



Global Anticoagulant Registry in the FIELD observing treatment and outcomes in patients with treated acute Venous Thromboembolic Events in the real world

GARFIELD-VTE Registry

Publication Guidelines

GARFIELD-VTE Registry Publications Committee

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Contents

A. INTRODUCTION	3
B. GARFIELD-VTE REGISTRY PUBLICATIONS COMMITTEE.....	3
Members	3
Role of the Publications Committee	3
C. TRI PUBLICATIONS SUPPORT GROUP	4
Plan management.....	4
Management of global publications.....	4
Management of publication proposals.....	5
D. PUBLICATION GUIDELINES	5
Origin of publication proposals	5
Abstract and manuscript development guidelines.....	5
<i>Approval by the Publications Committee</i>	5
<i>Congress submissions</i>	6
Manuscript writing deadline.....	6
High-priority papers.....	7
<i>Timelines for high-priority papers</i>	7
Journal submissions.....	7
Qualification for authorship	7
Two-paper limit for first authors	9
Publication approval and standard information for inclusion in all papers	9
Press releases	9
E. PUBLICATIONS COMMITTEE MEETINGS	9
F. PUBLICATION PROPOSALS	9
Appendix 1. Checklist for Authors Using Medical Writers: A Practical Tool to Discourage Ghostwriting ⁶	11
Appendix 2. STROBE Checklist for Observational Studies	12
Appendix 3. GARFIELD-VTE Publication Proposal	14
Box 1. GARFIELD-VTE Registry: Publication Proposal Keywords.....	16
References	17

A. INTRODUCTION

This document describes the membership, role, and working policy of the GARFIELD-VTE Publications Committee (PC), and presents guidelines for publications based on global and regional data.

The success of the GARFIELD-VTE Registry will be judged primarily on the number and quality of its scientific publications and presentations. The purpose of the policies given herein is to encourage and facilitate important analyses while providing guidelines that assure appropriate use of the GARFIELD-VTE Registry data, timely completion of projects, and adherence to authorship principles.

B. GARFIELD-VTE REGISTRY PUBLICATIONS COMMITTEE

Members

The GARFIELD-VTE PC comprises several members of the Steering Committee and a representative from the Thrombosis Research Institute (TRI).

GARFIELD-VTE Publications Committee

Steering Committee

Walter Ageno, Italy

Pantep Angchaisuksiri, Thailand

Henri Bounameaux, Switzerland

Joern Dalsgaard-Nielsen, Denmark

Sam Goldhaber, US

Sylvia Haas, Germany

Lorenzo Mantovani, Italy

Paolo Prandoni, Italy

Gloria Kayani, London, UK

Sebastian Schellong, Germany

Alexander Turpie, Canada

Jeff Weitz, Canada

Shinya Goto, Japan

Thrombosis Research Institute

Gloria Kayani (Chief Operating Officer)

External experts will be invited by the Publications Committee, with priority given to National Coordinators and TRI Statisticians.

The GARFIELD-VTE Registry Chair, Steering Committee members, and National Coordinators are the only voting members of the PC.

Role of the Publications Committee

The PC is responsible for overseeing all GARFIELD-VTE publications. The main roles are to:

- Develop, in collaboration with the TRI, the GARFIELD-VTE Publication Guidelines.
- Define, coordinate, and author the GARFIELD-VTE Publication Plan.
- Review, prioritize or reject (if unfeasible or duplicating another project), all GARFIELD-VTE publication proposals and manuscripts.
- Liaise with the TRI to facilitate the generation of publications and presentations.

The PC is also responsible for:

- Disseminating the scientific findings from the GARFIELD-VTE Registry.
- Facilitating the production of timely, high-quality manuscripts, abstracts, posters, and presentations, and maintaining the highest level of scientific integrity in this process.

