


BMJ Open From hospitalisation to primary care: integrative model of clinical pharmacy with patients implanted with a PICC line – research protocol for a prospective before–after study

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ABSTRACT

Introduction Clinical pharmacy improves patient safety and secures drug management using information, education and good clinical practices. However, medical device management is still unexplored, and proof of effectiveness is needed. A PICC line (peripherally inserted central catheter) is a medical device for infusion. It accesses the central venous system after being implanted in a peripheral vein. However, complications after implantation often interfere with smooth execution of the treatment. We hypothesise that clinical pharmacy for medical devices could be as effective as clinical pharmacy for medications. The main objective is to assess the effectiveness of clinical pharmacy activities on the complication rate after PICC line implantation.

Methods and analysis This is a before–after prospective study. The study will begin with an observational period without clinical pharmacy activities, followed by an interventional period where pharmacists will intervene on drug and medical device management and provide personalised follow-up and advice. Sixty-nine adult patients will be recruited in each 6-month period from all traditional care units. The main inclusion criteria will be the implantation of a PICC line. The primary outcome is the decrease in the number of complications per patient and per month. Secondary outcomes are the consultation and hospital readmission rates, the acceptance rate of pharmaceutical interventions, the patients' quality of life, the direct hospital induced or avoided costs and the participants' satisfaction. Data will be collected using case report forms during hospitalisation and telephone follow-up after discharge. The analysis will compare these criteria during the two periods.

Ethics and dissemination The study has received the approval of our Ethics Committee (Clermont-Ferrand Southeast VI, France, number AU1586). Results will be made available to the patients or their caregivers, the sponsor and other researchers when asked, as described in the consent form.

Trial registration number NCT04359056.

INTRODUCTION

Clinical pharmacy is a patient-centred health discipline whose practice aims to optimise

Strengths and limitations of this study

- This is the first study to assess the effectiveness of clinical pharmacy interventions for medical devices.
- As a primary objective, strong clinical criteria will be evaluated by measuring skin redness or fever (as signs of an infection), oedema, thrombosis and pain.
- This study proposes an integrative model of clinical pharmacy, from hospitalisation to primary care.
- The main limitations of this study are the lack of randomisation and the lack of blinding for patients and healthcare professionals.

therapy at each stage of the care pathway. Clinical pharmacy actions contribute to patient safety and the relevant and efficient use of health products.¹ To ensure health products are used in a safe and appropriate manner, pharmacists analyse physicians' orders to identify errors or potentially inappropriate prescriptions based on guidelines and evidence-based medicine. Moreover, they optimise drug intake, inform patients and caregivers, organise the discharge to primary care and disseminate clinical good practices. Pharmacists also focus on patient education, information and training for healthcare professionals.

Regarding medication approaches, the effectiveness of clinical pharmacy is well known. Several clinical studies have demonstrated significant impacts on rehospitalisations,^{2–5} drug management⁶ and treatment compliance,⁷ patients' quality of life⁸ as well as a decrease of iatrogenic risk.^{9–12} However, studies on clinical pharmacy in the context of medical devices (MDs) are rare.¹³ To our knowledge, no study has described the clinical impact of a pharmacist's intervention when an MD is implanted in patients. Only

one recent article refers to clinical pharmacy in dressings for complex wounds.¹⁴ The need for further clinical studies is undeniable.

MD classification is based on their risk of invasiveness and duration of use. Infusion equipment, such as catheters, can induce iatrogenic events, especially infections.^{15 16} Peripherally inserted central catheters (PICC lines) are associated with numerous clinical (eg, infections¹⁷) and mechanical complications (eg, catheter occlusions).^{18–27} PICC lines are useful for the administration of irritating products or for the repeated collection of blood samples. PICC lines are recommended when the duration of catheterisation ranges from 7 days to 3 months.²⁸ PICC line implantations are carried out in the interventional radiology operating room.

Our working hypothesis is that clinical pharmacy interventions will prevent clinical and mechanical complications and thereby reduce hospital costs.²⁹ Reducing complications could also prevent its consequences such as rehospitalisations³⁰ and physician visits.

METHODS AND ANALYSIS

A scientific committee (selected by the Research and Innovation Board of the Toulouse University Hospital) composed of scientific and methodological experts and statisticians oversaw the feasibility and methodology of the study. This committee ensures the quality and relevance of the research organisation. The study procedures and assessments comply with the Standard Protocol Items: Recommendations for Interventional Trials³¹ checklist.

