World Health Organization

Patient Safety Research

A guide for developing training programmes

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Foreword

Unsafe care is a global problem everywhere. WHO Member States, specialized agencies and institutions are working hard to develop solutions that can tackle the most pressing safety concerns. Much has been accomplished, but much more still needs to be done. Innovations and safety practices need to be developed and adopted by health-care staff and institutions. In many cases, they also need to be customized to maintain their efficacy. New interventions are also needed, and the benefits of all these efforts must be evaluated in order to assist decision-makers in making the right choices that lead to improved patient safety.

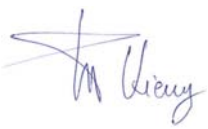
So, safer care needs systematic approaches and methodologies that lead to better understanding of the nature and magnitude of safety problems and of their contributing factors.

In 2008 WHO Patient Safety identified a set of core competencies needed for conducting patient safety research as a basis for improvement. These represent a recognition of the need to strengthen the health task force internationally in order to facilitate systematic improvements in patient safety in all parts of the world. The essence of these competencies is the science of patient safety, the methodologies for epidemiology and health services research and principles for knowledge translation.

How to effectively develop these competencies through tailored training programmes is the basis of this guide. It intends to guide educators in addressing the design and general content areas of training curricula for postgraduate researchers and practitioners aiming to apply those concepts in the area of patient safety.

By providing examples of learning objectives and the necessary steps for course development, educators can choose the specific competencies that need to be taught and the methods that best fit particular cases, based on the learner's profile, goals and resources.

I wholeheartedly hope that this guide will help to build the necessary capacity for improving patient safety worldwide, especially in those countries where it is most needed.



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1. Introduction

1.1 What is this guide?

This guide is a comprehensive document that provides guidance to educators for the development of training programmes in this important, but less well known, field of research. This guide addresses research for change or research for improvement – a form of translational and applied research that seeks to improve patient safety based on sound methodology.

It is based on the principle that effective improvement requires sound local evidence about the nature and extent of existing problems and risks and about the possible solutions, including the systematic analysis of how specific interventions fit and fare within the local context. Therefore, instead of prescribing a single, comprehensive curriculum, this guide seeks to build global capacity for patient safety and translational research by facilitating the development of many locally-specific curricula on these topics.

This guide brings current concepts on curriculum building, training and education to the field of patient safety research. It is designed to offer practical guidance for local educators to develop their own training programmes – adapted to their context-specific learning objectives. A key feature of this guide is the outline of the core skill and knowledge-based competencies that professionals at various levels of expertise may wish to acquire to conduct effective patient safety research and improvement efforts.

Based on extensive consultation with key international experts in education and training, this first edition is offered to the wider community of educators and trainers throughout the world as an illustration of the possible ways to build training programmes for patient safety research and improvement, with an aim to promote the expansion of training programmes in these areas worldwide. WHO welcomes further feedback from users from different parts of the world.

1.2 Why is this guide needed?

Increasing evidence suggests that an unacceptable number of patients are harmed every day in health care. Patient safety is a global public health problem affecting countries at all levels of development.[1] More knowledge and better use of that knowledge are essential for improving patient safety.[2] However, patient safety research is still in its infancy. New knowledge is required to measure and understand the risks and causes of harm and to develop solutions that prevent, reduce or mitigate the effects of harm. In many clinical settings worldwide, little is known about the epidemiology of patient safety problems. Although there have been many attempts to introduce solutions that improve safety, few of these interventions have been subjected to evaluation.[3,4] New and further research is thus imperative to reduce harm and improve the safety of care.

Despite significant progress in some areas of patient safety, infrastructure and funding for research are sparse in relation to the magnitude of the problem.[5,6] Consequently, established researchers in other areas of clinical research are less aware of the knowledge gaps in this field, and the skills needed to meet them. This hampers the development of the multidisciplinary research teams that are required to build the evidence base to support safer care.

Fostering research will require significant efforts to strengthen research capacity as the underdevelopment of this field is due in part to the scarcity of qualified research professionals trained to conduct research in patient safety. It is also important to bear in mind that the

primary purpose of patient safety research is to produce solutions and interventions for safer care. An important function linked to the conduct of research relates to the translation of research findings into actual solutions and improved practices and policies.[7] It is essential to develop professional leaders that are able to drive change through measurement and research.[8] This is especially important in developing and transitional countries where the need for more cost-effective and locally acceptable interventions is most acute.[9]

This guide attempts to address this limited capacity in patient safety research and research translation worldwide, by helping to develop leaders in patient safety research, implementation and change management. If leaders are armed with the knowledge and skills to conduct and use relevant research, they will be better able to influence the development of practices and policies that will make care safer on a global scale.

1.3 The audience for this guide

This guide is intended for course organizers, trainers or faculty members who contribute towards curriculum development and the organization of training programmes at their respective institutions. These could include: universities/colleges/other academic institutions, hospitals or care-providing facilities, health-related professional bodies or associations, ministries of health, governmental and non-governmental organizations. The guide aims to provide theoretical and practical directions on the learning objectives and the content materials. These learning objectives are required to help researchers, health-care professionals and postgraduate students acquire the set of core competencies required to conduct or participate in research for patient safety improvement.[10]

Students and researchers will be the ultimate beneficiaries of this guide since it will provide them with a clear idea of the competencies needed to be able to improve patient safety through research and measurement, and will give them ideas on research topics and information sources.

Our aim is that this guide will be useful to curriculum developers in different countries and regions of the world. Although this initial edition is in English, if the guide proves to be successful, a serious attempt will be made to make this guide available in other languages.

1.4 Rationale of this guide

The guide is based on the principle of flexibility. It provides training programme developers with a comprehensive list of core training objectives, based on a set of agreed core competencies, and examples for training programmes to be selectively chosen by educators based on their own programme objectives and target audience. When developing a training curriculum, the developer will have to decide which of these competencies most need to be taught. The selection depends on the level of competence that the trainees are expected to achieve, characteristics of the trainees (i.e., previous training in patient safety, in research methodology, in epidemiology or statistics, etc.), and on the level of training required (from specialized postgraduate degree in patient safety improvement, to basic knowledge and understanding of the discipline).

Some of the learning competencies described in this guide, such as epidemiology, research methodology, statistics, etc., are common to other general research disciplines and would be taught in other programmes. By including them in this guide, we are by no means suggesting these other programmes should be duplicated but, rather, that curriculum and training programme developers should be aware of the training requirements of students, The message given in this guide is that competency in research methodologies, as well as in knowledge translation, is core to the conduct of research on patient safety, and to the application of research findings to patient safety improvement activities.

1.5 What does this guide contain?

The content of the guide is organized around four major sections:

The global scope of patient safety: This section defines patient safety, what the needs are for research in patient safety, and how these needs vary across the globe. These concepts are not always clear given that the patient safety perspective represents a relatively new way of looking at health-care delivery. This is even more evident in developing countries in spite of the fact that patient safety is believed to be a greater problem there than in wealthier countries.[11] Research priorities for patient safety, although common to some extent across the globe, acquire specific meaning and perspective at the local level. These have been identified by experts under the auspices of WHO, and are described in this guide to give the reader an idea of the kind of research needed in different parts of the world, as well as examples of research questions.

A four-step guide to developing patient safety curricula[12]: This section outlines a logical framework for curriculum development, in a manner that allows educators to develop the training programmes required to meet the needs of specific learners and their local contexts.

A. First, training programme developers should conduct a **targeted needs assessment** to identify the background, prior expertise and motivations of the anticipated learners, as well as the expectations and resources available for putting into place the curriculum. Doing so will prepare curriculum developers to better meet learners' abilities and expectations, as well as the resource constraints of a given environment. In this sub-section, readers will find concepts and tools necessary to perform a thorough needs assessment.

B. Next, training programme developers should explicitly **set goals and objectives** for their curriculum in order to communicate what the guide addresses and what it hopes to enable learners, faculties, programme funders, and other stakeholders to achieve. To help curriculum developers generate meaningful objectives, this part of the guide lists the competencies that are needed for carrying out research and translating its results into policies and practices that improve patient safety.

C. Since listing goals and objectives does not automatically produce a guide, curriculum developers should also **design a training programme**. In this sub-section, readers will find descriptions of several training strategies as well as a discussion on which strategies are suitable for which learners and contexts.

D. Finally, curriculum developers should **conduct a programme evaluation**, so that they may assess the extent of their success and refine the training programme in accordance with quality improvement practices. In this part of the guide, readers will find guidance on how to assess both the learner and the teacher. Readers will also learn how to conduct evaluations for course planners and external stakeholders such as accreditation bodies and standards boards.

Examples of expected knowledge, skills and attitudes required for each competency are listed within the section bearing this title. The different levels of attainment, ranging from core to advanced, are specified within each competency area.

The final section of this guide provides additional resources to help readers generate patient safety curricula. It describes a variety of example training programmes in patient safety research as well as the content of an online introductory patient safety course that readers may wish to incorporate into their own curricula. The different types of learners, levels of learning and level of expertise expected to be attained from the course are also described in this section.

This guide ends with a **questionnaire for evaluating this training guide**. We encourage users of the guide to complete and return it to WHO Patient Safety, so that we may continually refine the material in this guide for future users.

1.6 What does this guide not contain?

This guide is not designed to cover very detailed curricula content. That is, it does not provide actual teaching materials. It is anticipated that institutions and organizations will use the guide to develop a curriculum and teaching content relevant to their own context, in a format that facilitates local delivery. For additional training materials relevant to patient safety, readers may refer to the WHO Patient Safety website http://www.who.int/patientsafety/en/

2. The global scope of patient safety

2.1 Different priorities in different parts of the world

Patient safety is a worldwide public health problem, but the issues around patient safety differ depending on the setting, local culture, and available resources. Although the competencies needed to conduct research will be the same all over the world, some of the elements in this training guide will have to be tailored to the local situation and priorities. WHO has published a list of priorities for patient safety as a result of an international expert working group consultation that indicate substantial knowledge gaps (See Table1).[13] In developing countries and in countries with economies in transition, the group identified that research on maternal and neonatal care, counterfeit and substandard drugs, health care-associated infections and the challenges of ensuring a trained and knowledgeable workforce needed special attention. The group strongly emphasized the importance of applied and evaluative research leading to the development of locally adaptive, effective, appropriate and affordable solutions. Experience shows that while many solutions exist for certain patient safety hazards, many countries cannot apply them as they are costly or inappropriate to the local context and circumstances.

The recommendations for developed countries focused more specifically on advancing knowledge about underlying processes and organizational factors that lead to unsafe care, such as those related to communication and coordination, human factors and the need to improve patient safety culture.

This all forms an important starting point, providing a focus on those areas where knowledge is limited. However, the WHO Patient Safety expert group emphasized the importance of identifying priorities at the local level, as well as of revising the global list periodically to ensure that it remains useful for improving patient safety.

Table 1. Six ranked research priorities

Developing countries	Countries in transition	Developed countries
Strong emphasis on applied and evaluative research leading to the development of local cost-effective solutions		
1. Counterfeit & substandard drugs	Inadequate competencies & skills	Lack of communication & coordination (including coordination across organizations, discontinuty & handovers
2. Inadequate competencies & skills	Lack of appropriate knowledge & transfer	Latent organizational failures
3. Maternal & newborn care	Lack of communication & coordination (including coordination across organizations, discontinuty & handovers	Poor safety culture & blame-oriented processes
4. Health care-associated infections	Health care-associated infections	Inadequate safety indicators
5. Unsafe injection practices	Maternal and newborn care	Adverse drug events due to drugs & medication errors
6. Unsafe blood practices	Adverse events due to drugs & medication errors	Care of the frail & elderly

Global Priorities for Patient Safety Research. Geneva, World Health Organization, 2009 (http://whqlibdoc.who.int/publications/2009/9789241598620_eng.pdf).

2.2 Examples of research questions

Many questions can be formulated around these research priorities in order to better understand the issues, and identify and test solutions. Standardized research methods should be used to address these questions and to ensure the feasibility and usefulness of the solutions suggested.[14] How to select adequate methods is also explained in this guide.

Below is a list of examples of research questions to give a flavour of the type of research addressed by this guide and which can also be used as exercises for specific training.[15]

Table 2. Research topics and questions

Topic	Research Question
Extent and nature of the problem of patient safety	What are the incidence and prevalence of patient safety problems in various health-care settings? What is the burden of unsafe care on the general population in terms of morbidity and mortality? What is the burden of unsafe care on special populations, such as the elderly, minorities and children?
Identification, design and testing of locally effective and affordable solutions	What are the costs and benefits of adapting already established guidelines as opposed to designing new solutions? What mechanisms are needed to ensure that specific solutions are valid, effective and responsive to changing needs, and sustainable and measurable over time? What solutions for preventing common adverse events are effective in low resource situations?
Counterfeit and substandard drugs	How effective are regulatory actions and interventions in addressing this problem? How much do counterfeit and substandard drugs contribute to the problems of patient safety? What are the factors that lead to the use of counterfeit and substandard drugs?
Inadequate competence training and skills	Are health-care professionals adequately trained in assessing and dealing with reported adverse events or medical errors? Is patient safety a specific topic in the core curricula of physicians, nurses and health managers? What kind of continuing medical education programmes are most effective at ensuring that physicians and nurses retain competency in patient safety?
Maternal and newborn care	What are the main safety issues in maternal and newborn care? What is the burden of unsafe maternal and newborn care? What are the most cost-effective strategies for improving the safety of maternal and newborn care? What resources and systems are needed to effectively implement the recommended maternal and newborn care interventions?
Health care-associated infections	What is the epidemiology of and risk factors for health care-associated infections in hospitals? What is the availability and cost of commercial handrub products and how does that affect hand hygiene promotion strategies? What strategies are effective in optimizing participation in infection control practices? Are there effective plans in place for the control of epidemic outbreaks of health care-associated infections? Does using new technologies or practices (e.g. silver-coated catheters) reduce the incidence of health care-associated infections?

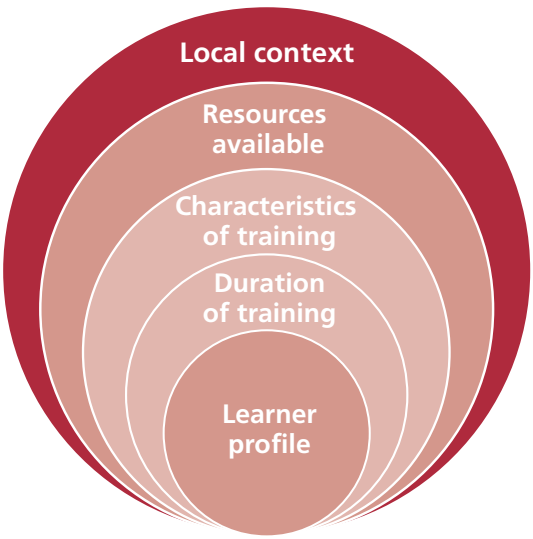
Global Priorities for Patient Safety Research. Geneva, World Health Organization, 2009 (http://whqlibdoc.who.int/publications/2009/9789241598620_eng.pdf).