- Assisting in the analysis and reporting of data.
- Liaising with the data management team to ensure the presentation of high-quality data.
- Providing the opportunity for all GARFIELD-VTE investigators to participate in, and receive publication credit for, the presentation/publication of the registry data.

The PC may delegate responsibilities to ad hoc authors, including National Coordinators or other experts, for specific projects.

C. TRI PUBLICATIONS SUPPORT GROUP

The PC will be assisted by a publications support group at the TRI, who will assist in daily administrative tasks and, when needed. This will include roles such as the Lead GARFIELD-VTE Statistician and GARFIELD-VTE Medical Writer. The TRI will interact with registry investigators and National Coordinators to identify, consolidate, and facilitate publication and presentation opportunities on a national and global level. TRI will also be responsible for publication plan management.

Plan management

The main plan-management responsibilities are:

- Creating, managing, and updating the overall publication plan with the manuscript status, authors, target journal(s), submission outcome, etc., of all manuscripts.
- Creating, managing, and updating the overall publication tracker with the project status, notes, tasks, person responsible, and start and proposed end dates.
- Attending PC meetings and teleconferences, providing agendas, meeting minutes, and action plans.
- Following up with the PC about the various activities and action plans.
- Providing regular updates for the GARFIELD-VTE publications to the National Coordinators via the GARFIELD-VTE web site.
- Maintaining a calendar of deadlines for major congresses.
- Maintaining a resource of current submission materials and style requirements for major meetings and journals.
- Maintaining a database of author affiliations, qualifications, disclosure information, submission information, etc, to facilitate submissions.
- Maintaining a record of the number of papers each Steering Committee member has coauthored, with the objective of offering equal authorship opportunities to all members.
- Ensuring that the standard agreed terminology is used in all GARFIELD-VTE papers (e.g., acknowledgements, byline, funding statement).
- Facilitating the timely submission of global publications.
- Providing material for the GARFIELD-VTE newsletter and web site.

Management of global publications

For manuscripts based on the global data, the TRI will be responsible for:

- Corresponding with the lead author during the writing and review phases.
- Offering assistance in editing and writing abstracts, posters, and manuscripts, but strictly avoiding ghostwriting (see Appendix 1).
- Coordinating the review, by the coauthors and the PC, of all abstracts and papers.

Management of publication proposals

The TRI will be responsible for:

- Receiving and maintaining a master list of all GARFIELD-VTE publication proposals.
- Categorizing proposals according to disease or therapeutic area and status.
- Identifying and advising the PC of any potential areas of overlap between new or existing proposals and ongoing manuscripts.
- Coordinating the review by the PC of all publication proposals.

National Coordinators will be responsible for coordinating national proposals and for submitting such proposals to the Publications Committee via the TRI.

D. PUBLICATION GUIDELINES

Origin of publication proposals

The PC may actively seek, solicit, and propose publication and presentation proposals. Proposals can be submitted by:

- Members of the Steering Committee.
- Any NCI or Investigator enrolling patients in the registry, **in collaboration with a Steering Committee member**.
- A non-investigator working **in collaboration with a Steering Committee member and an investigator** (e.g., expert in health economics).

Abstract and manuscript development guidelines

Approval by the Publications Committee

All abstracts and manuscripts that deal with the design of the GARFIELD-VTE Registry or are based on the registry data, whether they pertain to a single, several, or all participating centres, require approval, **in advance**, from the PC. The GARFIELD-VTE Chair has the right to veto PC decisions.

Approval is necessary to avoid:

- a) Duplicate publication.
- b) Jeopardizing other approved or ongoing projects.
- c) Presentation of erroneous, inconclusive, or incorrect data, thereby compromising the public reputation of the registry due to poor quality standards.
- d) Substantially diverting study resources at participating centres or the coordinating centre.

All substudy proposals (i.e. local datasets) derived from the registry dataset must be approved in advance by the Steering Committee. All analyses based on this dataset must meet the PC's requirements for scientific robustness and analysis.

