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► To cite this version:

C. Ostrowka, L. Journeau, L. Plaisance, G. Poenou, S.E. Mecherour, et al.. Educational diagnosis of patients under oral anticoagulant therapy: Development of a 4-category patient profiling score based on a retrospective study and prospective analysis. *JMV-Journal de Médecine Vasculaire*, 2020, 45, pp.184 - 191. 10.1016/j.jdmv.2020.04.013 . hal-03491115

HAL Id: hal-03491115

<https://hal.science/hal-03491115>

Submitted on 22 Aug 2022

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ORIGINAL ARTICLE

Educational diagnosis of patients under oral anticoagulant therapy: development of a 4-category patient profiling score based on a retrospective study and prospective analysis.

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Abstract

Background : Oral anticoagulants are used in numerous pathologies and their consumption is growing. However, to prevent their occurrence, their use should be supervised and the patients educated. Patients vary in understanding and compliance. Therefore, it seems necessary to standardize educational diagnosis with a patient profiling score to adapt therapeutic education to the individual patient profile.

Method : A retrospective study based on observation of consecutive patients treated by an oral anticoagulant therapy and involved in a therapeutic education program conducted between October 2014 and December 2015. A 12-item questionnaire distinguished 4 profiles based on the educational diagnosis. In a prospective double-blind study including consecutive patients with an indication to anticoagulants and admitted to the Internal Medicine department of the Louis Mourier Hospital, the patient's profile defined by a clinician using the questionnaire was compared to the one defined by the Therapeutic Education Leader after standardized educational diagnosis.

Results : The questionnaire was tested prospectively in 53 patients 26 of which had also a complete therapeutic education by the TEP leader. In any case, the assessment assisted by the questionnaire succeeded in identifying the patient profile, as determined by the therapeutic education specialist

Conclusion : The present questionnaire helps identify different patient profiles and therefore standardize educational diagnosis. The perspective is to adapt therapeutic education to individual patient profile, with the objective to improve compliance.

Keywords: anticoagulant, therapeutic education, educational diagnosis, profiling score, compliance.

Profiling on standardized educational diagnosis is the first step to enable the patient to acquire the minimum core knowledge, regardless of baseline compliance profile and provide him with more personalized therapeutic education, adapted to the patient's individual profile.

We designed a reproducible score to serve this objective.

The perspective is to adapt therapeutic education programs to each category of patient so that they can acquire the knowledge that is noteworthy for their treatment.

Background

Oral anticoagulants are the reference treatment for the prevention of thromboembolic events in atrial fibrillation (AF), venous thromboembolism (VTE) and mechanical cardiac valve prostheses. Their use doubled between 2000 and 2012 [1]. An American study suggested that the number of patients requiring long-course anticoagulation therapy will increase by 2.5-fold over the period 2000-2050 [2].

Unfortunately, these treatments have side-effects, the most feared of which is intracerebral hemorrhage [1]. A 2003 study by the French Health Authority found that vitamin-K antagonists (VKA) are the main cause of iatrogenic hemorrhage, leading to 17,000 hospital admissions and 5,000 deaths per year in France, with a mean cost of €315 m between 2012 and 2014 [1]. Direct oral anticoagulants (DOAC), being easy to use and requiring no biological monitoring, may be better accepted by patients [3] but clinical trial data have to be confirmed in real life [4].

According to Haynes et al. [5], treatment efficacy correlates directly with patient's compliance to the prescribed treatment. However, it is estimated that almost 50% of patients with chronic pathology do not adhere sufficiently to their treatment, and therefore fail to reach the expected benefit [6]. Borne et al.'s retrospective study of 2,900 outpatients, beginning DOAC treatment for non-valvular AF between 2010 and 2015, measured compliance in terms of the number of recharges according to the number of days' treatment during the first year [7]. A quarter of patients showed suboptimal compliance, and low compliance was correlated with vascular event rate.

The aim of therapeutic education according to the World Health Organization (WHO) is "to help patients acquire or maintain the skills they need to optimally manage living with a chronic disease" [8]. Worldwide, it has been an integral part of patient healthcare

management and the care-pathway. It should enable the patient to acquire knowledge in order to improve compliance and avoid clinical complications by ensuring safe use of medication. Therefore, it is essential to identify patients at risk of non-compliance, and target them for taking part to a Therapeutic Education Program (TEP). The first step of a TEP is educational diagnosis, as not all patients have the same understanding capacity and adherence before treatment initiation. After a personalized program has been drawn up, taking into account learning priorities, TEP sessions are scheduled, followed by knowledge assessment.

