

## **Topic Priority Setting for research on patient safety**

### **Operational Definitions**

#### **1. Adverse drug events/ Medication errors**

**Adverse drug events:** An injury caused by the use of medications, or the failure to use appropriate medications when indicated, rather than the patient's underlying condition; noxious and unintended outcome that occurs at doses used in man for prophylaxis, diagnosis, therapy, or modification of physiological function. (**American Hospital Association, Health Research & Educational Trust, and the Institute for Safe Medication Practices 2002**)

**Medication error:** A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packing and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (**Zipperer, et al) NPSF**

#### **2. Adverse Medical Device Events**

An adverse event produced by the use of medical devices

**"Medical device"** means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of: • diagnosis, prevention, monitoring, treatment or alleviation of disease • diagnosis, monitoring, treatment, alleviation of or compensation for an injury • investigation, replacement, modification, or support of the anatomy or of a physiological process • supporting or sustaining life • control of conception • disinfection of medical devices • providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. (**Global Harmonization Task Force document SG1/N029R11**).[www.ghtf.org](http://www.ghtf.org)

#### **3. Care of the frail and elderly**

**Frailty** is "a state of age-related physiologic vulnerability resulting from impaired homeostatic reserve and reduced capacity of the organism to withstand stress." (**NCBI Cancer and aging**)

#### **4. Counterfeit and substandard drugs**

**"A counterfeit medicine"**: is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging." **WHO**

**"substandard drug"** A drug that is of inferior quality i.e. do not meet the quality specifications claimed by the manufacturers or producers (Background Paper, page 71).

#### **5. Developing better safety indicators**

Developing indicators that measure safety.

**Indicators:** measures that: i) capture an important aspect of the intended concept; ii) are scientifically sound, and iii) whose collection is feasible.

Objectively verifiable and repeatable measurement of a result. Indicators support judgement on performance. Qualities of “good indicators” include validity, reliability, sensitivity, simplicity, practicality and usefulness (WHO)

## **6. Devices that lack "human factors" considerations built into their design and modus of operandi**

**Human factors:** Study of the interrelationships between humans, the tools they use, and the environment in which they live and work. (Kohn) NPSF

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## **7. Falls**

**Fall:** An unintended change of position which results in the person coming inadvertently to the ground or other surface lower than the person had been previously. This includes impacting against an adjacent surface (eg, wall or furniture), slips, trips and lowering/assisting a patient who is in the act of falling. (Monash University) David Fonda, Jennifer Cook, Vivienne Sandler and Michael Bailey MJA 2006; 184 (8): 379-382

## **8. Health care associated infections**

An infection occurring in a patient during the process of care in a hospital or other healthcare facility which was not present or incubating at the time of admission. This includes infections acquired in the hospital but appearing after discharge, and also occupational infections among staff of the facility (WHO)

## **9. Health information technology/information systems (including computerized physician order entry)**

Technology that encompasses all forms of technology used to create, store, exchange, and use information in its various forms (business data, voice conversations, still images, motion pictures, multimedia presentations, and other forms, including those not yet conceived) (American Hospital Association, Health Research & Educational Trust, and the Institute for Safe Medication Practices (2002)

**Computerized Physician Order Entry or Computerized Provider Order Entry (CPOE).** A networked computerized system that allows health care professionals to enter orders online. These orders include, but are not limited to, medications, diagnostic tests (clinical laboratory, imaging), nursing orders, and special orders (American Hospital Association, Health Research & Educational Trust, and the Institute for Safe Medication Practices (2002)

## **10. Impact of work pressure on patient safety**

The adverse events associated to work pressure.

**Production pressures** refer to the situations where the optimal care capacity is exceeded. (Harvey Murff)

### **11. Inadequate competences, training and skills**

A mismatch between the type or level of training, competencies and skills of the workforce and those as required by the health system (WHO)

**Competence** is the ability to perform some task (Wikipedia)

A **skill** is an ability, usually learned and acquired through training, to perform actions which achieve a desired outcome (Wikipedia)

**Training** refers to the acquisition of knowledge, skills, and competencies as a result of the teaching of vocational or practical skills and knowledge that relates to specific useful skills. It forms the core of apprenticeships and provides the backbone of content at technical colleges and polytechnics. Today it is often referred to as professional development (Wikipedia)

### **12. Inadequate manpower**

A mismatch between the type or level of health care providers needed to provide services

**Manpower:** The number of human productive units available/needed for professional or other tasks (Wikipedia)

### **13. Inadequate regulations**

There are insufficient, ineffective or lack of regulations or legal restrictions in relations to patient safety.

