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COMMISSION STAFF WORKING DOCUMENT

accompanying document to the Communication and Recommendation on patient safety, including the prevention and control of healthcare-associated infections

SUMMARY OF THE IMPACT ASSESSMENT

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SUMMARY OF THE IMPACT ASSESSMENT

1. PROBLEM DEFINITION

1.1. Nature of the issue or problem that requires action

Patient safety is defined by WHO as freedom for a patient from unnecessary harm or potential harm associated with healthcare. There is a limited but growing body of evidence concerning the prevalence and incidence of adverse events in health systems in EU Member States. National studies from the UK, Spain and France provide the bulk of current evidence in Europe on in-patient adverse event prevalence and its implications. From these studies and from Key Informant Interviews conducted for an external project informing the impact assessment, it is estimated that in EU Member States between 8% and 12% of patients admitted to hospitals suffer from adverse effects whilst receiving healthcare.

Healthcare-associated infections (HCAIs), a key focus of the current initiative, are among the most frequent and potentially harmful causes of unintended harm, affecting an estimated one in twenty hospital patients on average, corresponding to 4.1 million patients every year in the EU. HCAIs are often difficult to treat due to antimicrobial resistance of the micro-organisms causing these infections. Other causes of adverse events are medication-related errors such as patients receiving the wrong medicine, or the wrong dose, surgical errors, medical device failures and errors in diagnosis or the failure to act on the results of tests.

1.2. Consequences of no change in policy

The Commission has already taken specific steps in many areas to address the issue of patient safety. However; efforts to address the challenges of patient safety have focused mostly on specific sources of risk such as the safety of medicines, medical devices and resistance to antimicrobials. These actions, however, only tend to focus on specific causes or factors, and do not seek to address the overall cultural, leadership, systemic, communication and process barriers to improved safety.

Although the problem of patient safety is primarily the responsibility of Member States, the European Union can encourage cooperation between Member States and lend support to their actions in specific areas where EU intervention can have an added value. EU action is essential given the trans-boundary spread of infections, cross-border provision of healthcare resulting from mobility of patients and professionals, and a need for EU-wide data collection and monitoring. A further added value of EU intervention comes from the provision of political weight and visibility, thus putting patient safety at the centre of Member States' health priorities, offering economies of scale, and finally providing effective knowledge sharing through exchange of best practice. Without increased action by the European Union, adverse events will continue to constitute a considerable burden on Member States healthcare systems in terms of health and economic impacts.

2. OBJECTIVES

2.1. General Objective

The general objective is to prevent and reduce human illness and diseases and to obviate sources of danger to human health, as stipulated in Article 152 of the Treaty.

2.2. Specific objectives

(1) To protect EU citizens from preventable harm in healthcare, including from HCAIs.

(2) To support the Member States to put in place the proper and adequate strategies to prevent and control adverse events in healthcare, including HCAIs, by pooling the best available evidence and expertise in the EU.

(3) To improve EU citizens' confidence that they have sufficient and comprehensible information available on levels of safety and available redress in EU health systems, including healthcare providers in their own country and in other Member States.

2.3. Operational Objectives

A total number of ten operational objectives were identified that can be summarised as follows: To increase the political awareness of Member States on the scale and size of the patient safety issue; to gather homogeneous and comparable data on patient safety; to develop common terminology and indicators; to share best practice and experience; to develop and promote the research agenda on patient safety; to promote the availability of information for patients and their families and to promote collaboration on patient safety issues between Member States, EU institutions and key European and international organisations.

In the area of HCAIs, the operational objectives were to foster with the European Centre for Disease Prevention and Control (ECDC) the establishment of surveillance methods; of indicators to allow evaluation of the implementation and effectiveness of measures to prevent and control HCAIs and of guidance on best practices and minimum infrastructure requirements, as well as training curricula for healthcare workers.

3. POLICY OPTIONS

3.1. Options identified:

Four policy options have been considered as possible means to meet the policy objectives identified in the previous section.

(1) **No additional EU action – status quo:** Under this option, the Member States, stakeholders and international organisations would pursue their activities on patient safety without any further co-ordination or incentives from the Commission.

(2) **Strengthened cooperation with the Member States and other bodies, supported by technical guidance:** Under this option, the Commission would strengthen cooperation with Member States and other bodies. The Commission could for example increase the focus on patient safety in the Health Programme and the Framework Programme for research and technological development. The Commission could also

step up its efforts in stimulating Member States to cooperate on the issue of HCAIs and to develop technical guidance through the ECDC and the network of surveillance bodies.

