Public consultation on strategies for improving patient safety by prevention and control of healthcare-associated infections
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BACKGROUND

The Council Recommendation (2002/77/EC) on the prudent use of antimicrobial agents in human medicine focussed on the importance of using antimicrobials prudently to contain the problem of antimicrobial resistance, primarily by containing the emergence of resistance. The Council has invited the Commission to keep matters covered under review and to submit further proposals, as appropriate. Not only emergence, under selective pressure of antibiotics, but also spread is an important driver of the problem of resistance.

Healthcare-associated infections (HCAI) affect an estimated 1 in 10 patients and lead to considerable increase in illness, mortality and costs. These infections are not constrained by national boundaries and can rapidly spread between countries as evidenced by international spread of MRSA as well as the SARS coronavirus. Taking action in this area seems urgent also in light of the importance of infection control during a possible pandemic to contain or at least delay the spread of the influenza-virus.

Other challenges that make action particularly pressing are the increased patient mobility, the ageing society, rising public expectations and the advances in medical treatment. Health systems across Europe face common challenges as they adapt to constant developments in medical science. Although these health systems are primarily the responsibility of the Member States, cooperation at European level has great potential to bring benefits both to individual patients and to health systems overall.

The increasing numbers of older people will generate a proportionately greater demand for healthcare. The European Union provides freedoms for citizens to seek healthcare in other Member States, as confirmed by the European Court of Justice. When patients do seek healthcare in other Member States, it is essential to ensure that the well-being and safety of the patient is properly protected. Another important factor driving increases in health expenditure is constant innovation in medical technologies and techniques. HCAI is one of the most prominent reasons for failure of advanced medical treatment such as complicated surgery, intensive care, transplant medicine, and cancer treatment.

Due to all these reasons it is to be expected that HCAI will constitute an increasing proportion of the overall burden of disease in European societies. The Commission believes it may be appropriate to propose recommendations in the area of infection control and hereby seeks your consultation and comments on this document that could be the basis for formulating proposals.
I. INTRODUCTION

Infection in hospitals and other healthcare settings is a problem for health services around the world and is receiving considerable media and political attention. Health care interventions, although intended to benefit patients, may in some cases cause harm. Healthcare associated infection (HCAI) affects an estimated one in ten hospital patients each year. Infections caused by these agents are often difficult to treat due to antimicrobial resistance and difficult to eradicate from the health care environment and may spread to the community.

HCAI, in a certain way, is a price we pay for advances in medical technology and treatment. Many factors contribute to the worrying increase in healthcare associated infection rates. For example, the use of indwelling devices that breach normal defence mechanisms. Individuals receiving antimicrobial chemotherapy that change the composition of the host flora and patients with immune defects compromising their ability to suppress infections are at a particular risk. Also organisational and behavioural factors contribute like high bed occupancy, lack of entry screening of patients, increased movements of patients, poor staff to patient ratios, poor compliance with hand washing and other hygienic practices by health staff. Other factors, like the inappropriate use of antibiotics, go far beyond healthcare institutions.

Overall cost estimates

HCAI prolong the suffering of the patients, increase health care costs and have other direct and indirect economic implications, such as loss of productivity and disability. Although measurement of costs is difficult, the cost of hospital acquired infection is high, for example the UK National Audit Office estimated it at £1 billion per year for the UK. Costs will be different for other countries and will change with time, however the relative magnitudes will be similar. Overall in the European Union, it has been estimated that there are approximately 3 million healthcare associated infections and 50,000 attributable deaths per year. The US Institute of Medicine estimates that preventable adverse patient events, including hospital-acquired infections, are responsible for 44,000-98,000 deaths annually in the US at a cost of $17-$29 billion.¹

Cost benefit of infection control

Ways to improve this situation do exist. Although HCAI is a multifaceted problem ways to control it are understood and assessment of the cost of control programmes shows major savings can be achieved. Data available from the US show that the costs of maintaining one hospital bed for a year would support a full hospital infection control programme in a 250-bedded hospital. The Study on the Efficiency of Nosocomial Infection Control (SENIC)² estimated that the cost of infection control teams was only 7% of the infection costs. Therefore, if infection control programmes were effective in preventing only 7% of nosocomial infections, the costs of the programmes would already be covered. A UK study from 2000 indicated that a 10%

A reduction in the number of nosocomial infections could result in a saving of 150 million euros per year.  

