

# Medication Without Harm



**WHO Global Patient Safety Challenge**



**World Health  
Organization**

WHO/HIS/SDS/2017.6

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**Suggested citation.** Medication Without Harm - Global Patient Safety Challenge on Medication Safety. Geneva: World Health Organization, 2017. Licence: CC BY-NC-SA 3.0 IGO.

**Cataloguing-in-Publication (CIP) data.** CIP data are available at <http://apps.who.int/iris>.

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Designed by CommonSense, Greece

Printed by the WHO Document Production Services, Geneva, Switzerland

## Foreword



More than 10 years ago, with colleagues in the World Health Organization (WHO), I was involved in establishing the foundation programme of a global patient safety initiative that was the first of its kind. It was wide-ranging and led to the launching of two Global Patient Safety Challenges. It also created a programme led by patients and families who had suffered avoidable harm from health care, and it set a clear agenda for research and development, among many other areas of work aimed at improving safety globally.

In the last decade, the WHO Patient Safety Programme has raised awareness across the world of the key concepts and strategies in patient safety. It has inspired passion for the universal cause of making health care safer. It has secured commitment at the highest level among health ministers and health leaders in Member States of WHO. It has provided standards, evidence-based guidance and practical tools to support those involved in the design of patient safety programmes within countries' health care systems. It has championed the use of the stories of patients and families who have been the victims of unsafe care.

Significant portions of the Programme's initial work have been delivered and a new direction and new priorities are now required for the next phase in this programme. Moreover, the global context of patient safety as a science has evolved considerably since the creation of the Programme. At the time, there were few, if any, national agencies with a recognized mandate to work on patient safety and virtually no training and education programmes in patient safety globally. Currently, many Member States have active safety and quality programmes, campaigns and agencies, although some still ask the World Health Organization to provide implementation assistance.

The WHO Patient Safety Team has received strong feedback from major stakeholders and

experts that a third global patient safety challenge should be the first of these new priorities and would be greatly welcomed. The Global Patient Safety Challenge is essentially a programme of change aimed at improvement and risk reduction. The programme blends evidence-based interventions with multi-modal implementation strategies. They seek to achieve widespread engagement and commitment. They span the needs of all countries. They are most impressive when they develop the features of a social movement, as the first and second challenges managed to do.

I was delighted and honoured, two years ago, when Assistant Director-General, Dr Marie-Paule Kieny, asked me to advise on the design of a third Global Patient Safety Challenge on medication safety. Dr Kieny and WHO's Director-General, Dr Margaret Chan have given me, as well as the world's patient safety community, unfailing support in continuing to pursue the goal of safer care as a core component of universal health coverage. In the hard work of bringing this historic Challenge to life, the WHO Secretariat

and leading world experts and stakeholders have given invaluable advice and support. In participating in the work to create this third Global Patient Safety Challenge, I have been driven and inspired by three things. Firstly, an awareness of studies in the 1960s that identified sources of medication error that can, and do, kill and harm patients in hospitals around the world today, nearly sixty years on. Secondly, that there are many individuals and groups in the fields of pharmacy, medicine, nursing, and other professions, who have been fighting for decades to see the day when medication safety would become a global priority; their passion has always been to save lives from this long-standing intractable type of avoidable harm. Thirdly, over the years, I have spoken to many people who have lost loved ones to medication-related harm; their stories, their quiet dignity and their acceptance of situations that should never have arisen have moved me deeply. It is to the memories of all those who have died due to incidents of unsafe care that this Challenge should be dedicated.

**Sir Liam Donaldson**

WHO Envoy for Patient Safety



## Global Patient Safety Challenges

Global Patient Safety Challenges identify a patient safety burden that poses a significant risk to health, then develop frontline interventions and partner with countries to disseminate and implement the interventions. Each Challenge focuses on a topic that poses a major and significant risk to patient health and safety. WHO provides leadership and guidance in collaboration with Member States, stakeholders and experts, to develop and implement interventions and tools to reduce risk, improve safety and facilitate beneficial change.

