the A-DIVA Scale alone, and phase III, the A-DIVA Scale and the A-DIVA Tree) on the number of punctures required for the successful placement of PVCs. The content of the information given to practitioners will be adapted to minimise any impact on their behaviour during the punctures and any bias in declaration and interventions. Details of the collected quantitative data are provided in [table 2](#).

A human and social sciences research engineer will conduct semistructured interviews to collect practitioners' perspectives. The exchanges will be audio recorded, anonymously transcribed and stored on a secure server, accessible only by research team members ([table 3](#)).

Table 2 Description of quantitative data collected throughout the study

Quantitative data	Phase 1	Phase 2	Phase 3
Representativeness of the sample	X	X	X
Patient's age and gender	X	X	X
Workstation (Day, Night, Weekend)	X	X	X
Success or failure of the peripheral venous catheter placement	X	X	X
Number of punctures needed to place the peripheral venous catheter	X	X	X
Number of practitioners needed for the peripheral venous catheter placement	X	X	X
Function and seniority of the practitioner who placed the peripheral venous catheter (nurse, anaesthetic nurse, physician)	X	X	X
Pain assessment	Yes or Not*	Pain Scale	Pain Scale
Patient global comfort (Likert Scale)	No*	X	X
Difficulty of intravenous access	Described by the patient or identified by the practitioner	A-DIVA Scale	A-DIVA Scale
Alternative strategy for DIVA	Description of the chosen alternative	Description of the chosen alternative	Based on A-DIVA Tree

*Based on current practice.

Clinical procedure

Phases I–III

Patients who agree to participate in the study will receive, depending on the phase, PVC placement according to the protocol of the institution (ie, phase I) or an assessment of difficulties of vascular access risk (DIVA Scale) and PVC placement according to the protocol of the institution (ie, phase II) or a PVC placement according to the algorithm (A-DIVA Scale scoring and DIVA tool based decision for puncture, that is, phase III). After PVC placement, depending on the phase, the practitioner will complete the point-of-care questionnaire.

All the PVC placements during the study period will be annotated as to whether the patient was included in the study to evaluate the sample's representativeness. Each workstation will be equipped with a document allowing

the rapid tracing of all PVC placements. The procedure for collecting data from patients is shown in [figure 2](#).

Participation durations

Patients

The duration of participation for each patient corresponds to the necessary time to insert a PVC, which is between 5 and 60 min.

Practitioners

The duration of practitioners are as follows:

1. The mean duration of an individual semistructured interview is approximately 60 min.
2. Participation in a workgroup will also take 60 min.
3. Participation in satisfaction questionnaires at the end of the process is estimated to take 2–5 min.

Table 3 Description of qualitative data collected throughout the study

Modality	Phase	Qualitative data collected or analysed
Semistructured interview	1	<ul style="list-style-type: none"> ▶ Description of difficult venous access situations encountered and strategies developed to remedy them. ▶ Impact of the environment on the conduct of care, training and knowledge in the management of difficult venous access ▶ Obstacles or problems experienced.
Work groups	Interphase	▶ Analysis of the data collected in Phase 1 and 2.
Questionnaires	2	▶ Appreciation/feeling of practitioners (Likert scale on acceptability, feasibility, use and effect on practice).
	3	<ul style="list-style-type: none"> ▶ Appreciation/feeling of practitioners (Likert scale on acceptability, feasibility, use and effect on practice). ▶ End-study questionnaire with twenty-three statements requiring a description regarding the level of adherence.

