

Regulations of the clinical safety workgroup



Contents

Introductions	3
Goals of the Clinical Safety workgroup	3
Rationale of the present regulations	4
Membership of the workgroup	4
Workgroup structure	4
Duties of the workgroup officials	5
Coordinator.....	5
Secretary	6
Steering committee.....	6
Workgroup membership renewal	7
Workgroup functioning norms	8
Overview.....	8
Maintenance and funding of the workgroup	8
External relations.....	9
Development of educational and research projects.....	9
Other requirements.....	10
Meetings.....	11
Election of workgroup officials.....	11
Budgetary allocation	12
Trainee placements	13

Introduction

The sheer magnitude of the problems derived from unsafe clinical practice has resulted in patient safety being considered a leading priority at world level. In the European Union, the incidence of adverse events among hospitalized patients stands between 8% and 12%, with one death per 100,000 inhabitants a year resulting from such adverse events, equivalent to 5,000 deaths a year. High though this figure may seem, it appears that the real incidence may be even higher, as the published figures only reflect the data reported by healthcare professionals. In Spain, several studies (ENEAS, APEAS, SYREC, EARCAS and EVADUR) have been performed to gain an understanding of the magnitude of the problem and the most prevalent risk factors in different clinical settings.

The safe practices recommended by the main international organizations typically refer to the safe use of medications across different dimensions: conciliation, safe packaging and labeling, pharmacovigilance, high-risk drugs, antimicrobial resistance, etc.

The Spanish Ministry of Health's 2015-2020 patient safety strategy emphasizes the importance of promoting the safe use of medicines. The goals and recommendations included in that document are seldom pursued conscientiously in our country, with hospitals typically failing to implement continuous self-assessment mechanisms.

One of the recommendations stated in the document is to increase the vigilance and supervision procedures conducted by hospital pharmacies. In this regard, SEFH's clinical safety workgroup seeks to drive the development of multiple clinical safety initiatives that can be undertaken by hospital pharmacies, focusing its attention on those of particular import. The workgroup also aims to strengthen the role of hospital pharmacists so that they are perceived as leaders in the promotion of clinical safety and, particularly, in the safe use of medicines, both by other healthcare providers and by the general population.

Goals of the clinical safety workgroup

The purpose of the workgroup is to promote activities in the realm of clinical safety conducive to providing hospital pharmacies with the knowledge and the tools they need to implement safe practices, particularly regarding the safe use of drugs.

Rationale of the present regulations

The regulations of the workgroup are based, first and foremost, on the 3rd edition (2020) of the Workgroup Regulations of the Spanish Society of Hospital Pharmacists (SEFH). The information contained in those regulations should be regarded as a complement to the present regulations established by the workgroup itself.

- The regulations were established by the workgroup's coordinator with the support of the workgroup's secretary.

- The regulations will be shared with the steering committee, which will supervise their contents. Any suggestions for improvements will be discussed at a dedicated meeting of the workgroup.
- SEFH's representative on the workgroup's steering committee must attend the said meeting.
- The regulations will not come into effect until 75% of the steering committee members (6 members) vote in favor of its adoption. The secretary will reflect the resolution on the adoption of the regulations on an official document and send it to SEFH's Technical Secretariat together with a copy of the regulations themselves.
- The regulations may be revised every two years in order to adapt them to the new needs of the workgroup. They may be revised earlier if at least 75% of the steering committee members make a request to that effect.

Any SEFH member wishing to join the workgroup must previously read the present document and agree to its provisions, as well as to the official regulations of the Spanish Society of Hospital Pharmacists.

Membership of the workgroup

The clinical safety workgroup is regarded as a workgroup pertaining to a cross-sectional field of inquiry.

Date of approval by SEFH's Governance Board: 2 March 2021.

Workgroup structure

The workgroup comprises:

- A coordinator
- A secretary
- A steering committee (8 members).
 - Does not include the coordinator or the secretary.
 - It includes the officials responsible for training, research, and for managing the workgroup's website.
 - Ideally, the committee should ensure a broad geographical representation.
- SEFH's representative on the workgroup's steering committee. Appointed by SEFH, this official shall sit on the workgroup's meetings in representation of SEFH's Governance Board in order to ensure two-way communication between the workgroup and the Governance Board.
- A hospital pharmacy resident
- A social media content creator (not necessarily a member of the steering committee).
- An advisor to the steering committee. Given the high amount of work associated with the initial activities of the workgroup, an advisor may be appointed to help the steering committee with the organization of educational activities. This official may be invited to the meetings of the steering committee and the position should ideally be put up for reelection every two years at most.