However, the objectives and the corresponding benefits on adherence may depend on the included population. In the international prospective controlled, randomized IMPACT AF study including patients receiving DOACs for AF, one group received standard education and the other a TEP with regular follow-up, interaction between the health professionals involved in the treatment [9]. The proportion of patients still using DOACS after the first year of treatment was higher in the TEP group than in the standard education group, suggesting that educational intervention should improve DOACs patients' use.

In contrast, the AEGEAN trial, which was an international multicenter prospective controlled randomized study of 1,162 patients beginning apixaban treatment for AF, did not yield similar results. One group received a proactive TEP, the other standard information. TEP and anticoagulation clinic management seemed to show no benefit in terms of adherence to apixaban: the number of consecutive intakes measured by an electronic device was identical in both groups [10]. A recent meta-analysis failed to demonstrate a clear benefit from TEP in term of outcomes, knowledge scores, and time in therapeutic range [11]. These findings suggest that the patients included in the study

might have been selected, with better than usual understanding and compliance capacity due to the design of the study and the need for written informed consent). It suggests that TEPs may show greater benefit in patients with lower compliance capacity.

Indeed, Drouin et al. showed that high level of knowledge is not a pre-requisite for optimal compliance a quarter of patients reported not knowing the role of oral anticoagulation therapy, but overall compliance was nevertheless good [12]. Patients do not necessarily all need the same types of knowledge and knowledge does not always correlate with compliance, especially for those who do not wish to or cannot know any more about the treatment and the disease. The TEP, as defined by the “Agences Régionales de Santé” (the regional healthcare regulating agencies in France), seems to promote good compliance, but in practice is poorly adapted and non-standardized in terms of educational diagnosis [13]. Therapeutic education should therefore be guided by distinguishing certain patient profiles before referring the patient to different TEPs in order to improve subsequently compliance [10].

Given this diversity of needs, it seems necessary to define a minimal core knowledge base for all patients.

The internal medicine department of Louis Mourier Hospital, a university hospital belonging to the Assistance Publique – Hôpitaux de Paris (AP-HP) and Paris 7 University, France, has been running a TEP for patients taking oral anticoagulants since 2014 that has been authorized by the local Regional healthcare agency. Based on this experience, we were able to determine various patient profiles with specific needs in therapeutic education.

The present study consisted in drawing up and validating a simple questionnaire to identify different patient profiles in therapeutic education for anticoagulation. The score

was based on a retrospective analysis of patients receiving anticoagulant therapy involved in a TEP over a 1-year period and was then tested prospectively in another cohort.

Methods

Objective

The main objective of the study was to draw up a simple educational diagnostic tool able to distinguish different profiles of patients taking anticoagulants.

The secondary objectives were to assess the reproducibility of this tool, the feasibility of implementing this educational diagnosis in usual care, and having it performed by physicians non specialists in therapeutic education.

Methods

a) Ethics and Consent to Participate

Patients were included in the TEP after they provided oral and written consent to participate in the education program (Authorized by Regional Health Authorities number 14/20) and data are used for research purpose. The consent form was included in the education program project that was submitted and approved by French Health Regional Authorities (Authorization number ARS ETP/14/20).

b) Retrospective study

The first part of this research consisted in a retrospective observational study of consecutive hospital patients with indications for or ongoing anticoagulation therapy

and who had been included in the Louis Mourier Hospital's TEP between October 2014 and December 2015. There were no exclusion criteria.

For standard educational diagnosis, the department's trained and certified TEP leader organized individual 30-minute educational diagnosis sessions assessing the patient's needs and knowledge concerning TEPs. This assessment was identical for all patients and based as usual on four topics: "pathology", "treatment", "risk" and "caregiver". It was. The "pathology" category assessed the patient's knowledge regarding the pathology and the associated risks. The "treatment" category assessed the patient's knowledge regarding the treatment, the possible biological monitoring and difficulties or side effects; as well as the patients 'self-estimated compliance to the treatment and self-medication. The "risks" category assessed knowledge of treatment associated risks, overdose signs, and resources in case of problems. The "caregiver-assistance" category assessed which help was available in terms of treatment knowledge. (*See Appendix 2: Profile identification score after decision tree*)

Patients were interviewed on their living conditions, occupational status, place of residence, any difficulties in taking treatment, leisure activities (liable to cause wounds or hematomas), anticoagulation therapy, and associated pathologies. Problems, resources, hindrances, and gray areas were summed up to define personalized TEP objectives.