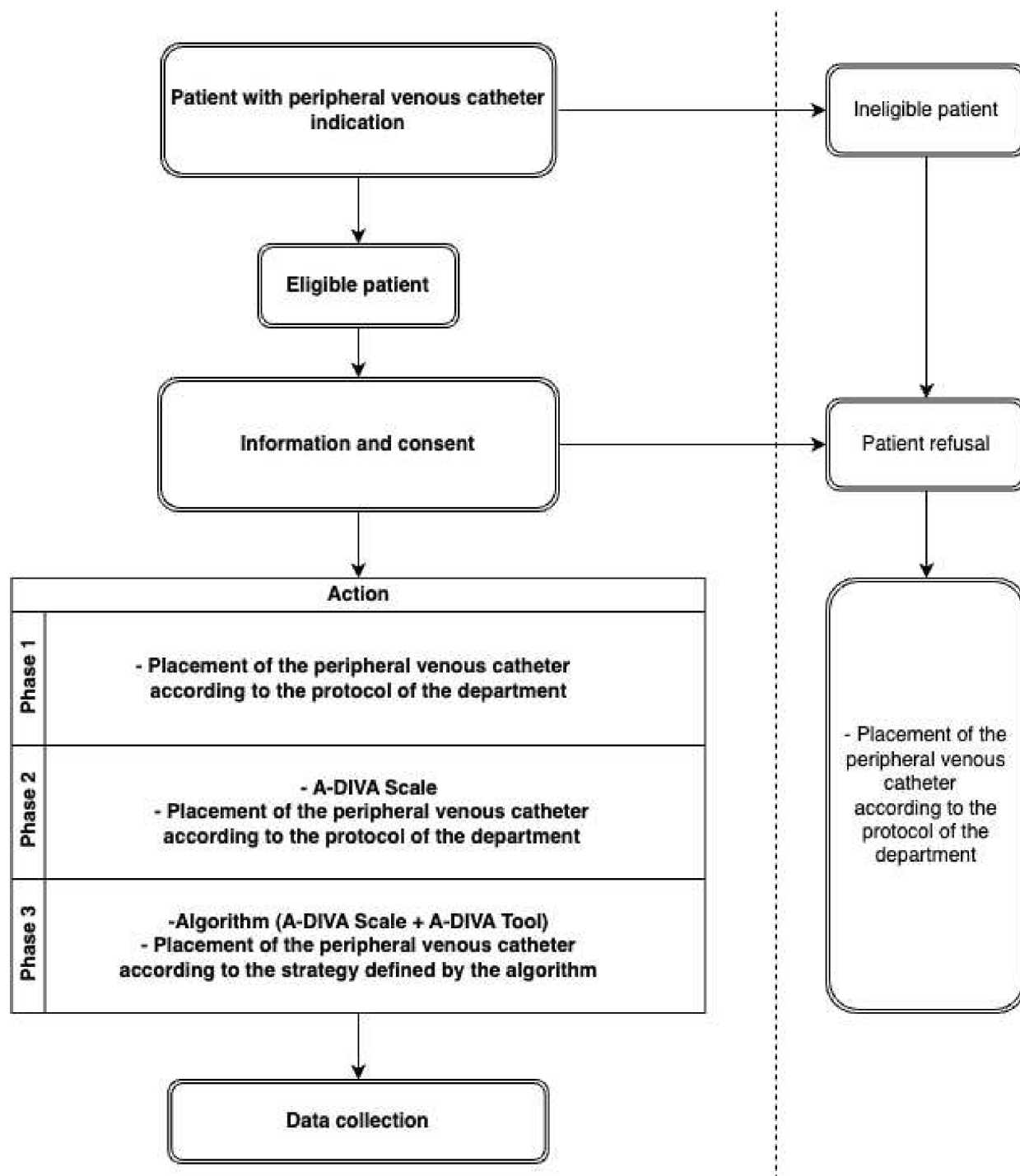


Figure 2 Clinical procedure flowchart. A-DIVA, adult difficult intravenous access.

4. The characteristics of the study phases are summarised in online supplemental table 3.

Statistical design

Sample size justification

Van Loon *et al* found a mean number of punctures per patient of 1.3.¹⁶ With an alpha risk of 5%, a power of 80%, an SD of 0.85 and a two-sided formulation of the hypotheses, 564 patients are needed to show a 15% decrease in the mean number of punctures per patient following the implementation of the

algorithm (we believe that a 15% decrease would be clinically relevant). Assuming that 5% of patients could be excluded, 594 patients should be included. The two inclusion centres will divide these patients equally (50/50). This number of subjects was calculated to meet the primary objective (comparison of the mean number of punctures per patient in phase I to phase III).

To be able to carry out phase II and meet specific descriptive secondary objectives (description of the effect

of the implementation of the venous access difficulty scale on the mean number of punctures per patient), 200 other patients (100 per centre) will be included for the phase II study. This number of patients will allow sufficiently accurate estimates of the measured data.

Overall, 794 patients will be included in the study.