(3) **Strengthened cooperation with the Member States and other bodies, supported by soft law instruments, such as a Commission Communication and a Council Recommendation:** Under this option, the Commission would strengthen cooperation with Member States and other bodies and, in addition, develop a Communication and a Council Recommendation on the issue in order to foster the political commitment towards patient safety in Member States and set out a series of concrete recommendations to reduce the number of adverse events in healthcare systems.

(4) **Strengthened cooperation with the Member States and other bodies, supported by a regulatory instrument, such as a Commission Decision:** This option would involve extension of Option 2 with a legislative proposal based on Decision No 2119/98/EC addressing certain aspects of the prevention and control of HCAIs in accordance with Article 7 of this Decision (Comitology). This legislative proposal could, however, not address general patient safety issues due to the lack of an appropriate legal basis.

3.2. Options discarded at an early stage

Legislation, including a Regulation or a Directive on patient safety, was ruled out as it would be extremely difficult to justify a specific and detailed legislative action covering all the aspects of the proposal on the grounds of subsidiarity and proportionality.

4. ANALYSIS OF IMPACTS

4.1. Methodology used in assessing the impacts

In order to assess the possible health and economic impacts of the different policy options, quantitative simulation scenarios have been developed to support the impact assessment. These scenarios use only data for hospital settings, not for outpatient care, as the former is much better documented than the latter and is also the main setting for HCAI. As of now, data gaps for the EU did not allow us to establish a direct causal relationship between good patient safety policies, systems and structures, and patient safety outcomes. Our estimates were therefore based on how close the Member States' patient safety systems are to what is generally considered best practice in the literature.

Our scenario for general patient safety policies starts from the assumption that patient safety outcomes in various Member State groups differ according to the systems in place and consequently are spread along the range of prevalence estimates for hospital-related incidents found in the literature that range from 7.5% to 16.6% with a median of 10%.We reviewed this overall scenario by also developing, with the help of infection control experts from ECDC, a separate potential reduction scenario for HCAI-related events only.

4.2. Health and Economic impacts

Policy option 1

The supporting study for this IA suggests that under the 'no policy change' option, i.e. no increased action on patient safety at the EU level, the EU is likely to see around 10 million adverse events related to hospitalisations (including those infection-related) of which almost 4.4 million would be preventable, resulting in more than 50.000 preventable person-years additional hospitalisation time.

For HCAI in particular, on the basis of recent national prevalence surveys in Europe and the results of hospital-wide surveillance programmes of nosocomial bacteraemia in different Member States, it can be calculated that HCAIs affect an estimated 5% of hospital patients on average and the total number of hospital patients acquiring at least one HCAI in the EU every year can be estimated at 4.1 million (with a total incidence of 4.5 million HCAIs per year). Approximately 37.000 deaths are estimated to occur every year as a consequence of infection.

Policy option 2

For this policy option, that requires a strengthened cooperation with the Member States and other bodies, we assumed more progress would occur, in particular through knowledge sharing. In our simulation scenario all EU Member States with ‘poor’ and ‘fair’ patient safety reporting and learning systems would therefore be able to advance and experience similar adverse event rates as countries classified as already having ‘good’ patient safety reporting and learning systems. That would mean that instead of having an average of 14% adverse events in hospital admissions, those countries would come closer to the performance of average countries which, in our scenario have 12%. In concrete terms that would mean that adverse preventable events would be reduced by 298.371 cases as compared to the baseline scenario, resulting also in a reduction of 3.450 prevented personal years of hospitalisation.

In our specific scenario on HCAIs we assume that strengthened cooperation with the Member States and other bodies, supported by technical guidance would reap an overall 5% decrease of HCAI, a quarter of the potential for reduction in infection-related incidents reported in the literature. In the absence of a political commitment to bring about the needed organisational and behavioural changes, reaching the achievable 20-30% decrease of HCAIs, (requiring an intensive prevention and control programme including surveillance and training of healthcare staff) is unlikely. We assume HCAI reduction successes are applicable across the board, given that some infection-related safety policies are in place in all EU 27.

A projected 5% decrease would, in our HCAI scenario, result in 225.000 fewer HCAIs every year. This high share of reduced HCAIs compared to the reduction in overall adverse events is due to the fact that HCAI cases are the easiest and quickest to prevent. 225.000 cases imply a considerable decrease of the HCAI morbidity and mortality burden. A 5% decrease would also save €274 million in health expenditure and represent a gain of €68.5 million in productivity.

