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REPORT FROM THE COMMISSION TO THE COUNCIL

**on the basis of Member States' reports on the implementation of the Council
Recommendation (2009/C 151/01) on patient safety, including the prevention and
control of healthcare associated infections**

(Text with EEA relevance)

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1. INTRODUCTION

In June 2009, the Council adopted a Recommendation on patient safety, including the prevention and control of healthcare-associated infections (2009/C 151/01), referred to here as the Recommendation.

The Recommendation consists of two chapters. In the first chapter on general patient safety, Member States are asked to put in place a series of measures with a view to minimising harm to patients receiving healthcare. These measures include developing national policies on patient safety, empowering and informing patients, establishing reporting and learning systems on adverse events, promoting the education and training of healthcare workers, and developing research. The Recommendation invites the Member States to share knowledge, experience and best practice and to classify and codify patient safety at EU level by working with each other and with the Commission.

In the second chapter on the prevention and control of healthcare-associated infections (HAIs), Member States are asked to adopt and implement a strategy at the appropriate level for the prevention and control of HAIs and to consider setting up an inter-sectoral mechanism or equivalent system for the coordinated implementation of such a strategy. This strategy should comprise infection prevention and control measures at national/regional level and at the level of healthcare institutions, surveillance systems, the education and training of healthcare workers, information to patients, and research.

The Recommendation complements other EU initiatives. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare¹, due to be transposed by October 2013, seeks not only to clarify the rights of patients when accessing care in another EU Member State: it also seeks to ensure that such care is safe and of good quality. It therefore includes several provisions relating to the safety and quality of healthcare: collaboration of Member States on standards and guidelines, information to patients on healthcare providers and on the safety/quality standards applied, and the possibility to refuse prior authorisation if there are doubts about the quality and safety of a healthcare provider in the Member State of treatment.

The implementation of the actions envisaged by the Recommendation (e.g.: sharing knowledge, experience and best practice; regularly reviewing and updating patient safety standards applicable to healthcare provided within the Member States; informing patients about safety measures to reduce or prevent harm and about patient safety standards; adopting and implementing a strategy for the prevention and control of healthcare-associated infections, including establishing an inter-sectoral mechanism or equivalent system for the coordinated implementation of the strategy) will be considered as a reference for assessing safety standards under the Directive.

Furthermore, Article 12 of Directive 2011/24/EU aims to foster the development of Centres of Excellence and European Reference Networks. As a first step, it authorises the Commission to define, through delegated and implementing acts, the criteria and conditions that such centres and networks must fulfil. Patient safety requirements and criteria are likely to be defined in this context. In addition, the healthcare centres of the future European Reference Networks,

¹ OJ L 88, 4.4.2011, p. 45.

by implementing common initiatives or practices in the field of patient safety, will help in defining best practices in complex procedures.

Finally, the five-year ‘Action plan against the rising threats from antimicrobial resistance’, adopted by the Commission in November 2011, aims to put in place effective ways to prevent microbial infections and the spread of micro-organisms. Strengthening infection prevention and control in healthcare settings (action 4 under the plan) will contribute to achieving this aim.

The Recommendation invites the Commission to present an implementation report to the Council, on the basis of information provided by the Member States. In April 2011, Member States were asked to report to the Commission on their progress in implementing the Recommendation based on a standardised questionnaire. The Commission received replies from all Member States, one EEA country (Norway²) on a voluntary basis and five regions (on general patient safety) / 15 regions (on HAIs). Additionally, 14 Member States updated information on the general patient safety part in July 2012.

This Report summarises the main actions taken at Member State and EU level by June 2011 (July 2012 for the general patient safety part) and highlights those areas of the Recommendation needing further attention. It is accompanied by a Commission Staff Working Document providing a more detailed technical analysis of the replies received. In this Report, only the replies at national level are presented³; the Commission Staff Working Document includes analyses of the replies both from national and regional levels. Where this Report refers to *countries*, it means the EU Member States and Norway.

