Spitzenverband

# Written Contribution of the National Association of Statutory Health Insurance Funds of 26.02.2014

## to the Public Consultation on Patient Safety and Quality of Care of the European Commission

**GKV-Spitzenverband**
Reinhardtstraße 30, 10117 Berlin
Telefon 030 206288-0
Fax 030 206288-88
politik@gkv-spitzenverband.de
www.gkv-spitzenverband.de

# I. Preliminary Remarks

The European Commission has launched a public consultation on patient safety and quality of care on 04.12.2013. The consultation focuses on the Council recommendation on patient safety, including the prevention and control of healthcare associated infections of 2009 and the implementation of these recommendations by member states. Furthermore, the European Commission inquires about potential future scope of action for the EU in the field of patient safety and quality of care.

# II. Contribution to the Consultation

## *2. Implementation of the Council Recommendation 2009/C 151/01*

***The Council Recommendation on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01) envisaged a number of measures to be implemented by EU Member States to increase patient safety in all types of healthcare settings.***

### *2.1. Is patient safety an issue in your country?*

Yes

### *2.2. To your knowledge, was the Recommendation implemented in your country?*

Yes, partially implemented

### *2.2.1. If the Recommendation was fully or partially implemented, do you think it contributed to improving patient safety in your country?*

Yes, to certain extend

### *2.2.2. If the Recommendation was fully or partially implemented, how the necessary changes were introduced?*

With regard to recommendations I.2.b “Disseminating information to patients” and II. “Additional recommendations on prevention and control of healthcare associated infections”:

Hospitals in Germany have been legally obliged since 2005 to publish regular, structured quality reports. The obligatory quality survey is carried out nationwide and made recognisable for all accredited hospitals through the use of quality indicators. The reports are used to provide information for patients and to help provide orientation to physicians who refer patients to hospitals.

Hospitals have had to submit an annual quality report since the year under report 2012. Prior to this, the interval was every two years.

The clinics are obliged to provide detailed information on hygiene amongst other things, this information including the precise number of hospital hygienists (physicians who have received special further training in the field of hygiene and infection risks) and hygiene experts. Since 2012, the Federal Joint Committee *(Gemeinsamer Bundesausschuss)* has issued directives defining suitable obligatory measures to safeguard hygiene in healthcare and determining indicators to assess the quality of hygiene for inter-institutional quality assurance.

In 2011, Germany reformed its Infection Protection Act *(Infektionsschutzgesetz)*, which governs hygiene measures both in hospitals and in out-patient healthcare. Hospitals are obliged to take account of and apply the recommendations of the Commission for Hospital Hygiene and Infection Prevention *(KRINKO)* and only to derogate from them in justified cases.

Moreover, the hygiene promotion programme of 2013 provided additional funding to promote the recruitment of new staff or to increase staff numbers, as well as furthering the education and training of qualified specialist hygiene staff in the medical and care spheres in hospitals in accordance with the Infection Protection Act. In out-patient healthcare, furthermore, possibilities were created for doctors to charge hygiene measures for MRSA eradication to health insurance funds.

In Germany, the German Antimicrobial Resistance Strategy *(DART)* was published in 2011 by the Federal Ministry of Health, together with the Federal Ministry of Food, Agriculture and Consumer Protection and the Federal Ministry of Education and Research, as well as large numbers of associations and organisations. The National Association of Statutory Health Insurance Funds *(GKV-Spitzenverband)* took part in drafting the strategy.

Regarding recommendation I.3. “Systems for reporting on adverse events”:

The Federal Joint Committee was commissioned by the legislator to expand the Directive on Intra-institutional Quality Management to include binding minimum standards for hospitals’ own risk management and error detection systems in order to improve patient safety. The hospitals’ quality reports will in the future also have to provide information on the implementation of risk management and of the error detection systems. The Federal Joint Committee moreover sets the requirements as to inter-institutional error detection systems.

There is an obligation in Germany to report incidents involving medical devices (material, functionality or performance malfunction, complications occurring during treatment). This obligation to report does not currently entail sanctions. These reports are collected by the Federal Institute for Drugs and Medical Devices *(BfArM)*, an independent superior federal authority operating within the portfolio of the Federal Ministry of Health. With regard to medical devices, a register for endoprosthesis (implants which replace natural structures of the body such as joints or blood vessels and as a rule remain in the body permanently) is being established. The goal is to expand this to include other types of medical devices.

With regard to recommendations I.2, to "Empower and inform citizens and patients" and I.4, to "Promote education and training of healthcare workers on patient safety" and I.7, to "Develop and promote research":

The Action Alliance on Patient Safety is a joint initiative of representatives from the medical professions, patients' organisations and statutory health insurance funds. The goal pursued by the Alliance is to establish a common platform to improve patient safety in Germany. This Alliance promotes the exchange of experts and publishes recommendations for the players in the healthcare sector.