- Ordinary members. Their duty is to support the workgroup's activities.
- Other officials could include:
 - A medical consultant
 - A patient
 - Other external consultants (non-members)

Workgroup officials' duties

Coordinator

- Functions:
 - To manage the workgroup's activities
 - To coordinate the workgroup's activities with those of other SEFH workgroups.
 - To liaise with SEFH's Governance Board.
 - To define, by consensus with the other members of the workgroup, the goals to be pursued, duties to be performed and the workplan to be followed.
 - To prepare the workgroup's regulations
 - To prepare, together with the secretary, a report of the year's activities, to be submitted to SEFH's Technical Secretariat.
- Duties:
 - To represent SEFH and its members as coordinator of the clinical safety workgroup.
 - To dynamize the workgroup to ensure it achieves its goals.
 - To define, together with the other members, the workgroup's annual goals, distributing specific tasks with specific deadlines to the members of the steering committee to ensure that the established goals are achieved.
 - To appoint a website manager by consensus with the other steering committee members.
 - To supervise the submission of an abridged version of the workgroup meetings to SEFH's Technical Secretariat, once they have been approved.
 - To submit an annual report of the workgroup's activities by the end of SEFH's fiscal year (June-July). The report must follow a specific format, which is provided by SEFH's workgroup coordinator.

Secretary

- Functions:
 - To convene and coordinate the workgroup's meetings
 - To liaise with SEFH's workgroup coordinator and with SEFH's Technical Secretariat.
 - To assist the workgroup coordinator in preparing a report on the workgroup's annual activities.

- Duties:
 - To prepare the minutes of the workgroup's minutes and send them to SEFH's Technical Secretariat once they have been approved.
 - To supervise the maintenance of the workgroup's website and of the members' and officials' database.

Steering committee

- Functions:
 - To execute the workgroup's different projects and strategic priorities.
 - To encourage hospital pharmacies to collaborate with the workgroup so as to obtain as much information as possible for the benefit of its members.
- Duties:
 - To play an active role in the workgroup's activities.
 - To ensure that each steering committee member is assigned specific functions and goals.

According to SEFH's workgroup regulations, a SEFH member cannot serve as coordinator of two cross-sectional or specific working groups. It is the members' responsibility to ensure they fulfil this requirement before they submit their candidacy to fill any position in the clinical safety workgroup.

Should a member wish to present a candidacy to become coordinator of a second workgroup, their application can only be considered if no other candidacies were submitted.

Workgroup membership renewal

The coordinator and the secretary shall be elected for 2-year terms which, according to SEFH's norms, may be extended to a maximum of 4 years (2 elections). To run for reelection, officials must demonstrate to SEFH's Governance Board the attainment of all the goals set for the previous term. Should it be decided that the coordinator take over the position of the secretary at the end of their term, or vice versa, the procedure will be the same as that used for reelections, i.e., they will be required to demonstrate to the Governance Board that they achieved all goals of the previous position.

- Although SEFH's regulations allow officials to run for election twice (4 years), the renewal of the coordinator and secretary positions should preferably take place every two years and in a gradual manner. The secretary will thus become coordinator of the workgroup, and the coordinator will become a member of the steering committee. The new secretary should have sat on the steering committee for at least one year and be elected by majority among the candidates proposed.
- At least 20% of the steering committee's membership must be renewed every two years.

- To ensure continuity of the workgroup, not more than 50% of the positions on steering committee can be renewed within one year, nor can the coordinator and the secretary resign from their positions at the same time.
- The renewal of the coordinator and secretary positions will be conducted by an internal call within the workgroup. Only steering committee members may stand to be elected as coordinator or secretary. In the absence of candidates from the steering committee, ordinary SEFH membership or recent steering committee membership shall be valued as an asset. In the event of multiple candidacies for the same position, the election will be decided by simple majority of steering committee members.
- The renewal of vacant positions on the steering committee will be performed by means of a public call, duly announced through SEFH's internal communication channels. The call will include the process to be followed for selecting the new officials.
- Membership in the workgroup will be open to any SEFH member who may be interested in joining it. Applications, which should be made through the workgroup's website, will be accepted right away, the only requirement being that candidates be members of SEFH. Members wishing to withdraw from the society or to have their details changed must send a request through the workgroup's website.