2. SUMMARY OF MAIN ACTIONS AT MEMBER STATE LEVEL

2.1. General patient safety

2.1.1. Development of national policies and programmes on patient safety

All countries have developed specific policies on patient safety and/or embedded them as priorities in their health policies. A competent authority responsible for patient safety at national or regional level has been officially established by a legal act in 19 Member States, and in six others has been designated without a legal act. Competent authorities mainly identify and promote best practices, collect information about patient safety programmes in place and develop guidelines on patient safety. There are regularly updated patient safety standards in 15 Member States and in 11 of them they are mandatory. Eight other countries have in place patient safety measures other than standards (e.g. evidence-based clinical guidelines, accreditation procedures and measurement of patient safety culture). However, five Member States do not report any existing patient safety standards or other measures in place. A large majority of countries (24) agree that guidelines on how to construct and introduce patient safety standards would be useful for them.

² Norway has been actively participating in patient safety activities at EU level and is included in the analysis of this Report.

³ Similar responses from the regions of a Member State that responded only at regional level were counted as a country response.

2.1.2. Information about adverse events

The Recommendation asks Member States to establish reporting and learning systems on adverse events. In July 2012, such systems were fully operational in 15 Member States and partly implemented in 11 others. They mainly provide information about the causes of adverse events and record their numbers by type. In 18 countries, they are separate from disciplinary procedures in order to ensure a non-punitive context for reporting. Health professionals and other health workers are encouraged to report about adverse events in nearly all countries where reporting and learning systems exist. In two thirds of countries, reporting by health professionals has increased over the last two years.

In 13 out of the 26 Member States in question, reporting and learning systems also provide an opportunity for patients and their families to report. However, information about reporting rates is routinely collected only in nine Member States, of which five inform that reporting by patients has increased between 2009 and 2012.

2.1.3. Empowering patients

The Recommendation encourages Member States to empower patients by involving patient organisations and individual patients.

Patient organisations are formally invited to participate in the development of patient safety policies in 14 countries, while in six others their involvement is not formally required but is the practice.

Member States are recommended to disseminate information to patients on patient safety standards, safety measures to reduce or prevent errors, the right to informed consent to treatment, complaint procedures, and available remedies and redress. In all reporting countries, at least one of these items of information is communicated to patients (the right to informed consent being communicated in all countries). However, only five Member States provide patients with all of these details. Information about patient safety standards is the least available. On the other hand, more than half of Member States report that a list of accredited healthcare institutions is available to citizens. Information is provided to patients mostly via public websites or by health professionals. Twenty-three countries have in place mechanisms to capture patients' feedback on the availability and accuracy of the information provided. Examples include written or on-line questionnaires upon discharge, annual patient experience surveys and the possibility to post comments on a dedicated website.

Core competencies for patients in patient safety have been developed and disseminated only in 12 Member States, and the reports show that the concept is interpreted differently from one country to another. Two Member States have developed a specific set of core competencies for patients, while 10 others include related elements in other health policies.

2.1.4. Education and training of healthcare workers on patient safety

All but one of the countries report that they have promoted the education and training of healthcare professionals on patient safety over the last two years. However, only 15 have formal requirements in place to include patient safety modules in one or more types of education. They are mostly offered to nurses and medical doctors as part of continuing professional education, postgraduate education or on-the-job training. There is less on offer for healthcare managers and healthcare workers other than medical doctors, nurses, and

pharmacists. No country embeds patient safety in all levels of education for all groups of professionals, but three countries do this for doctors, nurses and pharmacists.

2.1.5. Cross-border activities on patient safety

In addition to actions at national level, some Member States report examples of cross-border activities.

Three Member States developed a cross-border patient safety strategy, in addition to the national strategy. In two Member States, reporting and learning systems operate in a cross-border context. Fifteen countries have in place specific procedures to inform non-resident patients about patient safety standards and other measures. However, no further details are given on these procedures.

2.1.6. Research

Ten Member States report they have a national research programme on patient safety. Existing research covers patient safety culture, reducing the risk of medication errors, improving patients' competence in medication safety, healthcare-associated infections, prevention of falls in the elderly population, impact of the absenteeism of healthcare workers on patient satisfaction, impact of teleradiology on vital emergencies, instruments to measure adverse events, and the frequency of adverse events in hospitalised patients.

2.1.7. Areas most and least covered by implementation

Among the 13 actions envisaged by the Recommendation and analysed in this Report⁴, the following three have been implemented by the largest number of countries: embedding patient safety as a priority in public health policies (all countries); designating a competent authority responsible for patient safety (25 countries); and encouraging training on patient safety in healthcare settings (24 countries).