**Working together in Europe**

The growth in the frequency of infections that are resistant to the common antibiotics has been well documented and is worrying. Looking at Europe we see significant differences in levels of healthcare associated infections, such as rates of methicillin-resistant *Staphylococcus aureus* (MRSA). Southern European countries, the United Kingdom and Ireland report the highest MRSA-rates, whereas northern European countries still have proportions of MRSA in bacteraemia patients below 1%. The uncompromising “search-and-destroy” policy in the Netherlands and in Nordic countries appears to be effective in controlling the emergence of MRSA.

The recent Luxembourg declaration on Patient Safety recognizes that access to high quality healthcare is a key human right recognised and valued by the EU, its Institutions and the citizens of Europe. The ‘open method of coordination’ for healthcare and long-term care proposed by the Commission provides a framework for Member States to exchange experience and to compare policies and performance. The High Level Group on health services and medical care established by the Commission and Health Ministers provides a mechanism for practical cooperation on making health systems work together better. Of course, none of this puts into question the primary responsibility of the Member States for health in general and for health systems in particular.

Decision 2119/98/EC of the European Parliament and of the Council established a Network for the epidemiological surveillance and control of communicable diseases in the Community and Decision 2000/96/EC provided that surveillance of HCAI within this Community network will be performed by standardised collection and analysis of data in a way that will be determined when specific Community surveillance networks are put in place. Under the public health programme projects are financed addressing the problem of HCAI and preparing the establishment of such a Community surveillance network.

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Public reporting versus confidentiality of hospitals participating in surveillance systems

In the US there is a move to require the public reporting of healthcare-associated infections. More than 30 (US) states have introduced legislation on public reporting of healthcare-associated infection rates, and five states have passed reporting requirements. A consensus conference in February 2005 of associations of health care professionals in the US recognised HCAI as a problem and stated that infection prevention, surveillance and control programs must be continually improved but concluded that public reporting of infection data alone will not accomplish this improvement.

Advocates of mandatory public reporting of HCAI believe that making such information publicly available will enable consumers to make more informed choices about their healthcare and improve overall healthcare quality by reducing HCAI. Further, they believe that patients have a right to know this information. However, others have expressed concern that the reliability of public reporting systems may be compromised by institutional variability in the definitions used for HCAI, or in the methods and resources used to identify HCAI. Presently, there is insufficient evidence on the merits and limitations of an HAI public reporting system.

In Europe, some Member States like the UK and France have passed legislation that obliges hospitals to report publicly certain indicators related to HCAI. In the Netherlands, a recent Court ruling decided that data on incidence of HCAI collected through a national surveillance system do not have to be made public. Surveillance of post-operative infections, however, is recognised as one of the quality indicators of hospitals and may be made public in the future.

Reported rates of HCAI show large variations across the Member States of the European Union reflecting large differences in surveillance methodology, the functioning of the health services and the adoption of policies, guidelines and technologies. Therefore the interpretation of these figures has to be undertaken with great care and needs expert consultation. National surveillance systems, therefore, should be clear on regulation of data access and should comply with the data protection regulations and guarantee the confidentiality and security of data. Confidential treatment of the identity of healthcare institutions participating in a surveillance network should be encouraged in order to foster the validity of reported data and to prevent possible misinterpretation of data. Serious efforts and resources are needed to improve reporting systems and make data more comparable.

European Centre for disease prevention and control (ECDC)

The availability of European standardised comparable data is recognised as a considerable support to evaluation, risk assessment and control activities to reduce the burden of these infections. As laid down in the Regulation establishing the Centre for

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8 Consensus Conference, Healthcare-Associated Infections: Realizing the Benefits of Mandatory Public Reporting, February 7-8, 2005, in Atlanta, GA.
disease prevention and control\textsuperscript{9}, the ECDC will have an important role to coordinate European surveillance, also in the area of antimicrobial resistance and HCAI: “The Centre, through the operation of the dedicated surveillance networks and the provision of technical and scientific expertise, shall support the networking activities of the competent authorities recognised by the Member States”. “The Centre shall coordinate data collection, validation, analysis and dissemination of data at Community level, including on vaccination strategies.”

