### 3.5 Direct observation and related interviews

The case of injection safety

This protocol summarizes the features of direct observation and related interviews, highlights the method-specific key success factors and provides chronological step-by-step guidance for preparing and conducting these methods.

#### METHOD OVERVIEW

<table>
<thead>
<tr>
<th>Objectives</th>
<th>The objective of direct observation and related interviews is to assess if best practices and safe practice guidelines are being adhered to. Here, injection safety is used as an example but this method can also be employed to assess other procedures.</th>
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<tbody>
<tr>
<td>Approach</td>
<td>A team of investigators observes the facilities and injection supply stock, as well as injection practices, and conducts interviews with injection providers and their department supervisors. Each task is guided by a questionnaire that helps to record results and assess compliance with injection safety protocols.</td>
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| Responsibilities & time planning | **Responsibilities**  
*The principal investigator*, who arranges the observation and related interviews and leads the team of observers, starts preparing three weeks ahead of time.  

*Observers and interviewers* start preparing two weeks ahead of time. They conduct steps 5 and 6 of the preparation phase and all of the interview/observation conduct steps.  

**Time planning**  
Three investigators would need approximately half a day to collect the data of five wards/departments of a district hospital. |
| Requirements |  
- Three to four trained observers and interviewers  
- Availability of ward/outpatient nurses for observation and interviews  
- Availability of department supervisors/charge nurses for interviews  
- A copy of this protocol for each investigator  
- A pen for each investigator  
- One pack of the data collection sheets per department visited. |
| Next phase (optional) |  
- To develop an action plan to improve adherence to safe practices  
- If the purpose is to monitor and assess the impact of implemented solutions, direct observation and interviews can be repeated at a later stage to identify progress areas and those that require further action. |
Preparation of direct observation and related interviews

1. **Study method protocol**
The principal investigator studies this method protocol and the questionnaires (p. 57) in order to prepare the observation and interviews.

2. **Contact facility stakeholders**
The principal investigator presents the objective of the initiative to facility managers and other key stakeholders, such as the ethics and the works council, receives their approval, explains how they can support the project, agrees with them when the observation and related interviews will be held and explains next steps. A template to help introduce the study is available at http://www.who.int/patientsafety/research.

3. **Select wards/units and time for assessment**
The principal investigator agrees with facility managers which wards/units will be assessed (e.g. medical, surgical, maternity and paediatric wards, emergency care and outpatient or ambulatory care units). Ideally, several units/wards should be assessed. Assessing several units does not provide precise statistics on dysfunctions or a quantitative baseline for monitoring and improvement, but it does allow for wider involvement of the facility, it can highlight variations in injection practices, and it may be more informative for a first evaluation. If not all units can be assessed, it is advisable to choose those where most injections are given. For each ward, in ambulatory care or in the emergency unit, five injections should be observed and one nursing staff member and one supervisor should be interviewed. The time of the assessment should be scheduled when most injections will be given (consult the head nurse to find out about medication/vaccination rounds or peak times in the emergency unit).

4. **Select and train observers and interviewers**
The principal investigator collects together a team of three to four observers and interviewers who:

- are ideally external to the facility or at least not from the selected wards
- have a nursing or medical background
- have clinical experience and are familiar with safe injection practices
- have good interpersonal skills and are able to ensure full confidentiality.

The observers/interviewers must be trained in safe injection practices and structured observation/interviews. The principal investigator ensures that they receive a half-day’s training, a copy of this method protocol and the questionnaires approximately one week before the observation/interviews. If patients only agree to being observed by a same-sex observer, the team should comprise both men and women.

5. **Prepare to explain and conduct the observation and related interviews**
The investigators study this method protocol and the questionnaires, ensure they know how to explain and conduct the observation/interviews, and clarify any questions with the principal investigator. These preparations should be completed at least two days before the observation/interviews.

6. **Arrange meeting room and materials**
The investigators arrange for ward/outpatient nurses and department supervisors/charge nurses to be available and they prepare one pack of the data collection sheets for each department visited, as well as providing a pen for each investigator.
Conduct of direct observation and interviews

1. Introduction
The investigators present the objective of the initiative to the head nurse and explain how to help collect the data. (A template to help with informing facility staff involved in the study is available at http://www.who.int/patientsafety/research). The principal investigator ensures that there is sufficient time for this meeting before the selected round of vaccination starts.

2. Inform observed staff
The head nurse introduces the observers to the charge nurses/ of all participating clinical areas. Assisted by the investigators, he/she explains that no disciplinary measures will be taken against staff if unsafe injection practices are discovered, that staff names are not recorded on the data collection sheets, and that they have the right to refuse to participate in the assessment. It is essential that observed/interviewed staff feel comfortable and that they know that the purpose is not to assess observed individuals but to improve overall health-care provision.

3. Conduct observation and related interviews and complete questionnaires
Observers then complete questionnaire 1 based on observations of facilities and stock and questionnaire 2 based on observations of injection practices. The interviewer(s) complete(s) questionnaires 3a, based on interviews with injection providers, and 3b, based on interviews with department supervisors. The questionnaires are available on p. 57.

4. Conduct observation and related interviews and complete results tables
After completing the questionnaires the team fills in the four results tables based on the information contained in these. The results tables are available on p. 63.

For monitoring and improvement purposes only:
5. Compare results and identify improvement measures
If the purpose is to monitor and assess the impact of implemented solutions, the team compares the results tables of the current assessment with those of past assessments. A comparison of the answers to questionnaires 1 and 3 provides information on organizational improvement, but the results must be cautiously interpreted as the reliability of the answers may be moderate. A comparison of percentages of good practices (questionnaire 2) can only be performed if a large number of injection practices are observed (at least 60 if 80% of the practices are good; seek advice from an epidemiologist). If the same units/wards have been analyzed, the team attempts to identify in which areas progress has/has not been achieved and for what reasons through discussions with the department supervisor. If different units have been analyzed, the investigator and the department supervisor try to identify whether the observed HIs are the same or differ. For both cases, the investigators agree with the department supervisor which improvement measures should be implemented and when and how to re-assess the situation.

6. Conclude the observation and related interviews
The team ensures that all sections of the questionnaires and results tables are as complete, valid and clear as possible. The investigators then thank all involved staff and provide contact details for further questions or comments. If possible, the investigators immediately present the results to facility managers, or, if this is not possible, do so as soon as possible. A template to help present the study’s results is available at http://www.who.int/patientsafety/research.
# Method-specific key success factors

- Include both men and women in the team if patients might only agree to being observed by an observer of the same sex
- The assessment should take place when most injections are given, since investigators need to observe at least five injections per department
- Involve the head of nursing or the chief nurse from the health-care facility in the selection of participating wards and the timing of observations/interviews
- The head of nursing or the chief nurse should introduce the investigators to all concerned staff from the participating departments
- Facility managers/the director of nursing must reassure participating staff that no disciplinary measures will be taken against them if unsafe injection practices are observed
- Guarantee confidentiality to participating staff and do not record staff names on the data collection sheets (only departments)
- Only one observer needs to visit the waste and sterilization facilities
- Investigators should tactfully interrupt injection givers if they are about to observe a practice that may expose an injection recipient to substantial risks.