The actions implemented by the lowest number of countries are: embedding patient safety in the education and training of health professionals (three countries); providing full information to patients about patient safety (five countries); dissemination of core knowledge on patient safety to health workers (11 countries); and developing core competencies in patient safety for patients (12 countries).

Regarding the number of actions implemented by countries, the breakdown is as follows:

⁴ Designating the competent authority responsible for patient safety; embedding patient safety as a priority issue in health policies; development of safer and user-friendly systems, processes and tools; regularly reviewing and updating safety standards and/or best practice; encouraging health professional organisations to have an active role in patient safety; promoting safe practices to prevent the most commonly occurring adverse events; involving patient organisations in the development of patient safety policies; disseminating information to patients on patient safety standards, risk, safety measures, complaint procedures and available redress; establishment of reporting and learning systems; encouraging patient safety education and training for all staff in healthcare settings; embedding patient safety in the education or training of health professionals; developing core competencies, knowledge, attitudes and skills for all healthcare staff.

| | |
|--|---|
| Countries having implemented all 13 actions | 0 countries |
| Countries having implemented between 10 and 12 actions | 9 countries: CZ, DE, DK, ES, FR, IE, IT, NL, UK |
| Countries having implemented between 6 and 9 actions | 14 countries: AT, BE, BG, EE, FI, LT, LU, MT, NO, PL, PT, SE, SI, SK |
| Countries having implemented between 4 and 6 actions | 3 countries: CY, HU, LV |
| Countries having implemented between 1 and 3 actions | 2 countries: EL, RO |

In the 2008 Impact Assessment⁵ the Commission provided information on existing patient safety activities in Member States (including the existence and maturity of reporting and learning systems, the establishment of a competent authority responsible for patient safety, and the active participation of Member States in initiatives to develop and use knowledge and evidence on patient safety at either EU or international level). Comparing the situation now in 2012 with the situation in 2008, progress is mostly observed in the area of reporting and learning systems: 16 systems are blame-free as compared to only four in 2008; 11 offer the possibility for patients to report adverse events — in 2008 this was possible only in three systems. However, other areas have seen modest progress (e.g. evaluation of existing patient safety systems) or no progress at all. It should be noted that this comparison is subject to methodological limitations and can only be considered indicative.

2.2. Healthcare associated infections

2.2.1. *Adoption and implementation of a strategy for the prevention and control of healthcare associated infections (HAI)*

The Recommendation asks Member States to adopt and implement a strategy at the appropriate level for the prevention and control of HAI. Eighteen Member States consider that the national or federal level is the appropriate one for such a strategy. By June 2011, nine of these Member States had a national strategy in place, six were in the process of preparing a strategy and three had no strategy to report nor were they in the process of preparing one. Nine countries state that both the national and regional levels are appropriate. All of these have a national strategy and regional strategies in place. One Member State reports that the regional level is the appropriate level. Most of the strategies for the prevention and control of HAI are linked to strategies for the prudent use of antimicrobial agents in human medicine and/or patient safety strategies.

⁵ http://ec.europa.eu/health/archive/ph_systems/docs/patient_ia_en.pdf.

The Recommendation states that a strategy for the prevention and control of HAI should pursue the following main objectives:

- (a) *implement prevention and control measures at national or regional level to support the containment of healthcare associated infections*

Guidelines for hand hygiene are available in 22 countries, of which 19 refer to WHO guidelines. In addition, three Member States have guidelines under preparation and one has regulatory requirements for hand hygiene. Two Member States have no guidelines for hand hygiene. Hand hygiene campaigns have been carried out in 18 countries and are under preparation in four Member States.

On topics other than hand hygiene, guidelines for the prevention and control of HAI in hospitals are available in 23 countries and under preparation in three Member States. Two Member States have no agreed guidelines.

- (b) *enhance infection prevention and control at the level of the healthcare institutions*

- hospitals

Regarding infection control committees (or equivalent organisational governance arrangements) in hospitals, there are legal requirements and/or professional guidelines in 22 countries. Six Member States have no requirements/guidelines. Where requirements/guidelines are in place, they include the involvement of management in the infection control committee.