The ECDC should be able to assist the Commission and Member States in developing standard operating procedures and surveillance methodologies to allow for better comparability of HCAI data and establish texts on principles and guidelines of best practice on the prevention and control of HCAI. The ECDC could provide recommendations and expert guidance on outbreak control strategies and help in monitoring the implementation of recommendation proposals and action undertaken my Member States.

II. DEFINITION OF THE PROBLEM

- Health care-associated infections (HCAI, also referred to as nosocomial or hospital-acquired infections) are defined as any disease or pathology (illness, inflammation) related to the presence of an infectious agent or its products as a result of exposure to health care facilities or health care procedures.

- HCAIs represent a significant part of communicable diseases and are a frequent source of morbidity and mortality in all Member States of the European Union.

- HCAIs are caused by infective agents that include bacteria, fungi, viruses, parasites and other transmissible agents. Infections are often caused by the introduction and multiplication of pathogens within patients brought about by medical procedures. Individuals receiving antimicrobial chemotherapy that changes the composition of the host flora and patients with systemic or local immune defects which compromise their ability to suppress infections are at a particular risk.

- HCAIs mostly occur during or after hospitalisation but can also develop in the context of ambulatory care. Patients who acquire HCAIs may be acutely ill and more likely suffer co-morbidities and/or chronic disease and thus frequently involve the senior segment of the population that is an increasing proportion of the European population.

- HCAI is one of the most prominent reasons for failure of advanced medical treatment such as complicated surgery, intensive care, transplant medicine, and cancer treatment. Due to an increasing utilisation of advanced medical treatment and for reasons mentioned above, it is to be expected that HCAIs will constitute an increasing proportion of the overall burden of disease in European societies.

- Infectious agents that cause HCAIs are often derived from micro-organisms that are part of the normal human flora. Emerging strains have a propensity to spread, as they are more adapted to typical health care practices. Frequently they have acquired resistance to one or more antimicrobial agent, normally effective in the treatment of non-health care-associated infections. Consequently, infections caused by these agents are often difficult to treat due to antimicrobial resistance and difficult to eradicate from the health care environment and may spread to the community. They thereby pose a tangible threat to public health.

- HCAIs prolong the suffering of the patients, increase health care costs, have other direct and indirect economic implications (loss of productivity and disability) and represent a reservoir for the emergence of additional, i.e. multiple antimicrobial resistance traits. Considering this economical impact, it becomes clear that successful prevention and control strategies are highly cost-effective. Therefore, concerted action at the Community level shall be taken, to contain and control HCAIs by encouraging epidemiologically sound and evidence-supported control measures.
• Due to the ability of infectious agents that can cause HCAIs to colonise humans for prolonged periods, colonised patients may disseminate these agents both during and after their hospital stay. In this way entire health care collectives consisting of hospitals, long-term care facilities, nursing homes, ambulant health care institutions as well as the resident catchment community are carrying the burden of the increasing numbers of individuals colonised with healthcare-associated pathogens. Therefore, control efforts need to address all participants of health care collectives on a regional level and need to take into account their different roles and functions in order to control the further spread of these agents.

• With the increasing mobility of populations and the freedom in the European Union to seek medical treatment outside the country of residence, HCAIs are not constrained by national boundaries and can rapidly spread between countries as evidenced by international spread of epidemic clones of methicillin-resistant *Staphylococcus aureus* as well as the SARS coronavirus.
III. HOW TO BRING ABOUT CHANGE?

- To bring about the necessary changes, a first step is that all participants of the health care collectives, patients, patient support groups, health care workers, physicians, health care managers, and policy makers as well as the general public need to be informed about the problem of HCAIs and antimicrobial resistance through public awareness and professional undergraduate- and postgraduate training. The critical next step is to see to it that this awareness brings about the necessary behavioural and organisational changes.

