### 3.1 Retrospective record review

This protocol summarizes the features of retrospective record reviews, highlights the method-specific key success factors and provides chronological step-by-step guidance for preparing and conducting this method.

#### METHOD OVERVIEW

<table>
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<tr>
<th>Objectives</th>
<th>The objective of retrospective record review is to estimate the incidence of HIs in a health-care facility and understand their causes.</th>
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<tr>
<td>Approach</td>
<td>After gathering a random sample of medical records from patients admitted during the past year, a record screener determines, for each case, whether an HI is present or not. For all positively screened cases, a medical reviewer confirms/rejects the presence of HIs and assesses their causes and preventability. Both the record screening and the medical review are guided by structured questionnaires, using explicit criteria for screening and implicit ones for assessing the HIs. The incidences of HIs and preventable HIs are calculated.</td>
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| Responsibilities & time planning | **Responsibilities**
*The principal investigator*, who coordinates the record review and possibly acts as medical reviewer, starts preparing three weeks ahead of time. He/she conducts steps 1, 2, 3, 5 and 6 of the preparation phase.

*The record screener* starts preparing two weeks ahead of time. He/she conducts steps 4 and 6 of the preparation phase and steps 1, 2, 3, 4, 6 and 7 of the record review.

*The medical reviewer* starts preparing two weeks ahead of time. He/she conducts steps 4 and 6 of the preparation phase and steps 1, 2, 3, 5, 6 and 7 of the record review.

**Time planning**
A record screener and a medical reviewer need approximately one day to screen and review the records of a 30 to 40-bed ward. |
| Requirements | • A trained record screener (nurse) and medical reviewer (physician)
• Last year’s facility inpatients records
• A quiet room equipped with a table
• Two copies of this protocol as guidance for implementation
• Sufficient copies of the RF1 form (at least 120% of the expected sample size) and of the RF2 questionnaires (at least 30% of the expected sample size)
• Two blue and two red pens. |
| Next phase (optional) | If the purpose of the record review is to calculate the incidence of HIs and understand their causes, a next step could be to develop an action plan. |
1. Study method protocol
The principal investigator studies this method protocol and the RF1 and RF2 forms in order to prepare the record review.

2. Contact facility stakeholders and check whether records are appropriate
The principal investigator then presents the objective of the initiative to facility managers and key stakeholders to obtain their approval. (A template to help introduce the study is available at http://www.who.int/patientsafety/research). He or she then accesses a sample of medical records to check whether they are sufficient for a retrospective record review or not. To this end, the principal investigator looks in particular at the initial medical assessment, the medical progress notes, the nursing progress notes, the procedural documentation, the pathology reports and the discharge summary. If the records are not appropriate, another method should be selected. If the records are sufficient for a record review, the principal investigator informs stakeholders of the next steps, explains how they can support the initiative and agrees with them when the record review will be held.

3. Select and train record screener and medical reviewer
The principal investigator, possibly assisted by facility managers, selects a record screener (nurse) and a medical reviewer (physician), or, if fulfilling the criteria below, acts personally as a medical reviewer. Screeners and reviewers:

- are ideally external to the hospital, or at least not from the selected wards
- have a good understanding of how the facility is organized
- are familiar with medical records
- are able to ensure full confidentiality
- must have clinical experience, and the medical reviewer must additionally have clinical experience in the type of ward he/she assesses (e.g. medical ward records should be reviewed by medical doctors and surgical ward records by surgeons/anaesthetists).

The screener and reviewer should be trained in patient safety concepts, HIs and preventability, as well as completing record reviews and assessment forms. They should be trained and handed a copy of this method protocol and the RF1 and RF2 forms by the principal investigator approximately one week before the record review. Record screeners should receive at least one day of training and medical reviewers at least one, ideally two, days of training. If they are already trained and experienced, it is sufficient to hold a half-day refresher course. Training materials are available at http://www.who.int/patientsafety/research.