Regarding infection control teams (or equivalent organisational arrangements) in hospitals, there are legal requirements and/or professional guidelines in 24 countries. Only four Member States have no requirements/guidelines (but one has a legal requirement for an epidemiologist).

There are legal requirements for a dedicated budget at hospital level in five Member States.

Overall, only two Member States report that they have no requirements for governance arrangements in hospitals.

- nursing homes

Twelve countries report that they encourage nursing homes to have in place appropriate organisational governance arrangements for the preparation and monitoring of an infection prevention and control programme. Among those, legal requirements or professional guidelines for infection control structures in nursing homes were in place in 10 Member States.

- (c) *establish or strengthen active surveillance systems*

All but two countries have in place at least one type of surveillance network for HAI; in the two that do not (smaller Member States), surveillance is performed at hospital level and not through a national or regional network. Surveillance networks target multidrug-resistant bacteria (18 countries), surgical site infections (15), infections in adult intensive care units (16), and bloodstream infections (15). 19 countries have carried out prevalence surveys in the previous 20 years.

With regard to surveillance systems for the timely detection and reporting of alert healthcare associated organisms or clusters of HAI, such systems mostly cover clusters of some HAI.

A system for the external quality assessment of antimicrobial susceptibility testing is in place in 19 countries and under preparation in three Member States. Six Member States have no such system in place.

(d) foster education and training of healthcare workers

A nationally agreed common core of competencies (curriculum) for specialised training and/or education programmes for infection control staff is in place in 13 countries and under development in three Member States. Eleven countries do not have such an agreed curriculum. Non-sponsored continuing specialised training is mandatory in nine Member States for infection control doctors and in 11 countries for infection control nurses.

Regarding the education of healthcare workers other than infection control staff, 13 countries have a nationally agreed common core of competencies in the basic principles of hygiene and infection prevention and control and one country is in the process of developing a curriculum of this kind. 12 countries have mandatory induction training for all healthcare workers in healthcare institutions. Regular training for all healthcare workers in healthcare institutions is mandatory in 14 countries. Three Member States also have training for managers of healthcare institutions.

(e) improve the information provided to patients by healthcare institutions

Only three Member States have a national/regional template for information to be provided to patients during their stay in a healthcare institution, including information on HAI. In two of them, the templates include information on the measures taken by the healthcare institution to prevent HAI. In addition, the templates provide information on the risk of HAI (two Member States), on how patients can help to prevent infections (one), and specific information for patients colonised or infected with healthcare associated microorganisms (two).

Eleven Member States report that they have mechanisms to encourage healthcare institutions to provide information to patients. These mechanisms consist of a binding regulation in six Member States, professional guidelines in six Member States, and accreditation or certification systems in four Member States.

(f) support research

In six Member States calls for tender on HAI (epidemiology, new preventive and therapeutic technologies and interventions, cost-effectiveness of infection prevention and control) can be launched under the auspices of the ministry in charge of health or research. 10 countries use their inter-sectoral mechanism to define priorities for research in the field of infection prevention and control, while three additional Member States plan to have their inter-sectoral mechanism involved.

2.2.2. Establishment of an inter-sectoral mechanism or equivalent system

For the coordinated implementation of the strategy for the prevention and control of HAI, 17 countries have an inter-sectoral mechanism or equivalent system, while seven Member States are in the process of setting up one. In most cases (13 out of 17 countries), the inter-sectoral mechanisms or equivalent systems also coordinate the strategy for the prudent use of

antimicrobial agents in human medicine. Four Member States report that they have no inter-sectoral mechanism or equivalent system.

3. MAIN ACTIONS AT EUROPEAN UNION LEVEL

3.1. General patient safety

The European Commission has pursued the following activities to promote mutual learning among Member States and propose common definitions and terminology for patient safety.

Under the Working Group on Patient Safety and Quality of Care, the Commission has fostered the exchange of information on initiatives concerned with patient safety and quality of care. This Group is composed of all EU Member States, representatives of EFTA countries, international organisations (WHO, OECD and the Council of Europe) and EU umbrella organisations representing patients, health professionals, healthcare managers and quality-of-care experts. The Group has discussed the work of the WHO on the International Classification for Patient Safety (15 countries are involved in this work and two have translated it into their national languages) as well as several examples of national activities on patient safety. However, to date no classification on patient safety has been proposed at EU level.

