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# Assessing and tackling patient harm

A methodological guide for data-poor hospitals



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Mr Michael Spiess

The “Methodological Guide” project was conceived within the **International Expert Group for “Methods & Measures in Patient Safety Research”** of **WHO Patient Safety**. Members of this Group include William Runciman and Ross Baker (Co-Chairs), Carlos Aibar, Santawat Asavaroengchai, Susan Dovey, Rhona Flin, Richard Lilford, Philippe Michel, Claudia Travassos and William Weeks. David Bates, External Lead of WHO Patient Safety Research, provided overall guidance.

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# Foreword

Tens of millions of patients suffer disabling injuries or death every year due to unsafe medical care.<sup>1</sup> Behind these numbers lie the stories of devastated lives, not to mention the billions of dollars that are spent on prolonged hospitalizations, loss of income, disability care and litigation, resulting from unsafe care.<sup>2,3</sup>

While patient harm affects countries at all levels of development, evidence suggests that developing countries are disproportionately impacted. The risk of health care-associated infection, for example, is 20 times higher in some developing countries than in developed nations.<sup>4</sup> In spite of this, we know little about the magnitude of harm in developing and transitional countries. To date, the classical methods for measuring harm have only been tested and used in developed countries, where good medical records are generally available. Appropriate methods for data-poor settings have not been identified even though these are essential to assessing the magnitude of unsafe care in such settings and driving local patient safety improvements.

WHO Patient Safety has therefore piloted several such methods in selected developing countries across four world regions and compiled them into this guide. This document provides guidance on choosing the most appropriate methods, depending on the objectives and available resources, offers protocols describing how to conduct the methods and supplies the tools needed to implement these. The guide is particularly adapted for assessing and tackling patient harm in data-poor hospitals, but can also be used in developed countries or in non-hospital settings.

I sincerely hope that this document will assist health-care providers around the world with assessing their local patient safety issues, and that it will in turn be possible to use the results to guide improvements in patient safety.



A handwritten signature in black ink, appearing to read 'David Bates', written in a cursive style.

**Prof David Bates**

*External Programme Lead for Research, WHO Patient Safety*

# 1. Background and introduction



This guide describes a set of methodologies that can be used either to estimate the extent of harm caused by the delivery of health care in a particular health-care facility or to establish priority actions around perceived patient safety issues. It is meant to be used by researchers, quality managers, clinicians and other professionals with an interest in understanding and tackling patient safety concerns in hospitals, without relying too heavily on medical records. It is expected that the guide will provide its readers with a basic understanding of how to assess and tackle patient care concerns based on these methodologies.

### Background

The level of harm from health care has been extensively studied in developed countries since the early 1990s.<sup>5,6,7,8,9,10,11,12</sup> This wave of research was initiated by the publication of the Harvard Medical Practice Study in 1991<sup>5,6</sup> based on a structured **retrospective review of medical records**. Large scale epidemiological studies have been carried out based largely on this methodology in many developed countries, although not all have been fully reported in the international literature.

Despite the extensive use of the **retrospective record review** methodology, several alternative methods to gather information on the level of harm also exist. Information gained through **incident reporting**, **routine hospital data**, **claims and complaints analysis** and **central national/regional audits or enquiries** have all played a part in understanding the patterns and burden of harm from health care in resource-rich countries. For resource-poor regions, however, much of these data are not routinely available. Moreover, the level of detail and quality of information recorded in the medical case notes in resource-poor regions varies greatly and may not be sufficient to support traditional retrospective record review.<sup>13</sup> The suitability of retrospective record review for large scale epidemiological studies depends largely on the organisation of and the information contained in the medical records of the facilities where the research takes place and therefore varies between facilities, countries and regions.

Studies carried out in developing and transitional countries using the methodology of retrospective record review have demonstrated that while the methodology can be applied to resource-poor countries, it is only appropriate within the main flagship health-care facilities of these countries. Evidence shows that this methodology is costly and less suitable in smaller, poorly-resourced health facilities, where both the organisation of and information contained in medical notes is limited.

There was therefore a need for new research methodologies or adaptations of the existing ones to investigate the level and causes of harmful incidents (or adverse events) in smaller and poorly-resourced health facilities. In 2007, after recognizing the difficulties of measuring patient harm (related to unsafe care) in environments with insufficient data collection systems, WHO Patient Safety uncovered from the literature a set of methods to measure harm related to health care and applied adaptations of these methods in various data-poor environments throughout the world to test workload, obstacles (cultural or organizational), relevance, feasibility and acceptability and, when appropriate, validity.

Record reviews of current inpatients were conducted instead of retrospective record review as were alternative methods such as direct observations and interviews either with individuals or groups. The retrospective method review was tested in six countries of the WHO Eastern Mediterranean Region (Egypt, Jordan, Morocco, Sudan, Tunisia and Yemen) and in two African countries (Kenya and South Africa). The record review of current inpatients was tested in five countries in Latin America (Argentina, Colombia, Costa Rica, Mexico and Peru) and the other three methods were tested in five countries from four different world regions (Jordan, Kenya, Peru, Thailand and Tunisia).

Building on the lessons learned from this testing, the WHO Patient Safety Expert Advisory Working Group on Advancing Methods and Measures agreed to develop a **“Methodological Guide for Data Poor Hospitals”** to facilitate the understanding and use of these methods, which do not require robust information systems. This publication is intended to be used as a decision aid to help national and local stakeholders in charge of patient safety initiatives, as well as researchers, to choose methods most suitable for defining priorities for patient safety initiatives according to objective, resources and data available.

### What are data poor facilities?

Data poor facilities can loosely be defined as those institutions that either do not have adequate routine information systems necessary to conduct a particular investigation, or if they have them, the data sources are unreliable, incomplete or inaccessible. Many facilities in the world, in both developed and developing countries may fall into this category.

### What are harmful incidents or adverse events?

The Conceptual Framework of the WHO International Classification for Patient Safety (ICPS) defines *“Health care-associated harm”* as harm arising from or associated with plans or actions taken during the provision of health care, rather than an underlying disease or injury. It also defines *“Patient safety incident”* as an **event** or **circumstance** which could have resulted, or did result, in unnecessary **harm** to a **patient**. Finally, the ICPS considers *“Harmful incident”* or *“Adverse event”* as an **incident** which resulted in **harm** to a patient.

### Conducting research in data poor environments

Many facilities in the world may be considered as data poor environments due to the weakness of their information systems. Despite this important limitation, however, it is possible to conduct some research through methods that use alternative mechanisms of data collection, such as observations and interviews.

Methods based on direct observations and interviews for measuring the magnitude and nature of adverse events in health care and for defining priorities of action show certain important advantages. The potential benefits of these methods of data collection lie primarily in their capacity to engage the field health-care workers in the research process, thereby contributing to raising their awareness and interest in patient safety, facilitating their training in the identification of harmful incidents and hopefully increasing their commitment towards patient safety. A second advantage is that because these methods are less reliant on existing pre-recorded information, the total cost of collecting the data is in general lower. Moreover, the implementation of some of the methods requires minimal finances, training and competencies - although communication skills are very important, as well as some basic knowledge of qualitative research methods. Finally, a third advantage is that the results of some of the methods are rapidly available, sometimes in real time, enabling a quick and effective feedback loop with the stakeholders of the research process.

### Rationale and principles of the methods selected for this guide

On the basis of the above considerations, WHO Patient Safety conducted a series of pilot tests to assess the feasibility and acceptance of research methodologies based on observation and staff interviews in a number of hospitals in four WHO regions around the world. Methodologies based on retrospective and concurrent record review were also tested in large scale studies in three world regions to assess their usefulness in data-poor hospitals. The methods described in this guide are those that have been proved to be feasible and well accepted in these settings.





### *Retrospective record review*

The mainstay of the traditional record review method is external reviewers collecting the information using a two-phase data collection, the first being conducted by the nurse in charge of selecting patients with positive screening criteria and the second being conducted by a senior physician who assesses the presence of adverse events, their preventability and the main contributory factors. The method relies on the existence of good quality archived medical records.

### *Record review of current inpatients*

This is a variation of the retrospective record review which involves examining the medical records of current hospital inpatients. The study is based on the assessment of the adverse events on one given day. It is therefore called a cross-sectional survey and estimates the point prevalence of adverse events (number of current hospital inpatients presenting the consequences of an adverse event/total number of patients studied). It relies on external reviewers collecting the information using a two-phase data collection. This method has the advantage of being more efficient, less time-consuming and easier to perform than the retrospective record review and of being able to identify current trends and problems in care rather than problems from the past calendar year. Furthermore, using a real-time methodology opens up the options of using additional data sources with mandatory or voluntary consultation with the patient's health-care professionals for further information about the care delivered and any problems encountered.

### *Staff Interview of current inpatients*

The main characteristic of this method is that it is based on interview with hospital staff instead of record review. As with the record review of current inpatients, it measures point prevalence of adverse events, their preventability and the main contributory factors. This method has the advantage, particularly in data-poor environments, of removing the reliance on pre-recorded information regarding care. The methodology also consists of external reviewers collect information using a two-stage methodology for data collection.

### *Nominal group technique based consensus method*

The Nominal Group technique uses a highly structured meeting with key informants to gather information about a given issue. In a structured conversation, the key informants discuss, usually rate and re-rate a series of items or questions. They can be implemented quite rapidly, without extensive training, consume few resources (except time) and, if the interview is sensitively conducted it is usually well accepted. Ideally, they should be carried out by a person with local knowledge who works in the facility or in similar ones. They rely on participants' subjective perception of harm and cannot aim to precisely measure its extent. Instead, they may be useful to set common shared priorities for patient safety initiatives.

### *Assessment of injection safety by observation and interview*

The standards of safe care are well understood and can be assessed using staff trained in observation and using a relatively simple checklist. To further support the findings of direct observation, additional information can be gained from focus groups or interview/questionnaires with individual health-care workers of their practice.

A further description of commonly used methodologies for patient safety research can be found in Appendix 1.





## 2. Method selection

How to select the most appropriate method(s) for your hospital



This guide offers five methods of assessing and tackling harmful incidents (HIs) in data-poor environments:

- retrospective record review
- record review of current inpatients
- staff interviews on current inpatients
- direct observation and related interviews and
- nominal group meetings.

There is no 'best method', but some methods are clearly better adapted for a specific purpose and setting than others. Thorough method selection helps to achieve good results, avoiding frustration and making the best use of time and money.

**Read the following instructions and study the method selection aid on the next page to identify the most appropriate method(s) for your objective and hospital:**

- 1 **Select activities:** depending on your objective and the availability of resources, decide whether you wish to conduct one activity (e.g. count HIs) or several activities (e.g. count HIs and identify causes of HIs). You can also conduct each of the activities as part of a process.
- 2 **Select methods:** identify the most appropriate method for implementing each selected activity. You can also select several methods, but conducting one method thoroughly often yields better results than conducting two methods poorly.
- 3 **Consult additional method characteristics:** if you are hesitant as to which method(s) to use, please [click here](#) or refer to p. 65 for a more comprehensive overview of the advantages/disadvantages of each method.\*
- 4 **Check method appropriateness:** click on the title(s) of the selected methods in the method selection aid and read the method protocol. If you anticipate that that method cannot be conducted at your facility, read the protocol of the second most appropriate method.
- 5 **Implement method:** once you have found the method you will implement, closely follow the guidance given in the method protocol to prepare and conduct that method.

\* Once you have made a choice, read the method protocol for the selected method to ascertain that it is acceptable to key stakeholders and feasible in your context. If this is probably not the case, select the second most appropriate method from the method selection aid and follow the guidance provided in that method protocol to prepare and conduct the method.