Design

A pragmatic single-centre design is used. This is a before–after prospective study with two consecutive phases: observational (no clinical pharmacy activities) and interventional (execution of clinical pharmacy activities and logistics optimisation). Randomisation of patients is not possible in this study due to the high risk of contamination bias. Once the clinical pharmacist arrives in the care unit, he or she should address any medical apprehension by the PICC prescribers and nurses, explaining good clinical use, affecting all the future study patients, even the control group. This is an open study. Due to the nature of the pharmaceutical interventions, blinding is not possible for patients and care providers.

Setting

The study will take place in the Toulouse University Hospital Center. Every PICC line prescription will be picked up in the interventional radiology unit, and patients will be screened for eligibility. Patients will be recruited from their hospital ward prior to the PICC line insertion. All selected participants will be asked to read and sign a consent form (online supplemental file). Each phase (observational and interventional)

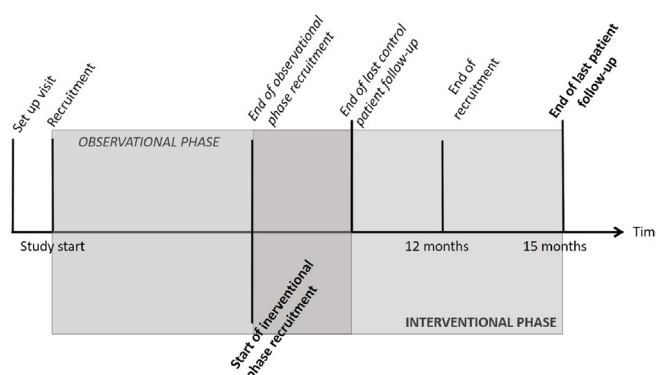


Figure 1 Study design.

will last approximately 9 months taking into account recruitment and patient follow-up. See figure 1 for the study timeline.

Recruitment began on Monday, 25 May 2020 and will end 1 year later on 25 May 2021. The study is scheduled to end on 25 August 2021.

Characteristics of participants: inclusion and exclusion criteria

Eligibility criteria are listed in table 1. For all included patients, the Charlson Comorbidity Index³² will be used to assess the degree of comorbidity at baseline.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	<p>Adult patient, 18 years of age or older.</p> <p>Patient capable of giving free and informed consent.</p> <p>Patient insured by the Social Security System in France.</p> <p>Patient living at home.</p> <p>Patient with a PICC line prescription.</p> <p>Patient whose discharge prescription should contain drugs and MDs.</p> <p>Patient for home discharge implanted with a PICC line.</p> <p>Patient reachable by phone.</p>
Exclusion criteria	<p>Under-aged patient, less than 18 years old.</p> <p>Patient not insurance by the Social Security System in France.</p> <p>Patient not living at home:</p> <ul style="list-style-type: none"> Institutionalized patient. Patient living in a facility for elderly dependent persons. Nursing home resident. ‘Hospital at Home’ patient. <p>Patient deprived of their freedom by a judicial or administrative decision.</p> <p>Patient under guardianship, curatorship or safeguard of justice.</p> <p>Patient unreachable by phone.</p> <p>Pregnant or breastfeeding women.</p>

MDs, medical devices; PICC, peripherally inserted central catheter.

Patient and public involvement

No patient involved.

Process

Regardless of the phase of the study, the occurrence of complications due to the PICC line will be recorded during hospitalisation and at home during a follow-up phone call. Patients are monitored for the entire duration of the PICC line implantation or for a maximum of 3 months. Data will be collected at days 3 and 7 (D3 or D7, respectively) after implantation and then after 1, 2 and 3 months (M1, M2 and M3, respectively).

The control period corresponds to usual care and represents the observational phase, where no pharmaceutical interventions will be done, unless necessary for the patient's safety (eg, life-threatening situations³³).

One participant can be included in only one phase. The interventional phase will start when the last patient is included in the observational phase. Physicians and nurses, as well as other healthcare professionals, will attend training sessions on updates, recommendations, indications and maintenance related the use of PICC lines. If necessary, training sessions will be repeated once to make sure the research team met all the healthcare professionals involved.

Two pharmacists and a pharmacy resident will participate in each phase.

The table 2 describes the research procedures and activities in the two phases.

At the end of the study, a satisfaction survey will be sent to every participant (patients and caregivers).

Outcomes and expected benefits

Primary outcome

The primary outcome is the number of complications per patient and per month. Complications will be documented on specific forms to harmonise data collection. Mechanical complications are defined as obstruction or occlusion,¹⁸ breakage or damage to the catheter,²⁷ migration³⁴ or dislodgment (accidental withdrawal) of the catheter.³⁵ Clinical complications are defined as redness around the insertion site (diameter >2 cm), oedema (size difference between the two hands), pain (numeric rating scale) and fever (internal temperature >37°C) as signs of an infection^{17 36} and thrombotic events³⁷ (confirmed by a medical modality such as echography).

