Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

The FMEA method applied to anticoagulation of patients with non-valvular atrial fibrillation

Authors

Francisco Atienza[1], Vivencio Barrios[2], María Isabel Egocheaga[3], Rafael Hidalgo[4], Núria Marín[5], Catalina Ramis[6]

[1] Virgen de África Clinical Management Unit. C/ Virgen de África, 1, 41011, Seville, Spain

[2] Cardiology Department of Hospital Universitario Ramón y Cajal. Ctra. De Colmenar Viejo, km 9,100, 28034, Madrid, Spain

[3] Centro de Salud Isla de Oza. C/ San Martín de Porres 6, 28035, Madrid, Spain

[4] Cardiology and Cardiovascular Surgery Clinical Management Unit. Hospital Universitario Virgen de Macarena. Avenida Dr. Fedriani, 3, 41009, Seville, Spain

[5] Bayer. Av. Baix Llobregat, 3, 08970 Sant Joan Despí, Barcelona, Spain

[6] GOC *Networking*. C/ Josep Irla i Bosch, 5-7, 1 planta, 08034, Barcelona, Spain

Corresponding author

Francisco Atienza

Virgen de África Clinical Management Unit.

C/ Virgen de África, 1, 41011, Seville, Spain

fatienzam@hotmail.com

Telephone: +34 662.10.34.20

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

Abstract

***Objetivos*:**

El propósito de este trabajo es contribuir a mejorar el proceso de la anticoagulación en pacientes con fibrilación auricular no valvular (FANV) mediante acciones de sensibilización y formación al colectivo de atención primaria (AP).

***Material y métodos*:**

Se realizaron 38 grupos focales secuenciados según una adaptación del método de Análisis Modal de Fallos y Efectos (AMFE). Cada reunión fue dinamizada mediante una metodología de "tormenta de ideas" (*brainstorming*). Participaron 482 médicos (444 de AP y 38 cardiólogos) de ámbito nacional con representación geográfica homogénea. El trabajo de campo se extendió entre el 28 de marzo y el 20 de junio de 2017.

***Resultados*:**

Las principales acciones inseguras que pueden comportar un evento hemorrágico o trombótico son la anticoagulación incorrecta o la falta de seguimiento del paciente, debidos sobre todo a carencias formativas en el manejo de la FANV y no tener en cuenta posibles interacciones que pueden darse con fármacos antagonistas de la vitamina K (AVK). Las principales recomendaciones para paliar estos fallos se centraron en un buen seguimiento de los pacientes con FANV, en realizar o actualizar los protocolos o guías de práctica clínica y en potenciar la formación continuada de los médicos que habitualmente manejan a pacientes con FANV tratados con anticoagulantes orales.

***Conclusiones*:**

Un porcentaje significativo de pacientes con FANV no están correctamente anticoagulados, y para paliar este problema se requieren acciones específicas, entre las que destaca la formación sobre anticoagulación en general, y sobre uso de los anticoagulantes orales de acción directa en particular.

PALABRAS CLAVE:

Fibrilación auricular; anticoagulantes; trombosis; Seguridad del paciente

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

The FMEA method applied to anticoagulation of patients with non-valvular atrial fibrillation

ABSTRACT

Objectives:

To contribute to improving the process of anticoagulation in patients with non-valvular atrial fibrillation (AF) through awareness and training actions for primary care physicians (PCP).

Material and methods:

38 focus groups sequenced according to an adaptation of the Failure Mode and Effects Analysis (FMEA) method. Each meeting was dynamized through a "brainstorming" methodology. The geographical representation was homogeneous, with a total of 482 national physicians (444 PCP and 38 cardiologists). The meetings were held between March 28 and June 20, 2017.

Results:

The main unsafe actions that can lead to a hemorrhagic or thrombotic event are incorrect anticoagulation or lack of patient follow-up. These events are mainly caused by training deficiencies in the management of non-valvular AF or by not taking into account possible interactions with vitamin K antagonist drugs. The main recommendations to alleviate these failures were focused on a good follow-up of patients with non-valvular AF, on creating or updating the protocols or clinical practice guidelines, and on promoting the continuous training of physicians who usually manage patients with non-valvular AF treated with oral anticoagulants.

Conclusions:

A significant percentage of patients with non-valvular AF are not correctly anticoagulated. Specific actions are required to alleviate this problem. Among them, the importance of a general anticoagulation training and, particularly, the use of direct oral anticoagulants were emphasized.

Key words: Atrial fibrillation; Anticoagulants; Thrombosis; Patient Safety

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

INTRODUCTION

Atrial fibrillation (AF) is the most common arrhythmia[1]. It is often associated with left ventricular hypertrophy[2] and heart failure, cognitive impairment and stroke, which is the leading cause of disability in Spain and the leading cause of death in women[3, 4]. Thus, in addition to great clinical significance, AF leads to important socioeconomic and health implications (health-related quality of life).