**Regulation:** A Legal restriction promulgated by governmental or quasi-governmental administrative agency through rulemaking supported by a threat of sanction or a fine (Wikipedia)

### **14. Lack of adequate test follow-up**

The absence or insufficient or ineffective observation, communication or action following a medical procedure or test

### **15. Lack of appropriate knowledge and transfer of knowledge**

Refers to a situation where access to needed knowledge is either absent, insufficient or ineffective and/or there is no effective mechanism for effective knowledge translation

**Knowledge translation:** The synthesis, exchange and application of knowledge by relevant stakeholders to accelerate the benefits of global and local innovation in strengthening health systems and improving people's health (WHO)

### **16. Lack of communication and coordination**

It refers to situations where the communication and/or coordination between the stakeholders involved in care processes are insufficient or ineffective to ensure patient safety

**Coordination:** A technique of social interaction where various processes are considered simultaneously and their evolution arranged for the optimum benefit of the whole (WHO WHR 2000)

**Communication:** is a process by which information is exchanged between or among individuals through a common system of symbols, signs, and behavior (Wikipedia)

### **17. Latent organizational failures**

Error that is removed from the direct control of the operator and includes things such as poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations. (American Hospital Association, Health Research & Educational Trust, and the Institute for Safe Medication Practices (2002))

## 18. Maternal and Newborn Care

It represents the synthesis of activities at different levels of the health care system and defines a basic set of health system interventions and activities needed before and during pregnancy, during delivery, and after delivery for mother and newborn. It outlines what can be done to prevent and manage the major obstetric complications in the community, at the health centre and at the hospital (**adapted from WHO**)

## 19. Misdiagnosis

The problem of incorrectly diagnosing a condition or health state, or of delaying the correct diagnosis), or of missing the correct diagnosis.

## 20. Patient adherence

**Patient Compliance** (or **Adherence**) in a medical context refers to a patient both agreeing to and then undergoing some part of their treatment program as advised by their doctor or other healthcare worker. Most commonly it is whether a patient takes their medication (**Drug compliance**), but may also apply to use of surgical appliances (e.g. compression stockings), chronic wound care, self-directed physiotherapy exercises, or attending for a course of therapy (e.g. counselling). (Wikipedia)

## 21. Patients' role in shaping the research agenda

The extent to which the participation of a patient influence the planning, implementation or the uptake of research

## 22. Pressure Sores / Decubitus Ulcers

**Decubitus ulcer:** A bed sore, a skin ulcer that comes from lying in one position too long so that the circulation in the skin is compromised by the pressure, particularly over a bony prominence such as the sacrum (sacral decubitus).

<http://www.medterms.com/script/main/art.asp?articlekey=20744>

**Pressure sore:** A sore area of skin that develops when the blood supply to it is cut off for more than two to three hours due to pressure on it and lack of movement  
<http://www.medterms.com/script/main/art.asp?articlekey=39827>

## 23. Procedures that lack human factors consideration built into design and operandi

**Human factors:** Study of the interrelationships between humans, the tools they use, and the environment in which they live and work. (**Kohn**) **NPSF**

**Medical procedures:** A series of steps taken to accomplish an end within the health care journey of a patient (a procedure: a particular course of action intended to achieve a result in the care of patients (Wikipedia))

## 24. Role of safety culture

The extent to which the organizational culture, that is an integrated pattern of individual and organizational behavior, based upon shared beliefs and values, contribute to patient safety

**Organizational culture, or corporate culture,** comprises the attitudes, experiences, beliefs and values of an organization (Wikipedia).

**Culture of safety:** an integrated pattern of individual and organizational behavior, based upon shared beliefs and values, that continuously seeks to minimize patient harm which may result from the processes of care delivery. (Aspden, 2004 in **Committee of Experts on Management of Safety and Quality in Health Care 2005**)

## 25. Safe injection practice

Those public health practices and policies which ensure that the process of injection carries the minimum of risk, regardless of the reason for the injection or the product injected. This is the preferred generic term for this subject. (WHO)

## **26. Stress and Fatigue**

**Stress:** is a physical or psychological stimulus that can produce mental or physiological reactions that may lead to illness. Technically speaking, stress is a disruption of homeostasis, which may be triggered by alarming experiences, either real or imaginary (wikipedia)

**Fatigue:** A condition characterized by a lessened capacity for work and reduced efficiency of accomplishment, usually accompanied by a feeling of weariness and tiredness. Fatigue can be acute and come on suddenly or chronic and persist.

## **27. Surgical errors**

The failure of a surgical procedure to be completed as intended causing or with a high probability of causing injury or harm.

## **28. Unsafe blood practices**

The opposite to Safe Blood Practices

**Safe Blood Practices:** The establishment of sustainable national blood programmes that can ensure the provision of safe, high quality blood and blood products that are accessible to all patients requiring transfusion and their safe and appropriate use. The WHO Blood Transfusion Safety team recommends the following integrated strategy to national health authorities: The formation of a nationally organized and managed blood programme ; promoting voluntary non-remunerated blood donation; Testing of all donated blood for transfusion transmitted infections (TTIs) such as HIV, Hepatitis B, Hepatitis C and Syphilis (WHO)