OBJECTIVES

Count HI	Identify causes of HIs <sup>1</sup>	Develop action plan	Monitor and improve
<p>If good quality medical records are available, use one of the following methods:</p> <p><b>Record review of current inpatients:</b> less time-consuming for medical staff than staff interviews, requires less researcher time and is less expensive compared to retrospective record reviews. It requires good current hospital admissions medical records (especially for cause analysis) and a list of randomly sampled records.</p> <p><b>Retrospective record review:</b> requires more investigator working hours than record reviews of current inpatients, as well as good quality medical records and a filing system.</p> <p><b>Staff interview on current inpatients:</b> more time-consuming for medical staff than any form of record review but allows cause analysis and provides more capacity building and awareness-raising opportunities. It allows for an easy sampling strategy.</p> <p>If good quality medical records are NOT available, use:</p> <p><b>Staff interview on current inpatients:</b> see above.</p>	<p>If good quality medical records are available, use one of the following methods:</p> <p><b>Record review of current inpatients:</b> same characteristics as for counting HIs.</p> <p><b>Retrospective record review:</b> same characteristics as for counting HIs.</p> <p><b>Staff interview on current inpatients:</b> same characteristics as for counting HIs.</p> <p><b>Direct observation:</b> helps to identify the causes of HIs that occur during specific procedures, such as injections.</p> <p><b>Nominal group technique:</b> provides qualitative data on health care professionals' perceptions of the causes of HIs.</p> <p>If good quality medical records are NOT available, use one of the following methods:</p> <p><b>Nominal group technique:</b> see above.</p> <p><b>Staff interview on current inpatients:</b> see above.</p> <p><b>Direct observation:</b> see above.</p>	<p>Regardless of whether records are available or not, use:</p> <p><b>Nominal group technique:</b> provides this is the only method that allows for the development of an action plan to tackle HIs. While the nominal group technique is not a root cause analysis, it does help to identify relevant underlying causes, based on which an action plan can be developed.</p>	<p>If good quality medical records are available, use one of the following methods:</p> <p><b>Record review of current inpatients:</b> easy to perform on a regular basis, provides up-to-date information and is less time-consuming for medical staff than staff interviews. It requires good current hospital admissions medical records and a list of randomly sampled records.</p> <p><b>Staff interview on current inpatients:</b> allows cause analysis and provides more capacity building and awareness-raising opportunities than the record review of current inpatients. It allows for an easy sampling strategy.</p> <p>If good quality medical records are NOT available, use:</p> <p><b>Staff interview on current inpatients:</b> see above.</p> <p><b>Direct observation:</b> to monitor specific procedures, such as injections.</p>

1) The following methods can help to identify some causes but are not a root cause analysis toll of individual HIs. Note: The methods described are not exhaustive and only reflect those deemed to be appropriate for data-poor hospitals.

### 3. Method protocols

How to prepare and conduct the selected method(s)



## 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

#### Objectives



The objective of retrospective record review is to estimate the incidence of HIs in a health-care facility and understand their causes.

#### Approach



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.

#### 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.



## Preparation of the record review

### 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.<sup>a)</sup>

### 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.

<sup>a)</sup> For questions about the RF1 and RF2 forms, consult the RF1 and RF2 review manual, available at <http://www.who.int/patientsafety/research>





## Conduct of the record review

### 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.

## 3.2 Record review of current inpatients

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

### METHOD OVERVIEW

#### Objectives



The objective of a record review of current inpatients is either to estimate the prevalence of HIs in a health-care facility and understand their causes, or to monitor and assess the impact of implemented solutions.

#### Approach



After gathering the medical records of current inpatients, a record screener determines, for each case, whether HIs are present or not. For all positively screened cases, a medical reviewer confirms/rejects the presence of HIs and assesses their causes and preventability. The doctor in charge can be asked for clarification or additional information. Both the record screening and the medical review are guided by a structured questionnaire and based on explicit criteria for screening and implicit ones for HI assessment. The point-prevalence of HIs and the preventability of HIs are calculated.

#### Responsibilities & time planning



##### Responsibilities

*The principal investigator*, who arranges the record review and possibly acts as medical reviewer, starts preparing three weeks ahead of time and conducts steps 1, 2, 3, 5 and 6 of the preparation phase.

*The record screener* starts preparing two weeks ahead of time and conducts steps 4 and 6 of the preparation phase and steps 1, 2, 3, 4, 5, 7, 8 and 9 of the record review.

*The medical reviewer* starts preparing two weeks ahead of time and conducts steps 4 and 6 of the preparation phase and steps 1, 2, 3, 6, 7, 8 and 9 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)
- Availability of the doctor in charge of the selected wards to clarify questions if needed
- 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 estimate the prevalence of HIs and understand their causes, a next step could be to develop an action plan.
- If the purpose is to monitor and assess the impact of implemented solutions, a record review could be conducted again at a later stage to identify areas where progress has been achieved and those where further action is needed.

## Preparation of the record review

### 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

The principal investigator presents the objective of the study to hospital managers and other key stakeholders to obtain their approval, explains how they can support the study and agrees with them when the record review will be held. A template to help introduce the study is available at <http://www.who.int/patientsafety/research>.

### 3. Select and train record screener and medical reviewer

The principal investigator selects a record screener (nurse) and a medical reviewer (physician), or, if fulfilling the criteria below, acts personally as medical reviewer. Screeners and reviewers:

- have clinical experience (the medical reviewer has at the least specific 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)
- are ideally external to the hospital, or at least not from the selected wards
- have a good understanding of how the hospital is organized
- are familiar with medical records
- should protect data.

### 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.<sup>b)</sup>

### 5. Test the local measurement reliability and validity of record reviews

Before conducting record reviews of current inpatients for the first time, the principal investigator arranges for a reliability and validity test. This helps to assess whether the method is adequate for local circumstances, 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, they 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, that medical records will be on hand, and that a doctor will be available to clarify any questions. The team also 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 questionnaires (at least 30% of the sample size). The RF1 and RF2 forms are available on p. 39 and p. 43, respectively.

## Conduct of the record review

### 1. Introduction

Hospital managers introduce the review team to staff from the selected wards and 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

Depending on the size of the hospital, either all inpatients or a sample of inpatients from all wards are studied. If only a sample is studied, the review team draws up a list of all current admissions and selects a random sample. It calculates the size of the sample as follows: For example, if the target precision is 5% (i.e. a confidence interval of about 5% to 15%), and the expected rate of HIs is 10%, with a risk  $\alpha$  of 5%, about 150 records need to be reviewed. If the target precision is 2.5% (i.e. a confidence interval of about 7.5% to 12.5%) about 500 records should be reviewed. The number of randomly selected records needs to be increased by 20% (lists of 180 and 600 records respectively) 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. If the study is intended to compare estimates over time, ensure a reasonable size for the confidence interval and seek advice from an epidemiologist prior to the study. 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, or otherwise. In that case, seek advice from an epidemiologist prior to the study.

<sup>b)</sup> For questions about the RF1 and RF2 forms, consult the RF1 and RF2 review manual, available at <http://www.who.int/patientsafety/research>

## Conduct of the record review

### 3. List inpatients

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

### 4. Fill in RF1 form

The record screener completes a copy of the RF1 form for each selected inpatient to determine for each case whether one or more screening criteria is/are present or not. The primary source of information is the medical record, but the doctor in charge, or the nursing staff working with the inpatient, can be asked for clarification/additional information to ensure that the forms are as complete as possible.

### 5. Separate records of positively and negatively screened patients

The record screener returns the records of negatively screened patients (patients whose records show no evidence of an HI) to the ward administrator/ward nurse and hands the records of positively screened patients (patients whose records show the possibility of an HI) to the medical reviewer.

### 6. Complete RF2 form

The medical reviewer completes a copy of the RF2 form for each positively screened patient. An admission is associated with an HI regardless of whether the HI occurred prior to or during the admission, as long as the patient still suffers the consequences or is undergoing treatment for it on the day of review. The primary source of information is the medical record but the doctor in charge can be asked for clarification/additional information. Ensure that the forms are as complete as possible and alert the facility's health-care team if the record review reveals a resolvable patient problem or patient risk. Destroy the list of names and the first page of all RF2 forms.

### 7. Calculate the estimated prevalence of HIs

The review team calculates the estimated percentage of HIs as follows:

$$\frac{\text{Number of patients suffering from at least one HI} \times 100}{\text{Total No. of screened records}}$$

If more than one HI has been identified within the admission, only 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 admission, as long as the patient still suffers the consequences on the day of review.

### 8. For monitoring and improvement purposes only: compare results and identify improvement measures

If the purpose of the record review is to monitor and assess the impact of implemented solutions, the review team compares the results of the two studies. It notes whether the estimated prevalence of HIs and the number of preventable HIs has decreased/increased over time and by how much, and whether the causes of HIs have remained the same or differed. The review team and the doctor in charge try to identify in which areas progress has/has not been achieved and for what reasons. They agree on further improvement measures and when and how to next assess the situation.<sup>c)</sup>

### 9. Conclude the review

The review team returns all medical records, explains next steps, and thanks all involved staff. If possible, they present the results to hospital stakeholders immediately, or, if this is not possible, agree on a time and date to do so at a later stage. A template to help present the study's results is available at <http://www.who.int/patientsafety/research>.

## Method-specific key success factors

- The medical reviewer has clinical experience in the type of ward he/she assesses
- The reviewers do not work in the wards whose records they are reviewing
- The record screener and the medical reviewer should work in the same room to simplify organizational matters
- The review team should alert the hospital's health-care team if the record review reveals a resolvable patient problem or patient risk
- The doctor in charge knows the clinical situation of the selected inpatients and the care they have received.

<sup>c)</sup> Given the characteristics of record reviews of current inpatients, this method could be an option for monitoring changes in the prevalence of HIs. However, this has not been tested and it is advisable to test the local measurement reliability of record reviews of current inpatients prior to conducting a major monitoring study based on this method. Guidance is available on p. 51.



### 3.3 Staff interviews on current inpatients

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

#### METHOD OVERVIEW

##### Objectives



The objective of staff interviews is either to estimate the prevalence of HIs in a health-care facility and understand their causes, or to monitor and assess the impact of implemented solutions.

##### Approach



The ward nurse is interviewed concerning all current inpatients and, if available, the records belonging to these patients are consulted to determine for each case whether an HI is present or not. For all positively screened cases, the doctor/physician in charge is interviewed to assess the causes and preventability of HIs. Both the screening and the review process are guided by a structured questionnaire, using explicit criteria for screening and implicit ones for HI assessment. The point-prevalence of HIs and the proportion of preventable HIs are calculated.

##### Responsibilities & time planning



###### Responsibilities

*The principal investigator*, who arranges and possibly conducts the interviews, starts preparing three weeks ahead of time and conducts steps 1, 2, 3, 5 and 6 of the preparation phase.

*The interviewer*, who conducts the interviews, starts preparing two weeks ahead of time and conducts steps 4 and 6 of the preparation phase and all steps of the conduct phase.

###### Time planning

The data collection and quality control process for a 30 to 40-bed ward will take an interviewer approximately four to six hours.

##### Requirements



- A trained interviewer who is ideally external to the facility, or at least not from the selected wards
- Availability of the ward nurse/nurse supervisor and the physician/doctor in charge of inpatients
- Records of current inpatients (if available, not necessarily required)
- A quiet room equipped with a table
- This protocol as guidance for implementation
- Sufficient copies of the RF1 form (120% of the sample size) and the RF2 form (at least 40% of the sample size)
- A blue and a red pen to fill in the forms.

##### Next phase (optional)



- If the purpose is to estimate the prevalence of HIs and understand their causes, the next phase could be to develop an action plan on that basis
- If the purpose is to monitor and assess the impact of implemented solutions, interviews could be repeated at a later stage to identify progress areas and those where further action is needed.

## Interview preparation

### 1. Study method protocol

The principal investigator studies this method protocol and the RF1 and RF2 forms in order to prepare the staff interviews.

### 2. Contact facility stakeholders and select participating wards

The principal investigator presents the objective of the initiative to facility managers and other key stakeholders. After receiving their approval, he/she explains how they can support the project and how much time will be needed from the nurse and doctor/physician, and agrees with them when the interviews will be held. (A template to help introduce the study is available at <http://www.who.int/patientsafety/research>). The investigator then explains that wards should be randomly selected to obtain a valid estimate of the point prevalence of HIs. However, if only selected wards can be assessed due to a lack of staff commitment, selection bias can be limited by including as many wards as possible. All patients on the selected wards on the day of study are included.<sup>d)</sup>

### 3. Select and train interviewer

Whether the principal investigator personally conducts the interviews or selects another interviewer, the selected person:

- is ideally external to the hospital, or at least not from the selected wards
- has a good understanding of how the facility is organized
- has an interest in hospital organization/management
- has clinical experience in the type of ward he/she assesses (e.g. inpatients from the medical ward are reviewed by medical doctors, and inpatients from the surgical ward are reviewed by surgeons/anesthetists)
- is capable of explaining the purpose of the interviews and of conducting them
- is a good listener and emotionally balanced
- is able to ensure full confidentiality.