According to the results of a cross-sectional study conducted in Spain in 2014 with a representative sample of 8,343 patients over 40 years of age treated in primary care (PC) centers[5], the overall age-adjusted prevalence of AF is 4.4%. It is similar in both genders, but increases with age until it reaches 17.7% in patients over the age of 80. These authors estimate that there are more than 1 million patients with AF in Spain, about 90,000 of whom are not diagnosed. Another cross-sectional study, also published in 2014, which groups the data of 17,291 patients from six studies, all conducted in Spain[6], estimated values reasonably consistent with those of the previous research. Specifically, it was observed that the prevalence of AF for all ages was 1.5% and, likewise, it increased progressively with age: 0.5% for the group aged 45-59 years, 2.3% for the group aged 60-74 years and 6.3% for those over 75 years; although, in this study, the prevalence of AF in men (1.9%) almost doubled that observed in women (1.1%). Likewise, it showed that 73.4% of patients with AF received anticoagulant treatment and that, in addition to age and gender, the main risk factors statistically associated with this arrhythmia were hypertension (HTN), obesity and a history of coronary artery disease. On the other hand, a nested case-control study in a population cohort of 9,380 men 25 to 79 years of age matched by age and gender, observed during the period

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

1999-2013, revealed that a P wave of more than 110 milliseconds also increases the risk of AF[7].

The Val-FAAP study, which included 119,526 subjects, showed that 6.1% had atrial fibrillation, a percentage that increased with age, hypertension and male sex[8].

In general, these data do not differ substantially from those obtained by investigations in other countries. Indeed, a prospective study conducted in Israel with a cohort of 2,420,000 adults between 2004-2012[9] found a prevalence of 3%, higher in men than in women, which increased with age; and a retrospective British review conducted in 2010 with computerized hospital records estimated that the prevalence of non-valvular AF (NVAF) was 1.5%[10].

The pharmacological treatment of NVAF is based on the administration of oral anticoagulants. The recent guideline from the European Society of Cardiology, published in August 2016[11], considers that both vitamin K antagonists (VKAs) and direct oral anticoagulants (DOACs) are effective for the prevention of stroke in AF. However, it later adds that a meta-analysis[12] with 42,411 patients treated with DOACs vs. 29,272 treated with warfarin showed that, despite increasing the likelihood of gastrointestinal bleeding, DOACs have a favorable risk-benefit profile since they significantly reduced strokes and intracranial hemorrhages regardless of the quality of control of the international normalized ratio (INR), in addition to mortality from any cause. This argument is shared by the National Institute for Health and Care Excellence (NICE) consensus[13] and, with certain nuances, the Spanish National Health Administration[14]. In this same sense, a recent review concludes that rivaroxaban in clinical practice has shown an efficacy and safety profile similar or, in some aspects even better, than those obtained in clinical trials[15].

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

However, studies such as PAULA[16, 17]have found that approximately 40% of patients with NVAF anticoagulated with VKAs in PC in Spain had inadequate control of anticoagulation during the previous 12 months. The CALIFA study[18] raised this figure to 46%, while the observational study ANFAGAL[19], which analyzed 511 patients with NVAF treated in PC and anticoagulated for more than a year with VKAs, found that 41.5% had less than 60% of the controls in therapeutic range. The ACTUA study also concluded that a considerable number of patients receiving AVK are not well controlled and that they could benefit from non-vitamin K antagonist oral anticoagulants [20].

It is believed that, in order to significantly reduce the risk of stroke, a time in therapeutic range (TTR) of more than 70% is necessary in patients with a score on the CHADS2 scale higher than 2. Lower times increase the risk of stroke by increasing this risk the lower the TTR. In addition, usually, the dose adjustment of anticoagulant only takes into account the latest INR measurement, which may imply a low therapeutic coverage. Likewise, questions are raised about the low use of DOACs being due to many causes, among which the erroneous perception of them stands out; in other words, a lack of knowledge about their efficacy and safety profile[21-23].

The FMEA (Failure Modes and Effects Analysis) method is a prospective risk analysis methodology that identifies and aims to prevent possible failures of a service or product, evaluating their probability of occurrence, the possibility of detection, the possible effects and their severity, facilitating the identification of possible improvement actions[24-26]. It was used initially by the industrial sector and, more recently, has delivered good results in the service sector. Specifically, it has been used in the Spanish health sector to improve training in

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

laparoscopic surgery[27], to improve safety in suction via an orotracheal tube[28] and to increase patient safety in hemodialysis[29].

For the aforementioned reasons, this project emerged with the purpose of contributing to alleviate this problem by carrying out actions to raise awareness among the PC group based on the analysis of the anticoagulation situation carried out using the FMEA methodology. The objectives, therefore, were: a) to identify the failures and the causes that lead to a thrombotic or hemorrhagic event in patients with NVAF; b) to plan improvement actions to prevent the occurrence of failures and improve their possible detection; and c) to reduce the uncertainties that may exist in the management of anticoagulated patients with NVAF.

METHODS

38 focus groups lasting 4 hours were carried out, modified by the FMEA methodology and moderated by two physicians (a family doctor and a cardiologist) and supported by two technicians who are experts in focus group methodology. A total of 406 primary care physicians participated, in addition to the 38 primary care physicians and 38 cardiologists who acted as moderators. The Autonomous Communities with the greatest participation were *Andalucía* (19%), *Cataluña* (13%), Galicia (13%), *Castilla y León* (12%), Madrid (12%) and *Comunidad Valenciana* (11%).

The fieldwork was carried out between March 28 and June 20, 2017.

Each workshop began with a presentation on the prevention of stroke in AF and the theoretical explanation of the work methodology. Next, two groups were formed to develop the FMEA method. The adaptation of the method consisted of starting the analysis based on two effects which had already been selected: hemorrhagic events and thrombotic events. Both groups worked according to the following sequence: a) detection of unsafe actions that

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

could be involved in the genesis of said events and prioritization of the three most relevant events; b) identification of causes of the three failures and prioritization of the three most relevant ones; c) calculation of the risk priority number (RPN) for each cause, which is obtained from the product of the estimated probability of occurrence of each failure, its severity and its probability of detection, and selection of the two with the highest RPN; and d) proposal for recommendation of improvement actions formulated to address the prioritized causes with a higher RPN in order to prevent or, at least, minimize the damage.

