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Patient Safety

A World Alliance for Safer Health Care

RESEARCH

Better knowledge for safer care

Assessing and tackling patient harm

A methodological guide for data-poor hospitals

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Acknowledgements

EXTERNAL LEAD
Dr Philippe Michel

RESEARCH TEAM
Dr Sisse Olsen, Dr Florence Saillour-Glénisson, Dr Ramón Limón, Dr Carlos Aibar, Dr Jesús Aranaz

NATIONAL TEAMS IN THE PARTICIPATING COUNTRIES

Jordan
National Coordinator: Dr Safa El Qoos
Investigators: Dr Badeah Shamoun, Dr Abbas Mansour, Dr Ahmad Kloub, Dr Zaidoon Ghnah

Kenya
National coordinator: Prof William Macharia
Investigators: Dr John M Tole, Dr James Jowi, Dr Abdulkarim Abdallah, Dr Joshua Mwangi

Peru
National coordinator: Dr Richard Inga
Investigators Dr Antero Razuri, Dr Vitaliano Mosquera, Dr Jorge Mezarina, Dr Williams Carrascal

Thailand
National coordinator: Dr Santawat Asavaroengchai
Team supervision: Dr Anuwat Supachutikul
Investigators: Dr Vipada Chaowagul, Dr Surawute Leelahakorn, Gr Catt. Dr Anantchai Dejamornthan

Tunisia
National coordinator: Prof Mondher Letaïef
Investigators: Dr Med Adel ben Mahmoud, Dr Med Salah Ben Ammar, Dr Mhammed Bahri, Dr Sana Elmhamdi, Dr Jihene Maatoug, Dr Med Said Berraihane, Dr Mehdi Gaha

EXTERNAL REVIEWERS
Dr Santawat Asavaroengchai, Prof Ross Baker, Prof David Bates, Prof Susan Dovey, Dr Rhona Flin, Ms Christine Goeschel, Prof Niek Klazinga, Prof Mondher Letaief, Prof Richard Lilford, Dr Ramón Limón, Prof William Macharia, Prof William Runciman, Dr Anuwat Supachutikul, Dr Claudia Travassos, Prof Charles Vincent, Dr William Weeks

EDITORIAL PRODUCTION
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.[1] 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.[2, 3]

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.[4] 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.

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.[5,6,7,8,9,10,11,12] This wave of research was initiated by the publication of the Harvard Medical Practice Study in 1991[5,6] 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.[13] 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 asses 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.