The European Commission co-finances, within the Health Programme, the project on healthcare quality indicators, led by the OECD. In 2011, the project published for the first time six indicators on patient safety: two concerning obstetric trauma and four concerning procedural and postoperative complications. Twenty of the reporting countries are involved in data collection within this project, including 11 collecting comparable indicators on patient safety.

The Commission has also allocated EUR 3 600 000 for a three-year collaboration on patient safety, in the form of a joint action for the years 2012-2015. One part of the joint action consists in selecting best practices on patient safety at healthcare provider level and testing their implementation in other Member States. The joint action will also map and analyse existing strategies on quality assurance and quality improvement, as well as propose a model for sustainable collaboration at EU level on patient safety and quality of care. All 27 Member States and Norway are involved in the joint action, which is coordinated by the Haute Autorité de Santé, France. Twenty one countries contribute financially to the project.

Twenty-two of the reporting countries have developed collaboration with other EU Member States on different provisions of the Council Recommendation, often as part of projects co-funded by the EU or by international organisations. The main areas of collaboration are: development of patient safety strategies and programmes (20 countries), developing blame-free reporting and learning systems (15 Member States), and development and review of patient safety standards (15 Member States). The areas least covered (by only nine Member States) are: disseminating information to patients about patient safety and developing core competencies on patient safety for patients.

Within the Seventh Research Framework Programme, the EU has co-financed six research projects on general patient safety, to a total amount of EUR 16 million.

3.2. Healthcare associated infections

The prevention and control of HAI is closely linked to antimicrobial resistance, another key priority for the Commission. The Commission's 'Action plan against the rising threats from antimicrobial resistance'⁶ contains 12 actions to be implemented with EU Member States, including action to 'strengthen infection prevention and control in healthcare settings'. As a follow-up to the action plan, priorities for funding European-wide projects will be identified on the basis of the findings of this Report.

In response to the recommendation that Member States use case definitions agreed at EU level⁷, a general case definition for a type of HAI (nosocomial infection or hospital-acquired infection) is included in a draft Commission Implementing Decision amending Decision 2002/253/EC⁸ laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC. This case definition has been developed in accordance with the opinion of a committee set up to implement Decision No 2119/98/EC.

The Commission has already been addressing HAI by funding several European-wide projects under the Health Programmes 2003-2007 and 2008-2013: IPSE⁹ (Improving Patient Safety in Europe), BURDEN¹⁰ (Burden of Resistance and Disease in European Nations), and IMPLEMENT¹¹ (Implementing Strategic Bundles for Infection Prevention & Management).

Within the Sixth and Seventh Framework Programmes for Research and Technological Development (2002-2006 and 2007-2013), the Commission funds numerous research projects in the area of HAI and antimicrobial resistance¹². For example, the MOSAR project sought to better understand the transmission dynamics of resistant pathogens and study the effectiveness of interventions to reduce HAI. Another example is the on-going R-GNOSIS project, which includes five clinical studies to identify evidence-based preventive measures and clinical guidance to combat the spread and impact of infections caused by multidrug-resistant Gram-negative bacteria. Finally, the on-going PROHIBIT¹³ project analyses existing guidelines and practices for preventing HAI in European hospitals, identifies factors that enable or reduce compliance with best practices, and tests the effectiveness of interventions of known efficacy.

The European Centre for Disease Prevention and Control (ECDC) coordinates the European surveillance of surgical-site infections, HAI in intensive care units¹⁴, and antimicrobial resistance¹⁵. In addition, a protocol and toolkit for national point prevalence surveys of HAI and antimicrobial use in acute care hospitals was developed by experts from the Member States and the ECDC in 2009-2010 and was implemented in the Member States in 2011-2012. Furthermore, the ECDC is supporting a European network for the surveillance of HAI and

⁶ Communication from the Commission to the European Parliament and the Council. Action plan against the rising threats from antimicrobial resistance (COM(2011) 748 final). Available from: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0748:FIN:EN:PDF>

⁷ OJ L 268, 3.10.1998, p. 1–7 in accordance with the provisions of Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community

⁸ OJ L 86, 3.4.2002, p. 44–62.

⁹ <http://ipse.univ-lyon1.fr/>.

¹⁰ <http://www.eu-burden.info>.

¹¹ <http://www.eu-implement.info/>.