To facilitate the operations of the workshops and the subsequent analysis of the results, the ideas that emerged were grouped into different categories (diagnosis, treatment, follow-up, training and others).

Each meeting was made more lively through a structured brainstorming technique, in order to generate an orderly debate that stimulates creativity, allows easy identification of the agreements and disagreements within the group, while guaranteeing a balanced and active contribution of all the participants and the achievement of the session's objectives in the allocated time[30].

RESULTS

Thrombotic events

As shown in table 1, the main failures identified by more than 50% of the participants in all workshops were:

- "Not diagnosing the patient with NVAF and/or not performing AF screening" was considered by 303 participants (62.9%) and prioritized in 32 workshops.
- "Not performing a correct INR/TTR assessment during patient follow-up" was considered by 300 participants (62.2%) and prioritized in 29 workshops.

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

- "Not properly anticoagulating the patient with NVAF due to: therapeutic inertia, incorrect dose, inadequate bridge therapy, treatment with antiplatelet agents instead of anticoagulants, transferring responsibility to another specialty, drug or food interactions, etc." was indicated by 248 participants (51.5%) and prioritized in 19 workshops.

Table 2 shows the causes detected in all the workshops and the corresponding RPNs calculated. The three causes with the highest RPNs are shown below:

- "The lack of training on the diagnosis, management and treatment of NVAF; specifically, on the indications for DOACs and the drug and food interactions of VKAs" obtained an RPN of 6,662.
- "Not performing systematic screening of high-risk patients (according to guidelines)" received an RPN score of 5,189.
- "Not taking into account the possible drug and food interactions of the treatment with VKAs" obtained an RPN of 4,067 points.

Table 3 shows the recommendations presented in all the workshops, while the four identified in more than 50% of the workshops are given below:

- "Implementing, updating, simplifying protocols and clinical practice guidelines on the diagnosis, management and treatment of NVAF. In this way, the physical examination of the patient would be systematized, paying special attention to patients with comorbidities or chronic conditions" was indicated in 37 workshops.
- "Carrying out adequate follow-up of patients with NVAF, with periodic visits in which the INR is reviewed and the TTR is calculated, evaluating the treatments, possible interactions, etc., and performing the additional tests deemed appropriate. All of this

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

should be carried out paying special attention to patients with comorbidities or chronic conditions" was supported in 26 workshops.

- "Carrying out ongoing training for the different specialties involved in NVAF (family medicine, nursing, cardiology, hematology, internal medicine, neurology, etc.) jointly, so that they can share experiences and improve the comprehensive approach to the condition and its correct treatment" was indicated in 25 workshops.
- "Creating alerts in the computer systems that warn of possible interactions, and facilitating the use of thrombotic and hemorrhagic risk scales. In addition, all this can be supported with the use of mobile applications" was assessed in 22 workshops.

Hemorrhagic events

As shown in table 4, the main failures identified by participants in more than 50% of the workshops were:

- "Not properly anticoagulating the patient with NVAF: therapeutic inertia, incorrect dose, inadequate bridge therapy, antiplatelet plus anticoagulant therapy, drug or food interactions, etc." was indicated by 446 participants (92.5%) and prioritized in all workshops.
- "Not carrying out adequate patient follow-up, specifically of the INR, the TTR and their adherence to treatment" was indicated by 352 participants (73.0%) and prioritized in 21 workshops.
- "Not taking into account the possible risk factors or comorbidities of the patient, including kidney and liver function" was considered by 212 participants (44.0%) and prioritized in 20 workshops.

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

Table 5 shows the causes detected in all the workshops and the corresponding RPNs calculated. The three causes with the highest RPNs are shown below:

- "Not taking into account the possible drug and food interactions of the treatment with VKAs" obtained an RPN of 6,836 points.
- "The lack of training on the diagnosis, management and treatment of NVAF; specifically, on the indications for DOACs" received an RPN of 4,678 points.
- "Therapeutic inertia at the time of establishing the treatment, which leads to not properly anticoagulating the patient with NVAF" was given a score of 4,417 points.

Table 6 shows the recommendations presented in all the workshops, while the four prioritized in more than 50% of the workshops are given below:

- "Carrying out adequate follow-up of patients with NVAF, with periodic visits in which the TTR, INR treatments, interactions, etc. are reviewed and the additional tests deemed appropriate are performed. All of this should be carried out paying special attention to patients with comorbidities or chronic conditions." This recommendation was identified in 36 workshops.
- "Implementing or updating protocols and clinical practice guidelines on the diagnosis, management and treatment of NVAF. In this way, the physical examination of the patient would be systematized, paying special attention to patients with comorbidities or chronic conditions" was a recommendation identified in 32 workshops.
- "Carrying out ongoing training for family doctors on the diagnosis, management and treatment of NVAF; and, specifically, on DOACs to promote their use. Conducting training activities in health centers is suggested" was a recommendation identified in 31 workshops.

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

- "Educating and involving the patient and family members in their illness and treatment, providing simple materials for their information" was identified in 26 workshops.

DISCUSSION

This work has been carried out using a novel methodology. Although the FMEA method was initially used by other industrial sectors, its use in the health field is limited[27-29]. In addition, most likely, it is the first time that FMEA methods have been combined with a moderation by structured brainstorming, which has earned the accreditation of the *Consell Català de Formació Continuada de les Professions Sanitàries* [Catalan Council of Ongoing Training for Healthcare Professionals] and the endorsement of the Clinical Cardiology Section of the Spanish Society of Cardiology (SEC).