The interviewer should receive training and be handed a copy of this method protocol and the RF1 and RF2 forms by the principal investigator approximately one week before conducting the interview. Doctors who have already conducted record reviews and are familiar with HIs should receive a day of training or a half-day refresher course; others should be given at least one to two days of training. Training materials are available at <http://www.who.int/patientsafety/research>.

### 4. Prepare to explain and conduct the interviews

The interviewer thoroughly reads this method protocol to ensure knowledge of how to explain and conduct the interviews and clarifies any questions with the principal investigator.<sup>e)</sup>

### 5. Test the local measurement reliability and validity of staff interviews

Before conducting staff interviews for the first time, the principal investigator arranges for a reliability and validity test. This helps to assess whether the method is adequate for local circumstances, whether the interviewer has understood the criteria and methodology, and whether he or she is evaluating the cases correctly. If the test yields poor results, the interviewer should receive additional training. Guidance for testing the local measurement reliability and validity of staff interviews is available on p. 51.

### 6. Arrange meeting room and materials

The interviewer arranges for a quiet room equipped with a table to be available and ensures that all available medical records belonging to selected inpatients are gathered and in the room before the interviews. The interviewer also brings along to the interview a blue and a red pen and a copy of this method protocol, as well as sufficient copies of the RF1 form (at least 120% of the expected sample size) and the RF2 form (at least 40% of the expected sample size). The RF1 and RF2 forms are available on p. 39 and p. 43, respectively.

<sup>d)</sup> If the target precision is 10% (i.e. a confidence interval of about 10% to 30%) and the expected rate of HIs is 20%, with a risk  $\alpha$  of 5%, about 60 patients need to be included. If the target precision is 5% (i.e. a confidence interval of about 15% to 25%), 250 patients should be included. If the study is intended to compare estimates over time, ensure a reasonable size for the confidence interval and seek advice from an epidemiologist prior to the study.

<sup>e)</sup> For questions about the RF1 and RF2 forms, consult the RF1 and RF2 review manual, available at <http://www.who.int/patientsafety/research>.





## Interview conduct

### 1. Introduction

Hospital managers introduce the interviewer to the nurse supervisor/ward nurse and the doctor/physician in charge of selected inpatients. The interviewer reassures them that the content of the interviews will remain confidential, explains the objective and procedure of the interviews, and tells them how the results will be used. (A template to help with informing facility staff involved in the study is available at <http://www.who.int/patientsafety/research>). The interviewer explains that an HI is “an injury caused by medical management or a complication instead of the underlying disease, that resulted in prolonged hospitalization and/or disability at the time of discharge from medical care.” In other words, an HI can be the result of a failure to provide care, of inappropriate or inadequate care being given, or of care being delivered wrongly.

### 2. List inpatients and gather records

The interviewer, assisted by the nurse, lists the names of all inpatients on the selected wards and ensures that all the records that are available are gathered into the room.

### 3. Fill in RF1 form

The interviewer interviews the nurse and consults any relevant documents that are available (at the very least, the admission notes and discharge summary, if available). On this basis, he/she completes a copy of the RF1 form for each selected patient. The RF1 form is available on p. 39. The interviewer then returns the records of negatively screened patients to the nurse.

### 4. Complete RF2 form

On the same day, or on the days immediately following the screening, the physician in charge of patients on the day of data collection is interviewed. Based on that interview, and any available medical records, the interviewer completes a copy of the RF2 form for each positively screened patient. Two types of HIs are counted: First, HIs that occurred prior to admission and are the reason for it, and second, HIs that occurred during the index admission, the consequences of which the patient is still suffering from on the day of the interview. After ensuring that the forms are completed as fully as possible, the interviewer destroys the list of names and the first page of all RF1 and RF2 forms.

### 5. Calculate the estimated prevalence of HIs

The interviewer calculates two types of estimates:

#### 1) The percentage of admissions caused by HIs

$$\frac{\text{No. of admissions caused by a HI} \times 100}{\text{Total No. of admissions}}$$

#### 2) The estimated point prevalence of HIs

$$\frac{\text{No. of patients suffering from HIs on the day of interview} \times 100}{\text{Total No. of patients included in sample}}$$

### For monitoring and improvement purposes only:

### 6. Compare results and identify improvement measures

If the purpose is to monitor and assess the impact of implemented solutions, the interviewer compares the results of the two assessments (not for a single ward; the number of cases in a single ward is too low for monitoring). The interviewer notes whether the estimated prevalence of HIs and the number of preventable HIs has decreased/increased over time and by how much, and whether the causes of HIs have remained the same or differed. The interviewer and the doctor in charge try to identify in which areas progress has/has not been achieved and for what reasons. They agree on further improvement measures and when and how to next assess the situation.<sup>f)</sup>

### 7. Conclude the review

The interviewer returns all medical records, thanks all involved staff and provides contact details for further questions or comments. If possible, the interviewer presents the results to facility stakeholders immediately, or, if this is not possible, agrees 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>.

<sup>f)</sup> There is evidence suggesting that staff interviews might be appropriate for monitoring prevalence of HIs (see reference 26). However, this has yet to be tested and confirmed. If you wish to conduct a major monitoring study based on staff interviews, test the local measurement reliability of this method first (see methods in the publication referred to above).



## Method-specific key success factors

- Patient care should not be compromised as a consequence of staff being interviewed (nurse and physician/doctor in charge of inpatients are backed up while participating in the interviews)
- The interviewer has clinical experience in the type of ward he/she assesses
- The interviewer allows sufficient time to build a relationship of trust with respondents and does not conduct the interview in an overly formal, noisy or public environment
- Respondents are aware of how much time is required for the interviews (up to 6 hours for a 30 to 40-bed ward) and know the purpose, objective and procedure of the interviews
- The doctor in charge knows the clinical situation of selected inpatients well and the care they have received
- There should be adequate hand-over between staff shifts so that respondents have a good understanding of the clinical situation in their ward
- Age, sex and cultural factors should be taken into account when planning the interviews and selecting an interviewer.

### 3.4 Nominal group meetings

This protocol summarizes the features of the nominal group technique, highlights the method-specific key success factors and provides chronological step-by-step guidance to preparing and conducting this method.

#### METHOD OVERVIEW

##### Objectives



The purpose of a nominal group meeting is to gather the experiences of health-care staff and develop an action plan to tackle HIs. While this method is not, and should not substitute a root cause analysis, the nominal group technique does help to identify relevant underlying causes as perceived by key hospital actors. On this basis, an action plan can be developed.

##### Approach



Five to twelve participants, who represent all hospital activities, meet together in a highly structured brainstorming session. Depending on the size of the health-care facility, one or several meetings are conducted, each of which is guided by a trained facilitator and based on comprehensive talking points.

##### Responsibilities & time planning



###### Responsibilities

*The principal investigator*, who organizes the meeting, starts preparing three weeks ahead of time and conducts steps 1, 2, 3, 4, 5 and 7 of the meeting preparation.

*The facilitator*, who conducts the meeting and can be the same person as the principal investigator, starts preparing two weeks ahead of time and conducts steps 6 and 7 of the meeting preparation and all the steps relating to the conduct of the meeting.

###### Time planning

The conduct of the meeting requires approximately one-and-a-half to two hours.

##### Requirements



- A trained nominal group meeting facilitator
- Availability of at least five staff members representing all hospital activities for two hours
- A quiet meeting room equipped with tables and a blackboard/whiteboard/flipchart
- The talking points provided
- A sheet of paper and a pen per meeting participant.

##### Next phase (optional)



The next phase could be to evaluate the results of the implementation of the action plan.

## Meeting preparation

### 1. Study method protocol

The principal investigator studies this method protocol in order to prepare the nominal group meeting.

### 2. Contact health care facility stakeholders

The principal investigator presents the objective of the initiative to hospital managers and other key stakeholders. After receiving their approval, the principal investigator explains how they can support the project and agrees with them when the meeting(s) will be held. A template to help introduce the study is available at <http://www.who.int/patientsafety/research>.

### 3. Select number of meetings

The principal investigator consults with facility managers to decide on the number of meetings to take place. Separate meetings should be conducted for doctors and for paramedical staff so that each group expresses itself as freely as possible. For a rural or middle-sized health-care facility, it may suffice to hold a single meeting with five to eight volunteers, but for a large hospital with more than 10 wards, two cross-departmental meetings might be needed for each type of professional.

### 4. Select and invite participants

The principal investigator and facility managers select between five and twelve staff profiles to participate in each meeting. For example, the “doctors’ meeting” group of a hospital with three medicine wards, two surgery wards, a rehabilitation ward, a laboratory and a pharmacy could be composed of two medical doctors, a surgeon, an anaesthetist, a rehabilitation doctor, a pharmacist, a biologist and the quality manager. It is essential that participants:

- represent all hospital activities
- are willing to contribute
- have good oral skills
- are able to stand back from their clinical activity
- represent all levels of hierarchy (except management).

The principal investigator and facility managers write a list of profiles, and facility or ward managers then invite participants a week ahead of time, explaining the purpose, meeting venue and time required (approximately 2 hours) to them. Facility managers should not be present during the meeting but are invited to attend a presentation of the results following the meeting. In contrast, the participation of the quality officer/risk manager, if applicable, can be very beneficial.

### 5. Select and train a facilitator

Whether the principal investigator personally facilitates the meeting or selects another facilitator, the facilitator:

- is external to the facility but has a good understanding of its organization
- is from the region or has worked there
- understands and is able to discuss clinical matters
- is interested in the management of a hospital
- is able to ensure the confidentiality of the discussion
- is able to rapidly gain the trust of participants
- has basic presentation skills
- has a constructive approach.

The facilitator should be trained and handed a copy of this method protocol by the principal investigator approximately one week before conducting the meeting. Facilitators who have never conducted nominal group meetings should receive at least one day of training, others should receive a half-day refresher course. Training materials are available at <http://www.who.int/patientsafety/research>.

### 6. Prepare to explain and conduct the nominal group meeting

The facilitator studies this method protocol to ensure knowledge of how to explain and conduct the meeting, clarifies possible questions with the principal investigator and prepares answers to questions participants might ask. The facilitator also prepares an “ice-breaker” game if meeting participants are likely to not know each other. These preparations should be completed at least two days before the meeting.

### 7. Arrange meeting room and materials

The facilitator arranges for a quiet meeting room to be available, equipped with tables and a blackboard/whiteboard/flipchart, prepares a sheet of paper and a pen per participant, and brings this method protocol along to the meeting.

## Meeting conduct

### 1. Facilitate the meeting

Conduct the meeting based on the comprehensive talking points provided on p. 53.

### 2. Present the results to facility stakeholders

If possible, 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

- Only conduct a nominal group meeting if staff is committed and able to openly discuss local safety issues; otherwise select a different method (see p. 11)
- Include staff from all hospital activities in the meeting (except management) but do not mix junior and senior staff and particularly doctors and nurses (conduct separate meetings for doctors and for nurses)
- Facility managers are not present during the meeting to ensure that participants express themselves as freely as possible, but management is briefed as soon as possible after the meeting to ensure ownership
- The facilitator proceeds with the meeting only after participants understand the definition of HIs and preventability and are clear on the meeting procedure
- Limit the number of HIs and contributing problems that each participant suggests according to the number of participants (one per participant if there are more than ten participants)
- Do not invite more than fifteen participants for each meeting
- The facilitator helps participants to be specific and precise: the more precise the problem/solution, the easier it is to take action
- The facilitator should ensure that all participants can freely express their views and all relevant ideas are taken into account.



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## 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

##### Objectives



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.

##### Approach



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.

##### 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.

## 4. General key success factors

How to achieve the best results



## How to achieve the best results

In addition to the method-specific key success factors, there are a number of factors which are relevant for all methods. The following general key success factors can improve or undermine the success of any study and should therefore be taken into account while preparing and conducting a method.

