

11. Guidelines to prepare onsite/online audits

The Evaluation Coordinator of the Independent Evaluation Body (IEB) will select the evaluation team for the onsite audit. It is highly recommended that the audit be carried out by the same evaluators that have performed the self-evaluation review.

Purpose

The main objective of the audit is to obtain information on those criteria that cannot be directly assessed from the information included in the self-evaluation because the source of information is either an interview with patients or professionals or the medical record.

During the audit an additional on-site document review can also be included at the discretion of the evaluation team if they consider that the information included in the self-evaluation should be completed.

Methodology

Group interviews with patients and professionals could be conducted both onsite and online, but the review of medical records is highly recommended to be carried out onsite. The IEB will decide in each case the most efficient alternative.

1. Group interview with patients

In this case, the online alternative is suggested as the most advisable, due to the difficulty of bringing patients together and because it will also allow the inclusion of cross-border patients.

Interview Preparation

- Participants: patients treated of any of the specific conditions assumed by the HCP team evaluated, within the framework of the processes defined by the Network.
- Population: patients treated and discharged or treated on an outpatient basis for the last 3 years, in order to minimize memory bias. In the case of the paediatric population if they are under 14 years of age, the interview will be conducted with one of the parents.
- Selection: a number between 6 to 8 patients is recommended and whenever possible of different specific conditions. The selection must be random: for this the evaluator will previously contact the HCP representative, to suggest the requirements for selection. For example, patients of different specific conditions, to include patients of each of the 3 years evaluated, hospitalized and outpatients and some cross border patient if the HCP team has cared for this type of patients.

The session will be conducted in English, so the presence of an interpreter (with no conflict of interest with the hospital) may be necessary.

- Recruitment: it will be carried out by the HCP team itself, after discussing the selection requirements with the evaluation team.

The HCP team must request the written consent of each participant. If the interview is to be

recorded, this aspect will have to be included in the consent. When contacted for the recruitment, patients will be explained the objectives of the session and its expected length.

- The evaluation team will prepare the interview script, which should include the topics of those measurable elements (ME) whose source of information is the patient. They are:

MEs to be evaluated during the interview with patients	ME 1.1.2
	ME 1.6.1
	ME 1.6.3
	ME 4.2.5

- Choose the virtual video conference system that is most easily accessible to participants
- Recommended length: 60 minutes.

During the interview

It is not recommended that any professional from the HCP team attends the interview, to avoid bias.

Before logging in, the evaluation team must verify that all attendees have signed the consent.

- The evaluation team will introduce themselves at the beginning of the session and comment on the objectives.
- A few minutes will be taken for each of the patients to introduce themselves.
- Attendees should be reminded that they can express their opinion freely and that the anonymity of opinions will be maintained.
- Next, the evaluation team will ask the questions of their script and promote the participation of all attendees in each of the topics.
- Before the end of the session, the evaluation team will agree with the attendees on the result of the answers, considering that the answers that have had the greatest consensus will be chosen and not include individual opinions.
- It is important not to exceed the expected time.

After the interview

The evaluation team will review and rate each ME based on the majority opinions of the attendees. They will follow the guidelines suggested in the scoring guide of the respective ME.

2. Group interview with professionals

This can be carried out both online and onsite since the professionals belong to the same centre.

Interview Preparation

The evaluation team will contact the HCP representative through an email or phone call, informing of the objectives of the interview and the ME that will be reviewed and jointly set a date to facilitate the presence of all the expected attendees.

- The evaluation team will prepare the script of the interview, which must include the topics of those measurable elements (ME) whose source of information is the professional. They are:

<p>MEs to be evaluated during the interview with professionals</p>	<p>ME 1.6.2 ME 1.6.4 ME 1.9.1 ME 2.5.1 ME 4.2.2 ME 4.2.4 ME 5.1.2 ME 5.1.7 ME 5.1.8 ME 7.1.3</p>
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- The evaluation team should recommend the HCP representative to have available for the interview some documents that can facilitate the required evidence, such as the safety protocols (ME 5.1.2) or information on the reporting system of patient safety incidents (ME 5.1.7 and 5.1.8)
- Participants: the HCP representative and all members of the multidisciplinary team deemed appropriate to provide information.
- Expected duration: 60-90 minutes.