### Previous Global Patient Safety Challenges

Beginning in 2004, the World Health Organization (WHO) working in partnership with the (then) World Alliance for Patient Safety, initiated the two previous Global Patient Safety Challenges: *Clean Care is Safer Care*, followed a few years later by *Safe Surgery Saves Lives*. Both aimed to gain worldwide commitment and spark action to reduce health care infection and risk associated with surgery, respectively.

The scale and speed of implementation of these Challenges remains unprecedented. They secured strong and rapid commitment from health ministers, professional bodies, regulators, health system leaders, civil society and health care practitioners. Their success resulted from the following solid basis and achievements:

- an evidence-based analysis of the key problems and proposed solutions;
- an invitation to Member States and other relevant parties to pledge, or sign up, to address the aims of the Challenge;
- high-profile actions to generate passion and enthusiasm;
- facilitation of implementation by the WHO Secretariat and associated experts and advisers;
- strong leadership and extensive internal and external communication.

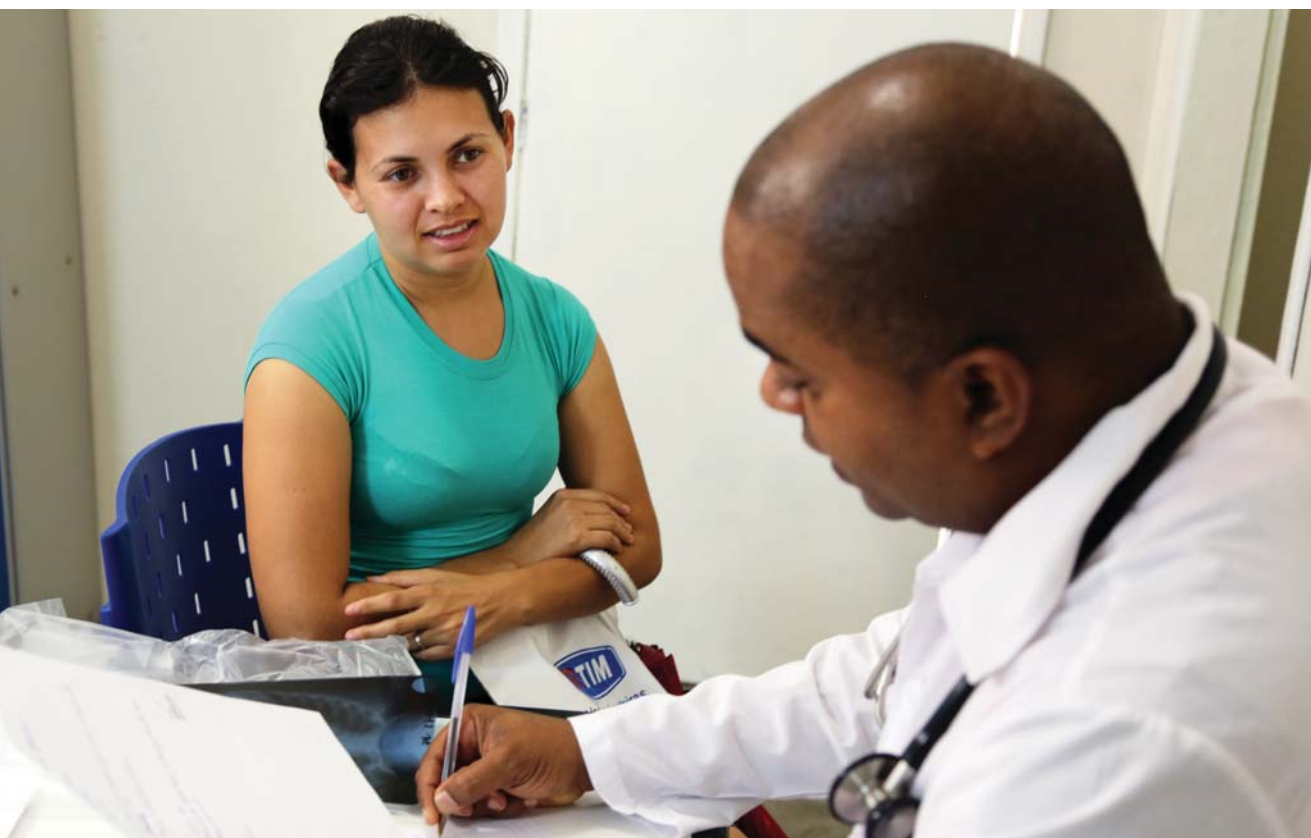
## The third Global Patient Safety Challenge