Secondary outcomes

The number of consultations and rehospitalisations post-discharge will be used to determine the clinical impact beyond the initial hospitalisation.^{11 38–40} The expected result is a decrease in the consultation and rehospitalisation rates at the end of the intervention phase compared with the observation phase.

The acceptance rate of pharmaceutical interventions during the interventional phase is used to assess the appropriateness of pharmaceutical interventions.^{41–45} A higher acceptance rate means the pharmaceutical interventions

are justified and relevant to the care providers. The criticality of the pharmacist's intervention⁴⁶ will be evaluated. Moreover, conformity of the hospital prescriptions for primary care after the discharge will be assessed. The aim is to avoid treatment breaks.

Another secondary outcome involves the conformity analysis of the PICC line logistics circuit (checklist related to stock, supply chain and traceability). Management of the hospital supply chain is a major financial challenge⁴⁷ and generally leads to decreased treatment risk and costs.⁴⁸ The objective is to streamline the various stages of the PICC line logistics circuit, from ordering to implantation. By streamlining the logistics, improved patient safety and reduced costs are expected.

The conformity of the PICC line indication will be evaluated according to recommendations.⁴⁹ Prescriptions too often seem to be trivialised and little guided by attending doctors. Therefore, errors are possible. The aim is to improve the team's knowledge and the communication between hospital units.

The patients' quality of life before and after the follow-up will be measured with the EQ-5D-5L questionnaire.⁵⁰ As previously described by Andrade *et al*,⁵¹ a standard value set for converting the profiles on the five dimensions onto a score will be used.

An improvement in the quality of life score is expected during the intervention phase.

Satisfaction of the patients and the healthcare providers involved will be evaluated. To develop clinical pharmacy activities in healthcare services, collaboration and communication with healthcare teams is essential.

The direct hospital costs will be estimated and described. The objective is to estimate whether additional costs are induced or whether costs are spared through better organisation and logistics management.⁵²

Statistical analysis

Sample size calculation

According to the ENEIS studies (2004 and 2009) and their final report,⁵³ at least 50% of iatrogenic serious adverse events are preventable whether due to medications or MDs. Assuming that clinical pharmacy integration could theoretically lead to a 25% decrease in the complication rate during the interventional phase, 62 patients are needed in each group (80% power, alpha 5%). Thus, 138 patients need to be recruited assuming that 10% are lost to follow-up. All early exits from the study will be considered as lost to follow-up, and the affected data will be processed in the statistical analysis as intent to treat.

Statistics

Statistical tests will be used that are appropriate for the distribution of the variables. All tests will be performed at an alpha risk of 5%. Categorical variables will be described by counts and percentages. Means and SD will be reported for continuous variables with normal distribution, and median and quartiles for other continuous variables.

Table 2 Detailed research process

Timepoint	Research steps	Observational phase	Interventional phase
Hospitalisation	<i>PICC line prescription</i>	Screening: eligibility assessment	
	<i>Intervention scheduled</i>	Enrolment: informed consent	
	<i>PICC line indication</i>	Document purpose and duration of catheterisation	Pharmaceutical analysis to identify errors or potentially inappropriate prescriptions*; discussion with prescribers; pharmaceutical interventions in the event of unjustified deviation from existing guidelines.
	<i>In the operating room (OR) before the implantation</i>	Verify that all necessary equipment is available for the surgery.	Help with ordering if necessary.
		Conformity assessment of the expiration date for all PICC lines stored in the OR's supply room.	Help with ordering if necessary. Rationalisation of the medical device stock if necessary.
		Conformity assessment of traceability from receipt of the medical device order by the pharmacy to delivery to the care unit.	Corrections if necessary.
	<i>Implantation of PICC line=day 0</i>	Number of medical devices used during the operation (implantation failures or non-functional devices). Implantation traceability to ensure lot numbers match in the patient's record, the OR book and the computer software.	Corrections if necessary.
Discharge	<i>Discharge prescription</i>	Pharmaceutical analysis of the patient's discharge order. The analysis will focus on drugs and MDs related to the PICC line (eg, dressing repair set). Conformity analysis of the hospital prescriptions issued by local pharmacy.	Pharmaceutical analysis of the patient's discharge order and optimisation* if necessary. Discussion with the physician and correction.
	<i>Patient discharge</i>	Quality of life assessment (EQ-5D-5L scale).	Pharmaceutical interview with the patient: Discuss the different treatments on the discharge order, answer any questions. Provide information about the PICC line, how to use it, maintain it and how to detect potential complications. Make sure that traceability documents are provided. Make sure that the PICC line's user booklet is provided. Transmission of the discharge order to the community pharmacist.
Primary care	<i>Day 3</i> <i>Day 7</i>	Phone calls to collect complications or any events regarding the PICC line and drugs ▶ Patient. ▶ Private nurse.	Provide personalised and appropriate advice. Pharmaceutical interventions if necessary.
	<i>M1, M2</i>	Phone calls to collect complications or any events regarding the PICC line and drugs: ▶ Patient. ▶ Private nurse. Phone calls to community pharmacist to record information related to care consumption.	Provide personalised and appropriate advice. Pharmaceutical interventions if necessary.
	<i>M3</i>	Quality of life assessment (EQ-5D-5L scale). Phone calls to collect complications or any events regarding the PICC line and drugs: ▶ Patient. ▶ Private nurse. ▶ Community pharmacist to record information related to care consumption. ▶ General practitioner to identify any consultations related to the PICC line and any other relevant information.	Sooner if there is a need to confirm clinical data on complications such as thrombotic events.