### Trainer

- *Train more people than are actually required for the study:* this allows for selecting the most promising candidates and compensating for drop-outs
- *Time the training:* Deliver the training for implementing staff approximately one week before data collection, but start to prepare it early (rehearse, prepare training materials, etc.)
- *Adapt to local context:* adapt the training slides to local requirements if needed (e.g. cultural peculiarities for nominal group meetings)
- *Facilitate understanding:* speak slowly and clearly, avoid creating a 'teacher-student' impression, encourage discussion and use role-playing to ensure optimal understanding
- *Assess participants' understanding:* ask questions, conduct the quiz and hands-on exercise thoroughly and provide participants with further training if necessary
- *Select implementing staff fairly:* use functional criteria such as their level of education or professional experience, as well as candidates' attitudes, including motivation or social skills, to select candidates. Do not select participants based on personal relationships, cultural factors or individual attributes, but take into account local requirements when selecting implementing staff (e.g. women may only consent to being observed by same-sex observers).

### Record screeners, medical reviewers, observers and interviewers

- *Be a team player:* help each other - what counts is not individual performance but collective improvement
- *Communicate appropriately* and with all stakeholders. Too many projects falter due to poor communication, coordination and transparency
- *Prepare the assessment thoroughly and in advance:* make contact with stakeholders well in advance and prepare the study ahead of time. Consider rescheduling if essential preparations are not completed at least two days before the data collection is due to begin
- *Seek clarification:* discuss any questions with the principal investigator or the trainer rather than hiding your uncertainty
- *Manage your stakeholders:* ensure stakeholders know the objective and process of the study and their roles and responsibilities. Your stakeholders may include health-care managers, ethical and works councils, involved staff from the hospital, and implementing staff (the latter for principal investigators only). It is your responsibility to ensure that these stakeholders are informed of the project and committed to it
- *Show respect:* never force anybody to participate in the study. Be respectful to your colleagues and help them improve
- *Lead by example:* be a good role model for your colleagues and counterparts
- *Combat 'blame culture':* such a culture will not bring safety issues to the surface and is not justifiable as patient harm is rarely the result of bad intentions. Rather, work towards a constructive spirit in which to understand and tackle HIs
- *Signal conflicts of interest:* inform the principal investigator of any conflict of interest in preparing or conducting the study
- *Ensure confidentiality:* ensure full confidentiality during and after the study.

## 5. Overview of method advantages and disadvantages



Type of criteria	Nominal group technique	Direct observation	Staff interview	Record review of current inpatients	Retrospective record review
<b>Appropriateness of method for</b>					
counting HIs	not applicable	not applicable	+++	+++	+++
understanding causes/contributing factors of HIs	++	++	++	+	+
developing an action plan to tackle HIs	+++	not applicable	not applicable	not applicable	not applicable
monitoring and improving patient safety achievements	not applicable	+	+++	++	not applicable
<b>Attributes of method</b>					
reliability	not applicable	++	+++	++	++
capacity to repeat	+++	++	+	++	+
<b>Urgency of results</b>					
appropriateness if results are urgent (time until results are available)	+++	+++	++	++	+
<b>Required resources</b>					
requires good quality records	not applicable	not applicable	+	++	+++
number of health facility staff working hours / impact on clinical ward service	++	+++	+	+++	+++
amount of involvement of other wards (med record department)	+++	+++	+++	+++	+
requires organizational flexibility	+++	+	++	++	+
requires investigator working hours	+++	+++	++	++	+
requires investigator expertise	++	++	+++	+++	+++
amount of financial resources needed (logistical and human costs)	+++	+++	++	++	+
<b>Ownership building</b>					
need for strong local institutional support or leadership	+	+	++	++	++
need for health-care facility staff commitment	+++	++	+++	++	+
sources of concern for participants before implementation	++	++	++	+	+
needs a safety culture (i.e. staff are able to openly discuss local safety issues)	+++	++	+++	++	+
<b>Expected gain</b>					
amount of opportunity for capacity building at local site	++	+	+++	+	+
amount of opportunity for investigator capacity building	++	+	+++	+++	+++
amount of interactivity between field workers	+++	+	++	+	+

+++ High    ++ Medium    + Low

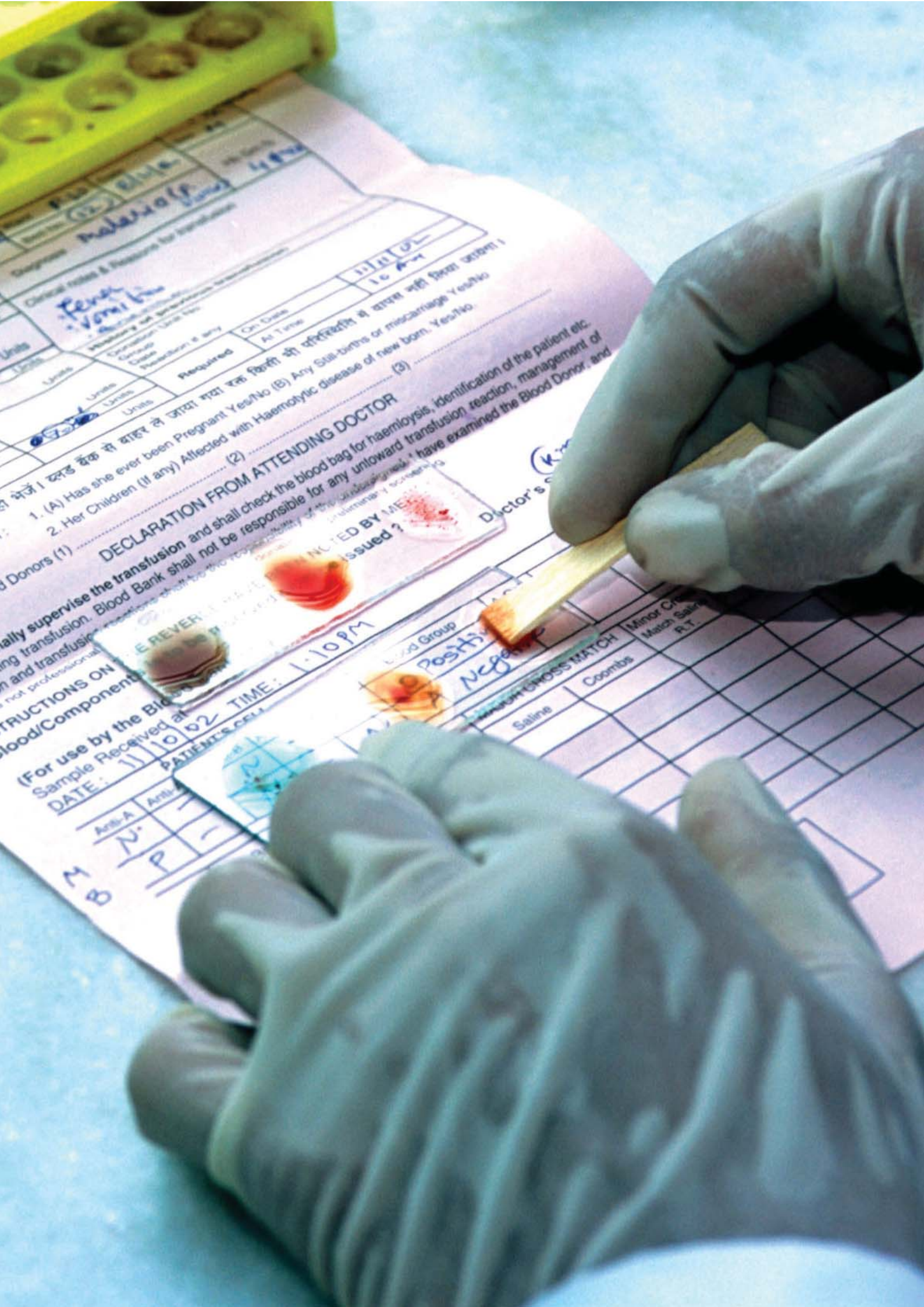
## 6. Method tools <sup>9)</sup>

What tools to use for conducting the method(s)

### 6.1 Tools for conducting record reviews and staff interviews (RF1 and RF2) and guidance for testing reliability and validity of measurements

<sup>9)</sup> The following tools are available at <http://www.who.int/patientsafety/research>





Group	Units	Units	Units	Units	Units
B	10	10	10	10	10

**Declaration from Attending Doctor**

1. (A) Has she ever been Pregnant Yes/No (B) Any Still-births or miscarriage Yes/No  
 2. Her Children (If any) Affected with Haemolytic disease of new born. Yes/No  
 3. I hereby declare that the blood bag for haemolysis, identification of the patient etc. is correct and safe for transfusion.

REVEREND ...  
 NOTED BY ME  
 Issued at  
 TIME: 1:10 PM  
 PATIENT'S CELL

Blood Group		GROSS MATCH		Coombs	
Saline	Minor Cross Match	Saline	Minor Cross Match	Saline	Minor Cross Match
Positive	Positive				
Negative	Negative				



**RF1: adverse event detection questionnaire**

**Reviewer**

Reviewer ID number:

Clinical department n°:

Date of admission:   /   /    
D D M M Y Y

Time commenced review:   :    
(Use 24 hour clock)

Time finished review:   :    
(Use 24 hour clock)

**Case number**

Case number:

Birth date:   /   /    
(at least the year of birth) D D M M Y Y

Gender:   
1 = male  
2 = female

Admission status:   
1 = elective  
2 = acute  
3 = do not know

Date of review:   /   /    
D D M M Y Y

Date of discharge:   /   /    
(if known) D D M M Y Y

## SCREENING CRITERIA

Please indicate for all of the below if the criteria are fulfilled and if so give details.

---

1. During the last 12 months, any unplanned ward admission related to any given healthcare for the same health condition?

Yes

No

2. Hospital-incurred patient accident or injury.

Yes

No

3. Adverse drug reaction/drug error or related to administration of fluids or blood

Yes

No

4. Hospital acquired infection/sepsis.

Yes

No

5. Unplanned removal, injury or repair of organ or structure during surgery, invasive procedure or vaginal delivery.

Yes

No

6. Unplanned return or visit to the operating theatre during this admission

Yes

No

7. Unplanned open surgery following closed or laparoscopic surgery.

Yes

No

8. Cardiac/respiratory arrest, low Apgar score.

Yes

No

9. Development of neurological deficit not present on admission

Yes

No

10. Injury or complications related to termination of pregnancy or labour and delivery including neonatal complications.

Yes

No

11. Other patient complications including MI, DVT, PE, CVA etc.

Yes

No

12. Patient/family dissatisfaction with care received documented or expressed during the current admission

Yes

No

13. Unplanned transfer from general care to intensive care / higher dependency.

Yes

No

14. Unplanned transfer to another acute care hospital

Yes

No

15. Unexpected death (i.e. not an expected outcome of the disease during hospitalisation)

Yes

No

16. Patients care delayed or lesser treatment given because the patient was unable to pay

Yes

No

17. Admission significantly prolonged compared to the expected length for this clinical condition.

Yes

No

18. Any other undesirable outcomes (not covered by any of the above)

Yes

No

Are any criteria present?:  Yes  No, (Then STOP; do not the second questionnaire)

If Yes, total number of criteria:

If Yes, number of potential injury or complication:

Short description of the potential injury or complication:

- Include all potential injuries or complications noted in the RF1 form.
- Complete **one form for each** potential injury or complication.
- If the patient has more than one, use two (or more) RF2 forms and quote “1 of 2”, “2 of 2”, etc.