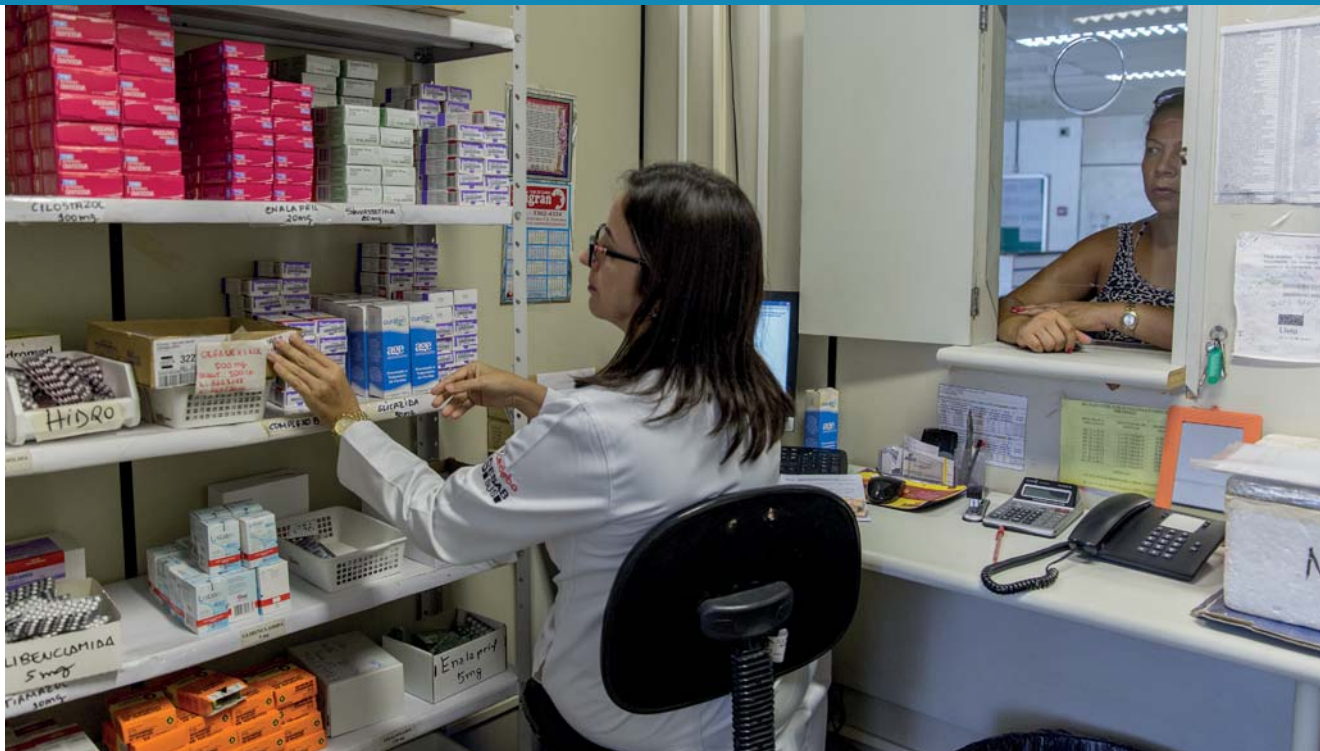
### Medication Without Harm

WHO is initiating the third Global Patient Safety Challenge with the theme of medication safety. It is set within the philosophy of patient safety previously developed by WHO, namely that errors are inevitable and provoked in large part by weak health systems, and so the challenge is to reduce their frequency and impact. The Challenge was launched in March 2017, at the Global Ministerial Summit on Patient Safety in Bonn, Germany. By seeking the commitment of high-level delegates, ministers of health and experts, the launch created an opportunity for leaders to drive change and work together to make real difference to the lives of patients, families and health workers at the frontline. This Challenge will draw on the experience accumulated during the previous Challenges and will drive a process of change to reduce patient harm generated by unsafe medication practices and medication errors.

