

### **Frequently Asked Questions**

#### What is a medical error?

A medical error is an incident that happens by mistake during medical care which may, but does not necessarily, result in temporary or permanent, physical, or psychological harm to an individual. An example of this might be the administration of an incorrect dose of medication to a patient.

#### How common are medical errors?

The WHO has estimated that as many as 1 in 10 patients are harmed while receiving hospital care in developed countries and predicts that the probability of patients being harmed in developing countries is even higher.<sup>1</sup>

## How can patients minimize their risk of being affected by a medical error?

Whilst there is no guarantee that an error will not occur, if patients know more about their healthcare they are more likely to notice when something is wrong and have the confidence to speak up. To minimize the risk of being affected by a medical error, patients can:

- Keep the healthcare team informed of any important health information about themselves
- Ask for information about their care and medicines in terms they can understand
- When in hospital, check that those in close contact with them have washed their hands
- When being discharged, ask the doctor to explain the home treatment plan
- Before surgery, make sure the doctor and other surgeons agree with them and are clear on what procedure will be carried out

## What should patients do if they experience a medical error?

If a patient has been injured during treatment it is important first to make sure that they are receiving the right treatment to try and correct the injury. The patient may need to get a second opinion or ask their doctor to refer them to another hospital or clinic. The patient will probably be feeling distressed and confused by what has happened, and in need of advice, information and support. This could be from friends or family or from specialist support groups. The patient could also talk to their health professional about what has happened to see if they can help.

#### What else can patients and patients' organizations do?

After steps have been taken to address their immediate health needs, patients or their family members need to consider what they want to do next. They might want:

- An explanation and/or an apology
- To make sure that the same mistake is not made again (which might include initiating changes in policies and procedures such as staff training, for example); and/or
- Some form of legal proceedings or compensation

There are a number of actions that can be taken to address these wishes, including writing to, or approaching, the particular centre or healthcare professional involved in the treatment to request an explanation or apology, or to request that they address the problems that led to the medical error so that it does not happen again to someone else.

Both patients and patients' organizations can drive improvements in healthcare and thereby help to minimize the chances that the same error will happen again to another person by taking action when an error occurs. Action can be taken, at a number of levels, with health professional regulatory bodies, the hospital itself or with Ministries of Health and government departments.

If a patient is considering pursuing legal proceedings or seeking compensation, they might first think of getting legal advice to see if there is a case for a legal claim. Taking legal action is often a long and complicated procedure and usually related to securing monetary compensation.

<sup>1</sup> WHO, 'Ten Facts on Patient Safety'. Available at: www.who.int/features/factfiles/patient\_safety/en/index.html

▶ These Frequently Asked Questions (FAQs) can be photocopied and distributed to individuals or organizations to provide basic information on medical error. Further information on this issue can be found in the relevant section of the main booklet in this Toolkit and in the Checklist overleaf, which is designed to be shared with patients. All sections of this Toolkit are also available electronically on the accompanying CD-ROM.



Notes:

Most medical treatment is carried out with considerable care and skill. Nonetheless, occasionally mistakes are made during medical care which may lead to harm to an individual. Below are some simple steps that you can take to protect yourself and your family from the effects of medical error.

- 1. Fully discuss the risks involved in any proposed treatment, and any alternatives, with your doctor, or other health professional treating you. Make sure you discuss this at a time when you can take it in. If necessary, make a second appointment to discuss it and consider taking someone with you. Ask for written material about the treatment and alternatives or references for reputable websites. Consider contacting a support group for the kind of condition being treated, to talk to others who have experienced it.
- 2. Ask your doctor (or treating health professional) how experienced they are at the treatment (especially surgery) being considered. How many times have they performed this procedure and how recently? What are the benefits and potential risks involved? Will they personally be carrying out the procedure? If not, who will?
- **3.** Do not be afraid to ask anyone treating you whether they have washed their hands. Hospital acquired infections are a very common problem affecting patients and it estimated that if hands were washed every time before touching patients, infection rates could be greatly reduced.
- 4. If something does go wrong, get treatment, advice and support. The most important immediate issue is to ensure that you receive appropriate treatment following the injury. The next step can be to seek recognition for what has happened. First speak to your health professional and the manager of the establishment where the error occurred. If you do not receive the information, treatment or the apology you need, then contact a patient group or get legal advice as appropriate.

