



Patient safety for sustainable healthcare

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Introduction

The rising emphasis placed on patient safety has highlighted existing gaps between and within the European Union Member States, many of them stemming from a lack of reporting of adverse events, insufficient exchange of best practice examples and incomplete implementation of the Council Recommendation on patient safety, including the prevention and control of healthcare-associated infections (HAI) of 9 June 2009.

Concerning healthcare-associated infections specifically, the European Centre for Disease Control and Prevention (ECDC) Point Prevalence Survey concluded in July 2013 shows that healthcare-associated infections are still a major issue in Europe with one patient in 18 suffering from an HAI every day.

The European MedTech industry is greatly concerned by the situation of HAIs and patient safety more generally, and calls on stakeholders involved in public health, policy development, and healthcare environments to work together on the development of clear-cut guidelines for the reduction of HAIs. While reaching zero risk is impossible, reaching zero tolerance for non-compliance with safety measures is an attainable objective and one that should be prioritised to avoid exposing patients to danger when at their most vulnerable and incurring the subsequent cost of treatment, which adds a further burden to healthcare budgets.

European leadership is needed

When in 2002 Member States of the World Health Organisation (WHO) agreed to a World Health Assembly resolution on patient safety, thereby identifying the topic as a critical danger for global public health, one in ten patients in developed countries were exposed to adverse events while in the hospital. This includes 4.1 million patients just in the EU becoming infected with at least one healthcare-associated infection. Yet, HAIs are not the end of the road with other adverse contributors to patient safety including:

- **Medication-related errors:** Unintentional exposure to medicines as well as errors in prescribing, preparing and delivering medication are too common in high-pressure and high-demand healthcare environments, causing serious health and economic consequences;
- **Surgical errors:** Malpractice, whether wrongful identification of a surgical site or inappropriate procedure, are largely avoidable and their avoidance can save patients from temporary injury or even death;
- **Failure to act based on the result of tests:** Inadequate or incomplete analysis of test results can produce wrongful diagnosis, which could lead to unsuitable treatment for a condition; and

- **Alarm management:** While alarms are mandatory to ensure patient safety, if not correctly managed, the clinical environment today can be noisy and disruptive, actually leading to a reduction of patient safety.

Such a broad spectrum of dangers in the healthcare setting is exacerbated by the austerity mechanisms being implemented in many Member States, which often include the reduction of healthcare budgets, leaving medical staff overburdened and, in some instances, reluctant to take up innovative solutions that could actually preserve high standards while still ensuring the sustainability of systems. It is this approach and the rising threat of adverse events that has prompted the Council and European Commission to increase their activities on patient safety by preparing legal tools and tracking their implementation across the Member States.

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

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

MedTech Europe supports these efforts to enhance patient safety and believes that together value-based innovation can create a public health environment whereby people’s health and well-being are improved.

Working toward improved patient safety

In every step of the patient pathway – prior to admission into the hospital all the way through to discharge and after care – there is room for safety improvements. A complete eradication of adverse events in patient safety is most likely out of reach at this time, but MedTech Europe calls on an ambitious approach to be adopted now. This can ensure that Europeans are gradually coming closer to a situation whereby they do not have to worry that they will be another of the 4.1 million patients who acquire at least one HAI or one of the 37,000 annual deaths caused directly by a healthcare-associated infection. ECDC estimates 20 to 30% of these HAI infections are preventable.¹

¹ European Centre for Disease Control and Prevention. Healthcare-associated infections. (2014) http://www.ecdc.europa.eu/en/healthtopics/healthcare-associated_infections/pages/index.aspx. Accessed 22/04/2014.

Yet there are also other adverse events affecting patient safety. For example, studies on excessive alarm frequency in clinical environments show that 50-80% of alarm signals are not actionable and more than 50% of nursing staff identify themselves as affected by alarm fatigue.²

Call to action

MedTech Europe recommends the following three proposals as a **primary step** bringing Europe closer to a safer healthcare pathway by focusing on the reduction of HAIs:

1. Realistic target setting at the EU and national levels based on consistent and accurate recording of data;
2. Creation of implementation committees, including mechanisms for process measures and real-time feedback; and
3. Continuous identification of best practice examples, including an easy-to-use exchange platform at the EU-level.