*According to the gold standard or START and STOPP method⁶⁴ or European PIM list⁶⁵ for older adults.
MDs, medical devices; PICC, peripherally inserted central catheter.

Table 3 Statistical analysis for the secondary outcomes

Variables types	Variables of interest	Description*	Tests*
Quantitative	<ul style="list-style-type: none"> ► Consultations and rehospitalisations after discharge. ► EQ-5D-5L scores. ► Direct hospital costs. 	Means±SD or medians and quartiles. Frequency table.	Student's t-test or non-parametric Wilcoxon's test.
Qualitative	<ul style="list-style-type: none"> ► Conformity rates (logistics, indications for implantation and prescriptions issued by local pharmacy). ► Satisfaction levels. 	Frequency table.	χ^2 test or Fisher's exact test.

*According to the distribution of variables.

Patient demographics and clinical characteristics will be described.

To assess the effectiveness of the intervention, means or medians of the number of complications per month and per patient for each phase will be estimated, and a Poisson regression will be used. An adjustment for confounding factors such as sex, age and Charlson Comorbidity Index is planned.

The secondary outcomes will be analysed as described in [table 3](#).

DISCUSSION

The main objective is to demonstrate the effectiveness of clinical pharmacy activities in preventing complications in patients implanted with a PICC line. This is a strong clinical criterion. There is abundant literature about the occurrence of complications following the insertion of a PICC line, in a hospital^{20–24} or at home.^{27 54 55} At the same time, reported rates vary widely across studies. These rates were pooled to estimate an 'average' complication rate. This method was used to calculate the number of subjects needed for this study. These assumptions have an impact on the robustness of the study and may require the use of statistical adjustments when analysing the results. As for complications, the numbers of consultations and rehospitalisations postdischarge have been used in several studies, particularly the 30-day readmission rate^{11 40 56–58} to assess the clinical effectiveness of a pharmacist's interventions. Despite the wide assortment of these rates in the literature, this indicator is relevant for comparing our study with others. However, it will be difficult to obtain exhaustive results, as the data will be derived from statements made by the different participants. The information will only be formally verifiable if the patient in question is readmitted or consults in one of our hospital's departments.

The acceptance rate of pharmaceutical interventions is a widely used and recognised indicator^{41 59} for assessing the appropriateness of interventions and an indicator routinely used in hospitals. A conformity analysis of the hospital prescriptions for primary care is one of the secondary endpoints. It seems essential to secure these prescriptions also because the patient's transition is known to be a high risk event.⁶⁰ Good clinical practices

allow health professionals to decrease errors and avoid potential errors in prescription. Iatrogenic events are associated with additional costs.⁶¹ A checklist of items was developed to evaluate the conformity of the PICC line's logistics circuit. This list is particularly exhaustive and will be used by all those who collect data. This will avoid an evaluation bias that could be linked to the large number of healthcare providers involved. The checklist will help to identify the most common errors or pitfalls encountered and to establish adequate corrective measures. Current guidelines are available for the device's logistics.⁴⁹

The prospective study design allows to assess the patients' quality of life using the EQ-5D-5L Scale before and after the intervention. This criterion is needed to assess the patient's point of view, as the patient is the central element in the care pathway. To avoid interference or influence due to the presence of pharmacists, they will not be present at the time of the first evaluation (day of discharge). However, the subsequent assessments will be done by telephone, thus pharmacists could influence patient responses. Likert scales have been developed to collect patient and healthcare professional satisfaction data.⁶² These tools are valid and reliable for collecting the opinions of different research participants. These scales capture more nuanced opinions, help to better understand the feedback and to identify areas for improvement. The various parties involved generally appreciate these tools. It should not be particularly difficult to collect and analyse these results. Nevertheless, different patients will be enrolled during the observational and interventional phases. Consequently, the differences in satisfaction, if any, may also be due to a difference in individuals between the two groups. A low response rate from professionals to the satisfaction survey is expected, as described in the literature.⁶³