The participation of a wide panel of experts with professional practice in most of the Autonomous Regions is also highlighted. However, to correctly interpret the results of these workshops, it must be taken into account that, although the results are expressed quantitatively, it is qualitative information that shows qualified opinion trends, since they correspond to professionals with extensive clinical experience. That is why this work can be very important for the deployment of other projects. For example, in the context of *SEC Primaria*, whose objective "is to reduce morbidity and mortality and increase the quality of life of patients with heart disease by making efficient use of available resources and other initiatives in this field"[31], as well as in other medical societies, above all in the field of primary care.

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

In general terms, the participants who worked on hemorrhagic events and those who worked with thrombotic events performed quite similar analyses and made consistent recommendations.

We can affirm that there is a widespread perception among primary care physicians in Spain that the management of NVAF is an important healthcare problem, with a large sector of these patients without effective anticoagulation therapeutic coverage (not anticoagulated or poorly anticoagulated), which increases their risk of stroke, as well as others at risk of hemorrhages of greater or lesser severity.

Thus, not properly anticoagulating and not carrying out adequate patient follow-up (of the INR, TTR and their adherence to treatment) were the two main unsafe actions detected by both working groups, which, logically, also agrees with the findings of the ANFAGAL[19], CALIFA[18] and PAULA[16, 17] studies.

Regarding the causes, there was also consistency in the opinions of both groups; meaning that the lack of training on the diagnosis, management and treatment of NVAF (specifically, on the indications for DOACs), and not taking into account the possible drug and food interactions of treatment with VKAs are the two causes that garnered the highest RPN in both groups.

Finally, the most prioritized recommendations in both groups were: (a) performing adequate follow-up of patients with NVAF; (b) implementing or updating protocols and clinical practice guidelines on the diagnosis, management and treatment of NVAF; and (c) carrying out ongoing training for the different specialties involved in NVAF (family medicine, nursing, cardiology, hematology, neurology, etc.) jointly in the health centers on the diagnosis, management and treatment of NVAF; and, specifically, on DOACs to promote their use.

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

The interest of this study lies in the use of a highly accredited qualitative research technique such as focus groups, combined with a safety problem analysis tool, modeled by a brainstorm, applied to analyze the perceptions of a large group of PC physicians on the whole process of anticoagulation in patients with NVAF (diagnosis of NVAF, evaluation of thrombotic and hemorrhagic risk and indication and follow-up of anticoagulant treatment).

This type of qualitative research provides great information, and it would be useful to continue in other professionals involved and in the patients themselves.

The limitations of this study are those of any qualitative research, and also the possibility that participating physicians were, in general, more motivated and interested in this particular condition. However, this bias can also lead to obtaining richer and more relevant information. However, the authors consider that the opinion of the expert group cannot be taken as representative of the entire primary care group, but it does show a tendency of opinion of the experts who have participated.

CONCLUSIONS

From the set of contributions made by the participants in these FMEA workshops, it can be inferred that there was a broad consensus in considering that:

1. A significant percentage of patients with NVAF are not correctly anticoagulated due to lack of training, involvement or co-responsibility of the professionals who treat them.
2. To alleviate this problem, training activities on anticoagulation in general, and on the use of DOACs in particular, are required, aimed at all professionals involved in the treatment of NVAF.

All this constitutes a first proposal of measures to be developed that will allow us to continue working towards improving anticoagulation in Spain.

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

ACKNOWLEDGEMENTS

The authors express their gratitude to all the participants of the work sessions, to the company GOC *Networking* for its methodological support throughout the process and to Bayer.

FINANCIAL SUPPORT

This study received financial support from Bayer.

CONFLICT OF INTERESTS

Francisco Atienza declares to have received fees for advice and speech of Bayer laboratories, fees per presentation from FAES laboratories, fees per presentation from Boehringer Ingelheim laboratories, and to have received the award for the best communication of the 12th Andalusian Congress of Primary Care Physicians (Semergen Andalucía) held in Almeria from May 11 to 13 of 2017 from Laboratories VIR. Vivencio Barrios, Mª Isabel Egocheaga and Rafael Hidalgo declare no conflicts of interest. Nuria Marín works in Bayer laboratories. Catalina Ramis works at GOC Networking.

REFERENCES (31 citations)

1. Perez-Villacastin J, Perez Castellano N, Moreno Planas J. Epidemiology of atrial fibrillation in Spain in the past 20 years. Rev Esp Cardiol (Engl Ed) 2013;**66**:561-565.

2. Proietti M, Marra AM, Tassone EJ, De Vuono S, Corrao S, Gobbi P, et al. Frequency of Left Ventricular Hypertrophy in Non-Valvular Atrial Fibrillation. Am J Cardiol 2015;**116**:877-882.

3. Matías-Guiu J, Villoria F, Oliva J, Viñas S, Martí J. Estrategia en ictus del Sistema Nacional de Salud. Ministerio de Sanidad y Política Social 2009.

4. Evaluación de la Estrategia en Ictus del Sistema Nacional de Salud. 2013 [cited 2017 28 Nov]; Available from: http://saludcantabria.es/uploads/pdf/noticias/Punto%2011-%20Evaluacion%20Estrategia%20en%20Ictus%20del%20SNS%202013.pdf

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

5. Gomez-Doblas JJ, Muniz J, Martin JJ, Rodriguez-Roca G, Lobos JM, Awamleh P, et al. Prevalence of atrial fibrillation in Spain. OFRECE study results. Rev Esp Cardiol (Engl Ed) 2014;**67**:259-269.