Patients then underwent 2 therapeutic education sessions of about 1 hour each. The first focused on learning and managing treatment, and the second on side-effects and precautions. With the patient's agreement, the TEP leader could run further sessions. (*See Appendix 1: Standard educational diagnosis.*). For this retrospective part of the study, data were extracted from the data of the TEP.

c) Questionnaire

We analyzed retrospectively patients' responses to the four topics covered in standard educational diagnosis (Appendix 1).

Twelve key items were defined based on the 4 topics discussed above and the TEP leader's experience in therapeutic education.

We have built a questionnaire (Appendix 4) comprised those 12 items, and taking into account whether the patients were willing to enhance their knowledge or not: (2 focused on pathology), 6 questions on treatment, 3 questions on risks), and 1 question on caregiver. The questionnaire determined what the patient wanted to know, through a final question: "Do you want to know more?" Questions were closed, with 1 point for each positive answer. Patients were scored and their profile was determined.

By questioning the patient about his knowledge of the disease (about the risks inherent to the disease or the reason why they were taking anticoagulant), signs of overdose, and who to contact for help regarding the treatment, the clinician can quickly identify gaps in the patient's knowledge or points that the patient wishes to be clarified. Moreover, the "treatment" section of the questionnaire focused directly on the possibility of forgetting treatment or difficulties in taking it, thus directly identifying factors for non-compliance via the interview, as recommended by Borne et al [8]. The questionnaire underlying the present score represents the minimum knowledge the patient need to acquire.

Overall, after completing educational diagnosis 4 different profiles were identified. The "initiation" profile was determined on the decision tree ahead of the questionnaire, depending on whether the patients had already received anticoagulation therapy.

Patients with a score superior or equal to 9 were deemed “competent”; those between 9 and 4 were deemed as “needing education”, below 4 they were in the “learning underway” category.

The questionnaire was pre-tested in patients by clinicians and the TEP leader. It was simple, for both patient and clinician, and could be easily administered by medical or paramedical staff. Educational assessment by a clinician (usually an intern) using the questionnaire took about 15 minutes; standard educational assessment was then performed by the TEP leader in the TEP premises and took about 35 minutes.

d) **Prospective study**

The second part of this research consisted in a prospective observational study of consecutive patients admitted to the internal medicine department with indications for – or who were on – anticoagulation therapy between January 1 and September 30, 2016, and included in the TEP.

Non-inclusion criteria comprised institutionalized patients or patients with dementia whose treatment was administered by the paramedical staff, and patients refusing to answer the questionnaire.

Scores were assessed in a double-blind procedure by a clinician and the TEP leader. The clinician’s score helped identify the patient’s profile while the TEP leader performed blindly standard educational diagnosis and identified the patient’s profile, considered as the reference. The two assessments were then compared. After 3 months, follow-up by telephone or in consultation determined whether there had been any hemorrhagic or thrombotic events (objective benefit assessment criterion), last INR, whether treatment was ongoing. (*See Appendix 3: Follow-up questionnaire*)

Data were collected orally during interviews, using a prescription software data form, anonymized and registered in a standard table numbered 1 to 100 and 1 to 39, then entered under Microsoft Excel (2011) for analysis.

e) Analysis

Basic statistical assessment was conducted with the Excel software (Microsoft). Quantitative variables were reported as mean, median, standard deviation and range. Descriptive variables were reported as numbers and percentages. Data for both studies were entered directly in a Microsoft Excel 2011 spread-sheet as figures and appropriate statistical analyses were performed, as numbers and percentages.

Results

Retrospective study

Thirty-eight patients were included; mean age was 69 years (range 30–91 years), and median age 71 years. Gender distributions were comparable between the various anticoagulants. Mean age of patients taking VKA and DOACS was similar (respectively 73.7 and 71.3 years). Forty percent of patients under VKA were aged ≥ 80 years, compared to 30% for DOACs. Of the 38 patients, anticoagulation therapy was indicated for non-valvular AF in 28.9% (n=11), in 56% (n=21) for pulmonary embolism (PE), in 15.8% (n=6) for deep venous thrombosis (DVT).