3. Four steps to developing patient safety curricula

3.1 Assessing training needs

A targeted needs assessment ensures that teaching content is appropriate for a specific location and for specific learners. When conducted properly, a needs assessment should occur at two levels: 1) it should identify the past experiences, motivations and expertise of the targeted learners; 2) it should identify the key characteristics of the learning environment to determine the availability of time, faculty, space and other resources that can influence whether learning occurs and is reinforced.

Figure 1.



Factors to consider when designing a needs assessment

Methods to assess training needs

Prior to developing a patient safety research curriculum, trainers need to assess the anticipated learners' interest and level of expertise, the local context and available resources, by applying one or more methods, including direct observation, surveys, and stakeholder interviews or focus groups. Feedback from a needs assessment can provide trainers with information necessary to determine what the targeted learners' current expertise and motivation level is, and what content is most suitable for their learning style. Additionally, a properly conducted needs assessment will give trainers knowledge of what resources are available to implement the manual, the frequency and type of teacher-learner interactions that are possible, and many other key issues.

Table 3 shows some of the advantages and disadvantages of these methods.

Table 3. Advantages and disadvantages of the different assessment methods

Method	Advantages	Disadvantages
Informal discussion (in person, by phone, or by e-mail)	• Convenient • Inexpensive • Rich in detail and qualitative information • Good method for identifying stakeholders	• Lack of methodological rigour • Variations in questions • Interviewer bias
Formal interviews	• Standardized approach to interviewee • Methodological rigour possible • Questions and answers can be clarified • With a good response rate, can obtain data representative of entire group of targeted learners • Quantitative and/or qualitative information • Good way of gaining support from stakeholders	• Methodological rigour requires trained interviewers and measures of reliability • Costly in terms of time and effort, especially if methodological rigour is required • Interviewer bias and influence on respondent
Focus group discussions	• Efficient method of "interviewing" several at one time (especially those with common traits) • Learn about group behaviour that may affect job performance (especially helpful to understand team-based learning) • Group interaction may enrich or deepen information obtained • Collects qualitative information	• Requires skilled facilitator to control group interaction and minimize facilitator influence on responses • Needs note-taker or other means of recording information (e.g. audiotape) • Views of quiet participants may not be expressed • No quantitative information • Information may not be representative of all targeted learners • Time and financial costs involved in data collection and analysis
Questionnaires	• Standardized questions • Methodological rigour relatively easy • With good response rate, can obtain representative data • Quantitative and/or qualitative information • Can assess affective traits (attitudes, beliefs, feelings) • Respondents can be geographically dispersed (Internet questionnaires increase the ease of reaching geographically dispersed respondents)	• Requires skill in writing clear, unambiguous questions • Answers cannot be clarified without resurveying • Requires time and effort to ensure methodological rigour in survey development, data collection, and data analysis • Dependent on adequate response rate (and resources devoted to achieving this) • Requires time, effort and skill to construct valid measures of affective traits
Direct observation	• Best method for assessing skills and performance • Can be informal or methodologically rigorous • Informal observations can sometimes be accomplished as part of one's teaching or supervisory role	• Can be time-consuming, especially if methodological rigour is desired • Guidelines must be developed for standardized observations • Observer must generally be knowledgeable of behaviour being observed • Observer bias • Impact of observer on observed • Assesses ability, not real-life performance (unless observations are unobtrusive)

Source: Kern DE, Thomas PA, Hughes MT. *Curriculum Development for Medical Education _ A Six-Step Approach*, 2nd ed. Baltimore, Johns Hopkins University Press, Baltimore, 2009

Understanding targeted learners

Learners are identified as anyone interested in conducting research in patient safety and in improving patient safety practices. Understanding learners' **motivations** may help trainers choose appropriate content. For example, some learners may be interested in improving the safety of the care provided in their daily practice, whereas others might want to be able to identify issues and the best solutions from a managerial point of view.

Learners' **background and previous experience** are likely to have a strong influence on their motivations for participating in patient safety research, and can thus have a strong impact on the type of training programme to be delivered. As patient safety and improvement science are trans-disciplinary fields, learners could come from a broad range of academic disciplines including health services research, clinical medicine, psychology, epidemiology, economics, engineering and the social sciences. Additionally, learners may come from a variety of professional backgrounds. Some may be academic researchers (e.g., university professors and their teams), who are actively engaged in theoretical research and teaching as their primary pursuits. Others may be operationally-oriented, clinician-researchers (e.g., health-care professionals), who actively engaged in patient care but who also conduct program evaluations to improve care. Finally, there are policy-makers, and health-care managers who are mostly engaged in designing policies or in using research evidence for making care safer on a broader scale. Therefore, any of the following disciplines could be potential learners targeted by this guide:

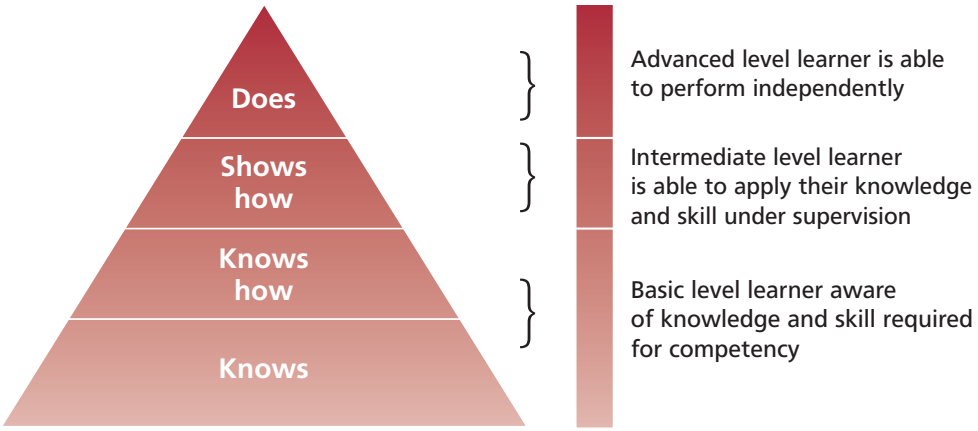
- Academics interested in conducting research on patient safety;
- Clinician-researchers with an interest in improving the safety of health care through evidence;
- Leaders, policy makers and managers

It is important to note that the different competencies may be more or less suitable for different professional profiles e.g., clinicians versus academics versus policy-makers. For example, clinicians may already have an understanding of health care and therefore of several patient safety issues (although they may not have previously considered them explicitly as patient safety problems e.g., falls or medication errors). These clinicians will therefore need less detail on the competencies described in Module 1 relating to health-care systems and common problems, for example causes of error, reporting error etc, but may require greater understanding of the design and conduct of research (Module 2). Policy-makers may require greater levels of competence in using research and research findings to make care safer (Module 3). They may, however, be less familiar with research principles and methodologies, so a training programme for this learner profile could emphasise these aspects – for example, methods to measure harm, study design, statistical analysis etc. In contrast, academic epidemiologists may already have a detailed understanding of the design and conduct of research, but may be less familiar with the basic concepts of patient safety. Selecting which competencies to teach this group should take this into account and thus focus more on the foundations of safety science. Managers and policy-makers, as well as patient safety officers and clinicians interested in patient safety improvement, may require greater levels of competence in implementing research findings and evidence to make care safer (Module 3). The choice of which competencies to include when designing a training programme should be dependent upon the learners to whom it is addressed.

Learners' current level of **expertise** may also determine what content is appropriate for a patient safety curriculum. For any given content area, learners may vary from novices who lack understanding of even foundational content, to experienced researchers with little exposure to patient safety issues, to experts in patient safety with little research capacity, or to policy-makers with little understanding of how to translate the results of patient safety research into policy.

A useful framework for categorizing learning levels for any of the above scenarios would be Miller's Triangle (Figure 2).[16]

Figure 2. Miller's Triangle



Source: Miller GE. The assessment of clinical skills/competencies/performance. *Academic Medicine (Supplement)*, 1990, 65:S63-S67.

As a learner progresses, he or she will move up the levels of the pyramid. Essentially this also suggests the order in which the learning objectives within each competency should ideally be acquired. For example, knowledge (***knows and knows how***) must come before skill (***shows how***), which in turn must be conducted in a supervised setting before independent practice (***does***).

The manner in which the competencies are achieved is expected to vary for students with different levels of prior knowledge/experience, and will depend upon which programme of study they are following. A learner may also progress from the core to the advanced stage within each competency as their training evolves. This is denoted by the different colours in the diagram next to Miller's Triangle in Figure 2 (reproduced for the learning objectives per each competency later on in this guide), which indicates content ranging from core to advanced.

Understanding the targeted learning environment

In addition to learners' motivation, background and current expertise, curriculum developers should also consider the learning environment and available resources, as these factors will also influence what content and teaching methods are appropriate for their patient safety research curriculum. Factors that trainers should consider include the timing/duration of the course, the preferred training methods, the space, faculty, and training materials available, and the cultural, political, organizational and geographical contexts in which the curriculum will be taught.

Duration of training

The length of the training programme is also a key consideration. For example, if limited time is available (e.g. one to two days), only a few areas in the curriculum can adequately be covered. It is important here to be highly selective in choosing which competencies to address in the time given. This will depend upon what is most important for that particular learner profile (see above), and how the patient safety research training fits in with the wider training of the learners (see below). If more time is available, for example several weeks, it would allow for many more components of the curriculum to be explored in greater detail. Even more time would allow for learners to apply their training and actually demonstrate their competencies through completing projects. Different examples of training programmes for different lengths of time are provided in section 6.4 below.

Characteristics of the training programme

The manner in which this guide is used is expected to vary according to the characteristics of the courses or training programmes within which the patient safety research component is to be embedded. It is equally plausible to use only one of the three modules, as it is to use the entire content of all three modules. It is also possible to select a subset of competencies from all modules, or to only focus on just a few topics within one module. The emphasis is to encourage integration of the curriculum into existing programmes, as well as to help build new ones specifically on patient safety. For example, patient safety may be taught as an entire master's degree or only as a module in a postgraduate programme. The former would not only be more focused on patient safety, but would also allow for in-depth study of the competencies. The latter would have to be more selective and would have to consider how the patient safety training would best fit within the wider training programme.

A stand-alone one-day course may not have to consider such vertical or horizontal integration, so one could pick and choose which competencies to teach.

Resources

The resources available for developing and delivering the training programme should also be considered when developing a curriculum. For example, simple training programmes, with most of the teaching done didactically by faculty, may be inexpensive to set up but significantly resource intensive in terms of faculty time required for delivery. We would recommend using this guide in innovative ways so as to maximise all resources available. For example, taking the opportunity to highlight human factors and teamwork in an operating theatre would be one way of teaching this competency in the natural clinical setting. Simulation centres may wish to use their facilities to teach some of the key skills, for example by using role-play to teach and demonstrate patient involvement. The main resources that must be considered in both designing and delivering the training programme are shown in Figure 3 below. Bearing these requirements in mind from the start coupled with careful planning and preparation should allow for optimal translation of this training guide into a curriculum for a training programme.

Figure 3. Resources required in developing and delivering a patient safety research and improvement training programme

Local context

The local sociocultural and geographical context must be considered when using this guide to devise a training programme. In particular, when selecting the competencies to be included, it would be beneficial to teach those that are most applicable to the local context. For example, patient safety problems in developing countries may be different to those in the developed world. Tailoring the training programme according to where it is being taught would thus be ideal, so that learners can understand the causes of harm in their own particular settings and how to best mitigate them in a locally appropriate manner. Wherever possible through the programme, trainers are encouraged to use local examples or local cases to demonstrate the competencies and their application.

3.2 Setting goals, objectives, and outcomes

Once learners' needs have been clarified, trainers can focus on developing the curriculum to address those needs. The first step is about setting goals, objectives and outcomes. Goals,objectives and outcomes are the ends towards which an effort is directed. Clearly written goals and objectives are important because they communicate what the curriculum addresses and what it hopes to achieve for learners, faculties, programme funders and other stakeholders. *Goals* facilitate the curriculum development process by helping trainers to identify and prioritize curricular content. *Objectives* direct curriculum developers to the most effective training techniques, and to the most appropriate evaluation methods.

Outcomes identify the criteria by which learners will be judged as having learned effectively, and how the curriculum will be judged as having taught effectively.

Goals

Goals are broad, general statements of what the programme, course, or activity intends to accomplish. Goals describe broad learning outcomes and concepts (what you want your students to learn) expressed in general terms (e.g., clear communication, problem-solving skills, etc.). Goals should provide a framework for determining the more specific educational objectives of a programme, and should be consistent with the mission of the programme and the mission of the institution. A single goal may consist of many different learning objectives.

Objectives

Objectives are brief, clear statements that describe the desired learning outcomes of instruction, i.e., the specific skills, values, and attitudes students should exhibit that reflect the broader goals. Well-written objectives are both *specific* and *measurable*. As such, they establish a strong foundation for assessment. A useful guideline for writing strong objectives is to include five basic elements:
Who(1) will do(2) how much (or how well)(3) of what(4) by when(5)?
In other words, the learning objectives should explicitly identify the learner (1), an action the learner will perform (2), a *measurable* performance criterion (3), and the conditions under which the performance criterion will occur (4 and 5).

There are three types of learning objectives, which reflect different aspects of student learning:

- *Cognitive objectives*: "What do you want your graduates to know?"
- *Affective objectives*: "What do you want your graduates to think or care about?"
- *Behavioural objectives*: "What do you want your graduates to be able to do?"

Unlike goals, which are broadly written and may be subject to interpretation by different readers, objectives should be specific and subject to only one interpretation. Thus, whereas goals might describe ambiguous action verbs such as "know" or "understand" (e.g., "learners will understand the principles of patient safety"), Objectives will describe specific actions, such as "recite" or "define" (e.g., "at the end of the curriculum, learners will be able to define the meaning of 'Reason's Swiss cheese model.'") Many trainers find it helpful to ask colleagues who are NOT involved in the programme to review the curriculum objectives to ensure that they clearly describe the ends that the trainers intend to reach.

Outcomes

The goals and objectives statements should provide guidelines for teachers, material writers, test writers, as well as learners. They should provide a focus for instruction and evaluation outcomes.

Learning Outcomes are statements that describe significant and essential learning that learners have achieved, and can reliably demonstrate at the end of a course or programme. Learning outcomes identify what the *learner will know and be able to do* by the end of a course or programme – the essential and enduring knowledge, abilities (skills) and attitudes (values, dispositions) that constitute the integrated learning needed by a graduate of a course or programme.