This study involves only one hospital and focuses on one type of implantation. This is a preliminary study before scaling up a larger, multicentre and randomised trial with several implantable medical devices (IMDs). This future study will follow a stepped-wedge method consisting of randomisation by centre and not by patient for the deployment of before-and-after phases in each of the participating centres. This study is a major step towards evaluating the efficacy of clinical pharmacy

applied to IMDs with the aim of a larger scale study with valuable randomisation. At this moment, the before–after design appears to be the closest to the stepped-wedge method since they share separate observational and interventional periods. Indeed, randomisation is not possible given the nature of the intervention and the high risk of contamination bias. This point is critical. Moreover, the measurement and analysis of costs is limited to direct hospital medical costs, which does not allow an overall analysis of the costs of care. Additional health economics analyses are planned for the multicentre study.

This study will investigate the impact of the integration of clinical pharmacy activities during the overall care pathway. This is the first step towards a change in practices, improved communication between professionals, better collaboration and the integration of a clinical pharmacist into multidisciplinary teams, including surgical ones. This study is the first, to our knowledge, to focus on clinical pharmacy for implantable MDs with a hard, clinical endpoint.

Potential limitations and bias

Since the study is not randomised, the selection bias and two non-comparable samples are risky. To overcome this limitation, an adjustment on the main confounding factors (such as age, sex and comorbidity index) will be considered.

Blinding is not possible due to the nature of the intervention. To limit a measurement bias, a blind methodologist will analyse the primary endpoint.

Recruitment may take longer than expected because all the PICC lines are placed in the operating room and are not a priority as opposed to life-threatening emergencies.

Phone calls to collect clinical data on complications, deaths and rehospitalisations are limited. The collected data are based solely on the patients' and care providers' statements. It is possible that they may intentionally or unintentionally omit some information. The plurality of involved counterparts may help to corroborate the given information. Data collection will be harmonised by double-checking the collection forms and the information collected at the time of the pharmaceutical interviews and phone calls.

Trial status

Recruiting since 25 May 2020.

National registration number: 2019-A02475-52.

Ethics and dissemination

The regional French Ethics Committee (CPP South-East VI, Clermont-Ferrand, France) assessed the scientific ethics of the protocol (version dated 3 February 2020) and approved this study.

All data collected will be anonymised, and access to the data will be restricted to those participating in the research (investigators, pharmacists and pharmacy residents).

The results of the study will be published when available.

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CLIPICC
Version 2 dated 03/02/2020**INFORMATION LEAFLET****INTEGRATION OF CLINICAL PHARMACY ALONG THE ENTIRE CARE PATHWAY OF PATIENTS IMPLANTED
WITH A PICC-LINE****CLIPICC - RC31/18/0459****VERSION 2 DATED 03/02/2020**

Study sponsor: Toulouse University Hospital Center

Acting Principal Investigator: Doctor Elodie CIVADE

Associate Principal Investigator: Doctor Charlotte LABORDE

Madam, Sir,

Your pharmacist has invited you to take part in a research study sponsored by the University Hospital Center of Toulouse. Before making a decision, it is important that you read these pages carefully as they will provide you with the necessary information about the different aspects of this research. Do not hesitate to ask your pharmacist or your doctor any questions you may have. Your participation is voluntary. If you do not wish to take part in this research, you will continue to receive the usual medical care in accordance with current knowledge.

❖ Why this research?

A PICC line is a central catheter or small tube designed to be inserted into a vein. It is placed at the edge of your arm and travels up into a vein that has larger flow. This allows for the administration of certain medications as well as repeated collection of blood samples if necessary. It is an implantable medical device.

Clinical pharmacy is a patient-centered healthcare discipline whose goal is to optimize therapeutic management at every stage of the care pathway. Clinical pharmacy procedures contribute to the safety, relevance and efficacy of drugs and medical devices. To achieve this, pharmacists must work in collaboration with other professionals such as the doctor, nurses, yourself and sometimes caregivers¹.

At present, clinical pharmacy in the field of medical devices (MD) is poorly developed in France. However, it has proven its effectiveness for medications. Thus, we would like to develop clinical pharmacy activities in the context of MDs, starting with the PICC line. We believe that we can improve the quality and safety of your hospital stay and home care through the clinical pharmacy activities detailed below.

❖ What is the purpose of this research?

Your usual treatments will not interfere with the study. You are hospitalized and require a PICC line for medication administration or repeated collection of blood samples. You will then go home with this device. The insertion of this medical device can sometimes lead to certain complications. We would like to show that the intervention of a clinical pharmacist during your treatment can prevent and therefore reduce the number of complications due to PICC lines by interacting with your doctor as needed and by giving you personalized advice on monitoring the PICC line. Similarly, your private nurse, your provider and/or your local pharmacist will receive information to help you follow up and monitor your PICC line.