If a participating physician/investigator plans to use their patient's medical records, **without accessing any data from the GARFIELD-VTE Registry**, for publication or presentation, they should refer to their normal institution/institutional review board guidelines for public dissemination of data. Participation in the GARFIELD-VTE Registry will not prevent sites from access to information that would otherwise be readily available without accessing the registry database.

Lead authors must wait for PC approval before developing an abstract into a manuscript.

All manuscripts based on the GARFIELD-VTE database must conform to the STROBE checklist (Appendix 2) [and the Uniform Requirements for Manuscripts Submitted to Biomedical Journals \(http://www.icmje.org\)](http://www.icmje.org). Authors will be required, when laid out in journal guidelines, to supply a completed STROBE checklist.

All proposed publications must be submitted to the GARFIELD-VTE PC for review **at least 60 days** before submission for publication in print or electronic media. The PC will be required to return comments to the lead author within 20 working days. The lead author will provide the PC with a copy of the revised version, for final approval, prior to submission. The PC will send any further comments or final approval for submission within 7 days.

Only manuscripts that have been approved by the PC and the coauthors can be submitted to journals.

Congress submissions

Abstracts based on the global data should be targeted for presentation at the major scientific meetings.

Each Principal Investigator has the right to publish data from their own clinic population, after approval by the PC. Usually, local data presentations and publications will be limited to data already presented from the global results.

The GARFIELD-VTE PC strongly encourages the use of a structured abstract format, even when not specified in the congress guidelines. We suggest that, at a minimum, each abstract be written in four sections, with the headings of **Background/Objectives, Methods, Results, and Conclusions**.

All proposed abstracts and presentations must be submitted to the GARFIELD-VTE PC for review **30 days** before submission. The PC will have 7 days in which to return their comments to the lead author. The lead author will provide the PC with a copy of the final version prior to submission.

Abstract development process

During the development of abstracts (and papers), a close-to-final draft will be distributed for review or approval to the coauthors (the 'working group'). Comments will be dealt with and the abstract revised accordingly; once approved by the authors, the abstract will be sent to the PC for final review and signoff.

Manuscript writing deadline

Once a publication has been presented at a major scientific meeting and the author received PC approval to develop it into a manuscript, the lead author has **3 months** in which to write the manuscript and circulate it to the PC for review (assuming all relevant data are available).

The Publications Manager at the TRI will contact the lead authors of all papers in progress at least four times each year, to request an update on the status of the papers. If a lead author does not respond to this request, they will be re-contacted twice within a month, with a warning that lack of response will result in the paper being classified as 'dormant'. If the lead author of a 'dormant' paper does not respond to the status update request at the next contact, the PC will review the authorship list and either reassign lead authorship to another member of the writing group, who commits to getting the paper written, or declare the paper 'withdrawn'. Withdrawn status means that any other GARFIELD-VTE investigator may propose to write this paper or another, overlapping paper.

High-priority papers

The PC will review the list of all ongoing manuscripts at least twice each year, with special attention to high-priority classification. Criteria for classifying a paper as high priority include:

- (1) scientific importance of potential findings;
- (2) potential impact of publication on the future of the GARFIELD-VTE Registry;
- (3) potential for high visibility in wide circulation scientific journals; and
- (4) urgency in making findings available to scientific community and/or public.

Timelines for high-priority papers

Lead authors of high-priority papers will be followed up regularly by the PC to encourage adherence to timelines. If the completed paper is not provided within 3 months of the initially approved timeline, the PC will request a new timeline from the lead author, which will be subject to PC approval. If the lead author and the PC cannot agree on a new timeline, or if the new timeline is not adhered to, the PC will ask the lead author to select another lead author from the initial writing group, who will commit to an acceptable new timeline. Should no member of the initial writing group be willing to make this commitment, the PC may select a new author to lead the paper to completion in a timely fashion.