In addition, health practitioners will be included to conduct 16 individual semistructured interviews. Data saturation is achieved when concepts and subconcepts cannot be further specified with additional data. Data collection in the context of inductive thematic analyses occurs until saturation point.³¹ We chose to estimate sample size based on literature without assessing and reporting thematic saturation using a calculation approach such as the one proposed by Guest *et al.*³² A number of interviews ranging from 11 to 20 corresponds to a satisfactory sample size for qualitative studies to obtain satisfactory findings.^{33–35} We reached thematic saturation with the inclusion of 13 participants. With narrowly defined objectives, as is the case in our study, saturation can be achieved with a relatively small sample size.

Statistical analyses

Preliminarily, we will verify variable distributions, assess outliers, check for errors in coding and check for missing data. Characteristics of the study sample and outcomes (patient and centre characteristics, puncture data, pain and comfort score) will be described as the mean (SD) or median (Q1; Q3) for quantitative variables (according to their distribution) and the number (%) for qualitative variables. Characteristics of the sample and outcomes will be reported per phase. Characteristics of the sample will be compared between phases using analysis of variance or the Kruskal-Wallis test for quantitative variables and χ^2 or Fisher's exact test for qualitative variables.

Then, the effect of the implementation of the algorithm (phase III vs I) and of the A-DIVA Scale (phase II vs I) on the mean number of punctures per patient will be evaluated using multilevel linear regression models (levels=centres and practitioners). First, crude models will be conducted. Then, models will be adjusted for potential confounding factors (sociodemographic and/or clinical characteristics of patients). The analyses will be conducted on an intention-to-treat basis. In case of missing data, the maximal bias hypothesis will be assumed. No intermediate analysis will be planned. If deviations from the algorithm are observed, a per-protocol analysis will be performed, considering only patients for whom there was no deviation.

The data from the interviews will be audio recorded and integrated. We will follow a general inductive approach to proceed to a descriptive thematic analysis.³⁶ Thus, we will identify themes from the participant discourse to properly capture their perception of the obstacles and levers during the implementation of the algorithm.³⁷ Data will be double-encoded to ensure the reliability of the qualitative analysis. Disagreement

between the two coders will be resolved by discussion to reach a kappa value from at least 0.81 per category. Data analysis will be performed using NVivo V.11. The same overall methodology orientation for the thematic analysis process will be applied to study the answers to the open-ended questions in phases II and III.

These data will be compared according to phase (I, II or III) using an expected level of statistical significance at 0.05. The analyses will be conducted in R.

Ethics and dissemination

Ethical permission

Personal data related to the study's participants will be processed.

These data will be collected and processed solely on the legal basis provided for by the regulations in the context of the performance of the CHRU de Nancy's public interest missions, in particular those related to ensuring and contributing to research and innovation (Article 6.1 in paragraph of the RGPD).

Per Article L.1122-1 of the CSP, each person will receive information before receiving any specific experimental procedure. This information will be summarised in a written document to the person whose consent is sought. The patient's consent will be obtained orally and in writing, dated and signed.

In accordance with Article L.1123-6 of the Public Health Code, the research protocol has been submitted by the promotor to the Institutional Review Board (Comité de Protection des Personnes (CPP)). The study and related consent forms were approved by CPP Sud-Méditerranée I on 25 April 2023 with reference number 2023-A00223-42. The study has also been registered in the clinicaltrials.gov registry under the trial number NCT05935228.

Protocol amendment

The sponsor will send requests for substantial modifications to the relevant regulatory authorities for authorisation and/or advice.

Data curation

Personal data relating to the participants will be stored in the information systems of the sponsor, the investigating centre or the practitioner involved in the investigation until the product studied is placed on the market or 2 years after the last publication of the results of the research or, in the absence of publication, until the final report of the study is signed. They will then be archived on paper or on a computer for the period of time required by the regulations in force.

Dissemination

This study will assess the relevance of using an ALCOV. First, these results will be disseminated in the form of an original article. Subsequently, they will enable the design of a national clinical implementation trial assessing the impact of the algorithm on the number of punctures (especially for patients with difficult venous



accesses). Finally, this work could provide some guidelines to improve the security and quality of care.