Policy option 3

Under this option, that includes the development of soft law instruments such as a Communication or Recommendation, a high level political commitment from Member States to take action on patient safety could be attained. The overall cultural, leadership, systemic, communication and process barriers to increased patient safety could be addressed and HCAI integrated as part of an overall patient safety policy. We assume substantial benefits for this option, where MSs' ownership is greatest. We therefore assumed in our general scenario a larger impact of EU-level action under policy option 3, with the result of all EU countries

advancing to the relatively better levels of adverse events reported by the literature. That means that we assume the exemplary countries remain as efficient as they are and all other Member States move towards the reported average of 10% adverse events ('very good'). This is still a conservative estimate (given the average preventability rate) but even so we could avoid more than 750.000 preventable adverse events and reduce by more than 8000 additional person-years of hospitalisation.

For our HCAI–only reduction scenario we came up with even better successes given that for infections, the ways to control them are well understood, and quick to implement, and above all they are highly preventable. We assume that the estimated reduction could actually reap the possible 20% decrease, meaning a decrease of up to 900.000 HCAIs every year, resulting in a saving of €1.10 billion in public health expenditure and representing a gain of €274 million in productivity.

Policy option 4

For this option, the strengthened cooperation with Member Sates and other bodies is supported by a regulatory instrument, such as a Commission Decision. Such a Decision could, however, address infection-related, and not general and systemic patient safety issues, given the lack of a legal base for this. Therefore, we assume the general patient safety benefits to be in the range of those identified under policy option 2.

As regards HCAI, we do not assume that the benefits would be much bigger than those identified in policy option 2. That is because our legal basis would not address all the operational objectives of the proposal and, therefore, essential parts of the integrated strategy to combat HCAIs would have to be left out. As a result, we do not expect this option to perform much better than the option of strengthened cooperation with the Member States (option 2).

4.3. Employment effects

In all policy options (with the exception of the status quo) slightly positive employment effects can be expected due to the need for more resources for reporting and surveillance as well as infection control in healthcare institutions.

Projected on the EU27 situation with a total of 2.88 million beds, employing one infection control nurse per 600 beds and assuming a current staffing level of one infection control nurse per 1000 beds would mean employing an additional 1.920 nurses. Assuming an EU average annual cost of €42.000 / infection control nurse, this would mean an additional annual expenditure of about €80 million for policy option 2. For policy option 3, we assumed that one additional infection control nurse per 250 beds has to be employed, resulting in employing an additional 8.640 nurses and an annual expenditure of about €363 million. The employment effect of policy option 4 would be comparable to the one of policy option 2.

4.4. Environmental impact

Environmental impacts seemed to be primarily confined to the specific area of healthcare-associated infections, and only to a much lesser extent can they be linked to other causes of adverse events. Under policy options 2 and 3, minor environmental impacts are likely to occur due to an increased use of disposable medical products and disinfectant chemicals, but it was

very difficult to estimate those. The environmental impact of policy option 4 would be comparable to the one of policy option 2.

5. COMPARING THE OPTIONS

A synoptic overview of the different policy options and the extent to which they could achieve the identified specific objectives is presented in the table below. Figures were rounded.

	Policy option I	**Policy option II**	**Policy option III**	**Policy option IV**
Specific objective 1 **Protect EU citizens from harm**	Little progress, which would occur basically in countries where patient safety is a political priority O with slight improvements	Reduction of 300.000 preventable adverse events in total +	Reduction of 750.000 preventable adverse events in total ++	 + to ++
Specific objective 2 **Support MS to put in place patient safety strategies**	No additional EU level support O	Some additional EU level support through technical guidance on HCAI +	Political ownership and leadership of all MS, exchange of best practice Quick implementation possible ++	Political ownership if accompanied by a Recommendation, Decision addresses some aspects of HCAI which would be legally binding. + to ++
Specific objective 3 **Improve EU citizens confidence**	O	+	++	+ to ++

Based on the above, the policy option of a proposal for a Commission Communication and a Council Recommendation on patient safety and quality of health services, including the prevention and control of HCAIs, appeared as the preferred one.

6. MONITORING AND EVALUATION

A set of indicators and data to be collected was proposed to enable future measurement of the economic and social impact of initiative. It is envisaged to evaluate the overall patient safety initiative, including implementation of the Recommendation, using external experts to assess its relevance, effectiveness and efficiency. This evaluation could be part of a comprehensive evaluation project for different health related initiatives.