The learning outcomes approach to education means basing programme and curriculum design, content, delivery and assessment on an analysis of the integrated knowledge, skills and values needed by both students and society. The ability to demonstrate learning is an integral part of this outcomes-based educational approach.

Outcomes play a critical role in curriculum planning and design. The outcomes dictate curriculum content, teaching methods, assessment strategies and curriculum organization and structure. Performance outcomes also provide a framework for curriculum evaluation.

Competencies for research in patient safety

Patient safety research competencies can be defined as 'the fundamental knowledge, skills and attitudes needed to carry out research and/or to use research findings in the area of patient safety.' WHO, assisted by an expert working group of scientists with expertise in curriculum development, education, patient safety and research methodologies, identified the set of core competencies that form the basis of this guide. The multi-stepped process involved developing an initial framework, reviewing the existing literature related to competencies in relevant areas, conducting a series of consultations with potential end-users and international experts in the field from over 35 countries, and, finally, convening a global consensus conference.[17] These core competencies for patient safety research were grouped into three main areas: (i) the science of patient safety (ii) the methodology needed to carry out

patient safety research and (iii) knowledge translation, or how to use research findings for policy and practice change aimed to improve patient safety. The final competency list is displayed in Table 4 below.

These competencies encompass a combination of knowledge, skills and attitudes that are considered essential for performing the functions required to: identify the main concerns associated with patient safety, help develop sound and effective solutions, assess their impact and foster sustained change. Moreover, these competencies provide a framework for the ongoing education and training of patient safety researchers, while acknowledging that competencies may differ slightly depending on the different target audience, regional context or level of research advancement.

The core competencies proposed here are not exhaustive. They were considered the core, or essential skills, that would be relevant to most professionals interested in advancing general knowledge around patient safety. Other competencies may be considered relevant to patient safety research under differing circumstances.

Establishing formal training programmes at accredited academic institutions, building on this set of competencies, seems to be the natural step forward. This training guide is based upon these patient safety research competencies and is intended to elaborate on them, by providing detailed learning objectives to guide the trainer and the learner. The knowledge, skills and attitudes for each competency can be found in Section 4 of this guide.

Table 4. Core competencies for patient safety research

1.	**The fundamental concepts of the science of patient safety in their specific social, cultural and economic context**
1.1	Basic definitions and foundational concepts, including human factors and organizational theory
1.2	The burden of unsafe care
1.3	The importance of a culture of safety
1.4	The importance of effective communication and collaboration in care delivery teams
1.5	The use of evidence-based strategies for improving the quality and safety of care
1.6	The identification and management of hazards and risks
1.7	The importance of creating environments for safe care
1.8	The importance of educating and empowering patients to be partners for safer care
2.	**How to design and conduct patient safety research**
2.1	Search, appraise and synthesize the existing research evidence
2.2	Involve patients and carers in the research process starting with defining research objectives
2.3	Identity research questions that address important knowledge gaps
2.4	Select an appropriate qualitative or quantitative study design to answer the research questions
2.5	Conduct research using a systematic approach, valid methodologies and information technology
2.6	Employ valid and reliable data measurement and data analysis techniques
2.7	Foster interdisciplinary research teams and supportive environments for research
2.8	Write a grant proposal
2.9	Obtain research funding
2.10	Manage research projects
2.11	Write up research findings and desseminate key messages
2.12	Evaluate the impact of interventions as well as feasibility and resource requirements
2.13	Identity and evaluate indicators of patient safety for use in monitoring and surveillance
2.14	Ensure professionalism and ethnical conduct in research
3.	**Be part of the process of translating research evidence to improve the safe care of patients**
3.1	Appraise and adapt research evidence to specific social, cultural and economic contexts
3.2	Use research evidence to advocate for patient safety
3.3	Define goals and priorities for making health care safer
3.4	Translate research evidence into policies and practices that reduce harm
3.5	Partner with key stakeholders in overcoming batteries to change
3.6	Promote standards and legal frameworks to improve safety
3.7	Institutionalize changes to build supportive systems for safer care
3.8	Apply financial information for knowledge translation
3.9	Promote leadership, teaching and safety skills

3.3 Designing a training programme

This training guide has so far highlighted the key competencies required for patient safety research. Teaching and training researchers in these competencies is essential in order to build sufficient capacity in this field. Although experienced trainers may be able to adequately devise a training programme based on the competencies themselves, for those who are relatively new to the field, this task might seem daunting. The following section, therefore, aims to provide more guidance in this process. It serves as a 'how to' guide for trainers covering the following:

- Tailoring the programme according to the learners' profile;
- Incorporating competencies into training programmes;
- Types of training modalities;
- Strategies to enhance learning when delivering a training programme;
- Types of teaching methods that could be considered;
- Examples of different training programmes;
- Examples of content for patient safety courses.

This guide highlights the key competencies for patient safety researchers and how they might be taught. It is anticipated that institutions and organizations will use this as a platform for developing teaching content relevant to their own context, and in a format that will aid local delivery. The following section clarifies how this might occur.

How can the competencies be embedded into training programmes?

Since the target audience in patient safety research and improvement is so diverse, a single method for offering training in these patient safety research and improvement competencies would be inappropriate. Although the entire curriculum could be delivered, it is equally possible to use only one of the three modules for training. It is also possible to select a subset of competencies of interest to guide learning in the relevant domain. The right choice would be a function of the specific learning objectives required to satisfy learners' needs, according to the particular context and resources available. The emphasis is to allow integration of the competencies into existing training programmes, as well as to help build new, specifically designed, courses. Potential strategies for implementing training in these competencies are described below.

- Incorporate training into the current curriculum of an institution, for example within an existing postgraduate programme. This would enable competencies to be embedded into existing formal degree programmes such as a Masters in Public Health or a PhD in Infectious Diseases. Such integration can be 'horizontal', for example, by applying a patient safety research angle to every module already being taught. Integration can also be 'vertical', for example, through developing a stand-alone module in patient safety research and improvement to complement the existing modules. It is not necessary that every competency is covered – rather, a tailored approach to each institution's particular needs and the profile of its own learners is encouraged.
- Develop a short course or workshop on patient safety research. Depending on the time available, training in the competencies deemed most appropriate could be delivered in one day, one week or even over a month. A careful analysis of the guide according to different learner profiles would allow for the most pertinent competencies to be selected and taught in an efficient and effective manner.
- Aid the development of face-to-face, online or distance learning courses. Information gleaned from the guide could shorten the process of course development after identifying the needs of learners.
- Develop a certificate/diploma/degree programme/postgraduate programme in patient safety research. The precise format would fit within the requirements of the host institution or organization. This guide can also be used to influence the development of a more extended programme of work, specifically on patient safety research. The competencies and the learning outcomes can then form the blueprint of the curriculum designed to fit local context and resources.
- Provide Continuing Professional Development or on-the-job training. Sessions could be based on specific competencies or learning objectives, so as to appeal to the needs of practitioners in the workplace.

Train-the-trainer programmes through specific short courses or workshops, as well as online distance learning modules. In this case, the needs assessment should include additional competencies related to serving as an instructor.

Table 5. Steps for developing a training programme from the core competencies

1. Decide which competencies to include (depends upon key factors listed above including learners, time available, resources, etc).
2. Look at the learning objectives for these competencies and decide which mode of learning is most suitable for reaching the objectives (e.g. didactic teaching, small group work, role play, etc.).
3. Decide who is available to teach each session and where it should be taught (e.g. classroom setting, virtual webinar).
4. Construct a programme outline based on the above (detailed examples of different ways of learning are provided below).
5. Consider the assessment of learners to be used. Think about how you can demonstrate that the learning objectives have been achieved. Knowledge tests such as multiple-choice questions may be suitable to demonstrate knowledge, but practical examples may be required to demonstrate skill. Here, the learner could conduct a project or analyse data to show that these competencies have been acquired.
6. Evaluate the training programme. Getting feedback from learners on what they found most useful and soliciting their suggestions for improvement will help determine what worked well and what should be refined for the next cohort.

Although the competencies listed in this curriculum are comprehensive, the trainer can and should select among them to decide what is most appropriate for their local training programme. No training programme is expected to cover every single competency. This would not be feasible in most circumstances. Rather, a critical analysis of the competencies across the three modules should be performed to determine which ones are most relevant to which cohort of trainees. It is anticipated, therefore, that a particular selection of competencies and the manner in which they are to be achieved will vary for different training programmes and for different contexts. When selecting competencies and the manner in which they are taught, trainers may find it useful to consider the factors in Figure 3.

Types of training modalities

Since the target audience in patient safety research is so diverse, a single method of delivery of the curriculum would be inappropriate. Different models of delivery of teaching may be suitable for the varying contexts and levels of experience of the learner.
Specific teaching and learning strategies to help achieve the learning objectives are highlighted below. Their respective advantages and disadvantages are also outlined.

Face-to-face training

Face-to-face training where the trainer and the learners are present in the same room is one of the most commonly used teaching methods in higher education. Although educationally effective, this method is particularly resource-intensive in terms of faculty time. It is, therefore, important that sessions are carefully planned to convey information, and to stimulate motivation and interest in the subject area as well as to generate understanding. When delivering face-to-face training, it is important not to overwhelm the learners with too much theory. Focusing on a clear, practical example can be much more useful than theory. Moreover, using one or two practical examples can capture and sustain the audience's attention so that they can really listen and learn about patient safety concepts such as the safety culture.
This face-to-face training could take different formats:

i) Didactic lecture

Didactic learning is a particularly instructive type of teaching which is designed to impart information to learners. It typically takes the form of lectures.

Advantages

- Can be an effective means of providing new information and clarifying existing information to a large heterogeneous group in a short period of time
- Is useful for covering underlying concepts, principles, and systems
- Can set the stage and lay the necessary groundwork and parameters for a subsequent activity
- May be recorded for future use.

Disadvantages

- Places the burden of promoting learning fully on the teacher, unless it is integrated with

other techniques (is a passive learning activity)
- May be presented at the teacher's level of understanding rather than at the learners'
- Can lead to learner overload
- Can hinder learner independent thinking
- Has very limited effectiveness in teaching anything other than knowledge.

ii) Small group work

This usually involves people working in groups (i.e., at least two people are involved, usually more). There may be group 'products' towards which the learners are working which are not easily achievable by people learning on their own. In addition, there may be individual 'products' which are achieved through the people in the group helping each other and working together. Also, as such group learning has a large social dimension to it, it is usually enjoyable and developmental – it gives rise to other outcomes than academic ones, such as increased competence in working with others and self-assurance.

Advantages

- Helps clarify ideas and concepts through discussion
- Develops critical thinking
- Provides opportunities for learners to share information and ideas
- Develops communication skills
- Provides a context in which learners can take control of their own learning in a social context.

Disadvantages

- Dependent on the success of the group process
- Difficult to assess individual learning outcomes
- May not suit all learning styles
- Teachers may be unsure of their role.

iii) Problem-Based Learning

Problem Based Learning (PBL) is being increasingly used as a major component for delivering curricula. Although there are many variations of the PBL process, it is generally well suited to patient safety teaching and learning. Characteristics of PBL include small group learning focused on a case study (e.g. on an adverse event) with a facilitator (tutor or teacher). Typically, as learners attempt to understand the case through group discussion, issues and problems arise that will form the basis of further study. The learners then undertake self-directed study and eventually reconvene as a group, to share their learning and collectively improve their understanding of the issues that arose from the case.

Advantages

- Integrates knowledge within the context of solving a real patient safety problem
- Identifies patient safety practices in the real world
- Promotes collaborative learning
- Promotes skills that will assist researchers in identifying potential solutions to patient safety problems and applying them in a multidisciplinary setting.

Disadvantages

- Can be time-consuming and resource-intensive
- Learners may not have the opportunity to reconvene to share their understanding
- The role of the teacher as facilitator may be ambiguous for both the teacher and learner, leading to dissatisfaction with the learning process

iv) Workshops and tutorials

Interactive workshops and tutorials provide an excellent opportunity to reinforce generic principles and to detail patient safety applications for a particular research methodology. Workshops and tutorials also provide an ideal forum for skills-based teaching, where learners have the opportunity to practise skills relevant to their own local context in a supervised environment.

Advantages

- Learners are able to build and practise their research skills under supervision
- Promotes the attainment of higher level competencies, difficult to capture in a lecture
- Promotes collaboration and the exchange of ideas and identifies best practice

Disadvantages

- Resource-intensive - requires the presence of at least one supervisor or teacher every time the workshop is delivered
- Weaker learners may not be identified
- Limited time frame in which to achieve competencies

v) A combination of the above

Ideally, to promote learning in all domains of knowledge, skills and attitudes, a variety of teaching and learning strategies are adopted. This approach consists of a combination of lectures, small group discussions, project work and practical workshops to reinforce learning, and also to support the practical application of skills for conducting patient safety research. Where possible, alternative training methods other than didactic teaching are particularly encouraged. Having face-to-face contact time provides an ideal opportunity for small group work, facilitation exercises and other such activities. Methods that actively involve learners are often more effective than lectures in encouraging them to take deep approaches,

which are likely to result in developing understanding, encouraging critical thought, challenging opinions or changing conceptions. Practical examples of this would include asking the audience for their own experiences of patient safety incidents which they have witnessed when discussing the burden of unsafe care. This would not only provide illustrative examples of the topic but would also help highlight how important this is to their individual contexts. Carrying out small group work with the trainer acting as a facilitator, for example, by asking the class to analyse local cases when teaching root cause analysis is also an invaluable method of learner participation.

Hands-on training

The aim of the patient safety research training programme is to build capacity, so that learners have the necessary knowledge and skills to conduct a research project and to apply research findings for patient safety improvement. Therefore, training is more useful if it can be integrated and adapted to practical research projects. One method for achieving this is to use a learning-by-doing approach, where researchers develop the necessary knowledge and skills 'on-the-job' outside of books and lectures. Learning can occur through work, for example, bedside teaching, in the form of simulations (i.e., experiences designed to mimic the real life environment).[18] Although some simulation training is technology-intensive, simulation training can also be conducted usefully in a very "low tech " manner.[19, 20] Learning can also occur within specific workshops, or within existing teams e.g., within clinical teams.

Advantages

- Hands-on training provides learning-by-doing – helping a learner to acquire knowledge and skills outside of books and lectures
- Students are more involved in their learning
- Students practice or demonstrate what they have learnt under supervision.

Disadvantages

- Limited availability of hands-on learning experiences
- Do not cover as much material
- Generally more resource-intensive.

For successful hands-on learning training it is crucial that trainers provide ongoing supervision, mentorship and support throughout this process. This project-based hands-on learning will ideally be preceded by, or interspersed with, more didactic coursework to acquire the theoretical foundation in both the content area and the research methods required to do good quality research. An advantage of combining hands-on learning with more didactic training is that it reinforces concepts learned in class.