## CONFIDENTIAL

### (RF2 Form)

Reviewer ID number:

Case number:

(same number as in RF1)

Date of data collection:   /   /    
D D M M Y Y

Time commenced review:   :    
(Use 24 hour clock)

Time finished review:   :    
(Use 24 hour clock)

Q1 & Q2 HI No  out of a total of  HI

Brief description of the harmful incident:

**Information sources used**

- Q3 Physician ..... 1 = Yes 2 = No
- Q4 Head Nurse ..... 1 = Yes 2 = No
- Q5 Nurse ..... 1 = Yes 2 = No
- Q6 Medical record ..... 1 = Yes 2 = No
- Q7 Nursing notes ..... 1 = Yes 2 = No
- Q8 Other source ..... 1 = Yes 2 = No
- Q9 *Did the patient experience any unintended injuries or complications?* ..... 1 = Yes 2 = No

**The questionnaire is complete if answer is No.**

**Q10** *Clinical summary of the case and description of the harmful incident*

**Main disease causing the admission:**

**Known comorbidities:**

**History of disease (in particular specify if the disease was known before admission):**

**Main events during hospitalization:**

**Harmful incident: (briefly answer the following “what, who, when, where, how” questions)  
*(Give any relevant laboratory/imaging results)* continue on back if needed:**

## Harmful incident determination

### SEVERITY

- Q11** Did the injury or complication cause the admission to the ward? ..... 1 = Yes 2 = No
- Q12** Is the injury or complication associated with death of the patient? ..... 1 = Yes 2 = No
- Q13** Is the injury or complication expected to be associated with disability/  
deficit at the time of discharge from the ward? ..... 1 = Yes 2 = No
- Q14** Is the injury or complication expected to be associated with prolonged ward stay? 1 = Yes 2 = No

**The questionnaire is complete if the answer to all four items is No.**

### CAUSATION

**Q15** *In your best judgement, is there evidence that health care management caused the harmful incident? In answering this question, consider, when relevant, the following questions and complete the appropriate boxes.*

- Q15.1** Could the event be expected, given the disease or the health status of the patient? ..... 1 = Yes 2 = No 3 = Don't know
- Q15.2** Are there indications that health care management caused the injury? ..... 1 = Yes 2 = No 3 = Don't know
- Q15.3** Does the timing of events suggest that the injury was related to the treatment or lack of treatment? ..... 1 = Yes 2 = No 3 = Don't know
- Q15.4** Are there other reasonable explanations for the event? ..... 1 = Yes 2 = No 3 = Don't know
- Q15.5** Was there an opportunity prior to the occurrence of the injury for intervention which might have prevented it? ..... 1 = Yes 2 = No 3 = Don't know
- Q15.6** Was the unintended injury or complication recognised during the current admission? ..... 1 = Yes 2 = No
- Q15.7a** Was appropriate action taken? ..... 1 = Yes 2 = No 3 = N/A
- Q15.7b** Did the unintended injury or complication respond to the appropriate action? ..... 1 = Yes 2 = Probably 3 = Too early to know 4 = No 5 = Don't know 6 = N/A

**Consider all of the above questions above before continuing.**

**Q16** *After due consideration of the clinical details of the patient's management, irrespective of preventability, what level of confidence do you have that the HEALTH CARE MANAGEMENT caused the injury?*

#### Confidence Score:

- 1 = Virtually no evidence of management causation (Then STOP, no HI)  
2 = Slight to moderate evidence for management causation (Then STOP, no HI)  
3 = Management causation not likely; less than 50-50 (Then STOP, no HI)  
4 = Management causation more likely than not, more than 50-50  
5 = Moderate/strong evidence of management causation  
6 = Virtually certain evidence of management causation

**Score:**

**The questionnaire is complete if your score is three or less.**

**Q17** *Location of occurrence*

**Q17.1** Where did the health care management causing the HI occur?

(choose one) 1 = outside this hospital 2 = inside this hospital

If 1, proceed with Q17.2 and Q19

If 2, proceed to Q17.3

**Q17.2** If outside this hospital

- 1 = Public hospital
- 2 = Private hospital
- 3 = Home with professional health-care management
- 4 = Home without professional health-care management
- 5 = Nursing home
- 6 = Primary health care facility outside this hospital/family practice
- 7 = other

**Q17.3** If the HI occurred inside this hospital, was it in the clinical unit where the data collection is currently taking place?

1 = Yes 2 = No

**Q17.4** Specify the clinical unit in which the HI occurred

**SURGERY**

- |                           |                         |                    |
|---------------------------|-------------------------|--------------------|
| 01 = Cardiac Surgery      | 05 = Paediatric Surgery | 10 = Neurosurgery  |
| 02 = Colon/Rectal Surgery | 06 = Plastic Surgery    | 11 = Obstetrics    |
| 03 = General Surgery      | 07 = Thoracic Surgery   | 12 = Ophthalmology |
| 04 = Orthopaedic Surgery  | 08 = Urological Surgery | 13 = ENT           |
|                           | 09 = Vascular Surgery   | 14 = Stomatology   |

**MEDICINE**

- |                             |                            |                                  |
|-----------------------------|----------------------------|----------------------------------|
| 15 = Cardiology             | 23 = Infectious Disease    | 30 = Paediatrics                 |
| 16 = Dermatology            | 24 = Internal Medicine     | 31 = Pulmonary Disease           |
| 17 = Endocrinology          | (not otherwise classified) | 32 = Psychiatry                  |
| 18 = Gastroenterology       | 25 = Physical Medicine     | 33 = Medical Intensive Care Unit |
| 19 = Geriatrics             | 26 = Neonatology           | 34 = Rheumatology                |
| 20 = Gynecology             | 27 = Nephrology            | 35 = A&E                         |
| 21 = Hematology             | 28 = Neurology             | 36 = Other                       |
| 22 = Immunology and Allergy | 29 = Medical Oncology      |                                  |

**Q18** *Where exactly?*

**INSIDE HOSPITAL**

- |                                       |   |
|---------------------------------------|---|
| 01 = Theaters                         | 09 = Radiology                              |
| 02 = Recovery Room                    | 10 = A&E                                    |
| 03 = ICU                              | 11 = Service Area (stairs, halls, elevator) |
| 04 = Catheterization, endoscopic unit | 12 = Other site in hospital                 |
| 05 = Consultation, outpatients clinic | 13 = Don't know                             |
| 06 = Therapy/Rehabilitation           |   |
| 07 = Patient's room                   |   |
| 08 = Labor and Delivery               |   |



**Q19** *Classification of harmful incident*

**Q19.1** To which type of care management was the harmful incident mainly related?

1 = prevention or prophylaxis    2 = diagnosis    3 = therapeutic    4 = rehabilitation

**Q19.2** What was the main cause of HI (the most important one)

- 1 = Error in the choice of management
- 2 = Delay in management implementation (including no implementation at all)
- 3 = Error during management implementation
- 4 = Other (mainly unavoidable events)
- 5 = Don't know

**Q19.3** Was the HI related to a procedure?

1 = Yes    2 = No

**If no proceed to Q19.4**

**Q19.3a** If yes, which procedure?

- |  |                                   |
|--|-----------------------------------|
| 1 = Surgery                                | 9 = Urinary catheter              |
| 2 = Anesthesiology                         | 10 = Gastric                      |
| 3 = Surgical intervention during radiology | 11 = Intubation                   |
| 4 = Radiology using contrast product       | 12 = Dialysis                     |
| 5 = Endoscopy                              | 13 = Radiotherapy                 |
| 6 = Biopsy                                 | 14 = Instrument assisted delivery |
| 7 = Puncture or tapping                    | 15 = Physiotherapy                |
| 8 = Catheter, perfusion or injection       | 16 = Other                        |

**Q19.4** Was the HI related to a substance or health product?

1 = Yes    2 = No

**If no proceed to Q20**

**Q19.4a** If yes, which product?

- 1 = drug
- 2 = blood product
- 3 = medical device
- 4 = equipment (laser, diathermy...)
- 5 = Dietetic product
- 6 = Local preparation (e.g. chemotherapy product...)
- 7 = Other

**Q20** *Patient-related contributing factors?*

**Q20.1** Patient's global health status and disease

1 = Yes    2 = No

**Q20.2** Patient's behaviour

1 = Yes    2 = No

**Q20.3** Patient unable to afford correct recommended care

1 = Yes    2 = No

**Q20.4** Family's behaviour

1 = Yes    2 = No

**Q20.5** Other

(Specify) \_\_\_\_\_

1 = Yes    2 = No

**Q21** *System-related contributing factors?*

- |  |                |               |                          |
|--|----------------|---------------|--------------------------|
| <b>Q21.1</b> inadequate or defective premises .....  | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q21.2</b> equipment or supplies not available or defective .....  | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q21.3</b> inadequate staffing at the time of the HI (not merely in terms of numbers, take account of balance among different competences and experience, in particular at weekends and during holidays) ..... | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q21.4</b> recent organizational changes inside the unit .....   | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q21.5</b> defective coordination inside the unit .....  | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q21.6</b> inadequate reporting or communication .....   | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q21.7</b> inadequate training or supervision of doctors or other personnel .....  | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q21.8</b> delay in the provision or scheduling of services (e.g. lab tests, x-rays or follow-up visits) .....   | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q21.9</b> failure to implement protocol or plan .....   | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q22</b> <i>Inadequate monitoring of patient</i> .....   | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q22.1</b> inadequate discharge procedure .....  | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q22.2</b> defective coordination between the unit and other units (e.g. pharmacy, blood bank or catering) .....   | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q22.3</b> no protocol/health care policy .....  | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |
| <b>Q22.4</b> other .....   | <b>1 = Yes</b> | <b>2 = No</b> | <input type="checkbox"/> |

**Describe the most important contributing factor to the harmful incident**

**Q23 Preventability**

Consider and evaluate the following questions before making a judgement on preventability.

**Q23.1** How serious was the clinical condition of the patient PRIOR to the occurrence of the HI?  
..... 1 = very serious 2 = moderately serious 3 = not very serious 4 = not serious

**Q23.2** How complex was the clinical condition (co-morbidity, global health status)?  
..... 1 = very complex 2 = moderately complex 3 = not very complex 4 = uncomplicated

**Q23.3** What was the degree of urgency in the management of the case prior to the occurrence of the harmful incident?  
..... 1 = critical and very urgent 2 = moderate 3 = low 4 = not urgent

**Q23.4** Was the choice of actual management of the disease appropriate?  
..... 1 = definitely 2 = probably 3 = probably not 4 = inappropriate 5 = do not know

**If Q23.4 is 3, 4 or 5 (wrong choice or omission) go to Q23.6.**

**Q23.5** If the choice was appropriate, was there a deviation in the implementation of the intended management?  
1 = none 2 = slight deviation 3 = moderate deviation 4 = marked deviation 5 = do not know

**Q23.6** What was the likelihood of benefits associated with the actual management of the disease which led to the HI?  
..... 1 = high 2 = moderate 3 = low 4 = absent

**Q23.7** What was the risk associated with the actual management of the disease which led to the HI?  
..... 1 = virtually absent 2 = low 3 = moderate 4 = high

**Q23.8** On reflection, would a reasonable doctor or health professional have managed the care in a similar manner?  
1 = definitely would have 2 = probably would have 3 = probably would not have 4 = definitely would not have

---

**Consider all of questions 23.1-23.8 above before continuing**

---

**Q24** *Rate on a 6-point scale your confidence in the evidence for preventability.*

**Confidence Score:**

- 1 = Virtually no evidence for preventability
- 2 = Slight to modest evidence for preventability
- 3 = Preventability not really likely; less than 50-50
- 4 = Preventability more likely than not; more than 50-50
- 5 = Strong evidence for preventability
- 6 = Definite certain evidence for preventability

**Score:**

**Q25** *Please describe how the harmful incident could have been prevented*

## Guidance for testing the measurement reliability and validity of record reviews of current inpatients, retrospective record reviews and staff interviews

It is strongly recommended to carry out a reliability test before using any of these methods for the first time.

### Objectives of the reliability test

The objective of the reliability test is to assess whether the method is adequate for local circumstances, whether the reviewers/interviewers have understood the criteria and methodology, and whether they are evaluating the cases correctly. A reliability test helps to understand whether one or several reviewer(s)/interviewer(s) obtain the same results on repeated occasions. If reliability proves to be insufficient, further training is required before the study can be conducted.

### How to conduct the reliability test

Two different reviewers/interviewers, or the same reviewer/interviewer on two occasions, evaluate(s) a sample of medical records/patient cases. The results obtained by the two reviewers/interviewers, or by the same reviewer/interviewer on the two occasions, will be compared. The higher the consistency of the two measurements, the higher the reliability.

*The items that should be subject to a reliability assessment are the reviewer's/interviewer's identification of:*

- a) positively screened cases
- b) health care-related HIs
- c) preventable HIs

The number of medical records/patient cases that are assessed should be large enough (around 50) to ensure that the reviewer(s)/interviewer(s) is/are exposed to all different possible outcomes. The principal investigator responsible for conducting the study can select the most suitable medical records/patient cases to ensure that most of the possible outcomes are present:

- negatively screened cases
- positively screened cases with no HIs or with HIs that are not caused by health care
- cases of preventable health care-related HIs
- cases of non-preventable health care-related HIs.