A high-priority paper will receive priority status by all parties involved in the preparation of datasets and data verification.

Journal submissions

Simultaneously with the submission of a manuscript to a journal (whether the first, second, third, etc., submittal), the first author will send a copy of the submitted version as well as a copy of the cover letter to the Publications Manager at the TRI. This will allow the TRI to have on file the final copy of all submissions whether accepted, rejected, or under revision and also to compile data on journal responses to GARFIELD-VTE Registry manuscripts.

All substantial changes to an approved manuscript prior to publication must be discussed with the coauthors. Coauthors should receive proposed resubmissions at least 1 week before journal resubmission.

Qualification for authorship

The *study design* and *primary publication* of the GARFIELD-VTE Registry results will be led by the TRI on behalf of the GARFIELD-VTE Investigators.

Lead authorship of the *key* GARFIELD-VTE publications (based on global data) will be with the Steering/Publications Committee; exceptions will be agreed by Steering Committee members.

The sentence 'for the GARFIELD-VTE Investigators' will be included in the byline of all GARFIELD-VTE papers.

National Coordinators or investigators will be invited by the PC to join the writing group on specific global abstracts and manuscripts. In the first instance, the list of approved substudies will be circulated to the National Coordinators, who will be asked to prioritize their preferred three to five topics. When the number of National Coordinators or investigators who express interest in a specific project exceeds the number of coauthor places available, author selection will be based on each individual's:

- specific areas of expertise;

- ongoing motivation of sites to support generation of good quality GARFIELD-VTE data;
- involvement in ongoing publications.

The PC is committed to offering authorship opportunities to all National Coordinators or investigators.

GARFIELD-VTE National Coordinators or investigators may initiate other publication proposals (e.g., subsequent international publications, secondary papers, review articles, substudies, and national or regional analyses).

The individual who initially generated the study proposal and delivers the abstract will lead all other GARFIELD-VTE Registry-related publications. The initiator is encouraged to contact other potentially interested individuals before the paper or abstract is proposed. At the time of proposal, individuals at each of the clinical centres and the TRI are given the opportunity to be coauthors. The first author is encouraged to involve individuals with specific expertise or experience, as necessary.

Each manuscript must include at least one GARFIELD-VTE investigator, as designated by the Steering Committee. Members of the Steering Committee/PC may be invited to coauthor and contribute to papers. The lead author will determine, in agreement with the PC, authorship of abstracts and manuscripts.

The PC may decide who assumes lead responsibility for a paper if there is more than one interested candidate. The PC also may reassess lead responsibility if reasonable progress on completing an abstract or manuscript has not occurred.

The criteria for authorship will be those of the International Committee of Medical Journal Editors¹⁻⁴ (ICMJE, the 'Vancouver Group').⁵ These criteria are similar to those of other major organizations concerned with authorship, especially those written recently. Excerpts of these criteria follow.

- All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article.
- Only significant contributors may be coauthors. Authorship credit should be based only on (1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published. Conditions 1, 2, and 3 must all be met. Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship.

In line with current guidelines,¹⁻⁴ the PC will ensure transparency regarding writing collaboration, with attribution between academic and industry investigators and medical writers. The contribution, role, and funding of professional medical writers and editors (if not listed as coauthors) will be acknowledged in all manuscripts.

At the PC's discretion, and if the criteria for authorship are met, medical writers may be invited to join the writing committees.

The statistician responsible for the data analysis will be invited to be a coauthor.

Participants (investigators, coordinators, others) will be listed in an appendix (journal permitting) or referenced to a published paper or the GARFIELD-VTE web site.

The GARFIELD-VTE PC will enforce a strict 'no-ghostwriting' policy. All lead authors will be encouraged to complete the 'Checklist for Authors Using Medical Writers' (see Appendix 1).

Two-paper limit for first authors

Investigators are limited to first authorship on no more than two papers in progress (before submission to a journal). Exemptions from this policy may be made by the PC in the case of demonstrated productivity of the investigator, invited papers, or other special circumstances.