Project-based training

Project-based training activities create opportunities for learners to work on problems in the real world, as well as contributing to the development of lifelong learning. Learners are able to develop hypotheses to answer research questions of interest. They then gather data and observations to confirm or refute these hypotheses. Typically, this activity is conducted under supervision in the first instance but then, as the learner progresses, they are able to design and run their own research project.

Advantages

- Supports active engagement of the learner in the learning process
- Applies knowledge and skills acquired from the curriculum to real world problems
- Enables the development of lifelong learning skills
- Promotes autonomy, responsibility and independence
- Enhances communication skills.

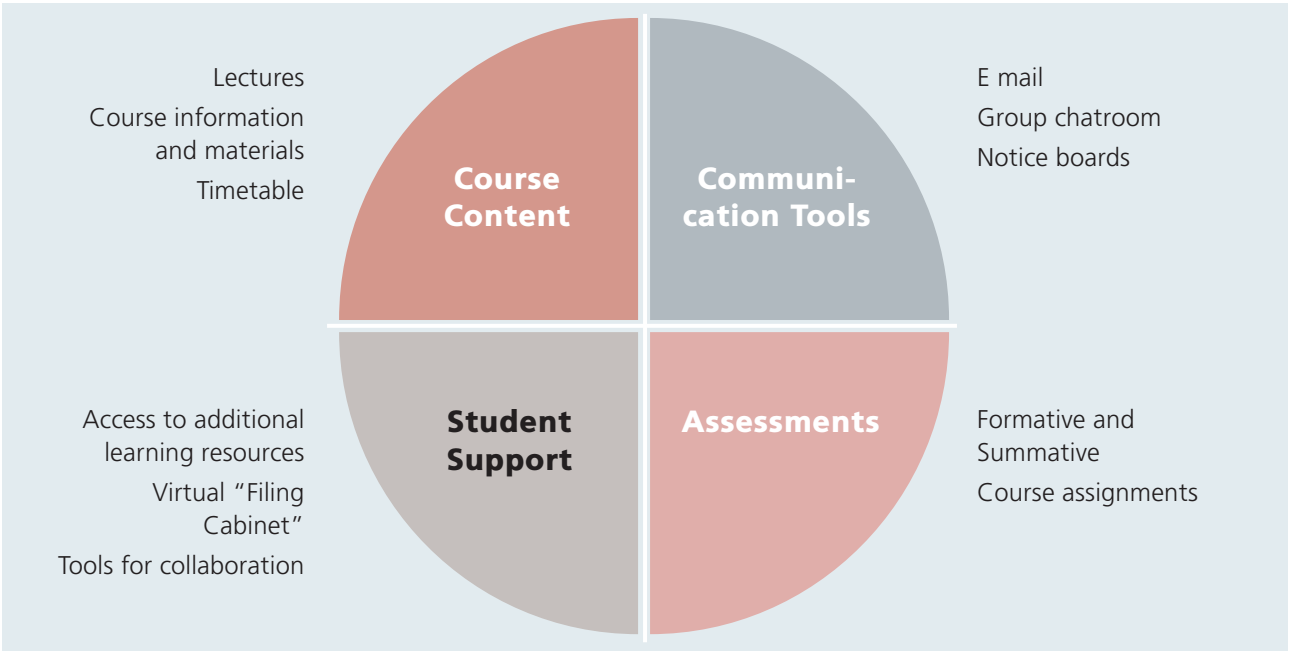
Disadvantages

- Emphasis placed upon the learner who may not know where to start
- Weaker learners may not receive enough supervision
- More resource-intensive
- Requires a sufficient number of supervisors.

Virtual training

Virtual Learning Environments (VLE) use computers to allow remote access to learning materials. A Virtual Learning Environment is essentially a collection of integrated tools enabling the management of online learning, providing a delivery mechanism, student tracking, assessment and access to resources. The VLE allows everyone to benefit from teaching even if unable to attend a face-to-face meeting. Learning outcomes can be developed in the meetings or online, and reporting can be delivered via the discussion boards to allow all members to benefit from the work of the group. This allows even those who were not present at a teaching session to take part. In addition, the course tutors can see the activity of the group, take part in the discussion as a co-learner, and facilitate if required. Figure 4 provides an example of the components of a VLE.

Figure 4. Components of a Virtual Learning Environment



Advantages

- Access available anytime, anywhere around the globe
- Provides learning that can be delivered "just in time" and "on demand"
- Learners can receive immediate feedback
- Efficient use of resources as learning is delivered directly to the learner saving on travel time and costs
- Provides direct access to other training resources.

Disadvantages

- Relies upon access to the internet which may not exist in all countries or contexts
- Lack of interaction with teacher or facilitator may impede learning
- Security issues
- Requires content to be updated regularly.

Blended training

Blended training is a teaching practice that combines teaching methods from both face-to-face and online learning.[20, 21] Typically, it is implemented in a variety of ways, ranging from models in which the curriculum is fully online with face-to-face interaction, to models in which face-to-face classroom instruction is integrated with online components that extend learning beyond the classroom or training day. An online course comprising recorded modules may have "live" discussion sessions either online or face-to-face. The advantage of this approach is that it provides learners with an enriched learning experience, through increased flexibility and personalization of their educational experience. Further, from a trainer's perspective, this instructional model helps to increase capacity without commensurate increases in budget or staff.

Strategies to enhance learning when delivering a training programme

This guide can be used in various different types of training methods. These can include face-to-face teaching, learning by doing and virtual training programmes. Regardless of which approach is used, the following strategies are suggested to make the patient safety research training programme more meaningful to learners. This would encourage learners to ultimately apply their knowledge and skills in a practical way to promoting patient safety.

a) Contextualise patient safety principles

Patient safety principles need to be made relevant to the daily activities of learners. Instruction should aim to show learners when and how patient safety knowledge can be applied to their own practices. When choosing strategies for teaching and examples in patient safety research and improvement, it is important to think about the local context and the sort of work most learners will be doing. For example, including a case about malnutrition or malaria is not particularly useful if these conditions are extremely uncommon in the local setting. Likewise, relying upon simulation centres or multiple faculty members to deliver teaching may not be appropriate if these resources are not available.

b) Identify practical applications

It is important to help learners identify the situations in which they can apply their patient safety research knowledge and skills. This way, they are more likely to recognise opportunities for conducting such research and improving practices in their own contexts. Also, identifying significant situations will help the relevance of the material be more apparent to learners, resulting in better motivation for learning.

c) Provide learners with an opportunity to practise applying their patient safety knowledge and research skills

By giving students the opportunity to practise their newly acquired research skills, it will help integrate their learning and develop long-term retention of their competencies. Importantly, it will also allow the learner to progress up the pyramid from simply "knows" to "shows how". This will provide evidence that students have achieved a deeper understanding of the competency, and is a first step towards conducting independent research in patient safety.

3.4 Assessment and evaluation

Purpose of assessment

Assessment concerns making a judgement regarding the extent to which an individual learner has acquired the desired competencies. Assessment closes the loop in helping to determine if relevant needs have been met. So, assessment forms an integral part of any curriculum. It is important to identify criteria for the assessment ahead of time.

Formative individual assessment provides feedback to a learner that can be used to improve the individual's performance. This type of assessment identifies areas for improvement and gives specific suggestions for applying these to future learning. Properly designed, such assessment also serves as an educational method.

Summative individual assessment measures the extent to which specific objectives were accomplished by the learner. This type of assessment places value on the performance of the individual, and can verify that certain objectives have been achieved, or certify competency in a specific area. Summative assessment provides feedback to the external stakeholders that the desired learning objectives have been achieved.

Assessment can thus be used to provide feedback to:

- The learner on their learning
- The teacher on the learning of learners
- The teacher on their own teaching
- Course planners and external stakeholders such as accreditation bodies and standards boards.

Best practice guidelines for assessment

1. All of the competencies or specific learning objectives taught should be assessed
2. Evidence gathered from assessment should relate clearly and directly to specified competencies (transparency)
3. There should be sufficient evidence to cover the full range of contexts and competencies
4. Evidence gathered from assessment should be traceable to its source (effective record-keeping)
5. Valid and reliable assessment methods should be employed
6. Assessment methods should be motivating and provide direction for how learners need to improve to achieve the competencies
7. Assessment methods should be feasible and acceptable to both faculty and learners

Making a decision on which assessment method to use

Decisions on which method to use for assessment are influenced by the following key factors:

What is to be assessed?

Competency-based assessment systems focus on the outcomes of learning and on the individuals themselves. Within this curriculum guide, the learning objectives are written specifically, so that the outcomes that learners should achieve are clear. It is essential, therefore, that assessment be aligned to the agreed learning objectives.

The assessment framework

An assessment framework or blueprint should be developed to highlight which competency the differing assessment methods can be used to address. As assessment involves generating evidence on whether learning outcomes have been achieved, different methods of assessment can be used to produce different types of evidence. Specific methods may provide evidence of knowledge, skills or attitudes or a combination of any of these domains. It is unlikely that any particular assessment format is suitable to assess everything required. It is best to be aware of the range of assessment methods and make a decision based on an understanding of their strengths and limitations.

The context of the assessment (operational constraints)

The choice of assessment methods needs to be tailored to the local context and the local

resources available to implement these methods. For example, an assessment of improved learner skill through observation in the workplace by a trained assessor may be ideal but not feasible in every country. A simple questionnaire to assess knowledge and skill may need to be used as a surrogate measure instead.

The skills of the assessor
In face-to-face instruction, an assessor is someone who is in regular contact with the individual and has the opportunity to monitor the outcomes of learning. It could be the course trainer, teacher or workplace supervisor. These assessors need skills in the selection and use of assessment methods.

Examples of assessment methods

Written
Written assessments provide a valuable tool for assessment in areas where knowledge forms a key component of competent performance. They can be well structured to elicit key areas of knowledge and understanding. The main concern, however, is that written assessment tends to only emphasize knowledge. There is a danger of assuming that "knowing" means "able to do".
Examples of written forms of assessment include:

1. Multiple choice questions (MCQs) and Extended matching questions (EMQ)
The basic model is a question followed by several possible answers for a learner to choose from (MCQ), or a short stem to be followed by the best possible answer (EMQ). These are attractive formats which can test a wide sample of the curriculum in a short timescale. Although the questions require careful construction, well-designed questions can be standardized.

2. Structured short answer questions
In this method, a question is posed and students write a response to it in free text. Providing a model answer and marking scheme helps examiners maintain some standardization in evaluating the response. Several short answer questions sampling a range of different areas of the curriculum can be written. They have the advantage of allowing students to evidence their critical thinking, reasoning and problem-solving skills.

3. Project work
Research projects are an ideal assessment tool for patient safety researchers, as the learning by doing can be relevant to their work or future work experience. It is not usually possible to conduct actual research projects, but aspects of these can be illustrated. Different projects cover different topic areas and disciplines, allowing students to demonstrate the integration of their learning. Project work allows students to develop their strategies for conducting research and helps link theories of patient safety with practice of research techniques. However, this kind of assessment can be resource-intensive and many students may lack the opportunity to carry out a research project.

4. Learning portfolios
This consists of documentation of evidence of achieving competencies. They can range from detailed learning plans to a log of research activities, a record of achievements and reflective diaries. These allow learners to exhibit the skills and attitudes they have developed, as well as gaining new knowledge. They can also reflect learner development and illustrate progression. However, it can be difficult to standardize such activities, making it difficult to establish an acceptable standard.

Observation of performance
This type of assessment provides detailed evidence of competence. The learner is required to demonstrate not only the knowledge that they have acquired, but also that they can apply it in performing the required skill. However, performance assessments do require the presence of trained and often multiple assessors for assessments to be reliable.
Methods for observation include global rating scales: A student is observed performing a particular task by the supervisor, who rates the student on several areas. This could be in the real work context or in a simulation.

4. The knowledge, skills and attitudes required for each competency

WHO convened an expert group of scientists with expertise in curriculum development, education, patient safety and research methodologies that identified learning objectives for the core competencies for patient safety research and improvement. In accordance with modern educational principles, each competency was broken down into the knowledge, skills and attitudes required to be demonstrated. The group followed an iterative process of writing and rewriting the objectives, supported by a broad external consultation with experts in education and patient safety from developed, developing and transitional countries.

The resulting learning objectives for each competency, which can be found in this section, are indicative of the type of knowledge, skills and attitudes that the learner should demonstrate. However, they are not limited to the list provided, as other learning objectives to address specific training needs may be added. It is also possible and desirable to adapt any of the learning objectives to local needs and training objectives.

The set of objectives finds synergies and is built upon related fields that share common interests such as epidemiology, health services research, quality improvement, human factors engineering, change management and knowledge translation. They are classified into three core modules as follows:
Module 1: Fundamental concepts of the science of patient safety
Module 2: Design and conduct of patient safety research
Module 3: Translating research evidence to improve patient safety
The manner in which these objectives will be achieved is expected to vary across different learners and different courses. It is equally plausible to use only one of the three modules, according to local requirements, as it is to use the entire set of modules. It is also possible to select a subset of competencies from all modules or to focus only upon a few topics within one module. The emphasis is to facilitate learning according to objectives and training needs. This may necessitate integrating specific training modules into existing training programmes, or building new ones. Different competencies may be suitable for different professional profiles e.g., academics versus patient safety improvers or policy-makers. The former may require greater understanding of the design and conduct of research (Module 2), whereas the latter may require greater levels of competency in implementing research to make care safer (Module 3). The relative importance of each competency will thus vary according to personal interest, local context and the instructor's area of expertise. It is intended that the competencies of interest can be extracted from the curriculum so as to guide learning in the relevant domain. The incorporation of the varying subsets of competencies into different training programmes offer the potential to provide different educational strategies to various target audiences, contexts and levels of expertise.

Each competency within the training guide is written as a spectrum of learning objectives that can be built upon as the learner becomes more advanced. This ranges from core knowledge through to advanced knowledge.

Every attempt has been made to ensure that the content of this guide considers the wide variety of contexts in which patient safety researchers learn. The competencies and teaching strategies are designed to take into account the diversity of available resources and environments, whether they be a simulation centre or a rural classroom.