¹² http://ec.europa.eu/research/health/infectious-diseases/antimicrobial-drug-resistance/projects_en.html.

¹³ <https://plone2.unige.ch/prohibit>.

¹⁴ <http://www.ecdc.europa.eu/en/activities/surveillance/hai/Pages/default.aspx>.

¹⁵ <http://www.ecdc.europa.eu/en/activities/surveillance/EARS-Net/Pages/index.aspx>.

antimicrobial use in long-term care facilities (HALT-2) and a project to support building capacity for the surveillance of *Clostridium difficile* infections (ECDIS-Net). In 2010, the ECDC carried out a needs assessment for infection control training in Member States and updated the IPSE⁹ core competencies for infection control training in the EU (TRICE). The ECDC has developed evidence-based guidance for the prevention and control of *Clostridium difficile* infections and issued recommendations to prevent the spread of carbapenemase-producing Enterobacteriaceae¹⁶. Finally, ECDC is also sponsoring the development of guidance and indicators for HAI prevention.

4. SOCIO-ECONOMIC CONTEXT

The economic and financial crisis has led to financial constraints in most European Union Member States. As part of the response to these fiscal constraints, some countries have been implementing extensive reforms of their healthcare systems since the beginning of the crisis.

Member States have introduced measures to cut costs and improve efficiency and productivity, such as: reducing healthcare spending; introducing ceilings to healthcare budget increase; reducing the operational costs of health services; reducing the fees paid to providers for their services; cutting pharmaceutical expenses; and restrictions on healthcare professionals in employment policies and retirement reforms (such as dismissing staff or not replacing retiring staff, implementing restrictive policies on recruitment and replacement of staff, and cutting wages in the public sector)¹⁷.

In such a context, most Member States report that implementation of the general patient safety provisions of the Recommendation has slowed down due to the financial constraints resulting from the crisis. Some Member States with the poorest implementation record are among those which have been most severely hit by the financial and economic downturn. Nevertheless, it would be premature to conclude that there is a positive direct causal relationship between the financial situation of Member States and the implementation of patient safety measures, as there are examples of Member States that have been severely hit by the economic crisis but have nonetheless invested considerably in patient safety.

Reduced resources should not jeopardise patient safety and quality of care, not only for the sake of the patient but also because evidence shows that healthcare-associated harm has additional costs¹⁸. An international literature review estimates that between 13 and 16% of hospital costs alone (one euro in seven) are due to healthcare-related injuries and ill health. In addition to this amount, the costs of treating the aftermaths of these events — not directly part of hospital costs — have to be taken into account to have a full picture. What is more, recent cost-effectiveness studies on patient safety interventions show that specific actions on patient

¹⁶ http://ecdc.europa.eu/en/publications/Publications/110913_Risk_assessment_resistant_CPE.pdf.

¹⁷ European Semester Country Specific Recommendations: http://ec.europa.eu/europe2020/making-it-happen/country-specific-recommendations/index_en.htm;
HOPE: http://www.hope.be/05eventsandpublications/docpublications/86_crisis/86_HOPE-The_Crisis_Hospitals_Healthcare_April_2011.pdf.

¹⁸ Canadian Patient Safety Institute, <http://www.patientsafetyinstitute.ca/English/research/commissionedResearch/EconomicsofPatientSafety/Documents/Economics%20of%20Patient%20Safety%20Literature%20Review.pdf>. Other studies suggest that international rates of avoidable harm are in the region of 10% (NES; http://www.nes.scot.nhs.uk/media/6470/Overview%20of%20patient%20safety_KHowe2009.pdf).

safety are cost-effective¹⁹. In order to design effective policy measures, to reduce the costs of unsafe care and to develop cost-effective patient safety programmes, further research as well as evidence specific to the situation of EU Member States is needed. Furthermore, further work is needed to better identify and design solutions that fit into existing institutional and organisational frameworks.

In addition, Member States highlight the insufficient time between adoption of the Recommendation and reporting. Some point to internal coordination issues between health and education ministries and to a possible lack of political priority at national level.