### *2.2.3. If the Recommendation was not or only partially implemented, which tools could help better implementation (more than 1 answer possible)?*

national binding legislation
involvement of health professionals

### *2.3. What are the barriers to implementation of patient safety recommendation?*

No statement.

*2.4. Which provisions of the Recommendation are of particular relevance in your country?*

| | Very relevant | Relevant | Not particularly relevant | Not relevant at all |
|---|---|---|---|---|
| Placing patient safety high at public health agenda | X | o | o | o |
| Empowering patients | o | X | o | o |
| Creating patient safety culture among health professionals (education and training, blame-free reporting systems, learning from errors) | X | o | o | o |
| Learning from experience of other countries | o | X | o | o |
| Developing research on patient safety | o | X | o | o |

*2.5. Which areas of patient safety, not covered by the Recommendation, are important for increasing safety of patients in the EU?*

Safe medical devices and medical products are particularly significant to patient safety. The European Union has a particularly strong role to play in setting high quality and safety standards for medical products and medical devices.

The EU should use its legislative competence in the field of medical devices in order to supplement the conformity assessment procedure that is currently valid all over Europe to include a benefit assessment at least for high-risk medical devices. Uniform standards for study designs should be drawn up for the approval of medical devices. Furthermore, there must be blanket product registers to which the data are to be mandatorily reported.

When it comes to the supply of medical products, greater focus could be placed on patient safety and quality at European level within the exchange of information on good practices. With the Act on the Reform of the Market for Medical Products of 2011, Germany has gathered positive experience with a new procedure for assessing the benefit provided by patented medical products, thereby achieving an improvement in the interest of high-quality treatment with medical products.

## 3. *Future EU action on patient safety and quality of healthcare*

***The European Commission has supported since 2005 co-operation of EU Member States and stakeholders on patient safety and quality of care, by organising and co-funding different fora of information exchange and practical mutual learning (ex. Working Group of Patient Safety and Quality of Care, EU Network on Patient Safety and Quality of Care, research projects). Some of these activities are time-limited and will end in the next months.***

### *3.1. What next should EU do on patient safety and in which specific patient safety areas beyond the existing Recommendation?*

The EU has been given legislative powers to set high quality and safety standards for medical products and medical devices. The safety of European patients is therefore to be improved at European level, particularly within the medical devices and medical products sector.

In the interest of improving patient safety, the statutory health insurance sector is calling for the Council to attach a high level of priority to the Regulation on Medical Devices *(Medizinproduk-teverordnung)*, so that an agreement is achieved in the inter-institutional trilogue in the ongoing legislative period of the European Parliament before the elections in May 2014. The National Association of Statutory Health Insurance Funds favoured the introduction of an approval authority for high-risk products. Since this call was not taken up, the National Association of Statutory Health Insurance Funds, together with the European Social Insurance Platform (ESIP), is supporting the compromise reached by the ENVI Committee. In the interest of the patients, the National Association of Statutory Health Insurance Funds is calling for the following in particular:

1. more systematic, independent opinions on the part of the scientific Advisory Committee on Medical Devices (ACMD) and the Medical Device Coordination Group (MDCG),
2. obligatory, high-quality clinical tests for high-risk products prior to their launch,
3. enhancing the rights of patients who have suffered harm, for instance by giving them a right to information in the event of harm, and mandatory liability insurance,
4. public access to information (e.g. EUDAMED).

Although the obligation exists in Germany to report incidents involving medical devices (material, functionality or performance malfunction, complications occurring during treatment) without entailing sanctions, so far not all incidents are being reported. In order to improve patient safety, there is a need to create mechanisms and incentives to heighten the willingness to report malfunctions.

The consequences of the scandal over French breast implants show that patients need independent, Europe-wide information concerning the risks and benefits of breast implants, as well as on the side-effects and cosmetic impacts of potential explantations. Comprehensible information should be accessible to the public on the websites of the national healthcare authorities. The UK's Medicines and Healthcare Products Regulatory Agency (MHCR) and the US Food and Drug Administration (FDA) are good examples of this.

In order to make sure that patients are provided with proper information, and in particular to protect the seriously ill against mistakes caused by improper advertising, a Europe-wide ban on advertising should be agreed on for medical devices from risk class III upwards. Advertising may only be addressed to doctors, dentists, veterinarians, pharmacists and individuals who are permitted to trade in these medical devices.

As a matter of principle, advertising for medical devices outside of professional groups may not refer to the detection, prevention, elimination or alleviation of specific diseases. The advertising ban helps improve patient safety and ensure that doctors inform patients properly.