Module 1: Fundamental concepts of the science of patient safety

1.1 Basic definitions and foundational concepts, including human factors and organizational theory

CORE

K

Define the concepts:

1. Systems versus individual approach
2. Adverse events versus preventable error
3. Organizational (safety) culture

Define the following terms:

1. Patient safety
2. Quality of care (also: quality)
3. Quality indicator
4. Patient-centered care
5. Systems approach
6. Process and outcome
7. Adverse event
8. Sentinel event
9. Near miss (also: near hit, close call, potential adverse event)
10. Complication
11. Error (also: preventable adverse event)
12. Errors of omission and commission
13. Mistake, lapse, slip, fumble
14. Latent condition (also: latent failure)
15. Hazard (also: dangerous situation, hazardous condition)
16. Causal factor
17. Contributing, intervening and mitigating factors
18. Patient-related factors
19. Sharp end and blunt end
20. Human factors
21. Malpractice and negligence
22. Incident reporting (also: critical incident reporting, event reporting)
23. Failure mode and effect analysis
24. Root cause analysis
25. Quality improvement (also: systems improvement, process improvement)
26. Human factors engineering (also: systems engineering, systems design)

Correctly identify components of the International Classification for Patient Safety (ICPS) framework

Describe examples of error models and use them to identify the various factors that contribute to error

S

Identify the principal concepts associated with the science of patient safety

A

Recognize that a systems approach is very likely to prevent adverse events

Understand that medical errors are nearly always attributable to multiple factors

Explain that the primary cause of errors is not individual incompetence, but poorly designed systems

K Knowledge S Skills A Attitudes

1.2 The burden of unsafe care

CORE ADVANCED

K **Understand the epidemiological concept of burden of disease and discuss its possible application to the field of patient safety**

Recognize landmark reports and benchmark numbers from the patient safety literature (examples)

1. Institute of Medicine (IOM) "To Err is Human"
2. IOM *Crossing the Quality Chasm* IOM *Preventing Medication Errors*
3. *Harvard Medical Practice Study I & II*
4. National, International studies and meta-analyses on the prevalence and incidence of adverse events
5. Essential research studies and meta-analyses measuring the magnitude of selected types of harm developed, transitional and developing countries

Delineate examples of ≥ 3 different types of preventable adverse events

1. Recognize common examples of unsafe medical care in different contexts
2. Hospital setting e.g. adverse drug events, falls/mechanical injuries, hospital-acquired infections
3. Ambulatory setting e.g. adverse drug events
4. Outpatient/Inpatient transitions e.g. adverse drug events
5. Surgical e.g. wrong –site surgery, retained foreign body, surgical-site infection
6. Perinatal/neonatal
7. Pediatric
8. Geriatric
9. Pharmaceutical

Correctly identify the direct and indirect costs of medical errors in >1 of the above contexts

S **Understand the data and metrics associated with the magnitude of preventable harm**
Be able to use the data and metrics in appropriate contexts

A **Recognize that medical errors commonly occur in health care**

K Knowledge S Skills A Attitudes

1.3 The importance of a culture of safety

CORE

K **Define safety culture and safety climate**

Recognize core conceptual domains used in safety climate surveys

1. Management/supervisory commitment to patient safety
2. Safety systems
3. Provider attitudes towards risk/safety
4. Communication/teamwork

Describe a safe and unsafe organizational culture

Describe potential barriers to patient safety embedded in the "medical culture" e.g.

1. Hierarchies of power
2. Expectation of perfection
3. Blame culture

Identify ≥ 2 reliable/valid methods for measuring patient safety culture, e.g.

1. PSCHO (Patient Safety Cultures in Healthcare Organizations)
2. HSOPS (Hospital Survey on Patient Safety)
3. SAQ (Safety Attitudes Questionnaire)
4. SCS (Safety Climate Survey)
5. ORMAQ (Operating Room Management Attitudes Questionnaire)
6. Agency for Healthcare Research and Quality (AHRQ) safety culture instrument

Identify >2 interventions used to improve patient safety culture including:

1. Executive walk rounds
2. Designate a Patient Safety Officer
3. Unit-based Safety Champion
4. Create a reporting system
5. Conduct safety briefings
6. Engage frontline staff
7. Involve patients in safety initiatives and teaching
8. Staff training and involvement in redesigning care processes
9. Recognition and reward mechanisms
10. Identify and learn from defects

Compare and contrast the approach to error in health care with the approach in other industries

S **Contribute to leading efforts to improve safety culture**

A **Outline why organizational culture is a significant contributor to patient safety.**

Recognize that errors in an institution eg hospital are mainly a result of a poor safety culture

K Knowledge **S** Skills **A** Attitudes

1.4 The importance of effective communication and collaboration in care delivery teams

CORE

K **Define the following concepts and explain why they are important to patient safety**

1. Communication
2. Teamwork
3. Situation awareness
4. Crew resource management

Describe an effective team

Understand the key communication issues that promote and detract from the provision of quality care

Identify an example of effective communication and an example of faulty communication resulting in an adverse outcome

S **Describe 1 method to measure clinical communication including threats to reliability and validity**

1. Direct observation in clinical settings
2. Observation in simulated settings (e.g. NOn-TECHnical Skills scale – NOTECHS)
3. Evaluations by team members

Identify > 2 methods that improve communication in clinical settings

1. Situation-Background-Assessment-Recommendation technique (SBAR)
2. Check-back
3. Call-out
4. Two challenge rule
5. Checklists
6. Timeouts

A **Recognize that effective communication is important for promoting patient safety**

Appreciate the roles of different team members

K Knowledge S Skills A Attitudes

1.5 The use of evidence-based strategies for improving the quality and safety of care

CORE ADVANCED

K

Define evidence-based medicine

Outline examples of patient safety interventions

S

Search for and identify empirical evidence for 2 (core) to 5 (advanced) patient safety interventions:

1. Patient education to encourage provider hand-washing
2. Simulation for patient safety
3. Crew resource management training
4. Multi-modal process change to improve vascular catheter placement and maintenance
5. Surgical safety checklist
6. Hand hygiene campaign
7. Increase nurse to patient staffing ratios
8. Use of standardized handoffs
9. Use of computerized decision support
10. Electronic control of transfusion process
11. Incident reporting systems locally and nationally
12. Antibiotic policies

Rank patient safety interventions according to the level of evidence supporting them

Be able to implement previously used patient safety strategies to improve patient safety

A

Understand the importance of patient safety interventions having a base in empirical evidence prior to broader implementation in a health-care system

Discuss the costs (financial, social, clinical) of non-evidence-based care and safety interventions

Appreciate the value of adopting standardized protocols and practice guidelines

K Knowledge **S** Skills **A** Attitudes

1.6 The identification and management of hazards and risks

CORE ADVANCED

K **Identify 2 patient care hazards/risks in their local environment and describe management strategies**

Recognize 3 (core) to 6 (advanced) methods for identifying threats to patient safety e.g.

1. Root Cause Analysis
2. Incident reporting systems
3. Six sigma
4. Administrative/claims data
5. Chart/medical record review
6. Routinely collected performance data e.g. hospital episodes statistics
7. Interview with provider and patients
8. Patient satisfaction survey
9. Direct observation
10. Morbidity and mortality conferences
11. Failure Modes and Effects Analysis

Describe the strengths and weakness of 3 (core) to 6 (advanced) methods for evaluating adverse events

Assess whether the above methods can be used prospectively, retrospectively or both

Explain how the following can be used to prevent future incidents:

1. Effective reporting systems and analysis of reported events
2. Improved systems of care
3. Technology, including information technology (IT), design of medical devices etc.
4. Learning from other safety critical industries e.g. aviation industry to include hazard analysis techniques and risk mitigation principles
5. Understanding diagnostic errors and methods to mitigate them

Describe why incident reporting is important and identify the barriers to it

Understand the importance of assessing and managing risk to prevent rather than react to harm

S **Formulate a plan to implement 2 these interventions in a local environment**

Review a case study to identify the multiple contributing factors behind an error and learning opportunities from it

List constructive approaches to managing an error or near miss

Identify and analyze the range of possible responses to error including issues around disclosure

A **Appreciate that systematic learning from failure is the best response for ensuring patient safety**

Understand the consequences of failures from the patient and clinician perspective

K Knowledge **S** Skills **A** Attitudes

1.7 The importance of creating environments for safe care

CORE ADVANCED

K **Recognize 2 methods to improve patient safety by changing the built environment or changing safety culture:**

1. Increasing nurse to patient staffing ratios
2. Ensure availability of key resources such as running water or alcohol gels
3. Packaging supplies for procedures together
4. Use of human factors approach to design new environments or to improve existing ones
5. Use of methods to improve safety culture (see competency 1.3)
6. Appropriate supervision of junior staff

Explain how technology can help reduce incidents

Explain how the interface between humans and machines can also lead to adverse events

S **Search and identify> 2 examples where empirical evidence links patient safety and either the structural environment or organizational culture**

1. Availability of electronic ordering systems with decision support and medication errors
2. Nurse to patient staffing ratio and patient outcomes
3. Availability of single-bed hospital rooms and hospital-acquired infections
4. Ready availability of sinks or alcohol gels for hand hygiene
5. Sleep physiology-based call schedules and medical errors

A **Understand the importance of creating the right environment for safe care**

K Knowledge S Skills A Attitudes

1.8 The importance of educating and empowering patients to be partners for safer care

CORE ADVANCED

K

Describe key concepts for involving patients in the delivery of safe care

1. Health literacy
2. Patient education
3. Patient participation
4. Patient bill of rights
5. Patient-led care

Recognize that increased health literacy correlates with improved patient outcomes and lower-cost care

Recognize that quality of patient-physician communication correlates with improved adherence, self efficacy, and outcomes

Outline >2 methods to improve patient safety or quality of care by involving patients and their families

1. Interviewing patients as part of incident investigation
2. Patient satisfaction surveys
3. Teach patient-provider communication skills
4. Include patients as part of the team
5. Encouraging patients to participate in decision making

Delineate the values and limitations of patient satisfaction measures

S

Identify an existing instrument for measuring patient satisfaction and construct a plan for implementing it in a local setting

Illustrate examples of how best to disclose medical errors to patients and families

A

Understand that educating and empowering patients to be partners for safer care is important

Discuss why disclosure of medical errors to patients and families is valuable to health-care quality

K Knowledge S Skills A Attitudes

Module 2: Design and conduct of patient safety research

2.1 Search, appraise and synthesize existing research evidence

CORE

K

- Define critical appraisal
- Define evidence-based practice
- Define systematic review and meta-analysis
- Distinguish between primary and secondary research
- Distinguish between audit and research
- Describe a framework for grading levels of evidence e.g. the Oxford classification
- Identify key online medical and social science literature databases e.g. Medline, Embase, PSNet

S

- Be able to conduct an online literature search, on a topic of interest to the learner
- Find specific articles relevant to a given topic and related to patient safety using an online search
- Critically appraise a study/paper using specific guidelines where present e.g. CONSORT, QUOROM & PRISMA* statements

A

- Understand that knowledge acquired using scientific methods should be the basis fo evidence-based clinical practice, management and policy

*CONSORT: Consolidated Standards of Reporting Trials; QUOROM: Quality of Reporting of Meta-analyses; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

K Knowledge S Skills A Attitudes

2.2 Involve patients and carers in the research process

CORE

K Describe a study in which patients and/or family members contributed to the research question

K Explain potential barriers to effective patient involvement

S Construct a study design for eliciting input from patients and family members

S Analyze strategies for involving patients/carers in research

A Discuss why the inclusion of patients and families in problem identification is valuable to patient safety research

K Knowledge S Skills A Attitudes

2.3 Identify research questions that address important knowledge gaps

CORE

K Define the key elements of a research question

K Define a research hypothesis

K Define a null and alternative hypothesis

S Formulate specific research questions, related to the learner's area of interest

S List testable hypotheses

S Be able to identify problems in the learner's work environment for which knowledge is needed

A Recognize that every study should pose an important question that can improve outcomes for patients or systems

K Knowledge S Skills A Attitudes

2.4 Select an appropriate qualitative or quantitative study design to answer the research question

CORE ADVANCED

K

Define and give examples of exploratory/descriptive research

Define and give examples of analytical/inferential research

Demonstrate an understanding of quantitative research methods, and their applications, strengths and weaknesses of interest to patient safety research, e.g.

1. Randomized controlled trial
2. Cohort study
3. Case control study
4. Cross sectional study
5. Time series study
6. Surveys

Demonstrate an understanding of qualitative research methods, their applications, strengths and weaknesses including:

1. Participant observation, ethnographic studies
2. Focus groups
3. Interviews
4. Consensus building techniques e.g. Delphi

S

Select an appropriate design to address a specific patient safety research question

Design a study to answer a research question of interest to the learner and explain reasons for selection

A

Evaluate how qualitative research methods can yield useful and valid inference data

Understand the important role for each of the research methods used in patient safety research

K Knowledge **S** Skills **A** Attitudes

2.5 Conduct research using a systematic approach, methodology and appropriate use of IT

CORE ADVANCED

K **Describe the key components of a research study including:**

1. Research question
2. Aims/objectives
3. Study design
4. Study population and sampling strategy
5. Variables
6. Measurement methods
7. Study endpoints
8. Data analysis
9. Results
10. Discussion

Understand different forms of sampling, sampling error and potential biases in interpretation of research findings

S **Write a research plan/outline**

Analyze the potential implications of the results of the study

Identify potential limitations of the study

Appropriately use IT facilities to aid research

A **Recognize that every study should use valid study design, measures and appropriate analytical methods**

K Knowledge S Skills A Attitudes

2.6 Employ valid and reliable data measurement and analysis techniques

CORE ADVANCED

K

Define the following terms:

1. Reliability
2. Validity
3. Bias, including the main types of bias and strategies to reduce them
4. Confounder

Distinguish between dependent and independent variables

Distinguish between continuous, ordinal and categorical variables

Explain different methods of primary data collection and their potential pitfalls including:

1. Telephone survey
2. In-person interview
3. Chart/record review
4. Questionnaire/survey
5. Direct observation
6. Patient satisfaction survey
7. Routinely collected data e.g. Hospital Episode Statistics and clinical quality registries
8. Hazard analysis techniques

Choose appropriate measurement methods for different variables

Set up an efficient system for collecting and organizing data

Select an appropriate analysis technique dependent upon research design

Understand and be able to apply techniques for the analysis of quantitative data including:

1. Descriptive statistics
2. Measures of central tendency and dispersion
3. Exploratory statistical data analysis using computer packages or other tools
4. Statistical inference and measures of association
5. Process control charts

S

Understand and be able to apply techniques for the analysis of qualitative data including:

1. Content analysis
2. Coding of interviews

A

Be prepared to maximize the validity and reliability of the study design

Be prepared to conduct a statistical plan that is adequate for the study design and research question

K Knowledge S Skills A Attitudes

2.7 Foster interdisciplinary research teams and supportive environments for research

CORE

K Describe the different disciplines that could contribute to Patient Safety Research
Define the possible different members of a research team

S Appropriately give, elicit and receive feedback in interactions with colleagues
Provide an example of a research question appropriate for interdisciplinary research in a local context
Participate in a working environment that fosters patient safety research

A Strongly agree that a multidisciplinary approach improves the products of patient safety research

K Knowledge **S** Skills **A** Attitudes

2.8 Write a grant proposal

ADVANCED

K Identify the components of a grant proposal
Understand strategies on how to make a proposal attractive

S Prepare a research proposal according to specified guidelines from a granting organization

A Understand the importance of writing grant proposals

K Knowledge **S** Skills **A** Attitudes

2.9 Apply for and obtain research funding

ADVANCED

K
- Identify 2 or more funders of patient safety research
- Discuss the characteristics of these funders and of the type of grants they provide