The consistency of the results of different reviewers/interviewers, or between the different evaluations of the same reviewer/interviewer, will be calculated by measuring the kappa index. If the kappa index is low (less than 60%), further training is required.



## 6.2 Talking points for nominal group meetings



The facilitator copies the following tables on the whiteboard before the participants arrive:

First page of the whiteboard:

HIs	Contributing factors

Second page of the whiteboard (draw one column for each participant in the “scoring” section):

Factors contributing to several HIs	Score				Final ranking

If possible, a facility manager delivers an introductory speech to explain how this meeting ties in with the facility’s efforts to improve patient safety. Then use the following talking points to facilitate the discussion:

### 1. Introduction (~15 minutes)

- briefly introduce yourself (name, occupation, personal background, etc.)
- conduct an “ice breaker game”<sup>h)</sup> if participants do not know each other or invite participants to briefly introduce themselves
- explain objective of the meeting: gather health-care professionals’ views to develop an action plan
- the purpose is not to test participants but to improve the facility’s work
- explain that the discussion is confidential: no names will be used when reporting results.

### 2. Define HIs (~15 minutes)

- read the definition of an HI and write it on the whiteboard: An HI is “an injury caused by medical management or a complication instead of the underlying disease, and that resulted in prolonged hospitalization and/or disability at the time of discharge from medical care”
- an HI can be the result of a failure to provide care, of inappropriate or inadequate care being given, or of care being delivered wrongly
- if participants require further clarification, provide examples of HIs (p. 56)
- do not proceed until all participants have understood what HIs are (but try not to discuss this for more than 15 minutes).

### 3. Explain meeting procedure (~5 minutes)

Explain that the meeting is structured as follows:

1. identify HIs observed in this facility
2. identify contributing factors
3. identify problems that contribute to several HIs
4. score problems that contribute to several HIs
5. agree on most important contributing problems
6. identify solutions
7. score appropriateness of each solution
8. agree on most important solutions
9. establish roles, responsibilities and time plan to implement solutions
10. select general actions for improving patient safety.

### 4. Identify HIs ( ~15 minutes and ~10 minutes for silent brainstorming)

- distribute a sheet of paper and a pen to each participant
- write the following question on the whiteboard: “What kind of patient harm have you witnessed in this hospital that was caused by failure to provide care, by inappropriate or inadequate care being given, or by care being delivered wrongly?”
- ask participants to brainstorm silently for a couple of minutes and to write down what are in their view the two or three most serious and avoidable HIs (limit to one HI per participant if there are more than 10 participants)
- ask participants to communicate in turn the first HI they have noted and write each in the “HIs” column
- each participant communicates a single HI per round, and there are as many rounds as responses
- no critiques should be made and comments should be limited
- ensure that HIs are defined as precisely as possible and that participants agree on their meaning
- continue in the same manner until all HIs are noted down.

<sup>h)</sup> Each participant writes his name on a piece of paper and all the pieces of paper are put into a basket and shuffled. Everybody randomly picks one and tries to find the person whose name is written on the piece of paper through talking to the other participants.



### 5. Identify contributing problems (~15 minutes and ~5 minutes for silent brainstorming)

- ask participants to brainstorm silently and write on their sheet of paper the problems that contributed to the first HI
- ask participants to communicate in turn their results and write these down in the “contributing factors” column
- proceed in the same way to determine the contributing problems for all HIs.

### 6. Identify problems that contribute to several HIs (~ 10 minutes)

- explain that one health-care mistake can lead to several HIs
- ask participants to identify problems that contribute to several HIs and write these down in the “problems contributing to several HIs” column.

### 7. Score problems that contribute to several HIs (~15 minutes and ~10 minutes for silent brainstorming)

- ask participants to score every common contributing problem on their sheet of paper
- scores range from 1 to the total number of common contributing problems: the most important contributing problem receives the highest score
- scoring criteria: frequency and seriousness of a contributing problem, expected staff acceptance of improvement measures, and the feasibility of improvement measures, particularly cost (most important criterion)
- ask participants to communicate in turns their score for each contributing problem and write these down in the “score” column (use one column per participant).

### 8. Agree on the most important contributing problems (~10 minutes)

- count the score attributed to each contributing problem
- ask participants to discuss the final ranking so that everybody agrees
- in cases of strong disagreement, allow the order of two contributing problems to be changed, or conduct a vote
- write down the final ranking in the “final ranking” column, beginning with the highest-scored contributing problem.

The facilitator then copies the following tables on the whiteboard:

Solutions	Scoring of solutions	Final ranking	Roles, responsibilities and time plan

Second page of the whiteboard:

General actions

### 9. Identify solutions (~15 minutes and ~5 minutes for silent brainstorming)

- write the most frequent contributing problem on the whiteboard
- ask participants to brainstorm silently and write a solution to this contributing problem on their sheet of paper
- ask participants to communicate in turn their results and write these down in the “solutions” column
- proceed in the same way for the 5 most important contributing problems.

### 10. Score solutions (~15 minutes and ~5 minutes for silent brainstorming)

- ask participants to score every proposed solution on their sheet of paper
- scores range from 1 to the total number of solutions: the best solution receives the highest score
- Scoring criteria: expected staff acceptance of improvement measures, and the feasibility of improvement measures, particularly cost (most important criterion)
- ask participants to communicate in turn their score for each solution and write these down in the “score” column (use one column per participant).

### 11. Agree on the most important solutions (~10 minutes)

- count the score attributed to each solution
- ask participants to discuss the final ranking so that everybody agrees
- in cases of strong disagreement, allow the order of two solutions to be changed, or conduct a vote
- write down the final ranking in the “final ranking” column, beginning with the highest-scored solution.

## 12. Establish roles, responsibilities and time plan (~10 minutes and ~5 minutes for silent brainstorming)

- ask participants to note on their sheet of paper:
  - who carries out the first solution, who is involved, and who is responsible
  - by when the solution should be implemented
  - how often the situation should be re-assessed
- ask participants to communicate their results in turn
- facilitate a discussion so that everybody agrees
- write the roles, responsibilities and time plan for implementing the first solution in the “roles, responsibilities and time plan” column
- proceed in the same manner for the five highest-ranked solutions.

## 13. Select general actions to improve patient safety (~15 minutes)

- explain that in addition to these facility-specific actions, there are more general activities for tackling HIs
- facilitate discussion of the following questions and note the agreed actions in the “general actions” column:
  1. How can the content of the action plan be communicated to staff?
  2. How can facility managers sensitize all staff about patient safety?
  3. How can staff be encouraged to acquire new knowledge, change work practices and share safety lessons?
  4. Could a patient safety committee be established and made responsible for monitoring and improving patient safety?
  5. How can staff be encouraged to identify, report and prevent HIs?
  6. How can medical records and reporting/surveillance systems – if these are not available to date – be introduced?
  7. How can patients be best involved in improving patient safety?
  8. How can the culture of blame be combated and awareness raised of the shared responsibility for ensuring patient safety?

## 14. Closure of the meeting (~2 minutes)

- thank all participants
- if possible, briefly present the meeting results to facility stakeholders, or, if not, 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>
- provide your contact details for further questions/comments
- take the flipchart pages with you or copy the results from the whiteboard on a sheet of paper.

## Examples to clarify the concept of HIs

1. Exploratory laparotomy mesenteric venous occlusion and intestinal gangrene was diagnosed in a 39 year-old man who was admitted with acute abdominal pain. Four days after resection and anastomosis was conducted, he developed a postoperative wound infection and became feverish. Antibiotics and fluid through CV line were started and the patient subsequently developed a left pneumothorax after CVP insertion. A chest X-ray showed left pleural effusion.
2. A 39 year-old woman was admitted with breathing difficulties, swollen limbs and general weakness. O/E very pale, tachycardic and tachypneic, Hb 5.6. She was admitted for transfusion (whole blood), haematinics and penicillin. There was no indication that the woman received blood or oxygen supplementation and she died 3 days later while awaiting transfusion.
3. A 70 year-old female patient with known co-morbidities, such as renal impairment diabetes, hypertension and congestive cardiac failure, was on full dose digoxin. She was presented to the emergency department with dizziness and shortness of breath. She was then admitted to the CCU and found to have hyperkalaemia and a digoxin level of 3.6. She developed confusion and irritability due to hyperkalaemia and digoxin toxicity.
4. A 23 year-old woman with severe headache and vomiting was received by the emergency room, treated with antiemetics and analgesia and then discharged. The woman returned a few hours later with a deteriorated level of consciousness and was found to be suffering from a brain haemorrhage.

## 6.3 Questionnaires for conducting direct observation and related interviews<sup>1)</sup>

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<sup>1)</sup> The following questionnaires are available at <http://www.who.int/patientsafety/research>



## Questionnaire 1: Observation of equipment and supplies

### Instructions

- Assess the equipment and supplies available at the facility based on questionnaire 1 and record the results therein
- The observer may talk with health-care staff but should complete the form solely based on observation and not on information provided by staff
- The stock of sterilized reusable or sterile single use injection equipment must be observed in each participating clinical area
- Box 1 is only completed for health-care establishments that have on-site sterilization facilities for injection equipment
- The on-site sterilization facility and waste disposal only need to be observed by one observer
- If the health-care facility is equipped with a steam sterilizer, boil water in it to check for steam leaks. In resource-poor settings, health-care workers may not have the means to purchase fuel for the sterilizer. This need only be assessed by one observer.

### Box 1 – Only for facilities with on-site sterilization facilities for injection equipment

Reuse of syringes or needles in this facility, either for immunisation or curative injections	1- yes	2- no	3 – cannot be assessed	
If yes, sterilisation method available (please circle all that apply)	1- steam sterilizer	2- boiling	3- both	4- other (specify)
Number of complete sterilizable injection equipment kits	Number of kit A.....	Number of kit B.....		
<b>Please complete the rest of this table if a pressure sterilizer is used in this facility</b>				
Number of routinely used steam-pressure sterilizers	Single rack .....	Double rack .....	Triple rack .....	
Absence of leaks in routinely used sterilizers	1- yes	2- no	3 – cannot be assessed	
Number of spare sterilizer seals available	Number of seals	.....	3 – cannot be assessed	
Number of spare sterilizer safety valves available	Number of valves	.....	3 – cannot be assessed	
Number of spare sterilizer pressure valves available	Number of valves	.....	3 – cannot be assessed	
Presence of a functioning heater for steam sterilizers in the facility	1- yes	2- no	3 – cannot be assessed	
Presence of a complete updated register for logging TST spot indicators	1- yes	2- no	3 – cannot be assessed	

**Box 2 – Stock (for all sites)**

Needle and syringes <b>pre-packed together</b>	
Size (please indicate)	Number

Total number of <b>SYRINGES</b> available				Total number of <b>NEEDLES</b> available			
Size/type <sup>1</sup>	Sterilizable <sup>2</sup>	Auto Disposable <sup>3,4</sup>	Disposable <sup>2</sup>	Size/type <sup>1</sup>	Sterilizable <sup>2</sup>	Auto Disposable <sup>3,4</sup>	Disposable <sup>2</sup>
1ml				25-27G			
5 ml				21-23G			
10 ml				18G			
Other				Other			

**Box 3 – preparation and disposal (for all sites)**

Presence of swabs for skin preparation that are dirty, bloodstained or kept wet	1- yes	2- no	Cannot be assessed			
Adequate facilities for hand wash/hygiene (alcohol gel, sink with running water, soap)	1- yes	2- no	Cannot be assessed			
Number of puncture-proof safety disposal bins (safety boxes) available	0	1-4	5-10	10-20	>20	Cannot be assessed
Presence of safety boxes where injections are given	1- yes	2- no	3- no boxes			
Presence of overflowing, open or pierced safety boxes	1- yes	2- no	3- no boxes			
Presence of full safety boxes awaiting disposal/incineration	Number.....					Cannot be assessed
Presence of full safety boxes awaiting disposal/incineration stored in an unsupervised fashion	Number.....					Cannot be assessed
Sharps in plastic bottles or open containers exposing staff to needle stick injuries	1- yes	2- no	Cannot be assessed			
Evidence of used sharps around the health-care facility or disposal site	1- yes	2- no	Cannot be assessed			
Type of waste disposal site used for the majority of sharps (circle only one)	1- open burning on ground 2- open burning in hole or enclosure 3- incinerator 4- burial				5- dumping in pit-latrine or other secure pit 6- dumping in unsecured area 7- transport for off-site treatment	

<sup>1</sup>Might need adjustment if different types of syringes are distributed.