Of the 16 patients already under anticoagulants at admission, 41% (n=7) were taking warfarin (Coumadine®), 24% (n=4) fluindione (Préviscan®), 22% (n=3) rivaroxaban (Xarelto®), and 14% (n=2) apixaban (Eliquis®). The remaining 12 patients were naive for anticoagulation

We identified four groups of patients, according to their profile, based on standard educational diagnosis and the questionnaire: 58% (n=22) were categorized as “Initiation”, 18% (n=7) were categorized as “Competent”: they had maximum scores for the 4 key items: “Pathology”, “Treatment”, “Risk” “Caregiver”. In addition, 21% (n=8) had gaps in their knowledge and were categorized as “learning underway”. One patient was categorized as “needing education”

Prospective study

The study flowchart is detailed in Figure 1. The population comprised 76 patients: thirty-eight percent (n= 29) male, mean age 84 years (range, 36-97 years). Finally, 53 patients were able to have the score assessed.

For 26 patients, scores were assessed in a double-blind procedure by a clinician and the TEP leader. Data collected are summarized in *Table 2*. Mean age was 84 years. Anticoagulation therapy was indicated for non-valvular AF in 65% (n=17), in 35% (n=9) for PE and/or DVT.

The profiles determined from the questionnaire were concordant with those determined by the TEP leader (*Table 1*).

Eleven patients were categorized as “Initiation”; 6 had little or no relevant knowledge (“Needing education”); for 3, learning was “Underway”; 6 were “Competent”, with sufficient core knowledge for good compliance. Three, classified as “Competent”, did not “want to know more”; all the other patients answered this question in the affirmative (*Table 2*).

Discussion

To our knowledge, this is the first study to standardize educational diagnosis using a tool able to distinguish 4 patient profiles in a study population representative of the general population under anticoagulants in terms of age and profile.

The objective was to propose a simple tool making it possible for any clinician in charge of a patient on anticoagulant to categorize him in terms of educational needs, the therapeutic education being provided afterwards by the specialist.

It should be borne in mind that it is difficult to grasp the determining factors of compliance. In previous studies, we hypothesized that compliance was linked to quality of life and satisfaction in patients with VTE and AF. Overall, the experience of patients under oral anticoagulation therapy for AF managed on an outpatient basis was good, with comparable quality of life under DOACs and VKA, and significantly greater satisfaction under DOACs, but without impact on adherence. Taking account of patient preference in “shared decision-making” for the choice of type of anticoagulant could improve the patients’ experience of treatment [4] [14].

Even when patients understand the risks and benefits of treatment, whether they will prove compliant or not is unpredictable. In theory, individuals are supposed to make rational choices on the basis of the information provided and/or available to them, but it has been shown that the information actually used in making choices is limited and that cultural and cognitive biases come into play. In both the choice of treatment – in which the patient should be involved – and compliance with the treatment, it is very difficult to know if the patient is acting in his or her own best interests or if some irrational factors remain, making prolonged treatment (which implies chronic disease) difficult for the

patient to accept [15]. The active involvement of health-care professionals associated with personalized therapeutic education based on educational diagnosis helps reveal the individual's intrinsic issues and can positively impact on his or compliance [15] [16].

The “Initiation” profile seems especially important, as the impact of TEP is greater at treatment initiation, as shown in the IMPACT AF study [9]. Twenty-two patients in the retrospective study (56%) and 11 patients in the prospective study (42%) were initiating treatment. The profile “Needing education” does not necessarily require more therapeutic education than the other profiles. Especially since the abilities of observance are different for everyone. It is more difficult to assess compliance with DOACs than with VKAs, for which there are intermediate markers of good compliance. Only half of patients receiving DOACs for the first time are able to say which drug they have been prescribed [17]. This may be different for VKAs, where regular INR assay should help patients keep in mind the usefulness of their treatment [18].

Standardizing educational diagnosis allows TEP leader to spend more time with patients who need it most. Profiles were thus determined independently of previous information and experience, but were directly related to individual needs, hemorrhage or thrombosis risk and level of knowledge.