Target setting

The European Parliament's Report specifically cited the need for *"monitoring the burden of healthcare-associated infections in all types of healthcare institutions, to identify priorities and targets for intervention, to evaluate the impact of interventions and to raise awareness"*. MedTech Europe not only supports this point, but calls on an additional step to be taken toward establishing common European performance indicators and fostering an environment whereby surveillance and reporting structures are taken up on an EU-wide level. With the European Centre for Disease Control and Prevention stating that 20-30% of healthcare-associated infections are preventable, the MedTech industry upholds its call for the inclusion of a specific 20% reduction target for HAIs. Ambitious, but achievable, targets for reduction of other adverse events should also be set.

Creation of implementation committees

The 2009 Council Recommendation on patient safety, including the prevention and control of healthcare associated infections, although non-binding carried substantial weight as a mechanism for possible legislation in the future. Follow-up initiatives like the European Commission's 2012 Report on the implementation of the Council Recommendation, the Joint Action on Patient Safety and Quality Care and the European Parliament Report on the report on patient safety, including the prevention and control of healthcare-associated infections in 2013, have thus far had limited impact on the ground. In order to strike a balance between EU-level initiatives and ensuring Member States remain in control of their public health expenditure and application, MedTech Europe recommends the creation of implementation committees that would monitor the compliance to guidelines as defined in nationally binding legislation and the development

² Aboukhalil, A., et al. Reducing false alarm rates for critical arrhythmias using the arterial blood pressure waveform. *Journal of Biomedical Informatics* (2008). 41, 442-451.

of a culture of patient safety, including patient and staff empowerment. The latter should include an open system of communication and rapid reporting at the provider level and fostering a no-blame culture.

Gathering of best practice examples

In 2014, it is anticipated that the European Commission will release an update on its 2012 Report on the implementation of the Council Recommendation, assessing how Member States have adhered to – or not – to the points set out by the Council. This type of monitoring is important for the assessment of progress made, which can be further bolstered by the showcasing of effective strategies that Member States can adapt nationally, regionally and locally to satisfy their needs. The Joint Action for Patient Safety has already developed an online database and toolbox, which can be accessed across the EU and can be further supported by the identification of top priority best practice examples by infection prevention experts that would foster their endorsement at the local level.

Examples include:

1. Pre-screening programmes for MRSA bacterial infections can reduce expenditure on antibiotics by 50% and incidence by 78%,³ why is more not being done?
2. Simple Surgical Site Infection (SSI) Prevention bundles, combining four measures and implemented in two departments of one hospital were able to reduce the incidence of SSI by 36 and 50%, thus also reducing the associated mortality. Five deaths per year were prevented while also reducing the cost to this hospital by over half a million euros.⁴

Next steps

Adverse events are not limited to certain countries or healthcare environments – they can strike at home, in ambulances, the offices of general practitioners or hospitals, exposing both patients and healthcare professions to risk. The European Union and its Member States must work together to ensure that the scope of damage is as limited as possible.

MedTech Europe believes that the Council Recommendation and the European Parliament's Report are moving in the right direction, but these are just the first steps and have not done enough to curb the adverse events plaguing healthcare facilities. It is up to the EU-level institutions to work with Member States in order to provide an effective approach toward ensuring continuous improvement are made in patient safety and combatting adverse events. MedTech Europe recommends that public health decision-makers look to the

³ Guleri, A. The cost and benefits of hospital MRSA screening. *British Journal of Healthcare Management* 2011. Vol 17, No 2.

⁴ Crolla, RM, van der Laan, L, Veen, EJ, et al. Reduction of surgical site infections after implementation of a bundle of care. *PLoS One*. 2012. Vol 7, No 9.

'STEP' model as a means of making strides toward helping healthcare professionals and providers avoid healthcare-associated infections and improve patient safety. These steps include:

- **Staff** – Training for staff on infection control practices and creating a hospital-wide culture of patient safety, built around training and empowerment of staff;
- **Technology** – Introducing cost-effective, innovative technologies to reduce infections;
- **Environment** – Reducing environmental risks through cleaning and disinfections of facilities and equipment, good hand-hygiene and isolation of infected patients;
- **Processes** – Setting out clear policies on risk prevention.

It is now up to policymakers to promote concrete actions and establish a culture of patient safety at European, national, regional and local level.

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