Workgroup functioning norms

Overview

- Every year, the workgroup must submit a workplan specifying the goals to be pursued, the projects it is currently working on and those it intends to embark on, potential external grants it intends to apply for, the meetings it intends to hold and the reports it intends to prepare. They must also enclose a work calendar, a report on the quality of its scientific production (as measured by appropriate indicators, an economic report and a conflict-of-interest declaration).
- Before the end of each fiscal year (30 June), the workgroup must submit a program of the meetings and conferences they intend to host over the next year in order that the logistics of each event can be properly managed. Without prejudice to the foregoing, slight changes may be made to the initial program of activities in response to unforeseeable situations arising during the year.
- Every year, the workgroup shall inform SEGH's governance organs of the activities they intend to organize, on their own initiative or following collaboration agreements with other entities, agencies, scientific societies or pharmaceutical companies. SEFH's Governance Board must evaluate the suitability of the activities, ensure that they are strategically aligned with SEFH's goals and verify their operational coherence.
- The workgroup will be provided with a section within SEFH's website, which must be maintained by a SEFH-appointed contents manager. One of the members of the steering committee must be made responsible for supervising the management of the website and ensuring that its contents are kept up to date. The workgroup will be responsible for the contents posted in their website.

Maintenance and funding of the workgroup

The workgroup must:

- Submit an annual workplan every year.
- Allow the participation of SEFH members in their activities.
- Keep up a minimum level that justifies its continuity.
- Ensure that all its activities are transparent to its membership.
- Annually submit a report of the activities performed during the previous year, as well as the minutes of the different meetings
- Comply with the established calendar for the renewal of elected officials, as stipulated by the present regulations and the workgroup's internal regulations.
- Prepare the minutes of the different meetings held, which should include a description of any resolutions adopted.

External relations

- Any agreement made by the workgroup with an external party that involves the exchange of scientific knowledge, the development of a research project or any other activity believed to make a positive contribution to the workgroup's goals should be based on some legal document such as a contract, which regulates the details of the agreement.
- Any agreement made by the workgroup that involves collaboration with manufacturers of medicines and healthcare products should be based on a legal document such as a collaboration or sponsorship contract, which regulates the details of the agreement.
- When one or more of the workgroup's members attend meetings or participate in joint activities or projects with third parties in representation of SEFH, they must in all cases submit to SEFH's workgroup coordinator and SEFH's Technical Secretariat a report of the meetings attended or the activities performed. They shall likewise be bound to inform SEFH of the goals established, the agreements made and any consensus documents that may have been produced as a result of the activity.
- Workgroup members who participate in joint projects or activities with third parties in representation of SEFH must ensure that all documents produced following the activity or project conducted expressly state that SEFH was involved in their preparation. Such workgroup members may, if required, request the support of SEFH's Governance Board and Technical Secretariat to ensure the success of these activities/projects.

Development of educational and research projects

- Should the workgroup wish to post any documents or position papers on its website, whether resulting from an educational, research or professional development project or not, they must previously submit them to SEFH's Governance Board for approval as such documents or position papers are necessarily a reflection of the views of SEFH as a whole.
- The workgroup shall be free to organize such training activities as it sees fit provided that they make the relevant information available to SEFH's workgroup coordinator, SEFH's Governance Board, through its representative to the workgroup, and SEFH's Technical Secretariat. Such educational activities may be managed centrally by SEFH's Technical Secretariat through the Spanish Foundation of Hospital Pharmacists (FEFH) - SEFH, as per the Foundation's bylaws. In all cases, the workgroup must specify the contents of the training program in question and work jointly with SEFH to prepare an economic report and identify potential sources of funding.
- The workgroup shall be free to conduct research projects as well as other professional development activities, provided that they keep SEFH's workgroup coordinator and SEFH's Governance Board, through its representative to the workgroup, informed about such activities. The Technical Secretariat shall be responsible for managing the different training and research activities, as required by SEFH's by-laws.
- Should SEFH consider that additional workgroups should participate in a given educational activity or research project, such activities or projects will not be implemented until the relevant workgroups have become involved.

Other requirements

- Collaboration with other SEFH workgroups will be encouraged for the development of both educational and research activities.
- The workgroup shall participate in SEFH's annual congresses. The coordinator and the secretary shall be responsible for the workgroup's participation but may delegate the organization of specific activities in a member of the steering committee.
- The workgroup coordinator and secretary must approve any educational activity or any meetings with third parties related with the workgroup's remit and organized by a workgroup member. Once the activity/meeting has been approved, all printed materials, if any, connected with it must be identified with the workgroup's and SEFH's logo. As the official responsible for preparing the workgroup's annual workplan, the secretary must keep a record of the activities performed.

- All scientific events/materials organized by the workgroup must be approved by SEFH. The society shall decide on the adequacy of the contents and make sure that SEFH's industrial and intellectual property attributes have been properly used.

