Addressing Global Patient Safety Issues
An Advocacy Toolkit for Patients’ Organizations

Advocate  Educate  Raise awareness

International Alliance of Patients’ Organizations
A global voice for patients
Introduction

Medical Error

Taking Medicines Correctly

Hospital Acquired Infections

The Quality and Safety of Medicines

Injection Safety

The Reuse of Single-Use Medical Devices

Maternal and Child Health and Safety

Patient Participation in Clinical Trials

Advocacy and Partnerships

Communications

Glossary of Abbreviations and Terminology

Acknowledgements
When we receive healthcare, we expect it to be safe. However, this is not always the case, with patient safety incidents affecting patients around the world, regardless of the status of national healthcare systems. The safety of patients can be compromised in many ways, including medical errors, counterfeit or substandard medicines, inadequate cleanliness of hospitals, and medicines not being taken correctly by patients.

The prevalence of patient safety incidents is shocking. The rate of adverse events in hospitals in the UK, New Zealand and Canada is estimated to be around 10% (one in ten people that stay in hospital). The human cost is unacceptable but the financial cost is also significant: in 1999 the Institute of Medicine in the United States of America published the report ‘To Err is Human: Building a Safer Health System’, in which they estimated that the cost of medical error was up to US$29 billion per year in hospitals nationwide.

IAPO’s Declaration on Patient-Centred Healthcare highlights a number of basic principles of healthcare that are relevant to patients all over the world: the right to quality and safe healthcare; and to have an opportunity to be involved in shaping healthcare policy and finding solutions to healthcare problems. Increasingly, patients and patients’ organizations are playing a pivotal role in bringing about changes that improve the safety of healthcare. We can all be part of this change.

The patient safety issues addressed in this Toolkit are those prioritized by IAPO members. The tools and information contained within will help you to build partnerships, advocate for safer care, provide information to patients and raise awareness of patient safety issues.

We hope you find our Toolkit useful. Please provide any feedback and suggestions to IAPO by emailing us at: info@patientsorganizations.org

Good luck!

International Alliance of Patients’ Organizations

1 World Alliance for Patient Safety 2005 Forward Programme.
2 Including the expense of additional care necessitated by errors, lost income and household productivity, and disability.
ACT NOW!

What can you do? There are many simple actions that your organization can take to raise awareness of patient safety. Use the ACT NOW! messages in the issue-specific sections of this booklet to support your advocacy initiatives. Consider the following simple advocacy techniques, which you might use on their own or as part of a wider campaign. The ACT NOW! messages incorporate three activity areas:

1. Advocate

Advocate for patient involvement in healthcare policy-making to improve patient safety.

It is only with the effective engagement of patients and patient advocates at all levels of healthcare policy decision-making that patients’ needs will be listened to and acted upon.

What can you ask for?
Advocate for patients to be involved at every level of healthcare – individual, organizational and health system level. Ask for patient advocates to be on boards of organizations, hospitals, health professional bodies and other decision-making bodies. Also advocate for research into the benefits of patient engagement in patient safety at all levels.

What tools in this Toolkit can help you?
- The IAPO Policy Statement and Guidelines on Patient Involvement (CD-ROM)
- The IAPO Declaration on Patient-Centred Healthcare (CD-ROM)
- The PFPS London Declaration (CD-ROM)

2. Advocate on specific patient safety issues to governments, hospitals and health professional organizations.

What can you do?
Get patient safety onto the political agenda and address specific patient safety concerns – write a letter to your hospital or government explaining your patient safety concerns and outlining the action that you would like them to take.

What tools can help you?
- Read the issue-specific sections of this booklet
- Use the letter to governments as a template for your own letters to follow up on a patient safety incident or concern (CD-ROM)

3. Partner and get involved with other patient safety initiatives – by working together we will be more effective.

What tools can help you?
- Read the Advocacy and Partnerships section of this booklet for details on some current initiatives and how to develop productive partnerships. You can partner with other patient groups, healthcare providers, health professional bodies and others

1. Provide information to patients to help them protect themselves from patient safety incidents.

Develop and/or distribute posters and leaflets through your networks, and to hospitals and healthcare settings.

What tools can help you?
- Read the issue-specific sections of this booklet
- Copy or adapt and distribute the Checklists on the patient safety issues (inserts or CD-ROM)
- Read the Communications section of this booklet for tips on communicating information to patients
- Read the IAPO Policy Statement and Guidelines on Health Literacy (CD-ROM)

2. Provide education on patient safety and patient safety issues and the value of involving patients in patient safety initiatives.
Hold a workshop on patient safety or a specific patient safety issue. Present on patient safety and engagement at conferences and meetings.

**What tools can help you?**
- PowerPoint presentation templates – tailor the workshop presentation to suit your audience, whether health professionals, hospital managers, patients or others
- Copy or adapt and distribute the Frequently Asked Questions (FAQs) inserts on patient safety issues (inserts or CD-ROM)

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**Raise awareness of patient safety with the media and the public**

1. Add a news item about patient safety to your website or develop a patient safety webpage on your website – aim to keep this updated.

2. Write and distribute a press release to the media highlighting your patient safety concerns and actions you would like to be taken.

**What tools can help you?**
- Read the Communications section of this booklet for tips and develop partnerships with the media such as newspapers, magazines, film-makers, journalists and radio, and ask them to do an interview with you or others on patient safety, or a film showing patient safety concerns
- Adapt the press release template (CD-ROM) and distribute to your networks and ask your networks to speak to their local media about it

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**Talk about the importance of improving patient safety and the value of patient involvement in patient safety at all appropriate opportunities!**

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**With our thanks**

IAPO would like to thank all those involved in this Toolkit, both in planning and supporting its development. A full list of acknowledgements can be found at the end of this booklet. The production of this Toolkit has been made possible thanks to an educational grant from F. Hoffmann-La Roche.

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ACT NOW!
Use these messages and activities to advocate, educate and raise awareness:

- Provide information and education to patients on patient safety and medical error
- Work with health professionals and patients to develop appropriate strategies to improve communication between them
- Advocate for further research into the scale of medical error occurrences and the impact of patient engagement activities to improve patient safety
- Advocate for good systems for reporting of, and learning from, medical errors
- Advocate for health systems to prioritize patient safety and implement strategies specifically aimed at improving patient safety
- Raise awareness of the importance of openness with patients, their families and carers when something goes wrong and ensuring that they are treated compassionately

Available tools: Checklist and FAQs on Medical Error + Advocacy section of Toolkit + IAPO Health Literacy Guidelines

An introduction to medical error
Medical error is a term used to describe 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. A number of other terms are also used to describe such incidents such as an adverse outcome or adverse event, unintended harm or mistake (Hofer et al, 2000).¹

Examples of medical errors include operating on the wrong side of the body during surgery, misdiagnosis, or failure to diagnose a condition, or incorrect administration of medication.

There are also occasions when harm is caused through negligent behaviour or with the explicit intention of causing harm, though these are rare.

A medical error can occur at any point during the course of care (see Figure 1).

Figure 1. The patient care pathway

Medical errors can occur in any setting, including but not limited to:
- A doctor’s surgery
- A hospital, clinic or community centre
- A pharmacy or drugstore
- A patient’s home

² DE Detmer et al (2003), The Informed Patient. Available at: www.jbs.cam.ac.uk
Why medical errors occur
Health professionals aim to deliver safe, high-quality healthcare while minimizing the chance of a medical error occurring. Occasionally, however, all human beings can, and do, make mistakes. The current thinking on medical error is that it is often not, or not solely, the fault of individual health professionals, but rather due to a variety of reasons, and occurs mainly as a result of deficiencies in the health systems themselves.

For example, a study in the USA found that 75% of adverse drug events are attributable to system failures and research by both the Institute of Medicine (IOM) and the Quality Interagency Coordination Task Force (QuIC) used a model to understand why medical errors occur. This model incorporates systems analysis and assumes that most errors result from problems with procedures and work processes rather than bad or incompetent people. For example, an error may result from increasing specialization and fragmentation of healthcare which impact on the continuity of care for a patient; higher than average patient to nurse ratios; and manufacturing errors (e.g. mislabelling of medicines).

Hospitals that are implementing error-reduction programmes based on this model have found that dealing with errors by improving systems rather than targeting individuals has improved morale among the staff and significantly reduced the number of medical errors.

Therefore, there need to be changes in the whole system to make errors less likely and to ensure that if a single error does occur, there is a ‘safety net’ which picks up the error before it leads to harm. It is the responsibility of the healthcare system to ensure that procedures for minimizing, catching and rectifying mistakes are implemented. This may require a redesign of the healthcare system to ensure a specific focus on improving patient safety.

Healthcare professional–patient communication
The aim of a safe healthcare system must be to prevent medical errors occurring in the first place. Studies have shown that clear healthcare professional–patient communication can be central to minimizing errors. This is because a well-informed and empowered patient is more likely to comply with and understand their treatment and therefore notice if something surrounding their treatment is different or unusual. Equally, a health professional who clearly and openly communicates with the patient is more likely to understand the problem and deliver a correct diagnosis (Hatlie et al, 2006).

When undergoing medical care, patients can help to keep themselves safe by understanding their treatment and communicating any questions or concerns with their doctor or health professional.

When error becomes injury
The term medical injury refers to injury or harm caused by an error during medical care. There are a number of courses of action that can be taken following a medical error, and the potential and appropriate course of action will vary according to personal situations, local and national policies and legislation.

The most important immediate issue will be to try to ensure that the patient receives appropriate healthcare or treatment following the injury. The next step can be to seek recognition for what has happened.

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4 Institute of Medicine (1999), To Err is Human: Building a Safer Health System. The National Academies Press.
Patients’ organizations can be instrumental in supporting individual patients to obtain a meeting with the health professional or the relevant authorities, a letter of apology, public recognition of the mistake, for example in front of a committee, or in finding other solutions which answer questions that patients and families have. Often what people want when something goes wrong is not to apportion blame or punishment, but the disclosure of information about what happened, as well as compassionate treatment of the patient and/or their families. This will help ensure that lessons are learnt from the adverse event so that it does not happen again to someone else.

In some cases there is a need to take further action and Table 1 above summarizes some of the most common possible actions following a medical error which are available in some countries around the world. Whichever action is chosen, it is often a long and difficult task and, if your organization or the individual you are supporting is not an expert in this field, it is worth contacting an organization or individual with specific experience and expertise.  

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### Table 1. Summary of actions taken in some countries following medical error or aimed at reducing its incidence

<table>
<thead>
<tr>
<th>Type of action</th>
<th>What is this?</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance improvement</td>
<td>Aims to improve systems by putting into place processes such as risk assessments and root cause analysis of adverse events, enabling diagnosis of causes of error and leading to implementation of change.</td>
<td>▪ Structured analysis of situation&lt;br&gt;▪ Focus on improving the system&lt;br&gt;▪ Proactive approach not dependent on an individual requesting action after an adverse event&lt;br&gt;▪ Not widely used</td>
</tr>
<tr>
<td>Avoidability testing</td>
<td>Asks if the organization could have avoided the injury. A component of no fault compensation is the use of an ‘avoidability’ test under which the patient would be compensated for an adverse outcome, whether or not any provider was demonstrably at fault.</td>
<td>▪ If the organization could have avoided the injury then there is a case for compensation&lt;br&gt;▪ Focused on an organization’s practices not on ‘blaming’ an individual&lt;br&gt;▪ Lessons may be learnt and measures taken&lt;br&gt;▪ Not widely used</td>
</tr>
<tr>
<td>No fault compensation</td>
<td>A system aimed at ensuring people receive adequate compensation when they suffer an injury but removing the need to prove fault.</td>
<td>▪ Individual receives compensation&lt;br&gt;▪ Less adversarial and threatening to health professionals&lt;br&gt;▪ Incentive for reporting error and learning from it and taking measures to prevent recurrence&lt;br&gt;▪ Still need to prove negligence, which is difficult to do</td>
</tr>
<tr>
<td>Litigation</td>
<td>A legal proceeding to determine a legal ruling of fault which may be combined with some monetary compensation.</td>
<td>▪ Individual can receive compensation for physical or psychological damage caused and to cover the costs of care as a result of the injury&lt;br&gt;▪ May require changes to be made to improve the system and prevent the same error occurring again&lt;br&gt;▪ Attaches blame to one or more individuals so healthcare professionals are forced into being defensive rather than open about what happened, which is stressful for them and the defendant and is not conducive to learning or to improving the system&lt;br&gt;▪ Negligence can be difficult to prove because often the system is at fault, not one person</td>
</tr>
</tbody>
</table>

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**Facts and figures**

In general both developed and developing countries lack comprehensive statistical information on medical error occurrences, making it difficult to understand the true scale of the problem, make comparisons or identify trends. However, the statistics below give a snapshot of the size of the problem in developed countries, where research is increasingly available. In developing countries, it is possible that the situation is more severe, but research is far more difficult to find, if available at all. One study, for example, reports that at least half of all medical equipment in most developing countries is unusable, or only partly usable, which presents a risk to patients.  

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6 Personal communication with Peter Walsh, Chief Executive of Action Against Medical Accidents. Available at: www.avma.org.uk. A list of medical accident organizations can be found on the CD-ROM with this Toolkit.

**USA:** A survey on consumer experiences of medical error in November 2004 shows the following.\(^8\)

- Have you been personally involved in a situation where a preventable medical error was made in your medical care or that of a family member?

- Did the error have serious health consequences, minor health consequences, or no health consequences at all?

- Percentage of people who have experienced a medical error that resulted in the following serious health consequences:

  - **Serious Health Consequences:** 21% (21% serious health consequences)
  - **Minor Health Consequences:** 10% (minor health consequences)
  - **No Health Consequences:** 3% (no health consequences)

- Also, 50% of people with chronic illness said they have suffered medical error.

**Spain:** The incidence of patients with adverse events related directly to hospital care (excluding those from primary care, outpatient treatment and those caused at another hospital) was 8.4% (473 out of 5,624).\(^9\)

**UK:** 10.8% of patients experienced an adverse incident during a hospital stay, of which half were considered preventable. 6% of these adverse events caused permanent impairment and 8% caused death.\(^10\)

**Australia:** In one 1995 study, an adverse event rate of 16.6% was found among hospital patients.\(^11\)

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Ruth’s story: the long road to recognition and compensation

This case study explores one family’s response to a medical error which led them to seek compensation through the legal system. Different approaches will be needed to meet the specific needs of families following a medical error and may include seeking an apology, information, improvements to medical procedures and/or seeking compensation and a legal ruling.

This is the story of a child who suffered trauma during childbirth due to mismanagement of care and which left him seriously disabled: unable to talk, walk and see, doubly incontinent and needing 24-hour nursing care. The child’s family was faced with difficulty obtaining official recognition that medical error had occurred, as well as potential compensation. The lead consultant said it was ‘just one of those things’. Hospital staff asked the parents if they would be suing. Generally, the parents wanted information and support; their questions were not answered.

After talking to many lawyers, the parents finally came across the number for an organization that supports and advises those that have experienced medical accidents, Action against Medical Accidents (AvMA). “AvMA were able to provide me with information on my rights and help me decide what to do next,” said Ruth. “They put us in touch with one of the specialist legal counsels whom they accredit. The solicitor was a compassionate lady who understood our journey and guided us throughout.”

Through AvMA, the parents eventually received compensation. “The legal process was at times liberating and at times totally debilitating,” said Ruth. “We were forced to face issues such as life expectancy, the need for 24-hour care and so on.” The case was not resolved until the child was eight and a half years old. The family was fortunate to get an early admission of causation and several interim payments, about which they said: “This made life so much easier, as we were able to buy a bungalow, equip it as needed and employ a care team.”

Key learnings

- It is possible that a patient will not be told that medical injury has occurred
- If the patient and/or family feel something has gone wrong, encourage them to keep their own records of visits, treatments, the health professionals that see them and so on
- If in doubt, help the patient and/or family to identify and talk to different staff in the relevant department or contact an organization in your country
- Be aware that legislative procedures can take many years to finalize and patients may not receive compensation
- There are a number of other systems that attempt to address the financial implications that can result from medical error, such as no fault compensation. Where these do not exist, encourage patients to find other ways to obtain recognition of error

Resources and further information

Contact details of some organizations that specialize in assisting people that have experienced a medical error can be found on the CD-ROM included in this Toolkit.

- Institute of Medicine (1999), To Err is Human: Building a Safer Health System. The National Academies Press.

Information and leaflets for patients on how to help reduce the chance of an error occurring:
- www.jointcommission.org/PatientSafety/SpeakUp
- www.ahrq.gov/consumer/20tips.htm

Information on reporting medical errors:
- www.who.int/patientsafety/reporting_and_learning/en

Use these resources and this information to advocate, educate and raise awareness!
ACT NOW!
Use these messages and activities to advocate, educate and raise awareness:

- Advocate for good quality information for patients, delivered using health literacy principles
- Provide information and raise awareness on the importance of taking medicines correctly
- Work with health professionals and patients to develop strategies to improve communication

Available tools: Checklist and FAQs on Taking Medicines Correctly + Advocacy section of Toolkit + IAPO Health Literacy Guidelines

An introduction to taking medicines correctly
Medicines are made of often potent active ingredients. They need to be taken in the correct dose and at the correct frequency as prescribed by a doctor or other health professional. If they are not taken correctly, then the patient's condition may worsen, or the patient may become less responsive to further treatment. For example, missed doses of glaucoma medicine can lead to optic nerve damage or blindness and missed doses of heart medication can lead to cardiac arrest. An overdose of a medicine can be very serious, potentially leading to an adverse reaction, hospitalization and even death.

If a patient is taking a number of different medicines at the same time, there is a risk that these may interact with each other or with certain types of food or supplements in a harmful way. The patient’s health professional should be aware of this. Patients should be educated on the need to inform health professionals if they are taking other medication and to ask whether the medicines can be taken together. To minimize potential adverse effects, patients should ask how best to take the combination of medicines.

Antibiotic resistance is increasingly a problem. When patients forget to take their medicine or discontinue their treatment before the end of the course because they feel better, microbes develop resistance to the antibiotics, adapting to their environment rather than being killed.1 This means that these antibiotics will no longer be as effective in treating the illnesses they were developed to address.

Concordance refers to a patient's agreement to take their medicine as discussed with and prescribed by their doctor or health professional. Others terms commonly used are compliance and adherence. The term concordance, however, recognizes the patient's involvement in the decision-making process regarding their treatment in a proactive way rather than just the patient's agreement to adhere to a treatment plan as directed by their doctor or health professional.

Why patients do not take their medicines correctly
There are a variety of reasons why patients do not take their medicines correctly, including:2

- Not understanding why treatment is needed, how to take the medicine or the benefits of taking the medication properly
- Failure to collect the prescription or forgetting to take the medicine
- Perceived or real lack of effectiveness or side effects
- Complicated regimen (for example, taking a combination of medicines at different times of day)
- Handling and storage difficulties (for example, the medicine is in packaging that is difficult to open, or else it needs to be stored at a certain temperature)
- Unpleasant odour or taste

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For patients to be able to take their medicines correctly, the availability and accessibility to medication need to be ensured. However, in some developing countries there is inadequate access to medication, due to:

- Unaffordable treatment, especially for chronic conditions where medicines need to be taken for long periods of time
- Absence of, or ineffective, health insurance schemes for citizens of some countries
- Insufficient manpower to provide the treatment services
- Lack of knowledge and skills among healthcare personnel to provide information to patients on how to take their medicines correctly

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. In the development and provision of health information to patients, the consideration of health literacy principles can help ensure that information materials address the information needs of patients (see Figure 2).

The National Patient Safety Foundation in the United States runs a campaign called ‘Ask Me 3’, which encourages patients to ask three questions about their healthcare:

1. What is my main problem?
2. What do I need to do?
3. Why is it important for me to do this?

The organization produces materials for patients and health professionals with guidance on developing good health professional–patient communications.

A copy of the Partnership for Clear Health Communication at the National Patient Safety Foundation ‘Ask Me 3’ patient brochure is contained within this Toolkit.

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

- 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

**Facts and figures**

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 limited access to medicines and healthcare services, poor adherence seriously affects efforts to address chronic conditions. For example, for the treatment of HIV and AIDS, adherence to antiretroviral agents varies between 37% and 83% depending on the drug under study.

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6. Ibid.
Case study

Taking medication correctly in the developing world: the experience of the Positive Life Association of Nigeria (PLAN)

A number of patients in Nigeria were unaware of their rights and responsibilities concerning concordance, often due to difficulties associated with providing such information to low-literacy and illiterate patients.

Obatunde Oladapo, Programme Coordinator, Positive Life Association of Nigeria (PLAN), says many of the issues relate to a top-down mentality. “In most cases, the approach of most healthcare providers is to hand down instructions to patients rather than working with them to map out strategies and arrive at workable and realistic treatment plans with the patients.” In Africa, the distance between healthcare facilities and where patients live can present a substantial obstacle to provision of services. “For example, it takes a patient living in Saki about three hours’ drive to get to the nearest antiretroviral therapy (ART) clinic at the University College Hospital (UCH).” PLAN is actively driving change in the area of patient concordance by:

- Mobilizing the community on treatment literacy and preparedness
- Providing information on treatment
- Actively participating in treatment advocacy coalitions (e.g. the Treatment Action Movement [TAM], Nigeria; International Treatment Preparedness Coalition [ITPC]; StopTB Partnership etc)
- Building the capacity of healthcare providers and patients (people living with HIV) in the provision of information on treatment at community levels

Key learnings

- Work with patients to map out and understand how and why it is important to take medicines properly
- Train healthcare workers in communication skills
- Join forces with similar organizations on campaigns to add strength and compound messages

Resources and further information

The following websites provide sample leaflets containing useful checklists for patients:

- [www.ahrq.gov/path/beactivetxt.htm](http://www.ahrq.gov/path/beactivetxt.htm)
- [www.jointcommission.org/PatientSafety/SpeakUp/speak_up_med_mistakes.htm](http://www.jointcommission.org/PatientSafety/SpeakUp/speak_up_med_mistakes.htm) (English and Spanish)

IAPO Guidelines on Health Literacy:

- [www.patientsorganizations.org/healthliteracy](http://www.patientsorganizations.org/healthliteracy)

Figures on adherence to antihypertensive medication regimens around the world include:7

- 43% in China
- 27% in the Gambia
- 26% in the Seychelles
- 51% in the USA

In Australia, only 43% of patients with asthma take their medication as prescribed all the time and only 28% use prescribed preventive medication.8

US figures show:

- In 1999, 87% of patients received written information with their prescriptions, but:
  - Only 35% of pharmacists referred to the written leaflet
  - Only 8% reviewed it with the patient9
- As many as 40% of cancer patients are taking alternative or non-conventional medical therapies but do not tell their physicians unless specifically asked. Examples of such therapies included St John’s Wort (Hypericum perforatum), shark cartilage and megadoses of vitamins10
- Researchers found a 76% discrepancy rate between what medicines patients were prescribed and what medicines (including non-prescription) they actually took11

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7 ibid.
8 ibid.
9 B Svarstad, University of Wisconsin-Madison, FDA-commissioned research presented in February 2000, Rockville, MD; and in June 2000, Kuopio, Finland.
ACT NOW!
Use these messages and activities to advocate, educate and raise awareness:

✓ Advocate for better hand hygiene and cleaner hospitals
✓ Provide information on the importance of hand hygiene and clean care to patients and health professionals
✓ Work with health professionals and patients to improve communications between the two, stressing the importance of providing good quality information
✓ Raise awareness about the seriousness of the problem of hospital acquired infections

Available tools: Checklist and FAQs on Hospital Acquired Infections + Advocacy section of Toolkit + IAPO Health Literacy Guidelines

An introduction to hospital acquired infections
Hospital acquired infections are largely avoidable infections that are picked up whilst staying in hospital. They are usually caused by bacteria (e.g. MRSA, C difficile), but can also be caused by viruses (e.g. hepatitis B, HIV, varicella [chickenpox] and norovirus).

The bacteria which cause hospital acquired infections are common and live on our skin, in nasal passages, and in the normal flora of the intestine, where they normally do not cause a problem. They can also survive on surfaces within a hospital environment for considerable periods of time, and can then be transferred (spread) to patients via the hands of staff.

Hospital acquired infections present a greater risk to those people whose immune systems are compromised, perhaps through an underlying disease such as cancer. Sometimes a patient’s medication may leave the patient more vulnerable to infection: some drugs suppress the immune system, or the use of one antibiotic to treat one infection may make it easier for other types of bacteria to thrive. Older people and the very young are also at increased risk.

Hospital acquired infections are also sometimes referred to as healthcare associated infections; however, healthcare associated infections is an all-inclusive term used for infections contracted in any healthcare setting such as the doctor’s surgery, clinics or care homes as well as hospitals.¹

Where hospital acquired infections occur in the body
Hospital acquired infections can occur in a number of different places in the body. The most common hospital acquired infections are found in:

- The urinary tract (pain on urinating)
- A surgical wound
- The respiratory tract (present in phlegm)
- The blood (circulating in the body)
- The gut (causing vomiting and diarrhea)
- The skin (in ulcers or sores)²

Types of hospital acquired infections
Across the world a range of infections caused by resistant microbes are common, including Pseudomonas, Escherichia coli (E coli) and Streptococcus. Some of the most well-known ones are:

- Meticillin-resistant Staphylococcus aureus (MRSA)
- Clostridium difficile (C difficile)
- Klebsiella pneumoniae
- Meticillin-sensitive Staphylococcus aureus (MSSA)

The difference between these diseases is important for patient safety organizations to understand as the cause, effect and therapy may be entirely different. In addition, patients may develop more than one infection.

¹ Health Protection Agency (HPA). Available at: www.hpa.org.uk/infections/topics_az/hai/general_information.htm
² Ibid.
Meticillin-resistant Staphylococcus aureus (MRSA): Common in developed countries, about 30% of healthy people naturally carry Staphylococcus aureus on their skin and/or in their nasal passages without a problem. Of these around 3–5% carry the Meticillin-resistant type. MRSA, unlike ordinary Staphylococcus aureus, is resistant to many common antibiotics and so it is important to stop it spreading in hospitals. It becomes a problem when the skin is broken and the bacterium enters the body. MRSA can cause a range of infections, depending on the state of health of the person affected, whether they have had surgery or have an existing medical condition or weakened immune system. It needs treating with special antibiotics.

Clostridium difficile (C difficile): This infection is common in developed countries where it is naturally found in the intestines of about 3% of the adult population. It only becomes a problem once the equilibrium of the stomach flora is disturbed. Such disturbance is caused by the use of some antibiotics, gastro-surgery, enemas and possibly the use of proton pump inhibitors designed to control digestive problems. Some strains of the disease can produce virulent toxins, which attach themselves to the colon and cause severe diarrhea, perforation of the bowel and, in some cases, pseudomembranous colitis, which can be fatal.

Klebsiella pneumoniae: This bacterium, common in developing countries, is found in the normal flora of the mouth, skin and intestines. It can be passed from one patient to another by faecal contamination on hands and instruments. It can lead to pneumonia, wound and urinary tract infections.

Meticillin-sensitive Staphylococcus aureus (MSSA): This infection is found in both developed and developing countries. MSSA is carried by about 30% of healthy people on their skin and/or in their nasal passages without a problem. When it has opportunity to enter the body, it can cause wound and urinary tract infections, pneumonia and bacteraemia.

How hospital acquired infections are spread and ways to reduce the spread of infection
The hands of staff play a central role in the spread of potentially harmful germs, and this is why good hand hygiene is a top patient safety priority. Surgery or any invasive procedure (e.g. having a drip put in) can provide a means for infection to enter the body.

A patient’s proximity to other (potentially infected) patients may aid the transmission of infection. Strains of bacterial infections are becoming increasingly resistant to disinfectants and antibiotics. Some of these infections are difficult to destroy and can survive for long periods on floors and other surfaces. Both hand hygiene and ensuring clean and sterile hospitals and medical devices are important ways to reduce the spread of these infections. Many hospitals are adopting a care bundle approach to prevent the spread of infection, with hand hygiene one of several measures which when combined maximize safety and minimize the risk of infection. As well as good hand hygiene, care workers should also wear protective clothing (aprons and gloves) when in contact with body fluids, and adhere to aseptic procedures.

- Hand hygiene is important to stop the spread of MRSA and C difficile
- Alcohol handrubs allow staff to clean their hands quickly and effectively at the right time, a more effective procedure than using soap and water for all microbes
- Alcohol rubs should never be used after handling a patient with diarrhea
- Staff should wash their hands when in contact with diarrhea (e.g. a patient with C difficile) and then use alcohol rubs to ensure all microbes are killed and the patient is safe

Facts and figures
Between 5–10% of patients admitted to modern hospitals in the developed world acquire one or more infections. In developing countries the incidence of healthcare associated infections is thought to be as much as 20 times higher than in developed countries.

Hospital acquired infections
1.4 million: Number of people worldwide suffering from infections acquired in hospital at any one time.

1 in 136 patients: Proportion of hospital patients in the US who become seriously ill as a result of acquiring an infection in hospital; this is equivalent to two million cases and about 80,000 deaths a year.

3 ibid.
4 World Health Organization (WHO). Available at: www.who.int/entity/patientsafety/events/06/CC_factsheet.pdf
Healthcare associated infections

Greater than 25%: Percentage of patients affected by healthcare associated infections in some developing countries.

100,000: Cases of healthcare associated infections in England each year, leading to over 5,000 deaths.

450,000: Estimated number of cases of healthcare associated infection in Mexico each year causing 32 deaths per 100,000 inhabitants.

£1 billion a year: Cost of hospital acquired infections in England as reported in 2002.

US$1.5 billion per year: Cost of hospital acquired infections in Mexico.6

Case study

Winning the support of official bodies to effect change

Bev Hurst’s mother died from MRSA, a hospital acquired infection, in a British hospital. Bev wanted to raise awareness about the risks of hospital acquired infections and improve measures taken by hospitals, and other public places in the community, to reduce illness and death from hospital acquired infections. She wants both patients and healthcare professionals to take action to reduce infection.

Bev wrote numerous letters and emails to all professional bodies such as the Royal College of Medicine and government departments. She says: “When approaching a hospital Trust or Board, I’ll always say that I would like to help change the system rather than threaten litigation. I find officials are much more responsive this way.” She made an appointment to consult her local Member of Parliament, who then helped her meet the Health Minister. Subsequently, a group known as the Patient Public stakeholder group was set up. This was comprised of a mixture of patients and healthcare professionals.

Bev is a founder member of National Concern for Healthcare Infections (NCHI) in the United Kingdom (UK). Most recently, Bev and her colleagues at NCHI have collaborated with the UK’s Department of

Health by developing leaflets which Hospital Trusts (organizations which manage hospitals) have agreed to consider placing in their hospital wards and clinics. She is now campaigning to make the provision of this information mandatory.

Key learnings

■ Work with, not against, the hospital. It is more beneficial to work in partnership and ensure that any proposal is beneficial to both campaigners/patients and healthcare providers. Attend local and national meetings

■ Campaigns and organizations gather momentum over time. Contacts and networks are all important. Success takes time and hard work. Bev has been campaigning for four years.7

Resources and further information

World Health Organization initiatives:

✓ WHO Global Patient Safety Challenge: Clean Care is Safer Care:
  www.who.int/patientsafety/events/05/global_challenge/en

✓ The five moments for Hand Hygiene:
  www.who.int/gpsc/tools/Five_moments/en

✓ Link to a training film on hand hygiene:
  www.who.int/gpsc/media/training_film/en/index.html

Patient focused organization:

✓ National Concern for Healthcare Infections (UK):
  www.nc-hi.com

Government agencies:

✓ Health Protection Agency (UK): www.hpa.org.uk

✓ Center for Disease Control (US): www.cdc.gov

✓ cleanyourhands campaign (UK): www.npsa.nhs.uk/cleanyourhands

✓ European Centre for Disease Prevention and Control:
  http://eucdc.europa.eu

6 All statistics from WHO Global Patient Safety Challenge document on Hospital Acquired Infections, Clean Care is Safer Care. Available at: www.who.int/patientsafety/events/05/GPSC_Launch_ENGLISH_FINAL.pdf

7 Further information about the National Concern for Healthcare Infections is available at: www.nc-hi.com
ACT NOW!
Use these messages and activities to advocate, educate and raise awareness:

✓ Work with patients and health professionals to improve communication of medicines information and the importance of monitoring of adverse drug reactions
✓ Advocate for good quality information for patients
✓ Advocate for stronger political will and action to combat counterfeit medicines, including appropriate penalties for counterfeiters
✓ Raise awareness of the dangers of counterfeit medicines

Available tools: Checklist and FAQs on the Quality and Safety of Medicines + Advocacy section of Toolkit + IAPO Health Literacy Guidelines

An introduction to the quality and safety of medicines
Medicines contain potent ingredients and therefore carry an inherent risk that they may cause unexpected, and sometimes harmful, reactions or side effects in some people. Because of this, many countries have laws and regulations to ensure that medicines are safe and meet certain quality criteria relating to their development, manufacture, storage and distribution.

These laws and regulations are often enforced by national or regional regulatory agencies (e.g. the Food and Drug Administration [FDA] in the United States, the European Medicines Agency [EMEA] in Europe, National Agency for Food and Drug Administration and Control [NAFDAC] in Nigeria, and the Sanitary Surveillance Agency in Brazil). The work of regulatory agencies may include the following:

- Overseeing the quality and safety of medicines, monitoring reports of potential or actual harmful effects
- Inspection of research laboratories and the sites of clinical trials, manufacturers and wholesalers
- Medicines testing, i.e. the sampling and testing of selected medicinal products destined for the market

Adverse drug reactions or side effects
Adverse drug reactions (ADRs) or side effects may occur due to an unanticipated reaction in an individual to a medicine or as a result of quality and safety issues. When health professionals prescribe medicines, they weigh up the risk of side effects to the individual versus the beneficial effects of taking the medicine.

However, some ADRs are unpredictable. Others may be more avoidable, including identifying a medical, genetic or allergic condition in the patient, which might cause a bad reaction to the drug, or where the patient is taking a large number of different drugs which may interact.

ADRs and other medicine-related problems differ between countries and these differences may be due to:

- Diseases and prescribing practices
- Genetics, diet and traditions of the people
- The drug manufacturing processes used, which can influence pharmaceutical quality and composition
- The use of traditional and complementary drugs (e.g. herbal remedies) which may pose specific toxicological problems when used alone or in combination with other drugs

Suspected ADRs should be reported to a health professional in the first instance. They can also be reported through the World Health Organization (WHO). See their guide to detecting and reporting ADRs at: http://whqlibdoc.who.int/hq/2002/WHO_EDM_QSM_2002.2.pdf

1 For information on medicines regulation, and to find out if there is a medicines regulatory agency in your country, contact your Ministry of Health.
Pharmacovigilance
After a medicinal product has been placed on the market, there is still a need to monitor the effects of the medicine when taken by individuals. This is because adverse events will only become apparent when the medicine is used extensively in large numbers of patients. This is due to a number of reasons, including:

- Tests in animals are insufficient to predict human safety
- Patients used in clinical trials are selected and limited in number, the conditions of use differ from those in clinical practice and the duration of trials is limited
- At least 30,000 people need to be treated with a drug to be sure that you do not miss at least one patient with an ADR (if the ADR has an incidence of 1 in 10,000 exposed individuals)
- Information about rare but serious adverse reactions, chronic toxicity, use in special groups (such as children, the elderly or pregnant women) or interactions between drugs is often incomplete or not available

This procedure is known as post-marketing surveillance or pharmacovigilance. There are a number of systems in place around the world to monitor adverse drug reactions, both during clinical trials and once medicines have been put on the market. In the EU, there are requirements within EU Directorates to report suspected adverse drug reactions through EudraVigilance, which collects and evaluates suspected adverse reactions.

Another example is the Uppsala Monitoring Centre (the WHO International Collaborating Centre for Drug Monitoring), which collects and monitors data from WHO member countries worldwide. In Africa, there is the African Drug Regulatory Authorities Network (AFDRAN), which shares information about drug safety and adverse drug reaction reporting throughout the continent. There is significant variation between the levels and types of pharmacovigilance systems in place in the regulatory authorities of the countries represented.

Counterfeit and substandard medicines
Counterfeit and substandard medicines are those whose ingredients and/or composition do not meet required standards as set by authorities and regulatory agencies. Counterfeiting may affect both branded and generic medicines, prescription and over-the-counter medicines, as well as medical devices. Counterfeit medicines are a truly global issue and pose an increasing threat to patient safety. Many counterfeits are bought unknowingly from unlicensed internet pharmacies or, in developing countries, from open markets. However, counterfeit medicines are also infiltrating legitimate medicines supply chains.

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

Substandard medicines are also medicines that do not meet quality standards, but they differ from counterfeit medicines in that there may not have been an intent to deceive, whereas counterfeit medicines have been deliberately and fraudulently mislabelled with respect to identity (e.g. active ingredient or amount of active ingredient) or source (e.g. manufacturing batch number). Medicines may be substandard because of negligence, human error and insufficient human and financial resources.

The risks for patients of taking counterfeit medicines or substandard medicines include:
- The patient’s condition gets worse
- The patient’s condition does not change; they do not get better or worse
- Death

The global threat of counterfeit medicines to patient safety is increasingly recognized and there are a number of in-country and cross-border initiatives to combat counterfeit medicines. The World Health Organization coordinates the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), which brings together WHO member countries and international stakeholder groups, including IAPO, to work on this issue.

Suspected counterfeit medicines should be reported to a health professional, the national regulatory authority or the WHO Rapid Alert monitoring system at: http://218.111.249.28/ras/default.asp

3 Ibid
5 The IMPACT website contains further information about counterfeit medicines and anti-counterfeiting initiatives. Available at: www.who.int/impact
The Quality and Safety of Medicines

Facts and figures

Adverse drug reactions
In many developed countries, ADR related hospital admissions represent around 10% of total admissions. For example, in Norway the figure is 11.5%; in France 13%; and in the UK 16%. Figures from developing countries are not readily available, but it is probable that adverse drug reaction related events are higher than in more developed regions.

The cost of detected drug-related illness and death in the USA was US$177 billion in 2000. Hospital admissions accounted for 70% of costs.

Counterfeit or substandard medicines
During a meningitis epidemic in Niger in 1995, 50,000 people were inoculated with fake vaccines (a gift from another country that thought they were safe), causing 2,500 deaths.

Due to contaminated paracetamol syrup, 89 children died in Haiti in 1995, and 30 infants died in India in 1998.

In 1999, 30 people died in Cambodia after taking counterfeit anti-malarials prepared with an old, less effective anti-malarial.

In South-East Asia in 2001, 38% of 104 anti-malarial drugs for sale in pharmacies did not contain any active ingredients.

In 2006, 5,000 packets of counterfeit Tamiflu at an estimated worth of £500,000 were confiscated in the United Kingdom. Counterfeit Tamiflu was also found in the Netherlands in 2006. The Dutch Healthcare Inspectorate warned consumers not to purchase Tamiflu through the internet as counterfeits containing no active ingredient were found.

Resources and further information

Background on regulatory agency work:
- www.emea.europa.eu/Patients/introduction.htm
- FDA Center for Drug Evaluation and Safety:
  - www.fda.gov/Cder/drugSafety.htm
- Handy guides on counterfeits:
  - www.fraud.org/fakedrugs/tips.htm
  - www.whpa.org/pubs
- WHO activities on quality and safety of medicines:
  - www.who.int/medicines/areas/quality_safety/ena
  - WHO International Medical Products Anti-Counterfeiting Taskforce: www.who.int/impact
- User orientated information on quality and safety of medicines:
  - Germany: core message of user-oriented guidance: www.coe.int/t/e/social Cohesion/soc-sppLeaflet_MedicinesandInternet_D.pdf
  - www.americansocietyofpharmacists.org survey of costs related to ADR. Available at: www.who.int/mediacentrefactsheets/fs293/en
- WHPA leaflet on counterfeit medicines for consumers: www.whpa.org/pubs

Use these resources and this information to advocate, educate and raise awareness!
Injection Safety

What’s in this section?
- ACT NOW!
- An introduction to injection safety
- Facts and figures
- Resources and further information

ACT NOW!
Use these messages and activities to advocate, educate and raise awareness:
✓ Advocate for information and education on injection safety, and foster a change in the behaviour of healthcare workers and patients, to ensure injections are administered safely
✓ Raise awareness and promote knowledge of safe practices and why these practices are necessary (i.e. knowledge of HIV and hepatitis viruses, sterilization)
✓ Advocate for increased access to healthcare equipment and supplies. The cost of a disposable syringe (5 US cents) is low compared to the price of the injection (about 50 US cents). Suppliers and donors of vaccines and contraceptives could provide a matching quantity of disposable equipment
✓ Advocate for safe and appropriate management of waste. Countries need to have national waste management policies, implementation programmes and training for staff

Available tools: Advocacy section of Toolkit

Facts and figures
- Each year unsafe injections cause an estimated 1.3 million early deaths, a loss of 26 million years of life, and an annual burden of US$535 million in direct medical costs
- Worldwide, up to 40% of injections are given with syringes and needles, reused without sterilization. In some countries this proportion is as high as 70%
- Unsafe injections account for 33% of hepatitis B virus cases each year in developing and transitional countries
- Unsafe injections cause two million new cases of hepatitis C each year in developing countries
- 2% of all new HIV infections are caused by unsafe injection practice each year in developing countries

Figure 3 opposite shows the extent of both sterile and unsafe injections worldwide.

An introduction to injection safety
In many countries injections are used as a method to administer medicines that aim to prevent or treat an illness. However, if precautions are not taken to administer injections safely, they expose patients to an unnecessary level of risk of infection.

Reuse of needles without appropriate sterilization is the prime source of infection. Diseases spread by unsafe injection practice include hepatitis C, hepatitis B and HIV. If these are transmitted through injection, the patient may not be aware that they have been exposed to disease until later on, when symptoms present themselves.

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2 WHO Fact sheet No 231, Revised October 2006, Injection safety. Available at: www.who.int/mediacentre/factsheets/fs231/en
3 Ibid.
4 Ibid.
5 Ibid.
Figure 3. Injections given with sterile and unsafe equipment worldwide

Resources and further information

WHO initiative to improve the safety of injections globally:
- www.who.int/injection_safety/en

Brochures on injection safety guidelines:
- www.who.int/injection_safety/WHOGuidPrinciples_InjEquipFinal.pdf
- www.who.int/injection_safety/Guiding_Principals_FR.pdf (in French)

SIGN-Safe Injection Global Network:
- www.who.int/medical_devices/collaborations/network/en

Brochure with guidance on injection safety for transitional and developing countries with examples from Romania, Burkina Faso, Côte d’Ivoire and others:
- www.immunize.org/genr/d/sign1.pdf

Presentation on injection safety from the Change Project for developing countries:
- www.changeproject.org/pubs/BuildingBehaviorChangeStrategies.ppt#267,12,Studies

SAFEPOINT: charitable trust that develops educational materials (films, posters etc):
- www.safepointtrust.org/home.html

Source: WHO – Progress Towards the Safe and Appropriate Use of Injections Worldwide (2000–2001)\(^6\)

\(^6\) Available at: www.who.int/injection_safety/about/strategy/en/ActivityReport200-2001.pdf
The Reuse of Single-Use Medical Devices

What’s in this section?

- ACT NOW!
- An introduction to the reuse of single-use medical devices
- Facts and figures
- Resources and further information

ACT NOW!

Use these messages and activities to advocate, educate and raise awareness:

- Advocate for no reuse of single-use devices, and for single patient use devices only to be used on the same patient
- Advocate for the training of health professionals to fully understand the implications of reusing single-use devices
- Advocate for reporting of the reuse of single-use devices
- Educate patients as to the dangers of reusing single-use devices

Available tools: Advocacy section of Toolkit

An introduction to the reuse of single-use medical devices

A number of medical devices are intended for single use, such as some surgical drills, biopsy forceps, catheters, scissors, bandages and surgical gloves. However, in many situations, single-use devices are reused, sometimes illegally. This may be for a variety of reasons, such as a lack of resources preventing the use of a new device for each patient or procedure, because the health professional is unaware of the dangers of reusing devices or to save money instead of buying new devices. Devices intended for single use which are reused may affect the safety, performance and the effectiveness of the product, and compromise patient safety.

Risks to the patient associated with reuse of single-use medical devices include:

- Cross infection: reprocessing may not thoroughly clean the device and some micro-organisms may remain
- Inability to clean and decontaminate: cleaning should reach all parts of the device and reprocessing does not necessarily do so. Also, cleaning materials need to be totally removed or may otherwise risk contaminating the patient
- Exposure to reprocessing agents may alter the device or degrade the material
- Reprocessing or cleaning may weaken or degrade a device and may cause fracture when reused

- Certain proteins which may cause serious illness may be left on devices after reprocessing, e.g. Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob due to resistance to standard reprocessing methods

Single-use devices should not be confused with reusable devices that can be reprocessed after each use and safely reused. For example, some syringes used for injections can be sterilized and safely reused. However, reprocessing a single-use device by cleaning and sterilizing may alter characteristics of the device that affect its performance and therefore patient safety.

Facts and figures

A study found that single-use biopsy forceps (designed to collect tissue for histological examination) that were reprocessed were non-sterile in 90% of the cases examined. Another study found that when analyzing reprocessed balloon catheters received from hospitals where devices were going to be reused, on average 50% were contaminated with residues including blood and proteinaceous material. This creates a risk of cross-contamination of residues that can cause a fever in a patient.

Resources and further information

Article on reuse of medical devices from FDA: www.fda.gov/fdac/features/2000/500_reuse.html

World Health Organization initiatives and information on medical devices: www.who.int/medical_devices/en

1 Eucomed Medical Technology Focus 50 (March 2006), Stop reprocessing ‘single use’ medical devices – Patient safety at risk! Available at: www.eucomed.org
ACT NOW!
Use these messages and activities to advocate, educate and raise awareness:

✓ Provide information and advice on the importance of good general health practice including hygiene and nutrition
✓ Advocate for improved sedation techniques and pain management services if they are substandard
✓ Provide information to individual patients and parents regarding access to medicine for children
✓ Advocate for improved availability and access to safe, child-specific medicines for all children under the age of 15, including appropriate clinical research on medicines for children
✓ Advocate for improved medical practice to improve the health of mothers and newborns

Available tools: Advocacy section of Toolkit – Maternal and Child Health WHO Initiatives including ‘Making Pregnancy Safer’ and the ‘Safe Motherhood Initiative’ (see below)

Making pregnancy safer
Safety, quality and equitable access of healthcare for mothers and neonates at policy, service and community levels must be driven through national health systems.

The World Health Organization (WHO) has global programmes called ‘Making Pregnancy Safer’ and the ‘Safe Motherhood Initiative’ which work to raise awareness of issues and improve health of mothers and newborns, especially amongst the poor and most vulnerable.

These initiatives have produced evidence for improved medical practice. For example, preventive use of magnesium sulphate has been shown to almost halve the risk of pre-eclampsia (raised blood pressure of mother), a major cause of maternal death.

The compilation of evidence relating to maternal and child well-being and safety has led to the development of a manual on ‘Managing complications in pregnancy and childbirth’, which consists of a package of evidence-based standards and tools.1

The Millennium Development Goals recognize these issues. Goal number 5 focuses on improving maternal health and aims to reduce by three-quarters the maternal mortality ratio and achieve, by 2015, universal access to reproductive health.

Medicines for children
Children respond very differently to medicines compared to adults. This is due to their size and variations in their metabolism, which have an impact on the way medicines work. Due to a lack of clinical trials, every time a paediatrician tries an adult-licensed drug on a child, they are effectively conducting a clinical trial of one and taking responsibility for the risks involved.

1 Managing complications in pregnancy and childbirth. Available at: www.who.int/reproductive-health/impac

An introduction to maternal and child health and safety
Around the world maternal and child patient safety issues vary widely. In the developing world, basic issues such as availability of treatment and care during pregnancy, for newborns and during the first few years are essential. Pronounced safety concerns relate to the availability and quality of nutrition, vaccinations, medicines and prevention of the major killer diseases such as malaria.

In developed countries, issues such as paediatric patient sedation, the development of effective and safe medicines for children, and ensuring safety of mother and unborn child during pregnancy are the most pressing issues.
Recently there have been moves to improve this situation both in the European Union and across the globe. In 2007, the European Commission introduced a directive, known as Regulations on Paediatric Medicines, aimed at improving trials and administration of medicines for children.²

‘Make medicines child size’ is a campaign run by WHO, which targets a range of medicines – including antibiotics, asthma and pain medication – that need to be better tailored to children’s needs. It calls for further research and development of combination pills for HIV/AIDS, TB and malaria, as well as appropriate child therapy for a number of neglected tropical diseases.³

Sedation

The standard of sedation received by paediatric patients can vary widely within one institution as well as between different locations. Care can also depend upon the caregiver, the time of day and the area within the hospital where sedation is being provided. Essentially, healthcare practitioners, who are all aiming to achieve the same result of sedating a child, can differ significantly in their prescribing habits. Furthermore, sedation may be required at any time of day or night and experts are not always available for this.

Paediatric sedation is still one of the few areas of medicine which remains non-standardized in the developed world.

Parents can help to improve this situation by requesting higher quality sedation techniques and pain management services if they feel the ones being received are substandard.

² EC medicines for children directive. Available at: http://ec.europa.eu/enterprise/pharmaceuticals/paediatrics/medchild_en.htm
³ Make medicines child size. Available at: www.who.int/childmedicines/en/index.html
ACT NOW!
Use these messages and activities to advocate, educate and raise awareness:

✓ Provide information to patients to enable them to make informed decisions about whether to participate in a clinical trial and what questions to ask before, during and after the trial
✓ Advocate for patient involvement in the development of clinical trial protocols, trial designs and dissemination of data to ensure that the trials meet patients’ needs
✓ Advocate for appropriate clinical trial legislation on a national level that includes ethical review of trials

Available tools: Advocacy section of Toolkit

An introduction to patient participation in clinical trials
A clinical trial usually involves testing a potential new therapy in a human being who is either a patient or a healthy individual. Clinical trials are the most effective way of determining whether a therapy is suitable for wide-scale use in humans. Trials may involve testing a new medicine against the standard treatment for a particular disease or trialling a new therapy against a placebo (a substance without any active ingredient).

Given that clinical research involves the testing of medicines in development, there will always be some risk associated with participation. This risk is usually minimal due to the numerous tests that are carried out in the laboratory to predict what the effect will be in humans. However, there is always a possibility that the test will have an unexpected or unpredictable reaction in humans, or that an individual will experience an adverse response due to their own physiology.

Considerations for the patient: to participate or not?
Sometimes when standard therapies do not work well, patients may consider participating in a clinical trial to help with the development of new medicines. In addition, patients may consider it worth participating in a trial if it provides access to new medicines before they are widely available or there are other benefits such as free examinations and medicines.

There is no guarantee that the trial medicine will be more effective than a current therapy, and it may be less effective. It may also have side effects.

Giving informed consent
Patients participating in trials should be given the full facts about the trial and any risks involved. They should be provided with appropriate information and encouraged to ask questions and discuss issues with their health professionals. This information should be ongoing throughout the trial.

Patients should be asked to sign a consent form which contains details of what the trial involves, the purpose, how long it takes, key researchers and their contact details. Patients should thoroughly understand this before participating. If not, they should ask for a clearer explanation or a translation into their native language. See Figure 4 overleaf for a useful checklist of questions patients can ask before participating in a trial.

There are certain situations where the issue of informed consent needs extra consideration, such as the participation of children in clinical trials, and trials conducted in developing countries where patients may not have sufficient literacy levels to make informed decisions, and the ethical review processes may not always be as rigorous as in other countries.
Patient Participation in Clinical Trials

Figure 4. Questions patients may need to ask before participating in a trial

- What is the purpose of the study?
- Who is going to be in the study?
- Why do researchers believe the experimental treatment being tested may be effective?
- Has it been tested before?
- What kinds of tests and experimental treatments are involved?
- How do the possible risks, side effects and benefits in the study compare with my current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- Will hospitalization be required?
- Who will pay for the experimental treatment?
- Will I be reimbursed for other expenses?
- What type of long-term follow-up care is part of this study?
- How will I know that the experimental treatment is working? Will results of the trials be provided to me?
- Who will be in charge of my care?

Resources and further information

- LD Tobias and J Harkness (2006), Briefing Paper on Paediatric Medicines and Clinical Trials, International Alliance of Patients’ Organizations. Available to order online (free for patients’ organizations) from: www.patientsorganizations.org/paediatrics

US website with comprehensive information on clinical trials:
www.clinicaltrials.gov

Information on ongoing clinical trials and results of completed trials by pharmaceutical industry:
http://clinicaltrials-dev.ifpma.org

World Health Organization International Clinical Trials Registry Platform:
www.who.int/ictrp

Use these resources and this information to advocate, educate and raise awareness!
Advocacy done well is a powerful tool

Advocacy or campaigning involves speaking out on an issue to authorities, the public or the media in an effort to get a policy changed or to draw attention to an issue. Your efforts may be aimed at solving:

- An individual problem such as access to a particular medicine
- A group problem such as the availability of healthcare services in a particular area
- A change in regulations such as those aimed at improving hospital cleanliness or changing the labelling on medicines

The key to success is developing an action plan where your aims and your methods are clearly defined. Figure 5 below outlines the steps involved which can be adapted for work on specific patient safety issues.

Methods of advocacy

A number of different methods can be used to help you advocate. Using a combination of methods will add to the reach and potential impact of your message. Advocacy can be either undertaken privately or through making issues public, depending on the situation. Often private advocacy is tried first, followed by public advocacy if private advocacy is unsuccessful.

Figure 5. Drawing up an advocacy plan of action

This flowchart outlines the main steps involved in developing an advocacy plan.
The power of partnerships

Partnerships, or coalitions, can help you achieve your goals to improve patient safety. An organized group can have a stronger influence on government and policy makers than an individual. A group enables you to share information, exchange ideas and plan strategies over a wide basis of opinion.

In the same way, developing partnerships or coalitions with other like-minded groups of patients or other stakeholders can help in the exchange of data and ideas, and together you can advocate with a strong and unified voice. Partnerships can be established with other patient groups, and with healthcare professionals, governments or industry sectors, amongst others.

What can you achieve through partnerships and dialogue?

- Raised awareness of patient safety with healthcare providers. You can:
  - Raise the profile of the seriousness and scale of the public health challenge related to patient safety
  - Create a patient safety community-based organization to serve your local facilities such as doctor’s surgeries, clinics, hospitals and care facilities. In smaller communities, it may be more effective to form coalitions with neighbouring localities
  - Promote discussion between health providers and patients on topics such as patient education, materials, policies and protocols, ethics, complaint management, facility design, and use of lessons learned from errors to improve safety

- Increased levels of confidence in patient safety and development of reliable public health safety records. You can:
  - Promote a non-punitive or even blame-free safety learning and reporting system
  - Promote patient and public involvement in reporting programmes which will improve confidence in accountability: patients should be involved in the development and governance of reporting programmes, and the reporting of errors
  - Encourage open discussion of errors and how systems might be improved

The power of partnerships

Case study

Harnessing the power of spokespeople in positions of power and the benefits of joining a board or working party group

Ms Wharton-Lang, an individual consumer who had experience in forming a coalition of blood user groups, persuaded the US government that consumers needed to be part of the government’s working party on blood. She personally served as Special Advisor on Consumer Issues.

Initially, Ms Wharton-Lang was only allowed to participate in specific discussions of the working group meetings. However, feeling that this was unacceptable, she rallied the support of the blood user groups to lobby for her full participation in the meetings.

Dr Wallace was a federal government representative who became a strong consumer group spokesperson within the working group. He convinced the federal minister that consumers need official recognition on committees. Dr Wallace also took messages from the consumer groups into the meetings and served as an internal advocate.

Key learnings
- A lay individual can be brought into the circle of decision-makers
- An internal advocate can forward messages and pass on suggestions at official meetings

Contribution to hospital patient safety boards and committees. You can:

- Promote the value of the patient experience: patients can relate experiences from a unique viewpoint, providing insights on how and why an adverse event occurred and how it can be prevented in the future
- Promote better management of complaints, which should restore trust and reduce the need for litigation, through open communication and a commitment to learn from the problem and prevent its recurrence

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Information sourced from Advocacy Fieldbook from Durhane Wong-Rieger.
Principles of partnerships
Whilst there are no defined rules for partnerships, there are some useful principles or ‘rules of engagement’ that will help a partnership to be successful:

- Engage in open and honest dialogue
- Work towards areas of mutual benefit
- Respect individual and organizational views
- Maintain your independence and therefore credibility
- Be clear with potential partners as to what you hope to achieve through the partnership and what the boundaries of the partnership are
- Ensure good practice in more formal partnerships, or joint initiatives, by drawing up a contract or letter of agreement
- Promote both patients and patient groups as equal partners

Some key points to consider when arranging meetings:

1. People are busy, so be focused and do not take up too much of their time. State how long the meeting will take
2. Use a tailor-made approach suitable for your region or situation. Do not be too ambitious – it is better to choose a few key contacts and give these the necessary time, consideration and follow-up, than to cast a wide but shallow net
3. An accusatory, aggressive or defensive approach is not helpful; it is more constructive and respectful to come with a willingness to help find a solution in partnership
4. Consider what patient safety issues are most important in your specific situation
5. Use the evidence in this Toolkit, along with evidence that you have, that is specific to the patients that you represent
6. Where possible and appropriate, involve patients, families and carers in your events and publications, as they can be very effective advocates. A personal story is often compelling, passionate and memorable. It can also be effective to highlight case studies of success to show how access, information and involvement can lead to better outcomes, whether they are health outcomes, better quality of life, cost savings or cost-effectiveness

Patient safety initiatives
Many patient safety initiatives provide channels through which patients can be involved. Further information on the following initiatives can be found on the CD-ROM included in this Toolkit.
Communicating is important to: provide information to patients to help them to keep themselves safe; and to convey your advocacy messages through the media. This section provides tips on the different approaches you can use to communicate information and messages to these two groups.

Communicating information to patients
Good patient information helps patients to be well informed about their treatment, to know how to take it correctly and what questions to ask regarding patient safety. This section outlines issues for patients’ organizations, and others, to consider when developing educational information for patients.

Finding good quality information from the many sources available can be a challenge, and patients do not always know where to start. Patients’ organizations are well placed to help patients to understand medical information, or a diagnosis, and provide advice on where to find further information.

A patient’s doctor, nurse or pharmacist is well prepared to provide information. They can be considered partners in patients’ healthcare, as they can help patients to understand and make decisions:

- Patients can write down their concerns and questions before the visit and take notes during it
- Patients should not wait for doctors to ask questions; they can provide information to their doctor openly, even if they feel uncomfortable about discussing some subjects
- If patients feel uncertain about the information received, they should seek a second opinion

Patients’ organizations can recommend the following steps to patients:

**STEP 1: TAKE THE TIME YOU NEED**
Do not rush important decisions about your health. In most cases, you will have time to examine your options carefully and decide what is best for you.

**STEP 2: GET THE SUPPORT YOU NEED**
Look for support from family and friends, from people who are going through the same thing as you, and from those who have ‘been there’. They can help you cope with your situation and make informed decisions.

**STEP 3: TALK TO YOUR HEALTHCARE PROFESSIONAL**
Good communication with your healthcare professional can help you feel more confident about the care you receive. Research shows that it can have a positive effect on things such as satisfaction, symptoms and pain. Getting a ‘second opinion’ may help you feel more confident about your care.

**STEP 4: SEEK OUT INFORMATION**
When learning about your health condition and its treatment, look for information that is based on a careful review of the latest scientific findings published in medical journals. Online databases such as PubMed (www.ncbi.nlm.nih.gov/pubmed) or The Cochrane Collaboration (www.cochrane.org) are reliable sources. Not all websites contain reliable information, but government, healthcare professional and patient group websites will generally contain reliable information.

As you take each step, remember this: research shows that patients who are more involved in their healthcare tend to get better results and be more satisfied!
Communicating with the media

The media is an important resource for your organization to communicate with a wide audience of patients, the general public and even decision-makers.

Communicating with the media can help you and your organization to:

- Promote your cause
- Press decision-makers into action
- Gain public support
- Obtain the interest of high-profile supporters
- Raise awareness of a new discovery, announcement or project
- Reverse decisions or at least cause public disquiet

As an organization, you need to progressively build your media relations by staying in regular contact with journalists and publications. Make sure you have something relevant and important to say so journalists know that speaking to you is a valuable use of their time.

You can take a variety of approaches, such as working on exclusive stories with particular journalists, or releasing information to a list of press contacts.

Consider with which media you need to connect. If you want to reach the general public you can target general newspapers, magazines, websites, radio and television at local, national and international levels, all of which are part of the mass media. Healthcare magazines, journals and websites are part of the specialized press and can help you reach academics, scientists and healthcare professionals amongst others.

Learn to think in terms of an editor’s needs

An editor is the person who decides what goes into the media and ensures that stories are covered. This means that to promote a story, you must understand what the specific publication needs.

Health literacy

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. 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. In the development and provision of health information to patients, the consideration of health literacy principles can help ensure that information materials address the information needs of patients.

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

When thinking in terms of an editor’s needs, you should consider the following points, relating to both print and online media:

- Is the readership specialist or generalist?
- How far in advance are stories commissioned? If the story is a feature (longer article), then this could be months ahead of publication; if it is news then you will need to release information to the press a day or so before with an embargo
- Always think in terms of what is new, different, exciting and timely – why should the story appear in the press now rather than next month or in six months’ time?
- Is the story of interest to the general pages of a newspaper or might it be more suitable for the specialist pages? There are often different editors for each section. Communicating with the right editor can make the difference whether your story runs or not
- Have you got spokespeople who can be interviewed and tell a good story?

Make your message count
The following points should be considered to make sure you maximize the impact of your story:

- Ensure your message is very clear and put succinctly. When you are communicating, make sure you repeat your message at different times
- If writing a press release, always use an informative short title and put the crucial, most important, most attention-grabbing information first (often editors will only skim the first paragraph when considering whether to use your story)
- In order to clarify your message, ask yourself the following questions:
  - Why is this story important?
  - What will happen if the public do not hear about the story (the wider significance)?
  - Why is your organization the expert organization in the field?
  - How will this finding or announcement affect people’s lives?
  - Who in your organization can speak about the topic from an informed position?
  - What would you like to achieve with broadcast or publication of this message?
  - What is the headline you would like to see or hear?
  - Are you avoiding jargon and ensuring that the story is easy to understand?

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**Case study**

**CHAIN’s media campaign to inform a local population of their rights to healthcare**

The Community Health and Information Network (CHAIN) in Uganda ran a media campaign for patient safety aimed at their local community of youth, women, religious leaders, local council leaders and healthcare professionals.

The campaign aimed to inform people, in a highly variable population, of their patient rights and safety. It also raised awareness of counterfeit medicines, an issue which is not considered very important by a community more concerned about price than authenticity and expiry dates.

Hygiene in hospitals and in the home was also addressed with medical practitioners, who often use unsterilized equipment and occasionally fail to wear gloves.

CHAIN used drama, videos and activity workshops, which helped those less able to read, whilst they translated materials into local languages for literate patients who could not speak English. CHAIN also organized debates and dialogues with local communities.

There was a considerable increase in awareness of patient rights, counterfeit medicines and interaction with doctors as a result of this campaign.

**Key learnings**

- Assess the needs and literacy levels of the local population – you may find that a media campaign in the local language using radio and/or television is preferable to print
- Evaluate the success of your campaign so that you can apply lessons learnt in terms of engagement and healthcare benefits to the next campaign and justify costs
- Co-ordinate your media campaign with interactive activities such as dialogue and debate to allow your audience to take an active role in the campaign

Use these key learnings in your efforts to advocate, educate and raise awareness!
How to write an effective press release
A press release lets an editor or journalist know that your organization has something exciting that their readers, listeners or viewers would be interested in knowing. You need to grab the attention of an editor who has hundreds of other releases to sift through every day. It is important that yours stands out.

In the upper left-hand margin you should provide, in capital letters, the embargo date and time if it is for release at a later date, or else the words ‘For immediate release’ if the information can be used immediately by the media.

The headline should give the reader enough information to get the gist of the story and interest them enough to make them read further. Keep it short and informative.

The dateline should be the date of sending the release out and the city/country in which it is written. This enables the journalist to confirm that it is newsworthy and timely.

Your lead paragraph or introduction should contain the five ‘Ws’ – What, Where, When, Why, Who – as well as a hook to entice someone to read further.

The main body of the release, which follows the lead paragraph, contains the detail – and often some quotes from key people. The quote may come from your organization’s CEO, from a scientist linked to the organization or from a patient in the organization.

Your organization should then provide its contact details as well as the details of all spokespeople or further sources of information. This means phone numbers, email addresses and postal addresses. This should be limited to four people at the very most.

‘Notes to editors’ is the final section, which provides extra information on relevant parties and your organization in particular.

How to deliver an effective interview
Preparation is pivotal to an effective interview:

- Think of the three key messages you would like to get across, and write them down and prioritize them
- If during the interview the journalist changes the angle of the interview then acknowledge the question but return the discussion to the message you wish to convey. Remember you are the interviewee and guest of the journalist
- Know your up-to-date facts and figures
- Avoid jargon and technical terms. Use simple analogies for complex ideas
- Provide personal examples if it adds to your message
- Answer questions directly
- Give short answers or soundbites
- If stuck for an answer, return to your key messages

Checklist for working with the media:

- Take time to build strong and long-term relationships with the media. Select particular individuals who show an interest in your organization and field.
- Journalists move from one medium to another – stay in touch. Build a relationship with replacements.
- Never underestimate the power of the media to promote your cause or influence a decision, particularly if it affects the general public.
- Target the publication and editor within that publication carefully. Then decide whether your story will be exclusive or not and which journalist is most likely to give you the best return.
- Press conferences are useful for high-profile, controversial announcements, while a media briefing may be more suitable for a smaller event.
- If giving an interview always prepare your message by summarizing, prioritizing, illustrating with examples or anecdotes and then practising some soundbites.
- Do not disturb a journalist for nothing. Ensure that each contact is well prepared, even if for an informal chat.
Bear in mind the following ‘interview don’ts’:

- Journalists are not your friends – your story needs to be engaging and ideally controversial to be used
- Don’t say ‘no comment’. If you don’t know an answer, promise to find out and report back
- If you are asked something and you do not want to answer, steer the interview to your message
- Avoid jokes or sarcasm
- Nothing is ever really ‘off the record’. Don’t say what you do not want to; be quiet instead
- Correct yourself if you have made a mistake – it builds credibility
- Don’t talk down to journalists or assume their motive is suspect

Tools to communicate with the media
A media briefing or press briefing/conference is conducted before a story breaks, arming the media with information:

- A media alert can announce an upcoming press release and a ‘save the date’ notification can announce an upcoming event or press conference
- Editorial board/media briefing: information session with print and/or broadcast media to prepare for an emerging or breaking issue
- A press conference as opposed to a briefing is usually only for major announcements or highly controversial issues
- You may wish to issue a backgrounder, which is a file containing facts and figures as well as emerging and breaking issues
- ‘B’ roll (film) that can supplement a story containing personal stories and expert opinion. Some media will choose to find their own interviewees so have a list of back-up spokespeople available

Resources and further information

These resources can be used by patients’ organizations in developing and providing patient information:

Ten questions to ask your doctor:
- www.ahrq.gov/consumer/diaginf4.htm#Questions

Toolkit for producing patient information:
- www.nhsidentity.nhs.uk/patientinformationtoolkit/patientinfotoolkit.pdf

International Alliance of Patients’ Organizations – Health Literacy Principles:
- www.patientsorganizations.org/healthliteracy

These resources can be used for advice on communication with the media:

Public relations advice:

Website with advice on working with the media:
- www.npaction.org/article/archive/236

Sample press release:
- www.bemedwise.org/tool_kit/SAMPLE%20PRESS%20RELEASE.doc

Use these resources and this information to advocate, educate and raise awareness!
**Active ingredient:** The substance in a medicine that is pharmacologically active, i.e. that has the effect in the body when it is taken by the patient.

**Adherence to treatment/compliance:** Adherence to treatment is when the patient sticks to the treatment schedule provided. Poor adherence is considered a critical barrier to treatment success.

**Adverse event/adverse outcome/adverse incident/medical error:** Terms used to describe 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.

**Adverse drug reaction (ADR):** Short-term and/or long-term side effects of medicines that may include immunologic or non-immunologic reactions.

**Advocacy:** Action to promote a cause, usually directed at key audiences to effect change.

**Antidote:** Medicine taken or given to counteract poison.

**Bacteria:** Very small, simple living organisms that can cause infection and disease.

**Compensation:** Payment provided to a patient to compensate for injury caused.

**Concordance:** Concordance is an approach that brings together the patient and their healthcare professionals and that regards the patient’s views and choices as paramount in the treatment prescribed.

**Counterfeit medicine:** Medicine manufactured below established standards of safety, quality and efficacy. The medicine is deliberately and fraudulently mis-labelled with respect to identity and/or source.

**Dose:** Amount of medicine to be taken at one time.

**Genetics:** Study of heredity and variation in animals and plants.

**Healthcare associated infections:** An infection which occurs as a result of a healthcare intervention. For example, an infection acquired from an injection at a GP’s surgery.

**Hospital acquired infections:** Infections that are picked up whilst staying in hospital and which are usually caused by bacteria.

**Litigation:** A legal proceeding to determine a legal ruling of fault which may be combined with some monetary compensation.

**Misdiagnosis:** Incorrect identification of a disease by means of a patient’s symptoms.

**Nosocomial infections:** Also called hospital acquired infections.

**Out-patient treatment:** Treatment that is dispensed to patients that does not require a hospital stay.

**Patient care pathway:** The symbolic path along which patients tread from diagnosis to treatment and recovery.

**Patient safety:** The safety of patients. Patient safety can be compromised in many ways, including counterfeit or substandard medicines, the cleanliness of hospitals and medical errors.

**Pharmacovigilance:** The detection, assessment, understanding and prevention of adverse effects, particularly long-term and short-term side effects, otherwise known as adverse drug reactions (ADRs). If ADRs are frequent and/or serious, in certain cases the medicine may be withdrawn from the market.

**Reprocessing:** To make good a medical device for reuse by any or a combination of the following processes: cleaning, disinfection/decontamination, sterilization, refurbishment and repackaging.

**Single patient use medical device:** A medical device that may be used on only one patient but can be used for more than one episode and may undergo some form of reprocessing between each use.

**Substandard medicine:** Medicine manufactured below established standards of quality and therefore dangerous to patients’ health and ineffective for the treatment of diseases.

**Toxicology:** The study of the effects potentially harmful (toxic) substances have on the body.
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