S
- Identify potential funding sources for the learner's work
- Write a report for the research funder

A
- Appreciate that it is important to obtain research funding
- Understand the roles and responsibilities of funders

K Knowledge S Skills A Attitudes

2.10 Manage research projects

ADVANCED

K
- Describe the characteristics of a good and bad manager
- Identify the skills required to manage a research project
- Describe the responsibilities and role of the principal investigator in a research study
- Describe the components of a project budget

S
- Write a job description for a research assistant
- Demonstrate small group leadership and participation skills including:
  1. Active listening
  2. Giving and eliciting feedback
  3. Facilitating a group discussion
- Prepare a budget for a study with proper allocation of funds to each component of the budget
- Assess the required resources of a research project

A
- Appreciate the roles of a manager in research
- Appreciate the roles of the members of a research team

K Knowledge S Skills A Attitudes

2.11 Write up research and disseminate key findings

CORE ADVANCED

K

Describe the structure of a research abstract, a manuscript, and ten minute oral presentations

Recognize major consensus statements of published patient safety research studies including:

1. Safety and Quality Instrument for Reform (SQuIRe)
2. Strengthening Reporting of Observational studies in Epidemiology (STROBE)
3. Consolidated criteria for reporting qualitative research (COREQ)
4. CONSORT
5. PRISMA

S

Write the following:

1. Abstract
2. Oral presentation
3. Manuscript for publication
4. Press release
5. Policy briefing

Design and implement a strategy for effective dissemination of study results

Identify implications of study results

Communicate findings effectively to multiple audiences

A

Explain why it is important to publish and otherwise disseminate research findings

Recognize the components of an effective strategy for

K Knowledge S Skills A Attitudes

2.12 Evaluate the impact of interventions, their feasibility and resource requirements

ADVANCED

K

- Describe the components of a project evaluation
- Identify the outputs, outcomes and broader impact of an intervention
- Identify the stakeholders and constituencies of an intervention
- Understand and discuss the difference between structure, process, and outcome and impact evaluation
- Understand the difference between process monitoring and evaluation
- Understand the data sources requirements to conduct evaluations
- Discuss different examples of evaluation methodologies

S

- Prepare a proposal for the evaluation of an intervention, identifying the specific outcome variables and research design
- Identify the information requirements for the different set of constituencies involved in the intervention

A

- Appreciate that the resources required for an intervention may not make it feasible in all settings
- Recognize the importance of evaluations, and the need for building them into the design of interventions
- Recognize the importance of the accountability of patient safety research studies, interventions and programmes and be ready to evaluate these and show their impact

K Knowledge **S** Skills **A** Attitudes

2.13 Identify and evaluate indicators of patient safety for monitoring and surveillance

ADVANCED

K

- Understand the concept of performance indicators, as well as of quality and patient safety indicators
- Define the concept of indicator and give examples of indicators for patient safety
- Define monitoring
- Define surveillance
- Be able to identify several examples of quality and patient safety indicator systems at national levels
- Understand the concept of psychometric properties of indicators
- Define the concept of validity, reliability, feasibility and propensity for change for quality and patient safety indicators
- Distinguish structural, process and outcome indicators
- Give examples of quality and patient safety indicators
- Understand which data sources are commonly used to define quality and patient safety indicators, and their limitations

S

- Define possible quality and patient safety indicators in the research proposal and discuss their limitations in terms of validity, reliability, and feasibility

A

- Agree that indicators are helpful for monitoring progress and carrying out surveillance
- Be ready to question and understand the validity and reliability of indicators

K Knowledge S Skills A Attitudes

2.14 Ensure professionalism and ethical conduct of research

K

- Describe the ethical principles of investigators of human subjects
- Describe measures for preserving patient respect, confidentiality and privacy in patient safety research
- Explain the concept of informed consent and how it applies in patient safety research
- Describe situations which require ethical consideration in patient safety research
- Describe the composition and role of the research ethics committee.

S

- Complete an application to an Ethical Review Board
- Prepare an informed consent document

A

- Understand the importance of respecting the rights of human subjects in patient safety research
- Be sensitive to issues of diversity in the conduct of research

CORE ADVANCED

K Knowledge S Skills A Attitudes

Module 3: Translating research evidence to improve patient safety

3.1 Appraise research evidence and adapt this to specific social, cultural and economic contexts

CORE ADVANCED

K

- Describe the organizational theory that underlies change in health-care organizations, including the role of social, cultural and economic factors
- Recognize potential social, cultural and economic barriers among health-care workers to adopting safety interventions
- Describe socioeconomic conditions or cultural settings when patient safety measurements may have less feasibility and validity
- Describe Rapid Cycle Improvement and how it applies to translating a patient safety intervention to alocal context
- Describe a case in which a developed-world, patient safety intervention was adapted for use in a developing country
- Describe the facilitating factors and barriers that may affect implementation of an evidence-based interventionin a local health-care organization

S

- Identify >5 organizational needs and barriers relevant to the adoption and implementation of safetyinterventions in the learner's local organization
- Assess the appropriateness of a patient safety intervention to a local context
- Participate in contextualizing evidence and in developing partnerships for change
- Apply the principles of change management to specific contexts and practices

A

- Recognize that itis important to adapt research evidence to specific social, cultural and economic contexts

K Knowledge **S** Skills **A** Attitudes

3.2 Use research evidence to advocate for patient safety

ADVANCED

K **Explain key concepts as they relate to Patient Safety**

1. Advocacy
2. Policy
3. Stakeholders

Describe a successful example of evidence based health care advocacy e.g. HIV medication coverage

Compare an example of a patient safety issue that was advocated for using research evidence (e.g. medication reconciliation) with an example of advocacy without an evidence base

Describe a systematic framework for developing a health policy objective

E.g. the Bardach 8-step policy framework:

1. Define the problem
2. Assemble evidence
3. Examine alternative solutions
4. Develop a "criteria matrix"
5. Estimate effect of the policy
6. Confront the trade-offs
7. Choose a policy and advocate for it
8. Implement and evaluate the chosen policy

S **Use research evidence to advocate for patient safety**

A **Understand that reliable, well presented data obtained from research can efficiently advocate for patient safety measures**

K Knowledge S Skills A Attitudes

3.3 Define goals and priorities for making health care safer

CORE ADVANCED

K

Define goals and objectives

Describe patient safety priorities based on evidence (e.g. the priorities identified by the WHO Patient Safety Programme)

Describe the patient safety goals of a large national organization in the context of the learner

Recognize the components of multiple frameworks used by organizations for strategic planning

1. Mission, vision and values
2. Writing SMART objectives (Specific, Measurable, Attainable, Relevant, Time bound)

SWOT analysis (Strengths Weaknesses, Opportunities, Threats)

Describe priority areas for implementing organizational change (e.g., "7 leverage points")

S

Write a mission, vision, or valuesstatement for either themselves or their organization

Identify >1 gap(s) in patient safety research literature

Write a SMART objective for a patient safety problem relevant to a local context

A

Recognize the importance of defining goals and priorities for patient safety research and improvement

K Knowledge S Skills A Attitudes

3.4 Translate research evidence into policies and practices that reduce harm

ADVANCED

K

Define the following key terms:

1. Guideline
2. Evidence-based practice
3. Translational research

Provide an example of translational research

Describe an example of how evidence-based practice was integrated into a local organization e.g.

1. Safe surgery checklist
2. Medication reconciliation
3. Simulation-based training

Describe similarities and differences in >2 analytic approaches to policy making

1. Political/legal
2. Ethical/moral
3. Need/demand
4. Economic/financial
5. Assessment/evaluation

Describe an example of a national policy intended to improve patient safety e.g.

1. Reduction in hospital payments for "avoidable complications"
2. Linking laboratory payments to certification and standard technique
3. National Patient Safety Agency (NPSA) campaigns in the UK
4. Safer Healthcare Initiative in Canada

Identify when it is appropriate to use specific process improvement displays

1. Ishikawa (fishbone) diagram
2. Histogram
3. Flow chart (process mapping)
4. Check sheet
5. Matrix
6. Run chart
7. Statistical process control charts
8. Caterpillar plots

S

Explain >1 conceptual framework for introducing organizational change e.g.

1. Plan, Do, Study, Act (PDSA)
2. Engage, Educate, Execute, Evaluate (4Es)

Participate in institutionalizing and embedding changes to build supportive systems for safer care

A

Appreciate the importance of translating research evidence into harm-reducing practices

K Knowledge S Skills A Attitudes

3.5 Partner with key stakeholders in overcoming barriers to change

ADVANCED

K

Define the following key concepts in relation to patient safety

1. Stakeholder
2. Negotiation
3. Persuasion
4. Organizational change

Identify key organizational stakeholders in patient safety

Describe some of the reasons why physicians do not follow clinical guidelines

Describe principles for engaging physician stakeholders in patient safety interventions/research

Describe key barriers and enablers to organizational change

Describe fundamental negotiation concepts

Negotiating with horizontal/peer stakeholders

S

Map the implications of organizational objectives onto stakeholder groups

Apply fundamental negotiation concepts in a local context

Be able to facilitate a meeting

A

Explain why the involvement of stakeholders is important for implementing research

K Knowledge **S** Skills **A** Attitudes

3.6 Promote standards and legal frameworks for improving safety

ADVANCED

K

Define the following key concepts as they relate to Patient Safety:

1. Policy
2. Law
3. Regulation
4. Rights
5. Obligation/responsibility
6. Malpractice
7. Negligence
8. Risk management
9. Ethics

Describe the factors that influence the development and adoption of health-care policy

1. Political drivers
2. Economic drivers
3. Ethical/moral drivers
4. Cultural/social drivers

Recognize similarities and differences in the use of public safety laws (e.g., traffic and food safety laws) with the use of health-care regulations to ensure safe patient care

S

Explain the legal system in the learner's own national context

A

Understand that standardization of processes is valuable to the provision of safe health care

Recognize that safe health-care delivery takes priority over research projects

K Knowledge S Skills A Attitudes

3.7 Institutionalize changes to build supportive systems for safer care

ADVANCED

K

- Describe 3 organizational factors that promote patient safety
- Describe 3 organizational factors that impede patient safety
- Recognize key aspects of how new ideas spread throughout an organization using the Diffusion of Innovations Theory
- Discuss the roles of effective leadership and governance in institutionalizing change
- Understand the role of developing systems that favour change

S

- Evaluate the capacity of stakeholders to support change efforts, and consider how stakeholder interests may be better aligned to achieve long-term consistency in goals
- Describe a negotiation in which they participated, and discuss >3 aspects of their role that were helpful inachievingtheir goals and >3 aspects that they intend to improve
- Describe, in the context of a case study, 3 strategies for influencing colleagues to accept or participate in organizational change
- Identify ways of effectively engaging institutional and team leaders in specific change programmes
- In the context of a case study, describe amenable systems change to facilitate the sustainability of interventions

A

- Understand the importance of institutional involvement and of a systems approach for favouring the sustainability of practice and policy change

K Knowledge S Skills A Attitudes

3.8 Apply financial information for knowledge translation

ADVANCED

K **Explain key concepts as they relate to Patient Safety**

1. Effectiveness
2. Efficacy
3. Cost-effectiveness
4. Comparative effectiveness
5. Cost (including opportunity cost, direct cost, indirect cost)

Identify the clinical/epidemiological burden of medical errors in various contexts

S **Identify and describe an example of a business case for patient safety**

Evaluate the direct and indirect costs of medical errors

Write a budget for a proposed research project specific to the learner's context

Be able to explain that safety can be profitable if hazards and errors are prevented

A **Recognize that the cost benefit ratio of a patient safety intervention varies according to the perspective of a given stakeholder**

K Knowledge **S** Skills **A** Attitudes

3.9 Promote leadership, teaching and safety skills

ADVANCED

K

- Define leadership and management in relation to patient safety
- Describe the attributes of a leader who promotes patient safety
- Describe strategies for teaching patient safety in a local context

S

- Develop competency in communicating effectively, and in justifying to organizational leaders and peers benefits of specific patient safety practices.
- Identify >3 potential sources for patient safety curricula and other teaching material
- Develop short presentations and/or teaching materials on specific topics based on research studies
- Practice giving these presentations to other colleagues

A

- Understand that every professional may develop his/her own leadership to promote patient safety and improve safer care
- Understand that sharing one's own knowledge on patient safety with other professionals is an essential component of professional leadership, and a critical step towards improving patient safety

K Knowledge **S** Skills **A** Attitudes

5. Examples of training programmes

The following section provides guidance on how to actually build competencies for patient safety research into a training programme. The section provides examples of training programmes for three types of potential learner. The first category are for those who are more familiar with research methodologies but less so with patient care and patient safety issues (e.g., epidemiologists and health service researchers). The second category includes those who are more familiar with health care and less so with research (e.g., clinicians) but who have an interest in understanding the essentials of clinical research. The third category is those who are more interested in applying evidence to improving health-care practices and policies related to patient safety. Examples are provided for each group for a one-day and a one-week training programme. Additional and more advanced programmes, leading to academic degrees such as a master's degree or PhD, can also be designed using the same principles as described here for simple training programmes, and following the curriculum development criteria of the academic institutions hosting such programmes.

5.1. Examples of one-day training programmes in patient safety research

If time is very limited and only one day (or the equivalent of one day) is available to train learners in some essential competencies, then it is crucial that the trainer carefully selects those competencies that will be most appropriate for the learners, for their background and for their desired outcomes. As indicated above, three examples are given below of one-day programmes, each focused on one major aspect of patient safety research for different profiles of professionals. It is important to highlight that these are just examples we would encourage local trainers to only use these as an illustration for developing programmes that best fit with their context.

a) One-day programme for learners with research experience but with limited understanding of health care

This course emphasizes the principles of patient safety, and outlines some research methodologies that are more specific to patient safety research and tend to be less frequently covered in regular research training programmes such as methods for measuring harm, understanding causes and implementing solutions. As the learners already have research experience there is only one session on developing a research plan and designing a study. It is intended that, once the learners have developed their research plan during the one-day training programme, they will have the necessary research background experience to go ahead and conduct the study.