6. Baena-Diez JM, Grau M, Fores R, Fernandez-Berges D, Elosua R, Sorribes M, et al. Prevalence of atrial fibrillation and its associated factors in Spain: An analysis of 6 population-based studies. DARIOS Study. Rev Clin Esp 2014;**214**:505-512.

7. Masso-van Roessel A, Escobar-Robledo LA, I RD, Grau M, Sala J, Ramos R, et al. Analysis of the Association Between Electrocardiographic P-wave Characteristics and Atrial Fibrillation in the REGICOR Study. Rev Esp Cardiol (Engl Ed) 2017;**70**:841-847.

8. Barrios V, Calderón A, Escobar C, de la Figuera M, Primary Care Group in the Clinical Cardiology Section of the Spanish Society of Cardiology. Pacientes con fibrilación auricular asistidos en consultas de atención primaria. Estudio Val-FAAP. Rev Esp Cardiol. 2012;65:47-53 2012;**65**:47-53.

9. Haim M, Hoshen M, Reges O, Rabi Y, Balicer R, Leibowitz M. Prospective National Study of the Prevalence, Incidence, Management and Outcome of a Large Contemporary Cohort of Patients With Incident Non‐Valvular Atrial Fibrillation. In: J Am Heart Assoc; 2015.

10. Khan MA, Raja S, Ibrahim MS, Hammersely C. Prevalence and management of atrial fibrillation in primary care: a case study. Prim Health Care Res Dev 2014;**15**:355-361.

11. Kirchhof P, Benussi S, Kotecha D, Ahlsson A, Atar D, Casadei B, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Eur Heart J 2016;**37**:2893-2962.

12. Ruff CT, Giugliano RP, Braunwald E, Hoffman EB, Deenadayalu N, Ezekowitz MD, et al. Comparison of the efficacy and safety of new oral anticoagulants with warfarin in patients with atrial fibrillation: a meta-analysis of randomised trials. Lancet 2014;**383**:955-962.

13. NICE Guidance: Non-vitamin K antagonist oral anticoagulants (NOACs) Key therapeutic

topic Published: 26 February 2016 pag 4 https://www.nice.org.uk/guidance/ktt16/resources/nonvitamin-k-antagonist-oral-anticoagulants-noacs-58757956094149.

14. Agencia Española de Medicamentos y Productos Sanitarios. Ministerio de Sanidad Servicios Sociales e Igualdad. Informe de posicionamiento terapéutico UT_ACOD/V5/21112016. Criterios y recomendaciones generales para el uso de los anticoagulantes orales directos (ACOD) en la prevención del ictus y la embolia sistémica en pacientes con fibrilación auricular no valvular. Fecha de publicación: 21 de noviembre de 2016.

15. Barrios V, Escobar C. [From clinical trials to clinical practice. Experience with rivaroxaban in the anticoagulant treatment of patients with non-valvular atrial fibrillation]. Semergen 2017;**43**:222-229.

16. Barrios V, Escobar C, Prieto L, Osorio G, Polo J, Lobos JM, et al. Anticoagulation Control in Patients With Nonvalvular Atrial Fibrillation Attended at Primary Care Centers in Spain: The PAULA Study. Rev Esp Cardiol (Engl Ed) 2015;**68**:769-776.

17. Polo Garcia J, Barrios Alonso V, Escobar Cervantes C, Prieto Valiente L, Lobos Bejarano JM, Vargas Ortega D, et al. Control de la anticoagulación en pacientes con fibrilación auricular

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

no valvular en práctica clínica de atención primaria en las diferentes comunidades autónomas. Estudio PAULA. Semergen 2017;**43**:207-215.

18. Anguita Sanchez M, Bertomeu Martinez V, Cequier Fillat A. Quality of Vitamin K Antagonist Anticoagulation in Spain: Prevalence of Poor Control and Associated Factors. Rev Esp Cardiol (Engl Ed) 2015;**68**:761-768.

19. Cinza-Sanjurjo S, Rey-Aldana D, Gestal-Pereira E, Calvo-Gomez C. Assessment of Degree of Anticoagulation Control in Patients With Atrial Fibrillation in Primary Health Care in Galicia, Spain: ANFAGAL Study. Rev Esp Cardiol (Engl Ed) 2015;**68**:753-760.

20. Barrios V, Escobar C, Lobos JM, Polo J, Vargas D. Uso de los anticoagulantes orales de acción directa en atención primaria: Estudio ACTUA. Semergen 2017;**43**:477-485.

21. Hylek EM, Go AS, Chang Y, Jensvold NG, Henault LE, Selby JV, et al. Effect of intensity of oral anticoagulation on stroke severity and mortality in atrial fibrillation. N Engl J Med 2003;**349**:1019-1026.

22. Morgan CL, McEwan P, Tukiendorf A, Robinson PA, Clemens A, Plumb JM. Warfarin treatment in patients with atrial fibrillation: observing outcomes associated with varying levels of INR control. Thromb Res 2009;**124**:37-41.

23. Lopez-Sendon J, Merino JL. Poor Anticoagulation Control in Atrial Fibrillation: How Much Longer? Rev Esp Cardiol (Engl Ed) 2015;**68**:740-742.