- Support of research, especially to improve the understanding of the epidemiology of HCAIs and the evolution and dynamics of healthcare-associated pathogens with antimicrobial resistance on a population basis should be supported by all Members States in order to address cost-effective ways for prevention and control. This shall include the development of diagnostic tools for rapid detection of colonisation, infection, and antimicrobial resistance.

- To develop strategies for the prevention and containment of infectious agents that can cause HCAIs, surveillance systems that provide valid, reliable, and comparable data on the prevalence and incidence of HCAIs and the dissemination of particularly successful strains need to be established throughout the Community.

- Moreover, strategies to improve health care hygiene and to control the dissemination of highly transmissible strains of healthcare-associated pathogens both within and outside health care institutions need to be upgraded and coordinated. They need to take into account the epidemiology and population biology of the causative agents, as well as the changing of medical technology and health care delivery systems.
IV. WHAT DOES THIS MEAN FOR MEMBER STATES?

In order to contain further the spread of antimicrobial resistance and improving patient safety by prevention and control of healthcare-associated infections a number of specific measures seem appropriate at national level:

First of all, it seems critical that a national strategy exists aimed at improving patient safety by prevention and control of healthcare-associated infections. Such a strategy should incorporate control and prevention of HCAI into national public health objectives and aim to reduce the risk of transmission of healthcare-associated infections (often multiply resistant to antimicrobial agents) within healthcare institutions and healthcare collectives. This strategy, complimentary to strategies targeted towards the prudent use of antimicrobial agents, should take account of the best available scientific evidence and should allocate resources necessary for taking control and preventive measures, for organising control and prevention programmes in health care institutions, for surveillance systems, and for education and training and research.

Secondly, it will be important to have in place a dedicated Committee for the coordinated implementation of the national strategy, complimentary to work of the intersectoral mechanism on the prudent use of antimicrobial agents in human medicine, as well as for the purpose of information exchange and coordination with the Commission, the European centre for disease prevention and control, and the other Member States.

Broad lines of strategy

Based on the above considerations, it may be possible to identify the main elements of a strategy to contain the spread of HCAI. This could include the following objectives and actions:

1. implement control and preventive measures to support the containment of HCAIs by:
   a. giving a high level of priority to the implementation of infection control measures in all healthcare settings for all healthcare activities. Standard measures and precautions will include:
      • precise guidelines for hand hygiene (such as use of alcohol-based hand-rubs) and for the use of entry screening and barrier protection, when and where appropriate,
      • policies for protecting healthcare staff from healthcare-associated pathogens (e.g. through vaccination, pre- and post-exposition prophylaxis and procedures, safety equipment, protective clothing),
      • recommendations for the routine management of healthcare equipment, patient environment, linen and waste,
      • cleaning, sterilisation and disinfection procedures, disposable medical equipment, etc.
   b. defining the criteria for deciding when to adopt (and when to discontinue) additional precautions such as use of isolation (single)-rooms in hospitals (when
available) and for alternative placement strategies, aimed at controlling specific routes of transmission from patients infected or colonised with antibiotic resistant organisms, or highly transmissible pathogens which could represent a special local, national or international threat (e.g.: methicillin-resistant *Staphylococcus aureus*, vancomycin resistant enterococci, multi-resistant tuberculosis, SARS).

c. adapting the above-mentioned recommendations in the context of long-term and rehabilitation facilities, and to ambulatory care practices (particularly in the growing sector of home care).

d. including control and prevention of HCAI in all relevant health-related legal or managerial activities such as: quality standards for building (including the definition and provision of isolation facilities), equipment and products, drug and food safety regulations, staff curriculum, education and training requirements, clinical governance framework, performance management, certification and accreditation processes, communication of data and public information.

e. encouraging the adoption of recommended control and prevention measures by using indicators provided by surveillance systems, as well as process and result indicators such as those arising from audits organised at national, regional and local levels.

f. ensuring that all relevant guidelines and recommendations are regularly evaluated and updated, publicly accessible and accountable for.

g. participating in collaborative EU and international initiatives aimed at confronting experiences and harmonising infection control and prevention policies.