<sup>2</sup>Number of syringes or needles manufactured for re-sterilization.

<sup>3</sup>Number of disposable syringes and needles in sealed packets or fitted with 2 caps.

<sup>4</sup>Number of AD syringes and needles in sealed packets or fitted with 2 caps.

## Questionnaire 2: Observation of injection practices

### Instructions

- Assess the injections given based on questionnaire 2 and record the data therein
- Observe a minimum of 25 injections per site and at least 5 injections in each department, given by one or more care-givers (an observer may need to return several times to a department to observe a minimum of 5 injections)
- Use one column for each observed injection that is observed in the same department
- Investigators should tactfully interrupt the care-giver if they are about to observe a practice that could expose an injection recipient to substantial risks (e.g. re-use of injection equipment without sterilization). The dangerous procedure that would have occurred should be recorded on the data collection form as if it had actually happened.

Type of injection type (please circle): <b>1. inpatient injection 2. Outpatient consultation</b> <b>3. Vaccination clinic</b>	Injection 1	Injection 2	Injection 3	Injection 4	Injection 5
Type of syringe used: <b>1-auto-disposable, 2- disposable, 3- sterilizable</b>					
Type of injection: <b>1- IV, 2- IV via cannula in situ, 3- IM therapeutic,</b> <b>4- IM vaccine, 5- Subcutaneous</b>					
<b>Y=yes, N=no, N/A = not applicable</b>					
Hand-washing/hand rubbing prior to preparation according to recommendations					
Preparation on a clean tray where contamination with blood or body fluids is unlikely <sup>5</sup>					
Did the patient bring his/her own needle and syringe for this injection?					
Was the NEEDLE for this injection taken from a new and unbroken sterile packet or sterilized using a sterile technique? <sup>6</sup>					
Was the SYRINGE for this injection taken from a new unbroken sterile packet, or sterilized using a sterile technique? <sup>6</sup>					
Removal of entire needle from vaccination/medication vial between injections					
If glass vial is used: use of a clean barrier (gauze or similar) to protect fingers when vial opened					
For each reconstitution, use of a sterile needle and syringe (from new sterile pack or taken from sterilizer using sterile technique)					
Reconstitution of vaccines/medication with correct amount of suitable dilutant from sterile single vial					
For heat-sensitive vaccines: vial kept at temperature between 2C and 8C during period of use					
Hand-washing/hand-rubbing prior to injection according to recommendations					
Adequate skin preparation/cleaning prior to injection					
IV cannula accesses for injection using aseptic technique					
Two-handed re-capping of needle after injection (this is a non-desirable technique)					
Single use and AD: collection of needle in a puncture proof container immediately after use					
Sterilizable equipment: flushing, disassembling and dropping into a bowl with enough water to fully cover immediately after use					

<sup>5</sup>Not an area also used for procedures that may lead to blood contamination (e.g. blood sampling, wound dressing etc.).

<sup>6</sup> If reuse of injection equipment is about to occur without sterilization, intervene to interrupt the procedure as tactfully as possible and a "N" should be marked on the checklist.

## Questionnaire 3a: Interviews with injection providers

### Instructions

- Interview each injection provider based on questionnaire 3a and record the data therein (use one form per injection provider)
- Complete the questionnaire based on answers to questions and not based on structured observations.

How many injections are given each week in your department?	..... immunisations/week		.....other injections/week			
<b>Circle only one answer</b>						
Do patients provide their own injection equipment for immunisations?	1-always	2-sometimes	3-never	4- don't know		
Do patients provide their own injection equipment for therapeutic injections?	1-always	2-sometimes	3-never	4- don't know		
Are new disposable or AD syringes and needles available for purchase in this community?	1-yes		2-no		3- don't know	
Do you use needle removers or needle cutters before disposing of injection equipment?	1-yes		2-no		3- don't know	
How many accidental needle sticks have you had in the past 12 months?	..... nr of needle sticks					
<i>For sterilizable equipment only</i>						
When was the sterilizer seal/gasket last changed?	<1month	<6month	<1 year	>1year	5-don't know	6- N/A
When was the sterilizer safety valve last changed?	<1month	<6month	<1 year	>1year	5-don't know	6- N/A
When was the sterilizer pressure valve last changed?	<1month	<6month	<1 year	>1year	5-don't know	6- N/A
Are you supplied with sufficient kerosene or other power source, or sufficient funds to purchase this from your health service?	1-yes		2-no		3- don't know	
Do you re-sharpen needles after a certain number of injections or when blunt?	1-yes		2-no		3- don't know	

## Questionnaire 3b: Interviews with department supervisors

### Instructions

- Interview the supervisor of each clinical area where injections have been observed based on questionnaire 3b and record the data therein (use one form per department)
- Complete the questionnaire based on the supervisor's answers and not based on structured observation.

Do you have a copy of the injection safety policy recommendations issued by your health service?	1=yes	2=no	3=don't know	4= n/a	
Do you have a copy of the sharps and health-care waste disposal policy issued by your health service?	1=yes	2=no	3=don't know	4= n/a	
<i>For sterilizable equipment only</i>					
In total, for how long have you been without kerosene or other fuel/power for the sterilizer in the last year?	never	<1 month	<3 months	3=months	4=don't know
<i>For disposable or AD equipment</i>					
For how long have you been without new disposable or AD syringes and needles in the last year?	never	<1 month	<3 months	3=months	4=don't know
For how long have you been without puncture-proof sharps containers in the last year?	never	<1 month	<3 months	3=months	4=don't know
Are stocks of vaccines always delivered with matching quantities of injection equipment?	1=yes	2=no	3=don't know	4= no vaccinations here	
Are stocks of vaccines always delivered with matching quantities of puncture-proof sharps containers?	1=yes	2=no	3=don't know	4= no vaccinations here	



## Results tables

### Instructions

- Once questionnaires 1, 2, 3a and 3b are completed, the team of investigators gathers to complete the results tables 1, 2, 3 and 4 below
- The first column indicates in which questionnaire the data for each item can be found
- Use one copy of each results table per department.

### Results table 1 – *risks to the recipient*

Data source	Item	Compliance /total	Description of non-compliance
Questionnaire 1	Presence of sufficient single use injection equipment		
Questionnaire 2	Presence of dirty or bloodstained swabs for skin preparation		
Questionnaire 2	Preparation of injections in clean dedicated area		
Questionnaire 2	Breaking vials with clean protective barrier		
Questionnaire 2	Reconstituting with sterile needle and syringe		
Questionnaire 2	Reconstituting with recommended solution (vaccine)		
Questionnaire 2	Administration with sterile needle and syringe (vaccine)		
Questionnaire 2	Reconstituting with recommended solution (curative)		
Questionnaire 2	Administration with sterile needle and syringe (curative)		
Questionnaire 2	Removal of syringe from multi dose vials between doses		
Questionnaire 2	Temperature-sensitive product kept cool during preparation		
Questionnaire 3b	No shortages of disposable injection equipment		
Questionnaire 3b	Supply of vaccines with matching quantities of sterile/AD syringes		

### Results table 2 – *risks to the provider*

Data source	Item	Compliance /total	Details of non compliance
Questionnaire 1	Presence of sufficient sharps containers		
Questionnaire 1	Absence of open, overflowing or pierced sharps containers		
Questionnaire 1	Absence of sharps in open containers		
Questionnaire 2	Absence of 2-handed recapping		
Questionnaire 2	Immediate collection of sharps in sharps boxes		
Questionnaire 3a	Reported absence of needle stick injuries in the past 12 months		
Questionnaire 3b	No shortage of sharps containers		

## Results tables

**Results table 3 – *risks to the community***

Data source	Item	Compliance /total	Details of non compliance
Questionnaire 1	Absence of sharps around the health-care facility		
Questionnaire 1	Absence of full sharps containers stored in unsupervised area		
Questionnaire 1	Waste disposal in adequate incinerator or transported off site		
Questionnaire 3b	Presence of a health-care waste management policy		

**Results table 4 – *information elements relating to reusable injection equipment and sterilisation***

Data source	Item	Compliance /total	Details of non compliance
Questionnaire 1	Absence of leaks in all currently used sterilizers		
Questionnaire 1	Presence of 1 set of sterilizer spare parts		
Questionnaire 1	Presence of an updated TST spot register		
Questionnaire 1	Presence of 2 days' supply of sterilized equipment		

# Appendix 1

## An overview of methods to estimate the level of harm from health care

A number of methods for studying patient harm have been developed over time and been adapted to different contexts. Each of them has particular strengths and advantages, as well as some weaknesses and limitations. The choice of the method must be based on the question one seeks to answer, taking into account the particular characteristics of each method as well as local data availability and expertise.

### Understanding the different methods for studying harm

Failing to understand that different methods have different purposes has led to considerable confusion and much fruitless debate over the years. Methods vary in several respects including in the extent to which they rely on different data such as medical records, observations, claims data, voluntary reports, mortality and morbidity reports, external audits, questionnaire based studies, autopsy data, etc. Some methods focus on single cases or small numbers of cases with particular characteristics, such as claims, while others attempt to randomly sample a defined population. Some are oriented towards detecting incidence of errors and adverse events, while others address their causes and contributory factors. Thomas and Petersen suggest that the methods can be placed along a continuum with active clinical surveillance of specific types of adverse event (e.g. surgical complications) being the ideal method for assessing incidence, and methods such as claims analysis and morbidity and mortality meetings being more oriented towards causes.

In 2003, the WHO World Alliance for Patient Safety (now WHO Patient Safety) commissioned Dr Philippe Michel to carry out an overview of available methods of estimating harm: “*Strengths and weaknesses of available methods for assessing the nature and scale of harm caused by the health care system: literature review*”.<sup>13</sup> This document specifically addressed the question of assessment methods used in developing and transitional countries and provided an extensive review of the strengths and weakness of each research methodology. Although the review found evidence of a wide range of research methodologies, the body of literature in this area was limited. Building on the findings of this review, a new literature search was performed to identify additional research conducted in developing and transitional countries and published after 2003. A brief summary of their strengths and advantages can be found below. For the complete report of the 2003 literature review go to [http://www.who.int/patientsafety/activities/system/en/rapid\\_assessment\\_methods.pdf](http://www.who.int/patientsafety/activities/system/en/rapid_assessment_methods.pdf).

### A summary of the strengths and weaknesses of the different methodologies

The summary below is a result of the literature review mentioned above and of the work done by Thomas, Petersen<sup>15</sup> and Vincent<sup>16</sup>. The available methods for assessing the nature and scale of harm caused by health-care systems have widely differing purposes, strengths and limitations, and should be considered as complementing each other by providing different levels of qualitative and quantitative information.

Selection of a particular study method must take into consideration the environment in which it is being carried out in terms of resources and level of data available, as well as the purpose of the study. The suitability of methods, their validity and reliability may vary widely, depending on their objectives and on the context. An understanding of the reliability and validity of the data obtained is also crucial in order to use the data to influence policy and create change.

This review has limitations. The available literature varies in quality and quantity and there are still relatively few studies of methodologies for studying harm from health care originating from developing and transitional countries. The majority studies originate from tertiary referral centres where larger amounts of routine data are available. There is still a gap in the body of research evaluating methods for studying harm in very data-poor environments.