❖ How is this research going to be carried out?

This is a single-center study at the UHC of Toulouse. Two successive phases are planned with 69 patients each: an observational phase and an interventional phase. Recruitment will last about 12 months to obtain the necessary number of patients.

¹ <https://sfpc.eu/presentation/>



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Depending on when your PICC line is implanted, you may be in the observational phase without clinical pharmacy activities or in the interventional phase with clinical pharmacy activities. You cannot choose which phase you will be in.

➤ If you are in the **observational phase**:

Your treatment remains unchanged within the framework of standard medical care. We will only collect information without any intervention from the pharmacist. We will call you twice in the week following your discharge and then once a month for a maximum of 3 months.

➤ If you are in the **interventional phase**:

1. A **pharmaceutical analysis** of the PICC line prescription will be done. We are likely to discuss the prescription with the hospital doctor at this stage. Once the medical device is implanted, we will speak with your hospital nurse to ensure the best possible follow-up.
2. We will have carried out **logistical activities in the operating room where the PICC line is placed**. For example, we will have checked the quantities of devices needed for the installation and their expiry date, and we will also have checked that the lot number of the device is recorded in the hospital's database.
3. Once the PICC line has been implanted, you will return to your hospital ward for further treatment and then return home.
4. **We will analyze your discharge prescription** (medical devices and medicines) and may discuss it with the doctor.
5. You will have a **pharmaceutical discharge interview** of about 20 minutes in your hospital ward. This interview will allow us to discuss your medications and the PICC line with you (what the medications are used for, possible adverse effects, clinical laboratory monitoring if any, etc.). You will be able to ask any questions you may have (medical, clinical, etc.), and we will try to answer them as soon as possible. If further research needs to be done, we will call you to give you the answer. We will give you **information documents** on the PICC line to help you monitor it and be aware of the signs that you to the need to talk to a health professional as soon as possible. The goal is to prevent the most common complications. Finally, we will give you a sheet with the lot number of your PICC line so that you will have information about the implantation of this device in your possession. French law requires this.
6. A private nurse will redo your dressings at home. We will ask you to give us his or her name so we can contact him or her during the study. We will provide your nurse with your PICC line **information booklet** as well as **information on how to monitor and maintain** your PICC line.
7. We will ask you for the contact details of your pharmacist and your general practitioner so that we can contact them if necessary and in case of complications following insertion of the device. We will forward the **discharge prescription** to your pharmacist to ensure optimal **continuity of care**. We can also send him/her information about the PICC line.
8. Follow-up calls are scheduled throughout the study to **monitor and optimize your care**:
 - 8.1. You will be called personally by a pharmacist to follow-up on your treatment. We will ask you questions about the care of the dressing and about any complications. These calls will take place approximately on the 3rd and 7th day after the implantation and after 1 month, 2 months and 3 months. These calls will last approximately 15 minutes.
 - 8.2. Your nurse will also be called **to follow-up** on your care. We will ask him/her the same questions as you about the dressing and any complications. **Pharmaceutical advice** will be given if necessary to improve your care in collaboration with your private nurse. These calls will take place approximately on the 3rd and 7th day of the dressing care and after 1 month, 2 months and 3 months.
 - 8.3. Your local pharmacist will be contacted if necessary to note any changes in your treatment.



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- 8.4. Your general practitioner will be contacted at the end of the 3-month follow-up period or earlier if necessary in the event of complications. Indeed, he/she is the one who knows your history best (in the event of a new medical condition or other diagnosis).

❖ **Who can participate?**

You can participate when all the following criteria are met:

- You are an adult, 18 years of age or older
- You are affiliated with the French social security system
- You live at home and can be reached by telephone
- You are scheduled to undergo insertion of a PICC line and you are destined to return home with this PICC line implanted
- Your profile suggests that your discharge prescription will include medications and a MD

You cannot be included if:

- You are a minor, under the age of 18
- You are not affiliated with the French social security system
- You do not live at home
 - You are institutionalized (specialized institutions)
 - You are living in a facility for dependent elderly persons
 - You live in a nursing home
 - You benefit from HAH (hospitalization at home)
- Your current health condition does not require a PICC line
- Your profile suggests that your discharge prescription will not include associated medications and MDs
- Your treatment plan does not include returning to home

Participation is voluntary. You will not be compensated for participating in this study.

No further examination is necessary before inclusion, only those corresponding to your treatment will be carried out.