4. Prepare to explain and conduct the record review
The screener and the reviewer thoroughly read this method protocol, ensure they understand and know how to explain the review process, and discuss any questions they might have with the principal investigator.a)

5. Test the local measurement reliability and validity of the method
Before using retrospective record reviews for the first time, the principal investigator arranges for a reliability and validity test. This helps to assess whether the screener and the reviewer have understood the criteria and methodology and whether they are evaluating the cases correctly. If the test yields poor results, the screener and the reviewer should receive additional training. Guidance for testing the local measurement reliability and validity of record reviews is available on p. 51.

6. Arrange meeting room and materials
The review team ensures that a quiet room equipped with a table will be available and prepares two blue and two red pens and two copies of this method protocol, as well as sufficient copies of the RF1 form (at least 120% of the sample size) and the RF2 form (at least 30% of the sample size). The RF1 and RF2 forms are available on p. 39 and p. 43, respectively.

a) For questions about the RF1 and RF2 forms, consult the RF1 and RF2 review manual, available at http://www.who.int/patientsafety/research
1. Introduction
Hospital managers introduce the review team to the medical records department. The review team reassures them that the content of the record review is confidential, explains the objective and procedure of the review, and tells them how the results will be used. A template to help inform facility staff involved in the study is available at http://www.who.int/patientsafety/research.

2. Select and gather records
The review team, assisted by local staff, draws up a list of all of last year’s admissions and selects a random sample. The size of the sample is calculated as follows: For example, if the target precision is 5% and the expected rate of HIs is 10%, with a risk $\alpha$ of 5% (i.e. a confidence interval of about 5% to 15%), about 150 records need to be reviewed. If the target precision is 2.5%, about 500 records should be reviewed (i.e. a confidence interval of approximately 7.5% to 12.5%). The number of randomly selected records has to be increased by 20% (lists of respectively 180 and 600 records) to allow for records that may be not be locatable or are found to be too incomplete for inclusion. Same day admissions should not be included. The survey may be performed in a single hospital if it is large enough. Alternatively, the survey may be conducted on a sample of hospitals, drawn randomly. In that case, seek advice from an epidemiologist prior to the study.

3. List inpatients
The review team, assisted by the nurse supervisor, lists the names of all selected inpatients, ensures that all available records are gathered and notes how many records are missing.

4. Fill in RF1 form and separate records
The record screener completes a copy of the RF1 form for all the selected records to determine for each case whether one or more screening criteria is/are present or not. After ensuring that each form is completed as fully as possible, the screener returns the negatively screened records to the ward administrator/ward nurse and hands the positively screened records to the medical reviewer.

5. Complete RF2 form
The medical reviewer completes a copy of the RF2 form for each positively screened patient based on the information contained in the medical record. He/she ensures that the forms are completed as fully as possible and destroys the first page of all RF2 forms.

6. Calculate the incidence of HIs
The review team can now calculate the previous year’s HI incidence rate as follows:

$$\frac{\text{Number of HIs} \times 100}{\text{Total No. of screened records}}$$

If more than one HI has been identified within the admission, only the most serious one is counted to estimate the total number of admissions associated with an HI. An admission is associated with an HI regardless of whether the HI occurred prior to or during the index admission as long as the patient still suffers the consequences during his or her hospitalization.

7. Conclude the review
The review team returns all medical records and thanks all involved staff. If possible, they present the results to facility stakeholders immediately, or, if this is not possible, agree on a time and date to do so. A template to help present the study’s results is available at http://www.who.int/patientsafety/research.
Method-specific key success factors

- Before planning the record review, ensure that the records of the hospital under assessment are sufficient for retrospective record review (staff are excluded as an additional source of information).
- The medical reviewer has clinical experience in the type of ward he/she assesses.
- The record screener and the medical reviewer should work in the same room to simplify organizational matters and clarify potential questions.