Data monitoring

The level of monitoring is adapted and weighted according to the estimated risk for the person undergoing the research and the logistical complexity, resources and impact of the research results. The monitoring visits (implementation, follow-up and closure) will be conducted by the Research and Innovation Department of CHRU de Nancy (or a representative of the sponsor mandated for this purpose). They will be conducted in accordance with the monitoring plan specific to the research and adapted to the level of monitoring previously defined, as well as the standard operating procedures. Depending on the monitoring reports and the deviations observed, the sponsor reserves the right to modify the planned monitoring level.

Risk and benefits assessment

Potential risk

Potential risk is placing PVCs is an invasive procedure, which leads to skin and vascular injuries. The risks inherent in this treatment are numerous, with more or less severe and more or less frequent impacts, for example, discomfort/pain, skin/nerve/vascular lesions, oedema, haemorrhages, infections, haematomas, psychological trauma, fear/anguish and gas embolism.^{19 10 13 14 38 39} Most of these consequences are minimal and are resolved almost instantaneously in a few minutes to a few days. In sporadic cases, complications may arise that require management that was not initially planned. The individual and collective (family, caregiver, economic) impacts could then be significant. No risk inherent in the puncture should be ascribed to the study because the patients included in the study are to receive a PVC as part of their care. Alternative PVC placement techniques are commonly used as part of routine care.

Anticipated clinical benefits

Benefits for patients

The implementation of the algorithm should optimise patient care with an expected decrease in the duration of care, a reduction in pain and discomfort (by reducing the number of punctures and adding a pain and comfort scale) and a reduction in risks (haemorrhagic, infectious, delays in care, psychological trauma).

Benefits for practitioners

A valuation of skills and experiences and a reduction in exposure to the risk of failure through the use of adapted tools should be the source of increased confidence and competence for practitioners.

Institutional benefits

The puncture-related costs will decrease due to reduced material consumption, a decrease in the number of

undesirable events, workflow improvement and a reduction in the time dedicated to the puncture.

Benefit–risk ratio

The benefit–risk ratio analysis indicates that this study is of significant interest. It presents few additional inconveniences (lengthening the procedure for completing the point-of-care questionnaire by a few minutes) on top of the standard procedure. Nevertheless, it proposes improvements likely to reduce the individual and collective risks incurred.

Final research report

The principal investigator and the mandated biostatistician will collaboratively write the final research report. This report will be submitted to each of the investigators for review. Once a consensus has been reached, the final version will be endorsed with the signature of each of the investigators and sent to the promoter as early as possible after the effective end of the research.

Patient and public involvement

We did not involve patients or the public in the design, conduct or reporting of our research.

DISCUSSION

This study aims to develop and evaluate an algorithm for decreasing the mean number of punctures per patient during the placement of PVCs. The collection of preliminary indicators from the ALCOV Study will also be used to optimise the parameters of a future national implementation trial in care services.

The first limitation of this study is that the participant practitioners will be solicited over a long period (three data collection phases of 4 months each and working groups during the interphase). The duration is sample size adjusted but may lead to a decrease in their interest in the study. Regular requests and progress reports are planned to prevent the participant practitioner's disinterest. Displays will be used as anchor points to facilitate the use and understanding of the study tools. The practitioners' feelings will be collected throughout the phases and will serve as a barometer to adjust the necessary follow-ups. Last, the variety of requests (workgroups, individual semistructured interviews) and the involvement of practitioners in decision-making will promote mobilisation.

The second possible limitation of this study is related to the practitioners' knowledge of the purpose of the study. Indeed, there is a risk that they will anticipate and thus modify their practices, making the data and interpretations obsolete. To address this difficulty, each stage will be blind to the next, with practitioners only being aware of the details of the phase in which they will be involved. Thus, their understanding of

the project will be built up step by step until a global vision is achieved in phase III.

This project aims to develop a prevention-based approach to optimise PVC placement. Catheter placement is the most common invasive intervention in hospitals, and the results may lead to a major improvement in the quality and safety of PVC placement.

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Contributors CS: Creation and development of the original idea, bibliography, methodological and scientific analysis, drafting and correction of the protocol and study tools; FM: quantitative and statistical methodological analysis and correction of the protocol; LR: qualitative methodological analysis and correction of the protocol; AO: drafting and development of ethical and regulatory aspects and proofreading of the protocol; SK: development, correction and drafting of the protocol and development of partnerships; HB: construction of the project, development of partnerships, scientific analysis and proofreading of the protocol; and GA-G: methodological and scientific analysis, drafting and correction of the protocol and linguistic aspects.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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Supplementary Table 1: Representation of the modified A-DIVA Scale by Van Loon et al.