❖ **What will you be asked to do?**

At the time of your inclusion, regardless of the phase:

We will ask you for your contact details and those of your GP and your pharmacist.

After the implantation of the PICC line, regardless of the phase:

We will ask you for the contact details of your private nurse who will monitor you at home.

Once you have returned home:

We will call you on the 3rd and 7th day after the implantation and 1 month, 2 months and 3 months after the implantation to:

- Gather information on the care of your dressing
- Collect information about possible complications due to the presence of the PICC line:
 - Related to your skin: any pain, redness or swelling
 - Related to the medical device: the catheter may become clogged, slightly cracked or displaced

We remind you that these events are relatively rare.

This phone call will last about 15 minutes.

If necessary, this information will be compared with the information given by your local healthcare professionals (doctors, nurse, healthcare provider and pharmacist) to confirm it.

If you are still hospitalized in the days following the insertion of the PICC line, we will visit you in your room on the 3rd and 7th day after the insertion.

You can withdraw from the study at any time.

If you withdraw from the study, you will continue to receive your current care.



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❖ **What are the expected benefits?**

For you, the benefits are as follows:

- Due to additional information about your care and coordination between professionals, we believe you will benefit in the following ways:
 - Better care in the hospital and back home
 - Fewer complications due to the PICC line and associated medications
 - Your PICC line will be more comfortable, thanks to the care and maintenance tips
 - Improved quality of life, and better satisfaction with your care
- You will also have documents to refer to if you have any questions and you can always contact the hospital pharmacist and your local health care professionals if necessary
- We offer a close follow-up and a privileged relationship thanks to regular telephone calls

This research does not expose you to any additional risk in your care.

For science: clinical pharmacists offer a new way of working by accompanying you from when the medical device is implanted in the operating room to when you are at home by working more closely with hospital professionals and with healthcare professionals outside the hospital.

❖ **What are the possible constraints?**

You will be called five times after the insertion of your PICC line according to the research protocol, after you return home. Each phone call will last approximately 15 minutes. This call could disrupt your day, your work, and your activities. At any time, you can tell the person whose is calling you to call you back at a more convenient time.

❖ **What are the possible medical alternatives?**

If you do not participate in the research, you do not lose any chance of treatment.

You benefit from the usual care and standard practices in accordance with current knowledge.

❖ **What are the medical treatment modalities?**

If you are excluded from the research, you will be informed and you will continue to benefit from the usual medical care.

If the study is discontinued, the reason for the discontinuation will be noted. Your data will be used in the statistical analysis of the group you were in at the time of your study participation.
At the end of the study, the results will be communicated to you if you wish.

❖ **What are your rights?**

Your hospital pharmacist must provide you with all the necessary explanations about this research. If you wish to withdraw from the study at any time, no matter the reason, you will continue to benefit from medical follow-up and this will not affect your future care.

In the context of the research in which the Toulouse University Hospital offers you the opportunity to participate, your personal data will be processed electronically to enable the results of the research to be analyzed in the light of the research objective presented to you.

The party responsible for data processing is the UHC of Toulouse. The study investigator and other study staff will collect information about you, your health, your participation in the study, and, if applicable, your lifestyle. This information, called "Personal Information", is recorded on forms, called case report forms, provided by the sponsor. Only the information necessary for the processing and aim of the research will be collected. This data will be kept for the duration of the study until the final report or until the last publication and then archived in accordance with current regulations. To ensure the confidentiality of your personal information, neither your name nor any other information that would allow you to be identified directly will be entered in the case report form or in any other file that the study pharmacist will provide to the sponsor or the sponsor's authorized



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representatives. Only a code and your initials will identify you. The code is used so that the study pharmacist can identify you if necessary.

In accordance with the provisions of the French Data Protection Act (Act No. 78-17 of January 6, 1978 on Data Processing, Data Files and Individual Liberties as amended by Act No. 2018-493 of June 20, 2018 on the Protection of Personal Data) and the General Data Protection Regulation (EU Regulation 2016/679), you have the right to access and rectify your personal information. In certain cases, you may also request that the processing of your personal information be restricted, object to certain types of processing of your personal information, and request that your personal information be deleted. However, certain data that was previously collected may not be erased if such deletion is likely to make it impossible or seriously compromise the achievement of the research objectives. You may exercise these rights by making a written request to the study investigator. The sponsor will respond to your request to the extent possible in accordance with its other legal and regulatory obligations and when required by law.

The sponsor may share personal information with regulatory agencies or research partners. These persons, companies and agencies may be in your country, in other EEA countries, or in other countries outside the EEA. Some non-EEA countries may not offer the same level of privacy protection as your country. The Sponsor will, however, maintain the confidentiality of all personal information it receives to the fullest extent possible within the limits of the law. The Sponsor will adopt appropriate contractual measures, including its certification under the Privacy Shield and its standard data protection clauses, to ensure that recipients outside the EEA provide an adequate level of protection for your personal information as set out in this form and in accordance with the law.