24. AMFE: Análisis Modal de Fallos y Efectos – Guía y ejemplos de uso| PDCA Home. 2017 [cited 23/10/2017]; Available from: https://www.pdcahome.com/3891/amfe-guia-de-uso-del-analisis-modal-de-fallos-y-efectos/

25. Ministerio de Trabajo y Asuntos Sociales: Instituto Nacional de Seguridad e Higiene en el Trabajo. NTP 679: Análisis modal de fallos y efectos. AMFE. In; 2004.

26. Atienza FJ. Análisis Modal de Fallos y Efectos (AMFE). Aplicación a la seguridad en el ámbito de la Atención Primaria. Itinerario para la Seguridad del Paciente An Atención Primaria (SPIF-AP). Curso virtual de la EASP. ISBN 978-84-608-5116-5.

27. Alba Mesa F, Sanchez Hurtado MA, Sanchez Margallo FM, Gomez Cabeza de Vaca V, Komorowski AL. Application of failure mode and effect analysis in laparoscopic colon surgery training. World J Surg 2015;**39**:536-542.

28. Vazquez-Valencia A, Santiago-Saez A, Perea-Perez B, Labajo-Gonzalez E, Albarran-Juan ME. Utility of Failure Mode and Effect Analysis to Improve Safety in Suctioning by Orotracheal Tube. J Perianesth Nurs 2017;**32**:28-37.

29. Arenas Jimenez MD, Ferre G, Alvarez-Ude F. Strategies to increase patient safety in Hemodialysis: Application of the modal analysis system of errors and effects (FEMA system). Nefrologia 2017;**37**:608-621.

30. Astier Peña MP, Maderuelo Fernández JÁ, Jiménez Julvez MT, Martín Rodríguez MD, Palacio Lapuente J, Oliveras Cañada G. Análisis proactivo del riesgo : el análisis modal de fallos y efectos (AMFE). Revista clínica electrónica en atención primaria 2010:0001-0008.

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

31. Sociedad Española de Cardiología. SEC-PRIMARIA. 2017 [cited 11/12/2017]; Available from: https://secardiologia.es/institucional/reuniones-institucionales/sec-calidad/sec-primaria

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

TABLES

Table 1: Identification of failures for the "thrombotic event" effect

FAILURES	VOTES n (%)
DIAGNOSIS	
Not diagnosing the patient with NVAF (not performing AF screening)	303 (62.9%)
FOLLOW-UP	
Not performing a correct INR/TTR assessment	300 (62.2%)
Not taking into account the possible risk factors or comorbidities of the patient	68 (14.1%)
Not assessing the change from VKAs to DOACs in patients with out-of-range INR (non-compliance of TPR)	26 (5.4%)
Not achieving good control of the patient despite having good therapeutic compliance	5 (1.0%)
TREATMENT AND INTERACTIONS	
Not properly anticoagulating the patient with NVAF: therapeutic inertia, incorrect dose, inadequate bridge therapy, treatment with antiplatelet agents instead of anticoagulants, transferring responsibility to another specialty, drug or food interactions, etc.	248 (51.5%)
Not anticoagulating the patient with NVAF	199 (41.3%)
EMPOWERMENT OF THE PATIENT	
Not providing the patient with health education	51 (10.6%)
COMPLIANCE	
Poor adherence to treatment by the patient	23 (4.8%)
COORDINATION	
Lack of communication and coordination among healthcare professionals	5 (1.0%)
TRAINING	
Lack of training in the diagnosis, management and treatment of NVAF by family doctors	1 (0.2%)
OTHER	
Not listening to the opinion of the patient who does not want to be treated with VKAs	1 (0.2%)

AF: atrial fibrillation; DOAC: direct oral anticoagulant; INR: international normalized ratio; NVAF: non-valvular atrial fibrillation; TPR: therapeutic positioning report; TTR: time in therapeutic range; VKA: vitamin K antagonist

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

Table 2: Identification of causes for the "thrombotic event" effect and calculation of the RPN

CAUSES	VOTES n (%)	RPN
DIAGNOSIS		
Not performing systematic *screening* of patients (according to guidelines)	219 (45.4%)	5,189
Not knowing or not giving enough importance to the symptoms associated with NVAF, which makes it difficult to diagnose	31 (6.4%)	897
TRAINING		
Lack of training on the diagnosis, management and treatment of NVAF; specifically, on the indications for DOACs and the drug and food interactions of VKAs	153 (31.7%)	6,662
Not anticoagulating the patient with NVAF, lack of knowledge of the need for anticoagulation to prevent stroke, fear of changing from VKAs to DOACs and fear of potential bleeding	40 (8.3%)	1,196
FOLLOW-UP		
Not carrying out adequate patient follow-up, specifically the control of the INR/TTR	126 (26.1%)	3,391
Not adequately controlling the patient due to concomitant diseases / comorbidities, risk factors or intrinsic variability of the patient	29 (6.0%)	703
Not evaluating the patient's cardiovascular risk factors	13 (2.7%)	864
TREATMENT AND INTERACTIONS		
Not taking into account the possible drug and food interactions of the treatment with VKAs	107 (22.2%)	4,067
Therapeutic inertia when evaluating the complete treatment of an anticoagulated patient (leads to not properly anticoagulating the patient with NVAF)	74 (15.4%)	3,207
Not evaluating the patient's thrombotic risk, especially through the use of scales	29 (6.0%)	684
Not assuming co-responsibility for the NVAF patient's anticoagulation, delaying the start of the treatment or "offloading" the responsibility onto another specialty.	22 (4.6%)	1,273
COORDINATION		
Lack of communication and coordination among healthcare professionals: change of treatment, incomplete medical records, evasion of responsibilities, etc.	89 (18.5%)	1,686
MANAGEMENT		
Not having enough time per patient in consultation	66 (13.7%)	562

