

Attitude to clinical research among health professionals affiliated with the Italian Federation of Centers for the Diagnosis of Thrombotic Disorders and the Surveillance of the Antithrombotic Therapies (FCSA)

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ABSTRACT

Clinical research is vital in supporting evidence-based practice. However, several barriers make participation in research difficult. We performed a survey to evaluate the attitude to research of the members of the Italian Anticoagulation Clinics. The survey includes 19 closed questions on the perception of participating in research and exploring the benefit that health professionals wish to obtain. A total of 167 questionnaires were returned from 97/220 (44.1%) Centers, of which 89.7% were not academic. Participants (median age 56 years, range 29-75y; 56.3% females) were equally distributed all over the country; 151/167 (90.4%) of respondents believe that participating in research helps to reduce the routine of their work and allows a better quality of work, 72/167 (43.1%) complain heavy workload. More than 74% of respondents would like to participate in scientific meetings, without difference in relation to age. Instead, inclusion in the authorship of a scientific paper is of relevance for 75.6% of respondents ≤50 years and for 65.2% of respondents >50 years. A substantial positive attitude towards research was evident, suggesting that independent scientific societies could be of valuable support for the growth of research culture.

INTRODUCTION

Clinical research is vital in providing optimal patient care and can lead to the development of better treatments through evidence-based practice.¹ Moreover, it has been shown to impact on processes and policy of healthcare services,^{2,3} positively influencing the clinical practice and the development of new treatments.⁴

Despite such benefits, several barriers have been identified amongst health professionals, who complain that lack of time, training, knowledge, and funding may prevent them from participating in research. Moreover, the fear that research activities may interfere with clinical care, thus reducing efficiency and productivity, has been reported.⁵ A recent systematic review reported that the development of a stronger research culture appears to be associated with benefits to patients, staff and organizations.⁵ All the studies analyzed in this systematic review reported a positive association between research activities and organizational performance of healthcare services, including lower patient mortality rates and higher levels of patient satisfaction. In addition, when the analysis was conducted among healthcare professionals, reduced staff turnover, improved staff satisfaction, and improved organizational efficiency were found.⁵ In addition, it has been highlighted that the adequate translation of high-quality research in clinical practice may lead to an improvement of health care and that the presence of a strong research culture may facilitate this process and provide benefits for health systems.⁶

Notwithstanding this evidence, the Italian National Health System does not organize specific programs to educate and promote clinical research among healthcare professionals. Despite these difficulties, since its foundation in 1989, the Italian Federation of Centers for the Diagnosis of Thrombotic Disorders and the Surveillance of the Antithrombotic Therapies (FCSA) promoted and performed many collaborative studies, all of which conducted as spontaneous research without the support of public or private funding.⁷⁻¹³ Several other studies have been performed by Centers (*i.e.* Anticoagulation Clinics) affiliated with FCSA, as monocentric studies or more restricted collaborative studies on specific laboratory and clinical aspects concerning the management of anticoagulation, and several FCSA Centers actively participate in patients enrollment of the ongoing Italian START Register,¹⁴ one of the biggest registry on anticoagulation therapy worldwide.

FCSA includes 220 affiliated Anticoagulation Clinics, distributed all over the Country, and following up to 300,000 patients on treatment with vitamin K antagonists (VKAs). FCSA organizes a specifically designed laboratory external quality control program, which runs three times yearly, and the yearly collection of data on the qual-

ity of anticoagulation of patients treated with VKAs. All affiliated Centers are invited to participate in the program. A periodic report of the laboratory and clinical results is sent to all the participants. Participation in laboratory exercises is mandatory for affiliated Centers, whereas participation in the clinical quality program is only recommended.

In order to evaluate the attitude to the research of the members of FCSA, we performed a survey among all the healthcare professionals affiliated with FCSA.

MATERIALS AND METHODS

The survey was available on a dedicated online form guaranteeing anonymity. An e-mail invitation to answer was sent to all 220 FCSA Centers and to 50 individual healthcare professionals affiliated with FCSA in February 2022, followed by two reminders in the subsequent weeks.

The survey included 19 closed questions and was developed into three main sections: the first explored general information about the respondents (affiliation, age, experience in participating in research studies and participation in FCSA clinical and laboratory yearly exercises); the second was focused on the respondents' perception about participating in research activities; the third was focused on knowing the benefit that health professionals wish to obtain in participating in research activities. Ten of the questions concerning attitude, perception, practice, and barriers towards medical research were assessed using a Likert scale, ranging from 1 to 5 (1 = strongly disagree; 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree).

The results were analyzed using only descriptive statistics: categorical data were reported as counts and percentages.

RESULTS

A total of 167 filled questionnaires were returned, 144 (86.2%) from Centers and 23 (13.8%) from individual healthcare professionals. In particular, the 144 questionnaires from Centers were filled by respondents working in 97 (44.1%) out of the 220 federated Centers, and 87 out of these 97 (89.7%) Centers do not belong to academic Institutions (see Table 1 for details). The median age of the participants was 56 years (range 29-75 years), 45 (26.9%) of them were aged less than 50 years and 94 (56.3%) were females. One hundred and thirty-seven (82.0%) were physicians, and 30 (18.0%) were biologists.