Every person around the world will, at some point in their life, take medicines to prevent or treat illness. Medicine has forever altered our ability to live with disease and generally increased the duration of our lives. However, medicines do sometimes cause serious harm if taken incorrectly, monitored insufficiently or as the result of an error, accident or communication problem.

Experience from other high-risk industries, and WHO's longstanding work with experts in health care safety, demonstrate that human beings make mistakes rarely through neglect, but instead because the systems, processes and procedures that they work with are often flawed or dysfunctional. This inevitably gives rise to errors and medication harm is no exception to this rule. All medication errors are potentially avoidable. They can thus be greatly reduced or even prevented by





improving the systems and practices of medication, including ordering, prescription, preparation, dispensing, administration and monitoring. Given that the subject is so vast, the approach of this third Challenge aims to save lives and reduce the medication-related harm caused by unsafe practices and errors, by specifically addressing the weaknesses of service delivery and developing more effective health care systems.

### Severity of the problem

- Unsafe medication practices and medication errors are a leading cause of avoidable harm in health care systems across the world.
- The scale and nature of this harm differs between low-, middle- and high-income countries. Globally, the cost associated with medication errors has been estimated at US\$ 42 billion annually.
- Patients living in low-income countries experience twice as many disability-adjusted life years lost due to medication-related harm than those in high-income countries.
- Medication errors occur when weak medication systems and/or human factors such as fatigue, poor environmental conditions or staff shortages affect prescribing, transcribing, dispensing, administration and monitoring practices,

which can then result in severe harm, disability and even death.

- Errors occur most frequently during administration, however there are risks at different stages of the medication process.

### Overall goal

The Global Patient Safety Challenge on Medication Safety focuses on improving medication safety by strengthening the systems for reducing medication errors and avoidable medication-related harm.

## Reduce the level of severe, avoidable harm related to medications by 50% over 5 years, globally

The goal of the third Global Patient Safety Challenge on Medication Safety is to gain worldwide commitment and action to reduce severe, avoidable medication-related harm by 50% in the next five years, specifically by addressing harm resulting from errors or unsafe practices due to weaknesses in health systems. The Challenge aims to make improvements at each stage of the medication process, including prescribing, dispensing, administering, monitoring and use.



## Objectives of the Global Challenge on Medication Safety

The Global Patient Safety Challenge on Medication Safety will facilitate a strengthening of systems and practices that can initiate corrective action within countries to improve patient safety and decrease avoidable harm related to medications.

In order to achieve this, the Challenge will adopt five specific objectives.

- 1. ASSESS** the scope and nature of avoidable harm and strengthen the monitoring systems to detect and track this harm.
- 2. CREATE** a framework for action aimed at patients, health professionals and Member States, to facilitate improvements in ordering, prescribing, preparation,

dispensing, administration and monitoring practices, which can be adopted and adapted by Member States.

- 3. DEVELOP** guidance, materials, technologies and tools to support the setting up of safer medication use systems for reducing medication errors.

- 4. ENGAGE** key stakeholders, partners and industry to raise awareness of the problem and actively pursue efforts to improve medication safety.

- 5. EMPOWER** patients, families and their carers to become actively involved and engaged in treatment or care decisions, ask questions, spot errors and effectively manage their medications.



## Shaping the Challenge – the Strategic Framework

The lessons for success drawn from earlier Global Patient Safety Challenges include high visibility, political and professional commitment, multileveled ‘spearheading’ interventions and WHO’s ability to lead and mobilize the global community to reach the proposed goals. The Strategic Framework for this Challenge should galvanize commitment to reduce medication errors and medication-related harm and strengthen measurement and safety monitoring systems.

Four fundamental problems lay the ground for the strategic framework:

- **Patients and the public** are not always medication-wise. They are too often made to be passive recipients of medicines and not informed and empowered to play their part in making the process of medication safer.
- **Medicines** are sometimes complex and can be puzzling in their names, or packaging and sometimes lack sufficient or clear

information. Confusing ‘look-alike sound-alike’ medicines names and/or labelling and packaging are frequent sources of error and medication-related harm that can be addressed.