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

EMPOWERMENT OF THE PATIENT		
Lack of empowerment of the patient in his/her illness and treatment, assessing his/her family and social environment	59 (12.2%)	1,765
COMPLIANCE		
Poor adherence by the patient	47 (9.8%)	1,964
PROTOCOLS AND CLINICAL PRACTICE GUIDELINES		
Not having protocols or clinical practice guidelines, and incorrect monitoring of those that are in place	29 (6.0%)	63
ALERT SYSTEMS		
Lack of alerts in the computer systems	6 (1.2%)	NP
OTHER		
Administrative obstacles to the use of DOACs	19 (3.9%)	225

DOAC: direct oral anticoagulant; INR: international normalized ratio; NP: not prioritized; NVAF: non-valvular atrial fibrillation; RPN: risk priority number; TTR: time in therapeutic range; VKA: vitamin K antagonist

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

Table 3: Proposal of recommendations for the "thrombotic event" effect

RECOMMENDATIONS	N
PROTOCOLS AND CLINICAL PRACTICE GUIDELINES	
Implementing, updating, simplifying protocols and clinical practice guidelines on the diagnosis, management and treatment of NVAF. In this way, the physical examination of the patient would be systematized, paying special attention to patients with comorbidities or chronic conditions**.**	37
FOLLOW-UP	
Carrying out adequate follow-up of patients with NVAF, with periodic visits in which the INR is reviewed and the TTR is calculated, evaluating the treatments, possible interactions, etc., and performing the additional tests deemed appropriate. All of this should be carried out paying special attention to patients with comorbidities or chronic conditions.	26
TRAINING	
Carrying out ongoing training for the different specialties involved in NVAF (family medicine, nursing, cardiology, hematology, neurology, etc.) jointly, so that they can share experiences and improve the approach to the condition and its correct treatment.	25
Carrying out ongoing training for family doctors on the diagnosis, management and treatment of NVAF, and in particular of the anticoagulated patient, updating DOACs so that they feel safer and modify the treatment of patients who are poorly controlled with VKAs.	18
Carrying out ongoing training for nurses on NVAF, encouraging their involvement in the condition and patient management.	5
ALERT SYSTEMS	
Creating alerts in the computer systems that warn of possible interactions, and facilitating the use of thrombotic and hemorrhagic risk scales. In addition, all this can be supported with the use of mobile applications.	22
Unifying computer systems between health centers and referral hospitals, which would improve the recording of information in the patient's integrated medical record. Once unified, carrying out training sessions on these systems is recommended.	5
MANAGEMENT	
Increasing the consultation time per patient, decreasing patient quotas.	18
EMPOWERMENT OF THE PATIENT	
Educating and involving the patient and family members in the full picture of his/her illness and treatment, providing simple materials for his/her information.	16
TEAM WORK	
Involving and working closely with nurses in patient management and training with NVAF.	16

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

COORDINATION	
Improving communication and coordination between the different healthcare professionals.	14
COMPLIANCE	
Monitoring the patient's adherence to treatment, actively asking or designing specific control measures, in order to raise awareness of the importance of good treatment adherence.	10
DIAGNOSIS	
Carrying out *screening* programs systematically on at-risk patients.	8
TREATMENT AND INTERACTIONS	
Assessing the change of treatment to DOACs, through the application of scales, recommendations and protocols for the evaluation of thrombotic and hemorrhagic risks.	8
Consulting the interactions before starting treatment with VKAs, and protocolizing their systematic review.	2
OTHER	
Establishing the day of the NVAF	1

DOAC: direct oral anticoagulant; INR: international normalized ratio; N: number of sessions in which that recommendation was indicated; NVAF: non-valvular atrial fibrillation; TTR: time in therapeutic range; VKA: vitamin K antagonist

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

Table 4: Identification of failures for the "hemorrhagic event" effect

FAILURES	VOTES n (%)
TREATMENT AND INTERACTIONS	
Not properly anticoagulating the patient with NVAF: therapeutic inertia, incorrect dose, inadequate bridge therapy, antiplatelet plus anticoagulant treatment, drug or food interactions, etc.	446 (92.5%)
Not evaluating the patient's hemorrhagic risk, through the use of scales	113 (23.4%)
FOLLOW-UP	
Not carrying out adequate patient follow-up, specifically of the INR, TTR and their adherence to treatment	352 (73.0%)
Not taking into account the possible risk factors or comorbidities of the patient, including kidney and liver function	212 (44.0%)
Not assessing the change from VKAs to DOACs in patients with out-of-range INR	21 (4.4%)
EMPOWERMENT OF THE PATIENT	
Not providing the patient with health education, taking into account his/her family and social environment	45 (9.3%)
COORDINATION	
Lack of communication and coordination among healthcare professionals	18 (3.7%)
DIAGNOSIS	
Incorrectly diagnosing the patient with NVAF	9 (1.9%)

DOAC: direct oral anticoagulant; INR: international normalized ratio; NVAF: non-valvular atrial fibrillation; TTR: time in therapeutic range; VKA: vitamin K antagonist

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

Table 5: Identification of causes for the "hemorrhagic event" effect and calculation of the RPN