The score makes it possible to move beyond the usual dichotomies of DOAC vs. VKA or young vs. old subjects, and to focus solely on the patient's needs. In addition, educational diagnosis standardized by using the score was quicker (15 min) than the usual procedure (about 35 min), and can be performed by any clinician, given its reproducibility by the questionnaire.

Twenty-three out of 26 patients (87%) wished to know more about their treatment among them 85% still had gaps in their core knowledge (“Needing education” or

“Learning underway” profiles), and so the time saved by the use of the score can serve for extra TEP sessions. This is also the case for patients with the greatest needs, such as those with high hemorrhage risk, CHA2DS2VASc score >2 or multiple pathologies [16] which was the case for 80% of patients who underwent double assessment. TEP can be adapted to the patient’s demands, needs, educational level and all factors affecting compliance [19] [20].

In the present study, 58% of patients without anticoagulant treatment were prescribed DOACs, and 6 patients receiving fluindione (Préviscan®) or acenocoumarol (Sintrom®) were transferred to DOACs (mainly apixaban (Eliquis®). This is due to difficulty in stabilizing the INR in most cases, or to relieve the patient from regular and unpleasant biological monitoring. The patient is thus actively involved in the treatment decision, which should influence compliance [21] [22]. It is essential to emphasize the provision of information and to put the patient in a position of responsibility from the outset of treatment. Borne et al. investigated factors for good compliance in a subgroup analysis of elderly subjects frequently presenting geriatric syndromes: malnutrition, low body-weight, sarcopenia, cognitive disorder, risk of falling [8]. Most authors showed multiple morbidities, and polymedication which complicated the initiation and long-term maintenance of anticoagulation therapy. Those patients would need more in-depth education, but also had more professional medical and paramedical support, with help in taking treatment, which may suggest better basic compliance capacity, as reported in AEGEAN study [10].

Score assessment showed a perfect reproducibility between patient profiles as determined by clinicians, who were clinicians with no specialization in TEPs, and by

the TEP leader. The questionnaire represents the minimum core knowledge the patient needs to acquire.

Given the good reproducibility of the questionnaire, this core knowledge could be imparted in community medical practice. Therapeutic education as it is today, and as recommended by guidelines, is time-consuming for both care-givers and patients, when at the same time hospital stays are getting shorter. It seems essential to transfer part of the patient profile assessment to non-specialist. The specialist in therapeutic education can therefore focus its activity on therapeutic education and therefore improve compliance.

Our findings and patient profile identification from educational diagnosis can have implications for the content and the progress of therapeutic education.

For patients who are categorized as « initiation », the ETP program will be the same as usual : educational diagnosis followed by a first education session about the disease and a second session about the risk of bleeding.

For patients who are categorized as « competent », the patient requires only reminders, the education sessions can help increase their knowledge but key points have already been acquired. A single session instead of two are required.

For patients who are categorized as « needing education », two education session have to be planned.

For patients who are categorized as « learning underway », those patients need more time to acquire the minimum knowledge and competence. Additional sessions to the two usual are required to know key points about the disease and the treatment. The participation of caregivers can be useful for those patients.

The present study has certain limitations. The score was tested in a double-blind procedure on 26 of the initial 76 patients. The score is not suited for institutionalized patients, who do not manage treatment by their own, or to patients with cognitive impairment. It could, however, be proposed to care-givers, although this was not the

objective here. Moreover, scores could not be established for 23 patients due to problems of understanding or to refusal.

It seems necessary to develop TEPs for care-givers, who are sometimes more directly than patients involved in compliance to treatment. Likewise, inviting spouses or relatives to the TEP could improve compliance. The present population was exclusively hospital-based; but administering the questionnaire towards the end of the hospital stay, to stabilized patients, makes the study population more similar to an outpatient population. Although therapeutic education was mainly designed by hospital teams, the general practitioner has a key role to play. Giving the appointments for the patient to take part in therapeutic education sessions is an integral part of the community-hospital education network [23], for which the general practitioner is indispensable [24]. The score need to be tested in a more general outpatient population.

Conclusion

Profiling on standardized educational diagnosis is the first step to enable the patient to acquire the minimum core knowledge, regardless of baseline compliance profile and provide him with more personalized therapeutic education, adapted to the patient's individual profile. The present score seems to serve this objective. The purpose is to be able to adapt TEPs to each category of patient so that they can acquire the knowledge that is noteworthy for their treatment.