Participants were distributed in 17 (81.0%) of the 21 Italian regions: 65 (38.9%) in the North, 33 (19.8%) in the Centre, and 42 (25.1%) in the South.

Of the 167 respondents, 132 (79.0%) regularly participate in the laboratory external quality program, and 109 (65.3%) regularly participate in the clinical surveillance exercise. The great majority of participants (142/167, 85.0%) have experience in previous research studies, whereas 41.3% of them were involved in only one study.

The majority of respondents (151/167, 90.4%) believe that participating in clinical research helps professionals to reduce the usual routine of their work and allow a better quality of the work (148/167, 88.6%), even if 72/167 (43.1%) of the participants complain that it requires heavy workload. The percentage of respondents who complains of worsening workload is reduced among participants younger than 50 years (37.8%) in comparison to participants older than 50 years (45.5%).

Seventy-five out of 167 (44.9%) of all participants answered that their institution encourages research participation, in particular among individual healthcare professionals (61.9%). One hundred and sixteen respondents (69.4%) were confident of having adequate professional skills to participate in research studies, without any difference according to age.

Seventy-seven of respondents (46.1%) dedicate more than 3 hours per month to research activities, 62 (37.1%) 2-3 hours per month, and 28 (16.8%) 1 hour per month.

More than 74% of respondents would like to participate in national or international scientific meetings, without any difference according to age. Conversely, inclusion in the authorship of a scientific paper is important for 75.6% of respondents younger than 50 years and for 65.2% of respondents older than 50 years. Similarly, appreciation by colleagues is more relevant for younger respondents (82.2%) than among the elderly (69.4%).

Table 1. Characteristics of respondents.

Respondents	167
Working in a Center, N (%)	144 (86.2)
Individual healthcare professionals, N (%)	23 (13.8)
Respondent FCSA Centers, N (%)*	97 (44.1)
Females, N (%)	94 (56.3)
Median age, years (range)	56 (29-75)
Age <50 years, N (%)	45 (26.9)
Physician, N (%)	137 (82.0)
Biologist, N (%)	30 (18.0)
Geographical distribution (%)	
North	65 (38.9)
Centre	33 (19.8)
South	42 (25.1)

FCSA, Italian Federation of Centers for the Diagnosis of Thrombotic Disorders and the Surveillance of the Antithrombotic Therapies.

*Calculated on a total of 220 FCSA Centers.

DISCUSSION

The results of this national survey conducted among physicians and biologists working in the Centers affiliated with the FCSA and individual health professionals - experts in the management of patients with thrombotic disease and of anticoagulated patients - associated with the FCSA, indicate a widespread positive feeling toward the participation to research during their routine practice. Indeed, the response rate to this survey was 44.1%, higher than other published papers using online surveys (median response rate was around 26.0%).¹⁵⁻¹⁷

Interestingly, from the first ISCOAT study to the last PLECTRUM study,^{7,13} the participation in the collaborative FCSA studies was quite stable over time, including 30 Centers on average (from 22 to 34). In addition, 59 FCSA Centers are actively participating in patients' enrollment of the Italian START Register,¹⁴ an Italian registry on oral anticoagulated patients. These results seem of particular interest taking into account the low publication rate of Italian academic and non-academic healthcare professionals.¹⁸

The attitude of healthcare professionals affiliated with FCSA seems to be stable over time, irrespective of age and different working conditions due to the progressive reduction of economic resources provided by the National Health Service. In particular, in our country, the annual health expenditure was estimated to be 7% of the domestic product in 2001 and 6.6% in 2019, with annual spending per capita that remains stable in the last ten years.¹⁹ To obtain a reduction in health expenditure, a strong reduction in the number of healthcare professionals has been made. The number of physicians has been reduced, and the median age of healthcare professionals is progressively increased.

Despite these difficulties, why do healthcare professionals affiliated with FCSA show a similar favorable attitude in participating in research? A possible explanation may be the feeling of being part of a successful scientific program with significant study results on daily clinically relevant questions concerning anticoagulation management. The perception of being a member of a scientific community may constitute a reason for satisfaction for healthcare professionals, independently by a clear economic benefit or career advance. FCSA is indeed an independent organization that seems to provide healthcare professionals with the desire to be more involved in research and the motivation to make extra efforts not directly required by their institutions.

Moreover, FCSA actively promotes a research culture, inviting affiliated professionals to participate in clinical research, and promoting an extensive educational program that reinforces the sense of belonging. In fact, FCSA regularly plans teaching courses, an annual national sci-

entific Congress, and the publication of a yearly updated practical guide for the management of antithrombotic therapies. Moreover, a mobile app has been recently developed to ensure rapid interaction among health professionals and to discuss practical daily clinical problems.