2. organise infection prevention and control programmes in health care institutions by ensuring that:

a. continuous improvement of the quality of care, as part of a total quality management approach, is a long-term strategic priority for health care institutions and involves all hierarchic levels and functions to achieve results-oriented behaviour changes. Health care institutions shall apply quality assurance methods to ensure that patient care procedures are efficient and meet the standards of best practice.

b. proper organisational and structural arrangements are in place that enable the implementation and maintenance of effective infection control and prevention activities in healthcare organisations, by defining responsibilities at all levels, by organising support facilities and reference centres, local technical resources (infection control committees and teams), funding and evaluation procedures.

- Each health care institution, such as hospital or long term care facility, should establish a **healthcare-associated Infection Prevention and Control Programme** as an essential component of quality of care management contributing to patient and staff safety. This Programme should consider
structural arrangements of the healthcare institution (including technical and architectural aspects), integrate standards in all diagnostic and therapeutic procedures (process quality), as well as quality assurance of disinfection and sterilisation procedures (including process- and outcome-quality control) and will be closely linked to the institution's antibiotic policy.

- The health care institution senior management should appoint and participate in an interdisciplinary advisory body, the **Infection Prevention and Control Committee** or a body under the institution’s health care quality management (with representation of management, nursing, clinical care, medical microbiology, pharmacy and occupational health staff) which can undertake the task to develop and monitor the healthcare-associated Infection Prevention and Control Programme.

- The health care institution management should appoint an **Infection Prevention and Control Team** or a body under the institution’s health care quality management which can undertake the task to implement the healthcare-associated Infection Prevention and Control Programme and contribute to the establishment and maintenance of infection control procedures, including surveillance and outbreak investigations, education of staff, auditing compliance of nursing and medical practices with recommended procedures and inspecting technical equipment. The size of the team should fit to the capacity and needs of the institution according to national standards. Physicians and nurses of the team must be specialised in the field according to national legislation.

- The **management of health care institutions** bears responsibility for quality of care, including the endorsement of the healthcare-associated Infection Prevention and Control Programme and the enactment of internal guidelines. These guidelines shall be in accordance with legal standards and regulations and recommendations of scientific societies. The management is responsible for occupational health and safety and adequate training and continuous education of healthcare staff.

3. **establish or strengthen active surveillance systems on healthcare-associated infections, pathogens, risk factors as well as process and structure indicators measuring compliance with best practice. These systems are needed:**

   a. at local level (hospitals, other institutions), in order to follow-up HCAI rates in time to guide and evaluate the implementation of infection control measures, to compare risk-adjusted local rates with those in other institutions as a measure of own performance (through the participation to a national/regional surveillance network) and to detect and follow-up local epidemics of HCAI. In some Member States institutions have the obligation to publicly report HCAI rates.

   b. at national level, in order to establish national reference data for meaningful comparisons between institutions, to benchmark and feedback results to the institutions taking into account the limitations of benchmarking, to follow-up the epidemiology of HCAI at the national level, to follow-up the occurrence of HCAI epidemics and the micro-organisms involved at the national level and to assess
the risk factors of healthcare-associated infections as well as the relationship between HCAI rates and process indicators.

HCAI surveillance systems should use, wherever possible, internationally recognised classification systems and comparable methods and definitions to feed into international surveillance systems, to follow international spread of healthcare-associated micro-organisms, to establish international reference data for risk-adjusted inter-country and inter-institution comparisons, and to monitor implemented measures for infection control and infection control policies in relation to HCAI indicators.

These surveillance systems should be sustainable with clear regulation of data access and ownership. They should comply with the data protection regulations and guarantee the confidentiality and security of data. The confidential treatment of the identity of healthcare institutions participating to a surveillance network should be encouraged in order to foster the validity of reported data and to prevent possible misinterpretation of data.

These systems should strive to achieve the best balance between simplicity and collecting enough information in order to make meaningful risk-adjusted comparisons of infection rates and process quality indicators. Wherever possible, electronic data collection making maximal use of available (administrative, laboratory, pharmacy and clinical) databases in the institution should be encouraged to reduce workload, facilitate the rapid detection of HCAI epidemics and enhance the sensitivity and thus the validity of the surveillance.