Publication approval and standard information for inclusion in all papers

The following information will be included in all manuscripts, irrespective of the journal guidelines:

- Author contributions to: study design; statistical analysis; analysis and interpretation of study data; review of literature; writing first draft; critical review; approval of final submission; individual responsible for the accuracy of the data.
- Contributions to the article or presentation from people not listed as authors, including name and affiliation or employer.
- The role of the sponsor in the study and its reporting will be outlined, including how the sponsor was involved in the study design; collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication.
- Funding sources.
- Involvement, role, and contribution of medical writers and editors.

In addition, a reference to the primary GARFIELD-VTE publication(s) should be included in all subsequent publications.

All GARFIELD-VTE publication proposals must receive approval from the Publications Committee before starting data analyses, and before submission, presentation, or publication.

Press releases

Press releases must be submitted to the GARFIELD-VTE PC (via Garfied@tri-london.ac.uk) for review, at least **7 working days** before they are issued for publication. Press releases cannot be released until the authors have received PC approval via email.

E. PUBLICATIONS COMMITTEE MEETINGS

The Publications Committee will meet at two face-to-face meetings each year. During these meetings the committee will ensure that sufficient time is allocated to both roles: Scientific Advisory Committee and PC.

F. PUBLICATION PROPOSALS

Publication proposals must be submitted (in English) using the online form, available at <http://www.tri-london.ac.uk/garfield>. The form requires information on study objectives, methods, population, analysis plan, etc. (see Appendix 3).

The GARFIELD-VTE Registry values collegiality and multicentre collaborations very highly. Therefore, it is strongly recommended that coauthors from more than one centre be included in each abstract or paper. We also encourage that the number of authors be kept at or below four at

time of submission of a proposal to the PC, in order to allow additional GARFIELD-VTE authors to join the writing group at the time of proposal approval by the PC. Occasionally it may not be possible to adhere to these recommendations, in which case, please include in the proposal an explanation of why there are more than four authors or why all authors are from the same centre.

After review by all initially named coauthors, proposals and abstracts should be submitted to the PC.

Incomplete publication proposals will be returned immediately to the lead author and will not be reviewed by the PC, but may be resubmitted for review subsequently.

The PC will review all proposal submissions and a response sent to the lead author within 30 days of receipt. All proposals will be included in the Publications Plan.

Appendix 1. Checklist for Authors Using Medical Writers: A Practical Tool to Discourage Ghostwriting⁶

Professional medical writers can be legitimate contributors to manuscripts, but ghostwriting is dishonest and unacceptable.

Authors: If a medical writer contributed to the preparation of your manuscript, you must answer the questions below.

No.	Question	Answer	
1	(a) Did the medical writer meet the three criteria for authorship, as specified by the ICMJE? (b) If not, has the writer been identified in the acknowledgments or as directed by the journal?	No	Yes
2	Has the source of funding for the medical writer's services been identified in the acknowledgments or as directed by the journal?		
3	Did the author(s) make the final decision on the main points to be communicated in the manuscript, particularly in the conclusion?		
4	Did the author(s) make the final decision on the primary and secondary outcomes and relevant data to be reported in the manuscript?		
5	If requested by the journal, can the medical writer provide evidence that the manuscript was prepared in accordance with international guidelines for ethical medical writing (e.g., Uniform Requirements for Manuscripts Submitted to Biomedical Journals ⁵ ; Good Publication Practice for Pharmaceutical Companies ⁷ ; Position Statements from the European or American Medical Writers Associations or the International Society for Medical Publication Professionals ⁸)?		

Appendix 2. STROBE Checklist for Observational Studies

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Reported on page
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	
Methods			
Study design	4	Present key elements of study design early in the paper	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	

		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) Summarise follow-up time (e.g., average and total amount)
Outcome data	15*	Report numbers of outcome events or summary measures over time
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(b) Report category boundaries when continuous variables were categorized
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.