CAUSES	VOTES n (%)	RPN
TREATMENT AND INTERACTIONS		
Not taking into account the possible drug and food interactions of the treatment with VKAs	202 (41.9%)	6,836
Therapeutic inertia at the time of establishing the treatment, which leads to not properly anticoagulating the patient with NVAF	104 (21.6%)	4,417
Not evaluating the patient's hemorrhagic risk, especially through the use of scales	76 (15.8%)	2,882
TRAINING		
Lack of training in the diagnosis, management and treatment of NVAF; specifically, on the indications for DOACs	144 (29.9%)	4,678
Not changing from VKAs to DOACs in patients with out-of-range INR, due to lack of experience in the treatment with DOACs and fear of change and the potential for bleeding	18 (3.7%)	288
Lack of training to provide the patient with health education, and lack of tools and methods so that the education is more effective	8 (1.7%)	144
Diagnosis, management and treatment of multiple conditions in the family medicine group	2 (0.4%)	NP
Being more afraid of the thrombotic event than of the hemorrhagic event	2 (0.4%)	NP
FOLLOW-UP		
Not adequately controlling the patient due to concomitant diseases, comorbidities, risk factors or intrinsic variability of the patient	91 (18.9%)	2,274
Not carrying out adequate patient follow-up, specifically of the INR, TTR and their adherence to treatment	70 (14.5%)	2,771
Not evaluating the patient's cardiovascular risk factors	14 (2.9%)	336
COORDINATION		
Lack of communication and coordination among healthcare professionals: change of treatment, incomplete medical records, evasion of responsibilities, etc.	82 (17.0%)	1,876
COMPLIANCE		
Poor adherence to treatment by the patient	81 (16.8%)	3,140
MANAGEMENT		
Not having enough time per patient in consultations	72 (14.9%)	280
Administrative obstacles to the use of DOACs	32 (6.6%)	528
EMPOWERMENT OF THE PATIENT		
Lack of decision about his/her illness and treatment, assessing his/her family and social environment	71 (14.7%)	2,288

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

PROTOCOLS AND CLINICAL PRACTICE GUIDELINES		
Lack of protocols or clinical practice guidelines, and outdated or lack of knowledge of those that are in place	40 (8.3%)	1,227
DIAGNOSIS		
Not performing systematic *screening* of the patient	22 (4.6%)	81
ALERT SYSTEMS		
Lack of alerts in the computer systems	16 (3.3%)	80
Not having unified computer systems between the health centers and reference hospitals, which allow an integrated medical record with easy access to the INR	6 (1.2%)	NP

DOAC: direct oral anticoagulant; INR: international normalized ratio; NVAF: non-valvular atrial fibrillation; NP: not prioritized; RPN: risk priority number; TPR: therapeutic positioning report; TTR: time in therapeutic range; VKA: vitamin K antagonist

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

Table 6: Proposal of recommendations for the "hemorrhagic event" effect

RECOMMENDATIONS	N
FOLLOW-UP	
Carrying out adequate follow-up of patients with NVAF, with periodic visits in which the TTR, INR treatments, interactions, etc., are reviewed and the additional tests deemed appropriate are performed. All of this should be carried out paying special attention to patients with comorbidities or chronic conditions.	36
Referring patients with NVAF to another specialty when they have complex comorbidities	1
PROTOCOLS AND CLINICAL PRACTICE GUIDELINES	
Implementing or updating protocols and clinical practice guidelines on the diagnosis, management and treatment of NVAF. In this way, the physical examination of the patient would be systematized, paying special attention to patients with comorbidities or chronic conditions.	32
TRAINING	
Carrying out ongoing training for family doctors on the diagnosis, management and treatment of NVAF; and, specifically, on DOACs to promote their use. Conducting training activities in health centers is suggested.	31
Carrying out ongoing training for the different specialties involved in NVAF (family medicine, nursing, hematology, neurology, etc.) jointly, so that they can share experiences and improve the approach to the condition and its correct treatment and become aware of the importance of providing patients with health education.	18
Carrying out ongoing training for nurses on NVAF, encouraging their involvement in the condition and patient management	1
Auditing the ongoing training of healthcare professionals	1
EMPOWERMENT OF THE PATIENT	
Educating and involving the patient and family members in his/her illness and treatment, providing simple materials for his/her information	26
ALERT SYSTEMS	
Creating alerts in the computer systems that warn of possible interactions, and facilitating the use of thrombotic and hemorrhagic risk scales. In addition, all this can be supported with the use of mobile applications.	18
Unifying computer systems between health centers and referral hospitals, thus improving the recording of information in the patient's integrated medical record. Once unified, carrying out training sessions on these systems is recommended.	7
MANAGEMENT	
Increasing the consultation time per patient, decreasing patient quotas	17
Creating the figure of coordinator of anticoagulation in health centers	2
Facilitating access to new treatments	1

Document downloaded from http://www.elsevier.es, day 12/02/2026. This copy is for personal use. Any transmission of this document by any media or format is strictly prohibited.

TREATMENT AND INTERACTIONS	
Assessing the change of treatment to DOACs, evaluating the patient's thrombotic and hemorrhagic risk using the HAS-BLED and CHA2DS2-VASc scales	13
COORDINATION	
Improving communication and coordination between the different healthcare professionals	10
Involving and working closely with nurses in the management and training of patients with NVAF	10
OTHER	
Carrying out community activities	1

DOAC: direct oral anticoagulant; INR: international normalized ratio; N: number of sessions in which that recommendation was indicated; NVAF: non-valvular atrial fibrillation; TTR: time in therapeutic range; VKA: vitamin K antagonist