During the interview

- The evaluation team will introduce themselves at the beginning of the session and comment on the objectives.
- A few minutes will be taken for each of the attendees to introduce themselves.
- Next, the evaluation team will ask the questions included in their script and promote the participation of all attendees in the assessment of each of the topics.
- Before the end of the session, the evaluation team will check the result of the answers with the attendees.

After the interview

The evaluation team will review each of the MEs that have been discussed during the interview and will score them following the guidelines suggested in the scoring guide of the respective MEs.

3. Medical records review

To perform the review of medical records the most recommended option is the onsite visit.

Preparation of the review medical records

- The evaluation team will prepare the contents of the medical records review, which must include the following measurable elements (ME):

<p>MEs to be evaluated during the medical records review</p>	<p>ME 1.2.2 ME 1.5.1 ME 1.5.3 ME 1.6.5 ME 1.7.1 ME 2.2.2 ME 2.3.1 ME 2.3.2 ME 2.5.2 ME 3.2.2 ME 7.2.2</p>
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- The coordinator of the HCP team will prepare a list of all the patients of the different specific conditions that the HCP team cares for. Inpatients and outpatients from the last 3 years will be included. The following information shall be specified in the list:
 - a) specific condition
 - b) age
 - c) if the patient has been part of a clinical trial (3.2.2)
 - d) if the patient has been transferred to another centre (2.2.2)
 - e) if the patient is cross border (2.3.2)
 - f) if the patient has been included in the CPMS (2.5.2)

In NO case will the name of the patient be included. A code will be agreed between the evaluation team and the coordinator to identify each case.

- This list will be sent to the evaluation team that will make a random selection of the necessary cases and will send the selection to the coordinator with enough time so that the HCP team can have the medical records available on the day of the review.
- Number of medical records selected: Most MEs are common to all types of patients, and 3 medical records will be sufficient.
- Selected medical records. The conditions from “c to e” are specific for this type of patients and 3 cases will have to be selected from each situation. These same medical records can be used to evaluate the rest of the ME.

Cases of patients included in the CPMS will be reviewed in that system.

During the review

- The review will be carried out with the presence and assistance of the team members that the HCP representative deems appropriate.
- The evaluation team will verify in each case if the contents of each of the MEs indicated above are met.
- Before the end of the session, the evaluation team will check the results of their review with the professionals present.

After the session

The evaluation team will assess each of the MEs that have been reviewed in the medical records and will score them following the guidelines suggested in the scoring guide of the respective ME.

Suggested agenda

The three types of activities could be carried out either on site or online, even though an onsite visit facilitates a deeper evaluation, and the online review of medical records could be hindered by regulation or data protection limitations, as well as depending on the medical record system used. Therefore, there can be 3 options:

- Option 1: on site audit
- Option 2: mixed method (online and onsite)
- Option 3: online audit

In all cases, logistically the HCP team will need some time for the preparation of the audit. Therefore, the evaluation team should contact the HCP representative as soon as possible to schedule the audit.

- Group interview with patients. It is advisable to provide about 3 weeks for the HCP team to recruit patients.
- Session with professionals. It will be scheduled only after the self-evaluation review has been carried out
- Review of medical records. It will be scheduled only after the self-evaluation review has been carried out. The possible preparation times to consider are:
 - a) Elaboration of the list of patients (1 week)
 - b) Selection of cases by the IEB (2 days)
 - c) Location of the selected medical records. If the centre has electronic medical records, the location can be immediate. If the medical records are on paper, it is convenient to allow at least 3 days so that they can be available for the evaluation team.

On site audit

The onsite visit is carried out in 1 single day, so it requires a good coordination between the evaluation team and the HCP. The contents suggested to be included in the agenda are:

Presentation of the evaluation team and confirmation of the agenda of the day	30 minutes
Presentation of the multidisciplinary team	30 minutes
Interview with professionals	90 minutes
Interview with patients	60 minutes
Review of medical records	120 minutes
Optional: tour of the facilities and review of pending documents (if applicable)	60 minutes
Feedback of the visit to the multidisciplinary team	30 minutes