Item	Assessment		Score
	Value	Value	
	YES	NO	
Nonvisible vein after tourniquet placement	1	0	0 to 1 Low-risk group
Nonpalpable vein after tourniquet placement	1	0	2 to 3 Moderate-risk group
Vein diameter less than 3 mm	1	0	
Practitioner's expectation of a difficult intravenous access	1	0	4 plus High-risk group
History of a difficult intravenous cannulation	1	0	

Supplementary Table 2: End-study satisfaction questionnaire proposal (minor changes may occur depending on the early phases of the study).

Theme	Totally disagree	Disagree	Agree	Totally agree
1. You were aware that you were participating in a study on the organization and optimization of the placement of peripheral venous lines.				
2. Overall (throughout the process), you found this project interesting.				
3. In your opinion, this study has had a lasting effect on your practice of placing peripheral venous catheters.				
4. In your opinion, this program allows for a real improvement in patient management in the context of peripheral venous catheter placement				
5. The fact that the risk of vascular access difficulties is rated allows for the optimization of patient management during the placement of peripheral venous catheters				
6. Using a graded management algorithm for peripheral venous catheter placement improves the quality of patient care				
7. Using a graded management algorithm for peripheral venous catheter placement decreases management time				
8. Using a graded management algorithm for peripheral venous catheter reduces the number of punctures required to perform the procedure				
9. The use of a graded management algorithm during the placement of a peripheral venous catheter reduces the discomfort and pain generated by the procedure				
10. Using a graded management algorithm during the placement of a peripheral venous catheter improves the quality of the relationship with the patient during care.				
11. The tools proposed during this study have enabled you to develop new skills				
12. The implementation of this protocol has enabled you to anticipate difficulties during the placement of peripheral venous catheter optimally				
13. The use of this protocol has enabled you to find the necessary resources in case of difficulty				
14. The use of this protocol for the management of peripheral venous				