Type	Time	Topic	Competency
One-day programme	**08.30-09.00**	Introduction to the training programme	
	09.00-10.30	What is patient safety (PS)? Key definitions and burden of unsafe care	1.1 1.2
	10.30-11.00	Methods for measuring harm: The tools of safety	1.6 2.4 2.5
	11.00-12.00	Methods for understanding why things go wrong: The systems approach and human factors	1.4 1.6
	12.00-13.00	Patient safety at home _ identification of local problems and potential areas for research (including methods to measure the problem and understand its causes)	1.2 1.4 1.6
	13.00-14.00	LUNCH	
	14.00-15.00	Improving patient safety: Interventions and solutions	1.3 1.4 1.5 1.7
	15.00-16.00	Developing a research plan in patient safety and designing a study appropriate to the local context	2.4 2.5
	16.00-17.00	Implementing and institutionalizing change for safer care: organizational barriers and facilitating factors	3.1 3.4 3.7

b) One-day programme for learners with health-care experience but with limited understanding of research methodology

Professionals in this group already have an understanding of health care so they will be more familiar with many of its problems. However, they will still require reframing of the issues through the lens of patient safety. The one-day training programme for this group, therefore, focuses primarily upon providing an understanding of basic research methodologies, so that by the end of the course learners develop a broad understanding of how to conduct a research project in patient safety. After completing the course, it is intended that students will be able to identify a local problem, understand core research considerations (such as key concepts related to different study designs and sampling, and internal and external validity), and be able to understand patient safety research findings and the importance and key concepts of research translation. Learners should thus be able to participate in a research study led by other principal investigators. They may not be expected to be able to lead such a study on their own.

Type	Time	Topic	Teaching method	Competency
One-day programme	**08.30-09.00**	Introduction to the training programme		
	09.00-10.30	What is patient safety? Key definitions, burden of unsafe care and understanding why things go wrong	Lecture Martin Bromley video "Why things go wrong" Video on human factors in PS	1.1 1.2 1.4 1.6
	10.30-11.30	Searching literature and defining a research question appropriate to local context	Small group work	2.1 2.3
	11.30-12.30	Research methods for measuring and understanding the causes of harm: The tools of safety – quantitative approaches	Lecture with illustrative examples (e.g. questionnaires, surveys, safety indicators)	1.6 2.4 2.5
	12.30-13.30	Research methods for measuring and understanding the causes of harm: The tools of safety – qualitative approaches	Lecture with illustrative examples (e.g. interviews, observations etc.)	1.4 1.6 2.4 2.5
	13.30-14.30	LUNCH		
	14.30-15.30	Improving patient safety: Interventions and solutions	Lecture with local case examples	1.3 1.4 1.5 1.7 3.2 3.3
	15.30-16.00	Principle of study design	Lecture	1.5 2.4
	16.00-17.00	Developing a research plan in patient safety and designing a study appropriate to local context	Small group work facilitated by trainer	2.4 2.5

c) One-day programme for learners with an interest in translating evidence into policy and practice.

The audience for this programme is likely to be multidisciplinary, possibly involving health-care managers, clinicians, administrators, patient safety and quality improvement officers, as well as other types of advocates for patient safety improvement. They probably have a background understanding of the health-care system, so will be more familiar with many of its problems but will require reframing of the issues in the context of patient safety, and in relation to the importance of evidence for achieving effective change.
The one-day training programme for this group therefore focuses upon providing an understanding of the essential concepts of patient safety, the basic principles underpinning research and evidence-based decision-making, and will emphasize the methodologies and key issues for effectively translating evidence into clinical practice and policy change. It is intended that by the end of the training programme, they will be able to identify a local problem, recognize the need for evidence and the existence of knowledge gaps surrounding the problem, identify some of the key stakeholders that need to be involved in its solution, and identify the core elements of a strategy for addressing the problem. Further training will be required, however, in order to understand the essential constraints and success factors for implementation, the principles for evaluation, and the core elements of essential communication, among other important elements of a successful research translation.

Type	Time	Topic	Teaching method	Competency
One-day programme	**08.30-09.00**	Introduction to the training programme		
	09.00-10.30	What is patient safety? Key definitions, burden of unsafe care and understanding why things go wrong	Lecture Martin Bromley video "Why things go wrong" Video on human factors in PS	1.1 1.2 1.3 1.4 1.5 1.6 1.7
	10.30-11.30	Understanding the essentials of research methods: Searching literature and defining a research question appropriate to local context	Small group work	2.1 2.3
	11.30-12.30	Understanding research findings: Appraise and adapt research evidence	Lecture with illustrative examples (e.g. systematic reviews, meta-analysis, qualitative surveys)	3.1 3.2 2.5
	12.30-13.30	Improving patient safety: Analyzing a problem	Small group work around a case	2.3 3.1 3.3 3.4
	13.30-14.30	LUNCH		
	14.30-15.30	Understanding principles for translating evidence into practical solutions	Lecture with local case examples	3.2 3.3 3.4 3.5 3.6
	15.30-16.00	Institutionalizing patient safety practices	Lecture	3.6 3.7 3.8 3.9
	16.00-17.00	Developing a strategy for improving patient safety appropriate to local context, and implementing relevant changes in policy	Small group work facilitated by trainer	3.1 3.2 3.3 3.4 3.5 3.9

5.2. Examples of one-week training programmes in patient safety research

If more time is available, then further competencies can be selected to be taught to learners. Additional time also allows for exploration of the competencies in greater detail and provides learners with the opportunity to demonstrate some of their newly acquired skills. Below are examples of training programmes for a five-day period. These could either be delivered together as a one-week module, or each of the 5 days could be spread over a longer period of time for cumulative learning.

a) Five-day programme for learners with research experience but with a limited understanding of health care

Day	Time	Topic	Teaching method	Competency
Day 1	**08.00-09.00**	Introduction to training programme		
	09.00-11.00	What is patient safety? Key definitions	Lecture	1.1
	11.00-12.00	Burden of unsafe care	Lecture Martin Bromley video	1.2
	12.00-13.00	Patient safety at home – identification of local problems	Small group discussion	1.2
	13.00-14.00	LUNCH		
	14.00-15.00	Defining a research question based upon local problems	Hands-on practice	2.1 2.3
	15.00-16.00	Global priorities in patient safety research	Lecture	1.2
	16.00-17.00	Understanding the evidence for safety	Lecture	
Day 2	**09.00-10.00**	Understanding error: Error theory		1.6
	10.00-11.00	Understanding why things go wrong: The systems approach	Lecture	1.6
	11.00-12.00	Understanding why things go wrong: Human factors	Lecture	1.4 1.6
	12.00-13.00	Understanding why things go wrong: Organizational level	Lecture, videos and discussion	1.1 1.6
	13.00-14.00	LUNCH	Small group discussion and lecture	
	14.00-16.00	Research methods for understanding why things go wrong	Lecture	1.5

Day 3	**16.00-17.00**	Case Analysis using RCA	Hands-on practice	1.6
	09.00-10.30	Research methods for measuring harm: Quantitative approaches e.g. IT info systems/ Reporting and learning systems	Lecture	1.6
	10.30-12.00	Research methods for measuring harm: Qualitative approaches e.g. observations, interviews	Lecture	1.6
	12.00-13.00	Developing a questionnaire/interview guide	Hands-on practice	1.6
	13.00-14.00	LUNCH		
	14.00-15.00	Improving patient safety: Measuring and creating a culture of safety	Lecture	1.3
	15.00-16.00	Improving patient safety: Safety indicators	Lecture	1.5 2.13
	16.00-17.00	Improving patient safety: communication and teamwork interventions	Videos, small group work Lecture	1.4
Day 4	**09.00-10.30**	Engaging policy-makers and managers	Lecture	3.5
	10.30-12.00	Improving patient safety in local setting – identifying interventions	Small group work	3.2 3.3
	12.00-13.00	LUNCH		
	13.00-14.00	Patient involvement in patient safety	Lecture	
	14.00-17.00	Putting it all together: Developing a full research plan including research question, study design, methodologies and endpoints (presented in group presentation on day 5)	Small group work	2.4 2.5
Day 5	**09.00-11.00**	Group presentations of research plan	Group presentation	
	11.00-12.00	Organizational change: Barriers and enablers	Small group work	3.5
	12.00-13.00	Implementing and institutionalizing change for safer health care	Lecture	3.1 3.4 3.7
	13.00-14.00	LUNCH		
	14.00-15.00	Using evidence to advocate for patient safety; skills in advocacy	Role play	3.2 3.5
	15.00-17.00	Managing a research project including resources and budget	Lecture	2.10 3.8

b) Five-day programme for learners with health-care experience but with limited understanding of research methodology

This five-day plan provides greater exploration of the basics of research for patient safety and training in research methodologies. It is intended that, by the end of the five-day programme, learners will have acquired the basic knowledge, skills and attitudes to be able to participate in a research project led by other researchers.

Day	Time	Topic	Teaching method	Competency
Day 1	08.00-09.00	Introduction to training programme		
	09.00-11.00	What is patient safety? Key definitions and burden of unsafe care.	Lecture Martin Bromley video	1.1 1.2
	11.00-12.00	Global priorities in patient safety research	Lecture	
	12.00-13.00	Patient safety at home – identification of local problems	Small group discussion	1.2
	13.00-14.00	LUNCH		1.3
	14.00-15.00	Defining a research question based upon local problems	Hands-on practice	2.1 2.3
	15.00-16.00	Searching and appraising the evidence	Lecture	2.1
	16.00-17.00	Conducting an online literature search	Hands-on practice	2.1
Day 2	09.00-10.00	Understanding error: Error theory	Lecture	1.6
	10.00-11.00	Understanding why things go wrong: The systems approach and human factors	Lecture, videos and discussion	1.4 1.6
	11.00-12.00	Study design principles: Sampling and bias		2.4
	12.00-13.00	Applied statistics I	Lecture	2.6
	13.00-14.00	LUNCH		
	14.00-16.00	Research methods for understanding why things go wrong	Lecture	1.5
	16.00-17.00	Case analysis using RCA	Hands-on practice	1.6
Day 3	09.00-10.30	Research methods for measuring harm: Quantitative approaches e.g. info systems/Reporting and learning systems	Lecture	1.6
	10.30-12.00	Research methods for measuring harm: Qualitative approaches e.g. direct observation, interviews	Lecture	1.6
	12.00-13.00	Developing a questionnaire/interview guide for patient safety	Hands-on practice	1.6
	13.00-14.00	LUNCH		

Day	Time	Topic	Teaching method	Competency
	14.00-15.00	Improving patient safety: Creating and measuring a culture of safety, safety indicators, and team training	Lecture Hands-on practice	1.3 1.4 1.5 2.13
	15.00-16.00	Applied Statistics II	Lecture	2.6
	16.00-17.00	Database design and data management practice	Small group work	
Day 4	**09.00-10.00**	Engaging policy-makers and managers	Lecture	3.5
	10.00-11.00	Quality improvement for clinical practice	Lecture	1.4
	11.00-12.00	Applying for funding: How to write a grant application	Lecture	2.8
	12.00-13.00	Applying for ethics review: How to write an ethics application	Lecture followed by small group work with case examples	2.14
	13.00-14.00	LUNCH		
	14.00-17.00	Putting it all together: Developing a full research plan including research question, study design, methodologies and endpoints (presented in group presentation on day 5)	Small group work	2.4 2.5
Day 5	**09.00-11.00**	Group presentations of research plan	Group presentations	
	11.00-12.00	Implementing and Institutionalizing change for safer health care	Lecture	3.1 3.4 3.7
	12.00-13.00	Using evidence to advocate for patient safety; skills in advocacy	Role play	3.2 3.5
	13.00-14.00	LUNCH		
	14.00-17.00	Managing a research project including resources and budget	Lecture	2.10 3.8

c) Five-day programme for learners with an interest in translating evidence into policy and practice

This five-day plan provides greater exploration of evidenced-based approaches to improve patient safety, and of how to effectively translate the results of research evidence into practice and policy change. The course will cover the essential constraints and success factors for implementation, principles for evaluation, and core elements of essential communication, among other important elements of successful research translation.

Day	Time	Topic	Teaching method	Competency
Day 1	**08.00-09.00**	Introduction to training programme		
	09.00-11.00	What is patient safety? Key definitions and burden of unsafe care	Lecture Martin Bromley video	1.1
	11.00-12.00	Global priorities in patient safety research	Lecture	1.2
	12.00-13.00	Patient safety at home – identification of local problems	Small group discussion	1.2
	13.00-14.00	LUNCH		
	14.00-15.00	Defining a research question based upon local problems	Hands-on practice	2.1 2.3
	15.00-16.00	Searching and appraising the evidence	Lecture	2.1 2.3
	16.00-17.00	Conducting an online literature search	Hands-on practice	2.1
Day 2	**09.00-10.00**	Understanding error: Error theory	Lecture	
	10.00-11.00	Understanding why things go wrong: The systems approach and human factors	Lecture, videos and discussion	1.4 1.6
	11.00-12.00	Improving patient safety: Analyzing a problem	Small group work around a case	2.3. 3.1 3.3 3.4
	12.00-13.00	Improving patient safety: Interventions and solutions	Lecture with local case examples	1.3 1.4 1.5 1.7
	13.00-14.00	LUNCH		
	14.00-16.00	Research methods for understanding why things go wrong	Lecture	2.5
	16.00-17.00	Qualitative and quantitative research methods	Lecture	2.4

Day	Time	Topic	Teaching method	Competency
Day 3	09.00-10.30	What do the statistics tell us? Representativeness, bias	Lecture	2.6
	10.30-12.00	How to appraise and adapt research evidence	Lecture	3.1
	12.00-13.00	Understanding principles for translating evidence into practical solutions		3.2
	13.00-14.00	LUNCH		
	14.00-15.00	Prioritizing patient safety issues	Hands-on practice	3.3
	15.00-17.00	Exercise: From a problem to a solution	Group exercise	
Day 4	09.00-10.00	The role of the policy maker	Lecture	3.4
	10.00-11.00	Policies and practices at different levels	Lecture	3.5
	11.00-12.00	Identifying and partnering with different stakeholders to promote change	Lecture	3.5
	12.00-13.00	Exercise to identify different stakeholders for a specific PS solution	Group work with case examples	
	13.00-14.00	LUNCH		1.4
	14.00-17.00	Putting it all together: Developing a plan to address a specific PS issue	Small group work	3.6
Day 5	09.00-11.00	Patient Safety at the national Level Examples of national plans and policies to improve patient safety	Lecture	3.7
	11.00-12.00	Patient safety at health institution level: Implementing and institutionalizing change for safer health care	Lecture	
	12.00-13.00	Using evidence to advocate for patient safety _ skills in advocacy	Role play	
	13.00-14.00	LUNCH		3.8
	14.00-16.00	Apply financial information for knowledge translation	Lecture plus exercise	3.9
	16.00-17.00	Promote leadership	Lecture	

Appendix 1

Additional Resources: Patient Safety online Introductory Course for Patient Safety Research

WHO Patient Safety, in collaboration with international expert professors, has been conducting an online Introductory Course for Patient Safety Research, in English ,French, Portuguese and Spanish. This course consisted of eight one-hour sessions with a 50-minute presentation and 10 minutes for questions and answers. The recordings and slides of these courses are available at http://www.who.int/patientsafety/research/online_course/fr/index.html for the French version and at http://www.who.int/patientsafety/research/online_course/ en/index.html for the English version. Also, PowerPoint presentations of a series of case studies which illustrate examples of patient safety research conducted by top researchers in the field (with advice for future researchers), and that demonstrate the different types of research methods that can be used in doing so, are available at http://www.who.int/patientsafety/research/strengthening_capacity/understanding_causes/en/index.html.