You also have the right to object to the transmission of data covered by professional secrecy that may be used during this research and processed. You can also access directly, or through the intermediary of the doctor of your choice, all your medical data pursuant to the provisions of Article L1111-7 of the French Public Health Code. These rights are exercised with the doctor or pharmacist who follows you in the context of the research and who knows your identity.

The competent authorities and the sponsor or its authorized representatives may also need access to your medical records and your study file to verify the data collected in the context of the study.

Your coded personal information may be used for further scientific research on your disease or other diseases in accordance with applicable laws and regulations.

If you have any additional questions about the collection or use of your personal information or the rights associated with this information, please contact the Data Protection Delegate of the UHC of Toulouse (DPO@chu-toulouse.fr) or the study investigator.

If you feel that your rights are not being respected, despite the measures put in place by the sponsor, you may file a complaint with the competent data protection supervisory authority in your country of residence (the CNIL for France).

In accordance with the French law No. 2012-300 of March 5, 2012 relating to research involving humans:

- This research has obtained a favorable opinion from the Committee for the Protection of Persons (CPP Sud Est 6).
- The sponsor of this research, the UHC of TOULOUSE has taken out civil liability insurance with Lloyd's Insurance Company S.A.
- This research falls within the framework of the Reference Methodology MR-001 of the CNIL (French National Commission for Information Technology and Civil Liberties)
- Persons who have suffered harm because of their participation in this study may assert their rights before the regional conciliation and compensation commission for medical accidents.
- When this research is completed, you will be kept personally informed of the results by the Investigator as soon as they are available, if you want.

After reading this information leaflet, do not hesitate to ask the investigator any questions you may have. After a waiting period, if you agree to participate in this research, you must complete and sign the Consent Form. A copy of the completed document will be given to you.

Thank you for your attention.



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CONSENT FORM

INTEGRATION OF CLINICAL PHARMACY ALONG THE ENTIRE CARE PATHWAY OF PATIENTS IMPLANTED WITH A PICC-LINE

CLIPICC - RC31/18/0459

VERSION 2 OF 03/02/2020

Research sponsor: Toulouse University Hospital Center

Acting Principal Investigator: Doctor Elodie CIVADE

Associate Principal Investigator: Dr. Charlotte LABORDE

I, the undersigned..... (surname, first name) hereby certify that I have read and understood the information leaflet that was given to me.

I was able to ask any question I needed to ask to the investigator, Elodie CIVADE, who explained to me the nature, objectives, potential risks and constraints related to my participation in this study.

I am aware of the possibility that I may interrupt my participation in this study at any time without having to justify my decision and I will do my best to inform the pharmacist who is following me in the study. Of course, this will not affect the quality of subsequent care.

I have been assured that the decisions that are necessary for my health will be made at any time, in accordance with the current state of medical knowledge.

I have been informed that some of the information gathered during this study may be retained for future research purposes. I have also been informed of my right to object to such retention and subsequent use for research purposes.

I am aware that this study has received the favorable opinion of the Comité de Protection des Personnes Sud Est 6 and falls within the scope of MR001 of the Commission Nationale Informatique et Libertés (CNIL).

The sponsor of this study (CHU de Toulouse, 2 rue de Viguerie, 31000 Toulouse) has taken out a civil liability insurance policy in case of harm with Lloyd's Insurance Company S.A (BARCET 19001).

I accept that the persons collaborating in this study or authorized by the sponsor, as well as potential Health Authority representatives, have access to the information in the strictest confidentiality.

I accept that the data collected during this study may be subject to computerized processing under the responsibility of the sponsor.

I have noted that, in accordance with the provisions of the law on data processing, data files and freedoms and the general regulations on data protection, I have the right to access, rectify and delete data, to limit processing and to make the data portable. I also have a right to object to the transmission of data covered by professional secrecy which may be used in the context of this study and processed. These rights are exercised with the pharmacist who is following me in the context of this study and who knows my identity.

My consent in no way relieves the investigator and the research sponsor of their responsibilities towards me. I retain all legal rights.

The results of the study will be communicated to me directly, if I so wish, in accordance with the French law of 4 March 2002 on the rights of patients and the health care quality.

Having had sufficient time for thought before making my decision, I freely and voluntarily agree to participate in the CLIPICC study.

I may at any time request additional information from the pharmacist who has invited me to participate in this research, telephone number: 05 67 77 11 15 or 05 67 77 12 14

Made in.....on Made in.....on

Patient's signature:

Investigator's signature: