



Healthcare-Associated Infections

*A health crisis requiring
European leadership*



MedTech Europe
from diagnosis to cure

A healthcare crisis requiring European leadership

Healthcare-associated infections (HAI) are infections that a patient acquires when receiving healthcare or during a stay in a healthcare institution.

HAI:

- prolong the suffering of patients
- increase healthcare costs

Every year in the EU it is estimated that 4.1 million people are affected by HAI. This results in 37,000 deaths and adds estimated costs of over €6 billion according to the European Centre for Disease Prevention and Control (ECDC). This is clearly a healthcare crisis requiring pan-European leadership.

In times of austerity and budget cuts, the provision of health services requires innovative solutions to preserve the highest standards of care whilst ensuring the sustainability of healthcare systems.

Patients expect that every effort along the clinical patient pathway, from admission to recovery back at home, is made to ensure their safety.

The medical technology industry has made significant progress in the research and development of technologies to prevent, detect and manage HAI at every stage of the patient pathway.

Eucomed, the European Medical Technology Industry Association and EDMA, the European Diagnostic Manufacturers Association, are working together to drive value-based innovation in the industry and to create more sustainability in healthcare systems throughout Europe.

“When a patient is treated in a hospital they expect to get well, and receive the best care possible without being exposed to medical errors that could lead to adverse health effects or infection (...) Ensuring the safety of anyone that comes into contact with healthcare services is one of the most pressing healthcare challenges to date.”

Martin Seychell, Deputy Director-General for Health and Consumers, European Commission
Health-EU newsletter 107 – Focus, March 2013

HAI: a true burden



Every year, approximately **37,000 deaths** are caused directly by HAI

4.1 million

The yearly number of patients in the EU with at least one HAI is estimated at **4.1 million patients**

The STEP model to fight healthcare-associated infections

The 'STEP' model helps healthcare providers and professionals to assess the risk of HAI and use the information to introduce policies which will help reduce and contain infections. It focuses on:

- **S- Staff** Training for staff on infection control practices
- **T- Technology** Introducing cost-effective, innovative technologies to reduce HAI
- **E- Environment** Reducing environmental risks through cleaning and disinfection of facilities and equipment, good hand-hygiene and isolation of infected patients
- **P- Processes** Setting out clear policies on risk prevention

"A crisis has been building up over decades, meaning that today common yet life-threatening infections are becoming difficult or even impossible to treat. It is time to take much stronger action worldwide to avert an ever-increasing health and economic burden."

WHO, The evolving threat of antimicrobial resistance: Options for action, 2012

The costs and benefits of bacterial screening



Pre-screening programmes for MRSA bacterial infections
reduced

related antibiotics spent by

50%

MRSA bacterial infections by

78%

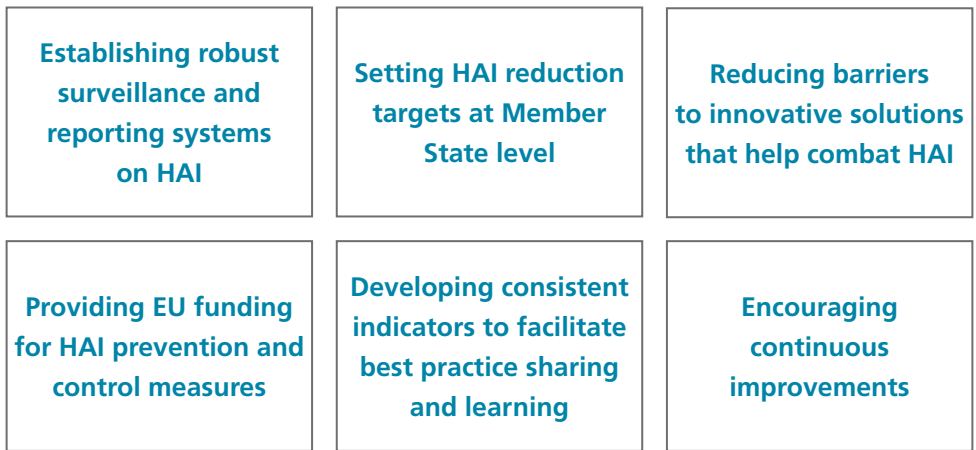
Call to action

It is impossible to get to zero risk but there should be zero tolerance of non-compliance to measures to reduce HAI.

There is a need for change and Member States and the EU need to act in a coordinated manner to reduce the burden imposed by HAI on our healthcare systems.

Eucomed and EDMA therefore call on the European Commission and Member States to build on the Council Recommendations of 9 June 2009 on patient safety, which include the prevention and control of healthcare-associated infections.

The European response to healthcare-associated infections needs to be improved and the following actions are proposed:



One in twenty hospitalised patients acquires an infection



The patient pathway

Before admission to hospital

For patients having an elective procedure in a hospital, as well as in the case of an emergency admission, programmes can be put in place to help reduce the risks of healthcare-associated infections and ensure better outcomes.



The magnitude of the problem

Everybody carries germs on their skin and in respiratory and digestive tracts, that usually do no harm. When hospitalised, some of these germs can lead to infections. This can lead to a longer stay in the hospital, increased costs of treatment and sadly even disability and death.

What can be done?

Screening programmes: Prior to being admitted to hospital patients are screened to establish if they are colonised with bacteria, before being moved to the ward.



Technology examples

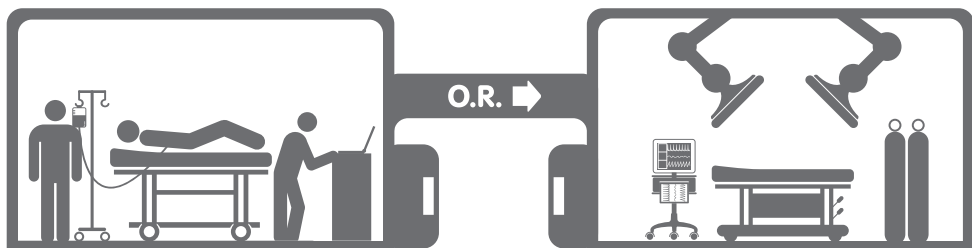
Pre-surgical nasal screening: This can be used to detect whether a patient is carrying a certain type of bacteria. Advanced screening technologies can provide sophisticated and rapid test findings before (e.g. during pre-admission consultation) or on admission. This can help to reduce the infection rate in patients during the medical intervention, facilitate appropriate use of antibiotics avoid contaminating other patients and staff.



Molecular screening techniques: These techniques are beginning to be applied to HAI control. These technologies allow for rapid identification of bacteria. The implementation of such diagnostic tools, in conjunction with appropriate patient management interventions (such as the use of antiseptics), can lead to a decrease in infection rate of up to 60%.

Arrival at the ward

For many medical interventions patients need catheters (thin, clean hollow tube usually made of soft plastic or rubber). These are introduced in the body to inject (e.g. saline solution or anaesthetics) or remove fluids (e.g. urine, wound fluids).



The magnitude of the problem

Many patients will require catheterisation following admission. The European Centre for Disease Prevention and Control (ECDC) has identified catheter related bloodstream infections (CRBSI) as one of the 5 top clinical priority areas for additional scientific guidance. CRBSI occurs when a patient develops a bloodstream infection with the site of the infection being an intravascular catheter. This may happen when bacteria or fungus grow in or around the catheter and spread to the patient's bloodstream. These infections have serious consequences: 30-35% of patients in intensive care with catheter-related bloodstream infections die.

What can be done?

The best way to prevent infections is through good professional practice including hand-hygiene and appropriate care when dealing with patients. Innovative medical technology can also help.



Technology examples

Cleaning and disinfection procedures: These procedures are essential to decrease the number of microbes in the area close to the patient. It is also crucial to put in place personal protective barriers (e.g. gloves, gown) to prevent healthcare workers from carrying bacteria to other patients.



Advanced medical technologies: Substantial reductions in CRBSI can be achieved with the aid of advanced medical technologies together with complementary improved practices. These include integrated safety catheter systems and closed IV access together with associated care and maintenance.

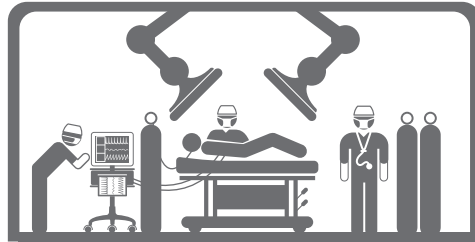


Use of antimicrobial dressings: In addition, the use of Chlorhexidine Gluconate (CHG) antimicrobial dressings that integrate a clear CHG gel pad reduce the level of bacteria from the skin flora which is the most common source of catheter related bloodstream infections.

Pre-filled saline flushing devices: The use of pre-filled saline flushing devices for maintenance of indwelling catheters reduces the potential for contaminated solutions, saves staff time and eliminates the need for needles, glass vials and ampoules.

Operating room surgery and invasive diagnostic procedures

An infection can occur after surgery in the part of the body where the procedure took place. In case of surgery, these are called surgical site infections (SSIs) and they account for more than half of all adverse events in this group of patients.



The magnitude of the problem

SSIs, if not prevented, can result in longer post-operative hospital stays, may require intensive care and even additional surgical procedures. It is estimated that approximately 6% of all patients undergoing surgery develop SSIs.

What can be done?

Approximately 40 to 60% of SSIs can be prevented by implementing good clinical practices, using innovative medical technologies including minimally invasive procedures and putting in place adequate surveillance mechanisms. Ensuring the right ventilation in the operating room, best practices of sterilisation and disinfection of surgical instruments, the adherence of healthcare workers to guidelines such as wearing gloves and gowns are important to control SSIs.



Technology examples

Active patient warming:

Hypothermia is a significant risk factor for developing SSIs. The use of active patient warming blankets to maintain patient temperature during the procedure is proven to significantly reduce the rate of SSIs.