Adapted from Action Against Medical Accidents - Safety Tips: Tips on how to protect yourself and your family. Available at: www.avma.org.uk

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### **Frequently Asked Questions**

## Why is it important that patients take their medicines correctly?

Medicines are made of active ingredients which need to be taken in the correct dose and at the correct frequency, as prescribed by their doctor or health professional, in order to work effectively. If medicines are not taken correctly, then the patient has less chance of experiencing an improvement in their health, or if an incorrect dose is taken or if medicines are taken in combination without the doctor's or health professional's advice, they can be dangerous.

#### How prevalent is the incorrect use of medicines?

It is estimated that in developed countries only 50% of patients with chronic disease take their medicines as directed. In developing countries, where there is often inferior access to healthcare and limited access to medicines, poor adherence seriously affects efforts to address chronic conditions.<sup>1</sup>

## Where can a patient find out how to take them correctly?

Instructions on the packaging of the medicine or in a separate leaflet should provide the patient with clear and reliable information on how to take the contents safely. A patient's doctor, health professional and/or pharmacist should also be able to tell them how to take their medicines correctly.

## What happens if a patient does not take their medicines properly?

Missing a dose can cause the concentration of the medicine in the body to drop and the effect of the medicine on the body to decrease. It might cause a return or worsening of the patient's symptoms or change how their medicine works. For example, missed doses of glaucoma medicine can lead to optic nerve damage or blindness, and missed doses of heart medicine can lead to cardiac arrest. Most medicines do not cause serious unwanted effects if a slightly different dose is taken by mistake. If this does happen, the patient should contact their doctor or health professional, as in some cases there may be serious symptoms, such as difficulty breathing or unconsciousness.<sup>2</sup>

### What should a patient do if they miss a dose or overdose?

If a patient has any concerns, they should seek medical advice either from a health professional such as a doctor, nurse or pharmacist or from a hospital or clinic.

## What can patients do to reduce the risk of taking medicines incorrectly?

The best thing a patient can do to avoid a mistake with their medicine is to ensure that they take an active interest in their healthcare. Patients should ask their doctor or health professional questions about what they are taking and how they should take it. If patients do not understand the language or terms used, they should ask for further explanation. Patients may be too ill or not have the capacity to do this (for example, young children). A family member or other advocate can also be included in healthcare consultations. The provision of good verbal and written information to patients is important in ensuring that they take their medicines correctly and safely.

# How can patients' organizations and health professionals provide good quality information to patients?

Low health literacy affects a person's ability to make informed decisions about his or her health and can result in the ineffective treatment and rehabilitation of a patient's condition. Poor levels of health literacy exist in all countries. Health literacy can include an individual's reading level, as well as language, education level, cultural background and readiness to receive health information by oral or visual means. All these factors may create barriers to understanding, and therefore to individuals' ability to take action to improve their health.<sup>3</sup> In the development and provision of health information to patients, the consideration of health literacy principles can help ensure that information materials appropriately address the information needs of patients.

Health information, whether posters, brochures, pamphlets, audio, video or television material, should incorporate the following health literacy principles:

- A clear and understandable message
- Relevant and tailored content
- A culturally and linguistically appropriate format
- Reader, viewer or listener involvement
- Pilot testing on key audiences

<sup>1</sup> World Health Organization (2003), Adherence to Long-Term Therapies: Evidence for Action.

<sup>2</sup> NHS Direct, 'Common Health Questions'. Available at: www.nhsdirect.nhs.uk/questions

<sup>3</sup> IAPO Policy Statement on Health Literacy (2002). Available at: www.patientsorganizations.org/healthliteracy

▶ These Frequently Asked Questions (FAQs) can be photocopied and distributed to individuals or organizations to provide basic information on taking medicines correctly. Further information on this issue can be found in the relevant section of the main booklet in this Toolkit and in the Checklist overleaf, which is designed to be shared with patients. All sections of this Toolkit are also available electronically on the accompanying CD-ROM.



Below are some points that you can consider when taking your medicines so that you know why they are necessary and how to take them.

- 1. Ask your health professional why it is necessary to take the medicine and the benefits, or potential side effects, you can expect.
- 2. Clarify with your health professional the instructions for taking the medicine, whether it can be taken in combination with other medicines, and take it as prescribed.
- **3.** Check whether the medicine will make you feel drowsy and that it is safe to drive or continue with certain activities that may be affected by your medication.
- 4. Check that you understand everything the health professional has told you and if not, ask for it to be explained again. Make notes, take a family member or friend with you and/or ask if there is any printed information that you can take home with you.
- 5. Buy medicines from a known and reliable pharmacy or source. Check your medicine to see if there are any signs of tampering and to see that it is within the expiry date. If you are not sure, speak to your pharmacist.
- 6. Read any attached or inserted medicine information leaflet before taking the first dose.
- 7. Keep a list of your medicines: what the doses are, when and how to take them, and what they are for.
- 8. Always store medication in the correct conditions, e.g. in a cool, dry place, a refrigerator or protected from the light.
- 9. Never stop or alter your medication without professional medical advice. If a dose is missed, or you take too much, do not try to guess how to rectify it, ask your health professional.
- **10.** If your condition does not improve, or worsens, talk to your doctor and ask why.

Notes:

Inis Checklist provides simple steps you can take as a patient or family member to help you or your family be confident that you are taking your medicines correctly. This document can be photocopied and distributed to patients, their families and carers to provide basic information on taking medicines correctly. Further information on this issue can be found in the relevant section of the main booklet in this Toolkit and in the Frequently Asked Questions overleaf. All sections of this Toolkit are also available electronically on the accompanying CD-ROM.



### **Frequently Asked Questions**

#### What is a hospital acquired infection?

Hospital acquired infections (HAIs) are largely avoidable infections that are picked up whilst staying in hospital and are usually caused by bacteria but can be caused by viruses (e.g. hepatitis B, HIV, chickenpox and norovirus). The most well-known bacteria are Meticillin-resistant Staphylococcus aureus (MRSA) and Clostridium difficile (C difficile). Others include: the non-resistant Staphylococcus aureus (in some countries this may be referred to as Meticillin-sensitive Staphylococcus aureus – MSSA); Pseudomonas; Escherichia coli (E coli); Streptococcus; and Klebsiella.

## What are the risks of contracting a hospital acquired infection?

Between 5% and 10% of patients admitted to modern hospitals in the developed world acquire one or more infections.<sup>1</sup> The incidence of healthcare associated infections (which include hospital acquired infections) is thought to be as much as 20 times higher in developing countries than in developed countries.<sup>2</sup>

#### How serious are hospital acquired infections?

The effects of hospital acquired infections vary, influenced by a person's health and treatment, but in the most serious cases can cause death. One of the most well known in the developed world is MRSA, which can cause a range of infections, depending on the state of health of the person affected, whether they have had surgery, have an existing medical condition, or a weakened immune system.

## What are the symptoms or effects of hospital acquired infections?

Symptoms vary depending upon the type of infection and the bacteria involved, but may involve diarrhea, fever, soreness, discomfort, skin redness and/or presence of pus within wounds.

#### Who is at risk of contracting them?

Anyone who is in hospital receiving care or treatment can contract a hospital acquired infection. However, they present a greater risk to people with weaker immune systems, perhaps either due to an underlying condition, such as cancer, or to the medication or antibiotics they are taking for another infection, which can make them susceptible to other infections and make it easier for other bacteria to thrive. The very old and the very young can also be more prone to hospital acquired infections.

#### How are they spread?

Hospital acquired infections are spread in the following ways:

- By hands: usually the hands of care workers having contact with the patient and their immediate environment (this usually refers to clinical staff, but in some countries family members provide the majority of care and therefore hand hygiene is very important in these settings)
- Through devices (e.g. drips and catheters) or procedures that break the skin

- By being exposed to infected blood and body fluids
- In the air

#### Can healthy people carry hospital acquired infections?

Healthy people can carry the bacteria which can cause hospital acquired infections in vulnerable patients. Staphylococcus aureus, for example, is common and can live harmlessly on the skin, and in nasal passages. Other bacteria can live normally in the bowel without causing a problem.

#### Can hospital acquired infections be treated?

Yes. Infections can be treated with antibiotics. Depending on the severity of the infection, antibiotics will be given as tablets, or in severe infection, via a drip.

## If a hospital acquired infection is contracted what should happen?

The first action of any health professional should be to address the infection with the appropriate treatment. Following this, steps should be taken to minimize the possibility of it spreading to other patients.

#### What can be done to reduce the spread of infection?

Many healthcare organizations have systems, policies and an infrastructure aimed at managing hospital acquired infections. One of the simplest but most important measures which can be taken in hospital to protect patients from harm is good compliance with hand hygiene by healthcare workers. A clean environment is also important. Healthcare workers should also wear protective clothes (aprons and gloves) when in contact with body fluids, and adhere to aseptic procedures. Together, this bundle of measures is designed to keep patients safe.

Strains of some bacterial infections are becoming increasingly resistant to disinfectants and antibiotics. Antibiotic policies are important in addressing this, together with good cleaning and hand hygiene.

 <sup>1</sup> World Health Organization (WHO). Available at: www.who.int/entity/patientsafety/events/06/CC\_factsheet.pdf
<sup>2</sup> WHO, 'Ten Facts on Patient Safety'. Available at: www.who.int/features/factfiles/patient\_safety/en/index.html

**Y** These Frequently Asked Questions (FAQs) can be photocopied and distributed to individuals or organizations to provide basic information on hospital acquired infections. Further information on this issue can be found in the relevant section of the main booklet in this Toolkit and in the Checklist overleaf, which is designed to be shared with patients. All sections of this Toolkit are also available electronically on the accompanying CD-ROM.



Minimize your risk of hospital acquired infections by considering the points below when going into hospital.

- 1. Tell the hospital about any antibiotics taken in the 60 days prior to admission.
- 2. Be vigilant at all times that healthcare professionals clean their hands before and after touching you. If they don't ask them to do so. More and more hospitals are encouraging patients to ask about hand hygiene. They can clean their hands using either soap and water or, if available, handrubs are an ideal method for hand hygiene.
- 3. If visitors have contact with your wounds or devices, they should clean their hands in some countries visitors play a central role in providing care and hand hygiene should be encouraged in these instances.
- 4. If you find the area around your bed, your bed linen or your bathroom is dirty and/or dusty, insist that it is cleaned immediately. It should not be necessary to clean the area around your bed. However, some people may feel safer if they have their own wipes and clean down surfaces.
- 5. Gloves should be worn by healthcare professionals if there is a risk of exposure to blood or bodily fluids. If they are not ask them to do so.
- 6. Ensure any cuts or minor abrasions are properly cleaned and covered until healed.
- 7. Wash your hands after using the toilet, before and after eating, and avoid contact with other people's bandages and wounds.
- 8. If you experience fever, soreness or discomfort, always inform a healthcare professional and keep telling them if you do not feel right.
- 9. Visitors should not come into hospital if they feel unwell, e.g. if they have a cold or other minor illness if in doubt check with one of the nurses.
- 10. If you feel that any healthcare professional is not taking any notice of you or are making you feel that you should not be making requests, then ask to speak with a more senior staff member or the manager. Hospital acquired infections are a serious problem and hospitals will want to deliver safe and quality care.

Adapted from information from National Concern for Healthcare Infections (www.nc-hi.com).

Notes:

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## The Quality and Safety of Medicines



### **Frequently Asked Questions**

## How do drug manufacturers ensure that their products meet safety requirements?

The pharmaceutical and other healthcare industries conduct trials of new medical treatments in both healthy people and patients who suffer from the disease under investigation. The trial investigates whether the medicine works as it is expected to, whether it causes adverse effects and how serious such adverse drug reactions (ADRs) may be. Prior to this, the candidate medicine will have been through pre-clinical testing in animals.

Trial data is submitted to regulatory authorities, who rigorously scrutinize results before a decision is made on whether to grant the medicine a licence to be marketed. Safety monitoring continues even after a medicine reaches the market as some adverse events will only become apparent when the medicine is used extensively in large numbers of patients.

#### How should patients report an adverse drug reaction?

Patients should first report their adverse drug reaction to their health professional. Many countries require health professionals to report adverse drug reactions through Case Report Forms (CRFs), which are obtained from the National Drug Regulatory Authority. There are different CRFs in different countries. Further information on CRFs can be found in the WHO Safety of Medicines: A guide to detecting and reporting adverse drug reactions:

http://whqlibdoc.who.int/hq/2002/WHO\_EDM\_QSM\_2002.2.pdf

## How can the patient personally take measures to ensure the safety of their medicine?

The patient should make sure they are clear about how and when to take their medicines following the advice of their doctor or health professional. Patients should make sure they buy their medicines from a known and reliable source. If buying medicines on the internet, patients should exercise caution and check the legitimacy of the pharmacy, as there is a greater chance of receiving a substandard medicine or even a counterfeit.

#### What is a counterfeit medicine?

A counterfeit medicine is one whose ingredients and/or composition are deliberately mislabelled with respect to identity or source. Counterfeit medicines may:

- Contain the correct ingredient but have fake packaging or labelling
- Contain the wrong ingredients
- Not contain an active ingredient or have too little or too much active ingredient

#### How can patients spot a counterfeit medicine?

 Be familiar with the size, colour, taste and packaging of their medicine, and if anything is different to ask their pharmacist or healthcare professional

- Be wary if the packaging has been tampered with or appears to be damaged
- Know what changes to expect from medicine and when: if nothing happens or their condition worsens, patients should speak to their healthcare professional

## What should patients do if they believe their medicine may be counterfeit?

- Retain the medication and packaging and return it to their pharmacist, explaining why they suspect it might be a counterfeit
- The health professional should be the first person a patient goes to regarding a possible counterfeit medicine; however, individual patients or patients' organizations may consider it important to inform the relevant authority, e.g. the FDA in the USA or the EMEA in Europe or the Therapeutic Goods Association in Australia, for example. If there is no relevant authority, they can either contact the WHO representative or see the Rapid Alert website at: http://218.111.249.28/ras/default.asp
- The company which makes the medicine can also be informed that a counterfeit is suspected. The company's contact details can be found on the internet

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Minimize your risk of taking substandard or counterfeit medicines by considering the points below when purchasing and taking your medicines.

- 1. Make sure you understand what the medicine you take is supposed to do and how your condition should improve by taking it.
- 2. Ensure you are very clear on how to take your medicine and for how long. Ask if you have any doubts.
- 3. Make sure you buy your medicine from a known and reliable source. If buying medicines on the internet you have a greater chance of receiving a substandard medicine or even a counterfeit.
- 4. Be familiar with the size, taste, smell, colour, the patient leaflet and packaging of your medicines and check the expiry date.
- 5. Be alert to your symptoms. If your condition does not improve or worsens, tell your healthcare professional.
- 6. If you suspect a medicine is counterfeit then do not take it. Retain the medicine and the packaging and return to your pharmacy or health professional. You can also report it to a patient group, your regulatory authority, or the WHO Rapid Alert monitoring system: http://218.111.249.28/ras/default.asp

Notes:

This Checklist provides simple steps you can take as a patient or family member to protect yourself and your family from the risk and effects of ubstandard and counterfeit medicines. This document can be photocopied and distributed to patients, their families and carers to provide basic information on the quality and safety of medicines. Further information on this issue can be found in the relevant section of the main booklet in this booklet in this booklet and in the Frequently Asked Questions overleaf. All sections of this Tooklit are also available electronically on the accompanying CD-ROM.