Appendix 3. GARFIELD-VTE Publication Proposal

1. Provide complete contact information for the first author.
2. Indicate if global or local data are required.
3. Include a proposed title, keywords and a timeline. All of this information is required; if it is not provided, the proposal will not be reviewed and will be returned to you for completion.
4. The GARFIELD-VTE Steering Committee member or National Coordinator participating on the writing group must review and approve the proposal prior to submission to the Publications Committee.
5. Provide the proposed conference or journal details (if relevant) and any other information that may be related to the review of your proposal.
6. Please complete the proposal and email it to the Thrombosis Research Institute for distribution to the Publication Committee. Email: echu@tri-london.ac.uk
7. Any questions? Contact the Thrombosis Research Institute at: echu@tri-london.ac.uk

TITLE OF PROPOSAL	
Primary keyword	<i>See Box 1 overleaf</i>
Secondary keywords	<i>See Box 1 overleaf</i>
AUTHOR INFORMATION	
Lead author	
Email	
Tel	
Affiliation	
Steering Committee member or National Coordinator (if not lead author)	
Email	
Tel	
Affiliation	
Other authors	
Other authors' contact details	
DATA	
Global (yes/no)	
National (yes/no)	
Data set (tick) <i>[please provide skeleton data tables]</i>	
Baseline	
1-year	
2-year	
3-year	
4-year	
5-year	
Background (please provide brief summary)	
Hypothesis / objective	
TIMING	

Proposed congress or journal, and year	
REFERENCES	

Please provide list of figures and skeleton data tables

Box 1. GARFIELD-VTE Registry: Publication Proposal Keywords

Primary keywords	Secondary keywords
Evidence-based medicine	Compliance / therapy persistence Geographic differences Adherence to guidelines
AF burden	AF type Baseline data Demographics Evidence-based medicine OAC use
Anticoagulation	INR testing Targets Time in therapeutic range
Bleeding events	Outcomes
Blood pressure	
Care setting/physician specialty	Time or day of presentation
Comorbidities/medical history	Alcohol Chronic renal disease Cirrhosis Dementia Diabetes Geographic differences Hyper/hypothyroidism Hypercholesterolaemia Hypertension Ischaemia/ACS/infarction Obesity Peripheral vascular disease Smoking Vascular disease
Demographics	Age Ethnicity Geographic differences Gender Risk stratification
Health economics	
Interventions/non-pharmacological therapy	Anticoagulation CABG Ischaemia/ACS/infarction PCI/stenting
Neurology	
Pharmacological therapy	Cardiac medications/other co-medications Changes in AF treatment (individual patient) Contraindications Initial treatment of AF Temporal trends: uptake of OACs Triple therapy
Risk factors	Risk scores Risk stratification
Symptoms and investigations	
'Other' (not listed in the above)	

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3. Institute of Medicine. Conflict of Interest in Medical Research, Education, and Practice. Date accessed: 23 April, 2010. Available: <http://www.iom.edu/Activities/Workforce/ConflictOfInterest.aspx>.
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5. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: Writing and editing for biomedical publication. Date accessed: 23 April 2010, 2010. Available: <http://www.icmje.org/>.
6. Gotzsche PC, Kassirer JP, Woolley KL, Wager E, Jacobs A, Gertel A, Hamilton C. What should be done to tackle ghostwriting in the medical literature? *PLoS Med* 2009;6:e23.
7. Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. *Curr Med Res Opin* 2003;19:149-154.
8. Norris R, Bowman A, Fagan JM, Gallagher ER, Geraci AB, Gertel A, Hirsch L, Ross PD, Stossel TP, Veitch K, Woods D. International Society for Medical Publication Professionals (ISMPP) position statement: the role of the professional medical writer. *Curr Med Res Opin* 2007;23:1837-1840.