Meetings

- At least three in-person or remote meetings will be held every year. The meetings must be attended by the workgroup's coordinator and secretary, by SEFH's representative on the workgroups steering committee and by other members of the latter.
- Should one of the officials above be unable to attend, they must justify their absence to the secretary, who shall record such absence in the minutes that will later be submitted to SEFH.
- The secretary will be responsible for calling and coordinating the workgroup meetings and for preparing the minutes.
- The coordinator shall be responsible for deciding the different points to be included on the agenda and for chairing the meetings.
- Votes shall be cast by a show of hands, each member being allowed to substantiate their position.

Election of workgroup officials

- Workgroup officials (members of the steering committee, trainees, resident, advisors, patients, etc.), shall be elected by majority vote at either one of the meetings of the steering committee or at a meeting specifically convened for that purpose.
- Officials responsible for specific areas (training, research, etc.) shall be elected by a vote among members submitting a candidacy for such positions. In the absence of volunteers, the officials will be appointed from the workgroup's general membership.
- The criteria followed to select members for a given office shall be established prior to the vote as a function of the workgroup's needs. The criteria shall be initially proposed by the coordinator and the secretary and then discussed with the members of the steering committee. At least 50% of steering committee members must be in agreement with the established criteria before a vote can be taken.
- A written record shall be made of the score obtained by each candidate on the different criteria. Every member in attendance must assign a score. The final decision will be made by calculating the mean score for each candidate, In the absence of consensus or in the event of a draw between two or more candidates, the process must continue until at least 50% of members show their support for the elected candidate.
- The secretary will reflect the result of the vote on the minutes of the meeting and inform SEFH of the result by e-mail. Candidates will be sent an e-mail informing them about the workgroup's final decision. The

scores assigned by individual steering committee members shall under no circumstances be disclosed to the candidates. Candidates will only be informed about their final score and about the criteria used to assign them.

- The officials in charge of training and research should be members of the steering committee and cannot sit on more than one steering committee.
- Trainee placements (including an economic allowance) must be offered following the standard procedure established in SEFH's regulations (see below). Placements will be for one year and may be extended to two years, in accordance with the current regulations.
- The resident's representative to the workgroup will be elected by means of a public call, prioritizing residents who are not in their 1st year of residency.

Budgetary allocation

- The workgroup shall receive an economic allowance from FEFH. The allowance will be a fixed amount intended to defray the workgroup's basic operational expenses. A variable sum will also be made available in the form of an annual grant, which the workgroup will have to apply for specifically.
- The fixed economic allowance awarded to the workgroup will be aimed at defraying the expenses incurred in running the workgroup, organizing its activities and executing its projects. If appropriate the allowance may include funds for the recruitment of trainees who may contribute to the workgroup's activities. The allowance may be increased, within the limits established by SEFH, depending on the society's financial situation in each given year and the workgroup's declared financing needs. Communication expenses and those incurred while travelling to attend workgroup meetings, which are to be held on SEFH's premises, shall be defrayed by directly the society.
- The workgroup will join forces with SEFH to try and obtain funding from third parties, whether grants from official entities or scientific development stipends from private organizations. In this endeavor, they will always strive to preserve their Independence and comply with the strategic priorities established by SEFH.
- Any initiative resulting from a collaboration agreement with any institution must be made known to SEFH's governance.
- The coordinator and the secretary must approve the allocation and distribution of the workgroup's budget, with the support of at least 50% of the steering committee members. The secretary shall state the details of such allocation in the minutes of the relevant meeting.

Trainee placements

A part of the workgroup's annual budget may be dedicated to the award of grants to trainees who may support the workgroup's activities, including the maintenance of the workgroup's website, the management of the workgroup's projects and other initiatives. The decision to launch a call for trainee placements must be previously communicated to SEFH's Governance Board, justifying the need for the placement and the tasks to be performed by the selected trainee.

The whole process must comply with SEFH's workgroup regulations, as well as with the requirements below:

- The call must be broadly publicized through SEFH's internal communication channels (SEFH's mailing list and website, among others). The call must also include the rules to be followed throughout the process, specify the requirements to be met by candidates, and the duties they will be expected to perform. The call must be published long enough in advance, allowing candidates at least fifteen days to submit their candidacies.
- The process followed to evaluate the different candidates shall be transparent. The workgroup shall draw up a report of the scores given to the candidates, providing a succinct justification in each case.
- By default, placements will be one year long, although they may be extended to two years with justified reason. Under no circumstances can they extend beyond two years.
- On expiry of the placement, or on requesting a renewal thereof, trainees must submit a report of the activities carried out. The workgroup must submit the report to SEFH's workgroup coordinator and SEFH's Technical Secretariat.
- Placement renewals must follow the same criteria mentioned above, with the decision adopted being stated in the minutes of the relevant workgroup meeting.