- **Health care professionals** sometimes prescribe and administer medicines in ways and circumstances that increase the risk of harm to patients.
- **Systems and practices of medication** are complex and often dysfunctional, and can be made more resilient to risk and harm if they are well understood and designed.

The actions planned in this Challenge are based on four domains of work, one for each fundamental problem identified. These are:

- patients and the public
- medicines
- health care professionals
- systems and practices of medication.

In each of these domains, there are many ways in which using medications can cause avoidable harm. There are many ways, too, in which care could be made safer.





## Key action areas

The actions embraced by the Challenge fall into three categories:

**Early priority actions.** Ask countries and key stakeholders to make strong commitments, prioritize and take early action, and effectively manage three key areas to protect patients from harm, namely:

- high-risk situations
- polypharmacy
- transitions of care

**Developmental programmes.** Ask countries to convene experts, health care professionals and leaders, key stakeholders and patient representatives to design targeted programmes of change and take action to improve safety in each of the four domains of the Challenge framework: 1) patients and the public; 2) medicines; 3) health care professionals; and 4) systems and practices of medication.

**Global action.** WHO aims:

- a) to provide guidance and develop strategies, plans and tools to ensure that the medication process has the safety of patients at its core, in all health care settings;
- b) to strengthen human resource capacity through leadership development and skill-building;
- c) to strengthen the quality of monitoring data;
- d) to promote and support research in this area as part of the overall agenda of patient safety research;
- e) to continue engaging with regulatory agencies and international actors and continuously improve medication safety through improved packaging and labelling; and
- f) to develop mechanisms for the engagement and empowerment of patients to safely manage their own medications.



## A mother's call for medication without harm

My oldest daughter, Martha went to study nursing with a strong desire of caring for the sick. But she had some health concerns of her own. She had chronic hypokalemia or low potassium that required supplementation from time to time and her EKG's were always abnormal. Even when further cardiac tests were done, the abnormal results were seen as normal for her and the results were simply filed away, and Martha and I remained unaware of her heart condition. Later, she developed mood swings that were seen as symptoms of bipolar affective disorder and she was prescribed lithium which helped to regulate her moods. We read the information sheet together and looked up the drug online, but we were not aware of a warning in her medical file specifically advising against prescribing lithium and we were not told of severe adverse reactions to look for. Even though her heart began to race at times, the lithium dosage was increased. Then 13 days later, her father went to wake her up one morning, and found Martha on her bedroom floor where she had died. She had not been able to get to the door to call for help. At just twenty-two years old,

our daughter had suffered a fatal cardiac arrhythmia.

Although a tragic series of medical errors and the adverse medication reaction took Martha's life, no reporting took place and her death was simply identified as 'natural'. It took six years of great effort, extensive media coverage, and two further death reviews to finalize Martha's death investigation and create meaningful changes to help prevent similar fatalities. So as patients and families, what can we do to help avoid medication-related harm? There are two things that stand out: 1) We can encourage reporting and can even report an adverse medication event ourselves; and 2) We can take an active role in the patient's own medical care and medication management.

Let's honour those like Martha who have been harmed, not by covering up what happened, but by demanding transparency and centralized reporting so these tragic events can lead to improved medication safety for everyone.

## High-risk situations

The impact of medication errors is greater in certain clinical circumstances, such as with inpatients in hospital, rather than in ambulatory care. This may be related to the more acute or serious clinical situations in these settings and the use of more complex medication regimes. Young children and the elderly are more susceptible to adverse outcomes, as well as those with concomitant kidney or liver disease. Medication errors in these circumstances often involve the administration of the wrong dose, use of the wrong route, and a failure to follow treatment regimens.

Understanding the situations where the evidence shows there is higher risk of harm from particular medicines, is key to this Challenge. Tools and technologies may help health care professionals using high-alert medications (those that are associated with a high risk of severe harm if used improperly), and also enhance patient knowledge and understanding of these medications.