Community assessment of the present profiling score is necessary to enable clinicians to guide their patients effectively and achieve optimal compliance with anticoagulation therapy, whatever the patient's baseline compliance capacity [25].

Abbreviations

AF : atrial fibrillation
CHA2DS2VASc score
DOAC : Direct oral anticoagulants
TEP : therapeutic education program
VKA : vitamin K antagonist
VTE : venous thromboembolism
WHO : World Health Organization

Disclosure of interest

The authors declare that they have no competing interest.

Declarations

Ethics approval and consent to participate : patients gave written consent to participate in the therapeutic education program as stated in the manuscript. This program including the consent form has been approved by French Health Regional Authorities (ARS ETP/14/20). All patients included in the TEP provided oral and written consent to participate in the education program (Authorized by Regional Health Authorities number 14/20) and data are used for research purpose. As patients gave consent to participate and for the use of their data for research purpose as presented in the project and approved by French Health Regional Authorities (ARS ETP/14/20), no additional submission to an ethic committee was performed

-Consent for publication : Authors declare that they consent to the publication if the manuscript is accepted

-Availability of data and material : yes

-Competing interests : Authors declare that they have no potential conflicts of interest that might be relevant to the contents of this manuscript.

-Funding : No external funding was used in the preparation of this manuscript

-Authors' contributions

CO : interview of patients, writing the manuscript

LJ : reading and improvement of the manuscript

LP : reading and improvement of the manuscript

GP : reading and improvement of the manuscript

SE : reading and improvement of the manuscript

HH : therapeutic education leader, interview of patients

IM : design of the study, co-writing the manuscript

All authors have read and approved the manuscript

-Acknowledgements : none

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Appendix 1: Standard educational diagnosis

EDUCATIONAL DIAGNOSIS	Date _____
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Agent: _____ **Department:** _____ **Tel.:** _____
 Referring physician's name: _____ Tel.: _____
 Referring physician's address: _____
 Community physician's name: _____ Tel. _____
 Community physician's address: _____
 Community pharmacist's name: _____ Tel.: _____
 Community pharmacist's address: _____

Patient

Address: _____ **Cell:** _____
Tel.: _____ **Age:** _____ **Weight:** _____ kg
Date of birth: _____
Country of birth: _____

<p>LIVING CONDITIONS: Married <input type="checkbox"/> Children <input type="checkbox"/> Living alone <input type="checkbox"/> Dependents <input type="checkbox"/> Care-givers <input type="checkbox"/></p> <p>RESIDENCE: House <input type="checkbox"/> Retirement home <input type="checkbox"/> Apartment <input type="checkbox"/></p>	<p>PRESENT OR PREVIOUS OCCUPATIO: Working <input type="checkbox"/> Occupation: _____ Retired <input type="checkbox"/> _____ Previous occupation _____ ;</p>
<p>INDICATIONS FOR ANTICOAGULANTS: Non-valvular AF <input type="checkbox"/> DVT <input type="checkbox"/> PE <input type="checkbox"/> Other <input type="checkbox"/></p> <p>SCORES: HAS-BLED=.....BEYTH=</p>	<p>Manages treatment alone: yes <input type="checkbox"/> no <input type="checkbox"/> Helped by his/her child Care-giver: yes <input type="checkbox"/> no <input type="checkbox"/> Anticoagulation clinic: yes <input type="checkbox"/> no <input type="checkbox"/> don't know <input type="checkbox"/></p>
<p>DISABILITIES: Hearing: yes <input type="checkbox"/> no <input type="checkbox"/> Understanding: yes <input type="checkbox"/> no <input type="checkbox"/> Visual: yes <input type="checkbox"/> no <input type="checkbox"/> Reading: yes <input type="checkbox"/> no <input type="checkbox"/> Locomotor: yes <input type="checkbox"/> no <input type="checkbox"/> French language: yes <input type="checkbox"/> no <input type="checkbox"/> Depression: yes <input type="checkbox"/> no <input type="checkbox"/></p>	<p>LEISURE: Handiwork: yes <input type="checkbox"/> no <input type="checkbox"/> Gardening: yes <input type="checkbox"/> no <input type="checkbox"/> Cooking: yes <input type="checkbox"/> no <input type="checkbox"/> Sport: yes <input type="checkbox"/> no <input type="checkbox"/> Other: Projects:</p>