5. CONCLUSIONS

Most Member States have taken a variety of actions as envisaged by the Recommendation. On general patient safety, most Member States have embedded patient safety as a priority in public health policies and designated a competent authority responsible for patient safety. Moreover, most countries have encouraged training on patient safety in healthcare settings, though only a few have formally embedded patient safety in education and training programmes for health professionals. The existing reporting and learning systems have been considerably improved in two main aspects: their blame-free character and offering patients the possibility to report. However, there is still room for improvement in this crucial area. The same applies to provisions for patient empowerment. Also, efforts focus on hospital healthcare, with only a few examples of actions addressing primary care. On the prevention and control of HAI, 26 out of 28 responding countries have implemented a combination of actions to prevent and control HAI, in most cases (77%) as part of a national/regional strategy and/or action plan. Thirteen Member States report that the Recommendation has triggered initiatives on HAI, in particular the implementation of an inter-sectoral mechanism or equivalent system, preparation/revision of strategies, and information campaigns addressing healthcare workers.

However, there are still various areas of the Recommendation with considerable room for improvement. Based on the findings of this Report, the priority areas on which future work should focus include:

(a) In the area of general patient safety:

At Member State level:

- Actively **involve patients in patient safety**, in particular provide information to patients on safety measures, complaint procedures and patients' rights to redress, work on a common understanding and development of core competencies for patients, and encourage patients and their families to report adverse events.
- Collect information on adverse events through further developing reporting and learning systems, ensure a **non-punitive context for reporting on adverse events** and **evaluate reporting progress**, i.e. the rate of reporting by health professionals, other healthcare workers and patients. The reporting systems should complement the provisions of the new

¹⁹ Møller A.H. (2010). A cost-effectiveness analysis of reducing ventilator-associated pneumonia at a Danish ICU with ventilator bundle. *Journal of Medical Economics* Vol. 15, No 2, 2012, 1–8.

legislation on pharmacovigilance (Directive 2010/84/EU) for adverse drug reaction reporting.

- Extend patient safety strategies and programmes from hospital care to **non-hospital care as well**.
- **At EU level:**
- Collaborate with a view to proposing **guidelines** on how to construct and introduce **patient safety standards** beyond the Recommendation.
- Make progress on **common terminology** on patient safety.
- Pursue exchange of best practice, mainly in the areas identified by Member States as suffering from insufficient domestic expertise or difficulties in accessing international or EU expertise, e.g. systematic integration of patient safety in the **education and training** of health professionals at all levels.
- Develop research in the area of patient safety, including **studies on the cost-effectiveness** of patient safety strategies.

(b) In the area of the prevention and control of healthcare associated infections:

- **At Member State level:**
- Ensure adequate numbers of **specialised infection control staff with time set aside** for this task in hospitals and other healthcare institutions.
- Improve the **training of specialised infection control staff** and better align qualifications between Member States.
- Reinforce tailored basic infection prevention and control structures and practices in **nursing homes and other long-term care facilities**.
- **Repeat national point prevalence surveys** of HAI as a means to monitor the burden of HAI in all types of healthcare institutions, to identify priorities and targets for intervention, to evaluate the impact of interventions and to raise awareness.
- Ensure that **surveillance** of infections in **intensive care units** and **surgical site infections** is in place.
- Implement **surveillance systems for the timely detection and reporting of alert healthcare associated organisms** and strengthen the ability to respond to the spread (including across borders) of such organisms and prevent their introduction into healthcare settings.
- Improve the **information on HAI for patients** and strengthen their involvement in the compliance with infection prevention and control measures.
- Develop an **evaluation system** with a set of indicators in Member States to **assess the implementation of the strategy/action plan** and its success in improving the prevention and control of HAI.

- **At EU level:**
- Continue the **development of guidance** on the prevention and control of HCA, including **tailored guidance** for nursing homes and other long-term care facilities.
- Develop **research** in the area of the prevention and control of HCA, including studies on **cost-effectiveness** of prevention and control measures.

The Recommendation invites the Commission to ‘consider the extent to which the proposed measures are working effectively’. However, as in many Member States and at EU level the actions have been implemented only recently or in some cases are still under implementation, it might be advisable to carry out such an assessment again in two years’ time, taking the current report as a comparative reference. This is why the Commission proposes extending the monitoring of the implementation of the general patient safety provisions of the Recommendation for another two years. In June 2014, the Commission will prepare a second progress report taking into account the mid-term results of the joint action on patient safety and quality of care.