## Polypharmacy

Polypharmacy is the routine use of four or more over-the-counter, prescription and/or traditional medications at the same time by a patient. Polypharmacy has increased dramatically with greater life expectancy and as older people live with several chronic diseases. Polypharmacy increases the likelihood of side effects, as well as the risk of interactions between medications, and may make adherence more difficult. If a patient requires many medicines, they must be utilized in an optimal manner, so that

the medicines are appropriately prescribed and administered, to ensure that they produce direct and measurable benefits with minimal side effects. The standardization of policies, procedures and protocols is critical to polypharmacy. This applies from initial prescribing practices, to regular medication reviews.

Patients can play a vital part if provided with the right information, tools and resources to make informed decisions about their medicines. Technology can also serve as a useful aid.

## Transitions of care

Transitions of care occur when a patient moves between facilities, sectors and staff members; for example: a transfer from the emergency room to the intensive care unit, from a nursing home to a hospital, from a primary care doctor to a specialist, or from one nurse to another during a shift change. Transitions of care increase the possibility of communication errors, which can lead to serious medication errors. Patients are at increased risk during transitions of care and so serious mistakes can and do occur at these times, in particular.

Good communication is vital, including a formal comparison of medicines pre- and post-care, so-called medication reconciliation. Patients can be valuable and active participants in this process by maintaining a current medicine list that is updated when any medicine changes occur.



## Political leadership, commitment and support

The third Global Patient Safety Challenge on Medication Safety invites WHO Member States to prioritize medication safety at the national level. Demonstrable commitment and leadership are needed to significantly reduce the level of severe, avoidable harm related to medications in their countries over a period of five years. The emphasis is on countries working out their own priorities and action programmes using the Challenge framework to support their work.

A five-point plan has been developed to facilitate adoption:

1. Take early action to protect patients from harm arising from: high-risk situations; polypharmacy; and transitions of care.
2. Convene national experts, health system leaders and practitioners to produce guidance and action plans for each of the targeted domains.
3. Put mechanisms in place, including the use of tools and technologies, to enhance patient awareness and knowledge about medicines and medication use process, and patients' role in managing their own medications safely.
4. Designate a national coordinator to spearhead the Global Patient Safety Challenge on Medication Safety.
5. Assess progress regularly.

The success of the Challenge will depend on the high prioritization of medication safety within health care systems, achieving widespread buy-in by stakeholders, a shift to the mainstream of care provision activities and taking concrete action to prevent harm.





## WHO action

In driving forward the Global Patient Safety Challenge on Medication Safety, WHO will provide support in 10 key areas:

1. Lead the process of change and take global action to make progress on the domains of the Challenge framework.
2. Facilitate the development and implementation of country programmes.
3. Commission expert reports to provide a starting point for in-country work to develop guidance and action plans in each of the domains of the Challenge.
4. Develop strategies, guidelines, plans and tools to ensure safety of medication practices.
5. Publish a strategy setting out research priorities and mobilize resources for an international research study on hospital admissions due to medication effects.
6. Hold regional launch events in each WHO region following on from the global launch.
7. Create and implement a communications and advocacy strategy and a global campaign, and produce promotional and educational materials.
8. As part of the WHO Patients for Patient Safety programme, ensure that patients and families are closely involved in all aspects of the Challenge and develop a tool to help patients protect themselves from harm.
9. Monitor and evaluate impact of the Challenge.
10. Mobilize resources to enable full and successful implementation of the Challenge.

Throughout the implementation process, WHO will also seek to develop a much greater understanding of the special problems of medication-related harm in low- and middle-income countries and to reshape the Challenge to meet needs in diverse settings.

## Collaboration and partnerships

Working with international experts, partners and interested stakeholders, WHO will develop the guidelines, tools, technologies and materials needed, and work in close collaboration with countries to implement the Challenge.

### Who should act as a catalyst for change?

Ministries of health and health system leaders  
Educational and research institutions  
Regulatory authorities  
Health care professional societies  
Patient advocacy groups  
Donors and development partners  
Pharmaceutical industry

In addressing the overall goal and action areas of the Challenge, WHO will work with a wide range of stakeholders including: ministries of health, national coordinators or programme managers for medication safety, health system leaders, experts, educational institutions, researchers, safe medication practice centres, regulatory agencies, patient representative bodies and professional societies and industry.





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