To improve quality and comparability of surveillance data regular training in surveillance methods to local surveillance teams should be provided. In order to assess and improve the quality of national, and international data on HCAI, it is essential that external data validity studies (assessing the sensitivity and specificity of surveillance data) using internationally comparable methods be performed at the level of the healthcare institution.

4. **foster education, training, research and information exchange on prevention and control of healthcare associated infections by:**

a. ensuring that healthcare institutions have a strategy in place for education, training and information exchange on HCAI epidemiology, control and prevention.

b. providing strategies for training for all people involved in patient care in order to increase awareness and to promote best practice of infection control.

c. targeting education programs to meet different learning needs by organising:
   - regular basic education for all patient care staff, trainees and health care organisers/managers and providers on basic principles of hygiene and infection control, local guidelines of good clinical practice, standard operating procedures, impact of the HCAI on mortality and hospital budget, management arrangements of infection control within the hospital. This should be implemented both at introduction training for all new employees and as an
integral part of in-service continuing professional development schemes provided by the employing organisation to its employees.

- regular advanced education for HCAI infection control personnel and link-staff from clinical wards. Specialty training for infection control professionals needs to be organised in every sector of the health care system (acute and long term care hospitals, home care and primary care). Specialty training curricula agreed upon at European level for physicians, nurses and other health professionals should be implemented by training programmes according to national education and certification systems.

- universal information for patients and their families about risks, monitoring, prevention and managing of HCAI infections. Patients receiving care in an institution should receive accurate information about these risks and about the necessary precautions to minimize them.

d. using modern techniques and methodology of training and education in order to meet different staff needs, availability and learning styles, e.g. workshops, internet, e-learning, practical training, case analysis financed from the healthcare budget.

e. establishing education practice audits and regular feedback monitoring to ensure effectiveness of training programmes.

f. funding education and information exchange in health care institutions as an integral part of overall health care cost according to regulations at national level.

g. support research to improve the understanding of the epidemiology of HCAIs and the evolution and dynamics of healthcare-associated pathogens with antimicrobial resistance on a population basis in order to address cost-effective ways for prevention and control. This shall include the development of diagnostic tools for rapid detection of colonisation, infection, and antimicrobial resistance.
V. WHAT IS NEEDED AT COMMUNITY LEVEL?

In order to contain further the spread of antimicrobial resistance and improving patient safety by prevention and control of healthcare-associated infections a number of specific measures seem appropriate at Community level:

- to facilitate mutual information, consultation, cooperation, and action through the procedures and mechanisms available in the Network for the epidemiological surveillance and control of communicable diseases in the Community (Decision 2119/98/EC) in this field.
- to foster with the European Centre for Disease Prevention and Control (ECDC) the establishment of texts on principles and guidelines of best practice on the prevention and control of HCAI, recommend on outbreak control strategies, and assist Member States in developing training and curricula.
- to propose case definitions for HCAI and operating procedures for the nature and type of data and information to be collected as well as epidemiological and microbiological surveillance methods. These case definitions should build on definitions developed by the European network for the surveillance of nosocomial infections (HELICS) and use microbiological diagnostic criteria where appropriate and by this encourage the use of validated methods and allow the integration of new laboratory developments such as reliable rapid tests.
- to explore indicators for quality of care with the high level group on health services and medical care and how to consider publicly reported healthcare-associated infection rates from single institutions as well as data collected through surveillance systems.
- to develop guidance on minimum requirements for isolation facilities in health care institutions and recommendations on other aspects of physical infrastructure (e.g. hand hygiene facilities, minimum space between beds, ratio of infection control doctors/nurses to acute beds) and develop “structure indicators” i.e., resources in personnel and material reserved to combat HCAI (possibly defined as a percentage of the total care budget related to the population or number of patients).
- to propose strategies and practical tools for preventing and reducing the exposure of health care staff to healthcare-associated pathogens.
- to develop a strategy for access to data from surveillance systems for HCAI, risk factors and indicators.
- to cooperate with the World Health Organisation (WHO) and other relevant international organisations on these issues.

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