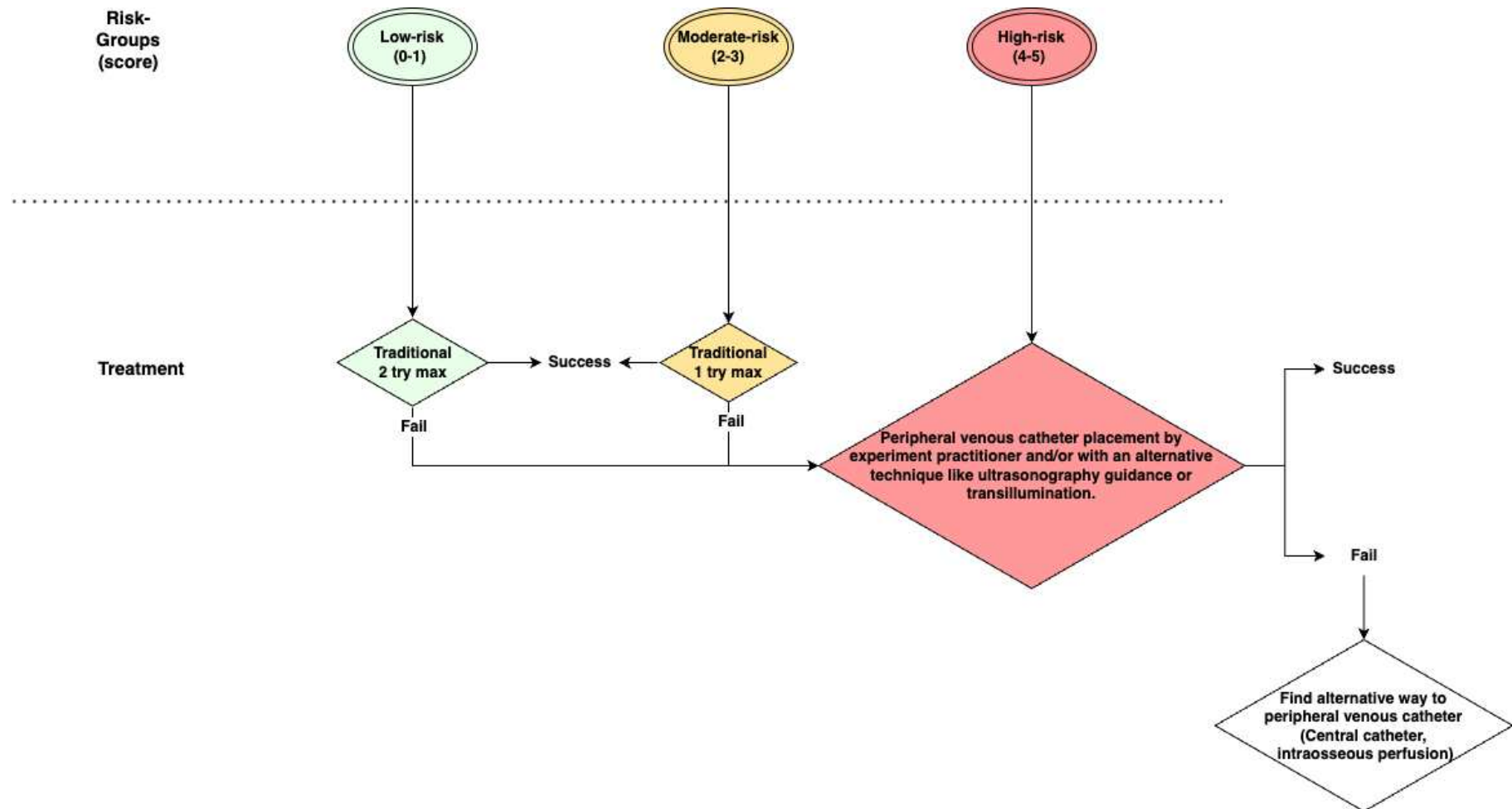
catheters optimizes the resources of nursing staff				
15. The implementation of this care protocol in your department has optimized collaboration between healthcare providers				
16. This protocol for the management of peripheral venous catheters has made you want to develop new skills				
17. You think that this protocol should be applied to all departments that insert peripheral venous catheters				
18. You think this protocol should be developed nationally				
19. You found the pain score easy to set up and use				
20. You found the implementation and use of the algorithm easy				
21. The proposed algorithm is adapted to the functioning and possibilities of your service				
22. You will continue to use this protocol when placing peripheral venous catheters in the future				
23. You think that this protocol allows you greater autonomy in the placement of peripheral venous catheters				

Supplementary Table 3: Characteristics of the study phases

Phase	Duration	Type	Aim	Measurement method	Inclusion	Analysis
1	4 months	Observational	- Provide an in-depth and detailed description of existing practices for peripheral venous catheter placement in the centers.	- Semi-structured individual interviews with professionals - Systematic collection of peripheral venous catheter placement practices by using point-of-care questionnaires.	- 16 healthcare professionals (8 per center) - 297 patients included (149 per center)	Descriptive thematic analysis. Description of characteristics of the study sample and outcomes (patient and center characteristics, puncture data, pain and comfort score): mean (SD) or median (Q1; Q3) for quantitative variables (according to their distribution) and the number (%) for qualitative variables.
2	4 months	Interventional	- Evaluate the impact of implementing the A-DIVA scale alone on practitioners' approaches to peripheral venous access placement.	- Systematic collection of peripheral venous catheter placement practices by using point-of-care questionnaires. - Ad hoc open-ended questionnaire on what is known, believed, and achieved with the A-DIVA scale	- 200 patients included (100 per center) Healthcare professionals of the center who used the A-DIVA Scale	Description of characteristics of the study sample and outcomes (patient and center characteristics, puncture data, pain and comfort score): mean (SD) or median (Q1; Q3) for quantitative variables (according to their distribution) and the number (%) for qualitative variables.