## Appendix 1

Method	Description	Advantages	Disadvantages
<b>Studies of Mortality and Morbidity reports</b>	The use of morbidity and mortality (M&M) meetings in determining the scale and causes of harm is dependent on the selection of cases, varying definitions of harmful incidents (or adverse events) and the style of analysis of cases (root cause or ad hoc).	This method is familiar to health care providers. Can suggest contributory factors.	The lack of a structured method of analysis in most M&M meetings brings the validity and reliability of the data into question. The practice of M&M meetings also vary between specialties, facilities and countries making it unsuitable for large scale studies of harm from health care. This method is susceptible to hindsight bias and reporting bias. It is infrequently used.
<b>Studies of external audits and confidential enquiries</b>	This type of data is reliant on a large central organisation for data collation and analysis as well as widespread local engagement to ensure the reporting of data.	Reliable data.	High costs and may limit its usefulness in resource-poor environments.
<b>Studies of claims and complaints</b>	The data from claims and complaints, where available, can yield information on the causes of harm.	Provides multiple perspectives (patients, health-care providers, lawyers).	This method is not suitable for estimating the scale of harm. The information is often several years out of date due to the time lag involved in bringing cases to court and the cost of analysing large numbers of claims is high. This methodology is not suited for the majority of data-poor areas and its use in developed countries has largely been superseded by other methods. This method is susceptible to hindsight bias and reporting bias.
<b>Studies of incident reporting data</b>	Although the number of reports in this area is still low, it is likely to increase over the next few years as more data collected is analysed and the implications understood.	Provides multiple perspectives over time. Can be a part of routine operations.	Effectiveness of incident reporting systems in capturing the extent of harm is limited and it is well recognised that underreporting is widespread and the reliability of the data is moderate. <sup>17,18</sup> The use of the data collected via this method is key and should be an important consideration before embarking on the cost of initiating such systems in resource-poor regions, as it has proved a challenge to the effectiveness of reporting systems in the developed world. <sup>19</sup> This method is susceptible to hindsight bias and reporting bias.
<b>Studies-based on retrospective record review</b>	The suitability of retrospective record review to provide large scale epidemiological studies depends largely on the organisation of and information contained in the medical record. Hence the suitability of this methodology will vary between regions and countries.	Uses readily available data and is a commonly used method.	The methodology is less useful in smaller, poorly resourced health facilities where both the organisation of and information contained in the medical notes is limited.
<b>Studies of information technology, electronic medical records and routine administrative data</b>	Studies of the use of information technology, electronic medical records or routine administrative data require a high level of data availability and investment.	Inexpensive after initial investment. Monitors in real time and integrates multiple data sources.	Susceptible to programming and/or data entry errors. Expensive to implement.

Method	Description	Advantages	Disadvantages
<b>Studies of direct observation</b>	The methodology has the potential to detect both the level and causes of harm in data poor environments as it is not dependent on previously collected information. Instead it relies on adequately trained skilled observers and can be deployed in a range of settings. In addition to the cost, by international standards, of the time of skilled observers in resource poor regions is likely to be relatively low.	Potentially accurate and precise. Provides data otherwise unavailable. Detects more active errors than other methods.	Time consuming and expensive. Difficult to train reliable observers. Potential concerns about confidentiality and possibility of being overwhelmed with the information.
<b>Interview or questionnaire based-studies</b>	This combination of data sources is potentially very useful in environments where there is scarcity of information in the medical notes. It has already proved its usefulness in health-care facilities of developed countries. <sup>12</sup>	Can be used in developing countries.	Time consuming for health personnel. Potential concerns about confidentiality.
<b>Studies of autopsy data</b>	The use of autopsy information for research purposes has also been used in some studies in developed countries. <sup>20,21,22,23</sup> The facilities for autopsy, however, are mainly concentrated in larger cities as many rural and mission hospitals do not often have the facilities for autopsy or a pathologist available. Studies of autopsy findings may explore the concordance between clinical and post-mortem diagnosis <sup>24,25</sup> and explore the causes of death and the occurrence of adverse events following health-care. <sup>26</sup>	Can suggest contributory factors. Familiar to health-care provider. Discordance between pre and post-morbid diagnosis is not necessarily an indication of misdiagnosis or medical error but may be a reflection of atypical symptoms or limited diagnostic testing facilities.	The availability of data is variable and its reliability depend on the underlying autopsy rate, facilities available for histopathological testing, the experience of the pathologist and availability of final reports. Methodologies based on autopsy findings are not suitable for large scale studies.

## Appendix 2

# List of selected patient safety research articles

These articles have been retrieved through:

The main Medline search strategy (search strategy No. 1) was as follows:

(Medical errors [title] OR Medication errors[title] OR Diagnostic errors[title] OR Iatrogenic disease[title] OR Malpractice[title] OR Medica\* error\* [title] OR Sentinel event\*[title] OR Adverse event\*[title] OR Human error\* [title] OR Sentinel event\*[title])

AND

(Adverse drug reaction reporting systems OR Sentinel surveillance OR (Retrospective studies AND Record\*) OR (Prospective studies AND Observation\* [title]) OR Data collection OR Record review [title] OR Risk management OR Safety management OR Medical audit OR Audit OR Mandatory reporting OR Autopsy OR Reporting system [title] OR Morbidity mortality conference OR Mortality morbidity committee \*[title])

The results from this search were only considered further if the studies originated from developing/transitional countries or data poor environments

In addition, a broader search was performed for the developing and transitional countries (search strategy No. 2):

(Adverse drug reaction OR reporting system OR risk management OR Safety management OR Medical audit) AND (Developing and transitional countries OR Africa OR India OR Brazil)

Below is a list of all included studies and papers organised into the methodology employed.

### *Review of medical records*

#### **- Selective audits**

K. A. Al Khaja, T. M. Al Ansari, A. H. Damanhori, and R. P. Sequeira. Evaluation of drug utilization and prescribing errors in infants: a primary care prescription-based study. *Health Policy* 81 (2-3):350-357, 2007.

J. S. Anwari, A. A. Butt, and M. A. Al-Dar. Obstetric admissions to the intensive care unit. *Saudi.Med J* 25 (10):1394-1399, 2004.

S. Danchaivijitr, S. Assanasen, A. Apisarntharak, T. Judaeng, and V. Pumsuwan. Effect of an education program on the prevention of ventilator-associated pneumonia: A multicenter study. *J Med Assoc.Thai.* 88 Suppl 10:S36-S41, 2005.

E. Daniel, T. J. Ffytche, P. S. Sundar Rao, J. H. Kempen, M. ener-West, and P. Courtright. Incidence of ocular morbidity among multibacillary leprosy patients during a 2 year course of multidrug therapy. *Br.J Ophthalmol.* 90 (5):568-573, 2006.

A. U. Ekere, B. E. Yellowe, and S. Umune. Mortality patterns in the accident and emergency department of an urban hospital in Nigeria. *Niger.J Clin.Pract.* 8 (9):14-18, 2005.

T. Ersumo, Y. Meskel, and B. Kotisso. Perforated peptic ulcer in Tikur Anbessa Hospital: a review of 74 cases. *Ethiop.Med J* 43 (1):9-13, 2005.

- M. N. Gandhi, T. Welz, and C. Ronsmans. Severe acute maternal morbidity in rural South Africa. *Int J Gynaecol.Obstet.* 87 (2):180-187, 2004.
- D. Hailu and B. Worku. Birth trauma among live born term neonates at a referral hospital in Addis Ababa, Ethiopia. *Ethiop.Med J* 44 (3):231-236, 2006.
- I. F. Hesse, A. Mensah, D. K. Asante, M. Lartey, and A. Neequaye. Adult tetanus in Accra, why the high mortality? An audit of clinical management of tetanus. *West Afr.J Med* 24 (2):157-161, 2005.
- F. Jaimes, Rosa G. De La, E. Gomez, P. Munera, J. Ramirez, and S. Castrillon. Incidence and risk factors for ventilator-associated pneumonia in a developing country: where is the difference? *Respir.Med* 101 (4):762-767, 2007.
- S. Mousavi, M. Nobahar, A. A. Vafaei, M. Malek, M. Babaei, F. Malek, and S. Yaghmaie. Complications of upper gastrointestinal endoscopy in unsedated patients. *Indian J Gastroenterol.* 23 (5):193, 2004.
- K. A. Mteta, J. Mbwambo, and M. Mvungi. Iatrogenic ureteric and bladder injuries in obstetric and gynaecologic surgeries. *East Afr.Med J* 83 (2):79-85, 2006.
- A. M. Nwofor and C. N. Ekwunife. Tube thoracostomy in the management of pleural fluid collections. *Niger.J Clin.Pract.* 9 (1):77-80, 2006.
- A. C. Oliveira and D. V. Carvalho. Postdischarge surveillance: the impact on surgical site infection incidence in a Brazilian university hospital. *Am.J Infect.Control* 32 (6):358-361, 2004.
- C. A. Padua, C. C. Cesar, P. F. Bonolo, F. A. Acurcio, and M. D. Guimaraes. High incidence of adverse reactions to initial antiretroviral therapy in Brazil. *Braz.J Med Biol.Res.* 39 (4):495-505, 2006.
- M. C. Passarelli, W. Jacob-Filho, and A. Figueras. Adverse drug reactions in an elderly hospitalised population: inappropriate prescription is a leading cause. *Drugs Aging* 22 (9):767-777, 2005.
- H. Trotman and M. Barton. The impact of the establishment of a neonatal intensive care unit on the outcome of very low birthweight infants at the University Hospital of the West Indies. *West Indian Med J* 54 (5):297-301, 2005.
- O. E. Yousif, A. M. Ahmed, M. E. Abdalla, and M. A. Abdelgadir. Deficiencies in medical prescriptions in a Sudanese hospital. *East Mediterr.Health J* 12 (6):915-918, 2006.
- AE based reviews**
- L. Herrera-Kiengelher, G. Chi-Lem, R. Baez-Saldana, L. Torre-Bouscoulet, J. Regalado-Pineda, M. Lopez-Cervantes, and R. Perez-Padilla. Frequency and correlates of adverse events in a respiratory diseases hospital in Mexico city. *Chest* 128 (6):3900-3905, 2005.
- T. Matsaseng and J. Moodley. Adverse events in gynaecology at King Edward VIII Hospital, Durban, South Africa. *J Obstet. Gynaecol.* 25 (7):676-680, 2005.
- R. ud-Gallotti, H. M. Dutilh Novaes, M. C. Lorenzi, J. Eluf-Neto, Okamura M. Namie, and Velasco Tadeu, I. Adverse events and death in stroke patients admitted to the emergency department of a tertiary university hospital. *Eur.J Emerg.Med* 12 (2):63-71, 2005.

## Appendix 2

### *Interview based studies*

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## Appendix 3<sup>1)</sup>

# Terminology

**Patient safety:** the reduction of risk of unnecessary harm associated with health-care to an acceptable minimum.

**Patient safety incident:** an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.

**Harmful incident (HI) (or adverse event):** an incident which resulted in harm to a patient. Operationally, it has been defined here as an unintended injury which results in temporary or permanent disability, a prolonged hospitalization or financial loss, and is caused by health-care management rather than the disease process.

**Near miss:** An incident which did not reach and therefore affect the patient.

**Contributing factor:** a circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.

**Incidence:** The number of admissions with at least one harmful incident divided by the total number of admissions studied. An admission is associated with an HI regardless of whether the HI occurred prior to or during the admission.

**Index admission:** The patient admission under study.

**Inpatient:** Patient admitted to a hospital for treatment that requires at least one overnight stay.

**Prevalence:** The number of patients presenting at least one harmful incident on the day of study, divided by the total number of patients in the hospital on the day of study.

**Preventable HI:** Harmful incident that would not have occurred if the patient had received ordinary standards of care in the particular set of circumstances

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<sup>1)</sup> Definitions are based on The Conceptual Framework for the International Classification for Patient Safety, Version 1.1. WHO, 2009. The document is available at <http://www.who.int/patientsafety>

# Appendix 4

## Further information

### WHO Patient Safety Programme website

<http://www.who.int/patientsafety/en/>

### Revised injection safety assessment tool (Tool C – revised)

Tool for the Assessment of Injection Safety and the Safety of Phlebotomy, Lancet Procedures, Intravenous Injections and Infusions. Available at [http://www.who.int/injection\\_safety/Injection\\_safety\\_final-web.pdf](http://www.who.int/injection_safety/Injection_safety_final-web.pdf)

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### Direct observation mixed methods approach

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### Malpractice claims analysis

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## Appendix 4

### Randomized clinical trial

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### Randomized clinical trial

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### Cost analysis

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### Cost Identification Analysis

Khan MM, Celik Y. Cost of nosocomial infection in Turkey: an estimate based on the university hospital data. *Health Services Management Research*, 2001, 14:49-54.

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