ANTICOAGULATION THERAPY (VKA/DOAC)
Name: _____ tbs, dose <u> x </u> daily every day _____ Administration time: _____ morning <input type="checkbox"/> evening <input type="checkbox"/> time(s): _____

Date of start of treatment: _____	
INR: Target INR: 2-3 <input type="checkbox"/> 3-4 <input type="checkbox"/> Last INR: Date of last INR:	BIOLOGY: Date of assessment: Creatinin_ μmole/L Creatinine clearance_ : ml/min Hemoglobin: _g/dL AST:_ ALT: _IU/L
OTHER PATHOLOGIES:	OTHER MEDICATION:

Appendix 2: Standard educational diagnosis ; Interview guide

Interview guide

Disease:

Do you know the name of the disease you're taking anticoagulants for?

What does this disease mean to you?

Do you worry about something (recurrence or complications)?

Difficulties encountered:

Treatment:

Can you tell me how your anticoagulant treatment works?

Do you know what the treatment is for?

Do you think it's effective? If so, how?

Do you think there can be drawbacks to this treatment (knowledge of risks, bleeding alarm signals)? _____

If so, what? _____

For VKA: Do you know the test used to monitor your treatment? Name, and what it's for.

Treatment compliance:

Can you tell me when and how you take your treatment? And your other medications?
 Method to avoid forgetting your drug

What do you think might be the consequences of forgetting treatment?

Can you tell me what you do if you forget or have a doubt?

Do you take any medication without medical advice? yes no

If so, what? _____

Do you think it could be a problem? yes no

What do you take for pain?

Sum up the interview: SUMMARY

Problems:

Resources:

Obstacles:

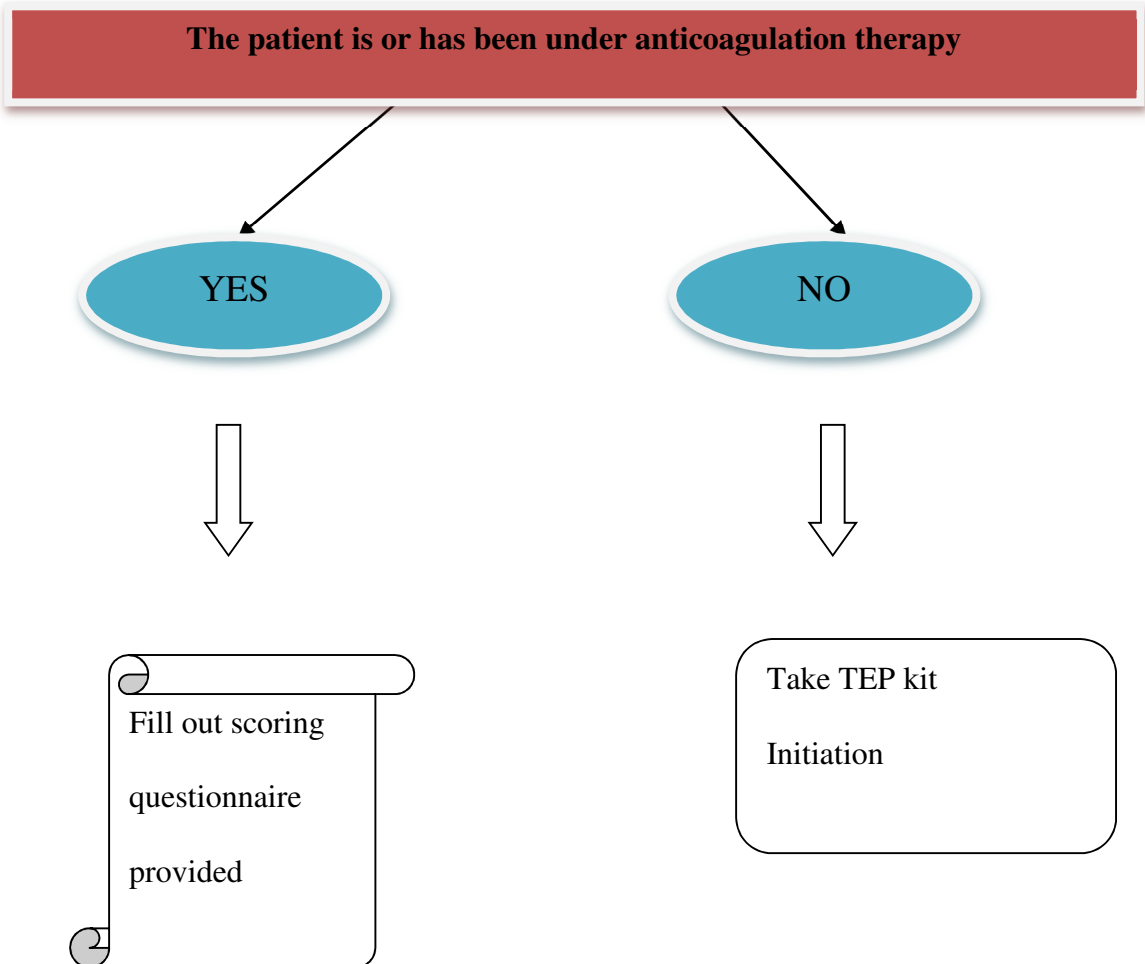
Gray areas:

PERSONALIZED OBJECTIVES

Appendix 3: decision tree and profile identification score

Profile score for patients under anticoagulation therapy, following decision-tree

➤ *Decision-tree for patient under anticoagulation therapy*



Appendix 4: Profiling questionnaire and score for patients taking or having taken anticoagulants.

Items	Points
<u>Pathology</u> 1) Do you know why you take this treatment? <i>*Clot, phlebitis, thrombosis, lung problem, embolism</i> <i>*Heart flutter, heart problem, rhythm problem, NVAF</i>/1
2) Do you know the risks associated with this disease? <i>*recurrence, hemorrhage, hematoma, paralysis, stroke, death</i>/1
<u>Treatment</u> 3) Can you name your treatment? 4) INR off-target in previous months/years? 5) Are your doctor and the doctors you see aware of your treatment? 6) Do you find the treatment has drawbacks? 7) Do you know what medicine to take for headache? 8) Have you ever forgotten to take your treatment?/1/1/1/1/1/1
<u>Risks</u> 9) No bleeding during the previous months/years? 10) Do you know the signs of alert? 11) Do you know who to contact with any questions?/1/1/1
<u>Help</u> 12) Do you have any help for taking your treatment? <i>*Pill-box, pharmacy, nurse, friend/ family, child, CREATIF (reference and educational center for antithrombotic agents, Ile de France region)</i>/1
TOTAL/12

⇒ **Do you want to know more?** **YES** **NO**

If no, STOP

12-9 points	<9-4points	<4-0 points
Competent	Learning underway	Needing education

Table 1: Double-blind assessment of educational diagnosis

Patient n°	Profile according to score (score/12)	Profile according to standard educational diagnosis
17	I	I
19	E (4)	E
21	I	I
24	I	I
25	I	I
28	I	I
30	I	I
35	E (2)	E
36	L (7)	L
41	L (6)	L
46	E (3)	E
53	I	I
55	C (10)	C
59	C (9)	C
62	E (4)	E
63	L (5)	L
72	I	I
73	C (9)	C
80	I	I
82	E (4)	E
83	C (11)	C
85	E (1)	E
86	I	I
96	C (9)	C
100	C (9)	C
110	I	I

Competent: **C**

Learning underway: **L**

Needing education: **E**

Initiation of treatment: **I**

Table 2: Characteristics of patients with double-blind educational diagnosis according to profile

	Competent	Learning underway	Needing education	Initiation
TOTAL	6	3	6	11
Female	4	1	2	7
Male	2	2	4	4
Mean age (years)	84.1	77	82.5	74.7
PE	2	1		5
DVT				
Persistent AF	3	2	6	6
Other	1			
History of cancer	1	1	1	
Thrombophilia				
History of hemorrhage	1		2	2
CHA2DS2-VASC >2	5	2	5	9
HAS-BLED >1	4	0	3	8
Treatment				
Xarelto®			1	
Eliquis®	2			
Previscan®	2	3	4	
Coumadin®	2		1	2
Sintrom®				
Other				
None				9
Wants to know more	3	3	6	11

Figure 1: flow chart

Flowchart