Interphase	8 months	NA	- Algorithm building.	- Analysis of data from phases 1 and 2 by the scientific team - Workgroup meetings, co-construction of the algorithm and validation by the teams	- 2 workgroups (1 group per center) of 3 to 6 healthcare professionals (included the principal investigator of the center)	NA
3	4 months	Interventional	- Evaluation of the impact of the algorithm on the efficiency of peripheral venous catheter placement.	- Systematic collection of peripheral venous catheter placement practices by using point-of-care questionnaires. - Ad hoc open-ended questionnaire on what is known, believed, and achieved with the A-DIVA scale - Satisfaction questionnaire (23 questions, Likert scales) addressed to professionals distributed at the end of phase 3	- 297 patients (149 per center) - Healthcare professionals of the center who used the algorithm	NA
Postprocessing	10 months	NA	Data analyse and scientific outputs	-Data description (overall and phase by phase) - Coding of interview grids and satisfaction questionnaires - Production of scientific reports and articles.	Scientific team	- Comparisons of characteristics of the sample between phases 2 and 1, and phases 3 and 1: analysis of variance/ Kruskal–Wallis test for quantitative variables, and Chi ² / Fisher's exact test for qualitative variables. - Effects of the implementation of the algorithm (phase 3 versus 1) and of the A-DIVA scale (phase 2 versus 1) on the mean number of punctures per patient will be evaluated using multilevel linear

regression models (levels = centers and practitioners): crude and adjusted multilevel linear regression models. Intention-to-treat and per-protocol (if protocol deviations are observed) analyses.



Supplementary Figure 1: Example of a decision-making tree that **could be** coconstructed in the interphase

Semi structured individual interview guide for professionals

Theme 1:

- Can you describe the characteristics of the difficult vascular access (DIVA) situations you encounter in your daily practice?

1.

2.

3.

4.

5..... Etc.

- Can you think of others that are less frequent?

Note: the interviewer will fill in the situations and investigate the practices of the careers for each situation encountered, which corresponds to the meaning of the explanatory interview (breaking down the structure of a complex task in a precise rather than general manner).

Theme 2:

- For each situation, can you describe precisely what you are doing and with whom (alone, in pairs, or in trios, and how the tasks are divided up)?

- What tips and tricks do you use (risk anticipation strategies) to manage these situations?

- For each situation, what difficulties might you encounter?

Theme 3:

- How do you feel you are supervised in the management of DIVA in your department?

- How do the care procedures in force in the department impact your DIVA practice?

Theme 4:

- How does the organization of the department affect the way you manage DIVA? (For example: staff present [number and duties/qualifications], position and working hours, presence of a student)?

Theme 5:

- Think about the place where you work most often and if it had to be reorganized to make it easier to deal with DIVAs. What would you do?
- What do you think of the type of equipment available to you? To what extent do you consider this equipment quantitatively sufficient?

Theme 6:

- Have you ever taken any training courses in this area? If so, in what context? Moreover, what did they teach you? Have you done any other research? If so, how, why, and what did you learn?

Theme 7:

- Are there any things you would like to do now but cannot?

Theme 8:

- Are there any other things you would like to tell me about your DIVA practices?

Supplementary Figure 2: Semi structured individual interview guide for professionals

Promoteur : CHRU de Nancy

Recherche : ALCOV

N°EudraCT / N°ID-RCB : 2023-A00223-42

CE participant en capacité de consentir version N°1.0 du 31/03/2023

**FORMULAIRE DE CONSENTEMENT
PARTICIPANT EN CAPACITE DE CONSENTIR**

A DESTINATION DES PATIENTS

Les détails concernant cette recherche impliquant la personne humaine vous ont été communiqués par l'investigateur et vous ont été remis dans un document d'information spécifique.
Après avoir lu ce document et après avoir posé toutes les questions utiles à l'investigateur, si vous acceptez de participer à cette recherche, veuillez compléter le formulaire de consentement ci-dessous.

Titre complet de la Recherche : Elaboration et évaluation d'un algorithme dans la prise en charge des abords vasculaires – Etude pilote

Titre court de la Recherche : ALCOV

Investigateur coordonnateur : M. Côme SLOSSE, Infirmier anesthésiste, Bloc Opératoire Lepoire, CHRU de Nancy

Nom et adresse du Promoteur (le responsable du traitement des données) : CHRU de Nancy, dont le siège social est situé au 29, avenue du Maréchal de Lattre de Tassigny – 54035 NANCY cedex, représenté par son Directeur Général en exercice.