A distinction needs to be made between advertising that targets patients and the provision of information to patients. All EU citizens should have access to quality-assured information on prescription medical products. Such information is currently already available in Germany: via the Institute for Quality and Efficiency in Health Care *(IQWIG)*, as well as through information media for doctors and information provided by health insurance funds. Such examples of good practice should be extended for use within the Member States. The medical product manufacturers could furthermore help enforce consumer protection by publishing all clinical studies that have been implemented in a publicly-accessible register, regardless of whether their results are positive or negative. Medical product manufacturers can already post officially-approved information on their websites in some countries.

When it comes to the supply of medical products, greater attention could be paid to patient safety and quality at European level. The Act on the Reform of the Market for Medical Products *(Arzneimittelmarkt-Neuordnungsgesetz – AMNOG)*, that came into force in 2011, constituted an important milestone on Germany's path towards a quality-orientated, economically-efficient supply of medical products. Patented medical products now have to prove when they are launched that they provide an additional benefit in comparison to comparable medical products which are already on the market. The introduction of this benefit assessment procedure is an improvement in the interest of high-quality healthcare with medical products. Other EU Member States have also already had good experience with the benefit assessment, for instance in the United Kingdom with the National Institute for Health and Care Excellence (NICE). The efforts to place greater emphasis on benefiting patients in the supply of medical products could also be stepped up at EU level.

The WHO recommends health objectives for each country. Germany will be paying considerable attention to the new "Patient Safety" health objective from 2014 onwards. Amongst other things, topics such as transparency and access to health information, as well as enhancing patients' rights and patients' empowerment, will play a major role here. It is a welcome development in this regard to observe that the European Commission is tackling this on a Europe-wide basis by supporting the "Patient Safety" health objective.

Potential for an exchange of best practices between the EU Member States is provided for instance by infection prevention. Cooperation within the "EurSafety Health-net – Euregional Network for Patient Safety and Infection Protection" between Dutch and German experts has proven itself to be a good trans-regional project. Cross-border communication, education and further training on the topic of infection prevention help to reduce the infection rates of MRSA and other pathogens.

The Member States of the European Union bear responsibility for the organisation of the health system and for healthcare. This includes quality assurance and patient safety in out-patient and in-patient care. It is not expedient for the EU to play a larger role here. Moreover, in Germany the Federal Länder have shared responsibility for instance in the field of in-patient care. When improving patient safety, hence, the Federal and Land Parliaments, as well as joint self-government, are called upon to take on the tasks which are important in this field in accordance with the subsidiarity principle.

It must be ensured that hospital planning does not clash with the quality requirements of the Federal Joint Committee and of the German Institute of Medical Documentation and Information *(DIMDI)*. The quality requirements originating from the federal level must be fully considered in the Federal Länder.

In the hospital sector, and particularly when it comes to complex medical interventions, it must be ensured that such services are only provided by staff who are subject to stringent quality requirements and are adequately qualified as well as having the requisite experience. It is therefore necessary for patient care to be consistently focussed on centres providing such services which have sufficient experience in terms of minimum case numbers or other necessary structures. Hospitals which do not meet these requirements may no longer bill these services to statutory health insurance funds. It must be ensured that data in the quality reports are plausible, error-free and complete. There must be mechanisms for effectively sanctioning players which evade the obligatory regulations such as those of the Federal Joint Committee in future.

The hospitals' quality reports are a first important attempt to satisfy patients' information requirements. In addition to the quality reports of German hospitals, there should therefore also be appropriate reports in out-patient care, including out-patient hospital services. Patient-orientated complaints management in in-patient facilities requires a suggestions system which actively takes up patients' suggestions for improvements.

Consequently, the National Association of Statutory Health Insurance Funds stresses that quality assurance and patient safety in both out-patient and in-patient care must remain within the responsibility of the nation-states. The activities at German level are intensive, and do not require any European intervention. Within its legislative powers, the European Union should however enhance patient safety by setting high quality and safety standards for medical products and medical devices.

### *3.2. Do you think there is an added value in enlarging EU work from patient safety only to wider quality of care?*

Yes

### *3.2.1. If yes, please specify.*

Safe, high-quality medical devices and medical products are particularly significant when it comes to patient safety. The European Union plays a particular role when it comes to setting high quality and safety standards for medical products and medical devices. The European Union should take

as an orientation in this field both patient safety and a broad understanding of quality (cf. also notes on 2.5).

In the interest of attaining a high level of safety, the European Commission should enable the Member States to set higher standards within their systems by proposing directives in preference to regulations.

*3.3. In the box below you can provide additional contribution related to EU action on patient safety and quality of care*

No statement.