This study has several limitations. First, research attitude was investigated by a self-reported questionnaire, and it is possible that respondents have been influenced by the mainstream opinion on FCSA instead to report their true feeling. However, the questionnaire was completely anonymous: therefore, a free personal opinion should be presumed. Second, the number of questions was limited, and no information is available on the role of the single healthcare professional in the hierarchical health services organization. In particular, the answers to the questions concerning the role of the institutions in promoting research could have been influenced by the role of the respondent. Finally, non-respondents did not provide any explanation for their refusal to participate in the survey. It should be noted that the majority of non-respondents were from Centers that did not participate in collaborative studies, whereas 85% of respondents had previous experience of active participation in research, even if in 41.3% of cases only in one occasion.

CONCLUSIONS

In conclusion, this survey presented an analysis of the levels of research awareness and attitudes toward research among health professionals affiliated with the independent scientific society FCSA. A substantial positive attitude towards research was evident and consistent across the age and professional groups. Participation in research is fundamental to the implementation of evidence-based medicine and ensuring high-quality patient care. Active programs for a culture of research should be implemented by the National Health Services and independent scientific societies could be of valuable support for the growth of research culture.

REFERENCES

1. Johnson C, Lizama C, Harrison M, et al. Cancer health professionals need funding, time, research knowledge and skills to be involved in health services research. *J Cancer Educ* 2014;29:389-94.
2. Mant D, Del Mar C, Glasziou P, et al. The state of primary-care research. *Lancet* 2004;364:1004-6.
3. Kalucy EC, Jackson-Bowers E, McIntyre E, et al. The feasibility of determining the impact of primary health care research projects using the Payback Framework. *Health Res Policy Syst* 2009;7:11.
4. Rahman S, Majumder MA, Shaban SF, et al. Physician participation in clinical research and trials: issues and approaches. *Adv Med Educ Pract* 2011;2:85-93.
5. Harding K, Lynch L, Porter J, et al. Organisational benefits of a strong research culture in a health service: a systematic review. *Aust Health Rev* 2017;41:45-53.
6. Skinner EH, Williams CM, Haines TP. Embedding research culture and productivity in hospital physiotherapy departments: challenges and opportunities. *Aust Health Rev* 2015;39:312-4.
7. Palareti G, Leali N, Coccheri S, et al. Bleeding complications of oral anticoagulant treatment: an inception-cohort, prospective collaborative study (ISCOAT). Italian Study on Complications of Oral Anticoagulant Therapy. *Lancet* 1996;348:423-8.
8. Palareti G, Legnani C, Guazzaloca G, et al. Risks factors for highly unstable response to oral anticoagulation: a case-control study. *Br J Haematol* 2005;129:72-8.
9. Pengo V, Cucchini U, Denas G, et al. Standardized low-molecular-weight heparin bridging regimen in outpatients on oral anticoagulants undergoing invasive procedure or surgery: an inception cohort management study. *Circulation* 2009;119:2920-7.
10. Poli D, Antonucci E, Testa S, et al. Bleeding risk in very old patients on vitamin K antagonist treatment: results of a prospective collaborative study on elderly patients followed by Italian Centres for Anticoagulation. *Circulation* 2011;124:824-9.
11. Poli D, Antonucci E, Dentali F, et al. Recurrence of ICH after resumption of anticoagulation with VK antagonists: CHIRONE study. *Neurology* 2014;82:1020-6.
12. Tosetto A, Manotti C, Marongiu F, et al. Center-Related Determinants of VKA Anticoagulation Quality: A Prospective, Multicenter Evaluation. *PLoS One* 2015;10:e0144314.
13. Poli D, Antonucci E, Pengo V, et al. Mechanical prosthetic heart valves: Quality of anticoagulation and thromboembolic risk. The observational multicenter PLECTRUM study. *Int J Cardiol* 2018;267:68-73.
14. Antonucci E, Poli D, Tosetto A, et al. The Italian START-Register on Anticoagulation with Focus on Atrial Fibrillation. *PLoS One* 2015;10:e0124719.
15. Chokshi NK, Simeone DM, Chari RS, et al. A survey of academic surgeons: work, stress, and research. *Surgery* 2009;146:462-8.
16. Paget SP, Lilischkis KJ, Morrow AM, et al. Embedding research in clinical practice: differences in attitudes to research participation among clinicians in a tertiary teaching hospital. *Intern Med J* 2014;44:86-9.
17. Caldwell B, Coltart K, Hutchison C, et al. Research awareness, attitudes and barriers among clinical staff in a regional cancer centre. Part 1: a quantitative analysis. *Eur J Cancer Care (Engl)* 2017;26.
18. Sistema di valutazione della performance dei sistemi sanitari regionali Available from: <https://www.santannapisa.it/it/erza-missione/sistema-di-valutazione-della-performance-dei-sistemi-sanitari-regionali>
19. Russo P, Staniscia T, Romano, F. Il valore della spesa sanitaria in Italia dal 1990 al 2016. *GIHTAD* 2019;12:1-6.