Promoteur : CHRU de Nancy

Recherche : ALCOV

N°EudraCT / N°ID-RCB : 2023-A00223-42

CE participant en capacité de consentir version N°1.0 du 31/03/2023

Partie à remplir par le(la) participant(e), de sa propre main	
Prénom du/de la participant(e) en majuscules	
Nom du/de la participant(e) en majuscules	
Je consens librement à participer à cette recherche, telle que décrite dans le document d'information et je confirme les points suivants :	
<ul style="list-style-type: none"> • J'ai eu le temps de lire le document d'information, de réfléchir à la recherche et j'ai obtenu des réponses appropriées à mes questions. • J'ai bien été informé(e) de la nature des objectifs de cette recherche, des risques potentiels et des contraintes liées à cette recherche. • Je certifie être affilié(e) à un régime de sécurité sociale ou bénéficiaire d'un tel régime, sauf dérogation exceptionnelle. • Je déclare que je ne suis pas placé(e) sous un régime de protection juridique des majeurs (sauvegarde de justice, curatelle ou tutelle) et visé(e) actuellement par une procédure tendant à cette fin. • J'ai le droit de refuser de participer à la recherche ou de retirer mon consentement à tout moment sans conséquence sur ma prise en charge médicale et sans encourir aucune responsabilité ni préjudice de ce fait. • J'ai bien compris la possibilité qui m'est réservée d'interrompre ma participation à cette recherche à tout moment sans avoir à justifier ma décision et j'informerai l'investigateur qui me suit dans la recherche. Cela ne remettra pas en cause la qualité des soins ultérieurs. • J'ai bien compris que l'investigateur peut interrompre à tout moment ma participation à la recherche s'il le juge nécessaire. • J'ai bien noté que je dispose d'un droit d'accès, de rectification, de limitation et, le cas échéant, d'opposition et d'effacement, concernant le traitement de mes données personnelles. Ces droits s'exercent en premier lieu auprès de l'investigateur qui me suit dans le cadre de cette recherche et qui connaît mon identité. • J'ai bien pris connaissance que cette recherche a reçu l'avis favorable du Comité de Protection des Personnes Sud Méditerranée I le 24/04/23. Le promoteur de la recherche a souscrit une assurance de responsabilité civile en cas de préjudice auprès de la société Relyens Mutual Insurance – 18 rue Edouard Rochet – 69 372 LYON Cedex 08 – Tél : 04 72 75 50 25, sous la référence 164437. • Mon consentement ne décharge en rien l'investigateur et le promoteur de la recherche de leurs responsabilités à mon égard. Je conserve tous mes droits garantis par la loi. • Les résultats globaux de la recherche me seront communiqués à la fin de la recherche, si j'en fais la demande auprès de l'investigateur. • Après le commencement de la recherche, je pourrai à tout moment demander des informations complémentaires à l'investigateur qui me suit dans le cadre de cette recherche. • Deux exemplaires de ce formulaire de consentement ont été établis : un m'a été remis, le second gardé par l'investigateur. Celui-ci sera conservé dans le dossier de la recherche au minimum 15 ans après la fin de la recherche. • J'ai été informé(e) sur la façon dont mes données personnelles pourront être collectés, utilisés et partagés comme décrit dans le document d'information. 	

Promoteur : CHRU de Nancy

Recherche : ALCOV

N°EudraCT / N°ID-RCB : 2023-A00223-42

CE participant en capacité de consentir version N°1.0 du 31/03/2023

CONSETEMENTS OPTIONNELS	
<p>Sachant que je peux à tout moment retirer mon accord, j'accepte que mes données personnelles codées soient utilisées, par le CHRU de Nancy ou par des partenaires disposant d'une convention avec le CHRU de Nancy, pour d'autres recherches liées à la santé ou à la médecine, exclusivement à des fins scientifiques relatives à la prise en charge des abords vasculaires ou dans le cadre d'études de validation de procédés ou de technique de contrôle qualité ou d'études de biovigilance.</p> <p>Je peux consulter la liste des recherches menées à partir de mes données et/ou échantillons biologiques en consultant le site du CHRU de Nancy : http://recherche.chru-nancy.fr (rubrique Les recherches / Études en cours et Les structures / Centre de ressources biologiques).</p>	<input type="checkbox"/> OUI <input type="checkbox"/> NON
Signature du/de la participant(e)	Date de signature :

Partie à remplir par l'investigateur ayant informé le/la participant(e), de sa propre main	
Signature	Date de signature
PRENOM en majuscules	
NOM en majuscules	
Nom de l'établissement	
Service :	
Téléphone :	

Supplementary Figure 3: Consent Form