Using adequate antimicrobial

measures: Using gowns and drapes that are resistant to microbial penetration is also important to prevent SSIs. Skin disinfection combined with the use of adequate drapes including antimicrobial incise drapes for high risk procedures, also reduces wound contamination while the use of antimicrobial coated sutures have been shown to reduce the risk of infection and thus improving patients' clinical outcome.

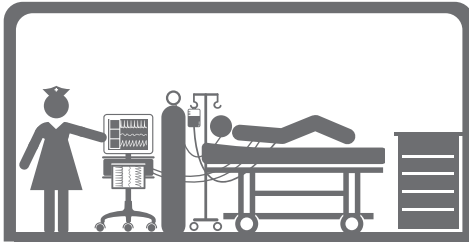


Reprocessing of reusable

instruments: Sterilisation of invasive devices is key in avoiding infections. Low temperature sterilisation protects delicate instruments and ensures functionality. Increasing automation of high level disinfection processes does ensure consistent outcomes and minimises risks.

Hospital stay (intensive care unit or ward)

Patients staying at a hospital expect to recover quickly and receive the best possible care without being exposed to any unnecessary harm. An infection acquired will diminish the patient's well-being. In severe cases such infections can cause prolonged illness, disability or even death.



The magnitude of the problem

Patients who acquire infections from surgery spend, on average, an additional 6.5 days in the hospital, are five times more likely to be readmitted after discharge and twice as likely to die.

What can be done?

Healthcare workers' adherence to adequate antibiotic stewardship programmes, suitable measures to detect bacterial infection avoiding the risks of transmission and the use of minimally invasive procedures during surgery, reduces patients' recovery time and risk of infections.



Technology examples

Safety devices: The use of needles or syringes with safety devices can prevent a healthcare worker from a needle stick injury and thus from being infected with HAI or blood borne diseases such as HIV or Hepatitis.



ECG cables: Reusable ECG cables are designed for multiple use, however these cables for patients receiving cardiac monitoring have been shown to still be colonized with pathogens even after cleaning.

In these circumstances, the introduction of a disposable single patient use product enables the ability to reduce the risk of cross contamination in a post treatment environment.



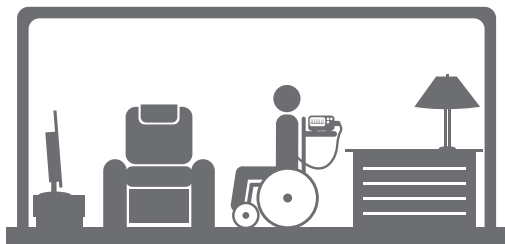
Automated systems for the disinfection of the environment:

The use of automated area decontamination using for example hydrogen peroxide as a biocidal agent, in conjunction with manual cleaning can reduce the environmental contamination by pathogens in the environment like patients' rooms, operating rooms and intensive care units. Automation ensures efficiency and that the level of disinfection achieved is consistent every time.

Discharged and back at home

The delivery of healthcare is constantly changing. There is an increasing trend towards outpatient clinics and day surgery which means that patients continue to be treated in other healthcare facilities or in their home environment. Patients expect their safety to be taken care of throughout the continuum of care.

The role of patients, carers and family in combatting healthcare-associated infections is crucial during recovery and back at home. They need to be educated on how they can contribute to reduce HAI to ensure safe recovery of the patient.



The magnitude of the problem

Patients and carers need to be vigilant when recovering back at home. Adherence to hygiene measures, detection of infections that may appear after the patient has been discharged and the adequate use and replacement of medical devices are crucial to complete the recovery of the patient. If not prevented, infections can lead to decreased quality of life, more time lost from work and increase the burden on family and healthcare systems.

What can be done?

The home care setting is a challenging environment because it is more difficult to control. Patients and their carers play an important role through adhering to good patient safety practices.



Technology examples

Wound care management: Dressings are important to maintain sterility and absorb blood and serum from wounds. Advanced dressings containing barriers to protect the wound site from bacteria as well as antimicrobial wound care products can contribute to improving patient recovery.



Timely detection of bacteria: Antibiotic treatment can be life-saving but constitutes also a risk factor for acquiring infections such as nosocomial diarrhoea and other intestine infections. Modern medical technology can help detect and identify the bacteria within a few hours. Clinicians can then determine the most appropriate and targeted therapy, infection prevention and control measures which will lead to better management of the disease and a reduced risk of undesired side effects.



MedTech Europe is

an Alliance of European medical technology industry associations. The Alliance was founded in October 2012 and currently has two members being EDMA, representing the European in vitro diagnostic industry, and Eucomed, representing the European medical devices industry. Other European medical technology associations are welcome to join the Alliance, established to represent the common policy interests of its members more effectively and efficiently.

Our mission is

to make value-based, innovative medical technology available to more people, while supporting the transformation of healthcare systems onto a sustainable path. We promote a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of its stakeholders. In addition, we demonstrate the value of medical technology by encouraging our members to execute the industry's 5-year strategy.

This document has been jointly elaborated by Eucomed and EDMA Task Forces on healthcare-associated infections