In this section we present the outline, summary of the contents and resources of these eight sessions, including an extra session on ethical issues in patient safety research.

1. The science of patient safety

Summary of contents

1.1 Basic definitions and foundational concepts in patient safety

- Patient safety
- Adverse event/harmful incident
- Error
- Close call/near miss
- Safety culture

1.2 Common types of incidents in health care

- Inadequate hygiene
- Prescription and medication errors
- Look-alike, sound-alike medication names
- Inadequate patient identification
- Inadequate communication during patient handovers
- Performance of procedure at wrong body site
- Inadequate use of concentrated electrolyte solutions
- Medication inaccuracy at transitions in care
- Catheter and tubing mis-connections
- Inadequate use of injections and other devices

1.3 Causation

- Systems approach — The Swiss cheese theory
- Vincent Framework for Risk Analysis

1.4 Epidemiology of unsafe care

- The global burden of unsafe care
- Unsafe care in hospital versus primary care
- Unsafe care in developed countries versus developing countries or countries in transition

1.5 The importance of a culture of safety

- Core conceptual domains used in safety climate surveys
- Potential barriers to patient safety embedded in the "medical culture" e.g. hierarchies of power, expectation of perfection, blame culture
- Methods for measuring patient safety culture,
  - PSCHO (Patient Safety Cultures in Healthcare Organizations)
  - HSOPS (Hospital Survey on Patient Safety)
  - SAQ (Safety Attitudes Questionnaire)
  - SCS (Safety Climate Survey)
  - ORMAQ (Operating Room Management Attitudes Questionnaire)
  - AHRQ Safety culture instrument
- Comparison between the approach to error in health care with the approach in other industries

1.6 The importance of effective communication and collaboration in care delivery teams

- 1. Define the following concepts and explain why they are important to patient safety
- Communication
- Teamwork
- Situational awareness
- Crew resource management
- 2. Describe an effective team
- 3. Understand the key communication issues that promote and detract from the provision of quality care
- Identify an example of effective communication and of faulty communication resulting in an adverse outcome

1.7 The importance of a common language

International Classification of Patient Safety

Suggested resources

1. *WHO Patient Safety Curriculum guide for Medical Schools*. Geneva, World Health Organization, 2009 (http://www.who.int/patientsafety/activities/technical/medical_curriculum/en/index.html, accessed 22 February 2012).
2. Kohn LT, Corrigan JM, Donaldson MS. *To Err Is Human:Building a Safer Health System*. Washington DC, National Academy Press, 2000.
3. Reason J. Human error: models and management. *British Medical Journal,* 2000, 320:786-770.
4. Leape LL. Error in medicine. *Journal of the American Medical Association,* 1994, 272:1851-1857.
5. Vincent C. *Patient Safety*, 2nd ed. Hoboken , Wiley-Blackwell, 2010.

2. Principles of patient safety research

Summary of contents

2.1 Five important aspects in patient safety research

- Measuring harm
- Understanding causes
- Identifying solutions
- Evaluating impact
- Translating evidence into safer health care

2.2 Types of studies used in patient safety research

- Descriptive research versus inferential research
- Quantitative and qualitative research
- Observational research, intervention research
- Cross-sectional, retrospective, prospective designs

2.3 Global research agenda: Patient safety research priorities

- Developing countries
- Countries with economies in transition
- Developed countries

Suggested resources

1. Baker GR et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *Canadian Medical Association Journal*, 2004, 170(11):1678-1686.
2. Hulley SB et al. *Designing Clinical Research: An Epidemiologic Approach,* 3rd ed. Philadelphia, Lippincott Williams and Wilkins, 2006.
3. Brown C et al. An epistemology of patient safety research: a framework for study design and interpretation. Parts 1-4. *Quality and Safety in Health Care*, 2008.
4. Full descriptions of more classic research studies on WHO Patient Safety Programme website, Geneva, World Health Organization, 2012 (http://www.who.int/patientsafety/research/en/, accessed 22 February 2012).

3. Patient safety specific research methodology to measure harm

Summary of contents

3.1 Concepts of what needs to be measured

- Outcomes: Types of incidents, severity, costs, etc.
- Contributing factors

3.2 Data sources

- Incident reporting systems
- Routine hospital data
- Administrative claims analysis
- Malpractice claim analysis
- Morbidity and mortality conferences/autopsy
- Central national/regional audits or enquiries
- Medical records

3.3 Methods for collecting data

- Review of medical records
- Interviews of staff
- Observation
- Clinical monitoring

3.4 Measuring harm in resource poor settings

- WHO guide for measuring harm in data poor settings

Suggested resources

1. Baker GR et al. The Canadian adverse events study: the incidence of adverse events among hospital patients in Canada. *Canadian Medical Association Journal*, 2004, 170:1678-1686.
2. Bates DW et al. Incidence of adverse drug events and potential adverse drug events. *Journal of the American Medical Assocation*, 1995, 274:29-34.
3. Brennan T et al. The incidence of adverse events and negligence in hospitalized patients: results from the Harvard Medical Practice Study I. *The New England Journal of Medicine,* 1991, 324:370-376.
4. Donchin Y et al. A look into the nature and causes of human errors in the intensive care unit. *Quality and Safety in Health Care*, 2003, 12:143-147.
5. Leape L et al. The nature of adverse events in hospitalized patients: results from the Harvard Medical Practice Study II. *The New England Journal of Medicine,* 1991, 324:377-384.

   Michel P et al. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *British Medical Journal*, 2004, 328(7433):199.
6. Thomas EJ, Petersen LA. Measuring errors and adverse events in health care. *Journal of General Internal Medicine,* 2003,18:61-67.

4. Understanding causes

Summary of contents

4.1 Concepts

- Vincent funnel model: Patient, task, individual provider, team, work environment, department, hospital, policy
- Swiss cheese model: Systemic approach

4.2 Data sources

- Medical record
- Administrative claims
- Malpractice claims
- Morbidity and mortality conferences / autopsy
- Incident reporting systems

4.3 Methods for collecting data

- Root Cause Analysis
- Provider surveys
- Malpractice claims analysis
- Reporting and learning system analysis
- Observation

Suggested resources

1. Aiken LH, Clarke SP, Sloane DM, Sochalski J, Silber JH. Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. JAMA, 2002: 288:1987-1993.
2. Berenholtz SM, Hartsell TL, Pronovost PJ. Learning from defects to enhance morbidity and mortality conferences. Am J Med Qual. 2009;24(3):192-5.
3. Cullen DJ, Sweitzer BJ, Bates DW, Burdick E, Edmondson A, Leape LL. Preventable adverse drug events in hospitalized patients: a comparative study of intensive care and general care units. Crit Care Med, 1997, 25:1289-1297.
4. Vincent C. Understanding and responding to adverse events. N Engl
5. J Med 2003;348:1051-1056.
6. Woloshynowych M, Rogers S, Taylor-Adams S, Vincent C. The investigation and analysis of critical incidents and adverse events in healthcare. Health Technology Assessment 2005; Vol 9: number 19.
7. Wu AW, Folkman S, McPhee SJ, Lo B. Do house officers learn from their mistakes? JAMA, 1991, 265:2089-2094.

5. Patient safety specific research methodology to identify solutions

Summary of contents

5.1 Concepts

- Global solutions that have proven to work

5.2 Methods for identifying solutions

For solutions not yet identified:

- Pre-post-intervention studies
- Randomized (double blind, controlled) trial
- Cluster randomization

For known solutions:

- Improving reliability of effective practices

5.3 Locus of Intervention

- Patient
- Health-care worker
- Workplace
- System

Suggested resources

a. Nielsen PE, Goldman MB, Mann S, et al. Effects of teamwork training on adverse outcomes and process of care in labor and delivery: a randomized controlled trial. Obstet Gynecol, 2007, 109:48-55.2. Pronovost PJ, et. al. An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU. New England Journal of Medecine, 2006, 355:2725-32. 3. Pronovost PJ, King J, Holzmueller CG, Sawyer M, Bivens S, Michael M, Haig K, Paine L, Moore D, Miller M. A web-based tool for the Comprehensive Unit-based Safety Program (CUSP). Jt Comm J Qual Patient Saf. 2006 Mar;32(3):119-29

a. Reggiori A et al. Randomized study of antibiotic prophylaxis for general and gynaecological surgery from a single centre in rural Africa. British Journal of Surgery, 1996, 83:356–359. 265:2089-2094.

6. Patient safety specific research methodology to evaluate impact

Summary of contents

6.1 Concepts

Donabedian model for assessing the quality of care

- Structure
- Process
- Outcome

Domains of Quality

- Safety
- Effectiveness
- Patient centeredness
- Efficiency
- Timeliness
- Equitable

6.2 What to measure to evaluate impact

- Frequency of harm
- Prevalence of appropriate care
- Changes in practice in response to learning
- Improvements in safety culture

6.3 Locus of Intervention

- Patient
- Health-care worker
- Workplace
- System

6.4 Outcomes from Different Perspectives

Clinical Perspective

Patient Perspective

- Subjective health status
- Quality of life
- Satisfaction

Societal Perspective

- Utilization
- Cost

Suggested resources

1. Bates DW, Spell N, Cullen DJ, et al. The costs of adverse drug events in hospitalized patients. JAMA. 1997;277:307-311.
2. 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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7. Translating research evidence to improve the safe care of patients

Summary of contents

7.1 Concepts

- Integrated approach to Translating Research Evidence into Practice (TRIP)

7.2 Strategy

- Summarize the evidence
- Identify local barriers to implementation
- Understanding context
- Measure performance
- Ensure all patients receive the intervention

Suggested resources

1. Grol R, Crimshaw J. From best evidence to best practice: effective implementation of change in patients' care. Lancet 2003;362:1225-30.
2. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009 Jan 29;360(5):491-9.
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5. How to Improve: Improvement Methods. Institute for Healthcare Improvement. http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/HowToImprove/

8. Ethical issues in patient safety research

Summary of contents

8.1 Concepts

Understanding the ethical issues when conducting patient safety research

WHO ethical guidance for patient safety research

8.2 Ethical issues in patient safety research

- Distinguishing practice (or audit) from patient safety research
- Determining level of risk in patient safety activities
- Changes in level of risk
- Minimizing risk in patient safety studies
- General disclosures
- Informed consent for providers
- Privacy and confidentiality
- Duty to intervene or report
- Deception

Suggested resources

1. World Health Organization. Global Priorities for Research in Patient Safety (first edition). December 2008. Available at:http://www.who.int/patientsafety/research/priorities/global_priorities_patient_safety_research.pdf.
2. Baily MA, Bottrell M, Lynn J, Jennings B. Ethics of Using QI Methods to Improve Health Care Quality and Safety. The Hastings Center 2006. Available at: http://www.thehastingscenter.org /Publications/SpecialReports/Detail.aspx?id=1342. Accessed 27 February 2010.
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Appendix 2

Appendix 2. Evaluation of this Training Guide, NOT of the training programme

The essential principle of evaluation applies to this training guide. The WHO Patient Safety Programme (PSP) encourages users of the guide to provide feedback by using the simple questionnaire attached. This feedback will be useful for improving the usability of the guide and will help PSP to understand how feasible, accessible and satisfactory the guide is perceived to be. For this purpose it is recommended to print out and make copies of the questionnaire, and to circulate these as widely as possible. Any user of the guide, whether a teacher, trainer or programme designer, is encouraged to report their own perceptions of it (an online version of the questionnaire is also available). This is an evaluation of the training guide itself and NOT of any training courses or programmes that are developed from it.

However, this evaluation does not substitute for the programme evaluation of any of the training programmes which will be developed out of this guide. WHO encourages this type of programme evaluation as discused in section 3 of this guide. Trainers are encouraged to develop evaluations in order to assess the knowledge, skills and attitudes acquired by learners after implementation of the guide.

The next page contains the questionnaire/survey form for evaluation of the training guide.

This should be printed out separately and used by any person who plans to use this guide or any part of it.

The completed form should be scanned and then sent to psresearch@who.int

Evaluation Survey for users of "Patient Safety Research: Guide for developing training programmes"
(Training programme developers/trainers/teachers)

SECTION 1: GENERAL INFORMATION

Name of your Institution/Organization: .....

Your current position: .....

Gender: ..... Age: ..... Country:.....

Name of training programme developed: .....

Potential end-users of training programme .....

Which part of this curriculum guide have you used or are you planning to use? Please specify.

.....

SECTION 2: EVALUATION OF THE GUIDE

Please read the following statements and rate whether you agree or disagree with each of them using the following scale:

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1	2	3	4	5

Regarding the content of the guide:					
It is well structured and laid out	1	2	3	4	5
Key content domains for training patient safety researchers are covered	1	2	3	4	5
It caters for different levels of learners or expertise	1	2	3	4	5
It will facilitate the education and training of researchers in patient safety	1	2	3	4	5
The aims and goals are clearly identified	1	2	3	4	5
The plans for evaluation are clear	1	2	3	4	5
The learning objectives are:					
Clear	1	2	3	4	5
Realistic/achievable	1	2	3	4	5
Measurable	1	2	3	4	5
Fit for purpose i.e. consistent with achieving competency	1	2	3	4	5
Appropriate/adaptable to local context	1	2	3	4	5
Directed towards learning in all three domains (knowledge, skills, attitudes)	1	2	3	4	5
The suggested teaching and learning strategies are:					
Easy to understand	1	2	3	4	5
Fit for purpose	1	2	3	4	5
Appropriate/adaptable to local context	1	2	3	4	5
The suggested assessment strategies are:					
Easy to understand	1	2	3	4	5
Fit for purpose	1	2	3	4	5
Appropriate/ adaptable to local context	1	2	3	4	5
Regarding the aims and goals, using this guide will help:					
Learners to develop a common understanding of patient safety science, paving the way for new patient safety research.	1	2	3	4	5
Learners to receive exposure to the current empirical basis for safety research, so that they can identify and address gaps in the literature.	1	2	3	4	5
Learners to develop the knowledge, skills and attitudes to actively participate in research, or lead to patient safety research projects.	1	2	3	4	5
Learners to develop the knowledge, skills and attitudes to effectively advocate and translate patient safety research into improving health care	1	2	3	4	5
Learners to achieve the competencies required for patient safety research	1	2	3	4	5
Educational and training organizations and institutions to be informed of the key topics in patient safety research	1	2	3	4	5
To raise the international profile of patient safety research	1	2	3	4	5

Suggestions for improvement

What did you like most about this guide?

.....
.....
.....
.....

What aspect(s) of the guide do you think could be improved?

.....
.....
.....
.....

PLEASE SCAN AND THEN SEND THIS QUESTIONNAIRE TO psresearch@who.int

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